

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURE MARKETING SERVICE (AMS)
NATIONAL ORGANIC PROGRAM (NOP)

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MEETING OF THE NATIONAL ORGANIC
STANDARDS BOARD (NOSB)

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MONDAY

OCTOBER 15, 2012

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The National Organic Standards
Board convened at 8:00 a.m. at the Biltmore
Hotel, 11 Dorrance Street, Providence, Rhode
Island, Barry Flamm, Chairperson, presiding.

MEMBERS PRESENT

BARRY FLAMM, Chairperson
HAROLD AUSTIN
CARMELA BECK

COLEHOUR BONDERA
JOSEPH DICKSON
TRACY FAVRE
JAY FELDMAN
JOHN FOSTER
WENDY FULWIDER
NICHOLAS MARAVELL

JEAN RICHARDSON
ZEA SONNABEND
MAC STONE
JENNIFER TAYLOR
CALVIN WALKER

STAFF PRESENT

MILES McEVOY, Deputy Administrator, National
Organic Program

MICHELLE ARSENAULT, Advisory Board Specialist

MELISSA BAILEY, Director, Standards Division,
National Organic Program

LISA BRINES, Standards Division, National
Organic Program

EMILY BROWN-ROSEN, Agricultural Marketing
Specialist

MARK LIPSON, Organic and Sustainable

Agriculture Policy Advisor, OSEC-MRP

JENNIFER TUCKER, Associate Deputy
Administrator

A-G-E-N-D-A

Call to Order 4
Dr. Barry Flamm, Chairperson

Secretary's Report. 17
Dr. Wendy Fulwider, Secretary

National Organic Program Update
Miles McEvoy, Deputy Administrator,
National Organic Program 20
Mark Lipson, Organic and Sustainable
Agriculture Policy Advisor,
OSEC-MRP. 49

Open Public Comment 70

Livestock Subcommittee

Subcommittee Proposals and Summarize
Written Comments. 210

Proposal
Nonanoic Acid (Pelargonic Acid) 210
Pet Food Amino Acids. 216

Discussion Document: Omnivore Diets
(Methionine). 223

GMO Vaccines Working Group Update:
Dr. Jean Richardson 230
Public Comments 242

Board Votes 305

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
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P-R-O-C-E-E-D-I-N-G-S

8:03 a.m.

CHAIRPERSON FLAMM: Good morning.

The meeting will please come to order. And welcome to the National Organic Standards Board fall meeting.

And this is a spectacular setting we have, not only the room but looking out. So it's great to be here in the Ocean State and I know how Rhode Islanders are really promoting local foods. I hope they'll be promoting also vigorously organic foods.

This week a major purpose of the meeting is to hear public comments. And we have approximately 80 people signed up to make comments. We've also received many very valuable written comments that will be considered in our deliberations this week.

Before proceeding we must approve the draft agenda. Is there any changes from -
- the board wishes to offer to the agenda?
Hearing none the agenda is approved and we'll

1 treat that as a final agenda.

2 We may have a couple of
3 announcements. Michelle I believe has some.
4 But before Michelle speaks I'd like to ask
5 everybody to turn off their cell phones. And
6 we have a little rule that we enforce, at
7 least with board members, NOP, if they
8 mistakenly have a cell phone go off they owe
9 everybody a drink. And of course the audience
10 could participate in that too if they would
11 like to enter the pool.

12 Michelle, would you please give
13 the announcements you have?

14 MS. ARSENAULT: So I just wanted
15 to let everyone know that we have a new timer
16 system this year. You'll see it on the
17 podium. If you're going to come up to speak
18 hopefully you signed in on the sign-in sheet
19 that's out on the table.

20 There's three lights on the timer.
21 There will be a green light -- a green light
22 will illuminate when you start your 4 minutes

1 and at 1 minute the orange or yellow light
2 will come on to warn you that you have 1
3 minute left. And when your time is over a red
4 light will illuminate and it will make a
5 really obnoxiously loud beep. So we're using
6 that this year instead of a low-tech sign that
7 we held up last year in case you were here.
8 All right, thanks.

9 CHAIRPERSON FLAMM: Thank you,
10 Michelle. Next I'd like the board members to
11 introduce themselves starting with Jennifer
12 down on the far end.

13 MS. TAYLOR: Good morning. I'm
14 Jennifer Taylor from Florida A&M University.
15 I'd like to welcome you here. It's such an
16 honor to be here and serve for you. I am
17 representing on the board the public community
18 consumers. Thank you.

19 MR. MARAVELL: Good morning, my
20 name is Nick Maravell. I'm an organic
21 producer from Maryland, crops, livestock,
22 vegetables, seed, et cetera. And this is my

1 second year on the board.

2 MR. FELDMAN: Good morning, Jay
3 Feldman with Beyond Pesticides. I chair the
4 Crops Committee and serve on the Materials --
5 Crops Subcommittee, sorry. I serve on the
6 Materials Subcommittee and the GMO task force
7 or working group as well as the Policy
8 Development Subcommittee. Thank you.

9 MS. SONNABEND: Good morning, Zea
10 Sonnabend, Watsonville, California. I sit in
11 the scientist's seat in the board and I'm also
12 as of August a newly certified organic apple
13 grower.

14 MR. STONE: My name is Mac Stone.
15 I represent the certifiers on the board. I
16 serve on the Certification, Policy and
17 Livestock Committee. It is my second year.
18 And I also farm with my wife and her family
19 certified organic vegetables, poultry, beef.

20 MS. FULWIDER: I'm Wendy Fulwider
21 and I have a certified organic farm in
22 Wisconsin, Ripon in Fond du Lack County. I

1 live there with my mother and my son, Cody.
2 And we operate a diversified livestock
3 operation with direct-to-market meat sales.
4 We have 65 dairy heifers that are in
5 transition and we will be selling organic milk
6 next fall. I am also the animal care
7 specialist at Organic Valley.

8 MR. AUSTIN: Good morning, my name
9 is Harold Austin. I'm with Zirkle Fruit
10 Company, a family-owned operation out of
11 Washington State. We grow, pack, ship and
12 sell our own produce, apples, pears, cherries,
13 blueberries, wine grapes. I'm on the Crops
14 Committee, the CAC Subcommittee and vice chair
15 of the Handling Committee. And I'm the
16 handler representative, one of the two handler
17 representatives.

18 MS. FAVRE: Good morning, my name
19 is Tracy Favre. I serve in the environmental
20 position. I'm from Texas and Colorado and I
21 have a pecan and fig orchard in Texas. And I
22 serve on the Handling and the Livestock

1 Committees.

2 MS. BECK: Good morning, my name
3 is Carmela Beck. I'm the organic
4 certification manager at Driscoll Strawberry
5 Associates. We're based out of Watsonville,
6 California. I'm on the Crops and the
7 Certification Subcommittees.

8 MR. FOSTER: My name is John
9 Foster and I have a bright light in my eyes
10 right now. I am one of the two handler
11 representatives. This is my third year on the
12 board. I chair the Handling Committee, also
13 sit on the Crops, Materials and Certification,
14 Accreditation and Compliance Subcommittees now
15 I guess we're calling them. And I am the
16 director of compliance for Earthbound Farm in
17 the areas of quality, food safety, and organic
18 integrity.

19 MR. DICKSON: My name is Joe
20 Dickson. I am the retail representative on
21 the board. I am with Whole Foods Market. On
22 the board I chair the Compliance,

1 Accreditation and Certification Subcommittee
2 and I serve on the Handling, Livestock and
3 Policy Development Committees.

4 MS. RICHARDSON: Good morning, my
5 name is Jean Richardson. I am a professor
6 emerita of environmental studies, University
7 of Vermont, consultant and independent organic
8 inspector. Maple syrup producer of course,
9 organic. And I'm on four committees,
10 Livestock, Handling, Policy, Accreditation and
11 I am also on the GMO Vaccine Subcommittee.
12 And I'm a consumer rep.

13 MR. WALKER: Good evening. Just a
14 check. My name is Calvin Reuben Walker. I'm
15 appointed to the board consumer public
16 interest. I serve on a few committees, CACC,
17 vice chair of the Policy Committee, Livestock
18 Committee, GMO Ad Hoc and the Materials
19 Committee.

20 MR. BONDERA: Hello, everybody.
21 Thank you for being here and thank you for
22 having me. My name's Colehour Bondera. And

1 I am a small-scale farmer in the state of
2 Hawaii. I am here in the role of not just a
3 farmer but a participant in the Livestock
4 Subcommittee, the Crops Subcommittee. I chair
5 the Policy Development Subcommittee and I also
6 serve on the GMO Ad Hoc Subcommittee as well.
7 And I look forward to listening to you all and
8 trying to represent the organic industry as
9 best I can. Thank you.

10 CHAIRPERSON FLAMM: And I'm Barry
11 Flamm serving as board chair this year. I'm
12 in one of the three environmental positions.
13 I serve on the Policy and CACC and Crops
14 Subcommittees. This is my fifth and final
15 year and this is my final meeting. I have 4
16 more days.

17 I'm from Polson, Montana. I live
18 on beautiful Flathead Lake and have been
19 probably all my life a conservationist either
20 as a vocation or avocation. But one of the
21 things I'm most proud of is I was an organic
22 grower and the first certified cherry grower

1 in the state of Montana.

2 With that I'd like Miles McEvoy to
3 introduce himself and his staff, please.

4 Miles?

5 MR. MCEVOY: Yes, I'm Miles
6 McEvoy, Deputy Administrator for the National
7 Organic Program. And I'll have each of the
8 NOP staff introduce themselves.

9 MS. BRINES: Good morning, I'm
10 Lisa Brines. I'm in the Standards Division of
11 the National Organic Program as the National
12 List manager.

13 MS. BAILEY: Good morning, I'm
14 Melissa Bailey. I'm the director of the
15 Standards Division for the National Organic
16 Program.

17 MS. BROWN-ROSEN: Good morning,
18 I'm Emily Brown-Rosen and I'm also in the
19 Standards Division.

20 MS. TUCKER: Good morning, I'm
21 Jenny Tucker. I'm the Associate Deputy
22 Administrator of the National Organic Program.

1 MS. ARSENAULT: Hi, I'm Michelle
2 Arsenault. Everyone knows my name from all
3 the annoying emails. And I'm the advisory
4 board specialist.

5 CHAIRPERSON FLAMM: Thank you.
6 And I would like the past board members to
7 stand so we could recognize them for all the
8 hard work they did when they served if you
9 would, please.

10 (Applause)

11 CHAIRPERSON FLAMM: Thank you very
12 much. It's been a tradition of these meetings
13 and the board to state the National Organic
14 Standards Board mission. Thank you.

15 Our mission briefly is to provide
16 effective and constructive advice,
17 clarification and guidance to the Secretary of
18 Agriculture concerning the National Organic
19 Program and to get the consensus of the
20 organic community. We also have a list of
21 activities. I think you can read those
22 quicker than I can read them. But it gives

1 you an idea of what we're all about. So,
2 thank you.

3 Next I'd like to say as I
4 mentioned before this is the 10th board
5 meeting that I've attended and from the very
6 beginning I've been terribly impressed by the
7 quality of the comments and the discourse that
8 we have at these meetings. There's a lot of
9 passion because we all care about organics.
10 We have different views because that's what
11 happens in our society anyway, in a democratic
12 society.

13 But I think we all really care
14 about in our part of this grand organic
15 community which I've worked with a lot of
16 different groups in my life and career and I
17 think the organic community is the finest of
18 the lot.

19 As always in such meetings we need
20 rules. And most of us don't even like rules
21 but we have to have them so we can proceed and
22 get our business done and so everybody gets

1 treated fairly. So it's sort of my obligation
2 to run through a few of these. These have
3 been discussed with all the board and I think
4 we're all onboard to do this. I can assure
5 you that I have no desire to make any rules or
6 be any tougher than necessary to keep the
7 meeting moving forward.

8 I'll just run through them very
9 briefly. All board members, we want all board
10 members to get a chance to speak before
11 another one takes a second turn, just a matter
12 of courtesy. And then closely related
13 questions, if the board member will ask
14 permission from the chair to ask that I'm sure
15 that will be granted.

16 We also don't want to give unfair
17 advantage to anybody to get more time than
18 others of you that have signed up. Everybody
19 needs to be treated equally. So we've asked
20 the board members not to ask a leading
21 question which has the purpose just to extend
22 comment time. And let's see. I think that is

1 enough. The -- next, please.

2 And then we have some things that
3 we'd like to ask the audience. And again,
4 many of you have been to many of these
5 meetings and this is not something that maybe
6 is really necessary but I'll go over this and
7 ask so we're all on the same level that we try
8 to talk about issues and not people. And that
9 people confine their comments to when they're
10 at the podium. And the people who have signed
11 up we'll give fair chance to speak but get a
12 chance to answer questions.

13 And sometimes we get so enthused
14 about what we may need to do we get to talking
15 about it in a group. So, if you need to talk
16 about something we'd ask that you go out in
17 the hall. There seems to be plenty of room in
18 this building. Unlike many of the ones we've
19 held meetings in we've got a spacious place to
20 meet and talk and that. So I think that
21 pretty much covers it.

22 I hope this is clear. If you

1 didn't, I'll give you a chance just to look at
2 what's on the board for a second and then I
3 think we can move on. Okay, thank you.

4 Next is the Secretary's Report.
5 Dr. Wendy Fulwider, please.

6 MS. FULWIDER: Thank you, Barry.
7 Last session's meeting transcripts are not yet
8 available so we will approve those at the next
9 meeting. The voting results were recently
10 sent to all of you for approval. So with
11 that, does anyone have any changes?

12 CHAIRPERSON FLAMM: Hearing no
13 changes the voting record is accepted and
14 we'll be, as Wendy stated, we'll be voting on
15 the transcript for the Albuquerque meeting at
16 our next board meeting. Thank you.

17 Next, Miles McEvoy, Deputy
18 Administrator, will give the report on the
19 National Organic Program. And also we're very
20 pleased to have Mark Lipson, the USDA Organic
21 and Sustainable Agriculture Policy Advisor
22 here to talk with us. So we're very

1 appreciative of Mark coming to this meeting.

2 I apologize. I missed something
3 on my notes here. Thank you, Miles, for
4 reminding me. And I don't know how I could
5 forget this because we've been talking about
6 it for quite awhile and had many, many
7 discussions.

8 Anyway, many -- as most of you
9 probably know we've been examining to begin
10 with at the request of the organic community
11 the board's conflict of interest policy. And
12 that will be discussed, proposals, later on in
13 the meeting.

14 Here I just want to run through
15 how this meeting will operate. I think for
16 one thing the National Organic Program
17 receives their guidance from the USDA Office
18 of Ethics. So they're getting advice on how
19 FACA committees like this board operate.

20 I think we all want the same
21 thing. Board members represent the interest
22 of those they represent. Board members will

1 recuse themselves when there is a conflict of
2 interest and the public has confidence in the
3 integrity of the board decision-making. And
4 that is so important to all of us and that
5 we're transparent. Next, please.

6 Procedurally what we did this time
7 is that the National Organic Program provided
8 a spreadsheet listing all the proposals before
9 the board members and seek them to evaluate
10 what their interests were and if there was a
11 conflict. And if a board member had a
12 conflict with a proposal that board member
13 would recuse themselves before voting, but if
14 a member wasn't sure that they were to consult
15 with the National Organic Program.

16 As it turns out we had nobody --
17 for the issues before the board here nobody
18 reported any problems and any need for
19 recusal. In this meeting to support the
20 transparency to start each subcommittee
21 session members may share any interest related
22 to a proposal and we'll announce if a recusal

1 is needed.

2 Let's see, I think that covers it.
3 And thank you, I apologize for missing that,
4 Miles. I don't know how I did that. Thank
5 you.

6 MR. MCEVOY: Okay, good morning.
7 Well, it's great to be here again in New
8 England, the first meeting in New England for
9 awhile, I don't know how long. It's hard to
10 keep track anymore, there's been so many
11 meetings.

12 This is -- one thing we're going
13 to celebrate during this week is 10 years of
14 the USDA Organic Program since the
15 implementation in October of 2002. So 10
16 years for that, but it's also the 20-year
17 anniversary of the National Organic Standards
18 Board. The first meeting was in the fall of
19 1992 so 20 years of board meetings. There's
20 been a few people that have been to most of
21 the board meetings which is really pretty
22 amazing.

1 I think Emily Brown-Rosen on the
2 NOP staff has been to most of the board
3 meetings. Anybody else want to claim they've
4 been to most board meetings? Katherine
5 DiMatteo, yes. And Zea, yes. Okay. So
6 really an amazing event that we do twice a
7 year, one of my favorite times of year. Just
8 kidding.

9 But what I'm going to do here is
10 I'm going to give an overview of the National
11 Organic Program, some of the things that we're
12 working on, implementation of a lot of the
13 NOSB recommendations. And then from there I'm
14 going to turn it over to Mark Lipson who's
15 going to have a short video from Deputy
16 Secretary Merrigan and talk about some USDA-
17 wide activities. So, next slide.

18 So just to get us started here,
19 USDA National Organic Program is responsible
20 for implementing the Organic Food Production
21 Act. It's a regulatory program. We have the
22 USDA organic regulations, or the National

1 Organic Program regulations as some people
2 call them. But we've been using the term
3 "USDA organic regulations" because it's the
4 USDA organic logo that people see on products.
5 And so that's what we think is a better way to
6 describe what the regulations are. And we,
7 the staff, are the National Organic Program.
8 So that's our vernacular that we're using.

9 So the regulations include crops,
10 livestock, handling, wild crops, labeling,
11 certification, accreditation, National List,
12 all kinds of things really germane to the
13 National Organic Standards Board in
14 particular. We're also responsible for
15 accreditation and oversight of the -- about 90
16 authorized certifying agents that operate
17 worldwide. There's about 30,000 certified
18 organic operations. We're also responsible
19 for the various recognition and equivalency
20 arrangements to make sure that they're
21 properly implemented as well.

22 And then compliance and

1 enforcement, handling complaints, doing
2 investigation, civil penalties and the appeals
3 process. And then the National Organic
4 Standards Board is a very integral part of
5 what we do in terms of supporting the work of
6 the board.

7 So about a year and a half ago I
8 went over the 10 points of organic integrity.
9 And I just want to give an update on how we're
10 doing on all these various aspects. So the 10
11 points of organic integrity as we've described
12 them, clear, enforceable standards,
13 communication, transparency, certification, a
14 complaint process, a penalty system, market
15 surveillance, unannounced inspections,
16 periodic residue testing and then a real
17 concept of organics is continual improvement.

18 So on the first one in terms of
19 clear and enforceable standards the things
20 that we've accomplished. We continue to
21 implement National List recommendations.
22 These are coming from the recommendations from

1 the NOSB.

2 We're almost done with Sunset
3 2012. We still have some things to do there.
4 We have a residue testing proposed rule that
5 is out and then we are -- we've implemented
6 the pasture rule.

7 We still have to get the -- finish
8 work on sodium nitrate, vitamins and minerals.
9 We have an interim rule out so we're still
10 working to get that to the final stage.
11 Origin of livestock we're actively working on,
12 should have a proposed rule out next year.
13 And aquaculture, mushrooms and pet food we're
14 also working on.

15 And then of course guidance. Both
16 products and seeds, we're working on final
17 guidance on those topics.

18 The pasture rule, just a little
19 bit about what we've been doing to ensure
20 implementation of the pasture rule. It's
21 about 2 years into the implementation. This
22 is the second full year of implementation of

1 the pasture rule. We've done pasture visits
2 or witness audits in numerous states. It's
3 part of the regular part of our accreditation
4 audits.

5 We've done over 50 accreditation
6 audits this year but we also do compliance
7 visits as well. So many states have been
8 included in this review of how they're doing
9 in terms of pasture rule implementation.

10 What we've seen is that a number
11 of producers have expanded the amount of
12 pasture land that they have by either
13 converting crop land to pasture or by
14 acquiring more pasture. We've also seen
15 operations reduce their herd size to meet the
16 30 percent dry matter from pasture during the
17 grazing season.

18 We've also heard from certifiers
19 and producers that there is a significant
20 increase in record-keeping that's required to
21 meet the requirements for the pasture rule and
22 about a doubling in the inspection time. So,

1 significant costs involved in verifying that
2 the pasture rule is being met.

3 But I would say that it is working
4 in terms of having a verifiable method to
5 measure compliance with a pasture-based
6 standard. We can say that the standards do
7 require that all organic operations have a
8 pasture-based system and that the rule does
9 ensure that they all are required to meet
10 that. And that what we're also seeing is
11 general compliance with the pasture rule.
12 There are certainly little problems here and
13 there but in general the organic producers
14 have adapted to meet the requirements of the
15 pasture rule.

16 The 2012 drought has been very,
17 very significant. There also was a
18 significant drought in 2011 but this year's
19 drought was the most severe since 1988. We've
20 gotten a number of requests for temporary
21 variances.

22 This has been a very challenging

1 thing for the program to figure out how do we
2 issue temporary variances that are fair and
3 consistent from year to year and from all the
4 different requests that we get. So we issued
5 a general temporary variance for all drought-
6 affected counties for non-irrigated land only
7 to reduce the dry matter intake from pasture
8 from 30 percent to 15 percent.

9 And we're evaluating additional
10 temporary variance requests on either a
11 county-by-county or a producer-by-producer
12 basis. One of the ones that we're looking at
13 is a request to reduce the grazing period from
14 120 days down to -- one request is down to 90,
15 one is down to 80. So what are the criteria
16 that we use to evaluate that. And so that's
17 been a challenge for the program but we have
18 issued that temporary variance for all
19 drought-affected counties.

20 Next slide shows the extent of the
21 2012 drought. So most of the United States is
22 affected except for the Northwest and the mid-

1 Atlantic states and New England. So it's very
2 severe.

3 Okay, next point around
4 communication. We've done a number of things.
5 Organic Literacy Initiative is something that
6 Mark Lipson will talk about in more detail, a
7 new initiative to get the word out about
8 opportunities in organic agriculture. We have
9 the newsletter that we publish on a consistent
10 basis, the Organic Insider, to try to keep
11 people up to date and improvements to the
12 website.

13 We still plan to do increased
14 outreach to increase the number of certified
15 operations so that they can get opportunities
16 of how to get into the organic marketplace,
17 improve the website more than we currently
18 have. This is just a part of the website that
19 takes you to learning more about other
20 resources in USDA that support organic
21 agriculture. There's a lot of information
22 there for lots of different programs. USDA

1 has lots of services that can benefit organic
2 agriculture.

3 A basic question is that this USDA
4 organic literacy helps users find information
5 on organic and organic-related USDA programs,
6 improves our customer service, helps farmers
7 and businesses determine if organic is an option
8 for me. We're trying to get this out to all
9 counties in the U.S. because the USDA has an
10 active part in all counties in the U.S.

11 Okay, moving onto transparency.
12 We've posted an improved list of certified
13 operations. We still have a lot of work to do
14 there to have it be a realtime list of
15 certified operations but we've made some
16 improvements there. We're posting suspended
17 and revoked operations. We post fraudulent
18 certificates.

19 Things that we still plan to do is
20 post certifiers' corrective action reports.
21 That was done in the past. We just are trying
22 to make sure that that happens in a consistent

1 and fair way. Posting cease and desist
2 letters that are issued as part of the
3 compliance process.

4 And then increasing transparency
5 of NOSB members' interests. We've been
6 talking to the board about how to do this
7 that's not a burden to the members. We're
8 looking at what the Europeans do is they have
9 a form that's filled out called a declaration
10 of interests and it's made publicly available.
11 And we're looking at some way that we could
12 have board members provide a declaration of
13 interest so there's a transparency that that's
14 provided to the public and to each other so we
15 can encourage transparency in all the
16 processes that we have.

17 Moving onto certification. As I
18 said we did over 50 audits of certifiers in
19 2012. What we find, there's a whole bunch of
20 audit criteria that are covered during these
21 audits and that there's 39 percent compliance
22 with those accreditation requirements. And

1 then we also put an increased focus on
2 biodiversity. So there's numerous -- dozens
3 of different points that certifiers have to
4 meet and they're doing for the most part an
5 excellent job at meeting the accreditation and
6 certification requirements though there's
7 always room for improvement.

8 We've published through NCAT
9 developing organic system plans that can act
10 as a template for certifiers and operations.
11 We've issued instructions to certifiers on a
12 penalty matrix and unannounced inspections.
13 These are coming out of NOSB recommendations.
14 Still planned is more publications on crops,
15 livestock, handling and certification through
16 NCAT. We're working on inspector
17 qualifications and grower group guidance.

18 And then classification and
19 permitted substances list for crops and
20 material review organizations. The
21 classification of permitted substances list
22 are in clearance so we should see those out

1 within the next few months. But it's always -
2 - the clearance process is always this
3 mysterious process of how long it will
4 actually take.

5 Okay, complaints. We've opened
6 279 complaints. This is a 54 percent increase
7 from Fiscal Year 2011. We've also closed 279
8 complaints which is more than double the
9 number of complaints that were closed in
10 Fiscal Year 2011. So a lot of improvement in
11 terms of our handling of complaints to
12 increase the number of closed complaints,
13 investigations, by more than double this last
14 year.

15 We still plan to continue rigorous
16 investigations and improved case closure
17 rates. This just shows you complaint
18 distribution of where -- the types of
19 complaints that we get. About half of the
20 complaints are on uncertified operations,
21 people making organic claims that are not
22 certified. About one-third are labeling

1 violations which can be having the lack of the
2 certifier name on the label or calling
3 something organic that's in the made-with
4 category. And then about one-sixth of the
5 violations are prohibited substances and
6 methods.

7 The other thing that is very good
8 for the program is that we've reduced the
9 average days to closure. For Fiscal Year 2010
10 we were at 269 days average from receiving the
11 complaint to closing the complaint, 2011 down
12 to 204 and last year about 80 days. So we've
13 made a lot of improvements there.

14 In terms of penalties which is an
15 important part in protecting organic integrity
16 we've issued nine civil penalties totaling
17 \$120,000. The certifiers primarily have
18 suspended or revoked over 263 operations. And
19 we still plan to explore alternative ways to
20 enforce the USDA organic standards to the
21 fullest extent of the law. So we're looking
22 at other mechanisms that we can work with

1 other USDA programs to ensure the integrity of
2 organic products and enforce the standards.

3 Market surveillance is an area
4 that we haven't had the resources to do much.
5 We've done some compliance visits to a small
6 number of markets. So we still plan to
7 implement a market surveillance program
8 depending upon resources working with some
9 other AMS programs to potentially do that.

10 In terms of unannounced
11 inspections we published instructions last
12 month that certifying agents should conduct
13 unannounced inspections on about 5 percent of
14 the operations they certify. So this is an
15 NOSB recommendation that we've implemented.
16 It also addresses one of the findings from an
17 OIG milk audit earlier this year.

18 We still plan to address this at
19 the annual training in January with the
20 certifiers to cover this to ensure that
21 they're properly implementing unannounced
22 inspections. And we'll evaluate the

1 unannounced inspections during the future
2 compliance audits for certifiers.

3 For periodic residue testing we've
4 published the proposed rule. We published
5 instructions on responding to positive
6 residues, selecting labs and a targeted,
7 prohibited pesticides list. We still plan to
8 publish the final rule which actually should
9 be quite soon. And we'll have updated
10 instructions and ensure compliance through our
11 certifying agent audits.

12 And then in terms of continual
13 improvement we continue to expand on the
14 number of training webinars and modules,
15 audits with increased rigor, outreach
16 materials, National List sunset dates, and we
17 still plan to update our database of certified
18 operations, continue to do the annual training
19 of certifiers, make improvements there. And
20 oversight of international agreements is
21 something that we take very seriously and
22 ensure that that's happening properly with

1 assessments of those agreements.

2 Also, a little update about peer
3 review. Peer review is required by the
4 Organic Food Production Act. We were working
5 with the National Institute of Standards and
6 Technology. They did a review of the program
7 in 2011. We've completed all the corrective
8 actions that were identified during that peer
9 review. That was a peer review that primarily
10 looked at the accreditation system and how the
11 program aligned with the requirements in
12 17011.

13 For next year we're planning on
14 working with the American National Standards
15 Institute that they'll be the ones that will
16 conduct a peer review of the program. And
17 we'll keep you informed of how that goes in
18 terms of the progress on that.

19 Office of Inspector General has
20 also been active in looking at the National
21 Organic Program. The 2010 audit that was the
22 extensive programmatic-wide review, there were

1 14 recommendations. All of those have now
2 been addressed and closed.

3 OIG, the milk audit phase I, there
4 were four findings. The corrective actions on
5 that are in progress. We've addressed the
6 unannounced inspections but still have work to
7 do on the other three findings.

8 And then the OIG National List
9 NOSB audit, they completed their review and
10 they found no findings which is a testament to
11 the good work of the board in terms of
12 following procedures when reviewing petitions
13 and the whole process of making
14 recommendations to the National List. It's
15 very unusual for the Office of Inspector
16 General to have no findings so we were very
17 pleased to see that.

18 And I would say though that this
19 is something that we've talked to the board
20 about, that there's still room for improvement
21 in terms of the process of reviewing
22 petitions, technical reports, technical

1 advisory panels. So it's nice that the OIG
2 had no findings but I still think that this is
3 something that the board and the program need
4 to work on to find improvements in that
5 process.

6 So how does this all fit into the
7 NOP's Strategic Plan? We have four major goal
8 areas around clear standards, making sure that
9 the standards are understandable for producers
10 and certifiers so that people know how to
11 comply. Consumer protection has to be our
12 number one priority in terms of protecting
13 organic integrity from farm to table.

14 Market access both for export
15 markets but also for local and regional
16 growers, that they can get into markets, get
17 certified, have certification be affordable,
18 attainable and accessible.

19 And then information technology.
20 We really want to make some improvements in
21 that area. There's a lot we could do to
22 improve the database and information.

1 So for 2012 our focus areas have
2 been Sunset 2012 to avoid the expiration, the
3 renewals or changes to over 200 substances.
4 We still have a couple of things that are
5 pending, the sodium nitrate and vitamins and
6 minerals. We've also made amendments to the
7 allowed and prohibited substances. We've
8 addressed the expiration dates for methionine
9 and tetracycline. And then conducting
10 certification audits that are required to be
11 done every 2 and a half years.

12 We've also worked on periodic
13 residue testing, pasture rule compliance,
14 penalty matrix, worked with FDA on the food
15 safety rules and organic standards, the
16 European Union trade partnership to make sure
17 that that's implemented effectively, Organic
18 Literacy Initiative and better communication
19 of actions and requirements.

20 For 2013, Sunset 2013 has many
21 less substances than 2012 but it is a time-
22 sensitive issue. We have to have that

1 completed by November of 2013 so we'll have a
2 proposed rule out on that sometime early next
3 year, right Melissa? Yes.

4 Also origin of livestock, pet food
5 standards, aquaculture standards and
6 implementation of residue testing
7 requirements. So we're hoping to have
8 proposed rules out on all those top three
9 origin of livestock, pet food and aquaculture.

10 And then additional guidance
11 documents for organic seeds, grower groups,
12 made with organic. Organic in the brand name
13 is a policy that we're working on and
14 hopefully we'll have out in the next few
15 months. Inspector qualifications and handling
16 bulk organic products. And classification of
17 materials, permitted substances, as I said,
18 that's already in clearance.

19 Organic pet food. This is just an
20 example of why it takes such a long time for
21 the life cycle of a rule. So the first step
22 is a working group recommendation from the

1 board. Then we get a final recommendation
2 from the NOSB. Then we have to put together
3 a proposed rule. We get public comments on
4 the proposed rule and then the final rule. So
5 that's part of the reason why it takes so
6 long. There's a lot of steps in the process.

7 But the other thing is that for
8 organic pet food if you think about it,
9 whether or not it's going to be economically
10 significant or not, how it relates to other
11 federal standards like FDA and the AAFCO
12 standards and the the whole issue of vitamins
13 and minerals and how they're unique to pets to
14 make sure that you have a full, balanced,
15 nutritional ration for pets.

16 All those things have to be looked
17 at as we work on the proposed and final rule,
18 and that's part of the reason why it takes so
19 long. Also because we have many different
20 rules that we're working on with a really
21 limited number of staff.

22 So for 2013 the focus areas are

1 market surveillance, OIG milk audit part 2, we
2 should be seeing that sometime in the next few
3 months. Continued verification of
4 international trade partnership, additional
5 international market access. We're looking at
6 Japan in particular. Posting additional
7 audits and compliance information, list of
8 certified operations, stakeholder engagement,
9 NOSB support. So that's a brief overview of
10 all the things that we're doing in the
11 National Organic Program and things that we
12 plan to do in the upcoming year.

13 So I just wanted to quickly go
14 over what the board already knows, but just
15 wanted to review the OFPA requirements for the
16 criteria for handling ingredients and also the
17 specific requirements in the USDA organic
18 regulations.

19 So OFPA permits exemptions if the
20 use of such substance would not be harmful to
21 human health or the environment -- of the
22 environment, is necessary to the production or

1 handling of agricultural product because of
2 the unavailability of wholly natural
3 substitute products and is consistent with
4 organic farming and handling. So these are
5 the things that are looked at by the board as
6 you're looking at petitions, as you're looking
7 at things that would be potentially added to
8 the National List.

9 The National List is based on
10 those proposals from the National Organic
11 Standards Board and the program. NOP cannot
12 add a substance to the National List that has
13 not been recommended by the NOSB.

14 The evaluation criteria by the
15 board includes the potential for detrimental
16 chemical interactions with other materials,
17 the toxicity and mode of action of the
18 substance and of its breakdown products or any
19 contaminants and their persistence in areas of
20 concentration in the environment, and the
21 probability of environmental contamination
22 during manufacture, use, misuse or disposal of

1 such substance.

2 So that's a lot of stuff to look
3 at right there. And then it continues. Also
4 the effect of the substance on human health,
5 the alternatives to using the substance in
6 terms of practices or other available
7 materials, and its compatibility with the
8 system of sustainable agriculture. Again, a
9 lot of things for the board to look at and
10 consider in this matrix of criteria to
11 determine whether something should be added to
12 the list.

13 There's also additional criteria
14 for processing substances that are in the USDA
15 organic regulations and they include that the
16 substance cannot be produced from a natural
17 source and there are no organic substitutes.
18 The substance's manufacture, use and disposal
19 do not have adverse effects on the environment
20 and are done in a manner compatible with
21 organic handling.

22 The nutritional quality of the

1 food is maintained when the substance is used
2 and the substance itself or its breakdown
3 products do not have an adverse effect on
4 human health as defined by applicable federal
5 regulations. It goes on to say the
6 substance's primary use is not as a
7 preservative or to recreate or improve
8 flavors, colors, textures or nutritive value
9 that are lost during processing except where
10 the replacement of nutrients is required by
11 law. The substance is listed as GRAS by FDA.
12 We met with FDA, was it last week?

13 And FDA doesn't like that term
14 because they do not list substances as GRAS.
15 There's GRAS notifications. So we're working
16 with them to try to provide better
17 clarification on that. But the way it's
18 listed in the regulations is that the
19 substance is listed as GRAS by FDA when used
20 in accordance with FDA's good manufacturing
21 practices and contains no residues of heavy
22 metals or other contaminants in excess of

1 tolerances set by FDA.

2 And I think this is the final
3 point. The substance is essential for the
4 handling of organically produced agricultural
5 products.

6 We also need to look at how these
7 substances have overlaps with other
8 regulations. The National List substances
9 must meet certain eligibility requirements.
10 FDA or EPA must have authorized the substance
11 for the petition use in conventional
12 production or handling if applicable. So
13 that's what we have to do in terms of the
14 rulemaking for pet food or other topic areas
15 as well.

16 In addition to the FDA
17 requirements, non-organic ingredients and
18 processing aids must not be produced using
19 excluded methods, genetic engineering. And as
20 we're working with the GMO vaccine issue the
21 definition of excluded methods and how, for
22 instance, APHIS looks at genetic engineering

1 may not be exactly the same so that's been a
2 challenge. Also ionizing radiation and sewage
3 sludge are also prohibited.

4 Okay, so we're celebrating 10
5 years of USDA organic. Mark Lipson is going
6 to cover that a little bit more.

7 And then I also wanted to thank
8 Barry Flamm for his service to the board and
9 the organic community. If you've ever had a
10 chance to talk to Barry he's had an amazing
11 career and the stories he can tell are just
12 all over the map.

13 When he was young he traveled
14 throughout the U.S. and has some wild stories
15 to tell of some of the places that we went and
16 the people that he encountered on the way.
17 But then after that he had a career with the
18 Forest Service.

19 He was on the National
20 Environmental Quality Board if I get that
21 correct during the Carter administration and
22 did a lot of really great work during that

1 time frame. It was part of -- USDA had a
2 program for environmental quality and Barry
3 worked there until a change of administration
4 where that program was eliminated as I
5 understand. So Barry has contributed a lot to
6 the environmental cause over many decades and
7 I just want to thank you for your service and
8 your time, Barry.

9 (Applause)

10 MR. MCEVOY: Okay, and this is
11 just a picture of a biodiverse coffee farm in
12 Costa Rica that I thought would be appealing
13 to Barry showing lots of different vegetation.
14 There's actually coffee in there somewhere but
15 also other, a polyculture of various crops.

16 Okay and from there I think I'm
17 turning it over to Mark. Okay, for those who
18 don't know, Mark Lipson has been at FDA for 2
19 and a half years, came in to be the organic
20 policy coordinator for USDA. So he works
21 across all USDA agencies to promote and
22 support organic agriculture. So whereas the

1 NOP focuses on the regulatory aspects of
2 things and he's a great support to us there
3 Mark gets to work with all the different
4 agencies, with APHIS on the GMO issues, with
5 crop insurance, with NRCS, many different
6 things. So Mark, thank you.

7 MR. LIPSON: All right. Thanks,
8 Miles. Good morning, everyone, thanks for
9 being here. Good morning, board members.

10 As you know this month does mark
11 the 10-year tenure of the organic seal and the
12 national organic regulations. Do we know what
13 the first date of the use of the seal was?
14 Somewhere like right around this week 10 years
15 ago.

16 And a lot obviously has happened
17 in that time. The organic seal has become a
18 much bigger deal than anybody really could
19 have expected. And especially given the many
20 daunting challenges that we all face in making
21 this the program that we want it to be.

22 We had a brief celebration at the

1 Department last week primarily to recognize
2 the staff members who have been working on the
3 NOP staff for much of this time. I think we
4 gave certificates to the folks who had been
5 there for more than 5 years as part of the NOP
6 and we had a wonderful home-baked cake from
7 Jenny Tucker. I loved it.

8 And the Deputy Secretary Kathleen
9 Merrigan, as you know one of the legislative
10 staffers who worked on the Organic Foods
11 Production Act and a former NOSB member and
12 Administrator of the Agriculture Marketing
13 Service at the time that the final rule was
14 promulgated wanted to send her regards to the
15 board and everyone attending to mark this
16 anniversary.

17 So we're just going to go ahead
18 and roll this video that she taped to send her
19 greetings and feelings on this occasion.

20 (Video playing)

21 DEPUTY SECY MERRIGAN: Hello, NOSB
22 members and those of you in the audience. I'm

1 Kathleen Merrigan, the Deputy Secretary of
2 Agriculture and maybe more important to this
3 day a former NOSB member.

4 I served nearly 5 years and some
5 days I say to myself whoever thought a 5-year
6 term was appropriate. Doesn't it seem long to
7 you now that you're sitting in those seats?

8 I really want to first acknowledge
9 the incredible service that you provide as
10 NOSB members. I really personally do know how
11 many hours you devote to the work that's so
12 important to the organic community and to
13 consumers who care so much about the organic
14 label.

15 It's hard work and it's never-
16 ending work because from the very start the
17 people who birthed the organic movement, we've
18 always said that organic is going to be
19 constantly evolving. With new science, new
20 knowledge we're going to be in the process of
21 continuous improvement. So the work of the
22 NOSB is never-ending. That's good news, it

1 really is, and so I just want to applaud you
2 for everything that you're doing.

3 You're grappling with a lot of
4 tough issues but the Secretary and I appointed
5 you and we're confident in your ability to do
6 the job. So, thank you.

7 I also wanted to come albeit by
8 video today to celebrate the fact that we're
9 hitting the 10-year mark of the implementation
10 of the final organic rule. Time flies.

11 I actually was out this morning in
12 Virginia. You can't see it but I'm actually
13 wearing jeans here at USDA because I was out
14 on a certified organic farm, really amazed by
15 what I was seeing in terms of innovations, so
16 thrilled that a lot of their food is going
17 directly into the schools and that the schools
18 are coming to visit the farm. We're really
19 into farm-to-school but we're also very into
20 school-to-farm. What a great way to start my
21 day.

22 And to know that we've had 10

1 years of this rule in place which has provided
2 a strength and a credibility to the National
3 Organic Program that has allowed the industry
4 to grow and prosper.

5 We just released on October 4th a
6 national survey of organic farmers and I
7 appreciate everyone who participated in that.
8 That really provides a lot of important data
9 that was something that the Risk Management
10 Agency took on because they really want to get
11 the kind of data necessary to improve crop
12 insurance instruments for the organic
13 industry.

14 They're just one of many agencies
15 at USDA. And what the Secretary and I have
16 said is that we're really proud of what the
17 National Organic Program is doing and we're
18 really glad to celebrate the 10 years of the
19 rule in place, but everyone in the house, all
20 of our different agencies, should be standing
21 up tall and helping the organic industry.

22 In fact, our Strategic Plan at

1 USDA calls for a 25 percent increase in the
2 number of certified operations between the
3 years 2009 and 2015. An audacious goal, but
4 if everyone around USDA does their part to
5 help organic farmers and ranchers and
6 processors we believe we will cross that
7 finish line.

8 We've had some incredible work on
9 my trade team opening up new doors in the
10 European Union and Canada. We have done some
11 important work with our colleagues in the
12 federal government, the International Trade
13 Commission, getting them to collect some
14 important data that you can now receive from
15 the Foreign Ag Service's website.

16 We've been doing incredible work
17 in the research arena. That continuous
18 improvement? That means research in the
19 pipeline. We've seen over \$100 million spent
20 on research. I remember a day when the
21 Organic Farming Research Foundation, Mark
22 Lipson came out with that report "Searching

1 for the 'O' Word" and it was less than one-
2 tenth of 1 percent of USDA research directly
3 pertinent to organic agriculture. Times sure
4 have changed.

5 So anyhow, I could go through and
6 catalogue all the different efforts that we're
7 undertaking here at USDA but we've got one-
8 stop shopping for you. If you go to our
9 website front page and hit "Results" you'll
10 see that among the handful of documents there
11 we have a results document for organic
12 agriculture. Please read it, please share it
13 with colleagues. We're really proud of the
14 work that we're doing.

15 And the Secretary and I are really
16 very, very proud of our association with the
17 organic farmers and ranchers who are out there
18 innovating on the field every day. Good luck
19 with your meeting.

20 (End of video)

21 MR. LIPSON: Okay. And then I
22 have a few slides to add.

1 I'll just reinforce the depth of
2 commitment that the Deputy Secretary has of
3 course to this program and all of the work
4 that all of you are doing in organic
5 agriculture.

6 As the Deputy mentioned the USDA
7 Strategic Plan -- first time there's ever been
8 anything like this -- calls for a numerical
9 increase in the number of certified organic
10 businesses in the U.S., 25 percent increase
11 between 2009 and 2015.

12 So I'm just going to run over a
13 couple of things very quickly that we're doing
14 towards that goal. Implementation of the 2008
15 Farm Bill provisions for organic of which
16 there were a number of very important ones.
17 My position was created in 2010 as an organic
18 policy advisor to the Secretary and to the
19 Office of the Secretary generally.

20 I chair the Department-wide
21 Organic Working Group which brings together
22 members from all across the Department, from

1 all the different agencies who have organic in
2 their portfolio either in a program or service
3 or interest within that agency. The working
4 group has a number of interagency projects
5 that it's working on trying to coordinate
6 efforts across the Department. And the most
7 notable example of that is the Organic
8 Literacy Initiative which Miles referred to
9 and I'll show you a little bit more about.

10 First of all, Farm Bill results.

11 As the Deputy mentioned, over \$100 million in
12 organic research and extension in the last 4
13 years. Many of those investments of course
14 are still in progress. We're just beginning
15 to see the actual results from that research
16 and extension work come out of the pipeline
17 and be available to producers and handlers.
18 So this is a very, very significant area of
19 work inside USDA and people should be getting
20 involved with their researchers and extension
21 folks in their area to start utilizing those
22 results.

1 This includes the e-Extension,
2 electronic extension service for organic, the
3 eOrganic. Another big accomplishment is in
4 terms of data that is available now to help
5 producers with financing and with business
6 planning. We've got a better baseline of data
7 about the organic sector and prices and
8 results that you can take to your banker than
9 we've ever had before. We know that this is
10 a significant barrier for many organic farmers
11 is being able to provide data for their
12 financiers.

13 We're making progress on crop
14 insurance. And this is related of course to
15 the data question. I'm going to talk about
16 that a little bit more in one second.

17 Certification cost-share, that is
18 support for producers and processors to bear
19 the cost of certification. Over \$21 million
20 has been allocated from money that was
21 appropriated -- or required in the Farm Bill
22 in 2008.

1 Conservation program support to
2 this date explicitly for conservation
3 practices within the context of organic and
4 transitional systems, over \$60 million. So
5 you can see that there's been almost an
6 exponential increase in resources devoted by
7 the Department to organic agriculture. And we
8 hope it's having impact. We know some of it,
9 we can measure some of it. Other parts of it
10 we won't be able to measure for some time.

11 Now, let me just say briefly as
12 the Deputy mentioned we just last week
13 released a new survey by the National
14 Agricultural Statistics Surveys of certified
15 organic producers. Just strictly certified
16 surveys was the object of this survey. It was
17 financed by the Risk Management Agency in
18 order to provide them with data necessary for
19 further improvements in providing equitable
20 crop insurance to organic producers.

21 So primarily this data will be
22 used by RMA to implement what we call price

1 election for organic producers, that is being
2 able to provide a payout price if you have a
3 loss that takes into account the actual market
4 value of the organic crops that were lost
5 instead of what has been the rule, that you
6 could only get paid out for the conventional
7 price because that was the data that USDA had
8 to work with.

9 So you just go to the NAS website,
10 nas.usda.gov. It's a hundred some pages of
11 very granular data there. And I'll just point
12 out that this is not exactly comparable to the
13 2008 Certified Organic Production Census
14 Report because that had a wider list frame.
15 That is, it included claimed organic,
16 producers who were exempt from certification
17 by virtue of being under \$5,000 in sales and
18 transitional organic producers. So the two
19 reports don't exactly match up but there is
20 important data that can be drawn from both of
21 them.

22 And I'll just mention very briefly

1 the situation with the Farm Bill programs
2 because I'm sure many of you are curious about
3 it. USDA is evaluating the implications of
4 the fact that Congress did not yet renew the
5 Farm Bill. Many of these programs that we're
6 speaking of have technically expired.

7 Some of them continue in the
8 current fiscal year by virtue of the
9 Appropriations Bill that was passed which was
10 what they call a 6-month continuing
11 resolution. So some programs continue to
12 function even though their Farm Bill
13 legislative authority expired. Other programs
14 we're figuring out what the implications of
15 that expiration are right now. We hope that
16 that will be temporary but because many of
17 these things are interlocking it's kind of a
18 complicated process. So that's really all we
19 can say at this point is that we are closely
20 evaluating the implications for all these
21 programs and the impacts on the users of them.

22 So, a very important product to

1 the Organic Working Group that several people
2 have mentioned, and I'm just going to say a
3 little bit more about this, is the Organic
4 Literacy Initiative. It helps users -- well,
5 you already saw this slide on Miles's
6 presentation.

7 The basic impetus for this was
8 recognition by the Organic Working Group that
9 many people, many employees of USDA still did
10 not know in some cases that there even was a
11 USDA National Organic Program, in many cases
12 what the details were and how it worked. So,
13 the primary drive of this initiative is for
14 USDA employees. It's a training program to
15 try and ensure that all USDA employees, all
16 those field offices know about the organic
17 rules, what certification means, what it takes
18 to be an organic producer. So if somebody
19 comes in and says hey, I'm interested in this,
20 how can you help me they aren't just getting
21 a blank wall, or that the USDA employees are
22 better able to help them answer that question.

1 One of the most important aspects
2 of this is the new USDA Organic Resource
3 Guide. This is the first time we've ever been
4 able to compile all the different resources
5 for organic producers and handlers in one
6 place.

7 This is a reference tool for both
8 USDA employees and members of the public to be
9 able to try and find resources that are
10 helpful to them. And it's got contact
11 information for actual physical people and
12 their phone numbers and all the relevant
13 agencies.

14 This is how the guide is
15 organized. It's basically a progression that
16 moves from most directly relevant, that is
17 direct support to organic producers and
18 handlers, moving outward to more general
19 programs that will occasionally be of
20 importance to a given organic producer but
21 also point out many useful resources that the
22 Department has that aren't necessarily focused

1 directly on organic.

2 In between there there's a section
3 on research and data and technical
4 information, and then marketing and
5 infrastructure. This is -- hopefully this
6 topical organization helps people find the
7 resources that they're specifically looking
8 for as quickly as possible.

9 And then there are two training
10 modules that are the result of this project,
11 Organic 101 and 201 that go into different
12 levels of detail about the program, about the
13 standards and about the other resources that
14 are available in USDA.

15 And there's a version of this that
16 is specifically for USDA employees but they
17 are also public. So it's essentially the same
18 material, just in a different system for
19 access.

20 And all this is bundled together
21 in what we call the Organic Literacy Toolkit.
22 So we have the registries guide, the training

1 modules and then these outreach materials as
2 the brochure and poster that are available for
3 USDA offices to use.

4 But we think that will also be
5 useful for members of the organic community to
6 use in their own outreach to others. If
7 you're recruiting producers for your business
8 or you're trying to explain to your consumers
9 what organic is about, we hope that this will
10 be a useful tool.

11 So this is the message from the
12 Deputy that went with the organic literacy
13 materials. This is part of what's going out
14 to all USDA employees. Every part of USDA has
15 some responsibility for helping the Department
16 reach that goal and for assisting the organic
17 community.

18 Now, one primary example of that
19 that I want to show you, and this is just the
20 same slide that Miles showed you, but that's
21 the website there, "Organic Info" where all
22 these materials are housed.

1 And so finally very briefly I'm
2 just going to talk to you about one of the
3 manifestations of the fact that organic is
4 relevant across the Department. One of the
5 crossovers has to do with the "Know Your
6 Farmer, Know Your Food" initiative which you
7 may know is the Department's effort to
8 coordinate resources across all the agencies
9 relevant to local and regional food systems.

10 What we call the Compass which is
11 the product of the "Know Your Farmer, Know
12 Your Food" initiative has two main parts.
13 One's a narrative. It contains a number of
14 case studies, videos, explanation about the
15 different aspects of local and regional food
16 systems that USDA supports through its many
17 different programs. And when you look at that
18 narrative you'll note that many of those
19 projects feature organic producers and organic
20 businesses.

21 And then the other main part of it
22 is this geospatial mapping tool which you see

1 on the right of the slide there which actually
2 electronically maps all the projects that are
3 encompassed within the "Know Your Farmer, Know
4 Your Food" initiative.

5 And this is just a slide of the
6 search that we did on the term "organic" with
7 the search function in this geospatial mapping
8 tool. Those are the projects that turn up
9 that have organic written into the text of the
10 project description or the project name. So
11 there's a very significant overlap here
12 between the "Know Your Farmer, Know Your Food"
13 initiative and the organic sector.

14 And then one of the great aspects
15 of this tool is that you can focus in on your
16 own community or region, look at all the
17 different things that USDA is supporting in
18 your area. You can find out where they got
19 their finding and then look at those programs,
20 see if that's appropriate for you. So it's a
21 great tool and we really encourage you to use
22 it.

1 So I'm just going to wrap up now
2 by coming back to the 10th anniversary. The
3 hallmark of the National Organic Program as
4 you all know very well is participation by the
5 entire community reflected both in the
6 composition of this board and the presence and
7 activity of all of you here.

8 As a token of that we'd like to
9 invite everybody to during the time over the
10 next couple of days sign the posters that we
11 have in the back of the room here celebrating
12 the 10th anniversary. There is some special
13 silver-inked Sharpies that the staff would
14 like you to use because that's what it was
15 designed for. But we'd like to get everybody
16 to put their name on that and be part of
17 documenting this juncture for us.

18 So I can take a couple of
19 questions from the board I guess if we have
20 time, if we're running ahead. Otherwise I
21 will leave it there and let you get on with
22 your meeting. Thank you for your time and

1 attention.

2 CHAIRPERSON FLAMM: Does anyone
3 have questions for Mark on the board? Mark,
4 do you wish to entertain any comments from the
5 audience?

6 MR. LIPSON: I think in the
7 interest of time we'll just, you know, go
8 ahead and keep moving.

9 CHAIRPERSON FLAMM: If there's no
10 comments then thank you very much, Mark. That
11 was a very interesting presentation. It's
12 wonderful to see such progress being made.

13 MR. LIPSON: Thank you all very
14 much.

15 (Applause)

16 MR. MCEVOY: Barry, yes, usually I
17 take questions from the board if there's any
18 particular questions on the presentation. So
19 I'm willing to answer any questions that the
20 board has.

21 CHAIRPERSON FLAMM: Miles is
22 willing to take any questions you have since

1 we have a few minutes on the accreditation
2 process or anything else for that matter I'm
3 sure. So we do have a few moments if any of
4 the board members would like to follow up with
5 Miles.

6 I've never seen the board so
7 quiet, Miles. Thank you very much. We'll
8 take our break now and return at 9:45 when
9 we'll begin the public comment period. Thank
10 you very much.

11 (Whereupon, the foregoing matter
12 went off the record at 9:20 a.m. and went back
13 on the record at 9:48 a.m.)

14 CHAIRPERSON FLAMM: I believe
15 we're ready to begin the public comment
16 period. Michelle, if you would announce the
17 first speaker, please, and also who needs to
18 be prepared to come right up afterwards.

19 MS. ARSENAULT: Sure. So, Mark
20 Castel, you're up first and then Terry, you're
21 next on deck. And we have an on-deck chair up
22 here so as the first person begins if the

1 second person could stand up here and be ready
2 so we can keep the public comment rolling
3 along at a nice pace. Thanks.

4 MR. CASTEL: Thank you, Mr.
5 Chairman. My name is Mark Allen Castel. I'm
6 the co-director of the Cornucopia Institute
7 and I act as their senior farm policy analyst.
8 I'm a hired man. I work for farmers.

9 I recently heard an allegation
10 that the Cornucopia Institute was biased in
11 its research, especially the research we do
12 and the analysis for the National Organic
13 Standards Board.

14 I'm here today to tell you folks
15 that these allegations are 100 percent
16 correct. We are biased.

17 Our POV is based on two
18 presumptions. First, we feel that the Organic
19 Foods Production Act of 1990 should be
20 respected by the NOSB and vigorously enforced
21 by the USDA as Congress intended. And
22 secondly, we feel the work and deliberations

1 of the NOSB should be based on objective
2 scientific review with an emphasis on public
3 research rather than being dominated by
4 corporate lobbying and self-serving industry-
5 funded research. So there you have it, guilty
6 as charged.

7 We believe in organics. We
8 believe the law should be enforced. But talk
9 is cheap. There are too many major
10 corporations and their trade groups that
11 profess their dedication and commitment to
12 organic integrity and then sell out the ideals
13 this industry and movement was founded upon.

14 So currently, so is the current
15 reality consistent with the letter of the law,
16 the spirit of the law and most importantly
17 consumer protection of the working definition
18 of the organic label?

19 Do consumers think that 9,000-cow
20 dairy farms are what the organic label is all
21 about in the desert? It took years to get the
22 USDA to enact any kind of meaningful pasture

1 enforcement language. And the byproduct? No
2 enforcement. And these CAFOs continue to be
3 allowed to bring in conventional cattle.

4 So now, 2012. Feed prices are
5 high and the factory farms are forcing
6 legitimate family organic farmers out of
7 business. This would be horrifying to our
8 most important stakeholders, our consumers.
9 Is this horrifying to the growth proponents on
10 the NOSB?

11 We need the NOSB to act like the
12 NOSB did. Please take the initiative and
13 promulgate new rules, preventing conventional
14 cattle from competitively disadvantaging
15 honest farmers. Don't wait for the NOP.
16 Congress gave you the power to do this.
17 Please use it.

18 Chickens. One hundred thousand
19 laying hens in one building with no access to
20 the outdoors. Illegal, but continuing to
21 operate. Plenty of ten and twenty thousand-
22 bird buildings with a few doors and no more

1 than 1 to 5 percent of the birds ever outside
2 and porches. Illegal. This is not outdoor
3 access. And now the NOSB is proposing 2
4 square feet of outdoor access. Sorry folks,
5 that's a joke.

6 Remember, the Europeans with a
7 larger commercial egg market for organics than
8 the United States requires 43 square feet but
9 their eggs are supplied by family-scale
10 farmers, not the giant CAFOs that the USDA in
11 action is supporting. So I'm sorry.

12 Ask consumers what they think.
13 They think organic birds are outside. We're
14 not going to fool anybody with 2 square feet.
15 Whether it's factory dairy farms, fraudulent
16 feed, risky synthetic chemicals that are
17 approved for organic food. Are you asking for
18 more New York Times stories or maybe worse, 60
19 Minutes, seriously endangering the equity
20 we've all built in the organic label.

21 We risk the wholesale abandonment
22 of the organic label by many farmers and

1 consumers. Who will invent the next
2 alternative farming vehicle? It's within your
3 power to prevent this from happening. Thank
4 you very much, Mr. Chairman.

5 CHAIRPERSON FLAMM: Thank you,
6 Mark. Questions for Mark from the board?
7 Seeing no questions -- oh, sorry. Yes,
8 Calvin, address your question to Mark, please.

9 MR. WALKER: Mark, thanks for your
10 comments. What solutions do you see on some
11 of the things you expressed?

12 MR. CASTEL: Speak into the
13 microphone a little bit more, Calvin. I'm
14 sorry.

15 MR. WALKER: You mentioned quite a
16 few things. In a nutshell what are some of
17 the solutions that you see?

18 MR. CASTEL: Well, I'd like to
19 touch on two -- expand on two areas. One is
20 the law of unintended consequences. First we
21 started with these factory dairies and we're
22 proud at Cornucopia we've been able to shut

1 some down. But others have not even been
2 investigated. Ten thousand cows on a farm.
3 Obviously we have a competitive balance.

4 It's the same macroeconomics that
5 forced conventional dairy farmers out of
6 business. The move to the West, the move to
7 industrial-scale dairy.

8 But now the lack of enforcement,
9 rigorous enforcement on the propriety of
10 organics is pinching us in a couple of new
11 ways, Calvin. One is that the feed prices
12 have escalated along with conventional feed
13 exponentially. And what we have is wildly
14 profitable organic egg producers that are
15 really this industrial CAFO model with thirty
16 to hundred thousand birds per building. Some
17 of these outfits own 1 million birds.

18 And it's so profitable in this
19 industrial setting that they are able to bid
20 up feed and force out of business legitimate
21 beef and dairy producers that cannot match
22 their deep pockets for procuring the feed. So

1 we have organic dairymen and women cutting
2 back on how much grain they're producing,
3 cutting back on how much milk their cows
4 produce. And all the difference in the
5 market, when their milk production is cut back
6 it's all being made up by factory dairy farms.

7 So this is a cyclical problem.
8 It's putting certified organic family-sized
9 egg producers at competitive disadvantage.
10 Simultaneously with putting dairy producers in
11 a competitive situation on the wholesale side
12 in terms of buying their feed.

13 And you might not think it's
14 directly related but the conflict of interest
15 provisions that you're going to deliberate
16 about right now have a direct involvement in
17 some of these decisions, whether they're a
18 chemical or whether -- how aggressively we
19 crack down on the abuses in organic livestock.

20 And I'll tell you, the macro
21 problem is that Congress created this board to
22 be an independent board with statutory

1 authority very unlike other policy advisory
2 panels. And in an advisory capacity to the
3 USDA Secretary. Just like the Cornucopia
4 board of directors, and I'm happy one of our
5 board members is here so I hope I don't screw
6 up too badly, when we hire an auditor or when
7 the board deliberates as you're going to be,
8 you deliberate on either setting policy or
9 recommending policy.

10 When the NOP staff and the USDA
11 come in and tell you how to do your job
12 they're usurping the authority that Congress
13 vested in you. You folks have to make the
14 decision whether conflicts of interest exist.
15 If they don't feel that you're executing your
16 responsibilities within the framework of the
17 law that the USDA is incumbent to govern upon
18 then they have to tell you that. But to hand
19 over that authority to the USDA I think is
20 wrong and we're going to get more problems,
21 not less, in terms of conflicts.

22 CHAIRPERSON FLAMM: Thank you,

1 Mark. Colehour, did you have a quick
2 question?

3 MR. BONDERA: Thank you. I think
4 that I was primarily interested in hearing
5 about Cornucopia's perspective on conflict of
6 interest of addressing some of what you mostly
7 mentioned, the livestock issues and whatnot
8 and how revealing those conflicts of interest
9 might affect our decisions or impact our
10 process. But I feel like you may have
11 addressed that. But if you have something to
12 add regarding that detail.

13 MR. CASTEL: Well, the only thing
14 I would add, Colehour, is twofold. The
15 proposal that this deliberation by the NOP,
16 not the NOSB, be done in essence in secret and
17 that we may or may not know until after the
18 fact. And we won't necessarily know what the
19 conflict is.

20 You know, we have always operated
21 in a transparent mode. That's why this
22 audience is here that not only represents

1 themselves but like Cornucopia and the
2 National Organic Coalition have a wide
3 constituency of stakeholders. We need to have
4 the sunshine enter into this room. So the
5 transparency is one important thing.

6 The other is what constitutes a
7 conflict of interest. If at the last meeting
8 during the deliberations for carrageenan if an
9 executive whose company uses carrageenan,
10 whose company has sent representatives to
11 testify before this panel to appeal to you to
12 renew the status of carrageenan, that the same
13 company produces written commentary, the same
14 company's chief executive officer actually
15 called some of the NOSB members lobbying for
16 approval.

17 And if this person doesn't take
18 the opportunity to recuse herself or that the
19 NOP doesn't rule that yes, there is an
20 economic interest for the employer who's
21 paying the paycheck of this NOSB, then maybe
22 it doesn't matter that conflict is going to be

1 deliberated in public or private because there
2 is no such thing as conflict unless I happen
3 to be an entrepreneur and I manufacture
4 carrageenan. Maybe that extreme example which
5 probably will never manifest itself, maybe
6 that will be a conflict.

7 So, I think that this is -- we all
8 bring some kind of conflicts. I used to be a
9 certified organic grower. If I was sitting on
10 the board and still growing I would bring some
11 conflicts. We're only asking that those be
12 disclosed and they should be disclosed at the
13 beginning of the subcommittee deliberations on
14 a material. And then it should be up to this
15 board to decide whether there's enough of a
16 direct conflict and a direct economic interest
17 that that individual should be encouraged on
18 that one issue to step down and not vote.

19 CHAIRPERSON FLAMM: Thank you,
20 Mark, for your comments. We're taking this
21 COI very seriously and we'll have further
22 debate on it. Some of the things you just

1 mentioned I think we will be doing at this
2 meeting and we're going to -- but this is only
3 interim procedure so I appreciate your
4 comment. Thank you.

5 MR. CASTEL: Thank you, Mr.
6 Chairman.

7 CHAIRPERSON FLAMM: Next speaker,
8 please. And please state your name and your
9 organization.

10 MS. SHISTAR: Okay. My name is
11 Terry Shistar and I'm an ecologist working
12 with Beyond Pesticides.

13 I wanted to start by thanking you
14 all for devoting so much of your time and
15 energy to making the Organic Foods Production
16 Act work. Your role is really crucial and we
17 really appreciate it.

18 We've submitted comments on all of
19 the proposals under consideration at this
20 meeting and a summary of those is attached to
21 what I've just passed out. Our comments here
22 have to do with process at several different

1 levels. We believe that the NOSB and the NOP
2 should be much more process-aware in carrying
3 out their missions.

4 On the level of governmental
5 processes we've been very concerned about the
6 turnaround on the conflict of interest
7 proposal. The COI process should be
8 transparent disclosure enforced by the NOSB.
9 If there's a violation of federal COI laws or
10 regulations, or the NOSB acts outside of its
11 authority the NOP can step in citing
12 applicable laws and regulations.

13 NOSB must review all synthetic
14 substances before they are approved for use in
15 organic production. And we congratulate the
16 Inerts Working Group and the Crops
17 Subcommittee for producing a workable
18 proposal.

19 On the other hand, the options
20 presented in the discussion document on other
21 ingredients all fail to meet the requirement
22 to review all non-organic ingredients in

1 organic products.

2 The issue of biodegradable bio-
3 based bioplastic mulch probably could have
4 been better handled through a discussion
5 document rather than a proposal that
6 establishes the expectation that a decision
7 will be made without a thorough vetting of
8 many complex and scientific studies that have
9 been raised by commenters. These issues need
10 to be reviewed through a supplemental TR
11 before bringing the proposal to the board.

12 Organic infant formula would also
13 benefit from an issue paper that looked at the
14 classification of soy protein isolate, whether
15 mixtures of mostly synthetic materials should
16 be considered to be organic formula, and the
17 desirability of labeling any infant formula as
18 organic in light of negative impacts of
19 replacing breast milk with formula.

20 On the other hand, the omnivore
21 diets discussion document was a good example
22 of a discussion document that frames an issue

1 in a broader context, allowing specific
2 alternatives to be elicited and considered
3 outside the debate of our proposal just prior
4 to board vote.

5 Finally, one process issue that
6 involves the interaction of the NOSB and NOP
7 with the rest of USDA is that of seed purity.
8 The USDA must require terms and conditions
9 that are necessary for organic products to be
10 grown, sold and labeled in accordance with
11 OFPA. Given the threat to organic production
12 posed by the contamination by GE organisms
13 USDA must take actions to prevent that
14 contamination.

15 A crucial process issue arose at
16 the Albuquerque meeting when the NOP announced
17 the potential issuance of guidance for
18 materials classification. This caused the
19 board to abandon the current policy adopted by
20 the board in 2009 and delay decisions about
21 classification pending publication and
22 adoption of the new guidance.

1 Can the NOSB really do its job
2 without having any policy or guidance on
3 materials classification? We believe it was
4 a huge mistake on the part of the NOP to
5 undercut the board process by introducing an
6 outline of the guidance that differs
7 substantially from currently accepted policy
8 without consultation with the Materials
9 Committee, and an equally huge mistake on the
10 part of the board to delay decisions based on
11 the expectation of that guidance when the
12 board has policy on the issue.

13 Similarly we saw a striking
14 breakdown in process with the publication of
15 the September 12 memo on aquatic plants.

16 Thank you.

17 CHAIRPERSON FLAMM: Does the board
18 have questions for Terry? I guess not. Thank
19 you very much.

20 Next speaker, please. And please
21 give your name and organization.

22 MS. HOODS: Leanna Hoods, National

1 Organic Coalition. I want to thank you all
2 for all that you do. It seems as though your
3 job at each meeting is exponentially more
4 complex than the last and your dedication is
5 greatly appreciated.

6 My comments will be a bit global.
7 You can see our written comments for the
8 details and ask me about them if you want. As
9 you delve into the deep weeds of organic we
10 ask you to keep your eye on the prize: organic
11 as an alternative food and agriculture system.

12 Currently there are strong
13 advocates at the Agency, Miles, Mark, NOP all
14 together and certainly Deputy Secretary
15 Merrigan, but please remember USDA policy as
16 a whole is not friendly to organic as an
17 alternative system. So when NOP tells you
18 that they don't have the resources to complete
19 all the work that you move from this board we
20 respectfully request that you stay your
21 course. It is true in all of the regulatory
22 arms of government, EPA, FDA, USDA that they

1 may not have enough resources to complete the
2 necessary regulations and there's intense
3 politics about that.

4 But when NOC and others go to
5 Congress asking for more money for NOP
6 Congress members want to know what is on NOP's
7 desk that isn't getting done. Not NOSB, NOP.
8 Obviously we're in some sort of purgatory or
9 hell of budget crises, but when dollars become
10 available that's how they'll get allocated.

11 But this is a lot more than
12 unachieved work plans of regulators. What you
13 do is to interface with the public perception
14 of the value of organic. What are folks
15 asking for in their food? It's too often
16 something relatively amorphous like local or
17 natural. Because of perceived issues of
18 integrity with the organic label organic is
19 not mentioned as the sustainable alternative.

20 We must all change that because we
21 know organic is the only system with clear
22 definition and by the way transparent

1 discussion of the standards. Nowhere else in
2 our food supply do we as citizens get to have
3 a say.

4 So, for the issue of inerts it's
5 vital that you proceed on an aggressive work
6 plan to review them all. It's bad for the
7 integrity of the label if this important piece
8 is stalled any longer. It says to the public
9 that organic still allows these dangerous
10 materials with some out-of-date blanket
11 approval. And by the way, rotenone is in that
12 category as well.

13 And when the label looks bad the
14 entire organic system gets relegated to
15 characterization that organic is an expensive
16 label that doesn't do what it claims. Yet the
17 work that you do so heavily in the public eye
18 is the only instance where we as citizens and
19 you representing us citizens are determining
20 what goes into our food. Again I thank you
21 for that even when I disagree with you.

22 So here's some general specifics.

1 Don't allow material on the list if you
2 acknowledge that you don't know enough about
3 it, hoping that 5 years will get you more.
4 The tendency in sunseting is to leave a
5 material on which is not conducive to balanced
6 review. If you need to defer for another
7 meeting it's better than jumping in too fast.

8 We also believe in increasingly
9 sophisticated annotations. In this \$30
10 billion industry new technologies are coming
11 along fast but need your oversight. And we
12 encourage the industry to look at what you're
13 doing and find the alternatives, for instance,
14 to EDTA as an inert of dubious safety.

15 Other ingredients, synthetic
16 nutrients in infant formula inerts,
17 antibiotics on tree fruits. Don't fall into
18 the trap that because bad decisions were made
19 previously you must uphold them. We support
20 option C on the other ingredients document
21 with some more protections.

22 You can't fix it all, but organic

1 consumers don't like surprises. They do not
2 want to hear from the media about synthetics
3 in their organic food. They do want to know
4 that the label is transparent and that you are
5 transparent and that you have reviewed any
6 synthetics in organic.

7 This is what makes the difference
8 between the industrial food system and a truly
9 alternative organic food and farming system.
10 So in all that you do embrace this
11 transparency and we thank you for
12 participating in such a democratic process.

13 I have handed out our aquaculture
14 letter that I had referred to in our comments
15 that discusses this. Thank you very much.

16 CHAIRPERSON FLAMM: Thank you,
17 Leanna. Does the board have comments for
18 Leanna? Yes, Nick.

19 MR. MARAVELL: Leanna, I noticed
20 in your written comments some indication that
21 perhaps not all organic products would have an
22 analogous conventional product to measure up

1 to. In other words, the implication being
2 that just because we have a conventional food
3 product doesn't mean that we can produce an
4 organic product that is equivalent to that.
5 Could you discuss that concept and how that
6 might limit or increase the desirability of
7 organic products?

8 MS. HOODS: Sure. In general we
9 absolutely agree that this board needs to be
10 careful in all areas that just because there's
11 a conventional product that you have to do
12 everything possible and approve as many
13 synthetics as possible to get to an organic
14 analogue on that.

15 Specifically we noted this in our
16 discussion of the infant formula
17 fortification. And it's very important there
18 because the entry point for organic is often
19 the mother's milk is the first, but mothers
20 looking for better food for their children is
21 really an important place. And they want to
22 know that the infant formula is not full of

1 synthetics.

2 Highly processed foods may not be
3 able to be organic. And I'll say in two areas
4 here on infant formula. I'm really confused
5 on the issue of soy protein isolate and
6 whether it's approved for use in organic. It
7 was my understanding it wasn't because it was
8 extracted with hexane and there's no other way
9 to get it. And so a soy formula for instance
10 may not be an appropriate thing for organic.

11 The fortification issue in
12 addition fortifying with and using
13 preservatives, synthetic preservatives I don't
14 believe that organic consumers want to see
15 that. They want to see a whole food way to
16 meet those nutrient needs. And there are some
17 requirements in infant formula from FDA but
18 otherwise adding fortification, synthetic
19 fortification is not what organic is about.
20 Therefore, if it means that you can't -- that
21 we can't have organic infant formula until the
22 industry finds ways that are compatible with

1 the organic system then so be it. And that
2 will encourage the industry to grow using
3 organic methods and not trying to have
4 synthetics meet this.

5 So does that answer what you
6 needed, Nick?

7 MR. MARAVELL: Well, do you see
8 any way it could hurt the organic industry if
9 it's perceived that organic products are
10 limited in their ability to mirror
11 conventional products? Do you see any way
12 that could hurt?

13 MS. HOODS: That it could hurt to
14 not have a product, an organic product?

15 MR. MARAVELL: Hurt the industry
16 in general, yes. In other words --

17 MS. HOODS: Well, I know that
18 mothers want to have an organic infant
19 formula, that's what they -- but they want it
20 to be something that's without synthetics.
21 And so it could temporarily hurt the
22 marketplace but I would bet that if it's

1 painful enough the industry will come up with
2 a way to make an organic infant formula that
3 is not made with hexane-extracted soy or
4 synthetic fortifications.

5 And it would on the other side
6 really hurt the industry for mothers to really
7 understand how many synthetics and some would
8 believe unnecessary synthetics are used in
9 infant formula. So there's two sides to what
10 could hurt the industry.

11 CHAIRPERSON FLAMM: Thank you,
12 Leanna. Colehour, a quick question?

13 MR. BONDERA: Yes, thank you.
14 Leanna, I want to ask you a question about
15 something you said that I wrote down. You are
16 transparent. And I think that when you said
17 that the suggestion was that related to the
18 transparency of our actions. And it struck in
19 me, and I think as the chair of the Policy
20 Development Subcommittee it struck in me this
21 whole conflict of interest question.

22 And I wonder if the National

1 Organic Coalition has something to say related
2 to how that transparency correlates with
3 conflict of interest topic. And I'm not sure
4 you do or if that was related to why you said
5 it, but if it is I would appreciate that.
6 Thank you.

7 MS. HOODS: Yes, we made detailed
8 comments about that. And I may have come
9 close to standing on a table yesterday
10 screaming about it. But conflict of interest
11 policy, for all of us who have been on any
12 sort of board is as much about the disclosure
13 as anything else.

14 And I think on boards, advisory
15 boards it's a significantly different
16 discussion than what regulators have to deal
17 with as paid staff who are regulators. That's
18 a discussion about -- that goes much deeper in
19 a lot of ways and is not -- and it's about our
20 belief in what our government is doing. It's
21 not particularly about -- not always entirely
22 about how it relates to the public. But you

1 as an advisory board, it's about -- it's all
2 seeing how you make your deliberations.

3 And so first of all, as I noted in
4 my comments, whatever USDA Board of Ethics
5 decides that they think they must do, and I
6 would take some disagreement at what I saw in
7 the proposal, but whatever they decide they
8 must do you can still do your own thing on
9 conflict of interest and disclosure.

10 And I think it brings a real
11 measure of accountability to each other as
12 colleagues and accountability to the public
13 when you all make some disclosures in the
14 public during these meetings related to each
15 of the deliberations that you're making. And
16 we can't prevent the conflict. We want there
17 to be some conflict in a lot of ways. So,
18 it's about everybody, you all understanding
19 from each other and us understanding as we
20 watch you where you're coming from on that.

21 So to the extent that as much
22 disclosure is needed to get that across to us

1 aids in all of us understanding and you being
2 accountable to yourselves and to us. So I
3 implore you to come up to -- I liked the
4 Albuquerque policy. I think it needed a
5 little more work but that you all have your
6 own policy and do your own disclosure on
7 conflict of interest. That's really, just a
8 really important thing.

9 CHAIRPERSON FLAMM: Thank you,
10 Leanna, for your comments and advice. We
11 appreciate that.

12 MS. HOODS: Thanks a lot.

13 CHAIRPERSON FLAMM: The next
14 speaker, please come up, give your name and
15 your organization, please.

16 MR. ROBINSON: Good morning. I'm
17 Bill Robinson, chairman of the board of BJE
18 Farms and Creamer Feed, Nature's Best Organic
19 Feed.

20 I have three subjects this morning
21 I'll try to rush through. I feel there's no
22 more important issue facing the NOSB than the

1 credibility of the organic meat, dairy, egg
2 and grain industries resulting from the
3 presence of GMOs in the grain supply.

4 The current position which I have
5 here from the NOP encourages the corruption of
6 integrity of the entire organic system which
7 consumes certified organic grains. It's like
8 a don't ask, don't tell policy.

9 My company, Kreamer Feed, Nature's
10 Best Organic Feed, has been testing all
11 incoming corn, beans, soybean, meal for years.
12 We stopped testing in 2012 due to the severe
13 grain shortages and the NOP's current position
14 on GMOs in grain. We simply could no longer
15 afford to be the only company that cares.

16 We have experience with Romer Labs
17 on qualitative testing which they call
18 AgriStrip for soybeans and meal. We have
19 experience with Envirolomics Companies
20 quantitative tests for corn and soybeans, and
21 I can share those results with the committee.

22 Prior to the meeting we did test

1 our organic seed corn and found it to be non-
2 detectable for GMOs. However, Envirolitics
3 Companies told us that they have no test kits
4 available for rye or wheat seed.

5 I'd just like to offer our
6 experience and our company, our personnel any
7 way to the subcommittee, anything that we can
8 help in this policy development. I'll be here
9 all week and we'll be attending the other
10 subcommittee meetings.

11 On GMO vaccines, after Albuquerque
12 I ascertained that our company, BJE Farms,
13 uses 11 vaccines from 5 different companies in
14 our organic poultry production. Four of these
15 vaccines are GMO-based. One is the salmonella
16 vaccine we talked about in Albuquerque. It's
17 produced by the Fort Dodge Company. The
18 vaccine is critical to minimize the threat of
19 salmonella bacteria in organic eggs. The
20 organic egg industry of course cannot afford
21 a human illness or an outbreak of salmonella
22 caused by organic eggs.

1 The other three GMO vaccines we
2 use are all produced by the Ceva Bioimmune
3 Company and they're used for broilers, turkeys
4 and young layers to protect them from various
5 diseases. They're technically given in ovo 3
6 days prior to hatching when they're
7 transferred from the incubator to the
8 hatchers. This procedure needs to be
9 clarified by the NOP as it looks at compliance
10 to the rule. Since the rule requires poultry
11 to be managed from the second day of life does
12 this violate that rule or technically is it
13 exempt? Currently I suspect some poultry
14 companies are also using antibiotics in ovo
15 because it seems to be allowed by the rule.

16 The last subject I have is on the
17 omnivore diets and methionine. Prior to
18 October we were allowed 5 pounds of synthetic
19 methionine in chickens, 4 pounds in layers and
20 6 pounds in turkeys. We're now allowed 2
21 pounds in layers and broilers and 3 pounds in
22 turkeys. This is a 50 percent reduction or

1 more and now leaves us with synthetic
2 methionine at 1 percent -- sorry, synthetic
3 methionine is now allowed at one-tenth of 1
4 percent in the diet in layers and broilers,
5 and 15 one-hundredth of 1 percent in turkeys.

6 I'm asking that the NOP give some
7 guidance to the certifiers as they calculate
8 compliance to this new rule because we're
9 really going to be working with some moving
10 targets here managing our flocks according to
11 their needs. Kind of like the way the
12 certifiers will be calculating the pasture
13 rule, they're going to have to calculate
14 compliance to that and I'd ask them to look at
15 total percent of the diet as opposed to the
16 hard and fast 2 pounds and 3 pounds.

17 I think I have a couple of seconds
18 left. I just urge the NOSB to allow the
19 omnivore diet because I think we're going to
20 need it with the reduced methionine levels as
21 another tool in our diet. I talk about like
22 fish meal, things like that that I'd like to

1 see allowed.

2 CHAIRPERSON FLAMM: Thank you,
3 Bill. Is there questions for Bill? Mac has
4 a question for you, Bill.

5 MR. STONE: What are the feed
6 formulators doing around the reduction in
7 methionine, or what are the growers going to
8 see if it's not quite meeting that nutritional
9 need that they've been accustomed to?

10 MR. ROBINSON: We don't really
11 know. We just started as the rule took effect
12 a couple of weeks ago so I haven't heard
13 anything from the production side yet as to
14 what effects we've had from the change. But
15 we're just going to need all the tools we can
16 get and that's why I'd urge the omnivore
17 allowance or discussion moves forward and get
18 policy developed on that.

19 Because, you know, we've gone,
20 like I said, it's a pretty significant
21 reduction of methionine, over 50 percent in
22 the diets. I expect slower growth rates for

1 one thing, effect on egg size in the layers,
2 slower growth rates in the turkeys and
3 broilers which in itself is just an economic
4 issue. That can be overcome. And we'll just
5 continue to monitor bird health and see what
6 effects we have there. Thank you very much.

7 CHAIRPERSON FLAMM: Thank you,
8 Bill.

9 MR. MARAVELL: Can I ask a
10 question?

11 CHAIRPERSON FLAMM: Can we call
12 Bill back?

13 MR. MARAVELL: Billy, I just
14 wanted to thank you for your remarks but also
15 to pick up on one that you made with regard to
16 vaccines in poultry products that were being
17 administered in ovo. And you were indicating
18 that you thought that that was an acceptable
19 practice because of the current USDA guidance
20 that poultry be managed from the second day
21 forward, second day of life forward
22 organically. Have you gotten any confirmation

1 out of the NOP on that issue?

2 MR. ROBINSON: No, we haven't. We
3 -- it's not a practice that we do in our
4 operations but I just thought if the NOP looks
5 at that and says okay, it's currently being
6 allowed in antibiotics or allowed to be
7 injected in ovo, then is that setting a
8 precedent that in the future GMO vaccines
9 would be allowed to be administered in ovo
10 because it's happening before the first day of
11 life. So I just think it needs clarification
12 for the industry.

13 MR. MARAVELL: So you say
14 currently you are not using eggs that have
15 been vaccinated.

16 MR. ROBINSON: No, we're not using
17 antibiotics. We are doing it with the GMO
18 vaccines in ovo currently. And that's
19 industry practice. That's why I just wanted
20 to get that out there to the committee so that
21 they could consider that in their policy
22 development.

1 MR. MARAVELL: Thank you very
2 much.

3 CHAIRPERSON FLAMM: Thank you,
4 Bill. Next speaker, please.

5 MS. ALLAN-FOSTER: All right, good
6 morning. My name is Robin Allan-Foster and so
7 in the interest of full disclosure, conflict
8 of interest, all kinds of potential and
9 perceived I was married a few weeks ago to Mr.
10 John Foster, a member of this board. So you
11 should know that.

12 (Applause)

13 MS. ALLAN-FOSTER: Thank you. So
14 I work as the director of quality farm and
15 global programs for CCOF Certification
16 Services out of Santa Cruz, California. We
17 are a non-profit organization founded in 1973.
18 We'll be celebrating our 40th anniversary next
19 year. We invite you all to come join us just
20 prior to EcoFarm in January.

21 We're one of the oldest and
22 largest organic certification agencies in

1 North America and we have over 2,300 certified
2 operations in 33 states in the U.S., Canada
3 and Mexico.

4 So I'm here to make some comments
5 on the proposals and discussion documents put
6 forth from the Livestock, GMO, Crops and CACS
7 as I guess it is now known. I'll be brief and
8 broad because we did submit numerous detailed
9 written comments.

10 So regarding the Livestock
11 Subcommittee documents on omnivore diets for
12 livestock we do not support the consideration
13 of allowing mammalian or poultry slaughter
14 byproducts to be used for organic livestock.
15 We believe synthetic methionine should
16 continue to be allowed until an alternative
17 natural source is found that could be produced
18 in sufficient quantities and acceptable
19 quality.

20 Regarding pet food amino acids we
21 do not think that materials for pet food
22 should be added to 205.603, the section of the

1 National List reserved for livestock
2 materials, until the rest of the NOSB pet food
3 recommendation has been implemented.

4 I understand that a version of the
5 proposal put forth publicly might not have
6 included relevant background information about
7 the committee's intentions on this. So if
8 that is true and I'm missing something I
9 apologize.

10 For the GMO Subcommittee regarding
11 seed purity we absolutely agree that GMO seeds
12 have no place in organic production. We are
13 concerned about a move away from process-based
14 certification to product-based certification
15 that would be determined by testing. Organic
16 producers already have to demonstrate that the
17 seeds they use were grown without the use of
18 GMOs. We believe that permitting producers
19 should be protected from GMO contamination and
20 that the financial and operational burden
21 should not be placed on the organic industry.

22 For the Crops Subcommittee

1 regarding biodegradable mulch CCOF is
2 supportive of biodegradable mulch being
3 allowed in organic production. The continued
4 use of such significant amounts of non-
5 biodegradable plastic is counter to organic
6 values and principles of resource conservation
7 and recycling. We think that allowing such
8 biodegradable mulches would have a
9 significantly net positive effect on the
10 environment that is worth moving forward with
11 the allowance of it.

12 Regarding ferric phosphate this is
13 very important to many of our clients. We
14 believe it should absolutely remain listed and
15 allowed for use while an independent review of
16 EDTA can be conducted.

17 And finally, for the CACS
18 regarding biodiversity we just wanted to let
19 you know that we have as an organization taken
20 steps to implement the 2009 biodiversity
21 recommendations which have overall had a
22 positive effect and have been not terribly

1 burdensome on us as a certifier or for our
2 farmer clients.

3 So that's all I have at this
4 point. Thank you and I'll open to questions.

5 CHAIRPERSON FLAMM: Questions for
6 Robin? Mac has a question for you, Robin.

7 MS. ALLAN-FOSTER: Sure, Mac.

8 MR. STONE: Robin, the annotation
9 on the biofilm talks about 90 percent
10 degradation or something. From a certifier
11 point of view what would you like to see so
12 that certifiers and inspectors can verify
13 degradation of the product without putting
14 undue burden on the grower or the certifier
15 for that matter?

16 MS. ALLAN-FOSTER: Well, the more
17 specific we can be about the requirement,
18 whether it's in an annotation or a definition,
19 however that is, you know, would go through
20 finally. We would expect that these materials
21 would end up being OMRI-listed or otherwise
22 reviewed and approved in a way that could be

1 applicable so that farmers do not have to be
2 trying to determine it themselves every year
3 for each material.

4 CHAIRPERSON FLAMM: Thank you very
5 much, Robin, and congratulations.

6 MS. ALLAN-FOSTER: Thank you.

7 CHAIRPERSON FLAMM: Next speaker,
8 please. Please give your name and your
9 organization.

10 MR. SANDLER: Thank you, Mr.
11 Chairman. My name is Joe Sandler. I'm an
12 attorney for and appearing on behalf of Dr.
13 Bronner's Magic Soaps of Escondido,
14 California.

15 Dr. Bronner's is the maker of the
16 nation's top selling natural brand of liquid
17 and bar soap in a number of varieties, all
18 certified, labeled, NOP-certified as made with
19 organic oils. And they also manufacture other
20 certified lotions, hair rinses and other
21 personal care products.

22 Dr. Bronner's appreciates this

1 board's recommendation made nearly 3 years ago
2 that NOP initiate a rulemaking to make the NOP
3 standards mandatory for personal care products
4 labeled organic, and wanted to briefly update
5 the board on a couple of significant
6 developments.

7 We pursued litigation for nearly 4
8 years against makers of personal care products
9 making outright organic claims when their
10 products -- for products which no reasonable
11 consumer in the organic marketplace would
12 consider organic because the main cleansing
13 and moisturizing ingredients in these products
14 weren't derived from organic material and they
15 contained petrochemical compounds, synthetic
16 preservatives and so forth.

17 Also, in January 2010 Dr.
18 Bronner's filed an administrative complaint
19 against these same producers with NOP. The
20 court in the litigation dismissed the case on
21 the basis that only NOP has authority to
22 regulate in this area, even the labeling of

1 personal care products, and no action has been
2 taken on the administrative complaint.

3 There have been a couple of
4 significant positive developments. First of
5 all, some of the defendants changed their
6 labeling practices to abandon any organic
7 claim.

8 Secondly, there was issued the
9 ANSI/NSF Standard 305 for labeling of personal
10 care products which does not allow any
11 outright claim that a personal care product is
12 organic unless it meets the NOP 095 standard
13 but does allow a product to be labeled
14 "contains organic ingredients" even if it has
15 cleansing and moisturizing ingredients made
16 with some non-organic plant materials but
17 meets other standards.

18 Third, thanks in no small part to
19 the efforts of one of the members of this
20 board, Whole Foods modified its policy to
21 require that any product it sells labeled
22 outright organic or made with organic has to

1 comply with NOP. But that policy does allow
2 the term "organic" or "organics" to be
3 included in a brand name even if it only meets
4 the contains organic ingredients standard of
5 the NSF standard.

6 So where does that leave us?

7 First, our products that remain in the mass
8 market and spa channels that are labeled
9 outright organic that comply with no standard
10 whatsoever. Secondly, there are products that
11 remain in the natural products marketplace
12 that have prominent organics claims in the
13 brand names but which are certified only to
14 the NSF standard that allows the main
15 cleansing and moisturizing ingredients to be
16 made from non-organic material.

17 Our -- Dr. Bronner's is asking NOP
18 as an urgent priority simply to take action to
19 clarify that any personal care product making
20 an outright organic claim has to comply with
21 the NOP 095 standard. We don't believe it's
22 as important now to deal with made with

1 organic claims and that just clarifying that
2 point as to outright organic claims but even
3 when contained in a brand name would not
4 require any protracted or lengthy rulemaking
5 because obviously would not require the board
6 or NOP to get into the weeds of allowances and
7 all of that.

8 So we hope that the NOSB will by
9 way of follow-up to its recommendation keep
10 this issue on the front burner and work with
11 NOP to address it as quickly as possible.
12 Thank you very much, Mr. Chairman.

13 CHAIRPERSON FLAMM: Thank you,
14 Joe. Any questions for Joe?

15 MR. SANDLER: All right, thank
16 you.

17 CHAIRPERSON FLAMM: Thank you very
18 much. Next speaker, please, and please give
19 your name and your organization.

20 MS. BAUMGARTNER: Hi, I'm Jo Ann
21 Baumgartner with the Wild Farm Alliance. I
22 had hoped to be here on Thursday to present my

1 comments on biodiversity and natural resource
2 conservation but couldn't and so I'm giving
3 them this morning.

4 As you know biodiversity
5 conservation is in the NOP regulations. It's
6 part of the definition of organic production
7 that biodiversity must be conserved.

8 The preamble goes much further.
9 It says that a producer must initiate
10 practices to support biodiversity and they
11 talk about compliance in how a producer must
12 incorporate biodiversity conservation
13 practices in the organic system plan.

14 Now, compare that with the natural
15 resources conservation part of the
16 regulations. Operators must maintain or
17 improve natural resources and the definition
18 is of natural resources soil, water, wetlands,
19 woodlands and wildlife. Soil, water,
20 wetlands, woodlands and wildlife.

21 The NOSB twice now has said
22 biodiversity includes much more than that. It

1 includes the variety of all life forms from
2 bacteria and fungi to grasses and insects and
3 mammals. It includes diversity from genetics
4 and species and populations, and also a range
5 of natural processes on which life depends
6 like water and nutrient cycling and predation.

7 We were really happy to see that
8 the NOP included natural resources -- soil,
9 water, wetlands, woodlands and wildlife -- in
10 the accreditation checklist this summer. We
11 think that biodiversity conservation needs to
12 be included in that.

13 The NOP also included in the
14 penalty matrix natural resources in three of
15 its four areas of violations. Again we think
16 biodiversity should be included in that and
17 that the fourth consideration where an
18 operators will actually get decertified needs
19 to address both biodiversity and natural
20 resource conservation. Right now it's only
21 soil and water.

22 So, for instance, an operator

1 could have egregious soil erosion problems and
2 they might get decertified, but if they were
3 to, say, take out a wetland, kill all the
4 wildlife on the farm and, you know, annihilate
5 all the biodiversity they'd still be in
6 business.

7 Another question that came up in
8 the biodiversity discussion document was if
9 the handlers should be conserving biodiversity
10 and they are considered operators. They can
11 address this by if they have effluent there
12 they would use -- put in a constructed
13 wetland. They could put up raptor perches
14 around grain situations, buildings that have
15 grains and they could use landscaping that
16 protects water quality.

17 Mother Jones a few years ago
18 published an article talking about how
19 thousands of acres of old growth forest in
20 Paraguay were cut down and then organic sugar
21 was grown in its place. And we feel like the
22 issue of converting high-value conservation

1 lands into organic grow crops really needs to
2 be addressed.

3 And this is happening here in the
4 U.S. where prairies are being converted to
5 organic land. It's a marketing competition
6 issue. It's not fair that some growers have
7 to wait 3 years and then these growers are
8 just converting. And prairies can support
9 rare species that aren't protected like sage
10 grass that then maybe eventually will get on
11 the endangered species list if we all don't do
12 a better job.

13 Also, oak woodlands are getting
14 converted to wineries -- or I mean wine
15 grapes. And oak woodlands support lots and
16 lots of bird species. Thank you.

17 CHAIRPERSON FLAMM: Thank you very
18 much, Jo Ann, and thank you for the very good
19 work that the Wild Farm Alliance does. Is
20 there a question for Jo Ann? Jay.

21 MR. FELDMAN: Thank you, Jo Ann.
22 Thank you for the work you do and Barry, thank

1 you for your work on this discussion document,
2 the work of the subcommittee. This is
3 absolutely critical to organic and its growth
4 into the mainstream.

5 So, in light of all of this work I
6 guess what I would like to know if you could
7 succinctly tell us what you think the most
8 important next steps are in this area.

9 MS. BAUMGARTNER: Well, since the
10 NOP added natural resources to the
11 accreditation checklist and to the penalty
12 matrix they need to publish directions so
13 certifiers know what that means.

14 And as you know we recorded
15 earlier at the last NOSB meeting that we
16 submitted a draft guidance for the NOP to
17 consider. But once the accreditation
18 checklist addition came out we realize that
19 guidance could take a long time. So we took
20 our guidance with broad-based support from
21 others and streamlined that to turn it into
22 instruction.

1 We'd love to see the NOP publish
2 instruction as soon as possible and then later
3 publish guidance. What the guidance doesn't
4 have and what's critical to incorporate is the
5 issue about high-value conservation lands. It
6 doesn't include definitions like biodiversity
7 conservation. It doesn't include the
8 definition of wetlands or riparian areas that
9 is part of the rule. So, first publish
10 instruction and then guidance.

11 CHAIRPERSON FLAMM: Thank you. Is
12 there any other question from the board for Jo
13 Ann? Thank you very much, Jo Ann. Next
14 speaker, please. If you would, give your name
15 and your organization.

16 MR. MALTBY: My name is Ed Maltby.
17 I am the executive director of the Northeast
18 Organic Dairy Producers Alliance and
19 coordinator for the Federation of Organic
20 Dairy Farms. I also consult with the state of
21 Massachusetts over both organic and dairy
22 issues, and I assist with the management of an

1 organically certified slaughterhouse in
2 western Mass. And I have three children and
3 one grandchild.

4 I'm going to jump first to the
5 origin of livestock rule even though this is
6 not before the NOSB but I never miss an
7 opportunity to push Miles and Melissa. If
8 there is a consideration of publishing just a
9 final rule we did have a proposed rule within
10 the proposed access to pasture which included
11 a lot of detail on the origin of livestock.
12 Then moving to a final rule immediately with
13 a short comment period would have overwhelming
14 support from all sides of the industry,
15 especially at this critical time for organic
16 dairy farmers where they are selling excess
17 cows onto the conventional market and losing
18 fine genetics.

19 I truly appreciate the work of the
20 board members and know exactly how much time
21 they put into what they do and the level of
22 commitment on all sides no matter what

1 discussion topics they're expected to be
2 experts on out in the field. And we've had a
3 very successful annual meeting with NODPA a
4 few weeks ago. You are very highly regarded
5 which is both good and an obvious burden
6 because they expect all the answers to come
7 from you rather than just recommendations to
8 an NOP that can take years to implement. So
9 thank you for your work and for your
10 protection of the integrity of the seal.

11 What we're facing in organic dairy
12 is we're losing organic dairy farms, we're
13 losing organic grain farms and that is the
14 economic reality. It is just not only because
15 of the high grain prices, it's because of the
16 increased costs and the lack of benefit,
17 economic benefit that dairy farmers find in
18 becoming organic.

19 One of the issues that we have to
20 be very much aware of is how to balance the
21 needs of the scientific community, the
22 consumer and organic production. What may

1 seem very necessary from a scientific point of
2 view, may have consumers jumping up and down
3 demanding it, may be impossible for the
4 organic production farmers to meet those
5 requirements within a set time.

6 Organic production is based on a
7 long time of building fertility with dead
8 livestock. It's building genetics, it's
9 building immune systems, it's building an
10 economic pattern that can work which can't be
11 changed overnight. So in your considerations
12 of this moving forward we ask that you take --
13 you consider the operational side and then
14 consider it again. Because without organic
15 farmers you don't have anything to eat that's
16 organic except if it's imported.

17 And this year we have for the
18 first time organic powder being imported into
19 the Northeast, organic milk powder being
20 imported into the Northeast. The majority of
21 the grain that we used in northeast dairy
22 farms will come from Canada and from South

1 America. And I had seven other things but
2 thank you.

3 CHAIRPERSON FLAMM: Thank you,
4 Edward. Do board members have questions for
5 Edward? Thank you very much. Next speaker,
6 please, and give your name and affiliation.

7 DR. HENDERSON: My name's Kent
8 Henderson. I am part of a six-person dairy
9 exclusive veterinary practice in Saint Albans,
10 Vermont.

11 As my wife and I were driving down
12 from Vermont yesterday, we took a 6-hour drive
13 down. She asked exactly why are you coming
14 down to this Organic Standards Board meeting,
15 Kent? And I -- the reason I am coming down is
16 to tell you what is happening on Vermont
17 farms.

18 We're losing farms in the state of
19 Vermont. Ag is a very important part of the
20 way of life in Vermont but a strong point
21 that's growing is the number of organic farms
22 in our state. It's up over 200 farms now.

1 But as a practice we're seeing a threat to our
2 organic farms and I'd like to impress upon the
3 board that organic farms in Vermont are being
4 limited in their biosecurity programs in that
5 their vaccine programs are being held up by
6 having parasitization in the dairy farms, in
7 the grazing farms that I'm seeing.

8 Another part of this is what is
9 the public's perception of organic products
10 going to be if they realize that their
11 products are coming from animals that have
12 higher parasite loads than animals that can be
13 on grazing programs and the parasite loads can
14 be taken care of safely with a product that
15 has actually been approved by this board 6
16 years ago for the treatment of emergency
17 situations. It's a product that went through
18 USDA testing and came up with a zero milk
19 withholding time. So my clients are having a
20 hard time understanding what's the difference
21 and why can't I have these products.

22 When I come to a farm and I see

1 animals like this it's gone too far. I've got
2 fenbendazole to use now. Even with a 90-day
3 milk withholding time this animal is too far
4 gone. We had to put her down and this was
5 what I found when I opened the cow up. This
6 is the lining of her gut. These are the worms
7 in her gut.

8 What we did is for the last 4
9 years our practice has canvassed at least 100
10 farms, organic and non-organic. All of the
11 organic herds are heavily parasitized. The
12 long up and down column reveals that every cow
13 that was tested was positive for internal
14 parasites. The smaller box at the bottom says
15 every animal had 20 eggs per slide.

16 And then I'm afraid my results are
17 covered up by the laptop up there, but what it
18 means is when we did the conversions we have
19 every cow making 80 pounds of manure,
20 spreading 80 pounds of manure in the pasture
21 every day. And she's transmitting almost
22 200,000 eggs, parasite eggs, every day she's

1 on the pasture. So if you've got 50 or 100
2 cows on the pasture every day they're
3 transmitting millions of parasite eggs to be
4 picked up. So we cannot maintain properly
5 controlled parasites this way.

6 Fenbendazole is the product of
7 choice. It clears out of the animal in 72
8 hours. It is absorbed by the nematode.
9 That's where the killing action takes care of
10 the parasite. When these parasite loads build
11 up it inhibits the TH2 helper cell that fights
12 off bacteria and viruses, therefore inhibiting
13 the effect of my vaccines.

14 What we do with these de-worming
15 programs, I have to de-worm all the animals in
16 the fall to keep them clean through the
17 winter, and then in the spring I de-worm them
18 again. After I put them to pasture they pick
19 up over-wintered parasites' eggs and if we
20 take them out then we can keep the pastures
21 clean all summer so there's no re-infestation.

22 I have to do the whole herd. I

1 have to reduce the 90-day milk withhold down
2 to a proper week. The 90-day milk withhold is
3 too long. It needs to be reduced to a week.
4 Sorry for going over.

5 CHAIRPERSON FLAMM: Thank you very
6 much, Kent. Is there questions for Kent?
7 Yes, Wendy.

8 MS. FULWIDER: Have any of these
9 producers used some of the alternative
10 treatments that are available and have they
11 been effective or not?

12 DR. HENDERSON: Yes. We've been
13 providing this information to our producers
14 for 4 years. I have seen the diatomaceous
15 earth tubs on their treatment cabinets and I
16 have not seen any reduction in worm eggs in
17 farms where these practices are taken care of.

18 I have to tell you that I've had
19 three herds that the next year showed up with
20 absolutely no parasites on the farm. I did a
21 little questioning. I'm not a certifier, it's
22 not my responsibility. I have a vet-

1 client/patient secret relationship but I can
2 tell you that those animals were de-wormed
3 with a non-organic improved substance. And I
4 think that may be where this is heading.

5 I have producers that are not
6 going into organic. They follow organic
7 processes in many things they do but they've
8 told me "I'm not going to go organic if I
9 can't de-worm my cattle." I've got a growing
10 number of producers that armed with this
11 information are thinking that way.

12 CHAIRPERSON FLAMM: Jean has a
13 question for you.

14 MS. RICHARDSON: Dr. Henderson, I
15 know that you're a big advocate of the use of
16 fenbendazole, for example, as a de-wormer. Is
17 there any new research that you're aware of
18 that's come up in the last few years since the
19 NOSB board looked at that that would help us
20 to have a better idea of how long fenbendazole
21 stays in an animal and if it does a better job
22 than Ivermectin, for example, and why that

1 would be?

2 DR. HENDERSON: I would like to
3 refer you to our consultant that can answer
4 this, answer in-depth and we will in the
5 petition when we send it in. And it is Dr.
6 Don Bliss in Madison, Wisconsin.

7 I have this slide to show the
8 level of fenbendazole in the bloodstream. And
9 if you look at the bottom lining you can see
10 that it drops very, very quickly. You know,
11 in a matter of 4 days it has dropped down to
12 a nearly imperceptible level and I would have
13 to defer to a parasitologist, Dr. Bliss, to
14 tell you when it is totally gone from the body
15 system. But I'd have to refer back to the
16 USDA study where there was none found in the
17 milk.

18 CHAIRPERSON FLAMM: Thank you.
19 Nick has a question for you.

20 MR. MARAVELL: Yes, actually I
21 have two quick questions. One is have you
22 done any of your work with meat animals or

1 beef in this case. And the second question is
2 parasite loads can be greatly affected by
3 management practices. What -- if you had the
4 perfect world and all of your farmers had
5 access to the natural resources, land, water,
6 et cetera, that they needed what do you find
7 would be your recommendation for any change in
8 management practice? Or if you prefer to
9 answer that from the other side, what is that
10 limit -- what do you find is the most limiting
11 factor that is driving -- that then results in
12 driving these parasite loads up?

13 DR. HENDERSON: All right. First,
14 on the question about beef production, I have
15 very limited experience because I am from
16 northern Vermont. We have very few certified
17 beef organic herds. But I do have one herd
18 and he's in the process of de-certifying
19 because we have been running these PECs for 4
20 years. We cannot reduce the exposure level.
21 We have lost calves. You know, they're losing
22 the calves.

1 And so he is insistent that he
2 wants to save his cattle. He's taken -- in
3 his view he's taking the high moral ground.
4 He's taking the high moral ground in trying to
5 save his animals. He's grazing 100 animals on
6 1,200 acres and that is an excessive amount of
7 farm land. With the high cost of farm land
8 now in the Northeast I don't see how anybody
9 economically can do any better than that. So
10 he basically feels he's being pushed out of
11 the beef market because he cannot de-worm his
12 animals this way.

13 What I am seeing is my clients do
14 very well with grazing and with the high cost
15 of grain they're going to want to do more
16 grazing. This should work very well in
17 organic systems, but the type of grazing that
18 we're doing in the Northeast is we're making
19 the small paddocks, we're trying to put the
20 animals through these paddocks, you know, six
21 or seven times a year. Because of the high
22 cost of the ground we have to conserve it and

1 move them through.

2 I think that in this case with the
3 safe, environmentally friendly product like
4 Safeguard or fenbendazole that is my best
5 solution economically for these farmers.

6 CHAIRPERSON FLAMM: Thank you very
7 much, Kent. Appreciate your comment. Very
8 valuable. Next speaker, please, and give your
9 name and your affiliation.

10 MR. O'NEIL: Good morning. My
11 name is Colin O'Neil. I'm the regulatory
12 policy analyst with the Center for Food
13 Safety. Good morning.

14 I'd like to talk on a couple of
15 different issues: conflict of interest,
16 biodegradable plastic mulch, omnivore diets
17 and biodiversity.

18 First, CFS supports continued
19 efforts to update the NOSB's conflict of
20 interest policies and procedures. However, we
21 are perplexed by the turn to make COI
22 disclosures and the recusal process more

1 opaque instead of more transparent. CFS does
2 not support allowing COI discussions and
3 evaluations to take place outside of the
4 public process and feels that the NOP should
5 not be the sole audience and arbiter of COI
6 decisions.

7 It is the NOSB's responsibility to
8 deliberate and decide upon the appropriateness
9 of their board members to vote on a given
10 issue at its public meetings. With the NOP
11 serving as a valuable advisor but risk losing
12 part of its independence as an advisory body.

13 CFS also calls for the inclusion
14 of a COI requirement for all contractors and
15 consultants who conduct technical or TAP
16 reviews. We believe that a robust COI process
17 must require the inclusion of all researcher's
18 names and their COI disclosures in final
19 reports.

20 CFS does not support the allowance
21 of bio-based biodegradable plastic mulch in
22 organic production systems at this time.

1 While theoretically bioplastic mulch is
2 preferable to petrochemical-based mulch
3 research has not conclusively demonstrated
4 that biodegradation occurs or that it is
5 possible under all conditions, even if those
6 bioplastics conform to the ASTM standards.

7 We strongly urge the NOSB to not
8 consider biodegradation in the field to be
9 equivalent with removing plastic mulches at
10 the end of the growing season as per the
11 subcommittee document. Bioplastic mulch has
12 not undergone long-term soil testing in the
13 field to ensure that it does not negatively
14 impact agro-ecosystems. More research is
15 needed to ascertain how to facilitate
16 biodegradation under the different field
17 conditions that exist across the U.S. and to
18 evaluate the long-term impacts of bioplastic
19 mulch residues and dyes on cropping systems,
20 soils, biodiversity and wildlife.

21 CFS urges you to reject both the
22 petition and the proposed annotation at this

1 time until outstanding issues surrounding
2 degradation and environmental impact can be
3 resolved.

4 With regard to omnivore diets, the
5 use of synthetic methionine allows organic
6 animal producers to speed growth and attain
7 higher profits. But this type of industrial
8 CAFO-type production is not consistent with
9 the spirit of organic. Synthetic methionine
10 can be eliminated from animal diets without
11 exposing the organic label to new risks posed
12 by using animal byproducts and slaughterhouse
13 wastes and feed which risk consumer confidence
14 and could also create unnecessary health risks
15 for animals and humans.

16 Natural sources of methionine must
17 be explored such as organic meat, worms,
18 insects, organically certified fish meal if
19 available in the future, corn gluten meal,
20 potato meal and dietary supplements derived
21 from organic and natural sources. Clear
22 research goals and a time line to identify

1 safe alternatives are essential to permanently
2 eliminating synthetic methionine from organic
3 animal production at sunset.

4 On biodiversity, CFS supports
5 inspector and certifier trainings and the
6 development of guidance or instruction in the
7 NOP handbook to provide information on
8 biodiversity and natural resource
9 conservation. We encourage clarifications to
10 standardize inspection certification processes
11 to facilitate uniform implementation of
12 biodiversity conservation plans.

13 CFS further urges the development
14 of a detailed protocol that puts restrictions
15 on conversion of high-value ecosystems into
16 organic farms. Therefore, we further support
17 the Wild Farm Alliance's recommendations to
18 involve certifiers in determining land
19 conservation value and assuring biological
20 monitoring of losses, and that appropriate
21 mitigation measures are taken if land is
22 converted.

1 Additional research is needed in
2 the areas of GMO vaccines, aquaculture and
3 antibiotics in tree fruits. And I'd refer you
4 to our written comments for more information
5 on that. Thank you.

6 CHAIRPERSON FLAMM: Thank you very
7 much. Questions from the board? Zea, please.

8 MS. SONNABEND: Hi, thank you. In
9 your organization's written public comment
10 Lisa Bunin uploaded a bioplastics document
11 that said "do not distribute" all over it and
12 was some sort of preliminary document or
13 something that was -- had a fair amount of
14 erroneous information in it, or
15 unsubstantiated information I guess I would
16 say. And I'm just wondering what that means,
17 do not distribute, and where did that come
18 from. And -- yes. Thank you.

19 MR. O'NEIL: So I think what
20 you're referring to is there was a colloquial
21 document about preliminary studies that are
22 currently being done on field tests of a

1 number of the bioplastic mulches. That was I
2 believe at the time she published it was 12
3 months had been conducted, 12 months of study.
4 Now the data is up to 18 months and there is
5 a final version of that and I'd be happy to
6 distribute that to all of you.

7 Really what that refers to is that
8 there isn't the solid data needed to move on
9 this issue now. What is in this final
10 document of 18 months, which still isn't the
11 full 2 years, is that there is zero
12 degradation in some sites in Washington to 90
13 percent degradation in the Texas site. And
14 that refers to the study of three different
15 climatic areas as far as looking at
16 biodegradation of those plastic mulches. But
17 I'd be happy to circulate that to clarify
18 that.

19 CHAIRPERSON FLAMM: Thank you.

20 Jay had a question.

21 MR. FELDMAN: Thanks, Colin, that
22 would be helpful to circulate that because I

1 too was interested in the data coming out of
2 that, the initial study at least.

3 You know, I guess CFS is not the
4 only organization that's asked the board to
5 delay. Organically Grown is another
6 organization that's looked at this as well.
7 So, the challenge of course that we have,
8 there's a lot of interest in seeing us get off
9 the petrochemical-based plastic treadmill and
10 move to something.

11 Do you think within some period of
12 time such as -- what would that be where some
13 of these questions would be resolved? Are we
14 talking about long-term research needed that
15 cannot be resolved for many years? Could you
16 put this in perspective for us in terms of the
17 time frame that you think would be required to
18 answer the questions that you and others have
19 raised?

20 MR. O'NEIL: Sure. I think on the
21 issue of bioplastic mulch, you know, namely a
22 number of folks who side with the not ready

1 for prime time argument feel that not enough
2 field testing has been done to corroborate the
3 ASTM testing protocols which as we all know
4 are laboratory protocols, not real-world
5 conditions. They test optimal conditions.

6 So, as you mentioned Zea, this
7 preliminary research that is now at 18 months
8 has shown really inconsistent results. So you
9 know, there may be optimal soil conditions in
10 Vermont, optimal soil conditions in Texas with
11 regard to temperature, soil moisture, you
12 know, the type of soil necessary. So as the
13 ASTM requires mixing of three different, three
14 or more soils to maximize biodegradation, that
15 may not be consistent across the U.S.

16 So I think for us we would like to
17 see more research, more data, at least the
18 complete study of this 18-month study, bring
19 it to the full 2 years, so that we can know as
20 the NOSB is proposing, if the window is 90
21 percent degradation within a 2-year time span,
22 we should at least know that that has been

1 corroborated, that 2-year time span.

2 I understand that there are
3 additional studies coming out of Europe and I
4 think a number of us in the public and many
5 members on the committee may not be familiar
6 with those studies either. So I think it's
7 not a question of permanently delay.
8 Certainly CFS wants to see us move away from
9 petroleum-based chemical products like this in
10 the organic standard. But we just need to
11 take a precautionary approach toward these
12 issues so that we don't have to back-pedal
13 later I think. So there is no clear time
14 frame but at least certainly corroborating
15 this 2-year window would be helpful.

16 CHAIRPERSON FLAMM: Thank you,
17 Colin. Colehour has a question for you.

18 MR. BONDERA: Yes, thank you. I
19 appreciate CFS's work on the topic you were
20 just speaking about but I'm not going to ask
21 about that because of time.

22 So, what I do want to ask about is

1 a comment you just made related to conflict of
2 interest and how you feel that -- CFS feels
3 that it shouldn't happen behind the scene I
4 think I jotted down as you spoke.

5 And in my opinion from a
6 transparency perspective that makes sense.
7 However, if a petition is received it's not
8 received -- even though it is public it's not
9 dealt with publicly. And so I wonder if you
10 could at least briefly address if you don't
11 think that the NOSB should be dealing with the
12 conflict of interest issue even if that isn't
13 done at these public meetings which is quite
14 a bit after, for example, like I said, a
15 petition is received. Or if you have any
16 suggestions for how we could or should best
17 handle conflict of interest as it affects our
18 consideration of issues prior to these public
19 meetings and then the vote.

20 Because some of the discussion,
21 and I think that CFS is aware of this, has
22 been related to does a conflict of interest

1 start at the very beginning so that there then
2 is consideration of whether or not somebody I
3 going to recuse themselves completely from
4 discussion and not just a final vote. And so
5 there's -- because there's different levels of
6 conflict of interest recusal processes. And
7 so if you could address that I'd appreciate
8 it. Thank you.

9 MR. O'NEIL: Sure. And I'll try
10 to address that, Colehour. But many of you
11 know my colleague Lisa Bunin who sadly
12 couldn't make it today. And we'd be happy to
13 send further comments on that issue to all of
14 you in writing.

15 You know, I think in short, yes,
16 certainly conflicts of interest arise at
17 multiple points throughout the process and we
18 certainly acknowledge that. At some points
19 maybe a conflict may not require recusal but
20 that may be apparent throughout the process.
21 And I think really where we stand and many of
22 our colleagues stand is that the process

1 should remain public and transparent and
2 should be a complete engagement with the board
3 so that the board can constantly be informed
4 by those conflicts as they do arise throughout
5 the process. That helps to inform the
6 conversation and I think the more information,
7 not less, can only inform transparency and
8 better governance.

9 Also, as an independent advisory
10 body your independence is really informed by
11 your collective knowledge about your peers and
12 those potential conflicts that your peers and
13 colleagues may have.

14 CHAIRPERSON FLAMM: Thank you very
15 much, Colin.

16 MR. O'NEIL: Thank you.

17 CHAIRPERSON FLAMM: Next speaker,
18 please. Please give your name and your
19 affiliation.

20 MS. DIMATTEO: Good morning. My
21 name is Katherine DiMatteo. I'm with Wolf
22 DiMatteo plus Associates. We're a small

1 consulting business. Our current clients
2 include members of the International Formula
3 Council and Biodegradable Products Institute.

4 Our written comments, and these
5 are all comments, are not made specifically on
6 behalf of any one client but do represent the
7 opinions of my partners based on our personal
8 values and experiences and our work with both
9 current and past clients.

10 First, we want to thank the Inerts
11 Working Group and Crops Subcommittee for their
12 recommendation. Although we had previously
13 recommended a different path forward we can
14 support what has been presented except for the
15 suggestion that all fit for 25(b) substances
16 of minimal risk be reviewed. We believe this
17 goes beyond the requirements of OFPA.

18 We urge the NOP, NOSB and/or the
19 working group to communicate extensively
20 during your tight time line with the input
21 suppliers in order to gather information and
22 inform them of deadlines.

1 In terms of other ingredients
2 discussion paper. Substances that are
3 formulated with other ingredients, synthetic
4 or natural, and are reviewed during the
5 petition process can be and have been allowed
6 on the National List and in our opinion align
7 with the requirements of OFPA. This approach
8 should be continued with use of annotations
9 rather than individual review of such
10 substances.

11 Thirdly, the organic label and NOP
12 seal are allowed on products with up to 5
13 percent non-organic non-synthetic and
14 synthetic substances. Don't sacrifice the
15 producers of the 95 percent organic
16 ingredients by overzealous interpretation of
17 review criteria based on personal opinion
18 about the essentiality of the 5 percent
19 substances or other concerns that fall outside
20 the scope of the National Organic Program such
21 as support for breast-feeding which is a
22 woman's choice issue and in many instances not

1 an option for parents who adopt, for our gay
2 brothers and lesbian sisters, and for women
3 who have had breast cancer.

4 Optimal nutrition based on sound
5 science and recommendations of nutrition
6 experts for those who cannot choose for
7 themselves such as infants and pets should be
8 a priority in determining the allowance of
9 synthetic and non-synthetic nutrients.

10 We appreciate the complexity of
11 reviewing materials and applying the criteria
12 required by OFPA and NOP regulations. We urge
13 you to not take an overly prescriptive
14 approach and be sure alternatives are widely
15 applicable, legally allowed and viable when
16 considering renewal or approval of materials.

17 Continuous improvement cannot be
18 forced through excessive regulation. It comes
19 from the organic process-based and holistic
20 management systems, from guidance, training,
21 models, mentors, from appropriate tools,
22 innovations and encouragement of individual

1 motivation and commitment.

2 The very existence of certified
3 organic farms, organic processing, the
4 National Organic Program and input and
5 ingredient suppliers who innovate compliant
6 materials has been continuous improvement from
7 business as usual in the farm and agricultural
8 product sector.

9 Please provide producers with new
10 tools such as biodegradable mulch film and
11 also the time to find alternatives to rotenone
12 by imposing a restrictive annotation in line
13 with the Codex guidelines for organic rather
14 than a complete prohibition at this time.

15 Lastly, although I have heard that
16 there are some organic supporters and
17 organizations that no longer believe that it
18 is important to increase the number of acres
19 in organic production we still stand behind
20 this goal as a means to sustaining our natural
21 resources and a liveable and healthy
22 environment. Thank you.

1 CHAIRPERSON FLAMM: Thank you,
2 Katherine. Questions for Katherine? Thank
3 you very much, Katherine. Next speaker,
4 please, and give your name and affiliation.

5 MS. BEDROSIAN: Hello. My name is
6 Carol Bedrosian and I've been publishing the
7 Spirit of Change holistic magazine in New
8 England for 26 years.

9 I recognized long ago that food is
10 my best medicine and the healthiest food I can
11 eat is fresh, organic, local, non-GMO and
12 preservative- and pesticide-free. My mission
13 through Spirit of Change is to inform the
14 public about food as medicine, including
15 awareness of which ingredients to avoid.

16 I'm also a member of the
17 Cornucopia Institute and here today as a
18 citizen lobbyist. My original presentation
19 time was for tomorrow but due to a funeral I
20 was rescheduled today. Thank you for your
21 accommodation.

22 When taxpayers have already funded

1 research and consensus within the scientific
2 community already exists why should this board
3 request research on basic questions that have
4 already been answered? That food-grade
5 carrageenan predictably causes
6 gastrointestinal inflammation has been
7 accepted by the scientific community. This is
8 not considered controversial other than by
9 scientists employed by the companies that
10 profit from the continued use of carrageenan
11 in foods.

12 In the Journal of Nutritional
13 Biochemistry in 2010 the first line of this
14 peer-reviewed study states, "The common food
15 additive carrageenan predictably causes
16 intestinal inflammation in animal models."

17 The aim of that study was to
18 identify the particular pathways by which
19 food-grade carrageenan causes inflammation.
20 Authors include Dr. Sumit Bhattacharya,
21 professor at the University of Illinois at
22 Chicago's College of Medicine, Dr. Robert

1 Linhardt, senior constellation professor at
2 Rensselaer Polytechnic Institute, and Dr.
3 Gerbin Michelle of the French National
4 Scientific Research Center in the Sorbonne in
5 France.

6 These M.D.'s and Ph.D.'s have
7 accepted that the food-grade additive
8 carrageenan predictably causes intestinal
9 inflammation in animal models. They moved on
10 to find out if they could identify the
11 specific ways in which this happens. The
12 results of their experiments have been
13 published in peer-reviewed academic journals.

14 The American Diabetes Association
15 is funding research after a connection was
16 found between the consumption of food-grade
17 carrageenan and insulin resistance in
18 laboratory animals. Results from the initial
19 studies were confirmed by studies performed at
20 Vanderbilt's Mouse Metabolic Phenotyping
21 Center that small amounts of food-grade
22 carrageenan lead to glucose intolerance and

1 insulin resistance in mice. After a study
2 using human subjects suffering from ulcerative
3 colitis is currently underway at the
4 University of the Chicago Medicine School.

5 The funding for this research
6 comes from the broad medical research program
7 headed by Dr. Daniel Hollander, professor of
8 medicine at the UCLA School of Medicine. All
9 these physician scientists from the Sorbonne
10 to the University of Chicago to the UCLA
11 School of Medicine have accepted that
12 carrageenan causes intestinal inflammation.

13 Again, a direct quote from a peer-
14 reviewed abstract authored by Dr. Stephen
15 Hanauer, chief of gastroenterology and
16 nutrition at the University of Chicago's
17 Medical School. The common food-grade
18 additive carrageenan produces inflammation in
19 animal models of colitis and activates
20 inflammatory pathways in cultured human
21 colonic epithelial cells. Yet a majority of
22 the NOSB decided that this research and these

1 researchers are, quote, "not believable."

2 Then as if to rub salt in the
3 wounds of these researchers the Materials
4 Subcommittee put carrageenan on its list of
5 research priorities. Opinion leaders like Dr.
6 Andrew Weil and respected institutions like
7 the Rodale Institute are urging people to
8 avoid carrageenan.

9 We urge you to respect the
10 scientific community and remove carrageenan
11 from your list of priorities, and we would
12 urge the board to vote for reconsideration of
13 carrageenan's approval. Thank you.

14 CHAIRPERSON FLAMM: Thank you,
15 Carol. Is there questions by the board for
16 Carol?

17 MS. BEDROSIAN: Thank you.

18 CHAIRPERSON FLAMM: Thank you very
19 much, Carol. Next speaker, please.

20 MS. ARSENAULT: It's Bradie
21 Metheny.

22 CHAIRPERSON FLAMM: Please state

1 your name and affiliation for the record.

2 MR. METHENY: Hi, I'm Bradie
3 Metheny. I live in South Dartmouth,
4 Massachusetts. I'm here as a citizen advocate
5 for Cornucopia which I'm sure you all know is
6 a 7,000-member non-profit. We look at it as
7 sort of a safeguard for those of us who are
8 interested in organics and use it as a way of
9 getting things certified and safety.

10 Organics is really our safe haven,
11 particularly for those of us who are only
12 organic consumers and we'd like to keep it
13 that way. The last thing we want is to see
14 the same corporations that pollute
15 conventional food supplies to chip away at the
16 meaning of the word "organic."

17 Folks like me depend on the
18 organic label. We don't know everybody's
19 background, we don't know everybody that's
20 involved, but if it has an organic label we
21 assume and largely because of your effort that
22 it's safe so we don't need to know all the

1 rest.

2 The very basic idea that without
3 your guiding and without your view organics
4 can suffer. We can suffer. We can lose
5 faith. And for those of you who are dependent
6 upon trying to get the area to grow it's that
7 trust between the organic farmers and the
8 consumers that is so very important.

9 For every material input or
10 ingredient used in agriculture and food
11 production today there is a manufacturer or
12 trade association often joined
13 enthusiastically by its customers that will
14 use whatever tactics necessary to defend the
15 products and their safety and efficacy.

16 It's deeply disturbing when this
17 board when voting on petitions or sunset
18 reviews for material discounts independent,
19 publicly-funded research and instead depends
20 heavily on industrial testimony and
21 industrial-funded research, ignoring the
22 precautionary principle.

1 Siding with a corporate lobby that
2 has a financial interest in your vote
3 certainly does destroy confidence all the way
4 around, not only in the board but also in the
5 whole organic idea. We all pay a price when
6 that happens.

7 The point that we can reach for
8 food products during the organic label, and
9 rest assured that everything in the input on
10 the farm, and every ingredient in the product
11 has been carefully reviewed and approved as
12 essential, not environmentally harmful and
13 safe to our health. That is the basic
14 expectation that we, the consumer of organic
15 foods, has, and it's that expectation that's
16 rooted in the organic law that we feel must be
17 respected by you all.

18 We hope that going forward this
19 board will vote with integrity on issues like
20 ferric phosphate, biodegradable bioplastic
21 mulch, synthetic so-called nutrients and
22 synthetic preservatives for infant formula,

1 synthetic nutrients in pet food and all other
2 issues that you'll be discussing this week.

3 We think that your discussion -- I
4 think that the discussion that you're having
5 on the conflict of interest and when people
6 should recuse themselves is probably one of
7 the most important discussions you can have
8 and have it before the situation arises.

9 One of the things that the board
10 has -- thank you.

11 CHAIRPERSON FLAMM: Thank you,
12 Bradie. Questions from the board for Bradie?
13 John Foster, please.

14 MR. FOSTER: I think it's a pretty
15 straightforward question. Who should have
16 access to organic food in your opinion?

17 MR. METHENY: Who should have ask
18 access to organic food?

19 MR. FOSTER: Yes.

20 MR. METHENY: I think everybody
21 should have access to organic food.

22 MR. FOSTER: Awesome. Thank you.

1 MR. METHENY: I mean, I really do.
2 Thank you.

3 CHAIRPERSON FLAMM: Is there
4 another question for Bradie by any board
5 member?

6 MR. METHENY: Thanks again and
7 thanks for your time being out here. We
8 appreciate it.

9 CHAIRPERSON FLAMM: Thank you for
10 your comments. The next speaker, please.
11 Please give your name and affiliation.

12 MS. CZERNICKA: Good morning. My
13 name is Susan Czernicka and I've been a
14 psychologist practicing in Massachusetts for
15 30 years mostly with children and families.
16 I've spent time at Childrens Hospital and
17 worked for a number of years with the early
18 intervention program.

19 I'm a member of the Cornucopia
20 Institute and here today as a citizen
21 lobbyist. I volunteered to present testimony
22 because I want to ensure the integrity of

1 organic food.

2 I'd like to speak about organic
3 infant formula. Cornucopia was pleased to see
4 the unanimous decision by the subcommittee to
5 reject the petitions for ascorbyl palmitate
6 and betacarotene which serve as preservatives
7 in infant formula. I would like to present
8 additional reasons why these materials should
9 be rejected.

10 The organic standards specifically
11 prohibit synthetic preservatives and they also
12 prohibit synthetic ingredients that are not
13 essential or potentially dangerous to human
14 health. These two materials preserve other
15 ingredients in formula, especially DHA and ARA
16 that are themselves not defined as essential.
17 In fact, there are serious concerns about the
18 safety of DHA and ARA in infant formula which
19 were ignored when this board voted by a one-
20 vote margin to approve these materials at the
21 fall -- at its fall 2011 meeting.

22 When these oils were first added

1 to infant formula healthcare professionals
2 started noticing symptoms like diarrhea,
3 vomiting and bloating in formula-fed infants.
4 These symptoms would disappear often overnight
5 when the infant was switched to formula
6 without Martex-patented DHA and ARA. The FDA
7 received hundreds of reports of these adverse
8 reactions to formula with DHA and ARA.

9 In fact, FDA data shows that the
10 incidence of complaints related to, quote,
11 "bloating and distension," end quote, in
12 formula-fed infants rose from zero percent of
13 adverse reaction reports in 2000 when DHA and
14 ARA were not yet added to formula to nearly 10
15 percent in 2009 when DHA and ARA were present
16 in nearly all formula.

17 DHA and ARA are added as marketing
18 tools. All three meta-analyses studies on the
19 issue have looked at whether these ingredients
20 benefit infant cognition and visual
21 development, and all three have determined
22 that no benefit exists.

1 Cornucopia and other groups like
2 the National Alliance for Breast-feeding
3 Advocacy and the California WIC Association
4 has for years advocated against DHA and ARA in
5 formula because these ingredients do much more
6 harm than good. Formula makers advertise
7 these ingredients as, quote, "naturally
8 occurring in breast milk," end quote, which
9 misleads mothers into thinking that formula
10 contains natural ingredients and that it is
11 equivalent to breast milk. Nothing could be
12 further from the truth.

13 The DHA algal oil in formula is
14 structurally different from the DHA in breast
15 milk. Breast milk contains hundreds of
16 additional nutrients that are not found in
17 formula. The balances of these nutrients can
18 change daily depending on the infant's needs.
19 Breast milk is alive with antibiotics and
20 probiotics that formula, a highly processed
21 and dead food, simply cannot match.

22 I am asking first and foremost

1 that no additional synthetic ingredients be
2 approved. None of them are healthy, proven to
3 be beneficial or produced in accordance to
4 organic standards. I'm also asking that you
5 seriously consider whether any formula,
6 especially soy-based formula, should carry the
7 organic label. The organic label on formula
8 suggests to new mothers that the product is a
9 natural, clean, wholesome food for their
10 child. It isn't. And the more synthetics the
11 formula makers add in their attempts to mimic
12 breast milk the further away they get from
13 providing safe alternatives to mothers who
14 have no alternative. Please reject all the
15 petitions on the agenda today.

16 CHAIRPERSON FLAMM: Thank you,
17 Susan. Any board member have a question for
18 Susan?

19 MS. CZERNICKA: Thank you.

20 CHAIRPERSON FLAMM: Next speaker,
21 please, and give your name and affiliation.

22 MS. WALDEN: My name is Jessica

1 Walden. I'm with QAI, an organic certifier.

2 We represent a diverse and varied
3 client base and so our perspective really is
4 of really hoping that the standards in
5 guidance documents become clearer so that our
6 jobs are easier. We're not really advocating
7 one way or the other for whether or not a
8 material should be allowed or not.

9 We recognize that the organic
10 standards is an evolution process and we're
11 happy to be a part of it. We thank you very
12 much for your work.

13 We partook in various task forces
14 during this process with the OTA as well as
15 the ACA task force on the issues of other
16 ingredients, biological diversity and
17 calculation of organic ingredients.

18 On the issue of other ingredients
19 we participated with the OTA and the document
20 that came out of that discussion sums it up
21 nicely in that it's a very complex issue and
22 one that deserves a lot of attention from the

1 NOSB. We feel that the decision or the
2 criteria by which certifiers are to review
3 whether or not a material allowed in organic
4 product and that material containing those
5 other ingredients or incidental additives. We
6 would ask that the NOSB please develop
7 procedure to carry out the review of those
8 incidentals.

9 And that requires a full review of
10 those materials and the incidentals that could
11 exist in those materials as well as the
12 functionality of those incidental ingredients,
13 whether or not they're essential for that
14 material to work, and also whether or not
15 there are alternatives. And then after that
16 review process, developing very clear, concise
17 annotations so that certifiers can carry out
18 their job.

19 Historically the NOSB, that was
20 the job, the function of the NOSB and
21 certifiers definitely go to old TAP reviews to
22 try to work out whether incidentals are a part

1 of that review process or not.

2 However, the sort of success of
3 the other ingredients document also is
4 dependent upon clear definitions of the
5 classification of materials. So whether or
6 not something is classified as synthetic or
7 non-synthetic, agricultural or non-
8 agricultural. So those two go hand in hand.

9 With regard to the calculation of
10 ingredients we worked with the ACA to develop
11 comments. And it looks like there's a lot of
12 consistency but if you look at the ACA
13 document under Section 9 there are still a lot
14 of questions, a lot of gray areas in this
15 regard among certifiers. So we're asking that
16 the recommendations to the NOP to develop
17 sound guidance, again, sound methodology on
18 determining organic content, calculation of
19 organic ingredients, and as well as developing
20 training for certifiers to make sure that
21 we're all on the same page to answer some of
22 those gray area questions.

1 Biological diversity. Again, we
2 participated with the ACA to develop comments.
3 We're in support of biological diversity
4 conservation and practice on farm as well as
5 extending to handlers or all certified
6 operations. We're supporting the need for
7 clearer instruction, training for certifiers
8 as well as for clients out there and having a
9 measurable standard. Thank you.

10 CHAIRPERSON FLAMM: Thank you,
11 Jessica. Does any board member have a
12 question for Jessica? Yes, John.

13 MR. FOSTER: What were you going
14 to say about measurable? I like things that
15 are measurable. Is that what you were about
16 to finish saying there?

17 MS. WALDEN: With regard to
18 biological diversity. Just having some sort
19 of measurable standard so that we can -- for
20 enforcement purposes.

21 MR. FOSTER: Okay, thanks.

22 CHAIRPERSON FLAMM: Any other

1 question for Jessica? Thank you very much,
2 Jessica.

3 MS. WALDEN: Thank you.

4 CHAIRPERSON FLAMM: I guess we --
5 we've had a couple of cancellations. Unless,
6 Michelle, is there anyone else for the
7 morning? Appreciate the discussion, comments,
8 this morning. We'll now break for lunch and
9 be back here at 1 o'clock. Thank you.

10 (Whereupon, the foregoing matter
11 went off the record at 11:33 a.m. and went
12 back on the record at 1:06 p.m.)

13 CHAIRPERSON FLAMM: We'll continue
14 the public comments now. Pat Kane will be our
15 first commenter. Pat?

16 MS. KANE: I would like to thank
17 the board for the opportunity to provide these
18 comments. I am Patricia Kane, coordinator of
19 the Accredited Certifiers Association. ACA
20 did submit written comments on the following
21 discussion documents, "Implementation of
22 Biodiversity Conservation in Organic

1 Agriculture Systems," "Calculating Percentages
2 in Organic Multi-Ingredient Products," "Other
3 Ingredients" and "GMO and Seed Purity."

4 I would like to summarize our
5 comments here but also urge you to review our
6 written comments as we included many specific
7 suggestions pertaining to these documents.

8 Regarding the implementation of
9 biodiversity conservation the ACA supports the
10 continued work on the implementation of
11 biodiversity conservation practices. We
12 believe that the primary reason for
13 inconsistent implementation of this is a lack
14 of guidance from the NOP. The development of
15 clear, concise educational information for
16 producers and ACAs is another key to moving
17 the biodiversity conservation forward.

18 Based upon our members'
19 experiences we believe that producers do not
20 have enough information regarding biodiversity
21 conservation to assess the necessity and
22 importance of this.

1 An additional impediment to
2 implementation of biodiversity conservation is
3 that there is a lack of specificity in the
4 rule regarding biodiversity conservation.
5 ACAs have difficulty determining the
6 enforcement provisions for biodiversity
7 conservation due to this lack of specificity.

8 The inclusion of requirements to
9 address conversion of high-conservation land
10 is also problematic in that there is no
11 reference in 7 C.F.R. 205 to conversion of
12 high-conservation land. Therefore, ACAs could
13 not enforce the requirements for this issue.
14 We encourage the board to request clear and
15 comprehensive guidance regarding biodiversity
16 conservation be published by the NOP.

17 Calculating percentages in organic
18 multi-ingredient products. ACA believes that
19 certifiers perform calculations of organic
20 ingredients in a consistent manner and that
21 standardized forms are not necessary to
22 accomplish this work.

1 We do believe, however, that
2 clear, comprehensive guidance from NOP would
3 ensure additional consistency in this task.
4 We encourage the board to move forward with a
5 detailed recommendation to the NOP regarding
6 the need for a clear and comprehensive
7 guidance document regarding calculation of
8 organic percentage in multi-ingredient
9 products.

10 Additional webinar-style training
11 for ACAs by the NOP should also be encouraged.
12 Our written comments provided suggestions
13 regarding information to be included in
14 guidance on this topic.

15 Other ingredients. The ACA
16 supports baseline criteria established in the
17 other ingredients discussion document and the
18 continued development and refinement of option
19 B.

20 We also believe that the success
21 of any of the options put forth is based upon
22 final guidance on the definitions of

1 synthetic/non-synthetic. We urge completion
2 of the work on classification of materials and
3 supporting guidance documents.

4 GMOs and seed purity. Our members
5 believe that the issue of contamination from
6 genetically modified crops is a larger issue
7 than just contamination of only organic crops.
8 Many producers of value-added identity-
9 preserved conventional crops are also affected
10 by this issue.

11 While to date the genetically
12 modified crop production industry has resisted
13 both the labeling of GMO products and
14 addressing the issue of contamination from
15 these crops we believe that ultimately the
16 entire agricultural industry must work towards
17 eliminating the genetic contamination issue.

18 The responsibility for prevention
19 of contamination of organic crops must not
20 rest solely with the organic producer. A
21 defined seed purity protocol would be welcome
22 providing that this protocol is primarily

1 focused on a process-based system to include
2 increased education and guidance for producers
3 and certification agency staff with genetic
4 contamination testing used as a last resort.

5 Thank you for your work and the
6 opportunity to provide feedback.

7 CHAIRPERSON FLAMM: Thank you,
8 Pat. Does any board member have questions for
9 Pat? Thank you very much. Next commenter?
10 And please give your name, Kevin, and your
11 affiliation. And you can take a moment for
12 your past in case people don't know your
13 affiliation.

14 MR. ENGELBERT: Okay. Hello,
15 everyone. I'm Kevin Engelbert, organic dairy
16 farmer, beef farmer and crop farmer, past NOSB
17 member, class of January 2011 with my last
18 meeting in the fall of 2010.

19 I threw these thoughts together as
20 I sat here this morning. I wasn't originally
21 going to comment so please bear with me. They
22 might not be as organized as I would like them

1 to be.

2 Thank you all for listening to my
3 thoughts. As a past board member I certainly
4 appreciate the task you're faced with, and
5 although I miss being on the board I must
6 admit that I do somewhat enjoy being back on
7 this side of those tables even though I'm no
8 longer one of the decision-makers and I only
9 have a few minutes to express my thoughts.

10 When I was a member I always
11 thought that the work of the NOSB would have
12 been much easier and gone much smoother if I
13 had simply been allowed to make all the
14 decisions because I'm very set in my beliefs
15 and opinions. Anyone I served with while on
16 the board will attest to that.

17 At any rate, I'll try to be brief
18 in my comments out of compassion for what I
19 know lies ahead of you in the next few days.
20 Due to a weather disaster that took place on
21 my family farm just over a year ago I've been
22 unable to follow the work of the NOSB for

1 nearly 15 months. Therefore, I'm not going to
2 give specific thoughts with regards to your
3 recommendations for this meeting. I will,
4 however, make a few general comments.

5 First, I must express my dismay
6 over some of the votes that have taken place
7 since I've been off the board. I cannot
8 understand why many of the substances that
9 came before the board were approved.

10 The goal should be to have organic
11 represent the most pure food possible, not the
12 most complete food available. After
13 consulting with their pediatrician or doctor
14 people should buy supplements if necessary to
15 meet specific dietary requirements. But your
16 objective must be to ensure organic food
17 reaches the store shelves with an absolute
18 minimum amount of processing and added
19 substances.

20 Consumers should come to expect
21 that organic foods will vary in texture, color
22 and even taste depending on the time of year,

1 where the crop was grown, the crop variety, et
2 cetera. Trying to ensure that every package
3 of any given product is identical no matter
4 where or when it's produced or purchased is
5 not compatible with organic agriculture. The
6 same holds true for the attempts to make
7 certain organic foods supply complete
8 nutrition that they do not naturally possess.

9 In the same manner as farmers when
10 they're growing organic food, processing and
11 marketing companies cannot expect to use the
12 same inputs when handling organic foods that
13 they do with conventional foods. Not only
14 should organic food start out pure on the
15 farm, it must remain so throughout the entire
16 manufacturing, packaging and/or handling
17 process.

18 Also remember that 100 years ago
19 or in some cases even more recently all food
20 was organic and that's the ideal the organic
21 label should represent today. In my opinion
22 that approach does not mean taking a step

1 backward with our food supply but actually a
2 step forward after decades of taking steps
3 backward.

4 Right or wrong, when I served on
5 the NOSB I was careful to weigh the
6 information that was presented based on one
7 major criteria first, namely, does the person
8 or entity providing the info have a financial
9 stake in the board's final decision.

10 Your role as the current foster
11 parents of organic agriculture has certainly
12 become more difficult as the program enters
13 its teenage years. In your deliberations
14 always remember that necessity is the mother
15 of invention. Protecting the organic label
16 from those who try to weaken the rule is
17 indeed a difficult process and I wish you
18 success in doing so.

19 Next, I've not had time to talk
20 with current board members to find out the
21 reasoning behind the change in order from --
22 I've got a long way to go. I thought I was

1 keeping this short but apparently I'm reading
2 very slowly.

3 CHAIRPERSON FLAMM: Since I asked
4 you to state a little of your background I'll
5 give you 30 seconds more.

6 MR. ENGELBERT: Okay. Let's see,
7 where did I pick up. I'm not in favor of
8 voting on any recommendation the same day that
9 it's presented. Even topics the board has
10 consensus on should not have a final decision
11 made until the last day of the meeting so that
12 there's time for additional thoughts or
13 information to surface.

14 I also believe that any committee
15 recommendation that differs from one posted on
16 the meeting agenda should have its vote
17 postponed until the following meeting to
18 ensure that community has an adequate time to
19 express their opinion.

20 Also, public comments should be
21 allowed for 5 minutes with unlimited time for
22 questions from the board. Anyone who wishes

1 to present oral comments must be allowed to do
2 so. Long days are not a viable reason to
3 limit public comments.

4 My first NOSB meeting had one day
5 that lasted over 13 hours but there were no
6 complaints from board members. We knew what
7 we were getting into. To truly fulfill the
8 intent of OFPA and the role of the NOSB public
9 participation cannot be restricted.

10 My last comments are for the NOP
11 but Miles has already heard all of them so I
12 will thank you once again for your dedication
13 and for listening to my comments.

14 CHAIRPERSON FLAMM: Thank you very
15 much, Kevin, and it's great to see you again.
16 Any board member have a comment, question for
17 Kevin?

18 MR. ENGELBERT: Thanks again.

19 CHAIRPERSON FLAMM: Thank you,
20 Kevin. Next commenter please state your name
21 and your affiliation.

22 MR. NORMAN: Hello, my name is

1 Drew Norman. My wife and I run One Straw Farm
2 and I'd like to thank you all for hearing my
3 comments today. Unfortunately the second half
4 of my comments were lost in cyberspace so I'm
5 going to have to wing the second half of it.

6 One Straw Farm has been operated
7 since 1983. We've always operated using
8 organic methods. Our goal has always been to
9 farm in an environmentally sound manner. We
10 first achieved organic certification in 1986
11 through the OCIA and have remained certified
12 through the 2011 season.

13 In 2011 One Straw Farm received
14 Rodale's Pioneer of Organics Award. We
15 currently farm 175 acres of hay and
16 vegetables, employing 25 people and three
17 generations of our family. Most of our
18 produce is marketed through an 1,800-person
19 CSA.

20 One Straw Farm has always used
21 agricultural films and drop irrigation for
22 their production benefits, higher yield, weed

1 control, and most importantly water
2 conservation, a savings of up to 60 percent
3 over conventional irrigation methods.

4 The downside of polyethylene mulch
5 is the cost of removal and disposal at the end
6 of the season. PE or polyethylene mulch is
7 too dirty to be recycled and therefore has to
8 be landfilled. I've always felt that PE mulch
9 compromises the integrity of the produce
10 raised on One Straw Farm.

11 Imagine my delight when I first
12 became aware of BioTelo, a cornstarch-based
13 biodegradable mulch film. This film offers
14 all the benefits of polyethylene films without
15 the downsides.

16 Our decision to use BioTelo was
17 not made lightly but was made openly. We were
18 up front with our certifying agency from the
19 very first roll that was used. We made this
20 decision because we felt it was the more
21 environmentally friendly way to farm.

22 We also assumed that we were not

1 in violation of our certification because the
2 law states that biodegradable mulches were
3 allowed. We also hope that because of the
4 reciprocity agreement between Canada and now
5 Europe that BioTelo would be allowed by the
6 NOP.

7 In February 2012 we were asked to
8 stop using BioTelo or have our certification
9 revoked. We chose to continue to use BioTelo
10 and withdraw our certification. This decision
11 was heart-wrenching because 20 percent of our
12 sales at the time were through organic
13 wholesale markets which we could no longer
14 supply without certification.

15 In 2009 I tried my first roll of
16 BioTelo with very positive results. The mulch
17 performed as needed and provided early season
18 moisture and weed control. This is where I
19 have to start ad-libbing. At the end of the
20 season we ran a ditch through our field and
21 planted our cover crop which was probably in
22 late October. By the following spring there

1 was no evidence of the mulch in the field.

2 When used in early spring for
3 early season crops and when the soil is very
4 active, biologically active, I find that the
5 mulch disappears within 6 weeks, as early as
6 6 weeks, maybe 2 months. So -- with virtually
7 no residue in the field. Several years ago I
8 had a field in hay that had been there for
9 about 5 years and when I worked the ground up
10 I found polyethylene mulch in that field which
11 had been in there -- had not been used in that
12 field for at least 5 years.

13 So regardless of how well you
14 remove polyethylene mulch from the field you
15 still find pieces of it. It's impossible to
16 completely remove it all. In a field with --
17 thank you. Any questions?

18 CHAIRPERSON FLAMM: Thank you,
19 Drew, for your comments. Any questions from
20 the board? Jay, go ahead.

21 MR. FELDMAN: Thank you, and
22 thanks for making your farm available for

1 field visits on this. Have you taken a look
2 at the annotation that the subcommittee came
3 up with, the Crops Subcommittee?

4 MR. NORMAN: Briefly.

5 MR. FELDMAN: I'm wondering about
6 the level of specificity that we put -- that
7 the NOSB puts on an annotation regarding the
8 practices that farmers utilize when using this
9 material. And to what -- where did you get
10 your instruction from and to what extent have
11 you followed the manufacturer's instructions
12 or innovated to ensure that you're seeing the
13 degradation in the time frame you're talking
14 about?

15 MR. NORMAN: We first started
16 using -- the first year we used it we used one
17 roll. And it just became very obvious that it
18 performed the way it was supposed to and that
19 it broke down very quickly at the end of the
20 season.

21 You know, I can see that there
22 would be situations where the mulch might not

1 work, or might not break down properly or
2 quickly, but I would think that a farmer who
3 was in a situation like in a very dry area
4 where if he stopped irrigating the soil
5 biology would stop and then the mulch would
6 stop breaking down. If it didn't work for him
7 he probably wouldn't use it.

8 I mean, it's very expensive so a
9 farmer's not going to choose to use this if it
10 doesn't really work for him. We sort of feel
11 that it's cost-effective for us because we
12 don't have the disposal, the removal and
13 disposal costs. But it costs two and a half
14 times as much as polyethylene mulch does. So
15 it's not a decision that's made lightly.

16 CHAIRPERSON FLAMM: Jay, go ahead
17 with your follow-up question.

18 MR. FELDMAN: Quick follow-up.
19 Some of the studies we're looking at, the
20 protocol for the studies involve plowing in or
21 disking in the material at the end of the
22 season. Is that the practice you utilize?

1 MR. NORMAN: That's the practice I
2 use. I mean I -- one of the advantages that
3 I find in using the biodegradable mulch, it
4 allows me to get my cover crops in quicker at
5 the end of the season. So you know, if we
6 have a wet fall I don't have to go through all
7 the time to remove a polyethylene mulch. I
8 can just quickly run a disk through the field
9 and plant my cover crop. So it's time-saving
10 for me as a farmer to be able to use this
11 mulch.

12 CHAIRPERSON FLAMM: Zea has a
13 comment for you, Drew. Or question, excuse
14 me.

15 MS. SONNABEND: Thank you, Drew.
16 Some of the commenters who have concerns about
17 the mulch have questioned whether it would
18 leave behind residues. Not that you can see,
19 but residues of some of the chemicals used as
20 pigments or plasticizing agents or things like
21 that. And I'm wondering if you thought about
22 that at all in your decision to use it and

1 what satisfied you that it wouldn't leave
2 chemical residues behind.

3 MR. NORMAN: Oh, well that's a
4 pretty tough question because you're talking
5 to a farmer and not a scientist.

6 MS. SONNABEND: But you made the
7 decision so I'm just interested in how you
8 made the decision.

9 MR. NORMAN: We made the decision
10 based on the fact that it had been certified
11 as being 100 percent biodegradable which is
12 something we read on the internet. So, you
13 know, we didn't enter into this lightly. We
14 did as much research as we could before we
15 decided to use it wholeheartedly and farm-
16 wide. So based on the information that I as
17 a farmer could find I felt like I was
18 comfortable using it.

19 MR. FOSTER: Yes, Drew, two-part
20 question. One is how long is your growing
21 season and what's your annual rainfall -- or
22 amount of precipitation?

1 MR. NORMAN: Our dormant season
2 starts in November and depending on the
3 weather goes into March. So what's that, 5
4 months? And our rainfall is 40-45 inches a
5 year. I live in central Maryland.

6 CHAIRPERSON FLAMM: Carmela has a
7 question for you.

8 MS. BECK: I was wondering, there
9 was public comment that said that the plastic
10 mulch shouldn't be used 2 years in a row
11 consecutively in the same field. Do you have
12 any thought on that or what your practices are
13 or why that would not be?

14 MR. NORMAN: I mean, the integrity
15 of the mulch is there in 2 years. The problem
16 that we've run into is the weed control
17 necessary to keep the weeds out for that long
18 of a period of time. You know, we get a lot
19 of winter annuals growing in our area and our
20 ground would be frozen so it would be very
21 difficult to control weeds over the course of
22 winter. And quite frankly I wouldn't want to

1 leave my ground open to erosion in order to
2 use the mulch 2 years in a row.

3 CHAIRPERSON FLAMM: Any other
4 board questions for Drew? Go ahead.

5 MR. MARAVELL: Drew, on the last
6 question I think the issue was would you
7 voluntarily want to skip every other year
8 rather than try to utilize it for 2 years in
9 a row. I think in your conditions there
10 wouldn't be anything the second year to
11 utilize. But would you have any reason to
12 want to as a policy for your operation skip
13 and never use it 2 years consecutively?

14 MR. NORMAN: Quite frankly I don't
15 see the point. It's not used on every field
16 every year anyway because part of our farm is
17 in hay, part of our farm is in direct-seeded
18 crops. So you know, out of the 50 acres of
19 produce that we grow half of that is in
20 direct-seeded crops where no mulch is used
21 anyway. And then you know, a large portion of
22 our farm is in hay at any given time. So,

1 conceivably it's only used on a given field
2 probably every third year just because of crop
3 rotation and what have you.

4 CHAIRPERSON FLAMM: Thank you very
5 much, Drew.

6 MR. NORMAN: Thank you.

7 CHAIRPERSON FLAMM: Next
8 commenter. Please give your name and
9 affiliation.

10 MS. NORMAN: My name is Joan
11 Norman. I am the other half of One Straw
12 Farm. You just heard my husband speak. We've
13 been farming obviously for a long time. I
14 always say we started farming back when the
15 dinosaurs roamed the Earth and organic farming
16 was not something you could Google on the
17 internet.

18 We originally started farming and
19 were selling organic produce but really didn't
20 know what it was. I had a farm who rented a
21 truck to organic farms and that's how we found
22 out about a certifying agency and we became

1 certified in 1986.

2 I am the other half of One Straw
3 Farm so when he wanted to use this
4 biodegradable mulch I was the one in charge of
5 looking up the research. Part of the reason
6 we said it was -- we decided it was okay and
7 was following organic standards was it was
8 certified biodegradable by a third party
9 agency, so it wasn't just the company saying
10 it.

11 And the second part of it was it
12 was made from a non -- it was not GMO corn, it
13 was GMO-free corn. You know, we could get
14 corn stalks from our next door neighbor and
15 put them down as mulch and that would be
16 allowed under organic certification law which
17 we wouldn't do. This was non-GMO and it was
18 breaking down so we saw no reason that we
19 could not use it.

20 On our farm we have a large CSA.
21 We roughly feed about 10,000 people a week
22 from our farm. And we polled most of them and

1 asked them their opinion on this. And all of
2 them said if we were not using BioTelo that we
3 would be environmentally irresponsible and
4 they would not want to get food from us. So
5 all of them have supported our decision. The
6 only person who cannot buy from us is our
7 organic wholesale and we gave up \$100,000 this
8 year to not sell organic produce.

9 But we felt it was important to
10 push forward. As Drew said we got the Pioneer
11 of Organic Award. Sometimes you just have to
12 go first. We were first 29 years ago when
13 nobody else was growing organically, at least
14 in our neighborhood, and they thought we were
15 growing marijuana though I had to remind them
16 that frankly if I was selling marijuana I
17 would have made a lot more money.

18 So this is not an easy decision
19 for us. We're not walking away from organic.
20 I feel like I'm having a partial divorce and
21 all I really want to do is get it back. It's
22 really hard to say that we're One Straw Farm,

1 the largest used to be organic vegetable farm
2 in Maryland and now I have this empty hole.

3 So we look forward to this being
4 approved. Organic farmers need it. It's
5 allowed in Canada. That was the other reason,
6 it's allowed in Canada. They can grow organic
7 produce and sell it in my country as organic
8 but I can't do the same thing.

9 The day after I mailed in my
10 certification they announced a reciprocal
11 agreement with Europe. It makes me furious.
12 Why can other countries sell organic produce
13 in my country and I can't do the same thing?
14 It's just not right. If it was that wrong
15 everywhere else in the world why do we allow
16 it into our country? If you didn't allow it
17 from other places I might feel differently,
18 but I don't.

19 So there has been research done in
20 other places. They're allowing it in Canada,
21 they allow it in Europe and it should be
22 allowed for organic production here.

1 My customers and ourselves
2 respectfully request that you vote in favor
3 for it. Can I answer any questions from
4 anyone? I even still have a green light. I
5 guess I'm done. Thank you very much.

6 CHAIRPERSON FLAMM: Will the next
7 commenter please come to the podium and give
8 your name and affiliation?

9 MS. BADEN-MAYER: Hello, I'm
10 Alexis Baden-Mayer. I'm the political
11 director of the Organic Consumers Association.
12 We have 385,000 members and 9,000 of them
13 submitted comments in opposition to adding new
14 synthetics to organic at this meeting.

15 Organic consumers oppose adding L-
16 methionine for use in infant formula made with
17 isolated soy-based protein. The main basis
18 for the Handling Subcommittee's recommendation
19 that L-methionine be allowed is that it is
20 essential for organic soy-based infant
21 formula.

22 Organic consumers disagree with

1 this notion of what's essential. We deserve
2 the right to know when the use of an
3 ingredient in organic infant formula is going
4 to require adding a synthetic.

5 Companies that manufacture infant
6 formula are notorious for hiding from us the
7 fact that infant formula provides inadequate
8 nutrition when compared with breast milk.
9 Infant formula companies depend on us being
10 ignorant of the fact that babies shouldn't
11 consume anything but breast milk for the first
12 9 months and that babies should be breast fed
13 for at least 2 full years.

14 The National Organic Program
15 becomes part of this problem just by allowing
16 infant formula to be marketed as organic. But
17 if you wanted to convince consumers that
18 organic food is the most natural store-bought
19 food available allowing synthetics in organic
20 infant formula completely destroys the idea
21 that the organic version is the most natural.

22 Of course, most parents aren't

1 going to know. They'll think that the infant
2 formula made with isolated soy-based protein
3 is just as organic as the infant formula that
4 doesn't contain synthetics. That would be a
5 fraud on parents considering buying organic
6 infant formula. This fraud should be stopped.

7 If this fraud continues we're
8 going to need new labels, USDA organic, made
9 with synthetic L-methionine, made with organic
10 ingredients and synthetic L-methionine. Then
11 parents could find out what L-methionine is
12 and when we looked into it we would learn that
13 it isn't an organic ingredient. We would
14 learn that while L-methionine could
15 potentially be developed from naturally
16 obtained sources the organic regulators chose
17 to allow the kind that comes from a source
18 that uses cyanide.

19 We would learn that the over-
20 supplementation of L-methionine has been shown
21 to have detrimental effects on the uptake of
22 other critical amino acids as well as causing

1 fatty deposits in the liver. Anyone who
2 learned these things about L-methionine would
3 wonder how in the world it ended up in organic
4 infant formula. It's not even allowed for
5 other organic foods.

6 How about not approving L-
7 methionine? Then you could be straight with
8 parents considering infant formula. You could
9 tell us the truth. Yes, there is infant
10 formula that contains organic soy, but that
11 formula isn't labeled organic because it
12 requires the addition of a synthetic that
13 isn't compatible with organic. Then parents
14 could make informed choices.

15 Please, when you are making
16 decisions about whether or not to allow foods
17 that contain synthetic ingredients to be
18 marketed as organic, please keep in mind that
19 consumers deserve the right to know. There
20 shouldn't be synthetics hiding in our organic
21 food. The organic seal shouldn't conceal.

22 CHAIRPERSON FLAMM: Thank you,

1 Alexis. Do board members have questions for
2 Alexis? Jay?

3 MR. FELDMAN: Thanks, Alexis. So
4 here's the dilemma as I understand it. If you
5 use soy you have to use methionine. So the
6 effect of not approving methionine would be to
7 disallow soy-based formula as being labeled
8 organic. Is that your understanding?

9 MS. BADEN-MAYER: Well, it's not
10 that it would be taken off of the market. It
11 would be there. You could have a formula that
12 was made with organic soy, but if it contained
13 this synthetic that we don't consider
14 compatible with organic it couldn't have a
15 front label claim that said organic. It
16 couldn't have a USDA seal on it and it
17 couldn't be marketed as made with organic. So
18 it couldn't be certified organic and marketed
19 to consumers that way.

20 But consumers who for some reason
21 are looking for a soy-based formula and would
22 prefer one that had organic soy in addition to

1 the synthetics that are necessary for this
2 type of formula, they could still seek that
3 out. But it wouldn't be marketed by the
4 organic program as organic.

5 MR. FELDMAN: Right, but the
6 problem is that, you know, if you talk to the
7 American Academy of Pediatrics and others the
8 fact that the soy does not have methionine
9 which is part of the nutritional balance
10 needed in the product, it would not be
11 marketable at that point. Which I'm not
12 suggesting is not an endpoint that the board
13 wouldn't want to embrace. I mean, that might
14 be the endpoint that the board wants to
15 embrace. But I'm just saying that the effect
16 of that decision by the board would limit the
17 marketability in the organic sector.

18 And that raises questions such as
19 so what. And that's why I'm glad that the AAP
20 folks are coming, we can address the question
21 with them as well. What would happen to the
22 organic consumer if soy, organic certified

1 soy-based formula were not available.

2 MS. BADEN-MAYER: I believe it
3 would be available, it just wouldn't be
4 marketed as organic.

5 MR. FELDMAN: Okay, thank you.

6 CHAIRPERSON FLAMM: Any other
7 questions for Alexis? Yes, Tracy.

8 MS. FAVRE: So, how would you feel
9 about a made with label with synthetic L-
10 methionine?

11 MS. BADEN-MAYER: Well, that's --
12 when I go shopping and I see made-with
13 products I know that those products also
14 cannot have unapproved synthetics in them.
15 And most consumers probably just believe they
16 don't have synthetics in them. And so I think
17 that we're mis-marketing these products if we
18 load them up with synthetics and label them
19 exactly the same as organic products that
20 don't have synthetics.

21 Now, we are going to have, you
22 know, if this L-methionine were approved we'll

1 have some organic infant formulas that don't
2 contain synthetics and some organic infant
3 formulas that do contain synthetics, but that
4 won't be apparent to the consumer. Nobody --
5 the consumers aren't sitting here with us
6 seeing how these decisions are made and
7 there's no information on the label other
8 than, you know, you could turn the product
9 around and see L-methionine but you would just
10 assume that was organic probably. And if you
11 didn't assume that it was organic at least you
12 would think it was non-synthetic, you would
13 think it was natural, because after all it's
14 allowed in organic.

15 And so we don't have a way right
16 now if informing the consumer about added
17 synthetics in organic. And I think that's a
18 big problem, especially since every single
19 meeting every 6 months we're adding new
20 synthetics to organic.

21 CHAIRPERSON FLAMM: Do you have a
22 follow-up question, Tracy? Go ahead.

1 MS. FAVRE: So, do I understand
2 from that comment that the difference between
3 the organic and the made with organic label is
4 not clear to consumers and you aren't
5 supportive of the made-with?

6 MS. BADEN-MAYER: I certainly -- I
7 buy made-with products and I know that the
8 made-with products have essentially the same
9 rule for the 30 percent as the USDA organic
10 products have for the 5 percent. So, and I
11 think that's a good thing, and I think that
12 that encourages consumers to buy made-with
13 products when USDA organic products are not
14 available. So no, certainly I don't want to
15 dismiss the value of the made-with label. But
16 I don't think it would be appropriate to add
17 synthetics to made-with products either
18 because consumers assume that those products
19 as well do not contain synthetics.

20 CHAIRPERSON FLAMM: Any additional
21 questions from the board? Thank you very
22 much, Alexis.

1 MS. BADEN-MAYER: Thank you.

2 CHAIRPERSON FLAMM: Next
3 commenter, please? Please give your name and
4 affiliation.

5 MR. LAROSE: Good afternoon, my
6 name is Rob LaRose. I'm the president of
7 BioSafe Systems. And I first attended this
8 meeting back in Savannah and I was a
9 petitioner for ammonium nonanoate herbicidal
10 soap.

11 And I just, I guess my role here
12 today is to just kind of report back to you
13 all as, you know, even though we were not
14 successful yet in our petition we did
15 successfully launch our product AXXE to the
16 parts of the market which is turf and
17 ornamental in landscapes where it is allowed
18 to be approved as organic use and it's been
19 very well received.

20 I must say that pretty much what
21 we thought was going to be the case is that
22 many of our customers are also organic growers

1 and they were wondering how come we're selling
2 this product and they can't use it. And we
3 tried to explain to them, well, this is what
4 happened at the meeting, this is what has been
5 said and this is where you folks are at.

6 And the amount of calls that we've
7 taken and the confusion that our people are
8 dealing with out in the field where they're
9 seeing something that's listed, NOP-listed,
10 it's allowed for certain uses on ornamental
11 landscaping and greenhouse growing but they
12 can't use it in any type of agriculture other
13 than maintenance of fencing lines and things
14 like that.

15 The interesting development is
16 that many of our sales lately have been to
17 conventional growers who see the benefits in
18 it and have bought into the program by a large
19 degree. So I guess I'm here to ask the board
20 to reconsider your position on this because I
21 think you're going to be hearing more and more
22 about it in the future. And there's really,

1 you know, there's nothing much our company can
2 do.

3 We're a small company. We're --
4 somebody wrote an article about our
5 presentation last year in the New York Times
6 and painted us as this big business. We're a
7 \$10 million company family business where my
8 three kids work in my business taking
9 advantage of their college education and
10 trying to get that back. And my wife's here
11 with me today.

12 So we've been serving the organic
13 industry since 1998. We have hundreds and
14 thousands of customers out there. So this is
15 a major issue.

16 One other one I want to point out
17 is that we're also involved in food safety and
18 I'm seeing a lot of issues being developed not
19 only having to address food safety in a
20 packing house or processing plant but also in
21 the field. And I don't believe right now
22 there's enough guidance to address how to --

1 for the organic growers, how to address food
2 safety issues in the field either treating
3 irrigation waters or treating the crops in the
4 field. And it seems to be progressing a lot
5 faster on the conventional side than on the
6 organic side. There seems to be -- the
7 awareness is just not there. And I think that
8 the board should take a serious look at that
9 and maybe create a position for itself there
10 because there's a lot of issues out there that
11 need to be addressed and this is a big hole
12 from what I can see.

13 CHAIRPERSON FLAMM: Thank you,
14 Rob.

15 MR. LAROSE: I want to say thank
16 you.

17 CHAIRPERSON FLAMM: Does any board
18 member have a question for Rob? Harold, go
19 ahead.

20 MR. AUSTIN: Rob, when your
21 product was approved for use as a herbicide or
22 a weed killer for ornamental and fence line,

1 what was the rationale given for its not being
2 allowed for agricultural use in tree crops or
3 whatever other crops you're trying to utilize
4 it in?

5 MR. LAROSE: I mean, what I heard
6 was that it met all the tenets of being an
7 organic product allowed for use in organic
8 production but really it came down to the
9 terminology I think is that we were calling it
10 an herbicide, it's an effective herbicide but
11 there's no place in organic farming for an
12 effective, low-cost herbicide. What I heard
13 was it makes it too easy, or it shouldn't be
14 that easy to be an organic grower. And when
15 I tell that to folks out there in the field,
16 a hard-working farmer, they're just
17 flabbergasted by that position. And so
18 there's just a lot of confusion. And they
19 take it out on us.

20 CHAIRPERSON FLAMM: Harold, do you
21 have a follow-up question?

22 MR. AUSTIN: Your comment on the

1 food safety issues. Could you clarify your
2 thought process behind that?

3 MR. LAROSE: Well, as we're going
4 along we focus primarily on high-value crops.
5 And what we're finding is there's a lot of
6 mitigation issues that have to happen out in
7 the field. In some cases with blueberries and
8 strawberries and raspberries we're doing pre-
9 harvest sprays out in the field as a
10 mitigation step for contamination. And you
11 know, it's -- there just doesn't seem to be a
12 place just yet to allow that in organic
13 production.

14 Also, there's a lot of -- there's
15 just confusion as to where, how you should
16 treat irrigation water, should we do these
17 pre-harvest sprays, is that part of, you know,
18 what types of products are we going to use for
19 that. So there's, you know, there's just
20 another level of mystery. And it's shared on
21 the conventional side too. We're working --
22 they seem to be working through it faster.

1 CHAIRPERSON FLAMM: Thank you. Is
2 there any other questions from the board?
3 Thank you very much for your comments.

4 MR. LAROSE: You're welcome.

5 CHAIRPERSON FLAMM: Michelle, is
6 there any other public comment? That
7 completes the general public comment session.
8 We can now move to the Livestock Subcommittee
9 and I will turn the gavel over to Chairperson
10 Wendy. It's all yours.

11 MS. FULWIDER: Thank you, Barry.
12 First, Lisa Brines would like to introduce the
13 petition for nonanoic acid.

14 MS. BRINES: Thank you, Wendy.
15 Yes, the first petition on the agenda for the
16 Livestock Subcommittee is nonanoic acid. It
17 was petitioned April 29, 2011 by Stratacor
18 Incorporated. The petition requests the
19 inclusion of nonanoic acid at Section 205.603
20 of the National List as an insect repellent
21 for organic livestock. It's not listed
22 elsewhere currently on the National List.

1 Regarding the technical review of
2 this material there's two technical reports
3 available for this material. The first one
4 was developed in 2006 and that was in response
5 to the petition to allow this use in crop
6 production. It was petitioned under an
7 alternate name at that time which is
8 pelargonic acid.

9 In reviewing the petition the
10 Livestock Subcommittee did decide to request
11 a new updated technical report to address the
12 livestock issues. Both that technical report
13 and the petition were posted on the NOP
14 website in advance of the opening of the
15 public comment period for this material. And
16 I believe the petitioner is in the audience
17 and signed up for in-person public comment as
18 well. Thanks.

19 MS. FULWIDER: And Jean Richardson
20 will present on nonanoic acid.

21 MS. RICHARDSON: The material that
22 came before the subcommittee is nonanoic acid

1 which is CAS-112050. And when we reviewed
2 this we determined that it was a synthetic.
3 We then reviewed the listing motion to add
4 nonanoic acid 112050 to 205.603 insect
5 repellant. And the subcommittee determined
6 that they would not recommend this to be added
7 to the list.

8 Some comments from our work on
9 this. We found that it's a nine-carbon
10 straight chain fatty acid, occurs in low
11 levels in foods such as grapes, milk, oranges
12 and apples. We were concerned obviously to
13 find that it is also an EPA registered
14 fungicide and herbicide. It can be used as a
15 weed killer and a blossom thinner. Obviously
16 it wouldn't be used in such large quantities
17 being used as an insect repellant. On the
18 other hand, this certainly was of concern to
19 us.

20 We found in looking at the
21 petition, the TR, that it does not appear to
22 be a permitted substance on any of the lists

1 in Canada, the European Union or Japan. We
2 were concerned reading the TR that it would
3 have a negative impact on a various range of
4 nematodes and other aspects of the soils and
5 would have potentially a negative impact on
6 the agro-ecosystem.

7 We also found in reviewing the
8 materials presented to us that there are
9 presently a wide range of effective
10 alternative treatments that are already
11 available in addition to the IPM and
12 management practices. And so for these
13 combination of reasons the committee voted not
14 to add this at this time. Thank you.

15 MS. FULWIDER: Any discussion from
16 the board members? John?

17 MR. FOSTER: So, when you said the
18 use of the material may -- I don't know
19 exactly what you said, but something to the
20 extent of may potentially have deleterious
21 effects on the soil ecosystems, something like
22 that. What do you mean by potentially? How

1 is that quantified or measured or tested or
2 evaluated? I'm just wondering if you could
3 better define what "potential" stands for
4 there.

5 MS. RICHARDSON: If I look at the
6 TR line 333 the Davis in 1997 reported that
7 nonanoic acid is toxic to nematodes. And
8 while, you know, we don't necessarily -- some
9 nematodes are not good, but beneficial
10 nematodes or earthworms may also be impacted.
11 There were the main aspects really that came
12 up that were of issue, in addition of course
13 to the potential impact as a weed killer and
14 a blossom.

15 I should also add that of course
16 there was public comment on this. And in
17 terms of the public comment there were two
18 universities and two corporations presented
19 supporting statements to consumers and one
20 non-profit environmental group opposed
21 addition. Those were the only comments that
22 we received to date.

1 MS. FULWIDER: Go ahead, John.

2 MR. FOSTER: So, I guess I'm not -
3 - I'm not following. The nematodes and the
4 earthworms may be impacted? Potential to be
5 impacted? Like were there studies that showed
6 it killed beneficial nematodes, it killed
7 earthworms? That's kind of what I mean by is
8 that evidence or is that the potential that's
9 not known. So it's a -- maybe there could be
10 a problem and therefore we don't want to risk
11 it. Is that it?

12 MS. RICHARDSON: All I can --
13 well, I can probably look again in more detail
14 at it but my notes here simply say that it is
15 reported to be toxic to nematodes. It doesn't
16 say potentially toxic to nematodes, it says
17 nonanoic acid is toxic to nematodes.

18 MS. FULWIDER: Colehour?

19 MR. BONDERA: Yes, my memory and
20 understanding is exactly what you just said,
21 Jean, is that it is toxic to nematodes and
22 therefore like you were asking, John, that it

1 may kill beneficial nematodes. You don't know
2 what nematodes it's going to kill because it
3 depends on what is impacted by its use. So,
4 therefore since it is toxic to nematodes it
5 could kill beneficial ones but depending on
6 the circumstance you don't know which
7 nematodes it will kill. That's my --

8 MS. FULWIDER: Any other
9 discussion? Okay, Lisa, if you would like to
10 introduce the petition for pet food amino
11 acids.

12 MS. BRINES: Thanks, Wendy. The
13 second petition before the Livestock
14 Subcommittee today is a petition for required
15 amino acids for pet food. This is a select
16 list of 13 amino acids which are specified in
17 the petition.

18 The petition was submitted on
19 January 30, 2012 from the Pet Food Institute.
20 And the petition is requesting amendment of
21 the National List to list these required amino
22 acids on Section 205.603 of the National List

1 as an ingredient in organic pet food.

2 In support of its review the
3 Livestock Subcommittee reviewed the petition
4 and requested the development of a third party
5 technical report. That report was completed
6 and both the petition and technical report
7 were posted on the NOP website in advance of
8 the opening of the public comment period for
9 this meeting.

10 And just one follow-up to the
11 specific petition. There was an initial
12 petition that came from the Pet Food Institute
13 for taurine. That individual petition was
14 withdrawn and replaced with this more
15 comprehensive petition for more amino acids
16 all under the one petition for review by the
17 Livestock Subcommittee.

18 And there is a representative from
19 the petitioner I believe in the audience who
20 is signed up for in-person public comment as
21 well. Thank you.

22 MS. FULWIDER: Thank you, Lisa.

1 Mac Stone will present the proposal on pet
2 food amino acids.

3 MR. STONE: Thanks, Wendy. Let me
4 preface the summary of this petition by saying
5 there was an e-glitch in posting our
6 recommendation and all of the background
7 wasn't posted for you all to witness. So
8 Robin, it will make a lot more sense when you
9 see the rest of it.

10 So at this time the subcommittee
11 is recommending that we not vote at this
12 meeting because you all are not privy to the
13 information that the subcommittee deliberated
14 on. And we'll make this decision at the
15 spring meeting in Portland.

16 So we would like to go through as
17 if we were voting, get as much feedback and
18 interest so that during the next semester we
19 can continue to get feedback and be sure that
20 we're making a sound decision on this
21 petition.

22 So briefly, organic pet foods or

1 mostly made with organic labels are allowed,
2 are being sold now. They're produced under
3 the livestock standards and labeled under the
4 handling standards.

5 It's a very vibrant market.
6 They're striving for continual improvement and
7 would like to have these amino acids available
8 so they can formulate diets with the various
9 ingredients that are available to them.

10 As Lisa said the Pet Food
11 Institute has petitioned for the 13 essential
12 amino acids as they are not grandfathered in
13 under the accessory nutrients as in the past.

14 In `05 there was a pet food task
15 force that was formed. They worked diligently
16 and this board in `08 proposed a
17 recommendation to the program which has -- the
18 program has in place and it is part of our
19 discussion document, our recommendation that
20 you can see when it's posted.

21 Pet foods are different than
22 livestock. Obviously dogs and cats, primarily

1 what we're talking about, they are meat-eaters
2 and since they're not part of the food chain
3 it seems appropriate to allow them to use meat
4 and poultry products or byproducts in
5 formulating their diets.

6 These foods are regulated by AAFCO
7 which is actually an association of feed
8 control officials. Each state manages these
9 standards through their own regulatory
10 process.

11 So what it came down to is the
12 essentiality of the specific amino acids.
13 Some of these can be synthesized by the
14 animals themselves from various proteins at
15 various levels. So which can be the
16 essentiality comes to, depending on how you
17 formulate the diet, which of these synthetic
18 amino acids might be added to call it a
19 complete and balanced ration if you will.

20 We didn't consider cost as a
21 factor. As any certified organic potato
22 farmer knows they're very expensive to get the

1 seed potatoes and we don't use cost as a
2 factor.

3 There is seasonality and
4 geographic constraints to sourcing the
5 ingredients to have a complete and balanced
6 organic ration. So, with the interim rule on
7 vitamins and minerals that the program posted
8 it has given time for these materials to stay
9 on the market as we complete this aspect of it
10 without disrupting their commerce.

11 Through the public comment we did
12 receive comment back that formulators need
13 these specific amino acids depending on what
14 ingredients are available so that they can
15 call these complete and balanced diets. The
16 diversity of the dog world, very large dogs
17 may need different amounts of different amino
18 acids to balance versus very small dogs, so
19 it's a very diverse audience that they're
20 addressing.

21 We members of the subcommittee, we
22 looked at hundreds of pet food ingredient

1 labels and there was not a consistent pattern
2 of need. These were not just organic labels,
3 these were commercial pet foods, high-end pet
4 foods, Ol' Roy and less involved pet foods.
5 So we looked at the full gamut.

6 And what became kind of apparent
7 to us is the only consistent that we could
8 find was taurine was being used in every
9 single cat food label that we found on the
10 market either organic or not. Taurine was in
11 some dog foods. DL-methionine, lysine were
12 also in a random array of dog foods but
13 there's no consistent pattern. Seemingly it
14 was kind of by manufacturers would tend to use
15 some and others wouldn't.

16 So, given that we do look forward
17 to public comment today. We do look forward
18 to continuing to work with -- listen to public
19 comment and take further input as we
20 deliberate on this through the next semester.

21 Any questions for the board?

22 MS. FULWIDER: Questions? No

1 discussion? Then we will move onto the
2 omnivore discussion document and Tracy Favre
3 will present.

4 MS. FAVRE: Thanks, Wendy. Calvin
5 and I worked on the omnivore discussion
6 document obviously to address some of the
7 concerns and issues related to the L-
8 methionine step-down that's currently under
9 consideration and in the works for us.

10 The discussion document was really
11 to seek public input on some potentially
12 controversial ideas for how we might address
13 the lack of L-methionine -- or excuse me,
14 methionine in the diet. Next slide, please.

15 Basically the discussion document
16 was a list of -- a series of questions trying
17 to seek specific input, having some
18 conversation about the fact that pigs,
19 chickens and turkeys are omnivore but yet we
20 forced a vegetarian diet.

21 The questions basically ask for
22 recommendations for 100 percent organic meat

1 scraps or byproducts to be used in omnivore
2 diets, specifically poultry and pigs, since
3 it's natural for the omnivores to consume it
4 anyway.

5 The feedback was sort of a mixed
6 bag but the majority of the respondents
7 responded no. And particularly it was in
8 regards to the perceived degradation of the
9 organic label should meat scraps or byproducts
10 be allowed back into organic. But there were
11 some pretty emphatic comments about the
12 positive benefits of organic meat scraps as
13 well.

14 The next question, question number
15 2 was about the herbal methionine and the
16 other sort of alternatives to meat scraps and
17 meat byproducts and how we should encourage
18 this type of research. Obviously that is less
19 controversial and received more overwhelmingly
20 positive support.

21 Some of the comments were that
22 until synthetic methionine is disallowed there

1 will be less incentive to further develop more
2 natural methods of L-methionine, and that it's
3 certainly worth exploring all potential
4 alternatives.

5 There were some concerns raised
6 about the potential scalability of some of
7 these naturals, quote, "natural" methionines
8 and the ability to scale it up for larger-
9 scale production. And certainly, you know,
10 what do we have to do to bring these products
11 to commercial viability within the next 3
12 years. It was positively received but
13 obviously there's still some question as to
14 how to go about doing it.

15 One of the suggestions was to
16 conduct detailed studies in the U.S. Pretty
17 consistently we heard please don't eliminate
18 the synthetic methionine until we have a
19 viable alternative for that.

20 And questions about how to spur
21 more production, manufacturing of natural
22 amino acids. Again, the comment about little

1 incentive as long as synthetic is allowed, but
2 also recognition that there's been a fair
3 amount of work and conversation about this,
4 not only recently but there was a methionine
5 task force that looked at it as well.

6 And then if we are to allow
7 organic-approved meat and slaughter byproducts
8 what do we do to ensure that safeguards are in
9 place to -- for public health as well as the
10 perception of it. And there were some issues
11 raised in regards to the rendering facilities
12 and the ability to separate organic versus not
13 organic.

14 And again, would the organic brand
15 be damaged. Pretty consistently we feel the
16 comments were that they felt the organic brand
17 would be damaged although some people came
18 with the comment that as long as the public
19 was properly educated it would be all right.

20 There were some comments about a
21 concern on the use of fish meal due to
22 threatened populations and the threat of over-

1 fishing. And would the rule change be
2 appropriate to help fulfill the essential
3 amino acids requirement, and if yes, state
4 what language would you use. And basically
5 the comments were very ambivalent about this.
6 Again, it was reiterated that even an
7 annotation about this would not really provide
8 an effective solution.

9 So, in the summary, you know,
10 there's strong broad-based support for
11 developing natural methionine. There's mixed
12 bag but a preponderance on negative response
13 to the introduction of meat byproducts and
14 meat scraps, and an emphasis on comments that
15 we need to enhance and further encourage the
16 development of natural methionine.

17 Any questions?

18 MS. FULWIDER: Mac?

19 MR. STONE: This document kind of
20 focused on meat and poultry products,
21 byproducts. The poultry industry, not just
22 organic but the outdoor poultry people are

1 looking at insects as a protein source with
2 the high cost of feed grains and availability
3 of feed grains. So I'd just be curious if any
4 commenters are commenting on this. We'd like
5 to hear any interest, if there's any issue
6 with public perception of raising insects. Or
7 if you all discussed that that I missed.

8 MS. FAVRE: There were comments in
9 regards to the fact that they thought that was
10 a great idea. We didn't see specifically any
11 negative comments about the perception of, you
12 know, feeding grubs or maggots or whatever to
13 poultry.

14 Calvin coauthored this document
15 with me. Calvin, do you have any comments
16 that you want to add to that?

17 MR. WALKER: I have none.

18 MS. FULWIDER: John?

19 MR. FOSTER: So, the insect thing
20 is really interesting to me. Some of us have
21 had conversations about that. But what came
22 up in conversation yesterday was really

1 interesting to me and I don't necessarily --
2 I don't think we have the time to discuss it
3 here but I like -- I think it's appropriate
4 that we recognize some very large macro issues
5 when they come up that maybe we don't get
6 often enough the chance to talk about.

7 The one that really struck me
8 yesterday was with respect to how use of
9 synthetics might be beneficial to ecosystems
10 in a very indirect, convoluted way.

11 With respect to, say, fish meal
12 being used as a protein source or a feed
13 source, well, if that does put undue pressure
14 on fish stocks then could that actually be, I
15 think the phrase we were using was a "deep
16 green" approach to actually tipping the scales
17 toward a few synthetics. And I'm not here to
18 make that proposal at the moment but I thought
19 that was a really good, large-scale, higher
20 than 30,000-foot view of the kind of issues
21 that we're probably going to need to contend
22 with more and more often. So I just encourage

1 people to be thinking about maybe there's some
2 advantage. Not just to synthetics, I don't
3 mean to direct it there, but to other natural
4 sources of other materials, that's great. But
5 I love the idea of looking at preserving fish
6 stocks as a means of -- as a driver if you
7 will of a very sustainable approach to feed
8 stocks for livestock for which is going to be,
9 like that pressure is not going to go
10 anywhere. It's going to get worse, it's going
11 to get higher. People want their protein and
12 there's more people so we're going to need to
13 deal with that at some point.

14 I really encourage us all to be
15 thinking about those indirect advantages that
16 may not be in our current discourse right now.
17 So that was really helpful for me yesterday
18 and I hope we have ongoing conversations about
19 that.

20 MS. FULWIDER: Other discussion?
21 Well, moving right along. Last but not least
22 we have a GMO Vaccine Working Group update.

1 And I will turn this over to Jean.

2 MS. RICHARDSON: Thank you, Wendy.
3 This is sort of just an update really from the
4 GMO Vaccine Working Group. The names of the
5 people that are on this are up there on this
6 slide. Where you have, it's a joint, this
7 USDA working group.

8 We've got Melissa Bailey from the
9 NOP and she's sitting across the other side of
10 the table from me, Scott Updike who's not here
11 who has been active on this subject and
12 continues to be, and then we began to work
13 with some people at the -- at APHIS. Patricia
14 Foley has been on our conference calls and a
15 very helpful and active member. And we've got
16 Nick Maravell who is another member of the
17 NOSB board and he'll make some comments after
18 I've done sort of the general introduction
19 here.

20 And it's important to understand
21 that this is a presentation of the subgroup.
22 It doesn't necessarily represent what our

1 Livestock Subcommittee was working on earlier
2 but it is in fact a group report.

3 And just for some background for
4 especially if there's other people in the
5 audience and other committees that don't know
6 where all the pieces on vaccines in organic
7 livestock production are found in our -- in
8 Section 205. There are four different areas
9 of relevance when we're trying to understand
10 what it is that we're trying to resolve, the
11 problem that's before us.

12 The first place is that in
13 238(a)(6) it states that the producer must
14 establish and maintain a preventive healthcare
15 practices including administration of vaccines
16 and other biologics. So there's the first
17 place.

18 And then in second place under the
19 National List of Allowed and Prohibited
20 Substances in terms of vaccines it simply
21 states at 603(a)(4) that biologics, vaccines
22 without any form of annotation.

1 The third place that vaccines are
2 found in 205 is to deal with emergency pest or
3 disease treatment, and also that includes
4 eradication programs.

5 The important thing I think for us
6 to be clear about is that under 205.105(e) the
7 use of excluded methods which we commonly call
8 GM or GMO which we should really use the term
9 "excluded methods" this is prohibited in
10 organic production. And as we all know,
11 producers must provide written documentation
12 for seeds to show that they're not -- what
13 their seeds are, non-GMO. And for handlers
14 they have to show that if they have non-
15 organic ingredients they have to have written
16 documentation that they were not produced
17 using excluded methods.

18 There is an exception, however,
19 for vaccines provided that they are reviewed
20 and recommended for addition to the National
21 List by the NOSB in accordance with 205.600.
22 So, all GMO are prohibited except for vaccines

1 but it's an important note provided that
2 they're reviewed and recommended by NOSB. And
3 I repeat that because that obviously has not
4 yet taken place.

5 So because of this inconsistency
6 within the rule in September of 2010 the NOP
7 requested the NOSB to review vaccines made
8 with excluded methods to be in accordance with
9 205.600. So, we on the Livestock Committee
10 proposed recommendations in a lengthy document
11 ready for the Albuquerque meeting.

12 But public comment prior to the
13 meeting clearly demonstrated that there were
14 two sort of divergent positions on this. The
15 general public very loudly stated that they
16 wanted no GMO vaccines, but certifiers and
17 producers felt that they needed more detailed
18 information about current vaccine use and
19 production. So therefore this subcommittee
20 was established following the tabling of the
21 subcommittee recommendation.

22 But the NOSB passed a resolution

1 requesting more information from the USDA and
2 we then set to work to try to unravel the
3 complexities of this. Initially we're trying
4 to determine which methods used to genetically
5 modify disease-causing agent could be
6 considered excluded and which could be
7 considered allowed. And there are a number of
8 nuances in there which we haven't really
9 sorted out at this point, but we're working on
10 it.

11 We also wanted to try to determine
12 if in fact we could find a list, could develop
13 a list. There is one presently published by
14 APHIS but would this list actually allow
15 organic producers, certifying agents and
16 veterinarians to determine if a vaccine was
17 made without the use of excluded methods. And
18 we did hear some public comment on that this
19 morning which I found very useful.

20 We also are trying to determine
21 what are the methods, can we verify the
22 methods by which the vaccines are being

1 produced. Can we understand the current use
2 of those vaccines. And this is where the
3 public comment comes in in terms of the need
4 for knowledge collection.

5 We need to know as much as
6 possible from the public those that are using
7 vaccines, whether they look to see if in fact
8 they are made with excluded methods or not.
9 What is the current use, who's using them, are
10 they in combined vaccines, what does it look
11 like, to get as much of that information as
12 possible from Europe, from your perspective.
13 Obviously we're still working with APHIS but
14 they may have a different perspective from
15 producers and certifying agencies.

16 And, finally we really want to try
17 to understand what would be the required use
18 of vaccines made with excluded methods. Could
19 they be legally used for eradication or for
20 emergency programs and under what
21 circumstances. So obviously this is a very
22 highly complex issue, there's a lack of

1 clarity in a number of different areas
2 including the definition of excluded methods
3 between NOP and the manufacturers, et cetera.
4 And so it's going to take us some time to come
5 up with a workable solution but we're going to
6 continue working on it.

7 And I would like to now ask Nick
8 if he would have some additional comments that
9 he wants to make.

10 MR. MARAVELL: Thank you, Jean.
11 Just for some of you out there in the audience
12 to give you a little bit of background if you
13 haven't been following this issue closely,
14 sort of how we got to where we are in
15 discussing the GMO vaccine issue is that there
16 was a previous board action recommending GMO
17 vaccines. It was reviewed by the USDA general
18 counsel. It was determined that a particular
19 process needed to be carried out in accordance
20 with the statute and the regulations to
21 evaluate it for adding it to the National
22 List. And so we received a request from the

1 program to go ahead and evaluate this.

2 And I just want to make it clear,
3 we are not considering a petition here. We do
4 not have a petition before us for a specific
5 vaccine or anything like that.

6 The Livestock Committee then
7 considered the issue and made a very minor
8 change to current policy which would have
9 affected the organic status of any product,
10 livestock or livestock product that received
11 a GMO vaccine as a result of an emergency
12 treatment program. And that's pretty much all
13 that the Livestock Committee recommended on
14 this.

15 We did not specifically consider
16 the impact of eradication programs but that's
17 certainly something that I think we plan to
18 explore with the working group.

19 We also recommended in a
20 resolution to the National Organic Program
21 that there would be potentially three things
22 that would be helpful to us to generate more

1 information on, "us" being the NOSB.

2 One was would it be possible to
3 encourage voluntary label claims on the part
4 of manufacturers to state the absence of GMOs
5 in their product and this way it would be more
6 easily accessible to a producer or certifier,
7 et cetera. And our reasoning there fell along
8 the lines of current practices whereby
9 producers are asked to provide documentation
10 about lack of GMO methods or excluded methods
11 used in let's say a seed inoculant or in seed
12 and in other products.

13 So currently there is some
14 precedent for this type of documentation. It
15 may not be a cure-all and an end-all but
16 certainly something worth exploring.

17 Then the second thing that we were
18 trying to get more information on is would it
19 be possible to eventually end up at a place
20 whereby there was a realtime list when
21 vaccines went into be registered with USDA
22 through APHIS where it would be easy to

1 determine is this vaccine indeed made with
2 excluded methods. So that was a second point
3 that we wanted to explore.

4 And then the third point where we
5 wanted more information is what do we know
6 about the existing vaccines that are
7 registered for use and whether or not these
8 vaccines are made with excluded methods or
9 GMOs, however you'd like to express it. So
10 those were the three things that we were
11 requesting.

12 We're hoping to continue to work
13 in those areas and come up with some answers
14 to those questions. But as I think Jean may
15 have alluded to, once you get into the GMO
16 issue it gets fairly complex fairly quickly.
17 It's not a monolithic, there isn't one single
18 thing that's a GMO or an excluded method for
19 that matter. So I think we are still
20 exploring the parameters, how big is this
21 question and how much can we come back with,
22 but we are working on it and we hope to come

1 up with something that can provide guidance to
2 the community in concert with the program.

3 MS. RICHARDSON: Melissa, would
4 you like to add something?

5 MS. BAILEY: No, I think that was
6 a great report, Jean. And Nick, appreciate
7 your follow-up comments there. Yes, I think
8 the only thing I would say is that it's been
9 I would say an open, collaborative
10 relationship with Jean and Nick and APHIS to
11 this point and I see that continuing. So
12 thanks for your work with us.

13 MS. FULWIDER: Okay, thank you.
14 Any discussion? Okay. Seeing none we can
15 break for 15 minutes. We all need to be back
16 at 2:45. And if the Livestock -- Jean?

17 MS. RICHARDSON: Wendy, perhaps
18 because we're the first subcommittee reporting
19 could you explain when we might be voting on
20 the items, like on nonanoic acid for example?

21 MS. FULWIDER: Yes, we may be
22 voting on nonanoic acid yet today but that's

1 why I wanted to have a subcommittee meeting
2 here right during the break. And so we can
3 decide if we're going to vote today or later.
4 So, everybody back here at 2:45.

5 (Whereupon, the foregoing matter
6 went off the record at 2:27 p.m. and went back
7 on the record at 2:56 p.m.)

8 MS. FULWIDER: Okay, we're calling
9 the meeting back to order. And we're ahead of
10 schedule a little bit so we are going to be
11 starting public comment a little earlier.

12 I have an announcement to make
13 before that. At this time in the interest of
14 transparency if any of the board members would
15 like to share any interest related to our
16 Livestock Subcommittee proposals and announce
17 recusal would they please go ahead. So,
18 Barry, is there any?

19 Okay, hearing none we -- hearing
20 none we will proceed with public comment.
21 Will Fantle is up first. And Christopher, I
22 don't have a name here, from Heritage is on

1 deck. And if you'd please state your name and
2 affiliation.

3 MR. FANTLE: My name is Will
4 Fantle. I'm the co-director, co-founder of
5 the Cornucopia Institute. I'm going to talk
6 about some livestock issues. You've got
7 copies, each of you, of our broader testimony.
8 I'm not going to reference that. I've got
9 some additional comments and observations I
10 want to offer.

11 There are operations engaging in
12 wholesale fraudulent marketing. We've worked
13 with farmers on both sides of the U.S.-
14 Canadian border to gather information about
15 the activities of a Canadian company, Jirah
16 Mills, that has been a major supplier of feed
17 for livestock in this country.

18 Last year under investigation by
19 the provincial authority in Quebec and knowing
20 that an audit of their company was forthcoming
21 Jirah voluntarily surrendered their organic
22 certification and that prevented the

1 investigation, further investigation of the
2 company for the activities that they were
3 suspected of engaging in.

4 The alleged fraudulent grain was
5 being sold to the giant egg operations and
6 grain mills servicing livestock producers in
7 the Northeast and directly to Organic Valley
8 farmers.

9 Now, here's the rub. One year
10 later they're back in business. They were
11 recently re-certified by Organic Tilth. No
12 one in Canada would touch this hot potato and
13 they're banned from selling their grain in
14 Quebec. But Jirah somehow managed to convince
15 Tilth to certify them. The get out of jail
16 free card was a voluntary surrender of the
17 organic certification.

18 Miles talked this morning about
19 the accelerated pace of NOP investigation and
20 that's good. We need aggressive and quick
21 enforcement. But we've lost thousands of
22 acres of production of organic feed grain in

1 the Midwest in the last several years because
2 our domestic farmers are unable to compete
3 with con artists and imports, cheap imports
4 coming in from other countries. In the real
5 world this means less organic acreage in U.S.

6 Every NOSB meeting I come to I
7 hear so much praise and rightfully so for the
8 efforts of family farmers and others to raise
9 and grow the bounty that so many of us enjoy
10 and treasure. But family farmers in some
11 sectors are being crushed by tight to non-
12 existent margins.

13 Such is the case right now in
14 dairy. Another suspect operator, Aurora Dairy
15 is a provider of private-label milk for some
16 of the biggest grocers in the country
17 including Walmart, Safeway, Costco, Target.
18 The USDA chose to put Aurora on probation for
19 their 14 willful violations several years ago
20 but they didn't fine them one cent. But
21 somebody else did.

22 You may have heard news recently

1 about consumers in 30 states bringing a class
2 action lawsuit charging that the production
3 practices pictured on the pretty cartons sold
4 in these stores of cows grazing contentedly in
5 pastoral conditions really didn't match the
6 reality of the situation. That class action
7 lawsuit was settled a few weeks ago for \$7.5
8 million. It should be an embarrassment to the
9 USDA and the organic community.

10 The organic production data cited
11 by Mark Lipson also contained some interesting
12 nuggets. For example, just eight organic
13 dairies in Texas have nearly 50 percent more
14 gross sales at the farm gate than the nearly
15 certified 400 farms in Wisconsin. Eight farms
16 in Texas. There are real world consequences
17 of enforcement actions or delays of
18 enforcement actions.

19 Lastly, I want to mention the
20 Petaluma egg operation in California. You may
21 have heard that they are being sued again for
22 carton picturing of the chickens being outside

1 and not matching the production practices that
2 are occurring at the operation. That suit has
3 been brought by an animal rights group.

4 Is this what we're coming to,
5 challenges for flagging practices from other
6 interests?

7 MS. FULWIDER: Questions for Will?
8 Okay, thank you.

9 MR. FANTLE: Thanks.

10 MS. FULWIDER: Christopher. State
11 your name and affiliation, please. And
12 Mohamed Mousa on deck.

13 MR. PIERCE: Good afternoon, my
14 name is Christopher Pierce, P-I-E-R-C-E with
15 Heritage Poultry Management Services. I'm
16 located in Annville, Pennsylvania. I serve as
17 the president of Heritage Poultry Management
18 Services and we're around 5 hours from here,
19 so 2 a.m. this morning got on the highway and
20 got past Manhattan, lower Connecticut, and got
21 here real easy so it's good to see you folks.

22 Our company partners with a

1 variety of egg companies providing technical
2 and hands-on support of egg farming in our
3 mid-Atlantic region's family-sized egg farms.
4 We have a team of certified poultry service
5 technicians, Ph.D. poultry nutritionists and
6 a support team with the emphasis of assisting
7 our farmers group in the detailed hen
8 husbandry care of their flocks in addition to
9 being a tool to assist the farmers in meeting
10 the various organic, hen welfare, food safety
11 requirements for the farm.

12 We work with many of the family
13 farms producing eggs that are sold here in the
14 cities such as Providence, Boston,
15 Philadelphia, Washington, Baltimore and
16 Manhattan. Of all the farms we work with the
17 families own the farms, personally provide the
18 care and management for the flocks as well as
19 pack the eggs, 7 days a week, 365 days a year
20 meanwhile raising their own families on the
21 farm.

22 So an important fact to share with

1 the board is that the average age of our
2 organic farmer is probably around 35. And due
3 to the increased demand of organic eggs
4 there's new opportunities for that next
5 generation family farm.

6 Our organic farmers are motivated
7 and committed to meeting the consumer's
8 expectations while meeting the increased
9 defined welfare and food safety requirements
10 that our farms follow.

11 I serve also another position as
12 the chairman of the Pennsylvania Egg Quality
13 Assurance Program which is a program which its
14 standard was used to introduce the FDA Egg
15 Rule which was implemented and followed. The
16 reason that we've had PEQAP is the great
17 importance for successful food safety offers
18 our egg farmers, processors and the end
19 consumers and that's why the FDA used it to
20 turn into their mandatory compliance program.
21 Because all consumers expect and should
22 receive the safest eggs that can be produced

1 whether they're organic or not.

2 It was our decision to participate
3 in that voluntary PEQAP program which is the
4 most rigorous egg safety program in the U.S.
5 that besides all the other details includes
6 two unannounced visits by our Department of
7 Agriculture every year. Why do we do that?
8 Because we're committed to producing and
9 providing the highest quality eggs for the
10 marketplace.

11 In addition, the detailed farm
12 management plan encourages the farms to follow
13 good practices for salmonella risk reduction.
14 Vaccination is an important and valuable tool
15 that even FDA encourages.

16 In addition, many national grocer
17 retailers also have specific requirements for
18 our flocks, that they must be vaccinated on an
19 FC program at the pullet stage and that's in
20 response to 2010 where half a billion eggs
21 were recalled from two Iowa farms. And that
22 was due to that, that the retailer now cares

1 more about where are those eggs coming from,
2 what was the vaccination program and they
3 mandate that there must be salmonella
4 vaccination programs.

5 So I want to encourage the NOSB
6 and the NOP to support standards that provide
7 organic egg farmers with known and effective
8 countermeasures including salmonella
9 vaccination that support future success in
10 those small organic family farms that have
11 committed their lives to organic egg farming.
12 Thanks to the NOSB and to the NOP for allowing
13 me to share this opportunity and happy
14 birthday, NOP.

15 And if there's any comments on
16 omnivore diets I'd like to throw some comments
17 back to Mac or anything else that I could be
18 helpful today.

19 MS. FULWIDER: Questions? Mac.

20 MR. STONE: I want to acknowledge
21 that wasn't a setup so I may not be asking.
22 But what are your growers doing with the high

1 cost of feed and grains? Are you looking at
2 alternative grains or alternative protein
3 sources?

4 MR. PIERCE: You know, and we're
5 at historic prices. As I'm sure everybody in
6 this room knows we're at just unthinkable
7 prices. So at this point we're absorbing that
8 price.

9 And one of the questions you asked
10 one of the commenters earlier, Mr. Robinson
11 from Kramer Feeds, was what is the effect of
12 the methionine. And one of the initial
13 effects that we have the cap on methionine is
14 we're being forced to raise the protein level
15 in our feed so that we can get the birds so
16 that they can obtain higher methionine. And
17 the birds aren't utilizing all that protein so
18 it is kind of passing through the bird into
19 the soil, into the ground, as well as it's
20 raising the cost of our feed then also.

21 Did you ask about insects, Mac?
22 Did I hear you ask about that? I'd love to

1 respond to that. So actually, insects are a
2 major challenge for us because the Food and
3 Drug Administration which oversees all the
4 farms that we work with. Any farm of more
5 than 3,000 hens is overseen. They want us to
6 get rid of the vectors. We can't even use
7 insects because they could potentially be a
8 carrier of a salmonella so we have to put in
9 our action plan how to eliminate insects of
10 all types including darkling beetles and any
11 insects on the farm.

12 If there's any questions on like
13 the omnivore diets. But anyway, I'll just
14 leave it the way it is.

15 MS. FULWIDER: All right, thank
16 you.

17 MR. PIERCE: Thank you.

18 MS. FULWIDER: Mohamed, can you
19 come up, state your name and affiliation. And
20 Brennan Herbruck on deck.

21 MR. MOUSA: Good afternoon,
22 everybody. Thank you for your hard work, NOSB

1 members and also NOP program.

2 My name is Mohamed Mousa. I am
3 vice president for production at Herbruck
4 Poultry Ranch. We're talking about genetics
5 and GMOs. I have a degree in genetics and
6 poultry disease or poultry medicine.

7 I want to start here with a slide
8 I obtained from CDC. The foodborne diseases
9 in United States is about 19,089 in 2010,
10 4,247 with hospitalization and 68 fatalities,
11 68 people dead. Salmonella accounted for
12 8,256, about 43 percent from that number and
13 hospitalization from salmonella species was
14 2,290 and 29 fatalities. It's about 42
15 percent from foodborne disease.

16 I would like to make sure that I
17 am very clear when I talk about vaccine.
18 There's two types of vaccine. There is viral
19 vaccine against viruses and there is against
20 bacteria.

21 Last meeting I stood and I said I
22 don't know how they make the vaccine. Well,

1 today I can tell you how they make it because
2 I went and I visited the vaccine companies.
3 I met with several of the specialists who make
4 that vaccine and I will make my comment here
5 about salmonella.

6 There is not any salmonella made
7 vaccine in United States is GMO. This
8 statement I clarified it from all the vaccine
9 companies making the vaccine. For Lohmann
10 Animal Health and I took their permission to
11 mention their names, the person whom
12 discovered that vaccine and manufacture it and
13 patent it with USDA, her name is Sandra Kelly.
14 She's a colleague, she's a friend and I had to
15 take her permission also to mention her name.

16 She found out how to make vaccine
17 by accident. She was tried to suppress the
18 salmonella typhimurium bacteria and she found
19 out that there is a virus available in the
20 environment called the bacteriophage can
21 disable that bacteria. Disable means I want
22 to take you with me here, everyone from us and

1 all ourselves, we have genetic makeup. All
2 those genetic have genes on them in the
3 chromosomes. They have switches. You can
4 turn them on and off like this light here.
5 She succeeded to find the bacteriophage to
6 turn two genes off, means to disable the cell.
7 And she obtained vaccine by this way.

8 Other companies which they did not
9 give me permission to mention their names,
10 they're using techniques similar to that or
11 use a different technique which is similar
12 which also through the pH and other treatment
13 they turn also the same two genes off.

14 So this is not GMO. It happen in
15 any composting pile behind your house or my
16 house. So please, if somebody stand over here
17 I researched that, okay? I researched it. I
18 am a geneticist, I know what I'm talking
19 about. Somebody stand over here and tell you
20 that the salmonella vaccine GMO, don't believe
21 him. Refer him to me.

22 If you need Dr. Kelly's phone

1 number, email, I can provide it with you. I
2 have it.

3 The other issue I want to talk to
4 you about is the viral vaccine. The viral
5 vaccine, there is GMO vaccine in the viral
6 vaccine. How they do it? They slice part of
7 the chromosome from a virus, what they call
8 it. Empty space we call it in genetic, empty
9 space in that chromosome. They take that
10 empty space and get another virus and they put
11 a piece in there. When you vaccinate the
12 chicken the immune system of the birds
13 summarize that and recognize it and develop
14 immunity against it.

15 Any questions?

16 MS. FULWIDER: Calvin.

17 MR. WALKER: Dr. Mousa, I have one
18 question with two parts. Methionine. Could
19 you speak to the impact of the step-down?

20 MR. MOUSA: Yes, sir.

21 MR. WALKER: And in the absence,
22 what would be other alternatives in the

1 absence of synthetic methionine?

2 MR. MOUSA: Thank you. The birds,
3 if you have 10,000 chickens they will eat
4 approximately 500 pounds of feed in their
5 lives. Two pounds of methionine per ton,
6 that's about 1,000 pounds of methionine.
7 Because we are restricted now to use only
8 maximum of 2 pounds in early of the bird life
9 when they are pullets growing or when they
10 start laying, and when they start laying, by
11 about 30 weeks or so this is the maximum
12 production. They need maximum amount of
13 methionine.

14 In the front of the bird life we
15 have to watch for the stage of life. And in
16 your comment in many NOSB literature I read
17 there is a stage of life that you watch for
18 the stage of life. Well, in methionine sorry
19 to say you did not. And those birds that's
20 going to suffer a lot in early life but we
21 don't need 2 pound after 45 weeks or 50 weeks
22 of age. We need only less than a pound after

1 60 weeks.

2 I would ask the board to consider
3 the average. We don't need more methionine,
4 we just need the average. Right now those
5 10,000 birds will use only about 75 percent
6 from the allocated protein methionine only.
7 Only 75 percent. We cannot use the other 25
8 percent because we are restricted and the
9 certifier of course will not accept the
10 average unless there will be a ruling with
11 that.

12 The alternative. Somebody was
13 talking about fish meal. I want to tell that
14 person who have that idea in their mind don't
15 destroy the organic egg production. As soon
16 as you feed high level of fish meal to get
17 methionine the brown birds is very unique.
18 They take the fish smell and scent and put it
19 in egg. The consumer is going to run away
20 from our organic eggs. Please don't do it.
21 I did that. I did research, that was my
22 research when I was in school. Don't do it.

1 The other issue is the insects. I
2 think Chris commented on that. The insect
3 meal is a phenomena. Guys over there in China
4 did that and they had a lot of salmonella in
5 the eggs, a lot.

6 The other issue which is also very
7 critical here, we have to look for the food
8 safety. We have to look for human who's going
9 to use that egg. We cannot contaminate the
10 egg by trying to supply the birds with
11 methionine. Can't do that. Thank you.

12 Any other questions?

13 MS. FULWIDER: Jean.

14 MS. RICHARDSON: Thank you.

15 Earlier today we heard that broilers and
16 turkeys can be given before hatching bunches
17 of vaccine which I found very interesting.
18 What I'd like to know from you is in your
19 experience how common that is.

20 MR. MOUSA: Yes. In ovo vaccine
21 is common in broiler industry. It's for viral
22 vaccine. You cannot vaccinate bacteria in the

1 egg. The immune system of that undeveloped
2 embryo is not capable of dealing with the
3 bacteria I will say yet because some research
4 working on that right now to try to see if
5 they can have some bacteria cells treated
6 certain ways and to be in ovo.

7 For the broiler industry we use
8 all males and females. In layer industry we
9 can't do that. Even if we vaccinate in ovo we
10 have to vaccinate again because the shelf life
11 of broilers is very short, you know, 6-7
12 weeks, but layers live about 14 months. So we
13 have to build the immune system. In layers we
14 build the immune system. We vaccinate about
15 9 times and some companies vaccinate 12. And
16 we have a very broad viral and bacteria we
17 vaccinate against and we can't do it all in
18 ovo because the immune system at that time
19 will not recognize it.

20 MS. FULWIDER: Any other
21 questions? Okay, thank you.

22 MR. MOUSA: Thank you.

1 MS. FULWIDER: Brennan Herbruck?

2 Okay, if Brennan's not here I have Ashley
3 Swaffer next on my list.

4 MS. SWAFFER: Hello, my name is
5 Ashley Swaffer and I'm the operations manager
6 for Arkansas Egg Company. And I'm here today
7 to comment on the Livestock Committee's
8 omnivore diet discussion document.

9 The committee has asked if they
10 should look to allow 100 percent organic meat
11 byproducts. My response is no.

12 My first reason is the commercial
13 availability of the product, or lack thereof.
14 For the estimated 8 million laying hens and 7
15 million replacement layers growing right now
16 you would need approximately 68 million pounds
17 of a product that's not even being certified
18 or produced right now.

19 And the second reason I'm against
20 the feeding byproducts to poultry is the fact
21 that many producers and marketers have built
22 brands centered on feeding a vegetarian diet.

1 Consumers are buying eggs that are fed a
2 vegetarian diet right now and they expect that
3 every time they go to the grocery store and
4 buy a carton of eggs. So I really feel that
5 the organic brand would be at risk and be
6 damaged if we fed byproducts to poultry.

7 And the discussion document has
8 also suggested we look at fish meal as a
9 solution. The problem with fish meal as
10 Mohamed said, it causes a flavor transfer into
11 eggs. And another product of fish meal is
12 that it's not an environmentally sustainable
13 resource. We should not have to use our
14 ocean's resources to feed chickens when we
15 have other options available.

16 The document also asked if the
17 committee should continue research efforts to
18 find natural alternatives to synthetic
19 methionine and I say yes. We need something
20 we can feed to our hens that meet their
21 nutritional needs in the organic regulations.
22 But there is not a solution right now to

1 synthetic methionine. And the maximum levels
2 put into place without a solution that is
3 commercially available to producers is
4 unacceptable.

5 Currently the 2-pound maximum
6 level does not meet the nutritional needs
7 required by chickens which is in direct
8 violation with 205.238(a) which states you
9 have to feed a diet that is nutritionally
10 adequate. Without commercially available
11 natural methionine sources to poultry
12 producers I ask you to please seriously
13 consider the new petition submitted by the
14 methionine task force at the spring 2013
15 meeting with the revised levels that meet the
16 changing demand in methionine as it relates to
17 age. Thank you.

18 MS. FULWIDER: Harriet. Dave
19 Carter on deck.

20 MS. BEHAR: I am Harriet Behar,
21 organic specialist with the Midwest Organic
22 Sustainable Education Service (MOSES) and we

1 work with a wide range of organic farmers
2 mostly in the upper Midwest doing education
3 and advocacy. MOSES is also a NOC member.

4 I appreciate the Livestock
5 Committee's discussion document on the
6 omnivore diet aspect of poultry and non-
7 ruminant animals and your wish to find an
8 alternative to synthetic methionine. However,
9 I do not believe that the use of poultry in
10 mammalian slaughter byproducts as a means to
11 provide this nutrient is workable or the right
12 direction to take.

13 I believe many consumers are
14 attracted to organic livestock products
15 specifically because of the prohibition of
16 slaughter byproducts as feed sources for
17 organic livestock. We have learned that
18 diseases can cross species with devastating
19 results with Mad Cow disease as one example.
20 This alone should rule out the use of
21 slaughter byproducts even if they are organic.

22 The usual infrastructure for

1 slaughter byproducts would need to be
2 significantly improved in order to meet
3 organic standards of livestock feed handling.
4 And if there is any fish meal used it must be
5 NOP certified organic.

6 Hogs and poultry are omnivores and
7 it is their natural behavior to consume meat
8 products. However, in their natural life they
9 would not be consuming meat every day. They
10 are opportunistic in their eating habits but
11 would not necessarily obtain mammalian or
12 poultry food sources on a daily basis.

13 I do not believe it serves farmers
14 or consumers in the long term to have a rule
15 change to allow this feeding. Instead, we
16 should be putting our resources toward the
17 research and ramping up of non-synthetic
18 methionine options. I am concerned that by
19 allowing this we would become complacent that
20 the synthetic methionine problem has been
21 solved and that our search for non-synthetic
22 plant or invertebrate methionine sources would

1 no longer be a priority.

2 Pet food standards should be more
3 clearly defined by the NOP before adding
4 materials to the National List so we have a
5 framework on how best to list them, preferably
6 individually and not as a category, and
7 provide clarity on the manufacturing protocols
8 of these organic pet foods.

9 I would like to encourage the NOSB
10 to join me in asking the National Organic
11 Program to move forward with the NOSB
12 recommendation on apiculture. This has
13 disappeared from the NOP working list kind of
14 like the honeybees who have succumbed to
15 colony collapse disorder.

16 Right now there is organic honey
17 being sold in the marketplace with widely
18 differing standards which is confusing to the
19 consumers and damaging to the overall organic
20 label and consumer confidence. My cab driver
21 even talked about it on my way here. Your
22 recommendation to the NOP was a good one and

1 should be added to the NOP 2013 working list.

2 I support the committee's position
3 to not approve nonanoic acid for 205.603.

4 And last of all, as an overall
5 caution, pay attention to what has happened
6 with Chilean nitrate at sunset and how
7 difficult it can be to remove a previously
8 allowed item from use due to the economic
9 ramifications of that removal. Whenever you
10 may think that an item that still has some
11 conserved could be approved now would have
12 thought that the future NOSB could remove it
13 with new information this removal may not be
14 as easy as you think.

15 I agree with Kevin Engelbert that
16 votes should be done on the last day to allow
17 the NOSB to ruminate on these proposals and
18 public comments over a few days instead of
19 doing them immediately after your discussion.

20 And I agree with Alexis from the
21 Organic Consumers Association that the current
22 use of GMO vaccines in organic livestock

1 production is an issue of great concern and
2 the NOP should be working with certifiers to
3 get a listing of all vaccines currently in use
4 so the working group can see what vaccines
5 they should review as a possibility from
6 excluded methods.

7 And if you want to know more about
8 the Minnesota Supreme Court decision about
9 denying pesticide drift as damage to an
10 organic farm ask me.

11 MS. FULWIDER: Questions? John.

12 MR. FOSTER: In thinking about
13 alternate food sources for I think
14 particularly poultry in this case if we came
15 to a world where insects and earthworms became
16 readily available as a food source, a provided
17 food source, not just the ones you might find
18 in the pasture but ones that would be raised
19 for that purpose would those earthworms and
20 insects and other invertebrates need to be
21 certified organic?

22 MS. BEHAR: Well, that has been --

1 I remember a few years ago we did talk about
2 that actually with ATTRA. There was a whole
3 group of farmers that were raising red worms
4 and we were trying to figure out if earthworms
5 were livestock and whether they would then
6 have to be fed organic feed to then be
7 considered, they themselves.

8 MR. FOSTER: Right. What's your
9 opinion about that?

10 MS. BEHAR: Well, I think that
11 there can be a system produced where the
12 invertebrates are consuming foods that are not
13 toxic. I don't know necessarily they would
14 have to come from organic feedstocks. But I
15 think that we need to be creative and be
16 looking as much as possible at producing
17 livestock feeds that have the least amount of
18 risk to the consumers and to the livestock
19 themselves.

20 MR. FOSTER: Okay, but should they
21 be certified organic? I mean, I hate to put
22 you on the spot. You're one of the most

1 knowledgeable people in the room about it.

2 MS. BEHAR: Well, I would think
3 actually the regulation would mandate that.
4 There would have to be a determination if bugs
5 and earthworms are livestock. But I would
6 imagine if they are being raised, I mean you
7 kind of went through this a little bit with
8 yeast, you remember.

9 MR. FOSTER: Oh, I know.

10 MS. BEHAR: Whether, you know,
11 something that's actually being agriculturally
12 produced is then livestock or plant or what is
13 it.

14 MR. FOSTER: Right, the intended
15 use plays into what production practices might
16 be necessary. Right. Totally there with you.

17 MS. BEHAR: Yes.

18 MR. FOSTER: But from your opinion
19 or MOSES, whomever you choose to represent,
20 should they be certified organic. If so, what
21 standard?

22 MS. BEHAR: Well, we never came to

1 the answer whether or not earthworms were
2 livestock. That was not really part of a
3 larger community discussion. So I don't have
4 the answer whether earthworms are livestock or
5 not, but I would think that they could be
6 raised organically, yes. So if someone could
7 raise them organically then they should be
8 able to be certified.

9 MR. FOSTER: Close enough. That's
10 cool. Thanks.

11 MS. FULWIDER: Mac.

12 MR. STONE: Well, this came up at
13 lunch the other day and the definition of
14 livestock includes a clause that says other
15 non-plant life. So yes, the insects,
16 earthworms would have to be organically
17 managed.

18 MS. BEHAR: Okay, let's raise some
19 crickets.

20 MS. FULWIDER: Miles.

21 MR. MCEVOY: Yes, in my
22 presentation this morning I only gave you a

1 tidbit of the things that we're working on.
2 We actually are working on apiculture. We
3 actually have the preamble that's being
4 reviewed by an ARS -- at ARS right now. So it
5 is on the work plan, we're working on it.
6 Whether or not we get a proposed rule out next
7 year or not depends upon lots of different
8 factors but it's on the work plan.

9 MS. BEHAR: Thank you. I just was
10 disturbed to not see it on the list.

11 MS. FULWIDER: Thank you. Oh,
12 Jay.

13 MR. FELDMAN: This may be a little
14 out of sequence but since you're here I might
15 as well try this. I'm trying to sort of get
16 an amplification on your position that trying
17 to revisit something when more information
18 becomes available is a difficult process so
19 that putting something before the board
20 before, you know, it's ripe and fully
21 understood becomes problematic under the
22 supposition that we may in intervening years

1 acquire information that we could then apply
2 to an adjustment or a revision of that
3 original decision. So you've seen that be
4 problematic over the years.

5 MS. BEHAR: Well, especially if
6 you say well, we'll put this on the National
7 List now because it looks okay although we
8 have some unanswered questions. And if
9 something comes up in the intervening 5 years
10 then we'll take it off the list. But my
11 caution is it's very difficult to take things
12 off the list. And so unless you're very
13 secure in your decision-making you probably
14 should defer until you get that information.

15 MR. FELDMAN: And as a follow-up,
16 if we're working on a complex issue like we
17 are in this class of biodegradable film mulch,
18 bioplastic, whatever we call it, and let's say
19 we want to, you know, address some of the
20 complexity with some guidance.

21 From a certification and
22 inspection standpoint what level of assurance

1 would this board have that that guidance,
2 assuming -- let's assume hypothetically that
3 it came out perfectly, that that guidance
4 would be instructive and enforceable enough as
5 opposed to putting the specificity into the
6 annotation or in somewhere else somehow in the
7 rule.

8 MS. BEHAR: I think that for
9 clarity and transparency for the purchasers of
10 the material, for the manufacturers of the
11 material and for the certifiers that needs to
12 be in the regulation. Because in guidance
13 that kind of gets lost, it doesn't have the
14 rule of law and not everyone's going to know
15 to go look to guidance. If a producer is
16 looking to figure out what kind of biofilm
17 they can use they're going to go to the
18 regulation.

19 They're not going to go back to
20 the minutes of the NOSB, they're not going to
21 go to the NOP program manual, they're going to
22 look at the regulation because that's enough

1 for them to read.

2 And the certifiers are also not
3 going to feel like they can enforce anything
4 unless it's in the regulation. Miles has a
5 response.

6 MS. FULWIDER: Miles.

7 MR. MCEVOY: Guidance in and of
8 itself is not enforceable. It has to be
9 backed up by the regulations. So you can't
10 make a regulation through guidance. Guidance
11 provides a method to comply with a regulation.
12 And so it basically gives you a path to
13 compliance and if you're not in line with the
14 guidance you have to demonstrate how you're in
15 line with the regulations. But it always
16 comes back to the regulations, that's what's
17 enforceable. If it's not in the regulations
18 then there is limited enforceability.

19 MS. FULWIDER: Thank you. Dave,
20 state your name and affiliation and we have
21 Sharon Sherman on deck.

22 MR. CARTER: Thank you. My name's

1 Dave Carter. From time to time I've been here
2 with the National Bison Association or Crystal
3 Springs Consulting. Today I'm here as a
4 consultant on behalf of the Pet Food
5 Institute.

6 And I just want to say that I
7 think myself and Kim Dietz are probably the
8 only two former NOSB members that were here in
9 October of 2002 so it's especially a great
10 birthday for the organic program.

11 I want to talk a little bit about
12 both the materials and the rulemaking for
13 organic pet food. The pet food category,
14 Miles said this morning that it's important to
15 talk about the economic impact of a category.
16 And the organic pet product is between \$210
17 and \$240 million. About 30 percent of that is
18 food, the rest is treats and other materials.

19 And I think that that's pretty
20 amazing given the roller coaster that the
21 folks who make those products have been on for
22 the last 8 years. Two thousand and four, the

1 Secretary of Agriculture said you cannot
2 certify pet food as organic and then she said
3 well, maybe you can but you've got to certify
4 it under the human food standards.

5 There was a pet food task force
6 set up that noodled around for awhile, took it
7 to the NOSB. The NOSB filed their report in
8 2008 and we're kind of moving on since then.

9 In the meantime, the whole issue
10 of accessory nutrients and vitamins came about
11 in terms of what can and can't be in because
12 we're under the human food standard. So you
13 can see that those folks that are out there
14 trying to do this and build this have been
15 pounding that square peg into that round hole
16 consistently. It's a lot of dedication to
17 build this sector.

18 In terms of well, let's let the
19 regulations get set before we address the
20 materials we think we need to follow a
21 parallel track. Miles, I'm very pleased this
22 morning that you reviewed the progress that's

1 being made in developing the pet food
2 standards and what's going on there.

3 But without having clear,
4 consistent regulations and the knowledge of
5 what you can and can't put in those products
6 it doesn't do any good. You have to remember
7 that with pet food we have one or two chances
8 every day to get it right. Unless that
9 product can be labeled as a complete and
10 balanced diet it has to be labeled as
11 intermittent and supplemental. It can't be
12 listed as a food and that's only right because
13 those pets require that nutrition. So we're
14 very concerned that we have the things that we
15 need to make that.

16 The NOSB reports in 2008 gave a
17 list of materials that would likely have to be
18 petitioned and that's why after filing the
19 initial petition for taurine then we came in
20 with the petition as a category.

21 Now, I think that -- I don't think
22 there's any argument about these being

1 essential or required. Remember, other
2 categories you talk of being accessory
3 incremental. Pets, it's essential and
4 required. I think the debate has been can we
5 get those from natural sources or not.

6 The Livestock Committee has said
7 well clearly they don't think that taurine for
8 cats falls into that category. Clearly
9 taurine is the critical one. But I think when
10 you look at taurine not only are not dogs and
11 cats all the same, all dogs are not the same,
12 all cats are not the same. And if you look at
13 the literature there's a lot of literature
14 that talks about the inability of large breed
15 dogs like Newfoundlands and the others to
16 synthesize taurine.

17 Also, remember that the things
18 that were in the TAP report that were cited as
19 an example were conventional companies. The
20 conventional manufacturers have a larger array
21 of ingredients, particularly chicken meal.
22 There is no source of certified organic

1 chicken meal and so it's much more difficult
2 for those folks to formulate those products.

3 And the products that are out
4 there in terms of the food that certified
5 organic are a very narrow range, primarily
6 adult dog maintenance. And if every pet out
7 there was an adult dog we needed to maintain
8 that would be fine, but we've got cats, we've
9 got puppies, we've got seniors, et cetera and
10 so on. So thank you very much.

11 MS. FULWIDER: Questions? Jay.

12 MR. FELDMAN: Thank you, Dave.
13 I'm trying to understand this citation in the
14 technical review that cites nature's logic.
15 You're probably familiar with that brand. And
16 they cite a full -- well, meeting AAFCO
17 nutrient standards thereby making their
18 products complete and balanced. And so I'm
19 trying to put that in perspective given what
20 you've said. Can you clarify?

21 MR. CARTER: Without looking at
22 that specific one there are (a) the companies

1 that have been formulating the complete and
2 balanced products using the materials that
3 have been allowed previously. And then there
4 are the ones that are doing the products but
5 not the full line of completely certified. A
6 lot of the products are in the made-with
7 category right now.

8 MR. FELDMAN: Okay, so I forgot to
9 say that their claiming these to be natural
10 food ingredients so that -- I imagine that's
11 a slippery slope there.

12 MR. CARTER: That's a very
13 slippery slope because you can have natural
14 chicken meal but not -- you could have
15 certified organic chicken meal, it's just that
16 we don't have it in the United States. And
17 the difference that that makes is when you're
18 formulating a product with a fresh meat or
19 poultry ingredient you're formulating it with
20 about 80 percent water in there. And so it's
21 very variable, it's very difficult to bring
22 that about.

1 If you can use the chicken meals
2 which is that dried product you can test that,
3 you can have a very consistent product there.
4 It gives you a lot more flexibility. And the
5 folks that are doing that under the organic
6 have kind of got one hand tied behind their
7 back in terms of that just because of the
8 availability. It's not a price factor, it's
9 just that it's not available.

10 MR. FELDMAN: If you take a
11 product like this which says that it contains
12 no synthetic ingredients according to the TR,
13 you know, and we, let's say the board is
14 interested in creating an incentive for
15 organics to fill that niche in terms of
16 natural food ingredients. Could it
17 conceivably be produced to create -- to meet
18 these AAFCO standards without synthetic
19 ingredients?

20 MR. CARTER: Theoretically,
21 perhaps. Right now I don't think anybody's
22 cracked the code. I mean, that's the problem

1 is we just don't have it, you know. And the
2 folks that are out there are doing it because
3 of this byzantine process -- excuse me, Miles,
4 nothing -- but it's just been this process,
5 you know, since 2004. And then without having
6 the access.

7 And one of the things that I
8 noticed from the TAP report was, you know, the
9 TAP report for example noted that you could --
10 that raw food was perhaps a viable alternative
11 although they do have this little provision,
12 concerns with feeding pets raw food include
13 risk of contamination from salmonella, E.
14 coli, and other pathogens, bacteria, dietary
15 imbalances and internal injuries from sharp
16 bones. Some dogs have reportedly died from
17 bacterial poisoning.

18 I always hate something that says,
19 you know, this is really good for you except
20 you could die from it. So you know, I just,
21 I think what we want to do is make sure that
22 we're getting the best thing out there and

1 really helping to build this sector.

2 And I would just say one other
3 thing too, that the folks that have really
4 been out in front of developing the organic
5 pet food have been a lot of the smaller
6 companies that have done this because of their
7 commitment to it through the years. Noticed
8 how I whipped in some of my testimony I didn't
9 get to give there.

10 MS. FULWIDER: Mac?

11 MR. STONE: Dave, is there a
12 relationship for the need for methionine in
13 lysine relative to the -- in formulating
14 relative to the grain component versus the
15 meat or poultry component in those feeds?

16 MR. CARTER: Well, there are, and
17 I think that, you know, some of the things --
18 I listened with interest to some of the
19 previous discussion of well, fish meal and
20 some other things would be a good source of
21 that. And it gets into those, you know, the
22 same arguments as do we really want to be

1 going down a path with something that could be
2 environmentally unsustainable in order to meet
3 those.

4 MS. FULWIDER: Okay, thank you.

5 MR. CARTER: Just one last thing.
6 When it comes to if you're classifying insects
7 as livestock I want to see the squeeze shoot
8 that you work them in. So, thank you.

9 MS. FULWIDER: Sharon, please
10 state your name and affiliation, and William
11 Reifenrath on deck.

12 MS. SHERMAN: I'm Sharon Sherman
13 and I'm with the PetGuard Company. My husband
14 and I co-founded the company in 1979. We're
15 perhaps the first natural foods company to
16 create foods with byproducts, artificial
17 flavors, colors and preservatives back then.
18 We like to be the voice for animals, that's
19 been our passion all these years. And so at
20 that time we actually created these foods.

21 When we created foods without
22 byproducts we followed the AAFCO standards

1 realizing that was the only way that they
2 could come to market and the safe way that
3 they needed the vitamins and minerals to be
4 able to -- for maintenance or an all-stage
5 food to make it complete.

6 We continued on down the road and
7 I would -- I guess people like to believe, you
8 know, they have a marketing company but we're
9 not really a marketing company and that we
10 kind of like listen to what our consumers are
11 saying they need and where there's a need we
12 create a product.

13 And such came about with the
14 organic issue. People wanted organic foods
15 for their pets. And so at that time when we
16 said, okay, well let's try to see if we can do
17 it. And this was a need for the same reasons
18 that they would eat organic foods, maybe their
19 pets had allergies, maybe that they just
20 understood the benefits of organic food and
21 wanted their pets to have it.

22 At that time I met Katherine

1 DiMatteo and she said these are the people
2 that you need to talk to so I met these two
3 gentlemen, Mr. Hutchinson. And then I was
4 turned onto a Mr. Jones. And I wrote a nice
5 letter and just kind of like communicated my
6 passion for being on the pet food task force
7 at the time.

8 And my passion was, relating back
9 to creating the first foods without
10 byproducts, was I didn't want to have
11 byproducts in my organic pet foods. And I
12 didn't want anybody else to have that as well.
13 I felt like they needed to have the same
14 standards as humans. The only difference is
15 we would be able to supply the pre-mix of
16 vitamins and minerals were necessary to
17 sustain their life because after all this is
18 all they eat. This is what we feed them every
19 single day and there's so much scientific data
20 that relates to the necessity for taurine.

21 We saw in the nineteen eighties
22 that cats were spontaneously having heart

1 attacks due to cardiomyopathy, or they were
2 having issues with reproduction. And they
3 could not synthesize the taurine in their
4 system. So you know, those amino acids are
5 important. The cats need the DL-methionine
6 because it acts as an acidifier.

7 And yes, we use whole meats in our
8 products but through the manufacturing process
9 you can't seem to supply enough to sustain
10 their life in an optimum situation.

11 So, I guess I'm, you know, I've
12 come here to basically advocate for the
13 animals and of course for our work. I mean,
14 we're 34 years old. We just want to continue
15 our work and do it safely because safety is
16 the answer when you put the product out on a
17 shelf. I think that the AAFCO stage helps the
18 consumer to feel secure in what they're
19 feeding their pet. This is for maintenance
20 and this is for all stages.

21 I can feed this to my pet and
22 they're going to produce beautiful litters,

1 they're going to be healthy. And I think
2 anything less would be a tragic situation. We
3 love our animals.

4 And I do appreciate your work and
5 I appreciate your time and I think it's just
6 very, very important for us to speak for them
7 because they can't speak for themselves.

8 MS. FULWIDER: Mac?

9 MR. STONE: Does access to these
10 synthetic amino acids improve your ability to
11 source organic ingredients to build these
12 formulations, these diets?

13 MS. SHERMAN: Well, yes,
14 absolutely. Because you know, they're
15 required. I mean, you can't get enough
16 taurine and you can't get enough of the
17 methionine.

18 MR. STONE: But if there's a lack
19 of organic inputs if you will --

20 MS. SHERMAN: Pardon me?

21 MR. STONE: If there's a lack of
22 organic chicken meal or organic beef products

1 available how does this help you to increase
2 the organic content of the feeds?

3 MS. SHERMAN: Well, we are
4 producing theoretically because we go back --
5 we are, not theoretically, back to 2004. We
6 just followed the human standards like 95
7 percent and added the vitamins and minerals
8 required through AAFCO. So the 5 percent are
9 those ingredients. And that's how -- you
10 know, and we have functioned that way, not any
11 health issues or so forth. I mean, we produce
12 all stage foods as well as an important vegan
13 dog food that veterinarians use as an allergy
14 type of product to determine which type of
15 allergy that they have.

16 MS. FULWIDER: Thank you.

17 MS. SHERMAN: Thank you.

18 MS. FULWIDER: William, please
19 state your name and affiliation and we have
20 Ann Petersman on deck.

21 DR. REIFENRATH: My name is Bill
22 Reifenrath. I am the author of the petition

1 that's before you for nonanoic acid. I'm the
2 founder of Stratacor whose sole employee
3 stands before you and I'm the inventor of the
4 C8910 mix of fatty acids that we're using as
5 a livestock fly control.

6 So this is -- the C8910 is a
7 natural fly repellent. It consists of three
8 fatty acids that are normally found on the
9 skin surface of animals and man. This
10 project, the natural fly repellent was
11 initially funded by USDA back in 2005 as a --
12 because of the lack of alternate and necessary
13 additives for IPM. And I think you have
14 testimony from three universities and South
15 Africa, from veterinary entomologists
16 expressing the same fact.

17 The 8910 repellent can be applied
18 to ranch cattle for horn fly control. And if
19 you look at this slide you can see the 8910
20 repellent can reduce the level of horn flies
21 competitive with cypermethrin, piperonyl
22 butoxin. The manufacturer of this concoction

1 in their own words said the C8910 is the only
2 natural insect repellent to compete with
3 existing organophosphates and pyrethroid
4 repellents, insecticides.

5 This is data from Kenya where they
6 looked at malaria-carrying mosquitoes to show
7 that with a single application of the 8910
8 repellent that it will result in mortality of
9 about 90 percent for malaria-carrying
10 mosquitoes. So by treating cattle for flies
11 humans also derive a benefit in killing the
12 malaria-carrying mosquitoes.

13 Laboratory data from CDC showed
14 that C8910 was effective against *Anopheles*
15 *gambiae*, the primary vector of malaria in
16 Africa at levels comparable to other
17 insecticides approved by WHO.

18 In summary, all the components of
19 8910 are grass. The only one that can compete
20 with synthetic pyrethroids or OPs. Supporting
21 fly control for livestock producers worldwide.
22 And I think it would enhance organic livestock

1 production if accepted.

2 I would like to spend the rest of
3 my time, there was a report and rebuttal.
4 There was a reference to a report by Davies
5 that said that nonanoic acid is toxic to
6 nematodes. But if you read lines 337 and 339
7 carefully from the independent report it says
8 that the authors did not report whether
9 nonanoic acid may be toxic to beneficial
10 nematode species or earthworms. However, an
11 EC review indicated that nonanoic acid is not
12 toxic to earthworms in short-term toxicity
13 tests.

14 The independent report further
15 goes on to say that when applied to livestock
16 as an insect repellent that the environmental
17 -- because of its rapid biodegradability and
18 low toxicity that it's not likely to be an
19 expected significant contaminant to the
20 environment.

21 MS. FULWIDER: Questions? Jean?

22 MS. RICHARDSON: Thank you. When

1 you have -- when you apply this sort of smelly
2 oil to the livestock, you know, which is part
3 of what it is. It's a nice, oily kind of
4 smelly thing that repels the insects. How
5 often do you have to do it? When I looked at
6 the technical report it seemed like for house
7 flies the effect lasted maybe less than a day
8 and then for other flies maybe 2 to 3 days.

9 So do you have to apply this on a
10 regular basis? And if so, can you give us
11 some idea of the actual amounts you would be
12 applying? Say if you're on a healthy beef
13 farm where you maybe have several hundred beef
14 cattle gathering in a hot sweaty day kind of
15 thing.

16 DR. REIFENRATH: Well first of
17 all, at the doses that we're using say for
18 livestock in the dust form, the use rate for
19 the 8910 dust is the same as the use rate for
20 conventional organophosphate pesticides or
21 permethrin-type pesticides.

22 A 12 and a half pound charge of a

1 dust bag will last for 6 weeks on a herd of 30
2 head of cattle. And that's about the rate of
3 use for the other products.

4 In terms of the -- you call it a
5 smelly oil. It's -- in the dust form at the
6 doses that we're using the odor is not that
7 perceptible. And in the context of your
8 applying it to a range cattle I don't think
9 that in the context of what it's being applied
10 to that the odor is a big issue.

11 For horses and other pets or
12 companion animals we can effectively mask the
13 odor through formulation. So I hope that
14 answers your question.

15 The work that Brad Mullens did at
16 UC Riverside for the oil formulation, a single
17 application would last approximately 2 to 3
18 days. And I think he indicates that in his
19 report to the posting on your website.

20 MS. FULWIDER: Jay?

21 MR. FELDMAN: Thank you. You
22 know, we always have around these types of

1 materials have a debate over whether it's
2 better, what you've created here, what is
3 being produced and petitioned is better than
4 organophosphate or synthetic pyrethroid or
5 something else that's typically used in
6 conventional systems. And no doubt it is and
7 congratulations on moving a product like this
8 into the market.

9 But as you can hear from being
10 here at this meeting the standard that is
11 applied to that product is very different than
12 an IPM standard for instance, or reduced
13 toxicity assessment. And so if you -- I
14 suspect you have looked at the technical
15 review on this product. We're looking at
16 issues around impacts on beneficial nematodes,
17 beneficial organisms under this standard which
18 for instance EPA would not be looking at in
19 the context of its pesticide registration
20 program. And so we have to apply that screen
21 and that criterion to this review.

22 The TRs looked at potential wind

1 drift impacts on blossoms and weeds and
2 concerns over negative impact as I mentioned
3 on nematodes and earthworms. So when you put
4 that additional screen on materials that are
5 allowed in the organic system it becomes much
6 heavier in terms of allowance in that system.

7 So what, you know, I know you've
8 studied these management systems and the
9 conclusion of those that have looked at it in
10 the subcommittee really has been that there
11 are alternative management systems that can
12 adequately control for flies or whatever the
13 endpoint is here. Do you disagree with that?
14 Do you feel that what is available now is
15 ineffective or not productive or something to
16 the effect?

17 DR. REIFENRATH: Well, I would
18 refer to the postings that you've gotten from
19 University of California Riverside, from the
20 University of Nebraska, from the University of
21 Arkansas and from a veterinary company in
22 South Africa that existing IPM for any kind of

1 livestock production is inadequate. That's
2 their opinion. They're veterinary
3 entomologists. I'm a toxicologist.

4 In response to your comments about
5 earthworms and nematodes, you know, we have an
6 old saying in toxicology that the dose is the
7 poison. So when you look at the way the 8910
8 is being applied to an animal it's being
9 sprayed directly on the animal or in the
10 picture that I showed it's being dusted on the
11 back of the animal. So the exposure to the
12 soil is minimal because we're directing it at
13 the animal.

14 And I don't have the data with me
15 but we've done studies to look at radiolabeled
16 fatty acids that are in these type of
17 formulations and applied to soil that the
18 majority of the fatty acids will evaporate
19 from the surface. So the combination of that
20 as well as we're directing it to the animal
21 rather than we're not tilling it into the soil
22 would minimize the environmental exposure.

1 And I think your technical report
2 in its summary basically says that, that
3 environmental contamination is not a
4 significant issue here. So that's your
5 report.

6 MS. FULWIDER: Thank you. Ann,
7 please state your name and affiliation, and we
8 have Susan Czernicka on deck.

9 MS. PETERSON: Hello. I'm Annie
10 Peterson. I'm from Emery Oleochemicals in
11 Cincinnati. The Emery family began making
12 fatty acids in 1860. They were making them
13 for soap and for candles. So they've been
14 there for a long time.

15 I'm here to petition to allow
16 nonanoic acid as a synthetic for livestock
17 control and I'm asking that you take a new
18 look. You know, they're saying well, there's
19 not maybe an organic registration or in
20 Canada. Well, what Bill came up with, I mean
21 he's been working on but you know, any
22 semblance of a registration that we would have

1 to even offer it or present it, it's really
2 only been completed in the last several
3 months. And it's the first step.

4 So I mean, it's new chemistry and
5 it's something that -- it's my job when I go
6 to -- I'll go to try to make people aware of
7 the chemistry because it's soft chemistry,
8 it's natural fatty acids and it's a low-risk
9 chemistry. And you take it into somebody like
10 a major, or like a big company and they say
11 that it doesn't work. They said that can't
12 work. And then they get a sample of it and
13 they say you know, that really works. And
14 they're surprised because they think how can
15 something natural and basic and low-risk work.

16 But the Production Act, okay, OFPA
17 permits certain organic -- or certain
18 chemistries that are synthetic. And nonanoic
19 acid that Bill's been using, it's one
20 component of a blend of fatty acids that are
21 used as a tool to control biting flies, ticks
22 and mosquitoes on livestock. And the base for

1 those, it's sustainable chemistry and it's no
2 residue and it can come from canola, some
3 parts of this can come from coconut, from beef
4 tallow, so it's all naturally sourced. It's
5 not anything that's going to have a
6 petrochemical base.

7 The -- I think one of the points
8 when we're looking at what's the basis is that
9 the material is safe, it's not harmful to
10 human health and that's supported by the DFDA
11 -- considered grass. Generally regarded as
12 safe since 1965. And it's used in very low
13 concentrations so you don't see issues when
14 you're using it because it's in such a small
15 amount.

16 And it's not really, you know,
17 it's not a high-toxicity material. And the
18 fatty acids are naturally occurring. And none
19 of the approved essential oils or pyrethrins
20 that are considered organic are part of the
21 normal diet. The pyrethrins are highly toxic
22 to bees and fish and that's the existing

1 products that are organic.

2 That's not the case for the fatty
3 acids. They're a significant part of daily
4 diets. Some of the fatty acids in the 8910,
5 they're in dietary lipids. They're also
6 present in a variety of plants and fruits.

7 This material is registered, the
8 8910, Bill's product is registered as a
9 biopesticide. And it is IPM-compatible
10 because Integrated Pest Management is an
11 effective, an environmentally sensitive
12 approach that relies on a combination of
13 common sense practices. And that's cultural,
14 biological and can be synthetic means to
15 control all pests while minimizing the public
16 health and environmental risk. This
17 represents good stewardship.

18 We've got the written
19 recommendations that Bill mentioned. Peter
20 Oberem, the South African Animal Health
21 Association, he's a member of that. And it's
22 a huge boost for organic in South Africa. Ed

1 Mullens and David Boxler, John Campbell, they
2 have 90 years experience between all four of
3 those people and they have been working with
4 the 8910 since 1999. And they are saying that
5 there really isn't any -- they are not seeing
6 any damage to the environment. They're saying
7 that it's soft chemistry and that it's
8 effective.

9 And the last thing is cost. But
10 just -- this is a natural material and it's
11 low-risk and it's low-cost. It's less toxic
12 than what's already in some of the materials
13 in the organic program. And I want to ask you
14 to allow this material as a tool.

15 MS. FULWIDER: Thank you. Any
16 questions? Okay. Being the last commenter of
17 the day thank you and we're going to have a
18 quick break. Please, everyone, be back at
19 4:15.

20 (Whereupon, the foregoing matter
21 went off the record at 4:04 p.m. and went back
22 on the record at 4:20 p.m.)

1 CHAIRPERSON FLAMM: Board members,
2 please take your seat. Board members, we're
3 back in business. And I'll ask the
4 chairperson, Wendy, if the Livestock Committee
5 has any proposals ready for voting.

6 MS. FULWIDER: Yes, we would like
7 to vote on nonanoic acid.

8 CHAIRPERSON FLAMM: Do we have a
9 motion on this substance?

10 MS. FULWIDER: Yes.

11 MS. RICHARDSON: Do you wish me to
12 read it?

13 CHAIRPERSON FLAMM: Jean? Jean,
14 are you prepared to make a motion?

15 MS. RICHARDSON: I am prepared to
16 make the motion. The first motion is
17 classification motion, that nonanoic acid CAS-
18 112050 as petitioned is synthetic.

19 CHAIRPERSON FLAMM: Do we have a
20 second?

21 MR. BONDERA: Yes, I second that
22 motion.

1 CHAIRPERSON FLAMM: We have a
2 motion which has been seconded to classify
3 nonanoic acid as synthetic. I believe we're
4 prepared to vote starting with Jennifer
5 Taylor.

6 MS. TAYLOR: Isn't there
7 discussion on motions?

8 CHAIRPERSON FLAMM: We can have
9 discussion on the motion to classify, yes. If
10 you would like to have discussion. Okay. I
11 didn't think there was need for it on the
12 classification, but thank you. So we're
13 prepared to vote on the motion to classify
14 nonanoic acid as synthetic beginning with
15 Jennifer Taylor.

16 MS. TAYLOR: Yes.

17 MR. MARAVELL: Yes.

18 MR. FELDMAN: Yes.

19 MS. SONNABEND: Yes.

20 MR. STONE: Yes, sir.

21 MS. FULWIDER: Yes.

22 MR. AUSTIN: Yes.

1 MS. FAVRE: Yes.

2 MS. BECK: Yes.

3 MR. FOSTER: Yes.

4 MR. DICKSON: Yes.

5 MS. RICHARDSON: Yes.

6 MR. WALKER: Yes.

7 MR. BONDERA: Yes.

8 CHAIRPERSON FLAMM: And the chair
9 votes yes. Do we have a motion to list the
10 material?

11 MS. RICHARDSON: The listing
12 motion is to add nonanoic acid CAS-112050 to
13 Section 205.603 as an insect repellent
14 insecticide.

15 CHAIRPERSON FLAMM: Do we have a
16 second?

17 MR. BONDERA: I'll second that
18 motion.

19 CHAIRPERSON FLAMM: The motion has
20 been seconded. Discussion on the motion.
21 John?

22 MR. FOSTER: I have a pretty good

1 feeling how this will end up going but I feel
2 like I just, I want to say the information
3 about the toxicity relative to beneficial
4 nematodes, or any nematodes for that matter,
5 or earthworms seems still like a maybe to me.
6 And I'm not a huge fan of voting down a
7 material for a maybe, particularly when the
8 use of the material leads me to believe
9 there's minimal contact.

10 And if a material is so ephemeral
11 as to need to be required many times to be
12 effective it can't be that persistent. And it
13 seems to me based on granted a limited amount
14 of time of me working on cattle ranches just
15 the kind of environment would lead me to
16 believe the material would degrade pretty
17 quickly.

18 Another argument I've heard is
19 that not a lot of producers are screaming for
20 the material. And that's marginally
21 compelling to me because if it's not listed a
22 lot of organic producers in organic production

1 environment don't have access to it right now.
2 So a lot of producers wouldn't have the
3 experience, wouldn't have the option of using
4 it. I understand that that's not, you know,
5 that's not a complete -- I understand it's not
6 a perfect rationale but I do know that a lot
7 of materials are useful for a lot of people
8 but not everyone.

9 And it's hard for me to believe
10 that a whole lot of producers are going to be
11 real vocal about a material that they've never
12 had experience with, hands-on experience with,
13 because most of my experience with producers,
14 both livestock and crop producers is that they
15 really don't believe it until they see it with
16 their own eyes.

17 So it makes sense to me that there
18 wouldn't be an outcry for this material just
19 on sheer numbers? Most people haven't
20 experienced it. Most organic producers don't
21 have experience with it. So I'm reluctant to
22 say because there's no outcry it's not a good

1 enough reason to try it.

2 It does sound to me that there is
3 pretty good evidence that this is a preferable
4 material to other things in current use.
5 That's pretty compelling to me. And I'll
6 leave it there.

7 CHAIRPERSON FLAMM: Any other
8 discussion? Zea, do you have a point you
9 wanted to make?

10 MR. FELDMAN: I raised my hand.
11 Just to respond, I mean I think as I said, you
12 know, the fatty acids are used extensively in
13 IPM systems and I understand all that. Again,
14 I feel we have a higher burden to establish
15 need and essentiality which doesn't, you know,
16 I just -- unless someone can show me something
17 I missed here in the comments I just don't see
18 that need established. And -- except from the
19 purveyor of the material which is fine. But
20 I think we have a statutory duty to establish
21 that need before we introduce a synthetic into
22 the organic system.

1 And that hasn't -- you know, I
2 don't think we've done that. We may be able
3 to do that in the future but we haven't done
4 it to date. So, on that count I would say
5 that we should vote this down and seek out
6 more information on need and also alternatives
7 as well.

8 And to the issue of establishing
9 hazard, you know, especially under the OFPA
10 standard you know when we talk about an
11 insignificant impact on beneficial organisms
12 in a situation where there is some non-target
13 exposure and there's an admission that there
14 is some. Whether it's deemed significant or
15 not is always going to be the issue of course.
16 But again, when you take that factor into
17 account with the lack of established
18 essentiality or need for a synthetic under
19 OFPA I don't think we have much of a choice at
20 this time. There may be better data that
21 comes along in the future.

22 CHAIRPERSON FLAMM: Any other

1 comments? John, do you want to have a follow-
2 up?

3 MR. FOSTER: The -- in terms of
4 alternatives I think the regulation covers
5 alternatives really well actually in 206.
6 This material or any chemical control wouldn't
7 be in play unless everything else in 206 ahead
8 of it were covered and found to be wanting.
9 So I agree, there are other alternative
10 management practices. The whole context --
11 we've talked about this at least for 2 and a
12 half years -- is that these materials, pest
13 control materials shouldn't come into play
14 unless those alternatives have been exhausted.

15 That's why there is this, the only
16 codification of mandated IPM I can find is
17 here, is right there in the regulation,
18 206(a)(b)(c). It's not till you get down to
19 (e) that you're even allowed to try this
20 stuff. So yes, there are alternatives, but in
21 the context of the whole it's not just a
22 matter of this material, it's that these other

1 things are found wanting.

2 So I want to make sure everyone's
3 clear. I'm not saying there's no alternative.
4 There are. Many of them are listed in the
5 regulation and my expectation would be that
6 those are demonstrated to be ineffective, or
7 at least ineffective here and there.

8 And the here and there is the part
9 where I get a little itchy assuming that
10 people who haven't had the opportunity to try
11 it because it isn't listed are somehow
12 expected to clamor for it. That's just not
13 the nature of producers that I know. Maybe
14 there's -- I'm sure there's other growers and
15 other livestock raisers that do things
16 differently. But my experience is that until
17 they see it used very few are going to start
18 pounding on the table for it to demonstrate
19 that need. I think it's something of a catch-
20 22 there. Not a perfect one, but one I have
21 experience with. So that's all I have to say
22 about that.

1 CHAIRPERSON FLAMM: Any other
2 board comments? If not we can begin the
3 voting on the petition to add nonanoic acid
4 CAS-112050 to 205.603 as an insect repellent,
5 as an insecticide. And we'll begin voting
6 with Nick.

7 MR. MARAVELL: No.

8 MR. FELDMAN: No.

9 MS. SONNABEND: No.

10 MR. STONE: No, sir.

11 MS. FULWIDER: No.

12 MR. AUSTIN: No.

13 MS. FAVRE: No.

14 MS. BECK: No.

15 MR. FOSTER: Yes.

16 MR. DICKSON: No.

17 MS. RICHARDSON: No.

18 MR. WALKER: No.

19 MR. BONDERA: No.

20 CHAIRPERSON FLAMM: And the chair
21 votes no. Oh, I'm sorry.

22 MS. TAYLOR: No.

1 CHAIRPERSON FLAMM: I did it
2 again. Sorry. I owe you. Jennifer, you
3 voted no? And the chair votes no.

4 MS. TAYLOR: Thank you.

5 CHAIRPERSON FLAMM: The vote is 1
6 yes, 14 nos, the petition failed. I believe
7 that concludes the business for today and
8 remarkably we've finished a little bit early.
9 Unless, Michelle, you have something to call
10 to my attention we'll be in recess until 8
11 o'clock tomorrow morning. Have a good
12 evening, everyone.

13 (Whereupon, the foregoing matter
14 went off the record at 4:34 p.m.)

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AAFCO 41:11	74:4 122:10 132:5	290:10 292:4,8	176:18 202:16	253:3
220:6 281:16	159:16,18,21	299:16,18 300:12	212:6 220:18	administrative
283:18 286:22	284:6 290:9 309:1	301:8,20 302:18	268:1 291:7	112:18 113:2
289:17 291:8	accessible 38:18	303:3,4 310:12	adding 93:18	Administrator 2:8
AAP 200:19	239:6	acknowledge 51:8	195:13,15 196:4	2:22 3:6 12:6,22
abandon 85:19	accessory 219:13	90:2 145:18	202:19 237:21	17:18 50:12
113:6	278:10 280:2	251:20	267:3	admission 311:13
abandonment	accident 255:17	acquire 274:1	addition 46:16	admit 175:6
74:21	accommodation	acquiring 25:14	93:12 120:18	adopt 149:1
ability 52:5 94:10	151:21	acreage 245:5	198:12 199:22	adopted 85:19
225:8 226:12	accomplish 171:22	acres 118:19 133:6	213:11 214:12,21	adoption 85:22
290:10	accomplished	150:18 181:15	233:20 248:8	adult 281:6,7
able 58:11 59:10	23:20	190:18 244:22	250:11,16	advance 211:14
60:2 62:22 63:4,9	accomplishment	act 21:21 31:9 36:4	additional 27:9	217:7
75:22 76:19 93:3	58:3	50:11 71:7,19	40:10 42:4,6	advantage 15:17
187:10 272:8	account 60:3	73:11 82:16	44:13 139:1 143:3	206:9 230:2
287:4 288:15	311:17	301:16	161:8 163:16	advantages 187:2
311:2	accountability	action 29:20 43:17	164:1 171:1 172:3	230:15
absence 239:4	97:11,12	74:11 113:1	172:10 179:12	adverse 44:19 45:3
257:21 258:1	accountable 98:2	114:18 128:9	203:20 237:8	162:7,13
absolute 176:17	accounted 254:11	237:16 246:2,6	243:9 298:4	advertise 163:6
absolutely 92:9	accreditation 9:14	253:9	additive 152:15	advice 13:16 18:18
108:11 109:14	10:1,10 22:11,15	actions 36:8 37:4	153:7 154:18	98:10
120:3 129:20	25:3,5 30:22 31:5	39:19 85:13 95:18	additives 166:5	advisor 2:20 3:8
290:14	36:10 70:1 117:10	246:17,18	292:13	17:21 56:18
absorbed 128:8	120:11,17	activates 154:19	address 34:18 75:8	135:11
absorbing 252:7	Accredited 169:19	active 29:10 36:20	115:11 117:19	advisory 2:10 13:3
abstract 154:14	accustomed 103:9	184:4,4 231:11,15	118:11 144:10	38:1 78:1,2 96:14
abuses 77:19	achieved 181:10	actively 24:11	145:7,10 171:9	97:1 135:12 146:9
ACA 165:15	acid 3:14,14 210:13	activities 13:21	200:20 206:19,22	advocacy 163:3
167:10,12 168:2	210:16,19 211:8	21:17 243:15	207:1 211:11	265:3
169:19 170:9	211:20,22 212:4	244:2	223:6,12 274:19	advocate 130:15
171:18 172:15	212:10 214:7	activity 68:7	278:19	156:4 289:12
academic 153:13	215:17 241:20,22	acts 83:10 289:6	addressed 37:2,5	advocated 163:4
Academy 200:7	268:3 292:1 294:5	actual 57:15 60:3	39:8 79:11 119:2	advocates 87:13
ACAs 170:16 171:5	294:9,11 300:16	63:11 295:11	207:11	advocating 165:6
171:12 172:11	301:19 305:7,17	Ad 10:18 11:6	addresses 34:16	advocation 11:20
accelerated 244:19	306:3,14 307:12	adapted 26:14	addressing 79:6	ad-libbing 183:19
accept 259:9	314:3	add 43:12 55:22	173:14 221:20	affect 79:9
acceptable 104:18	acidifier 289:6	79:12,14 164:11	adequate 179:18	affiliation 125:6
107:18	acids 3:14 107:20	203:16 212:3	264:10	134:9 146:19
accepted 17:13	197:22 216:11,15	213:14 214:15	adequately 298:12	151:4 156:1
86:7 152:7 153:7	216:16,22 217:15	228:16 241:4	adjustment 274:2	160:11 164:21
154:11 294:1	218:2 219:7,12	307:12 314:3	administered	174:11,13 180:21
access 38:14 42:5	220:12,18 221:13	added 43:7 44:11	104:17 105:9	191:9 195:8 204:4
64:19 73:19 74:3	221:18 225:22	107:22 120:10	administration	243:2 247:11
	227:3 289:4	161:22 162:14,17	47:21 48:3 232:15	253:19 276:20

286:10 291:19 300:7 afford 99:15 100:20 affordable 38:17 afraid 127:16 Africa 292:15 293:16 298:22 303:22 African 303:20 afternoon 204:5 247:13 253:21 Ag 54:15 125:19 age 249:1 258:22 264:17 agencies 48:21 49:4 53:14,20 57:1 63:13 66:8 106:22 236:15 agency 53:10 57:3 59:17 87:13 174:3 182:18 191:22 192:9 agenda 4:20,21,22 5:1 164:15 179:16 210:15 agent 35:11 235:5 agents 22:16 34:12 187:20 235:15 aggressive 89:5 244:20 aggressively 77:18 ago 23:7 49:15 103:12 106:9 112:1 118:17 123:4 126:16 151:9 175:21 177:18 184:7 193:12 245:19 246:7 270:1 agree 92:9 108:11 268:15,20 312:9 agreement 183:4 194:11 agreements 35:20 36:1 agricultural 2:16	43:1 46:4 59:14 150:7 167:7,8 173:16 181:21 208:2 agriculturally 271:11 agriculture 1:1,1 2:20 3:8 13:18 17:21 28:8,21 29:2 44:8 48:22 50:12 51:2 55:3 55:12 56:5 59:7 87:11 157:10 170:1 177:5 178:11 205:12 250:7 278:1 AgriStrip 99:18 agro-ecosystem 213:6 agro-ecosystems 136:14 ahead 50:17 68:20 69:8 175:19 184:20 186:16 190:4 202:22 207:19 215:1 238:1 242:9,17 312:7 aids 46:18 98:1 aim 152:17 Albans 125:9 albeit 52:7 Albuquerque 17:15 85:16 98:4 100:11,16 234:11 Alexis 195:10 199:1,2,3 201:7 203:22 268:20 algal 163:13 align 148:6 aligned 36:11 alive 163:19 Allan-Foster 106:5 106:6,13 110:7,16 111:6 allegation 71:9 allegations 71:15	alleged 244:4 Allen 71:5 allergies 287:19 allergy 291:13,15 Alliance 115:21 119:19 121:18 163:2 Alliance's 138:17 allocated 58:20 88:10 259:6 allow 90:1 102:18 113:10,13 114:1 194:15,16,21 197:17 198:16 209:12 211:5 220:3 226:6 235:14 262:10 266:15 268:16 300:15 304:14 allowance 103:17 109:11 135:20 149:8 298:6 allowances 115:6 allowed 39:7 53:3 73:3 101:15,18,20 102:3 103:1 105:6 105:6,9 107:16 109:3,15 148:5,12 149:15 165:8 166:3 175:13 179:21 180:1 183:3,5 192:16 194:5,6,22 195:19 198:4 202:14 204:17 205:10 208:2,7 219:1 224:10 226:1 232:19 235:7 268:8 282:3 298:5 312:19 allowing 85:1 107:13 109:7 135:2 194:20 196:15,19 251:12 266:19 allows 89:9 114:14 137:5 187:4	alluded 240:15 all-stage 287:4 alternate 211:7 269:13 292:12 alternative 33:19 75:2 87:11,17 88:19 91:9 107:16 129:9 164:14 213:10 225:19 252:2,2 259:12 265:8 284:10 298:11 312:9 313:3 alternatives 44:5 85:2 90:13 138:1 149:14 150:11 164:13 166:15 224:16 225:4 257:22 263:18 311:6 312:4,5,14 312:20 amazed 52:14 amazing 20:22 21:6 47:10 277:20 ambivalent 227:5 amendment 216:20 amendments 39:6 America 107:1 125:1 American 36:14 153:14 200:7 amino 3:14 107:20 197:22 216:10,15 216:16,21 217:15 218:2 219:7,12 220:12,18 221:13 221:17 225:22 227:3 289:4 290:10 ammonium 204:9 amorphous 88:16 amount 25:11 133:6 139:13 176:18 188:22 205:6 226:3 258:12 270:17 302:15 308:13	amounts 109:4 153:21 221:17 295:11 amplification 273:16 AMS 1:1 34:9 analogous 91:22 analogue 92:14 analysis 71:12 analyst 71:7 134:12 Andrew 155:6 and/or 147:18 177:16 animal 8:6 127:3 127:15 128:7 130:21 137:6,10 137:12 138:3 152:16 153:9 154:19 247:3 255:10 299:8,9,11 299:13,20 303:20 animals 126:11,12 127:1 128:15 130:2 131:22 133:5,5,12,20 137:15 153:18 220:14 265:7 286:18 289:13 290:3 292:9 296:12 Ann 115:20 119:18 119:20,21 121:13 121:13 291:20 300:6 Annie 300:9 annihilate 118:4 anniversary 20:17 50:16 68:2,12 106:18 annotation 110:8 110:18 136:22 150:12 185:2,7 227:7 232:22 275:6 annotations 90:9 148:8 166:17 announce 19:22
--	--	--	---	---

70:16 242:16	appeals 23:2	61:9	298:21	195:11 220:7
announced 85:16	appear 212:21	approval 17:10	armed 130:10	268:21 277:2
194:10	appearing 111:12	80:16 89:11	arms 87:22	303:21
announcement	applaud 52:1	149:16 155:13	arose 85:15	assume 156:21
242:12	Applause 13:10	approve 4:19 17:8	arrangements	202:10,11 203:18
announcements	48:9 69:15 106:12	92:12 161:20	22:20	275:2
5:3,13	apple 7:12	268:3	array 222:12	assumed 182:22
annoying 13:3	apples 8:12 212:12	approved 4:22	280:20	assuming 275:2
annual 34:19 35:18	applicable 45:4	74:17 83:14 93:6	ARS 273:4,4	313:9
123:3 188:21	46:12 83:12 111:1	110:22 126:15	Arsenault 2:10	assurance 249:13
annuals 189:19	149:15	158:11 164:2	5:14 13:1,2 70:19	274:22
Annville 247:16	application 293:7	176:9 194:4	155:20	assure 15:4
Anopheles 293:14	296:17	201:22 204:18	article 118:18	assured 158:9
ANSI/NSF 113:9	applied 292:17	207:21 268:11	206:4	assuring 138:19
answer 16:12 62:22	294:15 296:9	293:17 302:19	artificial 286:16	ASTM 136:6 142:3
69:19 94:5 131:3	297:11 299:8,17	approving 198:6	artists 245:3	142:13
131:4 132:9	apply 274:1 295:1	199:6	ascertain 136:15	Atlantic 28:1
141:18 167:21	295:9 297:20	approximately	ascertained 100:12	attached 82:20
195:3 272:1,4	applying 149:11	4:15 258:4 262:16	ascorbyl 161:5	attacks 289:1
289:16	295:12 296:8	296:17	Ashley 262:2,5	attain 137:6
answered 152:4	appointed 10:15	April 210:17	asked 15:19 125:13	attainable 38:18
answers 123:6	52:4	aquaculture 24:13	141:4 179:3 183:7	attempts 164:11
240:13 296:14	appreciate 53:7	40:5,9 91:13	193:1 239:9 252:9	177:6
antibiotics 90:17	82:3,17 96:5	139:2	262:9 263:16	attended 14:5
101:14 105:6,17	98:11 122:19	aquatic 86:15	asking 74:17 81:11	204:7
139:3 163:19	134:7 143:19	ARA 161:15,18	88:5,15 102:6	attending 50:15
anybody 15:17	145:7 149:10	162:6,8,14,15,17	114:17 163:22	100:9
21:3 49:18 74:14	160:8 169:7 175:4	163:4	164:4 167:15	attention 69:1
133:8 288:12	241:6 265:4 290:4	arbiter 135:5	215:22 251:21	165:22 268:5
anybody's 283:21	290:5	area 34:3 38:21	267:10 300:17	315:10
anymore 20:10	appreciated 87:5	57:18,21 67:18	aspect 221:9 265:6	attest 175:16
anyway 14:11 18:8	appreciates 111:22	112:22 120:8	aspects 23:10 49:1	attorney 111:12
190:16,21 224:4	appreciative 18:1	157:6 167:22	63:1 66:15 67:14	ATTRA 270:2
253:13	approach 143:11	186:3 189:19	213:4 214:11	attracted 265:14
APHIS 46:22 49:4	148:7 149:14	areas 9:17 38:8	assess 170:21	audacious 54:3
231:13 235:14	177:22 229:16	39:1 41:22 43:19	assessment 297:13	audience 5:9 16:3
236:13 239:22	230:7 303:12	46:14 75:19 92:10	assessments 36:1	50:22 69:5 79:22
241:10	appropriate 51:6	93:3 117:15 121:8	assist 121:22 248:9	135:5 211:16
apiculture 267:12	67:20 93:10	139:2 140:15	assisting 65:16	217:19 221:19
273:2	138:20 149:21	167:14 232:8	248:6	232:5 237:11
apologize 18:2 20:3	203:16 220:3	237:1 240:13	Associate 2:21	audit 30:20 34:17
108:9	227:2 229:3	arena 54:17	12:21	36:21 37:3,9 42:1
apparent 145:20	appropriated	argument 142:1	Associates 9:5	243:20
202:4 222:6	58:21	279:22 308:18	146:22	auditor 78:6
apparently 179:1	appropriateness	arguments 285:22	association 55:16	audits 25:2,4,6
appeal 80:11	135:8	arises 159:8	153:14 157:12	30:18,21 35:2,11
appealing 48:12	Appropriations	Arkansas 262:6	163:3 169:19	35:15 39:10 42:7

August 7:12	a.m 1:10 4:2 70:12 70:13 169:11 247:19	123:20 200:9 221:18	314:14	214:9 215:6 216:1 216:5 229:9 294:9 297:16,17 308:3 311:11
Aurora 245:14,18		balanced 41:14 90:5 220:19 221:5 221:15 279:10 281:18 282:2	becoming 123:18	
Austin 1:15 8:8,9 207:20 208:22 306:22 314:12	B	Baltimore 248:15	Bedrosian 151:5,6 155:17	benefit 29:1 84:13 123:16,17 162:20 162:22 293:11
author 291:22	B 172:19	balances 163:17	beef 7:19 76:21 132:1,14,17 133:11 174:16 290:22 295:12,13 302:3	benefits 181:22 182:14 205:17 224:12 287:20
authored 154:14	babies 196:10,12	banker 58:8	beep 6:5	best 11:9 98:18 99:10 134:4 144:16 151:10 267:5 284:22
authority 61:13 78:1,12,19 83:11 112:21 243:19	back 68:2,11 70:12 77:2,3,5 104:12 131:15 169:9,12 175:6 191:14 193:21 204:8,12 206:10 221:12 224:10 240:21 241:15 242:4,6,9 244:10 251:17 275:19 276:16 283:7 286:17 288:8 291:4,5 292:11 299:11 304:18,21 305:3	banned 244:13	bees 302:22	bet 94:22
authorized 22:16 46:10	backward 178:1,3	bar 111:17	beetles 253:10	betacarotene 161:6
authors 152:20 294:8	background 108:6 156:19 179:4 218:6 232:3 237:12	barrier 58:10	began 231:12 300:11	better 22:5 39:18 45:16 58:6 62:22 84:4 90:7 92:20 119:12 130:20,21 133:9 146:8 214:3 297:2,3 311:20
availability 228:2 262:13 283:8	back-pedal 143:12	Barry 1:12,14 3:2 11:10 17:6 47:8 47:10 48:2,5,8,13 69:16 119:22 210:11 242:18	beginning 14:6 57:14 81:13 145:1 306:14	beyond 7:3 82:12 147:17
available 17:8 30:10 44:6 57:17 58:4 64:14 65:2 88:10 100:4 129:10 137:19 176:12 184:22 196:19 201:1,3 203:14 211:3 213:11 219:7,9 221:14 255:19 263:15 264:3,10 269:16 273:18 283:9 291:1 298:14	bacteria 100:19 117:2 128:12 254:20 255:18,21 260:22 261:3,5,16 284:14	base 165:3 301:22 302:6	Behar 264:20,20 269:22 270:10 271:2,10,17,22 272:18 273:9 274:5 275:8	behavior 266:7
average 33:9,10 249:1 259:3,4,10	bacterial 284:17	based 9:5 43:9 71:17 72:1 84:3 86:10 124:6 147:7 148:17 149:4 170:18 172:21 178:6 188:10,16 308:13	behavior 266:7	Bhattacharya 152:20
avoid 39:2 151:15 155:8	bacteriophage 255:20 256:5	baseline 58:6 172:16	belief 96:20	biased 71:10,16
Award 181:14 193:11	bad 89:6,13 90:18	basic 29:3 62:7 152:3 157:2 158:13 301:15	beliefs 175:14	bid 76:19
aware 123:20 130:17 144:21 182:12 301:6	Baden-Mayer 195:9,10 199:9 201:2,11 203:6 204:1	basically 63:15 133:10 223:15,21 227:4 276:12 289:12 300:2	believable 155:1	big 58:3 130:15 202:18 206:6 207:11 240:20 296:10 301:10
awareness 151:15 207:7	badly 78:6	basis 27:12 28:10 112:21 195:17 266:12 295:10 302:8	believe 5:3 54:6 70:14 72:7,8 83:1 86:3 90:8 93:14 95:8 107:15 108:18 109:14 114:21 135:16 140:2 147:16 150:17 170:12,19 172:1,20 173:5,15 179:14 201:2,15 206:21 211:16 217:19 256:20 265:9,13 266:13 287:7 306:3 308:8 308:16 309:9,15 315:6	bigger 49:18
Awesome 159:22	bag 224:6 227:12 296:1	Baumgartner 115:20,21 120:9	believes 171:18	biggest 245:16
awhile 18:6 20:9 278:6	Bailey 2:12 12:13 12:14 231:8 241:5	beans 99:11	beneficial 164:3	Bill 56:15 57:10 58:21 61:1,5,9,12 98:17 103:3,3,4 104:8,12 106:4 291:21 300:20 303:19
AXXE 204:15	balance 76:3	bear 58:18 174:21		billion 90:10 250:20
A&M 6:14		beautiful 11:18 289:22		Billy 104:13
A-G-E-N-D-A 3:1		Beck 1:15 9:2,3 189:8 307:2		Bill's 301:19 303:8
				Biltmore 1:10
				bio 84:2
				Biochemistry

152:13	119:16 252:18	77:22 78:4,5,7	bottom 127:14	broad 107:8 154:6
biodegradability	258:8,14	81:10,15 84:11	131:9	261:16
294:17	birds 74:1,13 76:16	85:4,19,20 86:5	bought 205:18	broader 85:1 243:7
biodegradable 84:2	76:17 252:15,17	86:10,12,17 87:19	bounty 245:9	broad-based
109:1,2,5,8	257:12 258:2,19	91:17 92:9 96:12	box 127:14	120:20 227:10
134:16 135:21	259:5,17 260:10	97:1,4 98:17	Boxler 304:1	brochure 65:2
147:3 150:10	birthday 251:14	106:10 112:5	Brad 296:15	broiler 260:21
158:20 182:13	277:10	113:20 115:5	Bradie 155:20	261:7
183:2 187:3	birthed 51:17	121:12 122:20	156:2 159:12,12	broilers 101:3,21
188:11 192:4,8	Bison 277:2	125:4,14 126:3,15	160:4	102:4 104:3
274:17	bit 24:19 47:6 57:9	130:19 135:9	brand 40:12	260:15 261:11
biodegradation	58:16 62:3 75:13	139:7 141:4 146:2	111:16 114:3,13	broke 185:19
136:4,8,16 140:16	87:6 144:14	146:3 152:2	115:3 226:14,16	Bronner's 111:13
142:14	237:12 242:10	155:12,15 157:17	263:5 281:15	111:15,22 112:18
biodiverse 48:11	271:7 277:11	158:4,19 159:9,12	brands 262:22	114:17
biodiversity 31:2	315:8	160:4 161:19	break 70:8 169:8	brothers 149:2
109:18,20 116:1,4	biting 301:21	164:17 168:11	186:1 241:15	brought 247:3
116:7,10,12,22	BJE 98:17 100:12	169:17 171:14	242:2 304:18	brown 259:17
117:11,16,19	blank 62:21	172:4 174:8 175:3	breakdown 43:18	Brown-Rosen 2:16
118:5,8,9 121:6	blanket 89:10	175:5,16 176:7,9	45:2 86:14	12:17,18 21:1
134:17 136:20	blend 301:20	178:20 179:9,22	breaking 186:6	budget 88:9
138:4,8,12 169:22	Bliss 131:6,13	180:6,16 184:20	192:18	bugs 271:4
170:9,11,17,20	bloating 162:3,11	190:4 199:1	breast 84:19 149:3	build 128:10
171:2,4,6,15	bloodstream 131:8	200:12,14,16	163:8,11,14,15,19	261:13,14 278:14
biofilm 110:9	blossom 212:15	203:21 205:19	164:12 196:8,11	278:17 285:1
275:16	214:14	207:8,17 210:2	196:12	290:11
Bioimmune 101:2	blossoms 298:1	213:16 219:16	breast-feeding	building 16:18
biological 138:19	blueberries 8:13	222:21 231:17	148:21 163:2	73:19 76:16 124:7
165:16 168:1,3,18	209:7	237:16 242:14	breed 280:14	124:8,9,9
303:14	board 1:5,10 2:10	249:1 259:2	Brennan 253:20	buildings 73:22
biologically 184:4	3:22 4:6,21 5:7	273:19 275:1	262:1	118:14
biologics 232:16,21	6:10,17 7:1,11,15	283:13 305:1,2	Brennan's 262:2	built 74:20 262:21
biology 186:5	9:12,21,22 10:15	314:2	brief 42:9 49:22	bulk 40:16
biopesticide 303:9	11:11 13:4,6,13	boards 96:14,15	107:7 175:17	bunch 30:19
bioplastic 84:3	13:14 14:4 15:3,9	board's 18:11	briefly 13:15 15:9	bunches 260:16
136:1,11,18 140:1	15:9,13,20 17:2	112:1 178:9	59:11 60:22 66:1	bundled 64:20
141:21 158:20	17:16 18:19,21,22	body 131:14	112:4 144:10	Bunin 139:10
274:18	19:3,9,11,12,17	135:12 146:10	185:4 218:22	145:11
bioplastics 136:6	20:18,19,21 21:2	Bondera 1:16	bright 9:9	burden 30:7
139:10	21:4 22:13 23:4,6	10:20,22 79:3	Brines 2:14 12:9,10	108:20 110:14
BioSafe 204:7	30:6,12 37:11,19	95:13 143:18	210:12,14 216:12	123:5 310:14
biosecurity 126:4	38:3 41:1 42:14	215:19 305:21	bring 73:3 81:8,10	burdensome 110:1
BioTelo 182:12,16	43:5,11,15 44:9	307:7,17 314:19	142:18 225:10	burner 115:10
183:5,8,9,16	47:8,20 49:9	bones 284:16	282:21	business 14:22 58:5
193:2	50:15 68:6,19	boost 303:22	bringing 84:11	65:7 73:7 76:6,20
bio-based 135:21	69:3,17,20 70:4,6	border 243:14	246:1	118:6 147:1 150:7
bird 73:22 104:5	71:13 75:6 77:21	Boston 248:14	brings 56:21 97:10	206:6,7,8 244:10

businesses 29:7 56:10 66:20	called 30:9 80:15 255:20	carrageenan 80:8,9 80:12 81:4 152:5 152:10,15,19 153:8,17,22 154:12,18 155:4,8 155:10	133:2 292:18 293:10 295:14 296:2,8 308:14	60:16 62:17 106:15,22 108:14 108:14 138:10 174:3 181:10 183:1,8,10,14 192:16 194:10 243:22 244:17 274:21
butoxin 292:22	calling 9:15 33:2 208:9 242:8	carrageenan's 155:13	cause 48:6	certified 7:12,19,21 11:22 22:17 28:14 29:12,15 32:22 35:17 38:17 42:8 52:14 54:2 56:9 59:14,15 60:13 77:8 81:9 99:7 107:1 111:18,20 114:13 122:1 132:16 137:18 150:2 156:9 168:5 181:11 188:10 192:1,8 199:18 200:22 220:21 246:15 248:4 262:17 266:5 269:21 270:21 271:20 272:8 280:22 281:4 282:5,15
buy 176:14 193:6 203:7,12 263:4	calls 54:1 56:8 135:13 205:6 231:14	carry 164:6 166:7 166:17	caused 85:18 100:22	causing 197:22
buying 77:12 197:5 263:1	calves 132:21,22	carrageenan's 155:13	causes 152:5,15,19 153:8 154:12 263:10	caution 268:5 274:11
byproduct 73:1	Calvin 1:22 10:14 75:8,13 76:11 223:4 228:14,15 257:16	carried 237:19	CCOF 106:15 109:1	celebrate 20:13 52:8 53:18
byproducts 107:14 137:12 220:4 224:1,9,17 226:7 227:13,21 262:11 262:20 263:6 265:10,16,21 266:1 286:16,22 288:10,11	Canada 54:10 107:2 124:22 183:4 194:5,6,20 213:1 244:12 300:20	carrier 253:8	CDC 254:8 293:13	celebrating 47:4 68:11 106:18
byzantine 284:3	Campbell 304:1	carry 164:6 166:7 166:17	cease 30:1	celebration 49:22
<hr/>	Canadian 243:14 243:15	carrying 83:2	celebrate 20:13 52:8 53:18	cell 5:5,8 128:11 256:6
C	Canada 54:10 107:2 124:22 183:4 194:5,6,20 213:1 244:12 300:20	Carter 47:21 264:19 276:22 277:1 281:21 282:12 283:20 285:16 286:5	centered 262:22	cells 154:21 261:5
C 90:20	Canadians 243:14 243:15	CAS 305:17	Center 134:12 153:4,21	Census 60:13
cab 267:20	Canadian 243:14 243:15	case 6:7 32:16 66:14 112:20 132:1 134:2 174:12 204:21 245:13 269:14 303:2	centered 262:22	cent 245:20
cabinets 129:15	cancellations 169:5	cases 62:10,11 177:19 209:7	centered 262:22	Center 134:12 153:4,21
CAC 8:14	cancer 149:3	Castel 70:20 71:4,5 75:12,18 79:13 82:5	central 189:5	centered 262:22
CACC 10:16 11:13	candles 300:13	CAS-112050 212:1 307:12 314:4	certain 46:9 177:7 205:10 261:6 301:17,17	centered 262:22
CACS 107:6 109:17	canola 302:2	cat 222:9	cell 5:5,8 128:11 256:6	centered 262:22
CAFO 76:15	canvassed 127:9	catalogue 55:6	cells 154:21 261:5	centered 262:22
CAFOs 73:2 74:10	cap 252:13	catch 313:19	Census 60:13	centered 262:22
CAFO-type 137:8	capable 261:2	categories 280:2	cent 245:20	centered 262:22
cake 50:6	capacity 78:2	category 33:4 89:12 267:6 277:13,15 279:20 280:8 282:7	Center 134:12 153:4,21	centered 262:22
calculate 102:7,13	card 244:16	cats 219:22 280:8 280:11,12 281:8 288:22 289:5	Center 134:12 153:4,21	centered 262:22
calculating 102:12 170:1 171:17	cardiomyopathy 289:1	cattle 73:3,14 130:9	Center 134:12 153:4,21	centered 262:22
calculation 165:17 167:9,18 172:7	care 8:6 14:9,13 51:13 111:21 112:3,8 113:1,10 113:11 114:19 126:14 128:9 129:17 248:8,18		Center 134:12 153:4,21	centered 262:22
calculations 171:19	careful 92:10 178:5		Center 134:12 153:4,21	centered 262:22
California 7:10 9:6 106:16 111:14 163:3 246:20 298:19	carefully 158:11 294:7		Center 134:12 153:4,21	centered 262:22
call 3:2 22:2 59:22 61:10 64:21 66:10 99:17 104:11 220:18 221:15 233:7 257:7,8 274:18 296:4 315:9	cares 99:15 250:22		Center 134:12 153:4,21	centered 262:22
	Carmela 1:15 9:3 189:6		Center 134:12 153:4,21	centered 262:22
	Carol 151:6 155:15 155:16,19		Center 134:12 153:4,21	centered 262:22

34:12 35:11	195:6 198:22	304:7	citing 83:11	313:3
182:18 191:22	201:6 202:21	cherries 8:12	citizen 151:18	clearance 31:22
235:15 236:15	203:20 204:2	cherry 11:22	156:4 160:20	32:2 40:18
cetera 6:22 132:6	207:13,17 208:20	Chicago 154:4,10	citizens 89:2,18,19	clearer 165:5 168:7
177:2 237:3 239:7	210:1,5,9 305:1,4	Chicago's 152:22	civil 23:2 33:16	clearly 234:13
281:9	305:8,13,19 306:1	154:16	claim 21:3 113:7,11	267:3 280:7,8
Ceva 101:2	306:8 307:8,15,19	chicken 257:12	114:20 199:15	clears 128:7
CFS 134:18 135:1	310:7 311:22	280:21 281:1	claimed 60:15	client 147:6 165:3
135:13,20 136:21	314:1,20 315:1,5	282:14,15 283:1	claiming 282:9	clients 109:13
138:4,13 141:3	challenge 27:17	290:22	claims 32:21 89:16	110:2 126:19
143:8 144:2,21	47:2 141:7 253:2	chickens 73:18	112:9 114:12	133:13 147:1,9
CFS's 143:19	challenges 49:20	101:19 223:19	115:1,2 239:3	168:8
chain 212:10 220:2	247:5	246:22 258:3	clamor 313:12	client/patient 130:1
chair 7:3 8:14 9:12	challenging 26:22	263:14 264:7	clarification 13:17	climatic 140:15
9:22 10:17 11:4	chance 15:10 16:11	chief 80:14 154:15	45:17 105:11	close 96:9 272:9
11:11 15:14 56:20	16:12 17:1 47:10	child 164:10	clarifications 138:9	closed 32:7,9,12
70:21 95:19 307:8	229:6	children 92:20	clarified 101:9	37:2
314:20 315:3	chances 279:7	122:2 160:15	255:8	closely 15:12 61:19
chairman 71:5	change 48:3 88:20	Childrens 160:16	clarify 114:19	237:13
75:4 82:6 98:17	103:14 132:7	Chilean 268:6	140:17 209:1	closing 33:11
111:11 115:12	151:7,13 163:18	China 260:3	281:20	closure 32:16 33:9
249:12	178:21 227:1	chip 156:15	clarifying 115:1	Coalition 80:2 87:1
chairperson 1:12	238:8 266:15	choice 128:7	clarity 237:1 267:7	96:1
1:14 3:2 4:3 6:9	changed 55:4 113:5	148:22 311:19	275:9	coaster 277:20
11:10 13:5,11	124:11	choices 198:14	class 174:17 246:1	coauthored 228:14
17:12 69:2,9,21	changes 4:20 17:11	choose 149:6 186:9	246:6 274:17	coconut 302:3
70:14 75:5 78:22	17:13 39:3	271:19	classification 31:18	code 283:22
81:19 82:7 86:17	changing 264:16	chose 183:9 197:16	31:21 40:16 84:14	Codex 150:13
91:16 95:11 98:9	channels 114:8	245:18	85:18,21 86:3	codification 312:16
98:13 103:2 104:7	characterization	Chris 260:2	167:5 173:2	Cody 8:1
104:11 106:3	89:15	Christopher	305:17 306:12	coffee 48:11,14
110:5 111:4,7	charge 192:4	242:21 247:10,14	classified 167:6	cognition 162:20
115:13,17 119:17	295:22	chromosome 257:7	classify 306:2,9,13	COI 81:21 83:7,9
121:11 125:3	charged 72:6	257:9	classifying 286:6	134:21 135:2,5,14
129:5 130:12	charging 246:2	chromosomes	clause 272:14	135:16,18
131:18 134:6	cheap 72:9 245:3	256:3	clean 128:16,21	Colehour 1:16
139:6 140:19	check 10:14	Cincinnati 300:11	164:9	10:22 79:1,14
143:16 146:14,17	checklist 117:10	circulate 140:17,22	cleansing 112:12	95:12 143:17
151:1 155:14,18	120:11,18	circumstance	113:15 114:15	145:10 215:18
155:22 159:11	chemical 43:16	216:6	clear 16:22 23:12	coli 284:14
160:3,9 164:16,20	77:18 143:9 188:2	circumstances	23:19 38:8 88:21	Colin 134:11
168:10,22 169:4	312:6	236:21	137:21 143:13	140:21 143:17
169:13 174:7	chemicals 74:16	citation 281:13	166:16 167:4	146:15
179:3 180:14,19	187:19	cite 281:16	170:15 171:14	colitis 154:3,19
184:18 186:16	chemistries 301:18	cited 246:10 280:18	172:2,6 203:4	collaborative 241:9
187:12 189:6	chemistry 301:4,7	cites 281:14	233:6 238:2	collapse 267:15
190:3 191:4,7	301:7,9 302:1	cities 248:14	254:17 279:3	colleague 145:11

255:14	247:4 251:1	231:17 237:8	179:18 241:2	180:6
colleagues 54:11	comment 3:9 15:22	241:7 243:9	246:9 272:3	complete 87:18
55:13 97:12	70:9,15 71:2 82:4	251:15,16 268:18	companies 99:19	88:1 142:18 146:2
145:22 146:13	122:13 134:7	299:4 310:17	100:3,13 101:14	150:14 176:12
collect 54:13	139:9 144:1	312:1 314:2	152:9 177:11	177:7 220:19
collection 236:4	174:21 180:16	commerce 221:10	196:5,9 248:1	221:5,9,15 279:9
collective 146:11	187:13 189:9	commercial 74:7	255:2,9 256:8	281:18 282:1
college 152:22	203:2 208:22	222:3 225:11	261:15 280:19	287:5 309:5
206:9	210:6,7 211:15,17	262:12	281:22 285:6	completed 36:7
colloquial 139:20	214:16,17 217:8	commercially	companion 296:12	37:9 40:1 217:5
colonic 154:21	217:20 221:11,12	264:3,10	company 8:10 80:9	301:2
colony 267:15	222:17,19 225:22	Commission 54:13	80:10,13 99:9,15	completely 145:3
color 176:21	226:18 234:12	commitment 56:2	100:6,12,17 101:3	184:16 196:20
Colorado 8:20	235:18 236:3	72:11 122:22	192:9 206:1,3,7	282:5
colors 45:8 286:17	242:11,20 255:4	150:1 285:7	243:15,20 244:2	completes 210:7
column 127:12	258:16 262:7	committed 249:7	247:22 262:6	completion 173:1
combination	commentary 80:13	250:8 251:11	286:13,14,15	complex 84:8 87:4
213:13 299:19	commented 260:2	committee 7:4,17	287:8,9 298:21	165:21 236:22
303:12	commenter 169:15	8:14,15 9:12	301:10	240:16 274:16
combined 236:10	174:9 180:20	10:17,18,19 86:9	company's 80:14	complexities 235:3
come 4:4 5:17 6:2	191:8 195:7 204:3	99:21 105:20	comparable 60:12	complexity 149:10
52:7 57:16 70:18	304:16	143:5 179:14	293:16	274:20
78:11 95:1 96:8	commenters 84:9	213:13 234:9	compare 116:14	compliance 9:14,16
98:3,14 106:19	187:16 228:4	238:6,13 262:9	compared 196:8	9:22 22:22 25:6
123:6 124:22	252:10	263:17 280:6	Compass 66:10	26:5,11 30:3,21
126:22 130:18	commenting 228:4	305:4	compassion 175:18	34:5 35:2,10
139:17 176:20	comments 3:12,19	committees 9:1	compassion 175:18	39:13 42:7 101:9
195:7 205:1 229:5	4:14,16,17 14:7	10:3,9,16 18:19	compatibility 44:7	102:8,14 116:11
237:4 240:13,21	16:9 41:3 69:4,10	232:5	compatible 44:20	249:20 276:13
240:22 245:6	75:10 81:20 82:18	committee's 108:7	93:22 177:5	compliant 150:5
253:19 270:14	82:21 87:6,7	262:7 265:5 268:2	198:13 199:14	complicated 61:18
287:2 289:12	91:14,17,20 96:8	common 152:14	compelling 308:21	comply 38:11
302:2,3 312:13	97:4 98:10 107:4	154:17 260:19,21	310:5	114:1,9,20 276:11
comes 62:19	107:9 116:1 139:4	303:13	compete 245:2	component 285:14
149:18 154:6	145:13 147:4,5	commonly 233:7	293:2,19	285:15 301:20
197:17 220:16	160:10 167:11	communicate	competition 119:5	components 293:18
236:3 274:9	168:2 169:7,14,18	147:19	competitive 76:3	composition 68:6
276:16 286:6	169:20 170:5,6	communicated	77:9,11 292:21	composting 256:15
311:21	172:12 175:18	288:5	competitively	compounds 112:15
comfortable	176:4 179:20	communication	73:14	comprehensive
188:18	180:1,3,10,13	23:13 28:4 39:18	compile 63:4	171:15 172:2,6
coming 18:1 23:22	181:3,4 184:19	community 6:17	complacent 266:19	217:15
31:13 52:18 68:2	195:13 210:3	13:20 14:15,17	complaint 23:14	compromises 182:9
90:10 97:20	212:8 214:21	18:10 47:9 51:12	32:17 33:11,11	con 245:3
125:13,15 126:11	224:11,21 226:16	65:5,17 67:16	112:18 113:2	conceal 198:21
141:1 143:3	226:20 227:5,14	68:5 123:21 152:2	complaints 23:1	conceivably 191:1
200:20 245:4	228:8,11,15	152:7 155:10	32:5,6,8,9,11,12	283:17
			32:19,20 162:10	

concentration 43:20	95:21 96:3,10 97:9,16,17 98:7	199:13 220:20 238:15 259:2 264:13	38:11 72:17 112:11 123:22 137:13 158:14 200:22 202:4,16 259:19 267:20 289:18	108:19 173:5,7,14 173:17,19 174:4 209:10 284:13 300:3
concentrations 302:13	106:7 134:15,19 144:1,12,17,22	consideration 82:19 107:12 117:17 122:8 144:18 145:2 223:9	consumers 6:18 51:13 65:8 72:19 73:8 74:12 75:1 91:1 93:14 124:2 156:12 157:8 176:20 195:11,15 195:22 196:17 198:19 199:19,20 201:15 202:5 203:4,12,18 214:19 246:1 249:19,21 263:1 265:13 266:14 267:19 268:21 270:18 287:10	contend 229:21 content 167:18 291:2 contentedly 246:4 context 59:3 85:1 296:7,9 297:19 312:10,21
concept 23:17 92:5	145:6,19 159:5	considerations 124:11	considered 4:18 84:16 85:2 118:10 152:8 235:6,7 238:7 270:7 302:11,20	continual 23:17 35:12 219:6
concern 212:18 226:21 269:1	conflicts 78:14,21 79:8 81:8,11 145:16 146:4,12	considering 149:16 197:5 198:8 238:3	consistency 167:12 172:3	continue 23:20 32:15 35:13,18 61:7,11 73:2 104:5 107:16 169:13 183:9 218:19 237:6 240:12 263:17 289:14
concerned 83:5 108:13 212:12 213:2 266:18 279:14	conform 136:6	consistent 27:3 28:9 29:22 43:3 72:15 137:8 142:15 171:20 222:1,7,13 279:4 283:3	consumer's 249:7 consumes 99:7 consuming 266:9 270:12	continued 42:3 109:3 134:18 148:8 152:10 170:10 172:18 287:6
concerning 13:18	confused 93:4	consistently 225:17 226:15 278:16	consumption 153:16	continues 44:3 197:7 231:12
concerns 148:19 161:17 187:16 223:7 225:5 284:12 298:2	confusion 205:7 208:18 209:15	consists 292:7	contact 63:10 308:9	continuing 61:10 73:20 222:18 241:11
concert 241:2	congratulate 83:15	constantly 51:19 146:3	contain 197:4 198:17 202:2,3 203:19	continuous 51:21 54:17 149:17 150:6
concise 166:16 170:15	congratulations 111:5 297:7	constellation 153:1	contained 112:15 115:3 199:12 246:11	contractors 135:14
concludes 315:7	Congress 61:4 71:21 73:16 77:21 78:12 88:5,6	constitancy 80:3	containing 166:4	contributed 48:5
conclusion 298:9	connection 153:15	constitutes 80:6	contains 45:21 66:13 113:14 114:4 163:10,15 198:10 283:11	control 182:1 183:18 189:16,21 220:8 292:5,18 293:21 298:12 300:17 301:21 303:15 312:6,13
conclusively 136:3	consecutively 189:11 190:13	constraints 221:4	contaminant 294:19	controlled 128:5
concoction 292:22	consensus 13:19 152:1 179:10	constructed 118:12	contaminants 43:19 45:22	controversial 152:8 223:12 224:19
conditions 85:8 136:5,17 142:5,5 142:9,10 190:9 246:5	consequences 75:20 246:16	constructive 13:16	contaminate 260:9	convened 1:10
conducive 90:5	conservation 59:1 59:2 109:6 116:2 116:5,12,15 117:11,20 118:22 121:5,7 138:9,12 138:19 168:4 169:22 170:9,11 170:17,21 171:2,4 171:7,16 182:2	consult 19:14 121:20	contamination 43:21 85:12,14	conventional 46:11
conduct 34:12 36:16 135:15 225:16	conservationist 11:19	consultant 10:7 131:3 277:4		
conducted 109:16 140:3	conserve 133:22	consultants 135:15		
conducting 39:9	conserved 116:7 268:11	consultation 86:8		
conference 231:14	conserving 118:9	consulting 147:1 176:13 277:3		
confidence 19:2 137:13 158:3 267:20	consider 44:10 105:21 112:12 120:17 124:13,14 136:8 164:5	consume 196:11 224:3 266:7		
confident 52:5		consumer 10:12,15		
confine 16:9				
confirmation 104:22				
confirmed 153:19				
conflict 18:11 19:1 19:11,12 77:14 79:5,19 80:7,22 81:2,6,16 83:6				

60:6 73:3,13 76:5 76:12 91:22 92:2 92:11 94:11 122:17 156:15 173:9 177:13 182:3 205:17 207:5 209:21 280:19,20 295:20 297:6 conversation 146:6 223:18 226:3 228:22 conversations 228:21 230:18 conversion 138:15 171:9,11 conversions 127:18 converted 119:4,14 138:22 converting 25:13 118:22 119:8 convince 196:17 244:14 convoluted 229:10 cool 272:10 coordinate 57:5 66:8 coordinator 48:20 121:19 169:18 copies 243:7 corn 99:11,20 100:1 137:19 192:12,13,14 cornstarch-based 182:12 Cornucopia 71:6 71:10 75:22 78:3 80:1 151:17 156:5 160:19 161:3 163:1 243:5 Cornucopia's 79:5 corporate 72:4 158:1 corporations 72:10 156:14 214:18 correct 47:21 71:16 corrective 29:20	36:7 37:4 correlates 96:2 corroborate 142:2 corroborated 143:1 corroborating 143:14 corruption 99:5 cost 58:19 133:7,14 133:22 182:5 220:20 221:1 228:2 252:1,20 304:9 Costa 48:12 Costco 245:17 costs 26:1 123:16 186:13,13 cost-effective 186:11 cost-share 58:17 Council 147:3 Counsel 237:18 counsel 237:18 count 311:4 counter 109:5 countermeasures 251:8 counties 27:6,19 29:9,10 countries 194:12 245:4 country 194:7,13 194:16 243:17 245:16 County 7:22 county-by-county 27:11 couple 5:2 39:4 56:13 68:10,18 76:10 102:17 103:12 112:5 113:3 134:14 169:5 course 5:9 10:8 24:15 56:3 57:13 58:14 87:21 100:20 141:7 189:21 196:22	214:12,15 259:9 289:13 311:15 court 112:20 269:8 courtesy 15:12 cover 34:20 47:6 183:21 187:4,9 covered 30:20 127:17 312:8 covers 16:21 20:2 312:4 cow 127:5,12,19 265:19 cows 76:2 77:3 122:17 128:2 246:4 co-director 71:6 243:4 co-founded 286:14 co-founder 243:4 crack 77:19 cracked 283:22 create 137:14 207:9 283:17 286:16 287:12 created 56:17 77:21 286:20,21 297:2 creating 283:14 288:9 creative 270:15 credibility 53:2 99:1 crickets 272:19 crises 88:9 criteria 27:15 30:20 42:16 43:14 44:10,13 148:17 149:11 166:2 172:16 178:7 criterion 297:21 critical 100:18 120:3 121:4 122:15 197:22 260:7 280:9 crop 25:13 49:5 53:11 58:13 59:20 173:12 174:16	177:1,1 183:21 187:9 191:2 211:5 309:14 cropping 136:19 crops 6:21 7:4,5 8:13 9:6,13 11:4 11:13 22:9,10 31:14,19 48:15 60:4 83:16 107:6 108:22 119:1 147:11 173:6,7,9 173:15,19 184:3 185:3 187:4 190:18,20 207:3 208:2,3 209:4 cross 54:6 265:18 crossovers 66:5 crucial 82:16 85:15 crushed 245:11 Cruz 106:16 Crystal 277:2 CSA 181:19 192:20 cultural 303:13 cultured 154:20 cure-all 239:15 curious 61:2 228:3 current 61:8 72:14 85:19 99:4,13 104:19 147:1,9 178:10,20 230:16 234:18 236:1,9 238:8 239:8 268:21 310:4 currently 28:17 72:14 86:7 87:12 101:13 105:5,14 105:18 139:22 154:3 181:15 210:22 223:8 239:13 264:5 269:3 customer 29:6 customers 157:13 195:1 204:22 206:14 cut 77:5 118:20 cutting 77:1,3	cyanide 197:18 cyberspace 181:4 cycle 40:21 cyclical 77:7 cycling 117:6 cypermethrin 292:21 Czernicka 160:12 160:13 164:19 300:8 C.F.R 171:11 C8910 292:4,6 293:1,14 <hr/> D <hr/> daily 163:18 266:12 303:3 dairies 75:21 246:13 dairy 8:4 72:20 74:15 76:5,7,21 77:6,10 99:1 121:18,20,21 122:16 123:11,12 123:17 124:21 125:8 126:6 174:15 245:14,14 dairymen 77:1 damage 269:9 304:6 damaged 226:15 226:17 263:6 damaging 267:19 dangerous 89:9 161:13 Daniel 154:7 darkling 253:10 Dartmouth 156:3 data 53:8,11 54:14 58:4,6,11,15 59:18,21 60:7,11 60:20 64:3 140:4 140:8 141:1 142:17 162:9 246:10 288:19 293:5,13 299:14 311:20
---	---	--	---	---

database 35:17 38:22	188:15 192:6	definitions 121:6 167:4 172:22	depending 34:8 163:18 176:22 189:2 216:5 220:16 221:13	235:11,16,20 240:1 291:14
date 28:11 49:13 59:2 173:11 214:22 311:4	decides 97:5	degradation 110:10,13 137:2 140:12,13 142:21 185:13 224:8	depends 117:5 157:19 216:3 273:7	determined 108:15 162:21 212:2,5 237:18
dates 35:16 39:8	decision 78:14 84:6 161:4 166:1 178:9 179:10 182:16,20 183:10 186:15 187:22 188:7,8,9 193:5,18 200:16 218:14,20 250:2 269:8 274:3	degrade 308:16	deposits 198:1	determining 89:19 138:18 149:8 167:18 171:5
daunting 49:20	decisions 77:17 79:9 85:20 86:10 90:18 135:6 175:14 198:16 202:6	degree 205:19 254:5	depth 56:1	detrimental 43:15 197:21
Dave 264:18 276:19 277:1 281:12 285:11	decision-makers 175:8	delay 85:20 86:10 141:5 143:7	Deputy 2:8,21 3:6 12:6,21 17:17 21:15 50:8,21 51:1 56:2,6 57:11 59:12 65:12 87:14	devastating 265:18
David 304:1	decision-making 19:3 274:13	delays 246:17	derive 293:11	develop 166:6 167:10,16 168:2 225:1 235:12 257:13
Davies 294:4	deck 70:21 243:1 247:12 253:20 264:19 276:21 286:11 291:20 300:8	deleterious 213:20	derived 112:14 137:20	developed 103:18 197:15 206:18 211:4
Davis 214:6	dedication 72:11 87:4 180:12 278:16	deliberate 77:15 78:8 135:8 222:20	describe 22:6	developing 31:9 166:16 167:19 227:11 279:1 285:4
day 51:3 52:21 54:20 55:18 101:11 104:20,21 105:10 127:21,22 128:2 179:8,11 180:4 194:9 266:9 268:16 272:13 279:8 288:19 295:7,14 304:17	deemed 311:14	deliberated 81:1 218:13	described 23:11	development 7:8 10:3 11:5 95:20 100:8 105:22 138:6,13 162:21 170:14 172:18 205:15 217:4 227:16
days 11:16 27:14 33:9,10,12 51:5 68:10 101:6 131:11 175:19 180:2 248:19,19 268:18 295:8 296:18	deep 76:22 87:9 229:15	deliberates 78:7	desert 72:21	developments 112:6 113:4
dead 124:7 163:21 254:11	deeper 96:18	deliberation 79:15	deserve 196:1 198:19	devote 51:11
deadlines 147:22	dedication 72:11 87:4 180:12 278:16	deliberations 4:18 71:22 80:8 81:13 97:2,15 178:13	deserves 165:22	devoted 59:6
deal 49:18 96:16 114:22 230:13 233:2	deep 76:22 87:9 229:15	delight 182:11	designed 68:15	devoting 82:14
dealing 144:11 205:8 261:2	deeper 96:18	delve 87:9	desirability 84:17 92:6	de-certifying 132:18
dealt 144:9	deeply 157:16	demand 249:3 264:16	desire 15:5	de-worm 128:15,17 130:9 133:11
debate 81:22 85:3 280:4 297:1	defend 157:14	demanding 124:3	desist 30:1	de-wormed 130:2
decades 48:6 178:2	defendants 113:5	democratic 14:11 91:12	desk 88:7	de-wormer 130:16
decertified 117:18 118:2	defer 90:6 131:13 274:14	demonstrate 108:16 276:14 313:18	destroy 158:3 259:15	de-worming 128:14
decide 81:15 97:7 135:8 211:10 242:3	define 214:3	demonstrated 136:3 234:13 313:6	destroys 196:20	DFDA 302:10
decided 154:22	defined 45:4 161:16 173:21 249:9 267:3	denying 269:9	detail 28:6 64:12 79:12 122:11 215:13	DHA 161:15,18 162:6,8,13,15,17 163:4,13,14
	definition 46:21 72:17 88:22 110:18 116:6,17 121:8 237:2 272:13	Department 1:1 50:1 56:22 57:6 59:7 63:22 65:15 66:4 250:6	detailed 96:7 107:8 138:14 172:5 225:16 234:17 248:7 250:11	Diabetes 153:14
		Department's 66:7	details 62:12 87:8 250:5	
		Department-wide 56:20	detectable 100:2	
		depend 156:17 196:9	determination 271:4	
		dependent 157:5 167:4	determine 29:7 44:11 111:2 235:4	

diarrhea 162:2	189:21 268:7	disclosures 97:13	distension 162:11	doing 23:1,10
diatomaceous	273:18 274:11	134:22 135:18	distribute 139:11	24:19 25:8 31:4
129:14	281:1 282:21	discounts 157:18	139:17 140:6	42:10 52:2 53:17
Dickson 1:17 9:19	difficulty 171:5	discourse 14:7	distribution 32:18	54:16 55:14 56:4
9:20 307:4 314:16	dilemma 199:4	230:16	disturbed 273:10	56:13 82:1 90:13
die 284:20	diligently 219:15	discovered 255:12	disturbing 157:16	96:20 103:6
died 284:16	DiMatteo 21:5	discuss 92:5 229:2	ditch 183:20	105:17 133:18
diet 102:4,15,19,21	146:20,21,22	discussed 15:3	divergent 234:14	178:18 209:8
220:17 223:14,20	288:1	18:12 228:7	diverse 165:2	225:14 251:22
262:8,22 263:2	dinosaurs 191:15	discusses 91:15	221:19	265:2 268:19
264:9 265:6	direct 63:17 77:16	discussing 159:2	diversified 8:2	282:4 283:5 284:2
279:10 302:21	81:16,16 154:13	237:15	diversity 117:3	dollars 88:9
dietary 137:20	230:3 264:7	discussion 3:15	165:16 168:1,3,18	domestic 245:2
176:15 284:14	directing 299:12,20	83:20 84:4,21,22	221:16	dominated 72:3
303:5	direction 265:12	89:1 92:16 96:16	Division 2:12,14	Don 131:6
diets 3:15 84:21	directions 120:12	96:18 103:17	12:10,15,19	door 192:14
101:17 103:22	directly 52:17 55:2	107:5 118:8 120:1	divorce 193:20	doors 54:9 73:22
107:11 134:16	63:16 64:1 77:14	123:1 144:20	DL-methionine	dormant 189:1
137:4,10 219:8	244:7 299:9	145:4 148:2 159:3	222:11 289:5	Dorrance 1:11
220:5 221:15	director 2:12 9:16	159:4 165:20	doctor 176:13	dose 299:6
224:2 251:16	12:14 106:14	169:7,21 172:17	document 3:15	doses 295:17 296:6
253:13 290:12	121:17 195:11	213:15 216:9	55:11 83:20 84:5	double 32:8,13
303:4	directors 78:4	219:19 223:1,2,5	84:21,22 90:20	doubling 25:22
Dietz 277:7	direct-seeded	223:10,15 230:20	118:8 120:1	doubt 297:6
difference 77:4	190:17,20	241:14 262:8	136:11 139:10,12	downside 182:4
91:7 126:20 203:2	direct-to-market	263:7 265:5	139:21 140:10	downsides 182:15
282:17 288:14	8:3	268:19 272:3	165:19 167:3,13	dozens 31:2
different 14:10,16	dirty 182:7	285:19 306:7,9,10	172:7,17 219:19	Dr 3:2,4,18 17:5
27:4 28:22 31:3	disable 255:21,21	307:20 310:8	223:2,6,10,15	111:12,15,22
41:19 48:13 49:3	256:6	discussions 18:7	227:19 228:14	112:17 114:17
49:5 53:20 55:6	disadvantage 77:9	135:2 159:7	234:10 262:8	125:7 129:12
57:1 63:4 64:11	disadvantaging	disease 233:3 254:6	263:7,16 265:5	130:14 131:2,5,13
64:18 66:15,17	73:14	254:15 265:19	documentation	132:13 152:20,22
67:17 82:22 96:15	disagree 89:21	diseases 101:5	233:11,16 239:9	153:2 154:7,14
100:13 134:15	195:22 298:13	254:8 265:18	239:14	155:5 256:22
136:16 140:14	disagreement 97:6	disease-causing	documenting 68:17	257:17 291:21
142:13 145:5	disallow 199:7	235:5	documents 40:11	295:16 298:17
147:13 163:14	disallowed 224:22	disk 187:8	55:10 107:5,11	draft 4:20 120:16
219:21 221:17,17	disappear 162:4	disking 186:21	165:5 169:21	drawn 60:20
232:8 236:14	disappeared	dismay 176:5	170:7 173:3	Drew 181:1 184:19
237:1 256:11	267:13	dismiss 203:15	Dodge 100:17	187:13,15 188:19
273:7 297:11	disappears 184:5	dismissed 112:20	dog 221:16 222:11	190:4,5 191:5
differently 194:17	disaster 175:20	disorder 267:15	222:12 281:6,7	193:10
313:16	disclosed 81:12,12	disposal 43:22	291:13	dried 283:2
differing 267:18	disclosure 83:8	44:18 182:5	dogs 219:22 221:16	drift 269:9 298:1
differs 86:6 179:15	96:12 97:9,22	186:12,13	221:18 280:10,11	drink 5:9
difficult 178:12,17	98:6 106:7	disrupting 221:10	280:15 284:16	Driscoll 9:4

drive 62:13 125:12	easily 239:6	effort 66:7 156:21	emerita 10:6	72:8 83:8
driver 230:6	easy 193:18 208:13	efforts 55:6 57:6	Emery 300:10,11	enforcement 23:1
267:20	208:14 239:22	113:19 134:19	Emily 2:16 12:18	73:1,2 76:8,9
driving 125:11	247:21 268:14	245:8 263:17	21:1	168:20 171:6
132:11,12	eat 124:15 151:11	egg 74:7 76:14 77:9	emphasis 72:2	244:21 246:17,18
drop 181:21	258:3 287:18	99:1 100:20 104:1	227:14 248:6	engagement 42:8
dropped 131:11	288:18	244:5 246:20	emphatic 224:11	146:2
drops 131:10	eating 266:10	248:1,2,3 249:12	employed 152:9	engaging 243:11
drought 26:16,18	EC 294:11	249:14,18 250:4	employee 292:2	244:3
26:19 27:5,21	EcoFarm 106:20	251:7,11 259:15	employees 62:9,14	Engelbert 174:14
drought-affected	ecologist 82:11	259:19 260:9,10	62:15,21 63:8	174:15 179:6
27:19	economic 80:20	261:1 262:6	64:16 65:14	180:18 268:15
Drug 253:3	81:16 104:3	eggs 74:9 100:19,22	employer 80:20	engineering 46:19
dry 25:16 27:7	123:14,17 124:10	105:14 127:15,22	employing 181:16	46:22
186:3	268:8 277:15	127:22 128:3,19	empty 194:2 257:8	England 20:8,8
du 7:22	economically 41:9	129:16 248:13,19	257:8,10	28:1 151:8
dubious 90:14	133:9 134:5	249:3,22 250:9,20	enact 72:22	enhance 227:15
due 99:12 151:19	ecosystems 138:15	251:1 259:20	encompassed 67:3	293:22
171:7 175:20	213:21 229:9	260:5 263:1,4,11	encountered 47:16	enjoy 175:6 245:9
226:21 249:2	Ed 121:16 303:22	egregious 118:1	encourage 30:15	ensure 24:19 26:9
250:22 268:8	EDTA 90:14	eight 246:12,15	67:21 90:12 94:2	34:1,20 35:10,22
289:1	109:16	eighties 288:21	138:9 171:14	62:15 136:13
dust 295:18,19	educated 226:19	either 11:19 25:12	172:4 224:17	160:22 172:3
296:1,5	education 174:2	27:10 57:2 78:8	227:15 229:22	176:16 177:2
dusted 299:10	206:9 264:22	143:6 203:17	230:14 239:3	179:18 185:12
duty 310:20	265:2	207:2 222:10	251:5 267:9	226:8
dyes 136:19	educational 170:15	election 60:1	encouraged 81:17	enter 5:11 80:4
	Edward 125:4,5	electronic 58:2	172:11	188:13
	effect 44:4 45:3	electronically 67:2	encouragement	enters 178:12
	103:11 104:1	elicited 85:2	149:22	entertain 69:4
	109:9,22 128:13	eligibility 46:9	encourages 99:5	enthused 16:13
	199:6 200:15	eliminate 225:17	203:12 250:12,15	enthusiastically
	252:11 295:7	253:9	endangered 119:11	157:13
	298:16	eliminated 48:4	endangering 74:19	entire 68:5 89:14
	effective 13:16	137:10	ended 198:3	99:6 173:16
	129:11 208:10,12	eliminating 138:2	endpoint 200:12,14	177:15
	213:9 227:8 251:7	173:17	298:13	entirely 96:21
	293:14 303:11	email 257:1	end-all 239:15	entity 178:8
	304:8 308:12	emails 13:3	energy 82:15	entomologists
	effectively 39:17	embarrassment	enforce 5:6 33:20	292:15 299:3
	296:12	246:8	34:2 171:13 276:3	entrepreneur 81:3
	effects 44:19	embrace 91:10	enforceability	entry 92:18
	103:14 104:6	200:13,15	276:18	Envirolomics 99:19
	197:21 213:21	embryo 261:2	enforceable 23:12	100:2
	252:13	emergency 126:16	23:19 275:4 276:8	environment 42:21
	efficacy 157:15	233:2 236:20	276:17	42:22 43:20 44:19
	effluent 118:11	238:11	enforced 71:20	109:10 150:22
E				
e 284:13 312:19				
earlier 34:17				
120:15 232:1				
242:11 252:10				
260:15				
early 40:2 160:17				
183:17 184:2,3,5				
258:8,20 315:8				
earth 129:15				
191:15				
Earthbound 9:16				
earthworms				
214:10 215:4,7				
269:15,19 270:4				
271:5 272:1,4,16				
294:10,12 298:3				
299:5 308:5				
easier 165:6 175:12				

255:20 294:20 304:6 308:15 309:1 environmental 8:19 10:6 11:12 43:21 47:20 48:2 48:6 137:2 214:20 294:16 299:22 300:3 303:16 environmentally 134:3 158:12 181:9 182:21 193:3 263:12 286:2 303:11 eOrganic 58:3 EPA 46:10 87:22 212:13 297:18 ephemeral 308:10 epithelial 154:21 equally 15:19 86:9 equitable 59:19 equity 74:19 equivalency 22:19 equivalent 92:4 136:9 163:11 eradication 233:4 236:19 238:16 erosion 118:1 190:1 erroneous 139:14 escalated 76:12 Escondido 111:13 especially 49:19 71:11 122:15 161:15 164:6 202:18 232:4 274:5 277:9 311:9 essence 79:16 essential 46:3 138:1 158:12 161:13,16 166:13 195:20 196:1 219:11 227:2 280:1,3 302:19 essentiality 148:18 220:12,16 310:15 311:18	essentially 64:17 203:8 establish 232:14 310:14,20 established 172:16 234:20 310:18 311:17 establishes 84:6 establishing 311:8 estimated 262:14 et 6:22 132:6 177:1 237:3 239:7 281:9 Ethics 18:18 97:4 Europe 143:3 183:5 194:11,21 236:12 European 39:16 54:10 213:1 Europeans 30:8 74:6 evaluate 19:9 27:16 34:22 136:18 237:21 238:1 evaluated 214:2 evaluating 27:9 61:3,20 evaluation 43:14 evaluations 135:3 evaporate 299:18 evening 10:13 315:12 event 21:6 eventually 119:10 239:19 everybody 5:5,9 10:20 14:22 15:18 68:9,15 97:18 156:19 159:20 242:4 252:5 253:22 everybody's 156:18 everyone's 275:14 313:2 evidence 184:1 215:8 310:3 evolution 165:10 evolving 51:19	exactly 47:1 60:12 60:19 122:20 125:13 201:19 213:19 215:20 examining 18:9 example 40:20 57:7 65:18 81:4 84:21 130:16,22 144:14 241:20 246:12 265:19 280:19 284:9 excellent 31:5 exception 233:18 excess 45:22 122:16 excessive 133:6 149:18 excluded 46:19,21 233:7,9,17 234:8 235:6,17 236:8,18 237:2 239:10 240:2,8,18 269:6 exclusive 125:9 excuse 187:13 223:13 284:3 executing 78:15 executive 80:9,14 121:17 exempt 60:16 101:13 exemptions 42:19 exhausted 312:14 exist 78:14 136:17 166:11 existence 150:2 existent 245:12 existing 240:6 293:3 298:22 302:22 exists 152:2 162:22 expand 35:13 75:19 expanded 25:11 expect 103:22 110:20 123:6 176:20 177:11 249:21 263:2	expectation 84:6 86:11 158:14,15 313:5 expectations 249:8 expected 49:19 123:1 294:19 313:12 expensive 89:15 186:8 220:22 experience 99:16 99:19 100:6 132:15 260:19 304:2 309:3,12,12 309:13,21 313:16 313:21 experienced 309:20 experiences 147:8 170:19 experiments 153:12 experts 123:2 149:6 expiration 39:2,8 61:15 expired 61:6,13 explain 65:8 205:3 241:19 explanation 66:14 explicitly 59:2 explore 33:19 238:18 240:3 explored 137:17 exploring 225:3 239:16 240:20 exponential 59:6 exponentially 76:13 87:3 export 38:14 exposing 137:11 exposure 132:20 299:11,22 311:13 express 175:9 176:5 179:19 240:9 expressed 75:11 expressing 292:16 extend 15:21	extending 168:5 extension 57:12,16 57:20 58:2 extensive 36:22 extensively 147:19 310:12 extent 27:20 33:21 97:21 185:10 213:20 extracted 93:8 extreme 81:4 eye 87:10 89:17 eyes 9:9 309:16 e-Extension 58:1 e-glitch 218:5 <hr/> F <hr/> FACA 18:19 face 49:20 faced 175:4 facilitate 136:15 138:11 facilities 226:11 facing 98:22 123:11 fact 52:8 53:22 61:4 66:3 79:18 161:17 162:9 188:10 196:7,10 200:8 223:18 228:9 232:2 235:12 236:7 248:22 262:20 292:16 factor 132:11 220:21 221:2 283:8 311:16 factors 273:8 factory 73:5 74:15 75:21 77:6 fail 83:21 failed 315:6 fair 16:11 27:2 30:1 119:6 139:13 226:2 fairly 15:1 240:16 240:16
--	--	---	--	---

faith 157:5	110:2 174:16,16	favorite 21:7	193:20 194:17	figure 27:1 270:4
fall 4:6 8:6 20:18	174:16 186:2	Favre 1:17 8:18,19	201:8 226:15	275:16
90:17 128:16	187:10 188:5,17	201:8 203:1 223:2	263:4 276:3	figuring 61:14
148:19 161:21,21	208:16 220:22	223:4 228:8 307:1	289:18 298:14	filed 112:18 278:7
174:18 187:6	249:2	314:13	308:1 310:14	filing 279:18
falls 280:8	farmers 29:6 53:6	FC 250:19	feeling 308:1	fill 283:15
familiar 143:5	54:5 55:17 58:10	FDA 39:14 41:11	feelings 50:19	filled 30:9
281:15	71:8 73:6,15	45:11,12,13,19	feels 133:10 135:4	film 150:10 182:13
families 160:15	74:10,22 76:5	46:1,10,16 48:18	144:2	182:13 274:17
248:17,20	111:1 122:16	87:22 93:17 162:6	feet 74:4,8,14	films 181:21
family 7:18 73:6	123:17 124:4,15	162:9 249:14,19	Feldman 1:18 7:2,3	182:14
175:21 181:17	132:4 134:5 157:7	250:15	119:21 140:21	final 5:1 11:14,15
206:7 245:8,10	177:9 185:8 194:4	FDA's 45:20	184:21 185:5	24:10,16 35:8
248:12 249:5	243:13 244:8	feature 66:19	186:18 199:3	41:1,4,17 46:2
251:10 300:11	245:2,8,10 248:7	February 183:7	200:5 201:5	50:13 52:10 122:9
family-owned 8:10	248:9 249:6,18	fed 196:12 263:1,6	273:13 274:15	122:12 135:18
family-scale 74:9	251:7 265:1	270:6	281:12 282:8	140:5,9 145:4
family-sized 77:8	266:13 270:3	federal 41:11 45:4	283:10 296:21	172:22 178:9
248:3	farmer's 186:9	54:12 83:9	306:18 310:10	179:10
fan 308:6	farming 43:4 54:21	Federation 121:19	314:8	finally 66:1 85:5
Fantle 242:21	75:2 91:9 191:13	feed 73:4 74:16	fell 239:7	109:17 110:20
243:3,4 247:9	191:14,15,18	76:11,12,20,22	felt 182:8,20	236:16
far 6:12 127:1,3	208:11 248:2	77:12 98:18,19	188:17 193:9	financed 59:17
140:15	251:11	99:9,10 103:5	226:16 234:17	financial 108:20
farm 7:18,21 9:16	farms 72:20 73:5	137:13 192:21	288:13	158:2 178:8
38:13 48:11 52:14	74:15 77:6 98:18	220:7 228:2,3	females 261:8	financiers 58:12
52:18 56:15 57:10	100:12 121:20	229:12 230:7	fenbendazole 127:2	financing 58:5
58:21 61:1,5,12	123:12,13 124:22	243:16 244:22	128:6 130:16,20	find 29:4 30:19
71:7 76:2 106:14	125:17,18,21,22	252:1,15,20 258:4	131:8 134:4	38:4 63:9 64:6
115:21 118:4	126:2,3,6,7	259:16 263:14,20	fence 207:22	67:18 90:13
119:19 126:22	127:10 129:17	264:9 265:16	fencing 205:13	123:17 132:6,10
129:20 133:7,7	138:16 150:3	266:3 270:6	ferric 109:12	150:11 153:10
138:17 150:7	191:21 246:15,15	288:18 289:21	158:20	178:20 184:4,15
158:10 168:4	248:3,13,16,17	feedback 174:6	fertility 124:7	187:3 188:17
175:21 177:15	249:10 250:12,21	218:17,19 224:5	field 55:18 62:16	197:11 212:13
181:1,6,9,13,15	251:10 253:4	feeding 228:12	123:2 136:8,13,16	222:8 235:12
181:20 182:10,21	farm-to-school	262:20,22 266:15	139:22 142:2	256:5 263:18
184:22 188:15	52:19	284:12 289:19	183:20 184:1,7,8	265:7 269:17
190:16,17,22	fast 90:7,11 102:16	feeds 252:11	184:10,12,14,16	312:16
191:12,20 192:3	faster 207:5 209:22	270:17 285:15	185:1 187:8	finding 67:19 209:5
192:20,22 193:22	fatalities 254:10,14	291:2	189:11 190:15	findings 34:16 37:4
194:1 246:14	fatty 198:1 212:10	feedstocks 270:14	191:1 205:8	37:7,10,16 38:2
248:11,21 249:5	292:4,8 299:16,18	feel 71:18,22 78:15	206:21 207:2,4	finds 93:22
250:11 253:4,11	300:12 301:8,20	79:10 98:21	208:15 209:7,9	fine 122:18 245:20
269:10 295:13	302:18 303:2,4	118:21 142:1	fifth 11:14	281:8 310:19
farmer 11:1,3 66:6	310:12	144:2 158:16	fig 8:21	finest 14:17
66:11 67:3,12	favor 179:7 195:2	166:1 186:10	figh 128:11	finish 24:7 54:7

168:16	115:13,17 119:17	247:21 277:21	260:7 266:12	formed 219:15
finished 315:8	121:11 125:3	278:13 281:2	267:2 269:13,16	former 50:11 51:3
first 11:22 20:8,18	129:5 130:12	283:5 284:2 285:3	269:17 277:4,13	277:8
23:18 40:21 49:13	131:18 134:6	follow 70:4 130:6	277:13,18 278:2,4	forms 117:1 171:21
51:8 56:7 57:10	139:6 140:19	175:22 249:10	278:5,12 279:1,7	formula 84:12,16
63:3 70:17,20,22	143:16 146:14,17	250:12 278:20	279:12 281:4	84:17,19 90:16
71:18 75:20 92:19	151:1 155:14,18	312:1	282:10 283:16	92:16,22 93:4,9
97:3 105:10 113:4	155:22 159:11	followed 185:11	284:10,12 285:5	93:17,21 94:19
114:7 121:9 122:4	160:3,9 164:16,20	249:15 286:22	287:5,20 288:6	95:2,9 147:2
124:18 132:13	168:10,22 169:4	291:6	291:13	158:22 161:3,7,15
134:18 147:10	169:13 174:7	following 37:12	foodborne 254:8	161:18 162:1,5,8
152:13 161:22	179:3 180:14,19	169:20 179:17	254:15	162:14,16 163:5,6
163:22 169:15	184:18 186:16	183:22 192:7	foods 4:11,12 9:21	163:9,13,17,20
176:5 178:7 180:4	187:12 189:6	215:3 234:20	50:10 71:19 82:15	164:5,6,7,11
181:10 182:11,19	190:3 191:4,7	237:13	93:2 113:20	195:16,21 196:3,6
183:15 185:15,16	195:6 198:22	follow-up 115:9	152:11 158:15	196:7,9,16,20
193:12,12 196:11	201:6 202:21	186:17,18 202:22	176:21 177:7,12	197:2,3,6 198:4,8
204:7 210:12,15	203:20 204:2	208:21 217:10	177:13 198:5,16	198:10,11 199:7
211:3 232:12,16	207:13,17 208:20	241:7 274:15	212:11 218:22	199:11,21 200:2
241:18 242:21	210:1,5 305:1,8	Fond 7:22	219:21 220:6	201:1
262:12 286:15	305:13,19 306:1,8	food 3:14 9:17	222:3,4,4,11,12	formulas 202:1,3
288:9 295:16	307:8,15,19 310:7	21:20 24:13 36:4	267:8 270:12	formulate 219:8
301:3 305:16	311:22 314:1,20	39:14 40:4,9,19	286:15,16,20,21	220:17 281:2
fiscal 32:7,10 33:9	315:1,5	41:8 45:1 46:14	287:14,18 288:9	formulated 148:3
61:8	Flathead 11:18	52:16 66:6,9,12	288:11 291:12	formulating 220:5
fish 102:22 137:18	flavor 263:10	66:15 67:4,12	food-grade 152:4	282:1,18,19
226:21 229:11,14	flavors 45:8 286:17	74:17 87:11 88:15	152:19 153:7,16	285:13
230:5 259:13,16	flexibility 283:4	89:2,20 91:3,8,9	153:21 154:17	formulation 296:13
259:18 263:8,9,11	flies 52:10 292:20	92:2,20 93:15	fool 74:14	296:16
266:4 285:19	293:10 295:7,8	107:20,21 108:2	force 7:6 76:20	formulations
302:22	298:12 301:21	134:12 151:9,10	165:15 219:15	290:12 299:17
fishing 227:1	flocks 102:10 248:8	151:14 152:14	226:5 264:14	formulators 103:6
fit 38:6 147:15	248:18 250:18	156:15 157:10	278:5 288:6	221:12
fix 90:22	Florida 6:14	158:8 159:1,16,18	forced 76:5 149:18	formula-fed 162:3
flabbergasted	fly 292:5,7,10,18	159:21 161:1	223:20 252:14	162:12
208:17	293:21	163:21 164:9	forces 165:13	Fort 100:17
flagging 247:5	focus 31:1 39:1	176:11,12,16	forcing 73:5	forth 107:6 108:5
Flamm 1:12,14 3:2	41:22 67:15 209:4	177:10,14,19	foregoing 70:11	112:16 172:21
4:3 6:9 11:10,11	focused 63:22	178:1 193:4	169:10 242:5	291:11
13:5,11 17:12	174:1 227:20	196:18,19 198:21	304:20 315:13	forthcoming
47:8 69:2,9,21	focuses 49:1	206:17,19 207:1	Foreign 54:15	243:20
70:14 75:5 78:22	Foley 231:14	209:1 216:10,15	foremost 163:22	fortification 92:17
81:19 82:7 86:17	folks 50:4 57:21	216:19 217:1,12	forest 47:18 118:19	93:11,18,19
91:16 95:11 98:9	71:14 74:4 78:13	218:2 219:10,14	forget 18:5	fortifications 95:4
98:13 103:2 104:7	88:14 141:22	220:2 221:22	forgot 282:8	fortifying 93:12
104:11 106:3	156:17 200:20	222:9 248:10	form 30:9 232:22	forward 11:7 15:7
110:5 111:4,7	205:5 208:15	249:9,17 253:2	295:18 296:5	103:17 104:21,21

109:10 124:12 147:13 158:18 170:17 172:4 178:2 193:10 194:3 222:16,17 267:11 foster 1:18 9:8,9 106:10 159:13,14 159:19,22 168:13 168:21 178:10 188:19 213:17 215:2 228:19 269:12 270:8,20 271:9,14,18 272:9 307:3,22 312:3 314:15 found 37:10 100:1 107:17 127:5 131:16 153:16 163:16 184:10 191:21 212:9,20 213:7 222:9 232:7 233:2 235:19 255:16,18 260:17 292:8 312:8 313:1 Foundation 54:21 founded 72:13 106:17 founder 292:2 four 10:9 37:4 38:7 100:14 117:15 232:8 277:22 304:2 fourth 117:17 frame 48:1 60:14 141:17 143:14 185:13 frames 84:22 framework 78:16 267:5 France 153:5 frankly 189:22 190:14 193:16 fraud 197:5,6,7 fraudulent 29:17 74:15 243:12 244:4	free 244:16 French 153:3 fresh 151:11 282:18 friend 255:14 friendly 87:16 134:3 182:21 front 55:9 115:10 182:18 199:15 258:14 285:4 frozen 189:20 Fruit 8:9 fruits 90:17 139:3 303:6 fulfill 180:7 227:2 full 24:22 41:14 92:22 106:7 140:11 142:19 166:9 196:13 222:5 281:16 282:5 fullest 33:21 fully 273:20 Fulwider 1:19 3:4 7:20,20 17:5,6 129:8 210:11 211:19 213:15 215:1,18 216:8 217:22 222:22 227:18 228:18 230:20 241:13,21 242:8 247:7,10 251:19 253:15,18 257:16 260:13 261:20 262:1 264:18 269:11 272:11,20 273:11 276:6,19 281:11 285:10 286:4,9 290:8 291:16,18 294:21 296:20 300:6 304:15 305:6,10 306:21 314:11 function 61:12 67:7 166:20 functionality	166:12 functioned 291:10 funded 72:5 151:22 292:11 funding 153:15 154:5 funeral 151:19 fungi 117:2 fungicide 212:14 furious 194:11 further 59:19 81:21 116:8 138:13,16 145:13 163:12 164:12 222:19 225:1 227:15 244:1 294:14 future 35:1 105:8 137:19 205:22 251:9 268:12 311:3,21	<hr/> G <hr/> gabiae 293:15 gamut 222:5 gastroenterology 154:15 gastrointestinal 152:6 gate 246:14 gather 147:21 243:14 gathering 295:14 gavel 210:9 gay 149:1 GE 85:12 general 26:11,13 27:5 36:19 37:16 63:18 89:22 92:8 94:16 176:4 210:7 231:18 234:15 237:17 generally 56:19 302:11 generate 238:22 generation 249:5 generations 181:17	genes 256:2,6,13 genetic 46:19,22 173:17 174:3 256:1,2 257:8 genetically 173:6 173:11 235:4 geneticist 256:18 genetics 117:3 122:18 124:8 254:4,5 gentlemen 288:3 geographic 221:4 geospatial 66:22 67:7 Gerbin 153:3 germane 22:12 getting 18:18 54:13 57:19 62:20 88:7 119:13 156:9 180:7 284:22 giant 74:10 244:5 give 5:12 15:16 16:11 17:1,18 21:10 23:9 86:21 98:14 102:6 111:8 115:18 121:14 125:6 134:8 146:18 151:4 160:11 164:21 174:10 176:2 179:5 191:8 195:7 204:3 237:12 256:9 285:9 295:10 given 49:19 63:20 85:11 101:5 135:9 177:3 190:22 191:1 208:1 221:8 222:16 260:16 277:20 281:19 gives 13:22 276:12 283:4 giving 116:2 glad 53:18 200:19 global 87:6 106:15 glucose 153:22 gluten 137:19	GM 233:8 GMO 3:17 7:6 10:11,18 11:6 46:20 49:4 100:11 101:1 105:8,17 107:6 108:10,11 108:19 139:2 170:3 173:13 192:12 230:22 231:4 233:8,22 234:16 237:15,16 238:11 239:10 240:15,18 255:7 256:14,20 257:5 268:22 GMOs 99:3,14 100:2 108:18 173:4 239:4 240:9 254:5 GMO-based 100:15 GMO-free 192:13 go 5:8 16:6,16 42:13 50:17 55:5 55:8 60:9 64:11 69:7 88:4 110:19 130:8 166:21 167:8 178:22 184:20 186:16 187:6 190:4 193:12 201:12 202:22 207:18 215:1 218:16 225:14 230:9 238:1 242:17 263:3 275:15,17 275:19,21 291:4 301:5,6 goal 38:7 54:3 56:14 65:16 150:20 176:10 181:8 goals 137:22 goes 36:17 45:5 89:20 96:18 116:8 147:17 189:3 294:15
--	--	---	---	--	---

going 5:17 20:12 21:9,10,14,15 41:9 47:5 50:17 51:18,20 52:16 56:12 58:15 62:2 65:13 66:2 68:1 74:14 77:15 78:7 78:20 80:22 82:2 102:9,13,19 103:7 103:15 122:4 126:10 129:4 130:6,8 133:15 143:20 145:3 158:18 168:13 174:21 176:1 181:5 186:9 196:3 197:1,8 201:21 204:21 205:21 209:3,18 216:2 229:21 230:8,9,10 230:10,12 237:4,5 242:3,10 243:5,8 258:20 259:19 260:8 275:14,17 275:19,20,21 276:3 279:2 286:1 289:22 290:1 302:5 304:17 308:1 309:10 311:15 313:17	307:22 309:22 310:3 315:11 Google 191:16 gotten 26:20 104:22 298:18 govern 78:17 governance 146:8 government 54:12 87:22 96:20 governmental 83:4 grain 77:2 99:2,3 99:13,14 118:14 123:13,15 124:21 133:15 244:4,6,13 244:22 285:14 grains 99:7 118:15 228:2,3 252:1,2 grand 14:14 grandchild 122:3 grandfathered 219:12 granted 15:15 308:13 granular 60:11 grapes 8:13 119:15 212:11 grappling 52:3 GRAS 45:11,14,15 45:19 grass 119:10 293:19 302:11 grasses 117:2 gray 167:14,22 grazing 25:17 27:13 126:7,13 133:5,14,16,17 246:4 great 4:9 20:7 47:22 49:2 52:20 67:14,21 180:15 228:10 230:4 241:6 249:16 269:1 277:9 greatly 87:5 132:2 green 5:21,21 195:4 229:16 greenhouse 205:11	greetings 50:19 grocer 250:16 grocers 245:16 grocery 263:3 gross 246:14 ground 133:3,4,22 184:9 189:20 190:1 252:19 group 3:17 7:7 16:15 31:17 40:22 56:21 57:4 62:1,8 83:16 147:11,19 214:20 230:22 231:4,7 232:2 238:18 247:3 248:7 269:4 270:3 groups 14:16 40:11 72:10 163:1 grow 8:11 53:4 94:2 119:1 157:6 190:19 194:6 245:9 grower 7:13 11:22 11:22 31:17 40:11 81:9 110:14 208:14 growers 38:16 103:7 119:6,7 204:22 205:17 207:1 251:22 313:14 growing 81:10 125:21 130:9 136:10 177:10 188:20 189:19 193:13,15 205:11 258:9 262:15 grown 85:10 108:17 118:21 141:5 177:1 growth 73:9 103:22 104:2 118:19 120:3 137:6 grubs 228:12 guess 9:15 68:19 86:18 107:7 120:6 139:15 141:3	169:4 195:5 204:11 205:19 215:2 287:7 289:11 guidance 13:17 18:17 24:15,17 31:17 40:10 85:17 85:22 86:2,6,11 102:7 104:19 120:16,19,20 121:3,3,10 138:6 149:20 165:5 167:17 170:14 171:15 172:2,7,14 172:22 173:3 174:2 206:22 241:1 274:20 275:1,3,12,15 276:7,10,10,14 guide 63:3,14 64:22 guidelines 150:13 guiding 157:3 guilty 72:5 gut 127:6,7 Guys 260:3	handler 8:16,16 9:10 handlers 57:17 63:5,18 118:9 168:5 233:13 handling 8:15,22 9:12 10:2,10 22:10 23:1 31:15 32:11 40:15 42:16 43:1,4 44:21 46:4 46:12 177:12,16 195:18 219:4 266:3 hands-on 248:2 309:12 happen 81:2 144:3 200:21 209:6 256:14 happened 49:16 205:4 268:5 happening 35:22 75:3 105:10 119:3 125:16 happens 14:11 29:22 153:11 158:6 happy 78:4 117:7 140:5,17 145:12 165:11 251:13 hard 13:8 20:9 51:15 102:16 126:20 193:22 253:22 309:9 hard-working 208:16 harm 163:6 harmful 42:20 158:12 302:9 Harold 1:15 8:9 207:18 208:20 Harriet 264:18,20 harvest 209:9 hatchers 101:8 hatching 101:6 260:16 hate 270:21 284:18 haven 156:10
H				
good 4:3 6:13,19 7:2,9 8:8,18 9:2 10:4,13 12:9,13 12:17,20 20:6 33:7 37:11 45:20 49:8,9 51:22 55:18 84:21 98:16 106:5 119:18 123:5 134:10,13 146:20 160:12 163:6 203:11 204:5 214:9 229:19 244:20 247:13,21 250:13 253:21 267:22 279:6 284:19 285:20 303:17			habits 266:10 hair 111:20 half 23:7 32:19 39:11 48:19 181:3 181:5 186:13 190:19 191:11 192:2 250:20 295:22 312:12 hall 16:17 hallmark 68:3 Hanauer 154:15 hand 78:18 83:19 84:20 167:8,8 212:18 283:6 310:10 handbook 138:7 handed 91:13 handful 55:10 handle 144:17 handled 84:4	

Hawaii 11:2	help 54:5 58:4	229:19 230:11	horn 292:18,20	identified 36:8
hay 181:15 184:8	62:20,22 100:8	252:16 310:14	horrifying 73:7,9	identify 137:22
190:17,22	130:19 227:2	highest 250:9	horses 296:11	152:18 153:10
hazard 311:9	291:1	highly 93:2 123:4	Hospital 160:16	identity 173:8
head 296:2	helper 128:11	163:20 236:22	hospitalization	ignorant 196:10
headed 154:7	helpful 63:10	302:21	254:10,13	ignored 161:19
heading 130:4	140:22 143:15	highway 247:19	hot 244:12 295:14	ignoring 157:21
health 42:21 44:4	230:17 231:15	high-conservation	Hotel 1:11	Illegal 73:20 74:2
45:4 104:5 137:14	238:22 251:18	171:9,12	hours 51:11 128:8	Illinois 152:21
158:13 161:14	helping 53:21	high-end 222:3	180:5 247:18	illness 100:21
226:9 255:10	65:15 285:1	high-toxicity	house 53:19 206:20	illuminate 5:22 6:4
291:11 302:10	helps 29:4,6 62:4	302:17	256:15,16 295:6	imagine 182:11
303:16,20	64:6 146:5 289:17	high-value 118:22	housed 65:22	271:6 282:10
healthcare 162:1	hen 248:7,10	121:5 138:15	huge 86:4,9 303:22	imbalances 284:15
232:14	Henderson 125:7,8	209:4	308:6	immediately
healthiest 151:10	129:12 130:14	hire 78:6	human 42:21 44:4	122:12 268:19
healthy 150:21	131:2 132:13	hired 71:8	45:4 100:21 154:2	immune 124:9
164:2 290:1	hens 73:19 253:5	historic 252:5	154:20 161:13	257:12 261:1,13
295:12	262:14 263:20	Historically 166:19	260:8 278:4,12	261:14,18
hear 4:14 91:2	herbal 224:15	hit 55:9	291:6 302:10	immunity 257:14
228:5 235:18	herbicide 204:9	hitting 52:9	humans 137:15	impact 59:8 79:9
245:7 252:22	herbicide 207:21	Hoc 10:18 11:6	288:14 293:11	136:14 137:2
297:9	208:10,10,12	Hogs 266:6	hundred 60:10	213:3,5 214:13
heard 25:18 71:9	212:14	holds 177:6	73:18 76:16	238:16 257:19
103:12 150:15	Herbruck 253:20	hole 194:2 207:11	295:13	277:15 298:2
180:11 191:12	254:3 262:1	278:15	hundreds 162:7	311:11
208:5,12 225:17	herd 25:15 128:22	holistic 149:19	163:15 206:13	impacted 214:10
245:22 246:21	132:17 296:1	151:7	221:22	215:4,5 216:3
260:15 308:18	herds 127:11	Hollander 154:7	hurt 94:8,12,13,15	impacts 61:21
hearing 4:22 17:12	129:19 132:17	home-baked 50:6	94:21 95:6,10	84:18 136:18
79:4 181:2 205:21	Heritage 242:22	honest 73:15	husband 191:12	297:16 298:1
242:19,19	247:15,17	honey 267:16	286:13	impediment 171:1
heart 288:22	hexane 93:8	honeybees 267:14	husbandry 248:8	imperceptible
heart-wrenching	hexane-extracted	honor 6:16	Hutchinson 288:3	131:12
183:11	95:3	Hoods 86:22,22	hypothetically	impetus 62:7
heavier 298:6	hey 62:19	92:8 94:13,17	275:2	implement 23:21
heavily 89:17	he'll 231:17	96:7 98:12		34:7 59:22 109:20
127:11 157:20	Hi 13:1 115:20	hope 4:11 16:22	I	123:8
heavy 45:21	139:8 156:2	59:8 61:15 65:9	idea 14:1 130:20	implementation
heifers 8:4	hiding 196:6	78:5 115:8 158:18	157:2 158:5	20:15 21:12 24:20
held 6:7 16:19	198:20	183:3 230:18	196:20 228:10	24:21,22 25:9
126:5	high 73:5 123:15	240:22 296:13	230:5 259:14	40:6 52:9 56:14
hell 88:9	133:3,4,7,14,21	hoped 115:22	295:11	138:11 169:21
Hello 10:20 50:21	228:2 251:22	hopefully 5:18	ideal 177:20	170:8,10,13 171:2
151:5 174:14	259:16	40:14 64:5	ideals 72:12	implemented 22:21
180:22 195:9	higher 126:12	hoping 40:7 90:3	ideas 223:12	24:5 34:15 39:17
262:4 300:9	137:7 181:22	165:4 240:12	identical 177:3	108:3 249:15

implementing 21:20 34:21	improves 29:6	increasingly 90:8	161:3,7,18 162:1	114:15 148:1,3,16
implication 92:1	inability 280:14	incredible 51:9	162:5,20 195:16	151:15 161:12,15
implications 61:3	inadequate 196:7	54:8,16	195:20 196:3,5,7	162:19 163:5,7,10
61:14,20	299:1	incremental 280:3	196:9,16,20 197:1	164:1 165:16,17
implore 98:3	incentive 225:1	incubator 101:7	197:3,6 198:4,8,9	165:18 166:5,12
importance 63:20	226:1 283:14	incumbent 78:17	202:1,2	167:3,10,19 170:3
170:22 249:17	inches 189:4	independence	infants 149:7 162:3	171:20 172:15,17
important 19:4	incidence 162:10	135:12 146:10	162:12	197:10 198:17
33:15 51:2,12	incidental 166:5,12	independent 10:7	infant's 163:18	219:9 221:5,14
53:8 54:11,14	incidentals 166:8	77:22 109:15	inflammation	233:15 280:21
56:16 60:20 61:22	166:10,22	146:9 157:18	152:6,16,19 153:9	282:10 283:12,16
63:1 73:8 80:5	include 22:9 44:15	294:7,14	154:12,18	283:19 290:11
89:7 92:17,21	121:6,7 147:2	indicated 294:11	inflammatory	291:9
98:8,22 109:13	152:20 174:1	indicates 296:18	154:20	inhibiting 128:12
114:22 120:8	284:12	indicating 104:17	info 65:21 178:8	inhibits 128:11
125:19 150:18	included 25:8	indication 91:20	inform 146:5,7	initial 141:2 153:18
157:8 159:7 193:9	60:15 108:6 114:3	indirect 229:10	147:22 151:13	217:11 252:12
231:20 233:5	117:8,12,13,16	230:15	information 28:21	279:19
234:1 248:22	122:10 170:6	individual 81:17	29:4 38:19,22	initially 235:3
250:14 277:14	172:13	148:9 149:22	42:7 63:11 64:4	292:11
289:5 290:6	includes 43:15 58:1	217:13	108:6 129:13	initiate 112:2 116:9
291:12	116:22 117:1,3	individually 267:6	130:11 138:7	initiative 28:5,7
importantly 72:16	233:3 250:5	industrial 76:15,19	139:4,14,15 146:6	39:18 57:8 62:4
182:1	272:14	91:8 137:7 157:20	147:21 170:15,20	62:13 66:6,12
imported 124:16	including 151:14	industrial-funded	172:13 178:6	67:4,13 73:12
124:18,20	232:15 237:2	157:21	179:13 188:16	injected 105:7
imports 245:3,3	245:17 251:8	industrial-scale	202:7 218:13	injuries 284:15
imposing 150:12	253:10	76:7	234:18 235:1	innovate 150:5
impossible 124:3	inclusion 135:13,17	industries 99:2	236:11 239:1,18	innovated 185:12
184:15	171:8 210:19	industry 11:8 53:3	240:5 243:14	innovating 55:18
impress 126:2	incoming 99:11	53:13,21 72:4,13	268:13 273:17	innovations 52:15
impressed 14:6	inconsistency	90:10,12 93:22	274:1,14 308:2	149:22
improve 28:17	234:5	94:2,8,15 95:1,6	311:6	inoculant 239:11
38:22 45:7 53:11	inconsistent 142:8	95:10 100:20	informed 36:17	input 147:20 150:4
116:17 290:10	170:13	105:12,19 108:21	146:3,10 198:14	157:9 158:9
improved 29:12	incorporate 116:12	122:14 173:12,16	informing 202:16	222:19 223:11,17
32:16 130:3 266:2	121:4	206:13 227:21	infrastructure 64:5	inputs 177:12
improvement	Incorporated	260:21 261:7,8	265:22	290:19
23:17 31:7 32:10	210:18	ineffective 298:15	ingredient 150:5	insect 210:20 212:4
35:13 37:20 51:21	increase 25:20	313:6,7	157:10 158:10	212:17 228:19
54:18 149:17	28:14 32:6,12	inert 90:14	196:3 197:13	260:2 293:2
150:6 219:6	54:1 56:9,10 59:6	inerts 83:16 89:4	217:1 221:22	294:16 307:13
improvements	92:6 150:18 291:1	90:16 147:10	282:19	314:4
28:11 29:16 33:13	increased 28:13	infant 84:12,17	ingredients 42:16	insecticide 307:14
35:19 38:4,20	31:1 35:15 123:16	90:16 92:16,22	46:17 83:21,22	314:5
59:19	174:2 249:3,8	93:4,17,21 94:18	90:15,20 112:13	insecticides 293:4
	increasing 30:4	95:2,9 158:22	113:14,15 114:4	293:17

insects 117:2 137:18 228:1,6 252:21 253:1,7,9 253:11 260:1 269:15,20 272:15 286:6 295:4	integrity 9:18 19:3 23:8,11 33:15 34:1 38:13 72:12 88:18 89:7 99:6 123:10 158:19 160:22 182:9 189:14	147:2 internet 188:12 191:17 interpretation 148:16 intervening 273:22 274:9	310:13 312:16 IPM-compatible 303:9 irresponsible 193:3 irrigating 186:4 irrigation 181:21 182:3 207:3 209:16	223:7 226:10 229:4,20 243:6 289:2 291:11 297:16 302:13
inside 57:19 Insider 28:10 insignificant 311:11 insistent 133:1 inspection 25:22 138:10 274:22 inspections 23:15 31:12 34:11,13,22 35:1 37:6 inspector 10:8 31:16 36:19 37:15 40:15 138:5 inspectors 110:12 instance 46:22 89:18 90:13 93:9 117:22 297:12,18 instances 148:22 Institute 36:5,15 71:6,10 147:3 151:17 153:2 155:7 160:20 216:19 217:12 219:11 243:5 277:5 institutions 155:6 instruction 120:22 121:2,10 138:6 168:7 185:10 instructions 31:11 34:11 35:5,10 185:11 instructive 275:4 instruments 53:12 insulin 153:17 154:1 insurance 49:5 53:12 58:14 59:20 intake 27:7 integral 23:4 Integrated 303:10	intended 71:21 271:14 intense 88:2 intent 180:8 intentions 108:7 interaction 85:6 interactions 43:16 interagency 57:4 interest 10:16 18:11,21 19:2,21 30:13 57:3 69:7 77:14 78:14 79:6 79:8 80:7,20 81:16 83:6 95:21 96:3,10 97:9 98:7 106:7,8 134:15,20 141:8 144:2,12,17 144:22 145:6,16 158:2 159:5 218:18 228:5 242:13,15 285:18 interested 62:19 79:4 141:1 156:8 188:7 283:14 interesting 69:11 205:15 228:20 229:1 246:11 260:17 interests 19:10 30:5,10 247:6 interface 88:13 interim 24:9 82:3 221:6 interlocking 61:17 intermittent 279:11 internal 127:13 284:15 international 35:20 42:4,5 54:12	intervention 160:18 intestinal 152:16 153:8 154:12 intolerance 153:22 introduce 6:11 12:3,8 210:12 216:10 249:14 310:21 introducing 86:5 introduction 227:13 231:18 invent 75:1 invention 178:15 inventor 292:3 invertebrate 266:22 invertebrates 269:20 270:12 investigated 76:2 investigation 23:2 243:18 244:1,1,19 investigations 32:13,16 investments 57:13 invite 68:9 106:19 involve 138:18 186:20 involved 26:1 57:20 156:20 206:17 222:4 involvement 77:16 involves 85:6 in-depth 131:4 in-person 211:17 217:20 ionizing 47:2 Iowa 250:21 IPM 213:11 292:13 297:12 298:22	irrigating 186:4 irrigation 181:21 182:3 207:3 209:16 Island 1:12 Islanders 4:10 isolate 84:14 93:5 isolated 195:17 197:2 issuance 85:17 issue 27:2 39:22 41:12 46:20 81:18 84:2,13,22 85:5 85:15 86:12 89:4 93:5,11 98:22 104:4 105:1 115:10 118:22 119:6 121:5 135:10 140:9 141:21 144:12 145:13 148:22 162:19 165:18,21 171:13 173:5,6,10 173:14,17 190:6 206:15 214:12 228:5 236:22 237:13,15 238:7 240:16 257:3 260:1,6 269:1 274:16 278:9 287:14 296:10 300:4 311:8,15 issued 27:4,18 30:2 31:11 33:16 113:8 issues 16:8 19:17 49:4 52:4 79:7 84:9 88:17 121:22 123:19 134:15 137:1 143:12 144:18 158:19 159:2 165:15 206:18 207:2,10 209:1,6 211:12	itchy 313:9 item 268:8,10 items 241:20 Ivermectin 130:22
J				
				jail 244:15 January 34:19 106:20 112:17 174:17 216:19 Japan 42:6 213:1 Jay 1:18 7:2 119:20 140:20 184:20 186:16 199:2 273:12 281:11 296:20 Jean 1:20 3:18 10:5 130:12 211:19 215:21 231:1 237:10 240:14 241:6,10,16 260:13 294:21 305:13,13 jeans 52:13 Jennifer 1:22 2:21 6:11,14 306:4,15 315:2 Jenny 12:21 50:7 Jessica 164:22 168:11,12 169:1,2 Jirah 243:15,21 244:14 Jo 115:20 119:18 119:20,21 121:12 121:13 Joan 191:10 job 31:5 52:6 78:11 86:1 87:3 119:12 130:21 166:18,20 301:5 jobs 165:6 Joe 9:19 111:11 115:14,14

John 1:18 9:8 106:10 159:13 168:12 213:16 215:1,22 228:18 269:11 304:1 307:21 312:1	212:15 214:13 killing 128:9 293:11 Kim 277:7 kind 53:11 61:17 72:22 81:8 102:11 197:17 204:12 215:7 222:6,14 227:19 229:20 252:18 267:13 271:7 275:13,16 278:8 283:6 287:10 288:5 295:3,14 298:22 308:15	204:13 206:1 209:11,17,19 213:18 214:8 216:1,6 225:9 227:9 228:12 232:5 233:10 236:5 240:5 252:4 254:22 256:18 260:18 261:11 269:7 270:13 271:9,10 273:20 274:19 275:14 283:13 284:1,5,8 284:19,20 285:17 285:21 287:8 289:4,11 290:14 291:10 295:2 296:22 298:7,7 299:5 300:18,21 301:13 302:16 309:4,6 310:12,15 311:1,9,10 313:13	202:7 203:3,15 222:9 224:9 239:3 267:20 labeled 85:10 111:18 112:4 113:13,21 114:8 198:11 199:7 219:3 279:9,10 labeling 22:10 32:22 84:17 112:22 113:6,9 173:13 labels 197:8 219:1 222:1,2 laboratory 142:4 153:18 293:13 labs 35:6 99:16 lack 7:22 33:1 76:8 123:16 170:13 171:3,7 223:13 236:22 239:10 262:13 290:18,21 292:12 311:17	LaRose 204:5,6 207:15 208:5 209:3 210:4 lasted 180:5 295:7 Lastly 150:15 246:19 late 183:22 lately 205:16 launch 204:15 law 33:21 45:11 72:8,15,16 75:20 78:17 158:16 183:2 192:16 275:14 laws 83:9,12 lawsuit 246:2,7 layer 261:8 layers 101:4,19,21 102:4 104:1 261:12,13 262:15 laying 73:19 258:10,10 262:14 lead 153:22 308:15 leaders 155:5 leading 15:20 leads 308:8 Leanna 86:22 91:17,18,19 95:12 95:14 98:10 learn 197:12,14,19 learned 198:2 265:17 learning 28:19 leave 68:21 90:4 114:6 187:18 188:1 190:1 253:14 310:6 leaves 102:1 left 6:3 102:18 legally 149:15 236:19 legislative 50:9 61:13 legitimate 73:6 76:20 lengthy 115:4 234:10
K	kinds 22:12 106:8 kits 100:3 knew 180:6 know 4:10 5:15 18:4,9 20:4,9 38:10 48:18 49:10 49:12 50:9 51:10 52:22 58:9 59:8 62:10,16 66:5,6,7 66:11,11 67:3,3 67:12,12 68:4 69:7 79:17,18,20 88:6,21 90:2 91:3 92:22 94:17 103:11,19 106:11 109:19 110:19 116:4 118:4 120:6 120:13,14 122:20 130:15 131:10 132:21 133:20 141:3,21 142:3,9 142:12,19,22 145:11,15 156:5 156:18,19,22 174:12 175:19 185:21 187:5 188:13 189:18 190:18,21 191:20 192:13 196:2 197:1 198:19 200:6 201:13,22 202:8 203:7	knowing 243:19 knowledge 51:20 146:11 236:4 279:4 knowledgeable 271:1 known 107:7 215:9 251:7 knows 13:2 42:14 220:22 252:6 Kramer 252:11 Kreamer 98:18 99:9	Lake 11:18 land 25:12,13 27:6 119:5 132:5 133:7 133:7 138:18,21 171:9,12 landfilled 182:8 lands 119:1 121:5 landscapes 204:17 landscaping 118:15 205:11 language 73:1 227:4 laptop 127:17 large 190:21 192:20 205:18 212:16 221:16 229:4 280:14 largely 156:21 larger 74:7 173:6 225:8 272:3 280:20 largest 106:22 194:1 large-scale 229:19	
	L	L 195:15 198:6 201:9 223:7 label 33:2 51:14 72:18,20 74:20,22 88:18 89:7,13,16 91:4 137:11 148:11 156:18,20 158:8 164:7,7 177:21 178:15 199:15 201:9,18		

lesbian 149:2	294:6	64:21 65:12	lobby 158:1	30:8,11 33:21
letter 72:15 91:14 288:5	Linhardt 153:1	literature 258:16 280:13,13	lobbying 72:4 80:15	36:20 42:5 43:6,6 64:7 92:20 140:15
letters 30:2	lining 127:6 131:9	litigation 112:7,20	lobbyist 151:18 160:21	186:19 192:5 199:21 212:20
let's 15:22 20:2 179:6 239:11 272:18 274:18 275:2 278:18 283:13 287:16	Lipson 2:18 3:7 17:20 21:14 28:6 47:5 48:18 49:7 54:22 55:21 69:6 69:13 246:11	litters 289:22	local 4:11 38:15 66:9,15 88:16 151:11	228:1 230:5 252:1 270:16 275:16 281:21 297:15,18 302:8
level 16:7 83:4 122:21 131:8,12 132:20 185:6 209:20 252:14 259:16 264:6 274:22 292:20	liquid 111:16	little 5:6 24:18 26:12 36:2 47:6 57:9 58:16 62:3 75:13 98:5 129:21 179:4 225:22 237:12 242:10,11 271:7 273:13 277:11 284:11 313:9 315:8	located 247:16	looks 46:22 89:13 101:9 105:4 167:11 274:7
levels 64:12 83:1 102:20 145:5 212:11 220:15 264:1,15 293:16	Lisa 2:14 12:10 139:10 145:11 210:12 216:9 217:22 219:10	live 8:1 11:17 156:3 189:5 261:12	logo 281:14	lose 157:4
lies 175:19	list 12:12 13:20 22:11 23:21 29:12 29:14 31:19,21 35:7,16 37:8,14 42:7 43:8,9,12 44:12 45:14 46:8 60:14 90:1 108:1 119:11 148:6 155:4,11 210:20 210:22 212:7 216:16,21,21,22 223:16 232:19 233:21 235:12,13 235:14 237:22 239:20 262:3 267:4,5,13 268:1 273:10 274:7,10 274:12 279:17 307:9	liveable 150:21	Lohmann 255:9	losing 122:17 123:12,13 125:18 132:21 135:11
life 11:19 14:16 40:21 101:11 104:21 105:11 117:1,5 125:20 258:8,14,15,17,18 258:20 261:10 266:8 272:15 288:17 289:10	listened 285:18	liver 198:1	long 20:9 32:3 40:20 41:6,19 51:6 120:19 124:7 127:12 129:3 130:20 151:9 178:22 180:2 188:20 189:17 191:13 226:1,18 266:14 300:14	loss 60:3
light 5:21,21 6:1,4 9:9 84:18 120:5 195:4 256:4	listening 11:7 175:2 180:13	lives 251:11 258:5	longer 89:8 99:14 150:17 175:8 183:13 267:1	losses 138:20
lightly 182:17 186:15 188:13	listing 19:8 212:3 269:3 307:11	livestock 3:10 6:21 7:17 8:2,22 10:2 10:10,17 11:3 22:10 24:11 31:15 40:4,9 77:19 79:7 107:6,10,12,14 108:1 122:5,11 124:8 210:8,16,21 211:10,12 216:13 217:3,17 219:3,22 230:8 232:1,7 234:9 238:6,10,10 238:13 241:16 242:16 243:6,17 244:6 262:7 265:4 265:14,17 266:3 268:22 270:5,17 270:18 271:5,12 272:2,4,14 280:6 286:7 292:5 293:21,22 294:15 295:2,18 299:1 300:16 301:22 305:4 309:14 313:15	long-term 136:12 136:18 141:14	lost 45:9 60:4 132:21 181:4 244:21 275:13
lights 5:20	lists 212:22	load 201:18	look 11:7 17:1 44:2 44:9 46:6 66:17 67:16,19 90:12 102:14 131:9 156:6 167:12 185:1 194:3 207:8 214:5 215:13 222:16,17 236:7 236:10 260:7,8 262:10 263:8 275:15,22 280:10 280:12 292:19 299:7,15 300:18	lot 14:8,15,18 21:12 28:21 29:13 32:10 33:13 38:21 41:6 44:2,9 47:22 48:5 49:16 52:3 52:16 53:8 88:11 96:19 97:17 98:12 122:11 141:8 165:22 167:11,13 167:14 189:18 193:17 206:18 207:4,10 208:18 209:5,14 218:8 258:20 260:4,5 278:16 280:13 282:6 283:4 285:5 308:19,22 309:2,6 309:7,10
liked 98:3	literacy 28:5 29:4 39:18 57:8 62:4	loads 126:12,13 128:10 132:2,12	looked 36:10 41:16 43:5 84:13 130:19 141:6 162:19 197:12 221:22 222:5 226:5 293:6 295:5 297:14,22 298:9	lotions 111:20
limit 92:6 132:10 180:3 200:16			looking 4:8 27:12	lots 28:22 29:1 48:13 119:15,16 273:7
limited 41:21 94:10 126:4 132:15 276:18 308:13				loud 6:5
limiting 132:10				loudly 234:15
line 54:7 137:22 147:20 150:12 152:13 207:22 214:6 276:13,15 282:5				love 121:1 230:5 252:22 290:3
lines 205:13 239:8				

loved 50:7	maintained 45:1	271:3	mark 2:18 3:7	matching 247:1
low 212:10 294:18	maintenance	mandated 312:16	17:20 18:1 21:14	material 31:20
302:12	205:13 281:6	mandatory 112:3	28:6 47:5 48:17	64:18 81:14 90:1
lower 247:20	287:4 289:19	249:20	48:18 49:3,6,10	90:5 111:3 112:14
low-cost 208:12	major 4:13 38:7	Manhattan 247:20	50:15 52:9 54:21	114:16 157:9,18
304:11	72:9 178:7 206:15	248:16	69:3,3,10 70:19	165:8 166:3,4,14
low-risk 301:8,15	243:16 253:2	manifest 81:5	71:5 75:6,6,8,9	185:9 186:21
304:11	301:10	manifestations	79:1 81:20 87:13	211:2,3,15,21
low-tech 6:6	majority 124:20	66:3	246:11	213:18 275:10,11
luck 55:18	154:21 224:6	manner 44:20	market 9:21 23:14	302:9,17 303:7
lunch 169:8 272:13	299:18	171:20 177:9	34:3,7 38:14 42:1	304:10,14 307:10
lysine 222:11	maker 111:15	181:9	42:5 60:3 74:7	308:7,8,10,16,20
285:13	makers 112:8	manual 275:21	77:5 114:8 122:17	309:11,18 310:4
L-methionine	163:6 164:11	manufacture 43:22	133:11 199:10	310:19 312:6,22
195:19 197:9,10	makeup 256:1	44:18 81:3 111:19	204:16 219:5	materials 7:4,6
197:11,14,20	making 32:21	196:5 255:12	221:9 222:10	9:13 10:18 35:16
198:2 201:22	37:13 38:8 49:20	manufacturer	287:2 297:8	40:17 43:16 44:7
202:9 223:13	58:13 82:15 97:15	157:11 292:22	marketability	65:1,13,22 84:15
225:2	112:9 114:19	manufacturers	200:17	85:18 86:3,8
	127:19 133:18	222:14 237:3	marketable 200:11	89:10 107:21
	184:22 198:15	239:4 275:10	marketed 181:18	108:2 110:20
M	218:20 255:9	280:20	196:16 198:18	113:16 149:11,16
Mac 1:21 7:14	281:17 300:11,12	manufacturer's	199:17,18 200:3	150:6 155:3 161:8
103:3 110:6,7	malaria 293:15	185:11	201:4	161:14,20 166:10
218:1 227:18	malaria-carrying	manufacturing	marketers 262:21	166:11 167:5
251:17,19 252:21	293:6,9,12	45:20 177:16	marketing 1:1 2:16	173:2 213:8 221:8
272:11 285:10	males 261:8	225:21 267:7	50:12 64:4 119:5	230:4 267:4
290:8	Maltby 121:16,16	289:8	162:17 177:11	277:12,18 278:20
macro 77:20 229:4	mammalian 107:13	manure 127:19,20	243:12 287:8,9	279:17 282:2
macroeconomics	265:10 266:11	map 47:12	marketplace 28:16	297:1 298:4
76:4	mammals 117:3	Maple 10:8	94:22 112:11	304:12 309:7
Mad 265:19	man 71:8 292:9	mapping 66:22	114:11 250:10	312:12,13
made-with 33:3	managed 101:11	67:7	267:17	matrix 31:12 39:14
201:12 203:5,7,8	104:20 244:14	maps 67:2	markets 34:6 38:15	44:10 117:14
203:12,15,17	272:17	Maravell 1:19 6:19	38:16 183:13	120:12
282:6	management 53:9	6:20 91:19 94:7	married 106:9	matter 15:11 25:16
Madison 131:6	59:17 121:22	94:15 104:9,13	Martex-patented	27:7 70:2,11
magazine 151:7	132:3,8 149:20	105:13 106:1	162:6	80:22 110:15
maggots 228:12	213:12 247:15,17	131:20 190:5	Maryland 6:21	122:22 131:11
Magic 111:13	248:18 250:12	231:16 237:10	189:5 194:2	169:10 177:3
mailed 194:9	298:8,11 303:10	306:17 314:7	mask 296:12	240:19 242:5
main 66:12,21	312:10	March 189:3	mass 114:7 122:2	304:20 308:4
112:12 114:14	manager 9:4 12:12	margin 161:20	Massachusetts	312:22 315:13
195:17 214:11	262:5	marginally 308:20	121:21 156:4	maximize 142:14
mainstream 120:4	manages 220:8	margins 245:12	160:14	maximum 258:8,11
maintain 116:16	managing 102:10	marijuana 193:15	match 60:19 76:21	258:12 264:1,5
128:4 232:14	mandate 251:3	193:16	163:21 246:5	McEVOY 2:8 3:6
281:7				

12:2,5,6 17:17 20:6 48:10 69:16 272:21 276:7 meal 99:11,18 102:22 137:18,19 137:20 226:21 229:11 259:13,16 260:3 263:8,9,11 266:4 280:21 281:1 282:14,15 285:19 290:22 meals 283:1 mean 92:3 119:14 160:1 177:22 186:8 187:2 189:14 200:13 208:5 213:22 215:7 230:3 270:21 271:6 283:22 289:13 290:15 291:11 300:20 301:4 310:11 meaning 156:16 meaningful 72:22 means 54:18 62:17 93:20 120:13 127:18 139:16 150:20 230:6 245:5 255:21 256:6 265:10 303:14 measurable 168:9 168:14,15,19 measure 26:5 59:9 59:10 91:22 97:11 measured 214:1 measures 138:21 meat 8:3 99:1 131:22 137:17 220:3 223:22 224:9,12,16,17 226:7 227:13,14 227:20 262:10 266:7,9 282:18 285:15 meats 289:7	meat-eaters 220:1 mechanisms 33:22 media 91:2 medical 154:6,17 medicine 151:10,14 152:22 154:4,8,8 154:11 254:6 meet 16:20 25:15 25:21 26:9,14 31:4 46:9 83:21 93:16 94:4 124:4 176:15 263:20 264:6,15 266:2 283:17 286:2 meeting 1:4 4:4,6 4:14 11:15 14:5 15:7 17:7,9,15,16 18:1,13,15 19:19 20:8,18 31:5 55:19 68:22 80:7 82:2,20 85:16 87:3 90:7 99:22 103:8 120:15 123:3 125:14 161:21 174:18 176:3 179:11,16 179:17 180:4 195:14 202:19 204:8 205:4 217:9 218:12,15 234:11 234:13 242:1,9 245:6 248:9 249:7 249:8 254:21 264:15 281:16 297:10 meetings 13:12 14:8,19 16:5,19 20:11,19,21 21:3 21:4 97:14 100:10 135:10 144:13,19 meets 113:12,17 114:3 Melissa 2:12 12:14 40:3 122:7 231:8 241:3 member 15:13 19:11,12,14 50:11	51:3 106:10 151:16 160:5,19 164:17 168:11 174:8,17 175:3,10 180:16 207:18 231:15,16 265:3 303:21 members 1:13 5:7 6:10 13:6 15:9,10 15:20 18:21,22 19:9,21 30:5,7,12 49:9 50:2,22 51:10 56:22 63:8 65:5 70:4 78:5 80:15 88:6 113:19 122:20 125:4 135:9 143:5 147:2 170:18 173:4 178:20 180:6 195:12 199:1 213:16 221:21 242:14 254:1 277:8 305:1,2 memo 86:15 memory 215:19 mention 60:22 246:19 255:11,15 256:9 mentioned 14:4 56:6 57:11 59:12 62:2 75:15 79:7 82:1 88:19 142:6 298:2 303:19 mentors 149:21 Merrigan 21:16 50:9,21 51:1 87:15 message 65:11 met 26:2 45:12 208:6 255:3 287:22 288:2 Metabolic 153:20 metals 45:22 meta-analyses 162:18 Metheny 155:21 156:2,3 159:17,20	160:1,6 methionine 3:16 39:8 101:17,19 102:2,3,20 103:7 103:21 107:15 137:5,9,16 138:2 195:16 198:7 199:5,6 200:8 201:10 223:8,14 224:15,22 225:18 226:4 227:11,16 252:12,13,16 257:18 258:1,5,6 258:13,18 259:3,6 259:17 260:11 263:19 264:1,11 264:14,16 265:8 266:18,20,22 285:12 290:17 methionines 225:7 method 26:4 240:18 276:11 methodology 167:17 methods 33:6 46:19,21 94:3 181:8 182:3 225:2 233:7,9,17 234:8 235:4,17,21,22 236:8,18 237:2 239:10,10 240:2,8 269:6 Mexico 107:3 mice 154:1 Michelle 2:10 5:3,4 5:12 6:10 13:1 70:16 153:3 169:6 210:5 315:9 microphone 75:13 mid 27:22 Midwest 245:1 264:21 265:2 mid-Atlantic 248:3 Miles 2:8 3:6 12:2 12:4,5 17:17 18:3 20:4 49:8 57:8 65:20 69:21 70:5	70:7 87:13 122:7 180:11 244:18 272:20 276:4,6 277:14 278:21 284:3 Miles's 62:5 milk 8:5 34:17 37:3 42:1 77:3,5 84:19 92:19 124:19 126:18 127:3 129:1,2 131:17 163:8,11,15,15,19 164:12 196:8,11 212:11 245:15 million 54:19 57:11 58:19 59:4 76:17 206:7 246:8 262:14,15,16 277:17 millions 128:3 mills 243:16 244:6 mimic 164:11 mind 198:18 259:14 minerals 24:8 39:6 41:13 221:7 287:3 288:16 291:7 minimal 147:16 299:12 308:9 minimize 100:18 299:22 minimizing 303:15 minimum 176:18 Minnesota 269:8 minor 238:7 minute 6:1,3 minutes 5:22 70:1 74:19 175:9 179:21 241:15 275:20 mirror 94:10 misleads 163:9 missed 18:2 228:7 310:17 missing 20:3 108:8 mission 13:14,15 151:12
--	--	--	--	---

missions 83:3	202:19 261:12	72:13	156:1 160:11,13	116:1,14,17,18
mistake 86:4,9	301:3	moves 63:16	164:21,22 174:10	117:5,8,14,19
mistakenly 5:8	moral 133:3,4	103:17	180:20,22 191:8	120:10 132:5
misuse 43:22	morning 4:3 6:13	moving 15:7 29:11	191:10 195:8	137:16,21 138:8
mis-marketing	6:19 7:2,9 8:8,18	30:17 63:18 69:8	204:3,6 211:7	148:4 150:20
201:17	9:2 10:4 12:9,13	102:9 109:10	242:22 243:1,3	163:10 164:9
mitigation 138:21	12:17,20 20:6	122:12 124:12	247:11,14 253:19	196:18,21 202:13
209:6,10	49:8,9 52:11	170:16 230:21	254:2 255:13,15	224:3 225:2,7,21
mix 292:4	98:16,20 106:6	278:8 297:7	262:4 276:20	227:11,16 230:3
mixed 224:5	116:3 134:10,13	mulch 84:3 109:1,2	286:10 291:19,21	263:18 264:11
227:11	146:20 160:12	134:16 135:21	300:7	266:7,8 280:5
mixing 142:13	169:7,8 174:20	136:1,2,11,19	names 114:13	282:9,13 283:16
mixtures 84:15	235:19 244:18	141:21 150:10	135:18 231:4	286:15 292:7,10
mode 43:17 79:21	247:19 272:22	158:21 182:4,6,8	255:11 256:9	293:2 301:8,15
model 76:15	277:14 278:22	182:13 183:16	name's 10:22 125:7	304:10
models 149:21	315:11	184:1,5,10,14	276:22	naturally 163:7
152:16 153:9	mortality 293:8	185:22 186:5,14	narrative 66:13,18	177:8 197:15
154:19	MOSES 264:22	187:3,7,11,17	narrow 281:5	302:4,18
modified 113:20	265:3 271:19	189:10,15 190:2	NAS 60:9	naturals 225:7
173:6,12	mosquitoes 293:6	190:20 192:4,15	nas.usda.gov 60:10	nature 313:13
modify 235:5	293:10,12 301:22	274:17	national 1:2,4,10	nature's 98:18 99:9
modules 35:14	mother 8:1 118:17	mulches 109:8	2:8,13,14 3:5,6	281:14
64:10 65:1	178:14	136:9 140:1,16	4:5 12:6,11,11,15	NCAT 31:8,16
Mohamed 247:12	mothers 92:19	183:2	12:22 13:13,18	nearly 51:4 112:1,7
253:18 254:2	94:18 95:6 163:9	Mullens 296:15	17:19 18:16 19:7	131:12 162:14,16
263:10	164:8,13	304:1	19:15 20:17 21:10	176:1 246:13,14
moisture 142:11	mother's 92:19	multiple 145:17	21:19,22 22:7,11	Nebraska 298:20
183:18	motion 212:3 305:9	multi-ingredient	22:13 23:3,21	necessarily 63:22
moisturizing	305:14,16,16,17	170:2 171:18	35:16 36:5,14,20	79:18 214:8 229:1
112:13 113:15	305:22 306:2,9,13	172:8	37:8,14 42:11	231:22 266:11
114:15	307:9,12,18,19,20	mushrooms 24:13	43:8,9,10,12 46:8	270:13
moment 174:11	motions 306:7	mysterious 32:3	47:19 49:12 53:2	necessary 15:6
229:18	motivated 249:6	mystery 209:20	53:6,17 59:13	16:6 42:22 53:11
moments 70:3	motivation 150:1	M.D 153:6	62:11 68:3 71:12	59:18 85:9 88:2
MONDAY 1:7	Mousa 247:12		80:2 86:22 95:22	124:1 142:12
money 58:20 88:5	253:21 254:2	N	108:1 148:6,20	157:14 171:21
193:17	257:17,20 258:2	name 6:20 7:14 8:8	150:4 153:3 163:2	176:14 189:17
monitor 104:5	260:20 261:22	8:18 9:2,8,19 10:5	196:14 210:20,22	200:1 271:16
monitoring 138:20	Mouse 153:20	10:14 13:2 33:2	216:21,22 232:19	288:16 292:12
monolithic 240:17	move 17:3 76:6,6	40:12 67:10 68:16	233:20 237:21	necessity 170:21
Montana 11:17	87:19 108:13	71:5 82:8,10	238:20 250:16	178:14 288:20
12:1	134:1 140:8	86:21 98:14 106:6	267:4,10 274:6	need 14:19 16:14
month 34:12 49:10	141:10 143:8	111:8,11 114:3	277:2	16:15 19:18 38:3
months 32:1 40:15	172:4 210:8 223:1	115:3,19 121:14	nation's 111:16	46:6 73:11 80:3
42:3 140:3,3,4,10	267:11	121:16 125:6	natural 43:2 44:16	84:9 90:6,11
142:7 176:1 184:6	moved 153:9	134:9,11 146:18	88:17 107:17	102:20 103:9,15
189:4 196:12	movement 51:17	146:21 151:4,5	111:16 114:11	120:12 143:10

156:22 168:6	299:5 308:4,4	214:7 215:17	275:21	NOSB's 134:19
172:6 194:4 197:8	net 109:9	241:20,22 268:3	NOP's 38:7 88:6	135:7
207:11 221:12,17	never 51:15 70:6	292:1 294:5,9,11	99:13	notable 57:7
222:2 227:15	81:5 122:6 190:13	300:16 301:18	NOP-certified	note 66:18 234:1
229:21 230:12	271:22 309:11	305:7,17 306:3,14	111:18	noted 92:15 97:3
236:3,5 241:15	never-ending 51:22	307:12 314:3	NOP-listed 205:9	284:9
244:20 256:22	new 5:15 20:7,8	non-GMO 151:11	normal 302:21	notes 18:3 215:14
258:12,21,22	28:1,7 51:19,19	192:17 233:13	normally 292:8	noticed 91:19
259:3,4 262:16	54:9 59:13 63:2	non-irrigated 27:6	Norman 180:22	284:8 285:7
263:19 266:1	73:13 74:18 76:10	non-organic 46:17	181:1 185:4,15	noticing 162:2
269:20 270:15	85:22 90:10 102:8	83:22 113:16	187:1 188:3,9	notifications 45:15
278:20 279:15	130:17 137:11	114:16 127:10	189:1,14 190:14	notion 196:1
285:12 287:11,11	150:9 151:7 164:8	130:3 148:13	191:6,10,11	notorious 196:6
287:17 288:2	195:13 197:8	non-plant 272:15	North 107:1	November 40:1
289:5 306:11	202:19 206:5	non-profit 106:17	northeast 121:17	189:2
308:11 310:15,18	211:11 249:4	156:6 214:20	124:19,20,21	NRCS 49:5
310:21 311:6,18	264:13 268:13	non-synthetic	133:8,18 244:7	NSF 114:5,14
313:19	300:17 301:4	148:13 149:9	northern 132:16	nuances 235:8
needed 20:1 94:6	Newfoundlands	167:7 202:12	Northwest 27:22	nuggets 246:12
97:22 98:4 132:6	280:15	266:17,21	nos 315:6	number 25:10
136:15 139:1	newly 7:12	non-target 311:12	NOSB 1:5 21:13	26:20 28:4,14
140:8 141:14	news 51:22 245:22	noodled 278:6	24:1 30:5 31:13	32:9,12 34:6
183:17 200:10	newsletter 28:9	NOP 1:2 5:7 12:8	34:15 37:9 41:2	35:14 38:12 41:21
234:17 237:19	nice 38:1 71:3	21:2 43:11 49:1	42:9 43:13 50:11	54:2 56:9,16 57:4
281:7 287:3	288:4 295:3	50:3,5 73:15	50:21 51:3,10,22	66:13 111:17
288:13	nicely 165:21	78:10 79:15 80:19	71:20 72:1 73:10	125:21 130:10
needs 15:19 70:17	niche 283:15	83:1,11 85:6,16	73:11,12 74:3	140:1 141:22
92:9 93:16 101:8	NICHOLAS 1:19	86:4 87:13,17	79:16 80:15,21	143:4 150:18
102:11 105:11	Nick 6:20 91:18	88:5,7 99:5 101:9	83:1,8,10,13 85:6	160:17 224:14
117:11,18 119:1	94:6 131:19	102:6 105:1,4	86:1 88:7 98:22	235:7 237:1
123:21 129:3	231:16 237:7	112:2,2,19,21	102:18 108:2	254:12 257:1
163:18 263:21	241:6,10 314:6	113:12 114:1,17	115:8 116:21	numbers 63:12
264:6 275:11	nine 33:16	114:21 115:6,11	120:15 122:6	309:19
negative 84:18	nineteen 288:21	116:5 117:8,13	130:19 136:7	numerical 56:8
213:3,5 227:12	nine-carbon 212:9	120:10,16 121:1	142:20 144:11	numerous 25:2
228:11 298:2	nitrate 24:8 39:5	123:8 135:4,10	147:18 154:22	31:2 107:8
negatively 136:13	268:6	138:7 147:18	166:1,6,19,20	nutrient 93:16
neighbor 192:14	NOC 88:4 265:3	148:11 149:12	174:16 175:11,22	117:6 265:11
neighborhood	NODPA 123:3	167:16 170:14	178:5 180:4,8	281:17
193:14	non 100:1 109:4	171:16 172:2,5,11	185:7 231:17	nutrients 45:10
nematode 128:8	167:7 192:12	180:10 183:6	233:21 234:2,7,22	90:16 149:9
294:10	233:14 245:11	211:13 217:7	239:1 245:6 251:5	158:21 159:1
nematodes 213:4	265:6	231:9 234:6 237:3	251:12 253:22	163:16,17 219:13
214:7,9,10 215:3	nonanoate 204:9	244:19 251:6,12	258:16 267:9,11	278:10
215:6,15,16,17,21	nonanoic 3:14	251:14 254:1	268:12,17 275:20	nutrition 149:4,5
216:1,2,4,7 294:6	210:13,16,19	266:5 267:3,13,22	277:8 278:7,7	154:16 177:8
297:16 298:3	211:20,22 212:4	268:1 269:2	279:16	196:8 279:13

nutritional 41:15 44:22 103:8 152:12 200:9 263:21 264:6	249:17 Office 18:17 36:19 37:15 56:19 officer 80:14 offices 62:16 65:3 officials 220:8 OFPA 42:15,19 85:11 147:17 148:7 149:12 180:8 301:16 311:9,19	265:6 omnivores 224:3 266:6 OMRI-listed 110:21 onboard 15:4 once 120:17 180:12 240:15 ones 16:18 27:12 36:15 56:16 216:5 269:17,18 282:4	opinion 144:5 148:6,17 155:5 159:16 177:21 179:19 193:1 270:9 271:18 299:2 opinions 147:7 175:15 opportunistic 266:10 opportunities 28:8 28:15 249:4 opportunity 80:18 122:7 169:17 174:6 251:13 313:10 oppose 195:15 opposed 102:15 214:20 275:5 opposition 195:13 OPs 293:20 optimal 142:5,9,10 149:4 optimum 289:10 option 29:7 90:20 149:1 172:18 309:3 options 83:19 172:21 263:15 266:18 oral 180:1 orange 6:1 oranges 212:11 orchard 8:21 order 3:2 4:4 59:18 147:21 178:21 190:1 242:9 266:2 286:2 organic 1:2,4,10 2:9,13,15,18 3:5,6 3:7 4:5,12 6:20 7:12,19,21 8:5,7 9:3,17 10:7,9 11:8 11:21 12:7,11,15 12:22 13:13,18,20 14:14,17 17:19,20 18:10,16 19:7,15	20:14,17 21:11,19 21:20,22 22:1,3,4 22:7,13,18 23:3,8 23:11 26:7,13 28:5,8,10,16,20 29:1,4,5,7 31:9 32:21 33:3,15,20 34:2 36:4,21 38:13 39:15,17 40:11,12,12,16,19 41:8 42:11,17 43:4,10 44:15,17 44:21 47:5,9 48:19,22 49:11,12 49:17 50:10 51:12 51:13,17,18 52:10 52:14 53:3,6,12 53:17,21 54:5,21 55:3,11,17 56:4,9 56:15,17,21 57:1 57:7,12 58:2,7,10 59:3,7,15,20 60:1 60:4,13,15,18 62:1,3,8,11,16,18 63:2,5,17,20 64:1 64:11,21 65:5,9 65:12,16,21 66:3 66:19,19 67:6,9 67:13 68:3 71:12 71:18 72:12,18,20 73:6 74:13,17,20 74:22 76:14 77:1 77:8,19 80:2 81:9 82:15 83:15 84:1 84:12,16,18 85:9 85:11 87:1,9,10 87:16 88:14,18,18 88:21 89:9,14,15 90:22 91:3,6,9,21 92:4,7,13,18 93:3 93:6,10,14,19,21 94:1,3,8,9,14,18 95:2 96:1 98:18 99:1,6,7,10 100:1 100:14,19,20,22 106:22 107:14 108:12,15,21
O				
O 55:1 oak 119:13,15 Oberem 303:20 object 59:16 objective 72:1 176:16 obligation 15:1 obnoxiously 6:5 observations 243:9 obtain 252:16 266:11 obtained 197:16 254:8 256:7 obvious 123:5 185:17 obviously 49:16 76:3 88:8 115:5 191:13 212:12,15 219:22 223:6 224:18 225:13 234:3 236:13,21 occasion 50:19 occasionally 63:19 occurring 163:8 247:2 302:18 occurs 136:4 212:10 Ocean 4:9 ocean's 263:14 OCIA 181:11 October 1:8 20:15 53:5 101:18 183:22 277:9 odor 296:6,10,13 offer 4:21 100:5 243:10 301:1 offers 182:13	oh 75:7 188:3 271:9 273:11 314:21 OIG 34:17 37:3,8 38:1 42:1 oil 163:13 295:2 296:5,16 oils 111:19 161:22 302:19 oily 295:3 okay 17:3 20:6 21:5 28:3 29:11 32:5 47:4 48:10,16,17 55:21 82:10 105:5 168:21 174:14 179:6 192:6 201:5 216:9 241:13,14 242:8,19 247:8 256:17 261:21 262:2 270:20 272:18 274:7 282:8 286:4 287:16 301:16 304:16 306:10 OI 222:4 old 118:19 166:21 289:14 299:6 oldest 106:21 Oleochemicals 300:10 omnivore 3:15 84:20 101:17 102:19 103:16 107:11 134:16 137:4 223:2,5,19 224:1 251:16 253:13 262:8	One's 66:13 one-hundredth 102:5 one-sixth 33:4 one-tenth 102:3 one-third 32:22 ongoing 230:18 on-deck 70:21 opaque 135:1 open 3:9 110:4 190:1 241:9 opened 32:5 127:5 opening 54:9 211:14 217:8 openly 182:17 operate 8:2 18:15 18:19 22:16 73:21 operated 79:20 181:6,7 operation 8:3,10 190:12 246:20 247:2 operational 108:20 124:13 operations 22:18 25:15 26:7 28:15 29:13,15,17 31:10 32:20 33:18 34:14 35:18 42:8 54:2 105:4 107:2 168:6 243:11 244:5 262:5 operator 117:22 245:14 operators 116:16 117:18 118:10		

109:3,5 111:19	200:17,22,22	76:10 114:2,12	outside 74:1,13	paid 60:6 96:17
112:4,9,11,12,14	201:4,19 202:1,2	156:8,10 157:3	83:10 85:3 135:3	painful 95:1
113:6,12,14,22,22	202:10,11,14,17	181:14 283:15	148:19 246:22	painted 206:6
114:2,4,9,20	202:20 203:3,3,9	organic-approved	outstanding 137:1	palmitate 161:5
115:1,2 116:6,13	203:13 204:18,22	226:7	outward 63:18	panel 80:11
118:20 119:1,5	206:12 207:1,6	organic-related	out-of-date 89:10	panels 38:1 78:2
120:3 121:18,19	208:7,7,11,14	29:5	overall 109:21	paper 84:13 148:2
121:21 122:15	209:12 210:21	organisms 85:12	267:19 268:4	Paraguay 118:20
123:11,12,13,18	217:1 218:22	297:17 311:11	overcome 104:4	parallel 278:21
123:22 124:4,6,14	219:1 220:21	organization 64:6	overlap 67:11	parameters 240:20
124:16,18,19	221:6 222:2,10	82:9 86:21 98:15	overlaps 46:7	parasite 126:12,13
125:14,21 126:2,3	223:22 224:9,10	106:17 109:19	overly 149:13	127:22 128:3,10
126:9 127:10,11	224:12 226:12,13	111:9 115:19	overnight 124:11	128:10 132:2,12
130:6,6,8 132:17	226:14,16 227:22	121:15 141:4,6	162:4	parasites 127:14
133:17 135:22	232:6 233:10,15	organizations	overseen 253:5	128:5,19 129:20
137:5,9,11,17,21	235:15 238:9,20	31:20 150:17	oversees 253:3	parasitization
138:2,16 143:10	243:21 244:7,11	organization's	oversight 22:15	126:6
148:11,15,20	244:17,22 245:5	139:9	35:20 90:11	parasitized 127:11
149:19 150:3,3,4	246:9,10,12	organized 63:15	overview 21:10	parasitologist
150:13,16,19	248:10 249:2,3,6	174:22	42:9	131:13
151:11 156:12,16	250:1 251:7,10,11	organophosphate	overwhelming	Pardon 290:20
156:18,20 157:7	259:15,20 262:10	295:20 297:4	122:13	parents 149:1
158:5,8,14,16	263:5,21 264:21	organophosphates	overwhelmingly	178:11 196:22
159:16,18,21	264:21 265:1,14	293:3	224:19	197:5,11 198:8,13
161:1,2,10 164:4	265:17,21 266:3,5	origin 24:11 40:4,9	overzealous 148:16	part 14:14 23:4
164:7,7 165:1,9	267:8,10,16,19	122:5,11	over-wintered	25:3,3 28:18
165:17 166:3	268:21,22 269:10	original 151:18	128:19	29:10 30:2 31:4
167:18,19 169:22	269:21 270:6,14	274:3	ovo 101:5,14	33:15 41:5,18
170:2 171:17,19	270:21 271:20	originally 174:20	104:17 105:7,9,18	42:1 48:1 50:5
172:8 173:7,19,20	277:10,13,16	191:18	260:20 261:6,9,18	54:4 65:13,14
174:15 176:10,16	278:2 280:22	ornamental 204:17	owe 5:8 315:2	66:21 68:16 86:4
176:21 177:5,7,10	281:5 282:15	205:10 207:22	o'clock 169:9	86:10 113:18
177:12,14,20,20	283:5 285:4	OSEC-MRP 2:20	315:11	116:6,15 121:9
178:11,15 181:8	287:14,14,18,20	3:8	O'Neil 134:10,11	125:8,19 126:8
181:10 183:12	288:11 290:11,19	OTA 165:14,19	139:19 141:20	135:12 165:11
191:15,19,21	290:22,22 291:2	outbreak 100:21	145:9 146:16	166:22 190:16,17
192:7,16 193:7,8	293:22 298:5	outcry 309:18,22		192:5,11 196:15
193:11,19 194:1,4	300:19 301:17	outdoor 74:2,4	P	200:9 209:17
194:6,7,12,22	302:20 303:1,22	227:22	pace 71:3 244:19	219:18 220:2
195:11,14,15,20	304:13 308:22,22	outdoors 73:20	pack 8:11 248:19	239:3 257:6 272:2
195:22 196:3,14	309:20 310:22	outfits 76:17	package 177:2	295:2 302:20
196:16,18,19,21	organically 46:4	outline 86:6	packaging 177:16	303:3 313:8
197:3,5,8,9,13,16	104:22 122:1	outreach 28:14	packing 206:20	partial 193:20
198:3,5,10,11,13	137:18 141:5	35:15 65:1,6	paddocks 133:19	participant 11:3
198:18,20,21	193:13 272:6,7,16	outright 112:9	133:20	participate 5:10
199:8,12,14,15,17	organics 14:9	113:11,22 114:9	page 55:9 167:21	250:2
199:18,22 200:4,4	23:17 72:7 74:7	114:20 115:2	pages 60:10	participated 53:7

165:19 168:2	222:1,13	94:9 106:9 224:8	permitting 108:18	petition 46:11
participating 91:12	pay 158:5 268:5	percent 25:16 27:8	perplexed 134:21	131:5 136:22
participation 68:4	paycheck 80:21	27:8 30:21 32:6	persistence 43:19	144:7,15 148:5
180:9	paying 80:21	34:13 54:1 55:2	persistent 308:12	204:14 210:13,15
particular 22:14	payout 60:2	56:10 71:15 74:1	person 70:22 71:1	210:18 211:5,9,13
42:6 69:18 152:18	PE 182:6,8	101:22 102:2,4,5	80:17 178:7 193:6	212:21 216:10,13
237:18	pears 8:12	102:15 103:21	255:11 259:14	216:14,17,18,20
particularly 96:21	pecan 8:21	110:9 140:13	personal 111:21	217:3,6,11,12,13
156:11 224:7	PECs 132:19	142:21 148:13,15	112:3,8 113:1,9	217:15,16 218:4
269:14 280:21	pediatrician	148:18 162:12,15	113:11 114:19	218:21 238:3,4
308:7	176:13	182:2 183:11	147:7 148:17	264:13 279:19,20
partners 147:7	Pediatrics 200:7	188:11 203:9,10	personally 51:10	291:22 300:15
247:22	peer 36:2,3,8,9,16	223:22 246:13	248:17	314:3 315:6
partnership 39:16	154:13	254:12,15 259:5,7	personnel 100:6	petitioned 210:17
42:4	peers 146:11,12	259:8 262:10	perspective 79:5	211:6 219:11
partook 165:13	peer-reviewed	277:17 282:20	141:16 144:6	279:18 297:3
parts 59:9 66:12	152:14 153:13	291:7,8 293:9	165:3 236:12,14	305:18
204:16 257:18	peg 278:15	percentage 172:8	281:19	petitioner 204:9
302:3	pelargonic 3:14	percentages 170:1	pertaining 170:7	211:16 217:19
party 192:8 217:4	211:8	171:17	pertinent 55:3	petitions 37:12,22
passed 61:9 82:21	penalties 23:2	perceptible 296:7	pest 233:2 303:10	43:6 157:17 161:5
234:22	33:14,16	perception 88:13	312:12	164:15
passing 252:18	penalty 23:14	126:9 226:10	pesticide 269:9	petrochemical
passion 14:9	31:12 39:14	228:6,11	297:19	112:15 302:6
286:19 288:6,8	117:14 120:11	perches 118:13	pesticides 7:3 35:7	petrochemical-b...
pastoral 246:5	pending 39:5 85:21	perfect 132:4 309:6	82:12 295:20,21	136:2 141:9
pasture 24:6,18,20	Pennsylvania	313:20	pesticide-free	petroleum-based
25:1,1,9,12,13,14	247:16 249:12	perfectly 275:3	151:12	143:9
25:16,21 26:2,11	people 4:15 16:8,9	perform 171:19	pests 303:15	pets 41:13,15 149:7
26:15 27:7 39:13	16:10 20:20 22:1	performed 153:19	pet 3:14 24:13 40:4	279:13 280:3
72:22 102:12	22:4 28:11 32:21	183:17 185:18	40:9,19 41:8	284:12 287:15,19
122:10 127:20	38:10 47:16 51:17	period 27:13 70:9	46:14 107:20,21	287:21 296:11
128:1,2,18 269:18	57:19 62:1,9	70:16 122:13	108:2 159:1	pH 256:12
pastures 128:20	63:11 64:6 155:7	141:11 189:18	216:10,15,19	phase 37:3
pasture-based 26:5	159:5 174:12	211:15 217:8	217:1,12 218:1,22	phenomena 260:3
26:8	176:14 181:16	periodic 23:16 35:3	219:10,14,21	Phenotyping
Pat 169:14,15	192:21 205:7	39:12	221:22 222:3,3,4	153:20
174:8,9	226:17 227:22	permanently 138:1	267:2,8 277:4,13	Philadelphia
patent 255:13	230:1,11,12 231:5	143:7	277:13,16 278:2,5	248:15
path 147:13 276:12	231:13 232:4	permethrin-type	279:1,7 281:6	phone 5:8 63:12
286:1	254:11 271:1	295:21	285:5 288:6,11	256:22
pathogens 284:14	287:7,14 288:1	permission 15:14	289:19,21	phones 5:5
pathways 152:18	301:6 304:3 309:7	255:10,15 256:9	Petaluma 246:20	phosphate 109:12
154:20	309:19 313:10	permits 42:19	Peter 303:19	158:20
Patricia 169:18	PEQAP 249:16	301:17	Petersman 291:20	phrase 229:15
231:13	250:3	permitted 31:19,21	Peterson 300:9,10	physical 63:11
pattern 124:10	perceived 88:17	40:17 212:22	PetGuard 286:13	physician 154:9

prefer 132:8 199:22	103:20 159:14 188:4 204:20	probability 43:21	163:20	244:6 262:21
preferable 136:2 310:3	224:11 225:16 226:15 238:12	probably 11:19 18:9 81:5 84:3	processes 30:16 83:5 117:5 130:7	264:3,12 293:21
preferably 267:5	246:3 277:19	159:6 183:21 186:7 191:2	138:10 145:6	308:19,22 309:2
preliminary 139:12 139:21 142:7	307:22 308:16 310:3,5	201:15 202:10 215:13 229:21	processing 44:14 45:9 46:18 150:3	309:10,13,14,20
prepared 70:18 305:14,15 306:4 306:13	prevent 75:3 85:13 97:16	249:2 274:13 277:7 281:15	176:18 177:10 206:20	313:13
preponderance 227:12	prevented 243:22	probation 245:18	processors 54:6 58:18 249:18	producer-by-pro... 27:11
prescriptive 149:13	preventing 73:13	probiotics 163:20	process-aware 83:2	produces 80:13 154:18
presence 68:6 99:3	prevention 173:18	problem 77:7,21 189:15 196:15	process-based 108:13 149:19	producing 77:2 83:17 248:13
present 1:13 2:6 115:22 160:21 161:7 162:15 180:1 211:20 218:1 223:3 301:1 303:6	prevention 232:14	200:6 202:18 215:10 232:11 263:9 266:20 283:22	174:1	250:8 270:16 291:4
presentation 62:6 69:11,18 151:18 206:5 231:21 272:22	previous 237:16 285:19	263:9 266:20 283:22	procuring 76:22	product 43:1 61:22 66:11 91:22 92:3
presented 83:20 147:14 178:6 179:9 213:8 214:18	previously 90:19 147:12 268:7 282:3	problematic 171:10 273:21 274:4	produce 8:12 77:4 92:3 181:18 182:9	92:4,11 94:14,14 110:13 113:11,13 113:21 114:19 126:14,17 128:6
presently 213:9 235:13	pre-harvest 209:17	171:10 273:21 274:4	190:19 191:19 193:8 194:7,12 289:22 291:11	134:3 150:8 158:10 164:8 166:4 177:3
preservative 45:7 151:12	pre-mix 288:15	problems 19:18 26:12 78:20 118:1	produced 44:16 46:4,18 100:17	200:10 202:8 204:15 205:2 207:21 208:7
preservatives 93:13,13 112:16 158:22 161:6,11 286:17	price 59:22 60:2,7 158:5 252:8 283:8	Procedurally 19:6	101:2 107:17 164:3 177:4 219:2	238:9,10 239:5 262:13,17 263:11 277:16 279:9
preserve 161:14	prices 58:7 73:4 76:11 123:15 252:5,7	procedure 82:3 101:8 166:7	233:16 236:1 249:22 262:18 270:11 271:12 283:17 297:3	282:18 283:2,3,11 287:12 289:16 291:14 297:7,11 297:15 303:8
preserved 173:9	primarily 33:17 36:9 50:1 59:21 79:4 173:22 209:4 219:22 281:5	proceed 14:21 89:5 242:20	producer 6:21 10:8 62:18 63:20 116:9	297:15 303:8
preserving 230:5	primary 45:6 62:13 65:18 170:12 293:15	proceeding 4:19	116:11 173:20 232:13 239:6 275:15	production 21:20 36:4 42:22 46:12 50:11 60:13 71:19 77:5 82:15 83:15 85:11 100:14 103:13 108:12 109:3 116:6 123:22 124:4,6 132:14 135:22 137:8 138:3 150:19 157:11 173:12 181:22 194:22 208:8 209:13 211:6 225:9,21 232:7
president 204:6 247:17 254:3	prime 142:1	process 23:3,14 30:3 32:2,3 37:13 37:21 38:5 41:6 51:20 61:18 70:2 79:10 82:22 83:7 85:5,15 86:5,14 91:12 132:18 134:22 135:4,16 145:17,20,22 146:5 148:5 165:10,14 166:16 167:1 177:17 178:17 209:2 220:10 237:19 273:18 284:3,4 289:8	producers 25:11,19 26:13 38:9 57:17 58:5,18 59:15,20 60:1,16,18 63:5 63:17 65:7 66:19 76:14,21 77:9,10 108:16,18 112:19 121:18 129:9,13 130:5,10 137:6 148:15 150:9 170:16,19 173:8 174:2 233:11 234:17 235:15 236:15 239:9	
presiding 1:12	principle 157:22			
pressure 229:13 230:9	principles 109:6			
presumptions 71:18	prior 85:3 99:22 101:6,17 106:20 144:18 234:12			
pretty 16:21 20:21	priorities 155:5,11			
	priority 38:12 114:18 149:8 267:1			
	private 81:1			
	private-label 245:15			
	privy 218:12			
	prize 87:10	processed 93:2		

233:10 234:19	19:15 20:14 21:11	promoting 4:11,12	proud 11:21 53:16	222:17,18 223:11
244:22 246:2,10	21:19,21 22:1,7	promulgate 73:13	55:13,16 75:22	226:9,18 228:6
247:1 254:3	27:1,17 33:8 34:7	promulgated 50:14	proven 164:2	234:12,15 235:18
258:12 259:15	36:6,11,16,21	proper 129:2	provide 13:15	236:3,6 242:11,20
269:1 271:15	38:3 42:11 43:11	properly 22:21	30:12 45:16 51:9	268:18 303:15
294:1 299:1	48:2,4 49:21 53:3	34:21 35:22 128:4	58:11 59:18 60:2	publication 85:21
301:16 308:22	53:17 56:3 57:2	186:1 226:19	138:7 150:9	86:14
productive 298:15	59:1 62:11,14	proponents 73:9	169:17 174:6	publications 31:14
products 22:4	64:12 68:3 148:20	proposal 3:13	227:7 233:11	publicly 30:10
24:16 34:2 40:16	150:4 154:6	19:12,22 79:15	239:9 241:1	108:5 144:9
43:3,18 45:3 46:5	160:18 178:12	83:7,18 84:5,11	248:17 251:6	publicly-funded
84:1 85:9 91:21	196:14 200:4	85:3 97:7 108:5	257:1 265:11	157:19
92:7 94:9,11	205:18 219:17,18	218:1 229:18	267:7	public's 126:9
104:16 111:21	221:7 238:1,12,20	proposals 3:12	provided 19:7	publish 28:9 35:8
112:3,8,10,10,13	241:2 249:13,13	18:12 19:8 43:10	30:14 53:1 172:12	120:12 121:1,3,9
113:1,10 114:7,10	249:20 250:3,4,19	82:19 107:5	183:17 233:19	published 31:8
114:11 126:9,11	251:2 254:1	242:16 268:17	234:1 269:16	34:11 35:4,4
126:21 143:9	267:11 275:21	305:5	Providence 1:11	118:18 140:2
147:3 148:12	277:10 297:20	proposed 24:4,12	248:14	153:13 171:16
157:15 158:8	304:13	35:4 40:2,8 41:3,4	provider 245:15	235:13
170:2 171:18	programmatically-w...	41:17 122:9,10	provides 53:8	publishing 122:8
172:9 173:13	36:22	136:22 219:16	196:7 276:11	151:6
201:13,13,17,19	programs 28:22	234:10 273:6	providing 59:19	pullet 250:19
203:7,8,10,13,13	29:5 34:1,9 61:1,5	proposing 74:3	129:13 164:13	pullets 258:9
203:17,18 209:18	61:11,13,21 63:19	142:20	173:22 178:8	puppies 281:9
220:4 225:10	66:17 67:19	propriety 76:9	248:1 250:9	purchased 177:4
227:20 239:12	106:15 126:4,5,13	prosper 53:4	provincial 243:19	purchasers 275:9
265:14 266:8	128:15 233:4	protect 101:4	provision 284:11	pure 176:11 177:14
277:21 279:5	236:20 238:16	protected 108:19	provisions 56:15	purgatory 88:8
281:2,3,18 282:2	251:4	119:9	77:15 171:6	purity 85:7 108:11
282:4,6 289:8	progress 36:18	protecting 33:15	psychologist	170:3 173:4,21
290:22 296:3	37:5 57:14 58:13	38:12 178:15	160:14	purpose 4:13 15:21
303:1	69:12 278:22	protection 38:11	public 3:9,19 4:14	269:19
product-based	progressing 207:4	72:17 123:10	6:17 10:15 19:2	purposes 168:20
108:14	progression 63:15	protections 90:21	30:14 41:3 63:8	pursued 112:7
profess 72:11	prohibit 161:11,12	protects 118:16	64:17 70:9,15	purveyor 310:19
professionals 162:1	prohibited 33:5	protein 84:14 93:5	71:2 72:2 81:1	push 122:7 193:10
professor 10:5	35:7 39:7 47:3	195:17 197:2	88:13 89:8,17	pushed 133:10
152:21 153:1	232:19 233:9,22	228:1 229:12	96:22 97:12,14	put 31:1 41:2 68:16
154:7	prohibition 150:14	230:11 252:2,14	135:4,10 139:9	107:5 108:5
profit 152:10	265:15	252:17 259:6	143:4 144:8,13,18	118:12,13 122:21
profitable 76:14,18	project 64:10 67:10	proteins 220:14	146:1 151:14	127:4 128:18
profits 137:7	67:10 292:10	protocol 138:14	169:14 179:20	133:19 141:16
program 1:2 2:9,13	projects 57:4 66:19	173:21,22 186:20	180:3,8 189:9	155:4 172:21
2:15 3:5,6 12:7,11	67:2,8	protocols 142:3,4	210:6,7 211:15,17	185:6 192:15
12:16,22 13:19	prominent 114:12	267:7	214:16,17 217:8	229:13 245:18
17:19 18:16 19:7	promote 48:21	protracted 115:4	217:20 221:11	253:8 257:10

259:18 264:2	169:1 180:16	144:13 189:22	309:6	236:16 246:5
270:21 274:6	186:17 187:13	190:14	raw 284:10,12	263:4 272:2
279:5 281:19	188:4,20 189:7	quote 154:13 155:1	reach 65:16 158:7	284:19 285:1,3,22
289:16 298:3	190:6 200:20	162:10,11 163:7,8	reaches 176:17	287:9 298:10
puts 138:14 185:7	202:22 207:18	225:7	reaction 162:13	301:1,13 302:16
putting 77:8,10	208:21 224:14,14		reactions 162:8	304:5 309:15
110:13 266:16	225:13 240:21	R	read 13:21,22	312:5
273:19 275:5	257:18 296:14	radiation 47:2	55:12 188:12	realtime 29:14
pyrethrins 302:19	questioned 187:17	radiolabeled	258:16 276:1	239:20
302:21	questioning 129:21	299:15	294:6 305:12	real-world 142:4
pyrethroid 293:3	questions 15:13	rainfall 188:21	readily 269:16	reason 41:5,18
297:4	16:12 68:19 69:3	189:4	reading 179:1	125:15 170:12
pyrethroids 293:20	69:17,18,19,22	raise 245:8 252:14	213:2	180:2 190:11
P-I-E-R-C-E	75:6,7 86:18	272:7,18	ready 70:15 71:1	192:5,18 194:5
247:14	103:3 110:4,5	raised 84:9 141:19	141:22 234:11	199:20 249:16
P-R-O-C-E-E-D-...	115:14 125:4	182:10 225:5	305:5	262:12,19 310:1
4:1	129:6 131:21	226:11 269:18	real 23:16 97:10	reasonable 112:10
p.m 169:12 242:6,7	139:7 141:13,18	271:6 272:6	245:4 246:16	reasoning 178:21
304:21,22 315:14	151:2 152:3	310:10	247:21 309:11	239:7
	155:15 159:12	raisers 313:15	reality 72:15	reasons 161:8
Q	167:14,22 174:8	raises 200:18	123:14 246:6	213:13 287:17
QAI 165:1	179:22 184:17,19	raising 228:6	realize 120:18	rebuttal 294:3
qualifications	190:4 195:3 199:1	248:20 252:20	126:10	recalled 250:21
31:17 40:15	200:18 201:7	270:3	realizing 287:1	receive 54:14
qualitative 99:17	203:21 210:2	ramifications	really 4:10 6:5	221:12 249:22
quality 9:17 14:7	222:21,22 223:16	268:9	14:13 16:6 20:21	received 4:16 144:7
44:22 47:20 48:2	223:21 225:20	ramping 266:17	21:6 22:12 38:20	144:8,15 162:7
106:14 107:19	227:17 240:14	ran 183:20	41:20 47:22 49:18	181:13 204:19
118:16 249:12	247:7 251:19	ranch 254:4 292:18	51:8,10 52:1,14	214:22 224:19
250:9	252:9 253:12	ranchers 54:5	52:18 53:8,10,16	225:12 237:22
quantified 214:1	257:15 260:12	55:17	53:18 55:13,15	238:10
quantitative 99:20	261:21 269:11	ranches 308:14	61:18 67:21 76:15	receives 18:17
quantities 107:18	274:8 281:11	random 222:12	82:16,17 86:1	receiving 33:10
212:16	294:21 304:16	range 117:4 213:3	92:21 93:4 95:6,6	recess 315:10
Quebec 243:19	quick 79:1 95:12	213:9 265:1 281:5	98:7,8 102:9	reciprocal 194:10
244:14	131:21 186:18	296:8	103:10 117:7	reciprocity 183:4
question 15:21	244:20 304:18	rapid 294:17	119:1 140:7 142:8	recognition 22:19
29:3 58:15 62:22	quicker 13:22	raptor 118:13	145:21 146:10	62:8 226:2
75:8 79:2 95:12	187:4	rare 119:9	156:10 160:1	recognize 13:7 50:1
95:14,21 103:4	quickly 42:13	raspberries 209:8	165:3,4,6 186:10	165:9 229:4
104:10 110:6	56:13 64:8 115:11	rate 175:17 295:18	191:19 193:21,22	257:13 261:19
118:7 119:20	131:10 185:19	295:19 296:2	205:22 208:8	recognized 151:9
121:12 130:13	186:2 187:8	rates 32:17 103:22	214:11 223:10	recommend 212:6
131:19 132:1,14	240:16 308:17	104:2	227:7 228:20,22	recommendation
140:20 143:7,17	quiet 70:7	ration 41:15	229:7,19 230:14	34:15 40:22 41:1
159:15 160:4	quite 18:6 35:9	220:19 221:6	230:17 231:3	108:3 112:1 115:9
164:17 168:12	75:15 103:8	rationale 208:1	233:8 235:8	132:7 147:12

172:5 179:8,15 195:18 218:6 219:17,19 234:21 267:12,22 recommendations 21:13 23:21,22 31:13 37:1,14 109:21 123:7 138:17 149:5 167:16 176:3 223:22 234:10 303:19 recommended 43:13 147:13 233:20 234:2 238:13,19 recommending 78:9 218:11 237:16 reconsider 205:20 reconsideration 155:12 record 17:13 70:12 70:13 156:1 169:11,12 242:6,7 304:21,22 315:14 recorded 120:14 record-keeping 25:20 recreate 45:7 recruiting 65:7 recusal 19:19,22 134:22 145:6,19 242:17 recuse 19:1,13 80:18 145:3 159:6 recycled 182:7 recycling 109:7 red 6:3 270:3 reduce 25:15 27:7 27:13 129:1 132:20 292:20 reduced 33:8 102:20 129:3 297:12 reduction 101:22 103:6,21 129:16	250:13 refer 131:3,15 139:3 256:21 298:18 reference 63:7 171:11 243:8 294:4 referred 57:8 91:14 referring 139:20 refers 140:7,14 refinement 172:18 reflected 68:5 regard 104:15 137:4 142:11 167:9,15 168:17 regarded 123:4 302:11 regarding 79:12 107:10,20 108:10 109:1,12,18 170:8 170:20 171:4,15 172:5,7,13 185:7 211:1 regardless 184:13 regards 50:14 176:2 224:8 226:11 228:9 region 67:16 regional 38:15 66:9 66:15 region's 248:3 registered 212:13 239:21 240:7 303:7,8 registration 297:19 300:19,22 registries 64:22 regular 25:3 295:10 regulate 112:22 regulated 220:6 regulation 149:18 271:3 275:12,18 275:22 276:4,10 276:11 312:4,17 313:5 regulations 21:22	22:1,3,6,9 42:18 44:15 45:5,18 46:8 49:12 83:10 83:12 88:2 116:5 116:16 149:12 237:20 263:21 276:9,15,16,17 278:19 279:4 regulators 88:12 96:16,17 197:16 regulatory 21:21 49:1 87:21 134:11 220:9 Reifenrath 286:11 291:21,22 295:16 298:17 reinforce 56:1 reiterated 227:6 reject 136:21 161:5 164:14 rejected 161:9 related 15:12 19:21 58:14 77:14 95:17 96:1,4 97:14 144:1,22 162:10 223:7 242:15 relates 41:10 96:22 264:16 288:20 relating 288:8 relationship 130:1 241:10 285:12 relative 285:13,14 308:3 relatively 88:16 released 53:5 59:13 relegated 89:14 relevance 232:9 relevant 63:12,16 66:4,9 108:6 relies 303:12 reluctant 309:21 remain 109:14 114:7,11 146:1 177:15 remained 181:11 remarkably 315:8 remarks 104:14	remember 54:20 74:6 87:15 177:18 178:14 270:1 271:8 279:6 280:1 280:17 remind 193:15 reminding 18:4 removal 182:5 186:12 268:9,13 remove 155:10 184:14,16 187:7 268:7,12 removing 136:9 rendering 226:11 renew 61:4 80:12 renewal 149:16 renewals 39:3 Rensselaer 153:2 rented 191:20 rep 10:12 repeat 234:3 repellant 210:20 212:5,17 292:7,10 292:17,20 293:2,8 294:16 307:13 314:4 repellants 293:4 repels 295:4 replaced 217:14 replacement 45:10 262:15 replacing 84:19 report 3:4 17:4,18 54:22 60:14 204:12 211:11,12 217:5,5,6 232:2 241:6 278:7 280:18 284:8,9 294:3,4,7,8,14 295:6 296:19 300:1,5 reported 19:18 214:6 215:15 reportedly 284:16 reporting 241:18 reports 29:20 37:22 60:19	135:19 162:7,13 211:2 279:16 represent 7:15 11:8 18:21,22 147:6 165:2 176:11 177:21 231:22 271:19 representative 8:16 9:20 217:18 representatives 8:17 9:11 80:10 representing 6:17 89:19 represents 79:22 303:17 reproduction 289:2 request 18:10 27:13,14 87:20 152:3 171:14 195:2 211:10 237:22 requested 217:4 234:7 requesting 216:20 235:1 240:11 requests 26:20 27:4 27:10 210:18 require 26:7 85:8 113:21 115:4,5 135:17 145:19 196:4 279:13 required 25:20 26:9 36:3 39:10 45:10 58:21 141:17 149:12 216:14,21 236:17 264:7 280:1,4 290:15 291:8 308:11 requirement 83:21 110:17 135:14 227:3 requirements 25:21 26:14 30:22 31:6 36:11 39:19 40:7 42:15,17 46:9,17 93:17
---	--	---	---	--

124:5 147:17	263:13	265:19	260:14 294:22	Robert 152:22
148:7 171:8,13	resources 28:20	retail 9:20	305:11,15 307:5	Robin 106:6 110:6
176:15 248:11	34:4,8 59:6 63:4,9	retailer 250:22	307:11 314:17	110:6,8 111:5
249:9 250:17	63:21 64:7,13	retailers 250:17	rid 253:6	218:8
requires 74:8	66:8 87:18 88:1	return 70:8	right 6:8 9:10 40:3	Robinson 98:16,17
101:10 142:13	116:15,17,18	Reuben 10:14	44:3 49:7,14	103:10 105:2,16
166:9 198:12	117:8,14 120:10	revealing 79:8	61:15 67:1 70:18	252:10
rescheduled 151:20	132:5 150:21	reveals 127:12	77:16 106:5	robust 135:16
research 54:17,18	263:14 266:16	review 25:8 31:20	115:15 117:20	Rodale 155:7
54:20,21 55:2	respect 155:9 229:8	36:3,3,6,9,9,16,22	132:13 178:4	Rodale's 181:14
57:12,15 64:3	229:11	37:9 42:15 72:2	194:14 196:2	role 11:2 82:16
71:11,11 72:3,5	respected 71:20	83:13,22 89:6	198:19 200:5	178:10 180:8
130:17 136:3,14	155:6 158:17	90:6 109:15 148:9	202:15 206:21	204:11
137:22 139:1	respectfully 87:20	148:17 166:2,7,9	226:19 230:16,21	roll 50:18 182:19
141:14 142:7,17	195:2	166:16 167:1	242:2 245:13	183:15 185:17
152:1,3 153:4,15	respond 253:1	170:5 211:1 217:2	253:15 259:4	roller 277:20
154:5,6,22 155:5	310:11	217:16 234:7	261:4 262:15,18	rolling 71:2
157:19,21 188:14	responded 224:7	269:5 281:14	263:2,22 265:11	Romer 99:16
192:5 194:19	respondents 224:6	294:11 297:15,21	267:16 270:8	room 4:8 16:17
224:18 259:21,22	responding 35:5	reviewed 84:10	271:14,16 273:4	31:7 37:20 68:11
261:3 263:17	response 211:4	91:5 110:22	279:8,12 282:7	80:4 252:6 271:1
266:17	227:12 250:20	147:16 148:4	283:21 309:1	rooted 158:16
researched 256:17	262:11 276:5	154:14 158:11	312:17	rose 162:12
256:17	299:4	212:1,3 217:3	rightfully 245:7	rotation 191:3
researchers 57:20	responsibilities	233:19 234:2	rights 247:3	rotenone 89:11
155:1,3	78:16	237:17 273:4	rigor 35:15	150:11
researcher's	responsibility	278:22	rigorous 32:15	roughly 192:21
135:17	65:15 129:22	reviewing 37:12,21	76:9 250:4	round 278:15
reserved 108:1	135:7 173:18	149:11 211:9	rinses 111:20	row 189:10 190:2,9
residue 23:16 24:4	responsible 21:19	213:7	riparian 121:8	Roy 222:4
35:3 39:13 40:6	22:14,18	reviews 135:16	ripe 273:20	rub 155:2 244:9
184:7 302:2	rest 85:7 108:2	157:18 166:21	Ripon 7:22	rule 5:6 24:4,6,9,12
residues 35:6 45:21	157:1 158:9	revised 264:15	risk 53:9 59:17	24:18,20 25:1,9
136:19 187:18,19	173:20 218:9	revision 274:2	74:21 135:11	25:21 26:2,8,11
188:2	277:18 294:2	revisit 273:17	137:13 147:16	26:15 35:4,8
resistance 153:17	restricted 180:9	revoked 29:17	215:10 250:13	39:13 40:2,21
154:1	258:7 259:8	33:18 183:9	263:5 270:18	41:3,4,4,17 50:13
resisted 173:12	restrictions 138:14	re-certified 244:11	284:13 303:16	52:10 53:1,19
resolution 61:11	restrictive 150:12	re-infestation	risks 137:11,14	60:5 80:19 101:10
234:22 238:20	result 64:10 238:11	128:21	risky 74:16	101:10,12,15
resolve 232:10	293:8	Rhode 1:11 4:10	Riverside 296:16	102:8,13 103:11
resolved 137:3	resulting 99:2	Rica 48:12	298:19	121:9 122:5,9,9
141:13,15	results 17:9 55:9,11	Richardson 1:20	RMA 59:22	122:12 171:4
resort 174:4	57:10,15,22 58:8	3:18 10:4,5	road 287:6	178:16 203:9
resource 63:2	99:21 127:16	130:14 211:19,21	roamed 191:15	221:6 227:1 234:6
109:6 116:1	132:11 142:8	214:5 215:12	Rob 204:6 207:14	249:15 265:20
117:20 138:8	153:12,18 183:16	231:2 241:3,17	207:18,20	266:14 273:6

275:7,14 rulemaking 46:14 112:2 115:4 277:12 rules 14:20,20 15:5 39:15 40:8 41:20 62:17 73:13 ruling 259:10 ruminant 265:7 ruminant 268:17 run 15:2,8 18:14 56:12 181:1 187:8 189:16 259:19 running 68:20 132:19 rush 98:21 rye 100:4	100:19,21 250:13 251:3,8 253:8 254:11,13 255:5,6 255:18 256:20 260:4 284:13 salt 155:2 sample 301:12 Sandler 111:10,11 115:15 Sandra 255:13 Santa 106:16 sat 174:20 satisfied 188:1 Savannah 204:8 save 133:2,5 savings 182:2 saw 62:5 86:13 97:6 192:18 288:21 saying 168:16 192:9 200:15 218:4 287:11 299:6 300:18 304:4,6 313:3 says 62:19 89:8 105:5 116:9 127:14 215:16 272:14 283:11 284:18 294:7 300:2 scalability 225:6 scale 225:8,9 scales 229:16 scene 144:3 scent 259:18 schedule 242:10 school 154:4,8,11 154:17 259:22 schools 52:17,17 school-to-farm 52:20 science 51:19 149:5 scientific 72:2 84:8 123:21 124:1 152:1,7 153:4 155:10 288:19 scientist 188:5	scientists 152:9 154:9 scientist's 7:11 scope 148:20 Scott 231:10 scraps 224:1,9,12 224:16 227:14 screaming 96:10 308:19 screen 297:20 298:4 screw 78:5 seal 49:11,13,17 123:10 148:12 198:21 199:16 search 67:6,7 266:21 Searching 54:22 season 25:17 136:10 181:12 182:6 183:17,20 184:3 185:20 186:22 187:5 188:21 189:1 seasonality 221:3 seat 7:11 305:2 seats 51:7 second 7:1,17 15:11 17:2 24:22 58:16 71:1 101:11 104:20,21 132:1 181:3,5 190:10 192:11 216:13 232:18 239:17 240:2 262:19 305:20,21 307:16 307:17 seconded 306:2 307:20 secondly 71:22 113:8 114:10 seconds 102:17 179:5 secret 79:16 130:1 Secretary 3:4 13:17 21:16 50:8 51:1 52:4 53:15	55:15 56:2,18,19 78:3 87:14 278:1 Secretary's 3:4 17:4 section 64:2 107:22 167:13 210:19 216:22 232:8 307:13 sector 58:7 67:13 150:8 200:17 278:17 285:1 sectors 245:11 secure 274:13 289:18 SECY 50:21 see 5:16 15:22 20:2 22:4 31:22 37:17 52:12 55:10 57:15 59:5 66:22 67:20 69:12 75:10,17 87:7 93:14,15 94:7,11 103:1,8 104:5 110:11 117:7 121:1 126:22 131:9 133:8 142:17 143:8 156:13 161:3 179:6 180:15 185:21 187:18 190:15 201:12 202:9 205:17 207:12 218:9 219:20 228:10 236:7 241:11 247:21 261:4 269:4 273:10 278:13 286:7 287:16 292:19 302:13 309:15 310:17 313:17 seed 6:22 85:7 100:1,4 108:11 170:3 173:4,21 221:1 239:11,11 seeds 24:16 40:11 108:11,17 233:12	233:13 seeing 26:10 42:2 52:15 75:7 97:2 126:1,7 133:13 141:8 185:12 202:6 205:9 206:18 241:14 304:5 seek 19:9 200:2 223:11,17 311:5 Seemingly 222:13 seen 25:10,14 54:19 70:6 129:14,16 274:3 select 216:15 selecting 35:6 self-serving 72:4 sell 8:12 72:12 193:8 194:7,12 selling 8:5 111:16 122:16 191:19 193:16 205:1 244:13 sells 113:21 semblance 300:22 semester 218:18 222:20 send 50:14,18 131:5 145:13 senior 71:7 153:1 seniors 281:9 sense 144:6 218:8 303:13 309:17 sensitive 39:22 303:11 sent 17:10 80:10 separate 226:12 September 86:15 234:6 sequence 273:14 series 223:16 serious 161:17 207:8 seriously 35:21 74:19 81:21 164:5 264:12 serve 6:16 7:4,5,16
S				
s 153:6,6 sacrifice 148:14 sadly 145:11 safe 134:3 138:1 156:10,22 158:13 164:13 287:2 302:9,12 safeguard 134:4 156:7 safeguards 226:8 safely 126:14 289:15 safest 249:22 safety 9:17 39:15 90:14 134:13 156:9 157:15 161:18 206:17,19 207:2 209:1 248:10 249:9,17 250:4 260:8 289:15 Safeway 245:17 sage 119:9 Saint 125:9 sales 8:3 60:17 183:12 205:16 246:14 salmonella 100:15				

8:19,22 10:2,16 11:6,13 161:6 247:16 249:11 served 13:8 51:4 175:15 178:4 serves 266:13 service 1:1 29:6 47:8,18 48:7 50:13 51:9 57:2 58:2 248:4 264:22 services 29:1 106:16 247:15,18 Service's 54:15 servicing 244:6 serving 11:11 135:11 206:12 session 19:21 210:7 session's 17:7 set 46:1 124:5 175:14 235:2 278:6,19 setting 4:7 76:19 78:8 105:7 settled 246:7 setup 251:21 seven 125:1 133:21 severe 26:19 28:2 99:12 sewage 47:2 share 19:21 55:12 99:21 242:15 248:22 251:13 shared 209:20 Sharon 276:21 286:9,12 sharp 284:15 Sharpies 68:13 sheer 309:19 sheet 5:18 shelf 261:10 289:17 shelves 176:17 Sherman 276:21 286:12,12 290:13 290:20 291:3,17 ship 8:11 Shistar 82:10,11 shoot 286:7	shopping 55:8 201:12 short 21:15 122:13 145:15 179:1 261:11 shortages 99:13 short-term 294:12 show 57:9 65:19 131:7 233:12,14 293:6 310:16 showed 65:20 129:19 215:5 293:13 299:10 showing 48:13 shown 142:8 197:20 shows 27:20 32:17 162:9 shut 75:22 side 77:11 95:5 103:13 124:13 132:9 141:22 175:7 207:5,6 209:21 231:9 sides 95:9 122:14 122:22 243:13 Siding 158:1 sign 6:6 68:10 signed 4:15 5:18 15:18 16:10 211:17 217:20 significant 25:19 26:1,17,18 41:10 57:18 58:10 67:11 103:20 109:4 112:5 113:4 294:19 300:4 303:3 311:14 significantly 96:15 109:9 266:2 sign-in 5:18 silver-inked 68:13 similar 256:10,11 Similarly 86:13 simply 99:14 114:18 163:21 175:13 215:14	232:20 Simultaneously 77:10 single 202:18 222:9 240:17 288:19 293:7 296:16 sir 257:20 306:20 314:10 sisters 149:2 sit 7:10 9:13 site 140:13 sites 140:12 sitting 51:7 81:9 202:5 231:9 situation 61:1 77:11 159:8 186:3 246:6 289:10 290:2 311:12 situations 118:14 126:17 185:22 six 133:20 six-person 125:8 size 25:15 104:1 skin 292:9 skip 190:7,12 slaughter 107:13 226:7 265:10,16 265:21 266:1 slaughterhouse 122:1 137:12 slice 257:6 slide 21:17 27:20 62:5 65:20 67:1,5 127:15 131:7 223:14 231:6 254:7 292:19 slides 55:22 slippery 282:11,13 slope 282:11,13 slower 103:22 104:2 slowly 179:2 sludge 47:3 small 34:5 113:18 133:19 146:22 153:21 206:3 221:18 251:10	302:14 smaller 127:14 285:5 small-scale 11:1 smell 259:18 smelly 295:1,4 296:5 smoother 175:12 soap 111:17 204:10 300:13 Soaps 111:13 society 14:11,12 sodium 24:8 39:5 soft 301:7 304:7 soil 116:18,19 117:8,21 118:1 136:12 142:9,10 142:11,12 184:3 186:4 213:21 252:19 299:12,17 299:21 soils 136:20 142:14 213:4 sold 85:10 219:2 244:5 246:3 248:13 267:17 sole 135:5 292:2 solely 173:20 solid 140:8 solution 134:5 227:8 237:5 263:9 263:22 264:2 solutions 75:10,17 solved 266:21 somebody 62:18 145:2 206:4 245:21 256:16,19 259:12 301:9 somewhat 175:6 son 8:1 Sonnabend 1:21 7:9,10 139:8 187:15 188:6 306:19 314:9 soon 35:9 121:2 259:15 sophisticated 90:9	Sorbonne 153:4 154:9 sorry 7:5 74:4,11 75:7,14 102:2 129:4 258:18 314:21 315:2 sort 15:1 88:8 96:12 139:12 156:7 167:2 168:18 186:10 224:5,16 231:3,18 234:14 237:14 273:15 295:1 sorted 235:9 sound 149:4 167:17 167:17 181:9 218:20 310:2 source 44:17 107:17 197:17 228:1 229:12,13 269:16,17 280:22 285:20 290:11 sourced 302:4 sources 137:16,21 197:16 230:4 252:3 264:11 265:16 266:12,22 269:13 280:5 sourcing 221:4 South 124:22 156:3 292:14 298:22 303:20,22 soy 84:14 93:5,9 95:3 198:10 199:5 199:12,22 200:8 200:22 soybean 99:11 soybeans 99:18,20 soy-based 164:6 195:17,20 197:2 199:7,21 201:1 so-called 158:21 spa 114:8 space 257:8,9,10 spacious 16:19 span 142:21 143:1 speak 5:17 15:10
--	--	--	---	--

16:11 75:12 161:2 191:12 257:19 290:6,7 speaker 70:17 82:7 86:20 98:14 106:4 111:7 115:18 121:14 125:5 134:8 146:17 151:3 155:19 160:10 164:20 speaking 61:6 143:20 speaks 5:4 special 68:12 specialist 2:10,17 8:7 13:4 264:21 specialists 255:3 species 117:4 119:9 119:11,16 254:13 265:18 294:10 specific 42:17 85:1 110:17 153:11 170:6 176:2,15 217:11 220:12 221:13 223:17 238:4 250:17 281:22 specifically 64:7,16 92:15 147:5 161:10 224:2 228:10 238:15 265:15 specificity 171:3,7 185:6 275:5 specifics 89:22 specified 216:16 spectacular 4:7 speed 137:6 spend 294:2 spent 54:19 160:16 spirit 72:16 137:9 151:7,13 spoke 144:4 spontaneously 288:22 spot 270:22 sprayed 299:9	sprays 209:9,17 spreading 127:20 spreadsheet 19:8 spring 128:17 183:22 184:2 218:15 264:14 Springs 277:3 spur 225:20 square 74:4,8,14 278:15 squeeze 286:7 staff 2:6 12:3,8 21:2 22:7 41:21 50:2,3 68:13 78:10 96:17 174:3 staffers 50:10 stage 24:10 250:19 258:15,17,18 289:17 291:12 stages 289:20 stake 178:9 stakeholder 42:8 stakeholders 73:8 80:3 stalks 192:14 stalled 89:8 stand 13:7 71:1 145:21,22 150:19 256:16,19 standard 26:6 113:9,12 114:4,5 114:9,14,21 143:10 168:9,19 249:14 271:21 278:12 297:10,12 297:17 311:10 standardize 138:10 standardized 171:21 standards 1:5,10 2:12,14 4:5 12:10 12:15,19 13:14 20:17 22:13 23:4 23:12,19 26:6 33:20 34:2 36:5 36:14 38:8,9 39:15 40:5,5	41:11,12 43:11 64:13 71:13 89:1 112:3 113:17 125:14 136:6 161:10 164:4 165:4,10 192:7 219:3,4 220:9 251:6 266:3 267:2 267:18 278:4 279:2 281:17 283:18 286:22 288:14 291:6 standing 53:20 96:9 standpoint 274:22 stands 214:3 292:3 start 5:22 19:20 51:16 52:20 57:21 82:13 145:1 177:14 183:19 254:7 258:10,10 313:17 started 21:18 75:21 103:11 162:2 185:15 191:14,18 starting 6:11 242:11 306:4 starts 189:2 state 4:9 8:11 11:1 12:1 13:13 82:8 121:20 125:18,22 155:22 179:4 180:20 220:8 227:3 239:4 243:1 247:10 253:19 276:20 286:10 291:19 300:7 stated 17:14 234:15 statement 255:8 statements 214:19 states 1:1 25:2,7 27:21 28:1 74:8 107:2 152:14 183:2 232:13,21 246:1 254:9 255:7 264:8 282:16 Statistics 59:14	status 80:12 238:9 statute 237:20 statutory 77:22 310:20 stay 87:20 221:8 stays 130:21 step 40:21 81:18 83:11 177:22 178:2 209:10 301:3 Stephen 154:14 steps 41:6 109:20 120:8 178:2 step-down 223:8 257:19 stewardship 303:17 stocks 229:14 230:6,8 Stone 1:21 7:14,14 103:5 110:8 218:1 218:3 227:19 251:20 272:12 285:11 290:9,18 290:21 306:20 314:10 stood 254:21 stop 55:8 183:8 186:5,6 stopped 99:12 186:4 197:6 store 176:17 263:3 stores 246:4 store-bought 196:18 stories 47:11,14 74:18 straight 198:7 212:10 straightforward 159:15 Stratacor 210:17 292:2 Strategic 38:7 53:22 56:7 Straw 181:1,6,13 181:20 182:10	191:11 192:2 193:22 strawberries 209:8 Strawberry 9:4 streamlined 120:21 Street 1:11 strength 53:2 strictly 59:15 striking 86:13 striving 219:6 strong 87:12 125:20 227:10 strongly 136:7 struck 95:18,20 229:7 structurally 163:14 studied 298:8 studies 10:6 66:14 84:8 139:21 143:3 143:6 153:19,19 162:18 186:19,20 215:5 225:16 299:15 study 131:16 140:3 140:14 141:2 142:18,18 152:14 152:17 154:1 stuff 44:2 312:20 subcommittee 3:10 3:12 7:5,6,8 8:14 10:1,11 11:4,4,5,6 19:20 81:13 83:17 95:20 100:7,10 107:11 108:10,22 120:2 136:11 147:11 155:4 161:4 185:2,3 210:8,16 211:10 211:22 212:5 216:14 217:3,17 218:10,13 221:21 232:1 234:19,21 241:18 242:1,16 298:10 Subcommittees 9:7 9:14 11:14 Subcommittee's
--	---	---	--	--

195:18	147:15	supported 193:5	289:9	229:17 230:2
subgroup 231:21	suggestions 144:16	302:10	sustainable 2:18	synthetic/non-sy...
subject 101:16	170:7 172:12	supporters 150:16	3:7 17:21 44:8	173:1
231:11	225:15	supporting 23:5	88:19 230:7	syrup 10:8
subjects 98:20	suggests 164:8	67:17 74:11 168:6	263:12 264:22	system 5:16 23:14
154:2	suit 247:2	173:3 214:19	302:1	26:8 31:9 36:10
submit 107:8	Sumit 152:20	293:20	sustaining 150:20	44:8 64:18 87:11
169:20	summarize 3:12	supportive 109:2	Swaffer 262:3,4,5	87:17 88:21 89:14
submitted 82:18	170:4 257:13	203:5	sweaty 295:14	91:8,9 94:1 99:6
120:16 195:13	summary 82:20	supports 66:16	switched 162:5	116:13 131:15
216:18 264:13	218:4 227:9	134:18 138:4	switches 256:3	174:1 257:12
substance 42:20	293:18 300:2	170:9 172:16	symptoms 162:2,4	261:1,13,14,18
43:12,18 44:1,4,5	summer 117:10	supposed 185:18	synthesize 280:16	270:11 289:4
44:16 45:1,2,11	128:21	supposition 273:22	289:3	298:5,6 310:22
45:19 46:3,10	sums 165:20	suppress 255:17	synthesized 220:13	systems 59:4 66:9
130:3 212:22	sunset 24:2 35:16	Supreme 269:8	synthetic 74:16	66:16 124:9
305:9	39:2,20 138:3	sure 15:14 19:14	83:13 84:15 90:15	133:17 135:22
substances 31:19	157:17 268:6	22:20 29:22 38:8	93:13,18 95:4	136:19 149:20
31:21 33:5 39:3,7	sunsetting 90:4	39:16 41:14 55:3	101:18 102:1,2	170:1 204:7 297:6
39:21 40:17 44:14	sunshine 80:4	61:2 70:3,19 92:8	107:15 112:15	298:8,11 310:13
45:14 46:7,8	supplemental	96:3 110:7 141:20	137:5,9 138:2	
83:14 147:15	84:10 279:11	145:9 149:14	148:3,14 149:9	T
148:2,10,14,19	supplementation	156:5 167:20	158:21,22 159:1	table 5:19 38:13
176:8,19 232:20	197:20	218:19 252:5	161:11,12 164:1	96:9 231:10
substance's 44:18	supplements	254:16 284:21	167:6 196:4 197:9	313:18
45:6	137:20 176:14	313:2,14	197:10 198:12,17	tables 175:7
substantially 86:7	supplied 74:9	surface 179:13	199:13 201:9	tabling 234:20
substitute 43:3	supplier 243:16	292:9 299:19	212:2 220:17	tactics 157:14
substitutes 44:17	suppliers 147:21	surprised 301:14	224:22 225:18	take 32:4 35:21
succeeded 256:5	150:5	surprises 91:1	226:1 258:1	58:8 68:18 69:17
success 167:2	supplies 156:15	surrender 244:16	263:18 264:1	69:22 70:8 73:12
172:20 178:18	supply 89:2 99:3	surrendered	265:8 266:20	80:17 85:13 97:6
251:9	177:7 178:1	243:21	283:12,18 290:10	114:18 118:3
successful 123:3	183:14 260:10	surrounding 137:1	293:20 297:4	120:19 123:8
204:14 249:17	288:15 289:9	surveillance 23:15	300:16 301:18	124:12 128:20
successfully 204:15	support 19:19	34:3,7 42:1	303:14 305:18	135:3 143:11
succinctly 120:7	28:20 42:9 48:22	survey 53:6 59:13	306:3,14 310:21	149:13 174:11
succumbed 267:14	49:2 58:18 59:1	59:16	311:18	207:8 208:19
sued 246:21	63:17 90:19	surveys 59:14,16	synthetics 91:2,6	222:19 237:4
suffer 157:4,4	107:12 116:10	Susan 160:13	92:13 93:1 94:4	255:15,22 257:9
258:20	119:8,15 120:20	164:17,18 300:8	94:20 95:7,8	259:18 265:12
suffering 154:2	122:14 135:2,20	suspect 101:13	164:10 195:14	274:10,11 283:10
sufficient 107:18	138:16 147:14	245:14 297:14	196:19 197:4	300:17 301:9
sugar 118:20	148:21 168:3	suspected 244:3	198:20 200:1	305:2 311:16
suggested 263:8	217:2 224:20	suspended 29:16	201:14,16,18,20	taken 109:19 113:2
suggesting 200:12	227:10 248:2,6	33:18	202:2,3,17,20	126:14 129:17
suggestion 95:17	251:6,9 268:2	sustain 288:17	203:17,19 229:9	133:2 138:21

176:6 185:1	6:14 306:5,6,15	37:11,21 38:12	98:9 103:2 104:6	199:3 211:18
199:10 205:7	306:16 314:22	44:6 46:13 52:15	104:7,14 106:1,3	216:12 218:3
234:4	315:4	58:4 77:12 78:21	106:13 110:4	223:4 241:12
takes 15:11 28:19	team 54:9 248:4,6	85:8 141:16 148:1	111:4,6,10 115:12	247:9 251:12
40:20 41:5,18	technical 37:22,22	214:17 232:20	115:13,15,17	272:10
60:3 62:17 128:9	64:3 135:15 211:1	236:3 278:11,18	119:16,17,18,21	theoretically 136:1
talk 16:8,15,20	211:2,11,12 217:5	281:4 283:7,15	119:22,22 121:11	283:20 291:4,5
17:22 21:16 28:6	217:6 248:1	296:4 298:6 312:3	121:13 123:9	thereof 262:13
47:10 58:15 66:2	281:14 295:6	terribly 14:6	125:2,3,5 129:5	they'd 118:5
72:8 102:21	297:14 300:1	109:22	131:18 134:6	thing 18:16,21
116:11 134:14	technically 61:6	Terry 70:20 82:11	139:5,6,8,18	20:12 27:1 33:7
178:19 200:6	101:5,12	86:18	140:19 143:16,18	41:7 79:13 80:5
229:6 243:5	technicians 248:5	test 99:22 100:3	145:8 146:14,16	81:2 93:10 97:8
254:17 257:3	technique 256:11	142:5 283:2	147:10 150:22	98:8 104:1 156:13
270:1 277:11,15	techniques 256:10	testament 37:10	151:1,2,20 155:13	194:8,13 203:11
280:2 288:2	technologies 90:10	tested 127:13 214:1	155:14,17,18	228:19 233:5
311:10	technology 36:6	testify 80:11	159:10,11,22	239:17 240:18
talked 37:19	38:19	testimony 157:20	160:2,9 164:16,19	241:8 284:22
100:16 244:18	teenage 178:13	160:21 243:7	165:11 168:9,10	285:3 286:5 295:4
267:21 312:11	tell 47:11,15 71:14	285:8 292:14	169:1,3,9,16	295:15 304:9
talking 16:14 18:5	77:20 78:11,18	testing 23:16 24:4	174:5,7,9 175:2	things 11:21 16:2
30:6 118:18	99:8 120:7 125:16	35:3 39:13 40:6	180:12,14,19	21:11 22:12 23:19
141:14 185:13	129:18 130:2	99:10,12,17	181:2 184:17,18	24:3 28:4 29:19
188:4 220:1 254:4	131:14 198:9	108:15 126:18	184:21 187:15	39:4 41:16 42:10
256:18 259:13	208:15 255:1	136:12 142:2,3	191:4,6 195:5	42:11 43:5,7 44:9
talks 110:9 280:14	256:19 259:13	174:4	198:22 201:5	49:2,6 56:13
tall 53:21	tells 87:17	tests 99:20 139:22	203:21 204:1	61:17 67:17 75:11
tallow 302:4	temperature	294:13	207:13,15 210:1,3	75:16 81:22
TAP 135:15 166:21	142:11	tetracycline 39:9	210:11,14 213:14	102:22 125:1
280:18 284:8,9	template 31:10	Texas 8:20,21	217:21,22 231:2	130:7 156:9 159:9
taped 50:18	temporarily 94:21	140:13 142:10	237:10 241:13	168:14 187:20
Target 245:17	temporary 26:20	246:13,16	247:8 253:15,17	198:2 205:13
targeted 35:6	27:2,5,10,18	text 67:9	253:22 258:2	238:21 240:10
targets 102:10	61:16	texture 176:21	260:11,14 261:21	273:1 274:11
task 7:6 165:13,15	ten 73:21 76:2	textures 45:8	261:22 264:17	279:14 280:17
172:3 175:4	tend 222:14	thank 6:9,18 7:8	273:9,11 276:19	284:7 285:17,20
219:14 226:5	tendency 90:4	10:21,21 11:9	276:22 281:10,12	310:4 313:1,15
264:14 278:5	tenets 208:6	13:5,11,14 14:2	286:4,8 291:16,17	think 13:21 14:13
288:6	tenth 55:2	17:3,6,16 18:3	294:22 296:21	14:17 15:3,22
taste 176:22	tenure 49:11	20:3,4 47:7 48:7	300:6 304:15,17	16:20 17:3 18:15
taurine 217:13	term 22:2 45:13	49:6 52:6 68:22	306:12 315:4	18:20 20:2 21:1
222:8,10 279:19	51:6 67:6 114:2	69:10,13 70:7,9	thanking 82:13	22:5 38:2 41:8
280:7,9,10,16	233:8 266:14	71:4 75:3,5 78:22	thanks 6:8 49:7,8	46:2 48:16 50:3
288:20 289:3	terminology 208:9	79:3 81:19 82:4,5	71:3 75:9 98:12	65:4 69:6 72:19
290:16	terms 23:5,18 25:9	86:16,18 87:1	113:18 140:21	74:12,13 77:13
taxpayers 151:22	26:4 32:11 33:14	89:20 91:11,15,16	160:6,7 168:21	78:19 79:3 81:7
Taylor 1:22 6:13	34:10 35:12 36:18	95:11,13 96:6	180:18 184:22	82:1 95:16,19

96:14 97:5,10	193:14 204:21	143:21 147:20	top 40:8 111:16	60:18
98:4 102:17,19	209:2 228:9	150:11,14 151:19	topic 46:14 96:3	transmitting
105:11 107:21	229:18 268:12	160:7,16 176:22	143:19 172:14	127:21 128:3
109:7 117:11,15	thoughts 174:19	178:19 179:12,18	topical 64:6	transparency
120:7 130:4 134:2	175:3,9 176:2	179:21 183:12	topics 24:17 123:1	19:20 23:13 29:11
139:19 141:11,17	179:12	185:13 187:7	179:9	30:4,13,15 80:5
141:20 142:16	thousand 73:18,21	189:18 190:22	total 102:15	91:11 95:18 96:2
143:4,6,13 144:4	76:2,16 277:22	191:13 211:7	totaling 33:16	144:6 146:7
144:11,21 145:15	thousands 118:19	213:14 218:10	totally 131:14	242:14 275:9
145:21 146:6	206:14 244:21	221:8 229:2 237:4	271:16	transparent 19:5
159:3,4,14,20	threat 85:11	242:13 261:18	touch 75:19 244:12	79:21 83:8 88:22
186:2 190:6,9	100:18 126:1	263:3 277:1,1	tough 52:4 188:4	91:4,5 95:16
197:1 201:16	226:22	286:20 287:15,22	tougher 15:6	135:1 146:1
202:12,13,17	threatened 226:22	288:7 290:5 294:3	toxic 214:7 215:15	trap 90:18
203:11,11,16	three 5:20 11:12	300:14 308:14	215:16,17,21	traveled 47:13
205:21 207:7	37:7 40:8 98:20	311:20	216:4 270:13	treadmill 141:9
208:9 229:2,3,15	101:1 117:14	timer 5:15,20	294:5,9,12 302:21	treasure 245:10
233:5 238:17	122:2 129:19	times 21:7 55:3	304:11	treat 5:1 209:16
240:14,19 241:5,7	140:14 142:13,13	74:18 133:21	toxicity 43:17	treated 15:1,19
260:2 268:10,14	162:18,21 181:16	186:14 206:5	294:12,18 297:13	261:5
269:13 270:10,15	206:8 238:21	261:15 308:11	308:3	treating 207:2,3
271:2 272:5 275:8	240:10 292:7,14	time-saving 187:9	toxicologist 299:3	293:10
277:7,19 278:20	threw 174:19	tipping 229:16	toxicology 299:6	treatment 126:16
279:21,21 280:4,7	thrilled 52:16	today 52:8 71:14	TR 84:10 212:21	129:15 233:3
280:9 283:21	throw 251:16	145:12 151:17,20	213:2 214:6	238:12 256:12
284:21 285:17	Thursday 115:22	157:11 160:20	283:12	treatments 129:10
289:17 290:1,5	TH2 128:11	164:15 177:21	track 20:10 278:21	213:10
292:13 293:22	ticks 301:21	181:3 204:12	Tracy 1:17 8:19	treats 277:18
296:8,18 300:1	tidbit 273:1	206:11 216:14	201:7 202:22	tree 90:17 139:3
301:14 302:7	tied 283:6	222:17 241:22	223:2	208:2
306:11 310:11,20	tight 147:20 245:11	242:3 251:18	trade 39:16 42:4	tried 183:15 205:3
311:2,19 312:4	till 312:18	255:1 260:15	54:9,12 72:10	255:17
313:19	tilling 299:21	262:6 277:3 315:7	157:12	TRs 297:22
thinking 130:11	Tilth 244:11,15	token 68:8	tradition 13:12	truck 191:21
163:9 230:1,15	time 6:3 15:17,22	told 100:3 130:8	tragic 290:2	true 87:21 108:8
269:12	19:6 25:22 39:21	tolerances 46:1	training 34:19	177:6
thinner 212:15	40:20 48:1,8	tomorrow 151:19	35:14,18 62:14	truly 91:8 122:19
third 9:11 113:18	49:17 50:3,13	315:11	64:9,22 149:20	180:7
191:2 192:8 217:4	52:10 56:7 59:10	ton 258:5	167:20 168:7	trust 157:7
233:1 240:4	63:3 68:9,20,22	tool 63:7 65:10	172:10	truth 163:12 198:9
Thirdly 148:11	69:7 82:14 120:19	66:22 67:8,15,21	trainings 138:5	try 16:7 28:10
thirty 76:15	122:15,20 124:5,7	102:21 248:9	transcript 17:15	45:16 62:15 63:9
thorough 84:7	124:18 126:19,20	250:14 301:21	transcripts 17:7	98:21 145:9
thought 48:12 51:5	127:3 135:22	304:14	transfer 263:10	166:22 175:17
104:18 105:4	137:1,22 140:2	Toolkit 64:21	transferred 101:7	178:16 190:8
175:11 178:22	141:12,17 142:1	tools 103:15 149:21	transition 8:5	235:2,11 236:16
187:21 189:12	142:21 143:1,13	150:10 162:18	transitional 59:4	261:4 273:15

287:16 301:6	205:12 224:18	undeveloped 261:1	urgent 114:18	213:18 216:3
310:1 312:19	239:14 291:14,14	undue 110:14	urges 136:21	220:3 221:1
313:10	299:16	229:13	138:13	222:14 226:21
trying 11:8 29:8,21	types 32:18 209:18	unfair 15:16	urging 155:7	227:4 229:8 233:7
57:5 65:8 94:3	253:10 254:18	Unfortunately	USDA 17:20 18:17	233:8 234:18
111:2 133:4,19	296:22	181:3	20:14 21:16,19,22	235:17 236:1,9,17
157:6 177:2	typhimurium	uniform 138:11	22:3,4 28:20,22	240:7 253:6
206:10 208:3	255:18	unintended 75:20	29:3,5,9 33:20	256:11 258:7
223:16 232:9,10	typically 297:5	Union 39:16 54:10	34:1 42:17 44:14	259:5,7 260:9
235:3,20 239:18		213:1	47:5 48:1,20,21	261:7 263:13
260:10 270:4	U	unique 41:13	52:13 53:15 54:1	265:9,20 268:8,22
273:15,16 278:14	UC 296:16	259:17	54:4 55:2,7 56:6	269:3 271:15
281:13,19	UCLA 154:8,10	United 1:1 27:21	57:19 60:7 61:3	275:17 283:1
tubs 129:15	ulcerative 154:2	74:8 254:9 255:7	62:9,11,14,15,21	289:7 291:13
Tucker 2:21 12:20	ultimately 173:15	282:16	63:2,8 64:14,16	295:18,19 296:3
12:21 50:7	unable 175:22	universities 214:18	65:3,14,14 66:16	308:8 310:4
turf 204:16	245:2	292:14	67:17 71:21 72:22	useful 63:21 65:5
turkeys 101:3,20	unacceptable 264:4	University 6:14	74:10 78:3,10,17	65:10 235:19
101:22 102:5	unachieved 88:12	10:6 152:21 154:4	78:19 85:7,8,13	309:7
104:2 223:19	unanimous 161:4	154:10,16 298:19	87:15,22 97:4	users 29:4 61:21
260:16	unannounced	298:20,20	104:19 126:18	62:4
turn 5:5 15:11	23:15 31:12 34:10	unlimited 179:21	131:16 197:8	uses 80:9 100:13
21:14 67:8 120:21	34:13,21 35:1	unnecessary 95:8	199:16 203:9,13	197:18 205:10
134:21 202:8	37:6 250:6	137:14	231:7 235:1	usual 150:7 265:22
210:9 231:1	unanswered 274:8	unravel 235:2	237:17 239:21	usually 69:16
249:20 256:4,6,13	unapproved	unsubstantiated	245:18 246:9	usurping 78:12
turnaround 83:6	201:14	139:15	255:13 292:11	utilize 185:8
turned 288:4	unavailability 43:2	unsustainable	use 27:16 42:20	186:22 190:8,11
turning 48:17	uncertified 32:20	286:2	43:22 44:18 45:6	208:3
turns 19:16	undercut 86:5	unthinkable 252:6	46:11 49:13 65:3	utilizing 57:21
twenty 73:21	undergone 136:12	unusual 37:15	65:6 67:21 68:14	252:17
twice 21:6 116:21	understand 48:5	upcoming 42:12	73:17 83:14 93:6	U.S 29:9,10 47:14
two 8:16 9:10 60:18	95:7 108:4 143:2	update 3:5,17 23:9	101:2 108:17,17	56:10 107:2 119:4
64:9 66:12 71:17	176:8 199:4 203:1	35:17 36:2 112:4	109:4,15 118:12	136:17 142:15
75:19,19 93:3	231:20 232:9	134:19 230:22	118:15 127:2	225:16 243:13
95:9 131:21	236:1,17 281:13	231:3	130:15 137:5	245:5 250:4
161:14 167:8	309:4,5 310:13	updated 35:9	148:8 152:10	
186:13 211:2	understandable	211:11	156:8 157:14	V
214:17,18 234:14	38:9	Updike 231:10	177:11 182:16	vaccinate 257:11
250:6,21 254:18	understanding	uphold 90:19	183:9 186:7,9	260:22 261:9,10
256:6,13 257:18	93:7 97:18,19	uploaded 139:10	187:2,10,22	261:14,15,17
258:5 277:8,22	98:1 126:20 199:8	upper 265:2	188:15 190:2,13	vaccinated 105:15
279:7 288:2	215:20	uptake 197:21	192:3,19 195:16	250:18
twofold 79:14	understood 273:21	urge 102:18 103:16	196:2 199:5,5	vaccination 250:14
two-part 188:19	287:20	136:7 147:18	204:18 205:2,12	251:2,4,9
type 133:17 137:7	undertaking 55:7	149:12 155:9,12	207:21 208:2,7	vaccine 10:11
142:12 200:2	underway 154:3	170:5 173:1	209:18 211:5	46:20 100:16,18

126:5 230:22	vectors 253:6	violate 101:12	voting 17:9,13,14	105:19 109:18
231:4 234:18	vegan 291:12	violation 83:9	19:13 157:17	112:4 192:3
235:16 237:15	vegetable 194:1	183:1 264:8	179:8 218:17	196:17 234:16
238:5,11 240:1	vegetables 6:22	violations 33:1,5	241:19,22 305:5	235:11 240:3,5
254:17,18,19,22	7:19 181:16	117:15 245:19	308:6 314:3,5	242:1 287:14,21
255:2,4,7,8,9,12	vegetarian 223:20	viral 254:18 257:4		310:9
255:16 256:7,20	262:22 263:2	257:4,5 260:21	W	wanting 312:8
257:4,5,5,6	vegetation 48:13	261:16	wait 73:15 119:7	313:1
260:17,20,22	vehicle 75:2	Virginia 52:12	Walden 164:22	wants 133:2 143:8
vaccines 3:17	verifiable 26:4	virtually 184:6	165:1 168:17	200:14 237:9
100:11,13,15	verification 42:3	virtue 60:17 61:8	169:3	warn 6:2
101:1 104:16	verify 110:12	virus 255:19 257:7	Walker 1:22 10:13	Washington 8:11
105:8,18 128:13	235:21	257:10	10:14 75:9,15	140:12 248:15
139:2 232:6,15,20	verifying 26:1	viruses 128:12	228:17 257:17,21	wasn't 19:14 93:7
232:21 233:1,19	Vermont 10:7	254:19	307:6 314:18	174:20 192:9
233:22 234:7,16	125:10,12,16,19	visit 52:18	walking 193:19	218:7 251:21
235:22 236:2,7,10	125:20 126:3	visited 255:2	wall 62:21	wastes 137:13
236:18 237:17	132:16 142:10	visits 25:1,7 34:5	Walmart 245:17	watch 97:20 258:15
239:21 240:6,8	vernacular 22:8	185:1 250:6	want 15:9,16 18:14	258:17
268:22 269:3,4	version 64:15	visual 162:20	18:20 21:3 23:9	water 116:18,19
Valley 8:7 244:7	108:4 140:5	vital 89:5	38:20 48:7 49:21	117:6,9,21 118:16
valuable 4:17	196:21	vitamins 24:8 39:5	51:8 52:1 53:10	132:5 182:1
134:8 135:11	versus 221:18	41:12 221:7	65:19 87:1,8 88:6	209:16 282:20
250:14	226:12 285:14	278:10 287:3	91:2,3 92:21	waters 207:3
value 45:8 60:4	vested 78:13	288:16 291:7	93:14,15 94:18,19	Watsonville 7:10
88:14 138:19	vet 129:22	vocal 309:11	95:14 97:16	9:5
203:15	veterinarians	vocation 11:20	133:15 143:22	way 22:5 30:1,11
values 109:6 147:8	235:16 291:13	voice 286:18	147:10 156:13	45:17 47:16 52:20
value-added 173:8	veterinary 125:9	voluntarily 190:7	160:22 189:22	88:22 89:11 93:8
Vanderbilt's	292:15 298:21	243:21	190:7,12 193:4,21	93:15 94:8,11
153:20	299:2	voluntary 239:3	200:13 203:14	95:2 100:7 102:11
variable 282:21	vetting 84:7	244:16 250:3	206:16 207:15	110:22 115:9
variance 27:5,10	viability 225:11	volunteered 160:21	215:10 228:16	125:20 128:5
27:18	viable 149:15 180:2	vomiting 162:3	230:11 236:16	130:11 133:12
variances 26:21	225:19 284:10	vote 81:18 85:4	238:2 243:10	156:8,13 158:3
27:2	vibrant 219:5	135:9 144:19	246:19 251:5,20	165:7 178:22
varied 165:2	vice 8:14 10:17	145:4 155:12	253:5 254:7	182:21 185:18
varieties 111:17	254:3	158:2,19 161:20	255:21 257:3	199:19 202:15
variety 117:1 177:1	video 21:15 50:18	179:16 195:2	259:13 269:7	229:10 239:5
248:1 303:6	50:20 52:8 55:20	218:11 242:3	274:19 277:6,11	253:14 256:7
various 22:19	videos 66:14	305:7 306:4,13	284:21 285:22	267:21 287:1,2
23:10 48:15 101:4	view 110:11 124:2	311:5 315:5	286:7 288:10,12	291:10 299:7
165:13 213:3	133:3 157:3	voted 161:19	289:14 304:13	ways 33:19 76:11
219:8 220:14,15	229:20	213:13 315:3	308:2 312:1 313:2	93:22 96:19 97:17
248:10	views 14:10	votes 3:22 176:6	wanted 5:14 42:13	153:11 261:6
vary 176:21	vigorously 4:12	268:16 307:9	42:15 47:7 50:14	weaken 178:16
vector 293:15	71:20	314:21 315:3	52:7 82:13 104:14	wearing 52:13

weather 175:20 189:3	wetland 118:3,13	236:13 237:5	193:7 243:12	144:9 198:3
webinars 35:14	wetlands 116:18,20 117:9 121:8	240:12 241:18	wholesome 164:9	wonderful 50:6 69:12
webinar-style 172:10	we'll 4:22 16:11	242:3,8,9 247:4	wholly 43:2	wondering 139:16 185:5 187:21 189:8 205:1 214:2
website 28:12,17 28:18 54:15 55:9 60:9 65:21 211:14 217:7 296:19	17:14,14 19:22	252:4,6,7,14	WIC 163:3	woodlands 116:19 116:20 117:9 119:13,15
weed 181:22 183:18 189:16 207:22 212:15 214:13	34:22 35:9 36:17	254:4 273:1,5	wide 21:17 80:2 188:16 213:9 265:1	word 28:7 55:1 156:16
weeds 87:9 115:6 189:17,21 298:1	40:1,14 69:7 70:7	274:16 278:8,12	widely 149:14 267:17	words 92:1 94:16 293:1
week 4:13,18 20:13 45:12 49:14 50:1 59:12 100:9 129:2 129:3 159:2 192:21 248:19	70:9 81:21 100:9	279:13 284:22	wider 60:14	work 13:8 23:5 24:8 29:13 33:22 37:6,11 38:4 41:17 47:22 49:3 51:11,15,16,21 54:8,11,16 55:14 56:3 57:16,19 60:8 71:8,22 82:16 87:19 88:12 89:5,17 98:5 106:14 115:10 119:19,22 120:1,2 120:5 122:19 123:9 124:10 131:22 133:16 143:19 147:8 165:12 166:14,22 170:10 171:22 173:2,16 174:5 175:11,22 186:1,6 186:10 206:8 212:8 222:18 226:3 231:12 235:2 240:12 241:12 248:12,16 253:4,22 265:1 273:5,8 286:8 289:13,15 290:4 296:15 301:11,12 301:15
weeks 103:12 106:9 123:4 184:5,6 246:7 258:11,21 258:21 259:1 261:12 296:1	104:4 106:18	286:14 287:8	wife 7:18 125:11 181:1	worked 14:15 39:12,14 48:3
weigh 178:5	169:8,13 201:22	289:14 292:4	wife's 206:10	
Weil 155:6	218:14 274:6,10 314:5 315:10	295:17 296:6	wild 22:10 47:14 115:21 119:19 138:17	
welcome 4:5 6:15 173:21 210:4	we're 6:5 9:5,15 14:1 15:4 16:7 17:19,22 19:5 20:12 21:11 22:8 22:14,18 23:9 24:2,9,11,13,16 26:10 27:9,12 29:8,16 30:7,11 31:16 33:21 36:13 40:7,13 41:20 42:5,10 45:15 46:20 47:4 50:17 51:20 52:5,8,18 52:19 53:16,17 55:6,13,14 56:13 57:14 58:13 61:5 61:14 68:20 70:15 74:13 75:21 78:20 81:11,20 82:2 88:8 101:20 102:8 102:19 103:15 105:16 106:21 123:11,12,12 125:18 126:1 133:18,18,19 146:22 165:6,10 167:15,21 168:3,6 186:19 193:19,22 197:7 201:17 202:19 205:1 206:3,3,6,17 209:3,5,8,21 218:20 220:1 229:21 230:12 232:9,10 235:3,9	297:15 299:12,20 299:21 302:8 304:17 305:2 306:3,12	wildlife 116:19,20 117:9 118:4 136:20	
welfare 248:10 249:9		we've 4:16 15:19 16:18,19 18:5,9 22:2 23:11,20 24:5,19 25:1,5,10 25:14,18 26:19 28:4 29:12,15 30:5 31:8,11 32:5 32:7 33:8,12,16 34:5,15 35:3 36:7 37:5,19 39:6,7,12 51:17 52:22 54:8 54:16,19 55:7 58:6,9 63:3 74:20 75:22 82:18 83:5 103:14,19 123:2 129:12 169:5 181:7 189:16 191:12 205:6 206:12 231:8,15 243:12 244:21 249:16 281:8,8,9 299:15 303:18 311:2 312:11 315:8	William 286:10 291:18	
Wendy 1:19 3:4 7:20 17:5,14 129:7 210:10,14 216:12 218:3 223:4 231:2 241:17 305:4			willing 69:19,22	
went 23:8 47:15 65:12 70:12,12 126:17 169:11,11 239:21 242:6,6 255:2 271:7 304:21,21 315:14			wind 297:22	
weren't 112:14			window 142:20 143:15	
West 76:6			wine 8:13 119:14	
western 122:2			wineries 119:14	
wet 187:6			wing 181:5	
			winter 128:17 189:19,22	
			Wisconsin 7:22 131:6 246:15	
			wish 69:4 178:17 265:7 305:11	
			wishes 4:21 179:22	
			withdraw 183:10	
			withdrawn 217:14	
			withhold 129:1,2	
			withholding 126:19 127:3	
			witness 25:2 218:7	
			Wolf 146:21	
			woman's 148:22	
			women 77:1 149:2	
			wonder 95:22	

50:10 62:12	67:9 80:13 87:7	274:4,9 277:22	1:06 169:12	48:18 74:3,14
160:17 167:10	91:20 107:9 139:4	285:7 286:19	10 20:13,15 23:8,10	101:20 102:16
184:9 219:15	139:9 147:4	289:14 304:2	47:4 49:14 52:22	140:11 142:19
223:5 243:12	169:20 170:6	312:12	53:18 162:14	184:6 189:10,15
working 3:17 7:7	172:12 233:11,15	year's 26:18	10th 14:4 68:2,12	190:2,8,13 196:13
21:12 24:10,11,14	303:18	yeast 271:8	10,000 192:21	224:15 247:19
24:16 26:3 31:16	wrong 78:20 178:4	yellow 6:1	258:3 259:5	258:8,21 295:8
34:8 36:4,14	194:14	yesterday 96:9	10-year 49:11 52:9	296:17 312:11
40:13,22 41:20	wrote 95:15 206:4	125:12 228:22	100 71:15 127:9	2,290 254:14
45:15 46:20 50:2	288:4	229:8 230:17	128:1 133:5	2,300 107:1
56:21 57:3,5 62:1		yield 181:22	177:18 188:11	2-pound 264:5
62:8 72:17 82:11	Y	York 74:18 206:5	223:22 262:10	2-year 142:21
83:16 102:9	year 5:16 6:6,7 7:1	young 47:13 101:4	101 64:11	143:1,15
147:11,19 209:21	7:17 9:11 11:11		11 1:11 100:13	2:27 242:6
209:22 230:22	11:15 21:7,7 23:7	Z	11:33 169:11	2:45 241:16 242:4
231:4,7 232:1	24:12,22 25:6	Zea 1:21 7:9 21:5	112050 212:4	2:56 242:7
235:9 236:13	27:3,3 32:7,10,14	139:7 142:6	305:18	20 3:6 20:19 127:15
237:6 238:18	33:9,12 34:17	187:12 310:8	12 86:15 140:2,3	183:11
240:22 261:4	36:13 40:3 42:12	zero 126:18 140:11	261:15 295:22	20-year 20:16
267:13 268:1	61:8 106:19 111:2	162:12	120 27:14	200 39:3 125:22
269:2,4 273:1,2,5	124:17 129:19	Zirkle 8:9	13 180:5 216:16	200,000 127:22
274:16 300:21	133:21 175:21		219:11	2000 162:13
304:3 308:14	176:22 185:16	\$	14 37:1 245:19	2002 20:15 277:9
works 48:20 223:9	189:5 190:7,10,16	\$10 206:7	261:12 315:6	2004 284:5 291:5
301:13	191:2 193:8 206:5	\$100 54:19 57:11	15 1:8 27:8 102:5	2005 292:11
world 132:4 194:15	243:18 244:9	\$100,000 193:7	176:1 241:15	2006 211:4
198:3 221:16	248:19 250:7	\$120,000 33:17	17 3:4	2008 56:14 58:22
245:5 246:16	273:7	\$21 58:19	17011 36:12	60:13 278:8
269:15	years 20:13,16,19	\$210 277:16	175 181:15	279:16
worldwide 22:17	24:21 39:11 47:5	\$240 277:17	18 140:4,10 142:7	2009 54:3 56:11
293:21	48:19 49:14 50:5	\$30 90:9	18-month 142:18	85:20 109:20
worm 129:16	51:4 53:1,18 54:3	\$5,000 60:17	1860 300:12	162:15 183:15
worms 127:6	57:13 72:21 90:3	\$60 59:4	19,089 254:9	201 64:11
137:17 270:3	99:11 112:1,8	\$7.5 246:7	1965 302:12	2010 33:9 36:21
worse 74:18 230:10	118:17 119:7		1973 106:17	56:17 112:17
worth 109:10 225:3	123:8 126:16	0	1979 286:14	152:13 174:18
239:16	127:9 129:14	05 219:14	1983 181:7	234:6 250:20
wouldn't 186:7	130:18 132:20	08 219:16	1986 181:10 192:1	254:9
188:1 189:22	140:11 141:15	095 113:12 114:21	1988 26:19	2011 26:18 32:7,10
190:10 192:17	142:19 151:8		1990 71:19	33:11 36:7 161:21
200:3,13 201:3	160:15,17 163:4	1	1992 20:19	174:17 181:12,13
212:16 222:15	177:18 178:13	1 6:1,2 55:2 74:1	1997 214:6	210:17
309:2,3,18 312:6	184:7,9,12 189:10	76:17 102:2,3,5	1998 206:13	2012 1:8 24:3 26:16
wounds 155:3	189:15 190:2,8,13	169:9 315:5	1999 304:4	27:21 30:19 39:1
wrap 68:1	193:12 196:13	1,000 258:6		39:2,21 73:4
writing 145:14	225:12 245:1,19	1,200 133:6	2	99:12 183:7
written 3:12 4:17	270:1 273:22	1,800-person	2 24:21 39:11 42:1	216:19
		181:18		

2013 39:20,20 40:1 41:22 264:14 268:1	305 3:22 113:9 33 107:2 333 214:6 337 294:6 339 294:6 34 289:14 35 249:2 365 248:19 385,000 195:12 39 30:21	6 101:20 126:15 184:5,6 202:19 296:1 6-hour 125:12 6-month 61:10 6-7 261:11 60 74:18 182:2 259:1 603(a)(4) 232:21 65 8:4 68 254:10,11 262:16	129:2 95 148:15 291:6
2015 54:3 56:11 204 33:12 205 171:11 232:8 233:2 205.105(e) 233:6 205.238(a) 264:8 205.600 233:21 234:9 205.603 107:22 210:19 212:4 216:22 268:3 307:13 314:4 206 312:5,7 206(a)(b)(c) 312:18 210 3:12,14 216 3:14 22 313:20 223 3:16 230 3:18 238(a)(6) 232:13 242 3:19 25 54:1 56:10 181:16 259:7 25(b) 147:15 26 151:8 263 33:18 269 33:10 279 32:6,7 29 193:12 210:17 254:14	<hr/> 4 <hr/> 4 3:2 5:22 11:15 57:12 101:19 112:7 127:8 129:14 131:11 132:19 4th 53:5 4,247 254:10 4:04 304:21 4:15 304:19 4:20 304:22 4:34 315:14 40th 106:18 40-45 189:4 400 246:15 42 254:14 43 74:8 254:12 45 258:21 49 3:8	<hr/> 7 <hr/> 7 171:11 248:19 262:14 7,000-member 156:6 70 3:9 72 128:7 75 259:5,7	
<hr/> 3 <hr/> 3 101:5,21 102:16 112:1 119:7 225:11 295:8 296:17 3,000 253:5 30 25:16 27:8 160:15 179:5 203:9 216:19 246:1 258:11 277:17 296:1 30,000 22:17 30,000-foot 229:20	<hr/> 5 <hr/> 5 34:13 50:5 51:4 74:1 90:3 100:13 101:18 148:12,18 179:21 184:9,12 189:3 203:10 247:18 274:9 291:8 5-year 51:5 50 25:5 30:18 101:22 103:21 128:1 190:18 246:13 258:21 500 258:4 54 32:6	<hr/> 8 <hr/> 8 262:14 277:22 315:10 8,256 254:12 8:00 1:10 8:03 4:2 80 4:15 27:15 33:12 127:19,20 282:20 8910 292:17,19 293:7,19 295:19 299:7 303:4,8 304:4	
	<hr/> 6 <hr/> 6 101:20 126:15 184:5,6 202:19 296:1 6-hour 125:12 6-month 61:10 6-7 261:11 60 74:18 182:2 259:1 603(a)(4) 232:21 65 8:4 68 254:10,11 262:16	<hr/> 9 <hr/> 9 167:13 196:12 261:15 9,000 195:12 9,000-cow 72:19 9:20 70:12 9:45 70:8 9:48 70:13 90 22:15 27:14 110:9 140:12 142:20 293:9 304:2 90-day 127:2 129:1	

C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Meeting of the National
Organic Standards Board

Before: USDA

Date: 10-15-12

Place: Providence, Rhode Island

was duly recorded and accurately transcribed under
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UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURE MARKETING SERVICE (AMS)
NATIONAL ORGANIC PROGRAM (NOP)

+ + + + +

MEETING OF THE NATIONAL ORGANIC
STANDARDS BOARD (NOSB)

+ + + + +

TUESDAY

OCTOBER 16, 2012

+ + + + +

The National Organic Standards Board
convened at 8:00 a.m. at the Biltmore Hotel,
11 Dorrance Street, Providence, Rhode Island,
Barry Flamm, Chairperson, presiding.

MEMBERS PRESENT

BARRY FLAMM, Chairperson
HAROLD AUSTIN
CARMELA BECK

COLEHOUR BONDERA
JOSEPH DICKSON
TRACY FAVRE
JAY FELDMAN
JOHN FOSTER
WENDY FULWIDER
NICHOLAS MARAVELL

JEAN RICHARDSON
ZEA SONNABEND
MAC STONE
JENNIFER TAYLOR
CALVIN WALKER

STAFF PRESENT

MILES McEVOY, Deputy Administrator, National
Organic Program

MICHELLE ARSENAULT, Advisory Board Specialist

MELISSA BAILEY, Director, Standards Division,
National Organic Program

LISA BRINES, Standards Division, National
Organic Program

EMILY BROWN-ROSEN, Agricultural Marketing
Specialist

JENNIFER TUCKER, Associate Deputy
Administrator

A-G-E-N-D-A

GMO Ad Hoc Subcommittee
 Subcommittee Proposal and Summary of
 Written Comments. 4

 Public Comment. 21

 Crops Subcommittee
 Subcommittee Proposal and Summary of
 Written Comments. 65

 Proposals
 Ferric Phosphate. 66
 Oxidized Lignite. 76
 Propylene Glycol Monolaurate (PGML) . . 82
 Other ("Inert") Ingredients in Pesticide
 Formulations on the National List . . . 86
 Rotenone. 102
 Sulfuric Acid 117
 Biodegradable Mulch Film from
 Bioplastics 122
 Update from the Tree Fruit Working
 Group: David Granatstein. 148

 Presentations

 Consumers Union:
 Dr. Urvashi Rangan. 175
 Organic Seed Alliance:
 Kiki Hubbard. 196
 Public Comment. 221

 Board Votes 354

 Materials Subcommittee
 Subcommittee Proposal and Summary of
 Written Comments. 378

 Board Votes 394

P-R-O-C-E-E-D-I-N-G-S

8:04 a.m.

1
2
3 CHAIRPERSON FLAMM: The meeting
4 will please come to order. This morning we'll
5 begin with a session led by Zea, the Chair of
6 the GMO Ad Hoc Subcommittee. And I'll turn
7 the gavel over to her right now to conduct her
8 session.

9 MS. SONNABEND: Thank you, Barry,
10 and good morning everyone.

11 Michelle will put up the posted
12 recommendation. And I heard from some of you
13 in the audience last night that it was very
14 hard to hear in the back of the room so if
15 perhaps the sound people can be conscious of
16 that. And I'll try and speak up to the extent
17 possible.

18 Okay. As we talked about at the
19 last NOSB meeting in Albuquerque with the
20 mission behind forming this new Ad Hoc GMO
21 Subcommittee we wanted to keep the issues
22 around GMOs of which there are many because

1 you keep hearing them coming up all the time
2 in front of the board and in front of the
3 public to be able to call attention to the
4 fact that organic does not want to have any
5 GMOs and we consider the effects of the GMO
6 world on our organic industry to be
7 essentially chemical trespass.

8 And we need to take whatever steps
9 we can to keep them out. And one of the key
10 steps to do this will be to keep talking about
11 it, keep working towards clearer and clearer
12 definitions, places to draw the line and
13 associated issues around GMO presence in our
14 organic community.

15 So, we started work, and this was
16 at the request of some of the members of AC21
17 that we started to work on seed purity. We
18 wanted to find out by putting out a discussion
19 document from the organic community what was
20 going on out there in the GMO seed world --
21 or I shouldn't say GMO seed world -- in the
22 seed world for organic production that may or

1 may not be contaminated with GMOs. And that
2 includes both organically grown seed and
3 conventionally grown seed that is trying to be
4 kept -- have less GMOs.

5 I'm not going to read the whole
6 document because those of you interested in it
7 will have read it. But I'm going to summarize
8 the public comment and then along the way have
9 a few thoughts of where we're going to go from
10 here. And then I'm sure we're going to hear
11 some more public comment and we'll take that
12 under advisement as we do our work.

13 So we received 66 individual
14 comments. Eight-five of them, which I know
15 sounds weird, but it was actually in 7
16 letters, but one of them represented 79
17 people, copied the language from Beyond
18 Pesticides which we'll summarize in a moment.
19 Eight people put in comments on GMO subjects
20 not related to seed purity such as labeling,
21 keeping GMO citrus trees out and other things
22 that are important perhaps in the future but

1 are not the subject of this paper.

2 And then we got about 26
3 substantive comments. And then while some of
4 them were duplicative, like we support someone
5 else's comments, but I consider them
6 substantive if the person or group took time
7 to write a distinct letter of their own that
8 raised their own issues.

9 I'm going to only -- with 26
10 comments which really were all over the place
11 and we got some really good feedback and some
12 things we hadn't thought of concerns, but I'm
13 not going to be able to summarize every single
14 comment on every single question so I
15 apologize if I leave yours out but I tried to
16 capture all of the unique ideas and
17 suggestions that were present.

18 Okay. So, in the -- before we get
19 to the actual questions we posed we of course
20 had a number of people write in overarching
21 comments. And Michelle, if you can scroll up
22 just a bit.

1 Okay, so Blue River Hybrids which
2 is one of the more critical of our proposals
3 said, "Seed purity standard must consider
4 whether organic farmers' choice of seeds would
5 be limited to those of poorer genetics or
6 variety of genetics. It's disappointing that
7 the many positive reasons for using organic
8 seed are not considered."

9 We of course realize that we
10 didn't put in the many benefits of using
11 organic seed. That was not the focus of the
12 paper and we were trying to keep it short. So
13 we acknowledge the comment.

14 The ACOA along with the PCO: "The
15 discussion of seed purity standards need to
16 occur at all levels. Certification agency
17 staff, producers, handlers, buyers, marketing,
18 co-ops. Clarification on education on terms
19 in the field is needed." And although that
20 certainly goes with question 7 also but I
21 thought that was important to bring out.

22 ACOA recommends we take a

1 leadership role in establishing broadly
2 applicable USDA regulations. That is what we
3 are trying to do, we, the NOSB, and hopefully
4 through us the NOP.

5 Organic Seed Alliance believes
6 that the next step for the NOSB is to apply
7 more pressure on the Secretary to fulfill his
8 obligation to support the success of organic
9 ag. The NOSB can provide specific
10 recommendations that speak to lack of policies
11 and practices that eradicate GE material and
12 seed. And we need access to good data. We
13 definitely agree.

14 Organic Valley/CROPP Cooperative
15 feels that the policy memo from the NOP fails
16 to address the issue of adventitious presence.
17 And they believe this testing standard
18 represents -- while it represents a departure
19 from the process standard foundation and
20 carries some risks they think that market
21 expectations and seed industry practice demand
22 and enable such a shift. OTA cites the

1 benefits to seed growers and farmers of having
2 such a program.

3 Okay, so question 1, is there a
4 need to establish a seed purity standard or
5 protocol, and please explain. So, the 85
6 commenters plus Beyond Pesticides say roughly
7 we endorse the development of a seed purity
8 protocol only in combination with a
9 comprehensive plan to prevent GE contamination
10 along with a rigorous enforcement strategy.
11 This enforcement strategy should be
12 spearheaded by the USDA.

13 I would have to say in general our
14 subcommittee agrees with this. We talked
15 about this quite a bit on our work plan
16 although not -- it won't be immediate work
17 plan but we do have planning to prevent GE
18 contamination as one of the things we will be
19 working on.

20 OSGATA would like to encourage the
21 USDA to establish seed purity standard and
22 protocols to implement and ensure that organic

1 and conventional planted seed as well as
2 parental seed lines for breeding and
3 foundation stock seed maintain genetic
4 integrity.

5 ASTA does not believe there is a
6 need to establish an NOP-required seed purity
7 standard. And they feel it's an additional
8 burden for organic farmers and additional
9 costs would be incurred by organic farmers and
10 then passed onto the consumer.

11 CCOF is absolutely in support of
12 preventing GMO use in organic production and
13 would consider a seed purity standard but are
14 very concerned about the same thing as ASTA
15 which is additional cost to organic growers.
16 They would rather see a process-based
17 certification that looks to risk analysis and
18 mitigation rather than moving towards product-
19 based certification dependent on testing.

20 They also point out that the
21 regulations 205.670 requires the certifier to
22 bear the cost of all testing of products and

1 inputs that we would require as part of
2 certification. And that having the certifiers
3 pay for any testing of seed would become very
4 burdensome very fast. And so we'll have to
5 work on that consideration in our future work.

6 Blue River would not encourage
7 seed purity standard. It will create more
8 problems than it solves. OGC echoes OSA so
9 we'll get to that. Organic Valley/CROPP
10 recommends seed purity standard of none found
11 in the 3,000-seed sample for seed in the
12 organic production. The seed industry has
13 made it clear that they are technically
14 capable and willing to provide the organic
15 community with a continuous supply of elite
16 genetics that meet such a standard and they
17 can do so at an affordable price.

18 Oregon Tilth: the genetic purity
19 standard needs to be established by the USDA
20 to meet all seed -- to address all seed
21 organic heritage, convention and GMO. Any
22 farmer purchasing seed deserves assurance it

1 is pure. OTA believes setting a seed purity
2 standard can be consistent with process-based
3 standard when analytical limits are used to
4 verify that adequate measures are in place to
5 prevent contamination with excluded methods.
6 Seed purity standard if properly established
7 would protect rather than burden organic
8 farmers.

9 Organic Seed Alliance believes too
10 soon to implement a universal genetic purity
11 standard for reasons described. They're
12 concerned about the impact such a standard
13 would have on organic seed availability which
14 is another risk to organic integrity. They're
15 concerned that adding another risk point such
16 as a standard would discourage further
17 investments in organic breeding and
18 production, thus diminishing choice in seed
19 and undermining progress.

20 They're also concerned that the
21 potential to unintentionally encourage the use
22 of non-organic seed and therefore further more

1 the conventional seed industry which can
2 invest in meeting a genetic purity standard
3 where organic seed, it costs more to produce.

4 Okay, I'm not going to summarize
5 the answers to questions 2 and 3 which were
6 what's known about contamination and testing
7 and what testing methods are appropriate
8 because we didn't quite get the volume of
9 information we were hoping for. While we
10 thank those who did put in something it's kind
11 of all over the map and very difficult to
12 summarize. But the committee will look at it
13 in its future work.

14 Same with number 4 because that
15 was very specific to each person's business.
16 We're not going to try and just say that for
17 everyone and we'll talk about it within the
18 committee. It's all in the public docket so
19 everyone can read the comments for themselves.

20 Is there a better suggestion for a
21 seed purity standard? And this was key to us
22 because we were just using one that we had

1 heard was commonly used in the seed testing
2 world but not the only one. So we received a
3 few responses.

4 OSGATA's policy on genetic
5 engineering states, "Contamination of organic
6 seed constitutes irreparable harm to the
7 organic seed industry by undermining integrity
8 of organic seed. Any detectable level is
9 unacceptable. International experts in GE
10 detection recommend 10,000-seed sample size
11 for PCR which is one of the testing methods.
12 A 10,000-seed sample takes full advantage of
13 statistical limit of detection. In other
14 words, we're concerned that depending on the
15 lot size in question 3,000 seeds is too small
16 to statistically assess the minimal signal to
17 be determined as meaningful measurement.

18 And then they go on to suggest a
19 combination test method of qualitative and
20 quantitative PCR and give examples. We'll
21 have to look into the technical aspects and
22 feasibility of that suggestion.

1 ASTA which is the American Seed
2 Trade Association, by the way, as OSGATA is
3 the Organic Seed Growers Trade Association.
4 If there is for market reasons value in a
5 threshold then the AOSCA standards -- don't
6 ask me what this stands for but Kiki will tell
7 us later because I always forget what AOSCA
8 stands for.

9 The AOSCA standard for certified
10 seed may be suggested standard to use as
11 guidance. They are a seed certifying agency,
12 AOSCA. In any case regarding testing the
13 scope and appropriateness of testing should be
14 based on the crop. Frequency of testing
15 should consist of new harvest seeds and seed
16 safes for planning. They talk about ISO
17 quality system.

18 Organic Valley in response to the
19 question, they don't believe there's a better
20 type of seed-testing protocol. This standard
21 appears to strike the right balance between
22 rigor and feasibility. The standard will be

1 based on non-detectable sample so the
2 discussion therefore revolves around sample
3 size. A standard that would allow for
4 detection of any transgenic material in the
5 sample would be unacceptable to us and that's
6 why we don't like the words "threshold" or
7 "tolerance" and avoid using the statistical
8 equivalent expressions of less than 0.1
9 percent with 95 percent confidence because
10 such terms and expressions falsely imply some
11 level of presence.

12 The subcommittee has agreed with
13 us and that's why you don't find the words
14 "threshold" or "tolerance" anywhere in the
15 discussion document. Blue River says if
16 absolutely needed I would suggest a standard
17 of less than 1 percent.

18 Organic Seed Alliance. The NOSB
19 should apply real pressure on the USDA to
20 establish a system for ongoing testing and
21 monitoring organic and GE. Non-GE community
22 needs a comprehensive data set for

1 understanding the state of GE contamination.

2 Testing is necessary but not at
3 the total expense of the organic community.
4 Testing should occur in the context of
5 comprehensive regulatory framework
6 administered by the USDA for GE crops. This
7 would include proven prevention measures in
8 the field, adequate compensation for organic
9 farmers, shared costs for testing and
10 prevention on the part of owners and users of
11 GE products, and routine monitoring of
12 contamination at the seed level.

13 I would say we agree with that but
14 getting the USDA to do their part outside of
15 the NOSB who is trying to do their part, but
16 the rest of the USDA, not so much as we know.

17 Question 6. We're not going to
18 summarize that question. We did not get very
19 much response to it.

20 Training guidance or resources.
21 We did get some responses and I'm not going to
22 read them all out now but we got some good

1 information from expected groups like the ACA,
2 OTA and Organic Valley about training and who
3 can help with it such as AOSCA and things like
4 that.

5 Question 8, what approach should
6 an organic seed producer use to safeguard
7 against GMO contamination from adjacent and
8 neighboring farms? And this is something that
9 we will be working on, as I mentioned, in our
10 future work plan about a prevention strategy
11 guidance.

12 And we got comments similar to
13 some of the above. We need a comprehensive
14 approach that includes not just seed purity
15 but identifies and addresses sources of
16 contamination all along the supply chain. And
17 then Blue River pointing out the problems,
18 that you can do everything right and still get
19 contaminated. We do recognize this and it's
20 very unfortunate.

21 OSGATA seed growers and seed
22 companies supplying organic seed to the

1 organic community should follow protocols by
2 which design intercept GE contaminants. And
3 they talk about their prevention strategy that
4 OSGATA will be publishing fairly soon, I
5 believe early next year.

6 So, I think we have a good
7 starting place. We were hoping for a little
8 bit more specific data on what gets tested and
9 how often and what sample sizes are used and
10 things like that. And clearly one of our
11 first missions is to try and inform ourselves
12 of some of that information. I don't want to
13 say we're going to initiate a survey because
14 that is problematic for the department, but
15 we're going to look into working with maybe
16 the Economic Research Service or some other
17 ways that we can find out more what's
18 happening in the organic community.

19 We are going to be working towards
20 a recommendation. I'm not sure how fast this
21 work will take place. You will see it on our
22 work plan for the next meeting. But in light

1 of the fact that we're not really in a
2 consensus mode about this and we could
3 certainly use a lot more stakeholder input
4 we'll see how fast we're getting there. But
5 I'd like to thank all the commenters and that
6 concludes my presentation.

7 Okay. We're now ready to start
8 the public comment on this but I don't know
9 who's up. Beth Unger.

10 MS. UNGER: Good morning. I'm
11 Beth Unger with CROPP Cooperative, a farmer-
12 owned cooperative marketing organic products
13 through Organic Valley and Organic Prairie
14 brands.

15 I want to thank the Ad Hoc
16 Subcommittee for the work they did. I thought
17 this was an excellent start. And we are very
18 much behind you.

19 We believe that clean seed is the
20 first and most critical component of providing
21 consumers with the purity they expect from
22 certified organic products. In fact, without

1 first establishing a non-detect standard for
2 the seed used in organic production and
3 gaining the seed industry's cooperation in
4 providing such clean seed it will continue to
5 be very difficult to figure out how to deal
6 with GMO contamination in crops and products
7 further down the supply chain.

8 Our commitment to clean seed is
9 reflected in our written organic seed policy
10 that contains a phase-in period for our
11 members to begin using tested clean organic
12 seed. To that end we have been and will
13 continue to work with the seed industry to
14 find a path for seed companies to provide
15 farmers with seed that meets the genetic
16 purity standard of none found in a 3,000-seed
17 sample.

18 We're convinced that such clean
19 tested seed can be technically accomplished by
20 the seed suppliers and will be made available
21 to the organic community if we continue
22 exploring practical options with them and work

1 together to create an attractive market for
2 them.

3 Excuse me, I am not a reader for
4 comment, I'm always extemporaneous which
5 didn't work here. All right.

6 This is not a discussion of
7 process-based versus product-based standards.
8 OFPA requires residue testing. GMO
9 contamination is a residue. Rather, this is
10 an opportunity to work with seed companies to
11 resolve rather straightforward technical and
12 marketing issues in order to provide us with
13 a wide variety of clean foundation seed.

14 Some seed companies in the
15 comments that you were talking about, Zea, say
16 they can't meet a genetic purity standard.
17 Some don't know if they could and some believe
18 they can.

19 We believe that working together
20 we can make the standard happen. It is well
21 worth the conversations. The actions that we
22 take as an organic community can facilitate

1 the process of accessing clean foundation
2 seed.

3 As we go forward to further
4 discuss and refine the discussion document and
5 ultimately provide a solid proposal to the
6 National Organic Program that is a product of
7 cooperation among the organic community we
8 will protect and build foundation seeds and a
9 supply chain that ensures the future of
10 genetically pure seed.

11 We believe that establishing a
12 non-detect standard for seed use in organic
13 production and securing cooperation of the
14 seed industry in providing us with a wide
15 selection of varieties that meet the standard
16 will not harm or hinder the development of a
17 robust organic seed supply chain, but will
18 open the door to significant progress and a
19 new round in the growth and development of the
20 organic industry.

21 This discussion document is a
22 wonderful start. Let's engage the USDA, the

1 primary seed genetics companies, the companies
2 that grow and sell commercial seed and the
3 organic community to refine the proposal based
4 upon consensus by working with the supply
5 chain in a cooperative manner that will ensure
6 the integrity of the organic seed.

7 MS. SONNABEND: Thank you, Beth.
8 Are there any questions from the board? I see
9 Carmela.

10 MS. BECK: Beth, I was just
11 wondering, how do you handle your growers that
12 save their own seeds?

13 MS. UNGER: I believe -- well
14 first of all, we would definitely support
15 saving seeds. That's a foundation of
16 agriculture. And there are ways to get that
17 tested.

18 We for instance have established a
19 testing lab in-house where we can help with
20 the testing of seed. I think that that safe
21 seed is something that should be tested on
22 occasion to ensure there's no creeping

1 contamination. There's ways to do it.

2 MR. FOSTER: Good morning, Beth.

3 So this question won't be a surprise to the
4 board members. So, the -- do you foresee the
5 seed purity standard increasing, decreasing
6 the burden of testing on growers? No change?
7 How is it going to impact them?

8 MS. UNGER: Well, I think in a
9 perfect environment, John, you'd want to see
10 the seed companies taking responsibility. And
11 I'm not talking just about organic seed
12 companies. Any seed company supplying seed to
13 the organic community would need to be a part
14 of this. It would be, you know, the best case
15 scenario here is to really increase the
16 foundational varieties for the organic seed
17 suppliers and start growing the organic seed
18 market more and more.

19 Did I answer your question
20 adequately?

21 MR. FOSTER: It actually answered
22 a question I didn't ask but thought of. I

1 don't know how you did that but well done.

2 But you know, one of my things is
3 I don't want more pressure on -- undue
4 pressure put on growers for things that they
5 may or may not have control over. So as you
6 see these ideas rolling out I just, I want to
7 recognize that, you know, a lot of testing is
8 hard for a lot of growers, and sometimes it's
9 financially untenable.

10 So, do you see like the burden of
11 testing, do you see that squarely on the
12 manufacturers, or squarely on kind of an MRO,
13 like an OMRI, for example, for seed? Or do
14 you think that could fall to the growers and
15 do you feel like that would be a problem?

16 MS. UNGER: I feel that the
17 testing goes back to the seed companies, the
18 seed growers. And that's where engaging all
19 of the seed companies in this conversation is
20 critical. We've been doing that, you know,
21 been working on it. We'll continue to work on
22 it and certainly would be happy to work with

1 the committee in facilitating engagement.

2 MR. STONE: So Beth if we have a -
3 - anytime we put numbers in regulation it
4 seems to bite us at some point. So how do we
5 have a process-based without strict numbers?
6 I'm kind of along the line of John's question
7 too of it seems like the innocent could get
8 hurt pretty easily. And I'm also concerned
9 that do we have enough clout with the seed
10 industry that they're not going to throw up
11 their hands and kind of say wait, wait, you
12 all are asking too much and I'm just going to
13 get out of that market.

14 MS. UNGER: Well, you know, in the
15 comment that you received there was really a
16 mixed bag of where the seed companies were at.
17 And so it's really critical, Mac, that this is
18 an engagement of the seed suppliers.

19 We believe that this is doable.
20 And it's a matter of everybody sitting at the
21 table and figuring out, you know, a win-win
22 position for everybody.

1 MS. SONNABEND: Any more
2 questions? Thank you, Beth. Oh, sorry.
3 Jennifer.

4 MS. TAYLOR: I have a question,
5 thank you. What role do you see, or do you
6 see a role for others within the seed system?
7 The growers you're saying and the seed
8 producers as well as the transportation
9 system, other seed cleaners. Are there others
10 within this role?

11 MS. UNGER: There most likely is
12 and I think the conversation will bear that
13 out.

14 MS. SONNABEND: Anyone else?
15 Okay, next Dag Falk. Please state into the
16 mike.

17 MR. FALK: Hello. I am Dag Falk,
18 organic program manager for Nature's Path
19 Foods.

20 Dear National Organic Standards
21 Board, Nature's Path is North America's
22 largest certified organic breakfast cereal

1 producer and we want to keep organic standards
2 with a high level of integrity and to match
3 the expectations of the committed organic
4 consumer.

5 We recognize the standards also
6 have to be workable for producers and
7 production, and a balance needs to be found.
8 Maintaining organic principles is the highest
9 importance and sometimes must override
10 production and market conveniences. Without
11 consumer confidence in the organic label there
12 is no organic market.

13 Regarding GMOs we are glad that
14 the NOSB sent a letter to Secretary of
15 Agriculture Tom Vilsack and we would like the
16 NOSB to take an even stronger stance.

17 The organic industry is lagging
18 behind in its approach to protecting itself
19 from GMO contamination. This is likely
20 because GMOs were introduced after the early
21 organic standards were developed and because
22 GMO contamination cannot effectively be dealt

1 with in the same manner as other prohibited
2 substances because GMOs are linked to living,
3 reproducing organisms.

4 It is time to update the organic
5 standards to deal with the exposure to GMO
6 contamination risk which is growing at an
7 unprecedented rate.

8 Organic standards are built around
9 dealing with issues at the core, not applying
10 Band-Aids after the fact. So it makes perfect
11 sense that a key area of focus should be
12 developing a seed base for organic agriculture
13 that is as free as possible from GMO
14 contamination.

15 Our experience when using high
16 volumes of GMO risk ingredients, corn and soy,
17 that's what we deal with, is that the organic
18 supply chain is contaminated with GMO,
19 sometimes more than conventional ingredients
20 that are expected to be non-GMO. This is a
21 sad reality and our response has been to
22 enroll our products in the Non-GMO Project

1 verification program which addresses the
2 shortcomings in the organic standards.

3 Organic as a system has the
4 pitfall of not discovering existing
5 contamination and actually discourages testing
6 from being undertaken by organic farmers and
7 manufacturers. That's the reason to believe
8 that if no one knows there is contamination
9 then no one cares. The problem is someone
10 does care and concerned consumers will begin
11 to demand organic cleanup more than it is
12 today.

13 Without utilizing the tools of
14 testing for presence of GMO on an ongoing and
15 consistent basis there is no way to improve
16 the situation. Testing must be embraced by
17 the NOP rule as a tool to apply the practice
18 of avoiding GMO contamination for soy, corn,
19 cotton, canola and sugar beet, specifically
20 for seed and finished ingredients. And of
21 course you have to test precursors to some
22 ingredients like oils because they can't be

1 tested.

2 I want to make a couple of points
3 on the reason -- in order to make testing
4 meaningful a threshold needs to be established
5 and that's for three reasons. The first
6 reason, provide a safe level for farmers under
7 which they will not encounter the business
8 risk of rejection of their product.

9 Two, provide a level which
10 consumers can understand and can be
11 achievable, yet necessary because we live in
12 a polluted world and that they can accept.

13 And third and the most important
14 is to provide a tool to force the conversation
15 about cost and liability for contamination to
16 happen in arenas outside of organic. The
17 industries and farmers that are at the source
18 -- are the source of GE contamination of
19 organic farmers and products must be forced to
20 take responsibility.

21 We have seen for too long that
22 politely asking for this is not working.

1 Having a threshold is an essential and key
2 component that must be in place in order to
3 demonstrate the cost -- that cost, harm and
4 hardship has occurred.

5 There's more detailed answers in
6 my handout that I just passed around. There's
7 two other areas that I want to make brief
8 comments on outside of GE that I guess I don't
9 get to do. Thank you.

10 MS. SONNABEND: Thank you, Dag.
11 Are there any questions? Well I have one if
12 I don't see any other board members. How do
13 you suggest we as a board who is not the rest
14 of the USDA so we can't really deal with the
15 topics we need the rest of the USDA to deal
16 with, but how do you suggest we collect enough
17 information on the topics that we do need
18 information to proceed? Such as how
19 frequently to test how many seeds in a sample,
20 all of those types of details.

21 MR. FALK: I think that there is
22 quite a bit of experience out there in the

1 world internationally and also with the Non-
2 GMO Project and so because that's been ongoing
3 for awhile there's been a lot of experience in
4 dealing with these very complex issues. And
5 so I think that the information is there, we
6 just have to dive into it.

7 The other thing I think is that if
8 we don't take the first step and actually
9 require ourselves to do some looking, to do
10 some testing, to do some investigation by
11 setting in place some rule we won't start the
12 process of actually gathering information. We
13 need to start gathering it and we cannot
14 gather it unless we say we need to set a
15 threshold, we need to understand that we can't
16 actually get there without taking the first
17 step.

18 MS. SONNABEND: Thank you. John?

19 MR. FOSTER: So that made me
20 wonder, I don't follow that. Why is the
21 establishment of a number a necessary
22 precursor to gathering information? I've

1 never let a number establishment get in the
2 way of information-gathering before. So help
3 me understand that.

4 MR. FALK: You mean a threshold
5 number?

6 MR. FOSTER: Right, threshold.
7 Right. Maybe I misheard you.

8 MR. FALK: Well, if we -- you
9 know, this is what we're doing. We're saying
10 we're going to look for something but we're
11 not really looking.

12 We have a practice standard today
13 and yet contamination levels in organic are
14 increasing. And I feel like that's because we
15 are not establishing the level because it's
16 not safe to look. Because the number is
17 infinite or, anybody's imagination is where
18 the number is. So everybody is scared to do
19 any testing.

20 Everybody is scared to know or
21 talk about what their contamination levels
22 might be because there's no safe level.

1 There's no level which by if I tell you you're
2 going to think I'm okay. So we have to have
3 a level where farmers are safe. Otherwise
4 they're never, ever going to engage with us on
5 this very difficult issue.

6 MS. SONNABEND: Nick.

7 MR. MARAVELL: Yes, a follow-up on
8 John's questions. Would a number be identical
9 for all crops? How long would a number stay
10 constant?

11 MR. FALK: I think that a number
12 should start as high as we can afford to make
13 it as easy as possible as an entry point.
14 Because once we have established a number
15 we're going to start gathering data and then
16 hopefully we'd be able to tighten the number
17 so that we're cleaning up the issue.

18 So, yes. Does that answer your
19 question?

20 MR. MARAVELL: Not exactly, but
21 what you said is make the number as high as
22 possible in order to provide entry into this

1 process. Is that sort of like a "let's take
2 a look" number, or is that a number that would
3 disqualify a product from being in the organic
4 status?

5 MR. FALK: That's a question I
6 think the whole industry has to struggle with,
7 whether it's a pass/fail number or whether
8 it's an action threshold that means we take
9 certain actions based on it.

10 You know, preferably -- like we're
11 very concerned about causing hardship for
12 farmers in particular and processors, and
13 that's not the objective here. We're trying
14 to save our own industry. We're not trying to
15 create more hardship. But at the same time we
16 lose our confidence from the consumers if we
17 just let this thing get out of hand.

18 So we're sort of stuck between
19 these two places and we have to find the best
20 number possible to make it feasible at the
21 same time as we are aiming towards reducing
22 contamination. So we have to be preparing

1 ourselves to ratchet it down as it becomes
2 feasible. But why set it so low that we can't
3 achieve it? That's the reason why we'll have
4 to look at that, setting that number very
5 carefully.

6 MS. SONNABEND: Thank you, Dag.

7 MR. FALK: Thank you.

8 MS. SONNABEND: The next, Jim
9 Asta.

10 MR. LANGER: Yes, this is Dave
11 Langer. I'm a research director at Dupont
12 Pioneer Hybrid Seed Company and I'm here today
13 representing the American Seed Trade
14 Association. And I want to thank the board
15 for the opportunity to comment.

16 On my first slide here I take the
17 opportunity to kind of take you over the flow
18 chart, the basic flow chart of the seed
19 industry. And we have several things. Zea
20 already mentioned the Association of Official
21 Seed Certification Agencies (AOSCA) a process-
22 based approach. We also have ETS here,

1 Excellence Through Stewardship, by which we
2 identify protocol and procedures throughout
3 our industry.

4 And the first part there is a
5 module, is the lab research that we conduct.
6 And then we have greenhouse and contained
7 facilities growth chambers. The third module
8 is field trials. That's where we do our plant
9 breeding, our characterization, trait
10 integration work.

11 And then the fourth module is seed
12 multiplication. This is where associations
13 like the Seed Certification Agency, their
14 process-based protocols are followed in that
15 area to ensure that we produce quality seed
16 that is used then to make commercial seed for
17 sales and distribution. And as this chart
18 shows, and we're doing this all for the farmer
19 customer to provide them seed.

20 Zea read many of these comments
21 earlier from ASTA. The one on coexistence,
22 the fact that is coexistence between different

1 bodies is possible. We are an example of that
2 in the seed industry in our seed production.
3 We deal with coexistence issues all the time.

4 We do take deference to the use of
5 the phrase "GMO contamination." It is
6 misleading for products that have been through
7 a thorough safety assessment. GE things have
8 gone through EPA, USDA, FDA assessment so they
9 are deemed safe.

10 What testing methods? You know,
11 the standard for seed purity and seed purity
12 labeling is dictated by the Federal Seed Act
13 and compliance with that lies within the
14 Federal Seed Act and that's what the seed
15 industry follows.

16 There is a range of testing
17 available for testing GE. We, instead of
18 contamination we talk about it as being
19 adventitious presence, defined as unintended
20 low-level presence of GE material.

21 What testing methods? One thing
22 you have to be aware of is you have to make

1 sure you're using accredited labs. These
2 tests, the PCR tests that Zea mentioned
3 earlier, they are very sensitive tests. They
4 are prone to err based on that sensitivity.

5 And there's types of error.
6 There's sampling error. I don't care if it's
7 3,000 seed or 10,000 seeds, there's going to
8 be sampling error. And it doesn't matter what
9 the seed size is in that regard in some
10 respects. Certainly there is statistics
11 around that.

12 The other error is the lab error.
13 When the tests are that sensitive there is an
14 inherent level of false positives in the labs.

15 For purity reasons the summary I
16 would say is, again, the Federal Seed Act is
17 the standard for genetic purity. Adoption of
18 things like the Association of Official Seed
19 Certification protocols is testing positive
20 for adventitious presence does not prevent an
21 organic producer from receiving a label or
22 certification.

1 For market reasons if a threshold
2 is necessary certified seed standards might be
3 something to consider. Testing for
4 adventitious presence in conventional organic
5 seed needs to be addressed on a crop-by-crop
6 basis. Sample size would be different. Some
7 crops don't have transgenics.

8 Studies have indicated the
9 stricter the AP/LLP requirements, the higher
10 the cost of seed production. And that's not
11 just the cost of testing, that's also the cost
12 of producing the seed and inventory cost. And
13 those additional costs would be passed onto
14 consumers as well.

15 I think a final statement to say
16 is the seed industry, we are willing to keep
17 the dialogue open on this issue as we feel it
18 can lead to a reasonable conclusion for all
19 parties involved. Thank you.

20 MS. SONNABEND: Thank you. Any
21 questions?

22 MR. FOSTER: I was looking at the

1 written public comment you sent in. Does that
2 slide showing the process, the nice flow
3 chart, is that part of your written comment?

4 MR. LANGER: That is not part of
5 the written comment, no.

6 MR. FOSTER: That would be a
7 helpful diagram for me to look at again and
8 again, so if there's some mechanism to get
9 that to me or the board I certainly would
10 appreciate that.

11 MR. LANGER: Michelle has it on
12 her computer.

13 MR. FOSTER: That would be really
14 helpful. It's -- after this many days it's
15 very helpful to have pictures to look at.

16 MR. LANGER: Right. I understand.

17 MR. FOSTER: And then the -- oh.
18 The -- I'll ask you kind of the same question
19 I asked Beth. How do you see a seed purity
20 standard affecting the growers? I know it's
21 not your world necessarily but my concern is
22 organic growers. So how do you see that

1 shaking out relative to the burden of testing
2 on organic crop producers?

3 MR. LANGER: Well, I think I
4 understand your question from the standpoint
5 that it would be a consideration if we
6 establish a threshold for seed that it would
7 be the next logical step that somebody might
8 consider there needs to be a threshold for the
9 resulting product from the organic growers.
10 So you know, I can't sit here and say if that
11 would occur but that would certainly come to
12 people's minds I would think, yes.

13 MR. STONE: certifiers are
14 checking the -- we've heard that some of the
15 previous generations may have had some version
16 of excluded method and as the technology
17 changes our definition of, quote, "excluded
18 methods" may not hold up in the modern world.
19 So there's -- I don't know how to ask the
20 question even of how many -- could there be
21 seed development further up the food chain but
22 then it appears as a organic product by the

1 time it gets to the producer because of these
2 generational development of seeds? Or is it
3 more direct than what we're being told?

4 MR. LANGER: Well, I'm not sure I
5 understand your question but if --

6 MR. STONE: I'm not sure I do
7 either.

8 MR. LANGER: Let me offer a
9 suggested answer then. But with new research
10 techniques there's things, like you can,
11 genetically you can remove a transgenic event
12 from a product. So things like that. So it
13 was, you know, of course in Europe the issue
14 of "derived from" comes up as an issue as
15 well. So, I mean those type of things.

16 Typically today in the research
17 process for transgenics, it's a parallel
18 process between our base germ plasm breeding
19 and our transgenic efforts, then our back-
20 cross the transgenic into the base breeding.

21 So there is -- I know there's been
22 some concern about there won't be any germ

1 plasm but in fact today there is base germ
2 plasm that does not get exposed to
3 transgenics. Now, eventually a lot of it does
4 with the crops that are involved in the
5 transgenic aspects of the market.

6 MR. MARAVELL: I have two or three
7 questions but I just wanted to make sure I
8 understood something. You said that if you go
9 back in your parentage and you are indeed
10 using a genetically modified strain to get to
11 your current hybrid are you indicating that
12 that would no longer be considered a
13 genetically modified seed? And number two,
14 did you also say that you can go back and
15 reconstruct, in effect take a genetic event
16 out of a seed line?

17 MR. LANGER: Well, for labeling
18 purposes as in the Federal Seed Act and the
19 guidelines we have from the trait providers
20 usually in the seed aspects, if it's a
21 transgenic it's labeled as a transgenic.
22 That's the way all those around the label of

1 any seed that's sold.

2 I'm saying on the removal of the
3 transgene it's technically possible. If
4 there's a transgene inserted, we know where
5 it's inserted in the genome and you can
6 actually take it out actually through breeding
7 process. Because it's just like transgenic
8 has genetically enhanced whatever and in some
9 respects definition we've been doing
10 genetically enhanced forever.

11 We've been -- humans have been
12 making selection and characterization and
13 picking out inadvertent mutations for
14 thousands of years. So in some respects we've
15 been doing that forever.

16 MR. MARAVELL: Could you elaborate
17 a little bit about the additional costs? Many
18 people are looking at this as a testing
19 burden. I guess I should in the interest of
20 full disclosure say that I am a seed producer,
21 organically certified seed producer, corn,
22 soybean seeds among other seeds.

1 There are many other costs which
2 actually far exceed the testing cost of
3 establishing seed purity. And I was wondering
4 if you could just give your read on those,
5 just give some definition or some description
6 of all the things that a seed producer may
7 have to go through in trying to ensure purity
8 and absence of GMO that would not involve just
9 a testing cost.

10 MR. LANGER: Right, right, and
11 that's the point is I think the testing would
12 actually be the small cost. In the seed
13 production you'd have to take -- maybe you
14 want to take extra steps to ensure that you
15 would reduce the probability of having
16 adventitious presence. Maybe that is
17 increased isolation distance which would have
18 a cost associated with it. Maybe it's a
19 separate line in your conditioning operation
20 to keep the non-GE or the organic separate
21 from the other. That would have a cost to it.
22 Physical separation and stands to make sure

1 that things are kept physically separated
2 would have a cost to it.

3 And I think one of the largest
4 costs actually would be inventory costs.
5 Because if you do the testing and monitoring
6 and you find out some lots do not meet
7 whatever the requirement is then all of a
8 sudden you may have just doubled your cost of
9 production on something for that customer. So
10 I think the inventory cost is actually the
11 largest cost but there is a lot of best
12 practices that have a cost associated with
13 them as well.

14 MS. SONNABEND: Thank you very
15 much.

16 MR. LANGER: All right, thank you.

17 MS. SONNABEND: Our next person is
18 Kristina Hubbard from Organic Seed Alliance.

19 MS. HUBBARD: Good morning. My
20 name is Kristina Hubbard and I'm the director
21 of advocacy and communications for Organic
22 Seed Alliance. OSA is also a member of the

1 National Organic Coalition and my comments
2 reflect their position as well.

3 We are so grateful that the NOSB
4 is taking seriously the threat of GMOs to the
5 integrity of the organic label through the Ad
6 Hoc Subcommittee, through the thoughtful
7 discussion document.

8 And we also applaud the NOSB's
9 decision earlier this year to send a letter to
10 Secretary Vilsack outlining our organic
11 community's longstanding concerns about,
12 again, the threat of genetically engineered
13 products to the integrity of organic. We
14 believe this is a really important first step
15 since I think we can all agree that the onus
16 cannot and should not remain solely on the
17 shoulders of organic.

18 While we do have some questions
19 and concerns about some of the proposals I
20 don't want any of my comments to be construed
21 as supporting a do-nothing policy. We fully
22 support the GMO Subcommittee's efforts on this

1 issue and look forward to supporting your
2 ongoing efforts in any way we can.

3 Genetically engineered seed has
4 been planted in our fields and sold in the
5 marketplace for more than 15 years, yet we
6 lack a profound amount of knowledge on the
7 state of genetic purity of our seed. And the
8 USDA to date has not afforded the agricultural
9 community a transparent testing and monitoring
10 system that would provide useful data for
11 better understanding the state of
12 contamination in our breeding lines and seed
13 sold as organic.

14 We hope the NOSB will explore the
15 best way to collect this data, as Zea
16 mentioned perhaps through the ERS, or other
17 means. We believe this data is especially
18 important to understanding the feasibility of
19 a genetic purity standard. And ideally this
20 data would be made available publicly to
21 stakeholders and be accompanied by testing
22 protocols, proven prevention measures and

1 ongoing monitoring to ensure the access to
2 seed that meets an appropriate genetic purity
3 standard should one be implemented.

4 On the topic of a genetic purity
5 standard we believe the standard may be
6 warranted in at-risk seed, especially corn,
7 but we do caution against implementing it too
8 soon before some serious questions are
9 examined and explored. We're concerned that
10 what may seem like an easy solution could lead
11 to consequences that we have identified as
12 potential consequences, identified in some
13 questions that we developed and provided in
14 written comments.

15 We have been talking to a number
16 of stakeholders over the last year actually
17 about the adequacy and again any potential
18 consequences of a genetic purity standard. We
19 are most concerned that the standard should
20 not overly burden organic farmers or
21 discourage the overall growth of the organic
22 industry.

1 We're concerned about the
2 standard's effect on the commercial
3 availability of organic seed which is also an
4 organic seed integrity issue. We don't want
5 to discourage farmers who are producing
6 organic seed or private firms investing in
7 organic seed production and breeding, or
8 simply lose organic farmers who decide that
9 the cost of certifications are simply too
10 great.

11 Testing is absolutely necessary.
12 Farmers need access to information about the
13 genetic purity of the seed they're planting to
14 organic systems, but this cannot happen at the
15 total expense of organic farmers and
16 certifiers.

17 Earlier this year we completed a
18 survey with companies who supply organic seed.
19 The purpose was to start to identify some of
20 the risks that these companies are facing in
21 supplying organic seed and what the state of
22 contamination is in the seed that they're

1 producing and selling.

2 I encourage and hope that you read
3 through some of our findings in the written
4 comments. Not only do these findings show
5 more evidence of the problem, they do show
6 some uncertainty among companies about a
7 genetic purity standard, at least putting one
8 in place at this time.

9 As you've heard today, some
10 companies say that they can meet the standard
11 consistently while others have serious
12 concerns that without safety nets to cover
13 ongoing incidences of GE contamination the
14 financial burden and risk to organic seed
15 companies will become too great.

16 Thank you for your work on this
17 issue and again we look forward to working
18 with you in any way we can to support your
19 efforts to move this conversation forward.

20 MS. SONNABEND: Thank you, Kiki.
21 We will take a few questions but understanding
22 that there will be more opportunity to ask

1 questions of Kiki later when she gives a
2 presentation.

3 MR. FELDMAN: Thank you. I guess
4 I wanted to put this thing in perspective.
5 And we're talking about seed purity. Can we
6 back up a step and talk about the thinking
7 that you all have done on prevention in the
8 area of -- I mean as Zea mentioned, there was
9 real interest on the part of the subcommittee
10 in terms of identifying preventive strategies
11 and working with USDA and enforcement against
12 what she described as trespass.

13 How do we go down that road? What
14 can the NOSB do to sort of elevate that issue
15 or advance it in a better way?

16 MS. HUBBARD: Well, first of all I
17 think we just need to acknowledge that already
18 organic farmers and other stakeholders in the
19 organic community are doing testing at times
20 and taking measures to prevent contamination.
21 In fact, it's mandated through the organic
22 system's plans.

1 I passed around an article that I
2 recently had published in the peer-reviewed
3 journal Agriculture and Human Values. There
4 are further recommendations in that that point
5 to the inadequacy of the current biotech --
6 the current regulatory framework for biotech
7 crops as well as the role that the NOP plays
8 in protecting the genetic integrity of organic
9 food.

10 I know it is not an appealing
11 recommendation but I believe applying further
12 pressure on the USDA to fulfill their
13 obligation to the success of organic means
14 that they have to more fully confront in a
15 meaningful way the issue of contamination
16 prevention. Currently there is no requirement
17 on the part of growers and owners of
18 biotechnology products to prevent
19 contamination in the field.

20 That said, again I think the NOSB
21 should continue to explore some of the
22 questions that we raised in our written

1 comments and to engage diverse stakeholders.
2 Seed companies being the primary stakeholders
3 that should be at the table, both those who
4 believe that they are successfully preventing
5 contamination as well as those who are doing
6 their best and despite honest efforts not
7 having a ton of success meeting the standard
8 as proposed in the discussion document.

9 There is -- all the companies that
10 I spoke with for the survey, the fuel crop
11 companies, do conduct testing and they have
12 internal thresholds. And a lot of times they
13 are diverting seed that exceeds their internal
14 thresholds to the non-organic seed
15 marketplace, taking that financial hit. As we
16 know there is no compensation mechanism in
17 place to cover any of these costs and testing
18 alone for some of these small to mid-sized
19 scale companies ranges anywhere from forty to
20 seventy thousand dollars a year.

21 I will too say that there is an
22 opportunity for the NOSB to voice on behalf of

1 the organic community concern with some of the
2 recommendations coming out of the USDA's
3 Advisory Committee for Biotechnology. The
4 AC21 committee has been charged with exploring
5 an appropriate compensation mechanism in
6 instances of economic harm resulting from the
7 unwanted presence of genetically engineered
8 material.

9 Unfortunately their recommendation
10 worsens the status quo by saying organic
11 farmers should purchase crop insurance to
12 self-insure against potential harm. I believe
13 it's a really important for this board to
14 weigh in on that discussion as well.

15 MS. SONNABEND: Okay. Thank you,
16 Kiki. I'd like to use our remaining few
17 minutes to ask if the board, especially those
18 who are not on the committee to already
19 discuss this have any discussion points they
20 would like to bring up on the discussion
21 document.

22 Thoughts for our committee,

1 subcommittee, to move forward. Anyone? No.
2 Then that concludes the presentation of the
3 GMO Subcommittee and we look forward to our
4 future work.

5 DR. GRANATSTEIN: Thank you, Zea.
6 We'll take a break now and we'll return at --

7 MS. SONNABEND: Michelle is asking
8 to hold a minute. Do we have another
9 commenter? Sorry.

10 MR. KITTREDGE: Hi, I signed up
11 outside on the table and I guess nobody got
12 that.

13 MS. SONNABEND: Okay.

14 MR. KITTREDGE: My name is Jack
15 Kittredge. I'm with the Northeast Organic
16 Farming Association, Massachusetts chapter.

17 I want to first thank you for
18 visiting in New England. It's very nice that
19 you have come and I'd like to -- I know some
20 of our farmers and representatives of NOFA
21 will be here to speak with you.

22 We represent a somewhat unique

1 region in that our farming is at a very far
2 different scale for most of us. We represent
3 farmers' markets, farm stands, CSAs. We're
4 not talking about the major kinds of crop
5 production acreages but rather small high-
6 value crops.

7 But we are very much concerned
8 about this issue of genetic modification. We
9 think that already in some areas farmers have
10 dropped corn, for instance, as a product
11 because of the issue of contamination. There
12 is already some corn and soy production in our
13 region that we're concerned about.

14 We're much more concerned about
15 the developing line of crops that are going to
16 be directly modified we believe that are in
17 the pipeline now and that will be increasingly
18 of concern to our farmers who are producing
19 these high-value crops. As these genetically
20 modified crops become available and
21 contamination takes place, and we do believe
22 it's contamination because we do not believe

1 there's effective regulation of health and
2 safety at the federal level. So it is
3 contamination or pollution in our minds.

4 The primary way that the current
5 level of genetic modification is affecting us
6 is through animal feed. We find increasingly
7 there is a local agricultural movement that is
8 strongly supported by our consumers and we're
9 glad to see that. But a number of those
10 producers say we would love to be organic but
11 we cannot afford to buy organic feed and
12 therefore we're going to have to buy local
13 feed. And it turns out that of course much of
14 that feed is GMO. And so for us this is
15 becoming a life or death issue at that level
16 even before the new variety issue becomes more
17 apparent.

18 In terms of solutions we think
19 that obviously testing by farmers is not a
20 realistic thing, especially in our region
21 where farmers are very small. They're going
22 to drop those crops long before they're going

1 to be able to afford testing. I agree with
2 Kiki that insurance is not realistic. I would
3 love to see the NOSB speak out against that
4 insurance plan and against the whole idea of
5 coexistence with GMOs which we believe is not
6 realistic.

7 Some of the things that would be
8 helpful that the USDA could do, maybe some
9 random testing by the USDA of different kinds
10 of crops and samples so that we could get a
11 sense of where we are in terms of the level of
12 threat. Identify contamination sources. Set
13 up some protocols to deal with that. Develop
14 compensation schemes that are in fact
15 realistic and enable small farmers to deal
16 with these problems. One of our members once
17 suggested if GMOs are like pesticide
18 contamination why shouldn't we license GMO
19 farmers and they should be trained so that
20 they can plant things properly instead of
21 contaminating their neighbors. Interesting
22 direction.

1 But probably the most important
2 realistic thing that USDA can do is help in
3 developing non-GMO seed varieties, and we
4 would like to see as much energy put in that
5 direction as possible because ultimately we
6 are going to have to have seeds that are
7 developed and bred for organic farming
8 purposes. So, thank you very much.

9 MS. SONNABEND: Thank you. Are
10 there any questions from the board?

11 MR. FOSTER: No surprise here.
12 Amongst your grower community is there
13 awareness or concern or discussion over the
14 cost that establishment of thresholds might
15 have for them? Is that part of the dialogue?
16 And if so, what's the -- can you capture that?

17 MR. KITTREDGE: Yes. Very little
18 in Massachusetts. We have virtually no
19 farming of this nature. A little bit more,
20 some of our other states, Vermont, New York
21 have more serious grain crop farming
22 operations. But in Massachusetts there has

1 been none really.

2 MS. SONNABEND: Okay, thank you.

3 Now we conclude the presentation of the GMO
4 Subcommittee.

5 DR. GRANATSTEIN: Thank you. That
6 concludes the GMO presentation. We'll take a
7 break and return at 9:20 and begin the Crop
8 Subcommittee discussions.

9 (Whereupon, the foregoing matter
10 went off the record at 9:08 a.m. and went back
11 on the record at 9:31 a.m.)

12 CHAIRPERSON FLAMM: We're now back
13 in order. The next session will be Crops
14 Subcommittee and I'll turn the gavel over to
15 the subcommittee chair Jay Feldman.

16 MR. FELDMAN: Thank you, Barry.
17 Just to lay out the process for everybody we
18 have a number of materials we need to get
19 through. And we've allocated -- and this is
20 for the board specifically just so you know.
21 We've allocated 13 minutes for every material
22 that we'll be discussing, 5 for presentation

1 and 8 for discussion except for bioplastic.
2 We've left 10 for the presentation and 12 for
3 discussion.

4 Now, remember we have a lot of
5 witnesses today so we'll have more time to
6 discuss with the witnesses. But just, we're
7 going to be moving at a pretty quick clip
8 here. And I apologize in advance if I have to
9 interrupt you so that we can move this thing
10 along. Because when -- we don't want to stand
11 between these folks and lunch. That's always
12 a problem for us.

13 Okay, so the first material,
14 Carmela is going to lead us on ferric
15 phosphate. I'm sorry, I need to recognize
16 Lisa first to explain the petition and the
17 background on this. Thank you.

18 MS. BRINES: Thank you, Jay. Yes,
19 the first petition on the agenda for the Crops
20 Subcommittee today is ferric phosphate. This
21 petition was received on July 7, 2009 and was
22 submitted by Steptoe & Johnson.

1 The petition requests the removal
2 of ferric phosphate from Section 205.601(h) of
3 the National List. It's currently permitted
4 as a slug or snail bait.

5 There's three pieces of technical
6 information that's available for this petition
7 substance. There was an original technical
8 advisory panel report prepared in July 2004 in
9 response to the original petition to list this
10 material.

11 And there have been two additional
12 technical reports since that date. There was
13 one prepared in 2011 and then a supplemental
14 technical report that was prepared and
15 available in 2012. Both the petition and the
16 three technical reports were available and
17 posted on the NOP website in advance of the
18 opening of the public comment period.

19 There was written comment received
20 in response to this proposal and the
21 petitioner is signed up for in-person public
22 comment as well. Thanks.

1 MR. FELDMAN: Thank you. Carmela.

2 MS. BECK: Okay, so the Crops
3 Subcommittee recommends to vote down the
4 petition to remove ferric phosphate from the
5 National List. The generic active ingredient,
6 ferric phosphate, needs to be considered
7 separately from any other ingredient, either
8 active or inert.

9 The supplemental TR addressed four
10 questions that are posted on the screen. And
11 I'm not going to go through the questions or
12 the answers as most of you have probably
13 already read those. So I'll jump straight to
14 the public comment.

15 The total in favor of maintaining
16 the listing of ferric phosphate were 26. Of
17 those 26, 17 were farmers, 4 were consumers
18 and 5 were organizations.

19 Those in favor of keeping ferric
20 phosphate on the National List cited the
21 following reasons. One, research has shown
22 that ferric phosphate by itself does have an

1 effect on snails and should not be prohibited
2 because EDTA is questionable.

3 Second, EDTA is an allowed list
4 for inert per 205.601(m). Three, the Inerts
5 Working Group will determine inerts policy
6 within the next 5 years. Four, currently
7 there is no process in place to add or remove
8 allowed inerts.

9 Five, in 2010 the NOSB re-listed
10 the EPA list for inerts until 2017. Six, in
11 2010 the NOSB re-listed ferric phosphate on
12 the National List.

13 Seven, essentiality. Eight, that
14 there is a real lack of effective practical
15 alternatives. And the last reason cited was
16 that there's a large potential for detrimental
17 economic yield and ecological consequences if
18 the product is removed.

19 The total in favor of de-listing
20 ferric phosphate was 11. There were zero
21 farmers, nine consumers and two organizations.

22 Those in favor of de-listing

1 ferric phosphate cited the following. One,
2 lack of essentiality. Two, incompatibility
3 with organic agriculture. Three, availability
4 of cultural practices and alternative control
5 measures. Four, the TR documented a negative
6 impact on earthworms and soil organisms.

7 The ARS report and supplemental TR
8 responses supported the petition's reasons for
9 removal. They state that the argument is that
10 due to the 2007 sodium hydroxyl EDTA petition,
11 due to the fact that that was denied by the
12 NOSB the same argument should be carried
13 forward and that the NOP should now prohibit
14 EDTA in all organic formulations.

15 The commenters feel that the NOSB
16 can't wait on the Inerts Working Group for
17 forthcoming recommendations. In line with the
18 Crops Subcommittee minority opinion ferric
19 phosphate is not effective alone. It must be
20 combined with a synergist such as EDTA to
21 function.

22 I'm going to go ahead and let Zea

1 continue the conversation.

2 MS. SONNABEND: The majority of
3 the Crops Subcommittee did vote in favor of
4 maintaining the listing of ferric phosphate.
5 And truthfully for me as well as a number of
6 the others in the majority the key reason has
7 to do with proper materials review, procedures
8 and protocol. It is not the right thing to
9 remove an item from the list because something
10 else that might be used with that item is a
11 problem. The correct thing would be to put an
12 annotation on that so that it could not be
13 formulated with the other thing if it's shown
14 to be a problem.

15 The key question here then boiled
16 down to -- and there was a lot of -- if I want
17 to say red herrings and unclear information
18 because both sides tried to impress us with
19 volume in their comments I would say. And it
20 was hard to drill down through everything to
21 get to what the key issues were. That's one
22 of the things that took so long. And also to

1 try and get some unbiased information.

2 So the key thing here is whether
3 ferric phosphate belongs on the list by itself
4 because it does have an effect against snails
5 and slugs. And there were three studies that
6 did show that by itself it had some activity.

7 One of those studies was very hard
8 to find because it had been redacted when it
9 was first sent in as the comments. And the
10 whole study was redacted even though only one
11 clause of it actually was the confidential
12 information. So we did finally get that study
13 after the docket closed and it will be posted
14 into the docket after the meeting I believe.

15 And that study as well as the
16 other two showed clearly that the ferric
17 phosphate by itself had some activity against
18 snails, more activity than either EDTA by
19 itself or nothing, the two controls. But
20 there's more activity when the ferric
21 phosphate is combined with EDTA, but that
22 doesn't mean that without EDTA it doesn't have

1 some activity.

2 So, because we are going to be
3 reviewing EDTA in our proposal on inerts that
4 we'll be talking about in a few minutes, and
5 that review can happen within the next 3 to 5
6 years the majority of the committee felt that
7 ferric phosphate should be kept on the list.
8 Thank you.

9 MR. FELDMAN: Board discussion.
10 Any questions? Calvin.

11 MR. WALKER: The TR. My question
12 is how was the additional information not in
13 the TR. Because there seemed to be a lot of
14 information that came afterwards.

15 MS. SONNABEND: In 2010 when
16 public comments were accepted on this quite a
17 bit of the attachments were redacted as
18 confidential business information. Typically
19 the TR contractor does not have access to the
20 redacted information nor do we. And therefore
21 when we asked for a supplemental TR and we
22 asked them to review all the new information

1 that was submitted they could only review the
2 information that was accessible to them, and
3 that's how it got missed. And similarly the
4 ARS who we asked for a further objective
5 opinion, they had access to otherwise of the
6 three studies, but not the third one.

7 Clarification from Lisa, I
8 believe.

9 MS. BRINES: Yes. For the
10 supplemental technical report, the most recent
11 one, the contractor did have access to the
12 confidential business information from the
13 original petition as well as I believe the
14 second petition that came in to remove it.
15 Thank you.

16 MR. FELDMAN: Other questions?
17 I'd like to just make a quick comment on this
18 because I sort of led the charge on the flip
19 side of this. And just to point out that we
20 did do a supplemental TR on this question of
21 the active properties of EDTA.

22 And this is where there is

1 disagreement. Obviously the manufacturer of
2 this product claimed that the ingredient that
3 is at issue here was an inert, or is an inert
4 ingredient. And this board has previously
5 denied this product as an active ingredient.
6 It was applied as an active ingredient. And
7 the TR, this is sodium hydroxyl. And the TR
8 supplemental indicated that yes, in fact these
9 were the same materials.

10 So really what this comes down to
11 is that there is a difference of opinion as to
12 whether this actual product formulation can
13 work, can have efficacy, without the use of
14 this particular ingredient as -- because of
15 its active properties.

16 Having said all that, Zea's
17 correct. We will be evaluating this material
18 one way or another. We'll either make a
19 choice on it today or we will do it through
20 the inerts process. So I think that's an
21 important point to keep in mind as you think
22 about this and ask questions of the

1 commenters. Just, that's a clarification and
2 hopefully you feel it's accurate. Okay.

3 So now we'll move on. Unless
4 there are any other questions on that we'll
5 move onto the next material on the list which
6 is oxidized lignite. Zea will be managing
7 this and we'll turn first to Lisa on the
8 petition.

9 MS. BRINES: Thanks, Jay. This
10 petition was received on June 22, 2011 and was
11 submitted by SHAC Environmental Products
12 Incorporated.

13 The petition requests the addition
14 of oxidized lignite to Section 205.601 of the
15 National List for use as a soil amendment.
16 There is one related listing currently on the
17 National List regarding this particular
18 product because it is a humic acid derivative.
19 There is a current allowance at Section
20 205.601(j)(3) for humic acids, naturally
21 occurring deposits, water and alkali extracts
22 only.

1 In its review the Crops
2 Subcommittee did request the development of a
3 new technical report in response to the
4 petition. There are also two previous
5 technical reports available that were
6 prepared, previously prepared in response to
7 the existing listings for humic acid, most
8 recently from 2006 and one from 1996 for the
9 original review of humic acid derivatives.
10 Thank you.

11 MR. FELDMAN: Thank you. Zea?

12 MS. SONNABEND: Thank you. This
13 one was somewhat confusing to us as a
14 committee at first because it was unclear how
15 to exactly list the product. Although
16 commonly called oxidized lignite by the
17 manufacturer and others there is a truly non-
18 synthetic oxidized lignite that can occur in
19 nature in the process of humates being
20 oxidized by natural processes.

21 And we didn't want to create a
22 listing that would somehow interfere with, be

1 confused with a non-synthetic listing for
2 something that does appear to be synthetic.

3 So the product in question was created
4 basically by taking the natural humates and
5 treating them with hydrogen peroxide.

6 Hydrogen peroxide is on the National List by
7 itself and does serve the function of an
8 oxidizing agent, and creates a more readily
9 available humic acid derivative.

10 And so it was decided that instead
11 of putting oxidized lignite on the list we
12 would call it another humic acid derivative
13 and propose the language that adding to what
14 is already in the rules which is humic acids
15 naturally occurring deposits, water and alkali
16 extracts only, and adding to that water,
17 alkali and hydrogen peroxide extracts only.
18 And this would be the clearest listing for
19 everyone to be able to work with.

20 That being said we looked at our
21 OFPA and we looked at the rule and while this
22 material may in fact be preferable to the

1 alkali extracted humic acids because it
2 doesn't -- the hydrogen peroxide leaves only
3 behind hydrogen and oxygen, but while the
4 alkali extracts leave behind excess synthetic
5 phosphorus or potassium. It was felt that
6 there was no real category in the exemptions
7 in OFPA to put synthetic fertilizers onto the
8 list, and therefore the committee -- Michelle,
9 can you scroll down to the committee vote?
10 Because I can't remember what it was. But we
11 did not decide to put a committee
12 recommendation forward to add this to the
13 National List. Three yes and five no, thank
14 you.

15 The public comment consisted of
16 comments from the manufacturer and then a few
17 people who I didn't think were growers saying
18 that they didn't want more synthetics in
19 agriculture. And I didn't see any comments
20 from growers saying that they wanted or needed
21 this material except one from OGC that said
22 they thought this was a preferable material to

1 the extract. But while they represent some
2 growers who are their clients they are
3 actually a handler.

4 MR. FELDMAN: Thank you, Zea.
5 Questions? John.

6 MR. FOSTER: So my question is
7 around the ability to list synthetic
8 fertilizers. And to what degree -- I wasn't
9 part of the discussion on this, unfortunately.
10 To what degree was the discussion focused on
11 whether this extract could be categorized as
12 a fertilizer versus a fertility input or a
13 soil amendment? How was that discussion
14 handled or was it?

15 MS. SONNABEND: Well, we did
16 discuss that in general but there's no
17 category for soil amendment or fertility input
18 either. And you know, my personal opinion,
19 and I'm stepping aside from the committee
20 here, but this appears to be way more benign
21 in general than other alkali derivatives. So
22 in a perfect agronomic world I would want this

1 but I just don't see from an interpreter of
2 the OFPA and the federal rule how this could
3 be added.

4 MR. FOSTER: So, is alkali
5 extracted humic acid? So help me understand
6 that rationale.

7 MS. SONNABEND: That also is no
8 category for it but we weren't on the board
9 when that was put on.

10 MR. FOSTER: Okay, well -- okay.
11 But someone was on the board when that passed.

12 (Laughter)

13 MR. FOSTER: So.

14 MS. SONNABEND: I was in the
15 audience. I remember it.

16 MR. FOSTER: So, I mean, I
17 understand you don't want to throw good money
18 after bad, for example, but if -- I'm going to
19 go back to one of my old saws is if we have
20 the opportunity to list a preferable material
21 it's hard for me to say no to that when we
22 have the opportunity. I mean, it sounds to me

1 from your comment as well as others this is
2 clearly a preferable material to the alkali
3 extracted. Alkali extracted is on there.
4 It's really hard for me to say no to something
5 that's better.

6 MR. FELDMAN: Other questions?
7 Thank you. And we'll get a chance to ask
8 questions about this as we proceed here.

9 The next material is propylene
10 glycol monolaurate. We refer to it as PGML.
11 So Lisa, if you could cue that up. Thank you.

12 MS. BRINES: Thanks, Jay. The
13 petition for PGML was received on April 24,
14 2009, and was submitted by the Technology
15 Services Group Incorporated.

16 The petition requests the addition
17 of propylene glycol monolaurate to Section
18 205.601 of the National List for use as a
19 miticide and acaricide.

20 In support of the review of this
21 material the Crops Subcommittee did request
22 the development of a technical report. The

1 report was developed and both the report and
2 the petition were posted on the NOP website in
3 advance of the opening of the public comment
4 period. Thanks.

5 MR. FELDMAN: Your voice was
6 trailing off at the end there so I know it's
7 a lot to --

8 MS. BRINES: I'll get closer to
9 the mike. Thanks.

10 MR. FELDMAN: Thank you, Colehour,
11 for leading us on this.

12 MR. BONDERA: Very good, thank
13 you. I hesitate since -- is it going to be up
14 on the screen, Michelle? Yes.

15 So, propylene glycol monolaurate
16 (PGML), petition to add it to 205.601(e) is
17 the topic. And PGML is petitioned as an
18 acaricide which is a pesticide that kills
19 members of the acari group, ticks and mites.

20 The petition states that the PGML
21 is, quote, "a broad-spectrum antimicrobial
22 agent to control fungi and bacteria that cause

1 decay of post-harvest fruit and vegetables."

2 So we did go through the process
3 and Crops Subcommittee members were to some
4 degree divided. And those that were in
5 support of PGML I summarized their thoughts
6 into these three.

7 While there are other organic
8 options they are very sporadic in their
9 control. The impact of crop quality and the
10 potential environmental impact when using the
11 alternative materials can be somewhat of a
12 concern as well. And then third is we can
13 give organic farmers another tool that is
14 better than those they currently rely upon if
15 we can properly look at the risk-benefits.

16 The majority of the Crops
17 Subcommittee opposed the petition and said
18 that it is not needed as it can be substituted
19 with alternatives, including cultural
20 practices as well as biological controls; that
21 the other options do not have the impacts on
22 human and environmental health; that the

1 environmental impacts leave more damage
2 overall than the benefit; and that as a
3 synthetic product and tool designed for non-
4 organic agriculture this material is not
5 consistent with either organic or sustainable
6 production systems because it is a broad
7 spectrum and affects beneficial predators as
8 well as the target mites.

9 So, commenters are opposed to
10 listing of PGML, saying things such as PGML
11 kills natural predators that control the mite
12 pests, that it reduces biodiversity on organic
13 farms, that its manufacture is fossil fuel-
14 dependent, that it is not essential and may
15 actually exacerbate problems, and that it's
16 incompatible with organic production because
17 it's not in any allowed category of synthetic
18 input and is a broad-spectrum pesticide.

19 And in summary our classification
20 vote and our listing motion vote were such as
21 you see there. Like I said, we were divided.
22 It was two people in favor and six opposed on

1 listing it. And that's all I had. Thank you.

2 MR. FELDMAN: Board discussion.

3 That gives me more time for inerts. Thank

4 you. Okay.

5 I will cue this one up since it's

6 not a petitioned material. Oh, thank you.

7 Thank you, Michelle.

8 Let me run through this

9 PowerPoint. We are -- obviously we as a

10 community have addressed this issue for many

11 years, the policy and procedure proposal for

12 inert or so-called "other" ingredients in

13 pesticide formulations on the National List.

14 So, by way of background, and Zea

15 will be helping me with this, or feel free to

16 chime in at any point since she was so

17 instrumental. We'll get to the committee and

18 who all worked on this. But as background

19 we're dealing with inert ingredients and as

20 all of you know I hope we have a definition

21 for this. And it goes back to the EPA

22 definition as well. So the definition on the

1 screen here is both the definition for inert
2 and active and how they are distinguished.

3 What is clear to us all as a
4 community is that the word "ingredient" in
5 found in both of this and that's what is
6 driving this process on the one hand.

7 The statute, the Organic Foods
8 Production Act, has identified inerts of
9 toxicological concern as a focus for us here.
10 And so typically what we've looked at in the
11 past are the lists 4(a) and 4(b) eventually,
12 a category of inerts that were allowed as a
13 group by -- under the National List in
14 addition to list 3 inerts that were allowed in
15 certain pheromone dispensers.

16 The other element that's driving
17 this process besides a concern about inerts
18 generally -- or ingredients generally is the
19 fact that EPA decided that it was no longer
20 going to maintain a list of inerts. So that
21 left the NOSB with somewhat of a problem in
22 terms of what it would do if it couldn't

1 reference an EPA list that was kept up to
2 date.

3 So as a result of all this we
4 formed the working group with NOP and EPA and
5 NOSB. And that group met for a couple of
6 years. Zea joined the group last year when
7 she joined the NOSB. And we brought a
8 discussion document as you recall to this body
9 back in the fall of 2011.

10 The Inerts Working Group developed
11 this proposal which as a matter of process
12 went to the Crops Committee which then brought
13 the proposal or the discussion document to the
14 board. And we summarized the results of that
15 discussion document at our spring meeting.

16 So this is what we're proposing
17 today, basically a road map for beginning this
18 process of inerts review. The concern of
19 course was that this was an overwhelming task
20 and there were a lot of materials. So part of
21 the role of the Inerts Working Group was to
22 figure out what the scope of this project was

1 and whether it was feasible, in what time
2 frame and so forth.

3 So, we -- our goal here as we're
4 proposing it today is to put together a road
5 map that would address the requirement for
6 review under 205.601 which is crops and 603
7 which is livestock as these materials move
8 through the process and as they affect the
9 allowance of materials on the National List.

10 So this is what we're proposing in
11 terms of both the working group and the Crops
12 Committee. This is coming to you with
13 unanimous support from the Crops Committee.
14 New regulatory language, a series of steps to
15 use in preparing for inerts reviews, screening
16 guidelines that the technical reviews will
17 address, a tentative list of groupings that
18 will allow us to address multiple materials in
19 groups because of common mechanisms of effect
20 and so forth. And then a rough time line of
21 how we would review and complete that process.

22 The new regulatory language would

1 fit, as I said, into 601 and 603 and establish
2 a review for substances permitted for use in
3 minimal risk products. This is a category
4 that EPA uses under its Federal Insecticide,
5 Fungicide and Rodenticide Act Section 25(b)
6 and then a reserve list of approved or other
7 ingredients. So that simply replaces what's
8 in our language currently which is in the
9 document that you got, the committee document.

10 MS. SONNABEND: The procedure
11 includes several steps for review, grouping
12 the chemicals into clusters -- and we've given
13 you some examples of where we are at now but
14 we aren't done with the groupings. Full group
15 listing including chemicals to be presented in
16 spring 2013. Anticipated that four to six of
17 the clusters will be evaluated each year with
18 TRs and committee review of the TRs.
19 Manufacturers will have time to identify
20 ingredients in use that are not on the list to
21 request review. And after completion of this
22 process new, other or inert ingredients must

1 be petitioned.

2 MR. FELDMAN: Okay, so the
3 proposed procedure includes the NOSB working -
4 - continuing to work with the Inerts Working
5 Group to finalize the proposal. The NOSB will
6 rely on the working group to consult with OMRI
7 and WSDA, the Washington State Department of
8 Agriculture for updated inert lists.

9 The NOSB will request that NOP
10 investigate and adopt within 6 months of the
11 announcement of this proposal which would be
12 the spring of 2013 the appropriate mechanism
13 for notifying manufacturers. And the NOSB
14 would request under this proposal that NOP
15 commission one TR per group except where noted
16 and coordinate review with the board.

17 And the NOSB again would request
18 that the NOP determine an appropriate format
19 and commission a special inerts TR for each
20 group. And here's, you know, this is
21 delineated in the documents you have. I'm not
22 going to read all this but these are the steps

1 that we would go through.

2 And based on the results of the TR
3 the NOSB Crops Committee would accept these
4 groups to move forward to the NOSB agenda or
5 single out one element or one formulation, one
6 or another formulation or material that was
7 needed for individual review.

8 The NOSB working with the working
9 group will prioritize and order the reviews
10 considering based on a priority system that
11 looks at the most problematic first and then
12 works through those that are used most often
13 in organic production, et cetera.

14 And then this would be part of our
15 priority system, having a screening process
16 where we're trying to elevate to the head of
17 the class those materials that go through the
18 screen of highly toxic or ECOTOX or, you know,
19 indicative of some problem that we would
20 consider a concern when it comes to hazard or
21 adverse health effects.

22 These are the proposed clusters.

1 Right now we have, for about 126 inerts we
2 created 16 clusters. As noted by OMRI one of
3 those is a non-synthetic cluster. Why is that
4 on there? Well, it was one of the inert
5 materials that showed up so we figured we'd
6 put it on the list. We probably don't have to
7 review those. If they're non-synthetic
8 materials we don't have jurisdiction over
9 those unless they end up being ones that would
10 be natural that we would think we would need
11 to prohibit as we'll be discussing later like
12 with rotenone. But these are the categories,
13 alkali alcohol, alkali alkoxyates, I'm not
14 going to read them all. I'll let Zea read
15 them all. But -- I can't read them all.

16 The public comment, 17 supporting.
17 We had one that was asking for clarification,
18 asking whether we really needed to look at
19 25(b) at all. There was this massive influx
20 of organic consumer association sign-ons to a
21 petition which was nice to see at least in
22 terms of public involvement.

1 Those supporting the proposal say
2 the review of inert ingredients is overdue.
3 We've heard that for a couple of years. I
4 mentioned OMRI pointed out the 14 non-
5 synthetics. Wolf and DiMatteo stated again as
6 I said earlier that the 25(b) review is not
7 necessary and we'll be hearing from them
8 later.

9 There's some commenters who
10 expressed concern, and this is coming from,
11 you know, everybody has concern about the time
12 line, will it work. That's why this is a
13 procedure. During this procedure one of the
14 elements as I mentioned earlier is to assess
15 the viability of meeting the time frame.

16 And then Wolf DiMatteo said it
17 would be helpful -- this is a useful comment -
18 - to include in this recommendation the list
19 of 126 individual inerts so that pesticide
20 formulators would be notified in advance of
21 the decision of the NOSB, so they know it's
22 coming.

1 And then once we go through this
2 procedure if it's adopted by the board we'll
3 finalize a procedure by the spring meeting in
4 2013 to review all these things. We'll see if
5 it still looks like we can meet this schedule
6 by the 5-year sunset period that we have to
7 align with which is 2017 for the sunseting of
8 the inert ingredients in the list 3 of
9 pheromones and pheromones in dispensers.

10 So that's our plan, that's our
11 proposal. I neglected to thank the NOP, Emily
12 and Lisa for their work on this. And the work
13 of the EPA staff, Chris Pfeiffer and Kerri
14 Leifer. Everybody put an extraordinary effort
15 into this. A lot of information had to be
16 evaluated and we all appreciate it very much.

17 Any questions? Yes.

18 MS. RICHARDSON: I'm not on Crops
19 Committee so it's sort of mind-blowing the
20 range of things that you're going to try to do
21 on this topic.

22 And so what I'm sort of interested

1 in trying to understand is really probably
2 just to get the perspective of NOP staff on
3 the feasibility of being able to deal with
4 such a large number of inerts in such a
5 relatively short time line.

6 MR. MCEVOY: Yes, we've looked at
7 this. We are concerned about the resources
8 that we would need to commit to make this
9 happen and the time frame. But we do need to
10 look at these inerts. They're in the list 1,
11 2, 3, 4, the EPA list of inerts is being
12 maintained. It just seems like the best
13 proposal in terms of moving forward. And so
14 we support getting on with this project and
15 let's see how it goes.

16 The technical reports are probably
17 going to be a lot more complicated than ones
18 that have been done in the past on single
19 substances. So this is very technically
20 complex but we support moving forward. Let's
21 give it a go and the part that is really
22 important that's part of the proposal is that

1 there's a reassessment how it's going I think,
2 what is it, a year into the process to see
3 whether or not the process needs to be tweaked
4 or the time frame needs to be modified to get
5 through all these substances.

6 MS. SONNABEND: Thank you. Partly
7 in response to Jane I think that while the NOP
8 has concerns, they have indicated that they
9 will be willing to do it. The truly scary
10 part of it is that you and I as board members
11 are going to have to be looking at and voting
12 for a lot of things that are like oxy-, loxy-,
13 epoxy-, -ethoxylate that we can't even
14 pronounce. And if we don't put them on it has
15 grave impact.

16 We're going to have to do this
17 without knowing which products they're in
18 probably with a few exceptions, and the
19 outcome will have grave impacts on the
20 industry. And so that's the part that for me
21 is the hardest thing to grapple with but we
22 are going to have to come to terms with that.

1 MS. RICHARDSON: So I want to
2 follow up that then, Zea. It's that I know
3 they're all inerts and therefore they just,
4 they do nothing, they just sit there, right?
5 So, I would like to be sure that when we get
6 this scientific technical report coming in
7 that we really do ask them to address synergy
8 and synergistic impacts. Even though we're
9 not looking at individual products we do need
10 to understand the interactions and know, I
11 mean, a huge amount of detail really to make
12 a logical decision.

13 MR. FELDMAN: One thing we're
14 going to have to grapple with along those
15 lines is the limited information that is often
16 available on a lot of these materials. And
17 that's just a fact of life. Synergy is one
18 category of very limited information. So I
19 appreciate that comment.

20 MR. FOSTER: So, didn't we just
21 hear that we probably will be -- well, maybe
22 not me but the board will be looking at these

1 materials outside of the context of each
2 formulation? So then the synergy question
3 becomes pretty much impossible. If you don't
4 know the context you won't know the synergy.
5 So I know that's a vigorous head-nodding from
6 you, Jay.

7 MR. FELDMAN: It's true.

8 MR. FOSTER: And it is of concern
9 but if that's the realistic context or lack of
10 context that we have then that better be an
11 up-front kind of agreement or common
12 expectation we should have on that. Otherwise
13 it's not going to be a functional
14 deliberation.

15 MS. SONNABEND: Yes, that is true,
16 John. One of the things that I've been
17 grappling with is I would really like to give
18 some incentive for those companies who do
19 choose to disclose what their product is that
20 has those inerts. And some companies are
21 willing to.

22 And for the ones who disclose it

1 would be nice to give them some incentive like
2 getting their thing reviewed faster, or some
3 other way to say okay, if you disclose we can
4 review it better because we know what all the
5 inerts are.

6 But that is one detail that while
7 I put in many drafts of our proposal we
8 couldn't really figure out what to say about
9 it. But we will have a call for voluntary
10 disclosure I'm sure in the process of doing
11 this.

12 MR. FELDMAN: Thank you. Other
13 questions? Okay. Oh, I'm sorry. Go ahead.

14 MR. MARAVELL: Sort of to follow
15 up on Jean and John's comments here. You
16 don't see a subsequent time period? That's
17 the wrong word. You don't see a subsequent
18 process of review where these questions of the
19 synergies will eventually come to light?

20 MR. FELDMAN: This is a systemic
21 problem that we have in terms of the
22 proprietary nature of this data. That is why

1 it falls into this inerts category as you know
2 because manufacturers have been protected,
3 their proprietary interests have been
4 protected.

5 Hopefully as Zea says we'll get to
6 a point in time where the organic community
7 believes and the manufacturers associated with
8 it that full transparency of product
9 ingredients on a formulation basis does not
10 hurt their proprietary interests and that it's
11 in the interest of public understanding and
12 the transparency of organic that we will have
13 full disclosure. At that point we can do
14 this, John.

15 And I think in many cases, you
16 know, we have done this. OMRI has done it
17 under a protection clause. There are ways to
18 get around this. There may be some creative
19 ways down the road where the board can
20 envision having the ability to review these
21 things with some protection for the
22 manufacturer if they feel there are

1 proprietary interests.

2 But to answer your question, Nick,
3 there is no way around that. The law provides
4 in the registration process for disclosure now
5 -- for non-disclosure.

6 Now, having said that full
7 disclosure is required on 25(b) products. And
8 if you take the position that most
9 manufacturers involved with organic are moving
10 toward the 25(b) category they must disclose
11 all ingredients on the product label. So,
12 that's the silver lining in all of this and if
13 we drive products toward the 25(b) list we
14 will have full disclosure.

15 MR. FELDMAN: Thank you all.
16 We'll move on to rotenone. And Zea is going
17 to cue this up because there was no petition
18 involved in this process.

19 MS. SONNABEND: We certifiers and
20 others in the industry have kept getting
21 questioned about rotenone since it's been in
22 the news a lot lately as more and more studies

1 come out that show a link between rotenone and
2 Parkinson's disease.

3 I feel our posted document goes
4 into the regulatory history, how the EPA short
5 of recalling it has accepted a voluntary
6 cancellation of the uses in the United States.
7 Because much as we would like to be aware of
8 the whole world, but mostly we have to be
9 focused in United States policy we decided it
10 was time to take this up again. Also, the
11 OFPA calls for a special review of botanicals
12 before creation of the National List.

13 This review was done in 1994. I
14 was there for it and helped prepare for the
15 review. At that time a lot less was known
16 about rotenone than is now and there was no
17 clear link to health effects.

18 In the course -- while the
19 transcript of the meeting doesn't say this,
20 but in the course of researching this paper we
21 found a statement from the board at that time
22 requesting from the program that the

1 botanicals have a special review every 5
2 years.

3 Well, a little time has passed
4 since 1994 and we're only getting around to
5 re-review of one of them at this time. In the
6 re-review we have presented some of the more
7 recent literature. And it's important to note
8 that this literature shows a very strong link
9 between rotenone and Parkinson's disease for
10 the applicators and the people who are in
11 contact with this material. It does not show
12 any residual so there's no danger at all of a
13 consumer eating something that was sprayed
14 with rotenone and being exposed to the hazards
15 that lead to Parkinson's disease.

16 However, we couldn't in good
17 conscience leave something as allowed that had
18 such a clear health effect. And so the
19 committee is proposing adding it to the
20 prohibited natural list in Section 205.602.

21 The public comment, we received
22 relatively little public comment. Three

1 people wrote specific comments against it,
2 against rotenone. I think we can infer from
3 all the comments that said no synthetics in
4 organics that they might extend that to
5 natural products that were shown to be
6 hazardous and we didn't count those but there
7 are quite a few of them as you know.

8 And then we heard from banana
9 growers who it turns out we hadn't realized
10 this but it is commonly used in bananas in
11 many countries in Latin and South America. We
12 got four comments in from banana growers, one
13 of them representing 57 growers in Ecuador,
14 100 growers in Ecuador, thousands of growers
15 throughout Latin America and one family from
16 Peru.

17 All of these expressed the issues
18 that there's no other control for thrips that
19 cause a staining on the fruits that make them
20 unmarketable, and that their main control at
21 the moment is alternating rotenone product
22 which is made in the countries in which it is

1 used with pyrethrin products. And they stated
2 that they do this to avoid building resistance
3 to either one of the products.

4 So, in response to this concern we
5 started looking into what alternatives there
6 might be at least in this country, recognizing
7 that these alternatives might not be available
8 or might not work or be researched in the
9 other countries.

10 But we found that as far as this
11 country goes controls for thrips include
12 Entrust which is spinosad, Ryania, another
13 botanical which has recently been -- the
14 formula changed hands and the new company
15 intends to expand the label so it may be
16 labeled for more uses than it is now.
17 Organocide, SucraShield and then some thrips
18 are susceptible to oils. Numerous parasitoids
19 attack thrips and some generalist predators
20 like minute pirate bugs, six-spotted thrip and
21 lacewing.

22 Also, we heard from an expert that

1 there has never been reported resistance to
2 pyrethrin as they contain six different
3 compounds at least that are toxic to insects
4 and thrips and therefore have six modes of
5 action to the insects and so they have not
6 been able to mutate for it.

7 So, we realize a couple of things.
8 We realize that all of these things we
9 mentioned may not be available in the
10 countries where the bananas are grown, but
11 this is a fairly long list and so some of
12 these things could start being researched and
13 start trying to determine what the
14 alternatives are.

15 And we also realize that unlike a
16 regular petitioned item we kind of sprang this
17 on people fairly quickly. When something is
18 petitioned there's usually at least a year in
19 which you're aware that the petition is in
20 progress and in TR and like that.

21 And so the Crops Committee is
22 going to consider amending our motion so that

1 it would say to add rotenone to the National
2 List 205.602 as a prohibited natural substance
3 to take effect on January 1, 2016. This will
4 give 3 years for the potential research and
5 development of alternatives. The Crops
6 Committee did not feel that we could not
7 prohibit it based on the very large volume of
8 research showing it has a link to health
9 problems. Thank you.

10 MR. FELDMAN: Thank you, Zea.

11 Board questions?

12 MR. MARAVELL: Zea or Jay or the
13 program may want to respond to this. Given
14 our normal process of making a recommendation
15 to the NOP and having a rule finally
16 implemented what's the likelihood that a final
17 rule would be issued before the proposed
18 phase-out date anyway? In other words, is the
19 phase-out date fairly consistent with what
20 might occur in the natural rulemaking process?

21 MR. MCEVOY: Well, the phase-out
22 date is for use within the United States and

1 rotenone is not as far as we know being used
2 on organic production in the United States. So
3 we're talking about banning it for organic
4 production where it's used in foreign
5 countries. So, the phase-out date and the ban
6 on the use of rotenone in organic production
7 is not directly related.

8 MR. FELDMAN: Okay, that's helpful
9 because my question is if this board adopts
10 allowable materials, you know, in this case a
11 prohibition on a natural, doesn't that affect
12 all USDA certified, all labeled products
13 whether it's domestic or international?

14 MR. MCEVOY: Yes, that's right.
15 It would affect all products that are produced
16 under the standard. Whether they're produced
17 domestically or in a foreign country they have
18 to meet the same requirement.

19 MR. FELDMAN: Okay.

20 MR. MCEVOY: Yes.

21 MR. MARAVELL: My understanding,
22 and I could be wrong here, is that with the

1 voluntary cancellation that any existing stock
2 of rotenone sort of still in the stream of
3 commerce, still on the shelf is still
4 permitted to be used or am I incorrect?

5 MS. SONNABEND: We received
6 information from the EPA fairly recently that
7 the existing stock had been used up as of
8 August of this year. This has been going on
9 for several years now. And one of the
10 citations showed a 2011 survey that showed
11 some still on the market but as of 2012 it is
12 now all gone.

13 MR. FELDMAN: But if a certifier
14 shows up, Nick, or an inspector and somehow
15 somebody -- you know, EPA doesn't know what's
16 in everybody's barn, right? Somehow somebody
17 has this stuff it wouldn't be illegal unless
18 it was prohibited. It would not be illegal.
19 The existing -- there's no stop-use date in
20 other words.

21 MR. MARAVELL: Right. So, I'm
22 just thinking of farmers. So there is going

1 to be a specific date. Let's just say -- I
2 don't use rotenone personally, but let's just
3 say I was a farmer and I had rotenone tucked
4 in the back of my barn. There would be a date
5 though after which I would not be allowed to
6 use it if it were still in my possession. Am
7 I reading that correctly?

8 MR. MCEVOY: If we put it on the
9 National List as a prohibited natural then it
10 would not be allowed as of the date that it
11 became a prohibited natural substance.

12 MR. MARAVELL: And by specifying
13 that date now we're giving people notice.

14 MR. MCEVOY: Right, but it still
15 has to go through the proposed and final
16 rulemaking process. So it would not become
17 final until there was a final rule that put it
18 on the National List as a prohibited natural.

19 MR. MARAVELL: And I guess my
20 question is are we doing it right here, Miles?
21 Do we have an appropriate date given how the
22 regulatory process sort of lumbers through the

1 bureaucracy if I can be so blunt?

2 MR. MCEVOY: Yes. We think we
3 could get it completed by January 1st of 2016.

4 MR. MARAVELL: Thank you.

5 MR. FELDMAN: Zea.

6 MS. SONNABEND: Just to supplement
7 that. Oh, Melissa, do you want to go first?

8 MS. BAILEY: Just wanting to jump
9 in here. So, just for clarification. So if
10 the board makes a final recommendation here at
11 this meeting we have that recommendation. Say
12 we begin our rulemaking work which as you know
13 takes awhile. January `13, so we plan 2 years
14 for proposed to final rule. I'm just working
15 out the time line here. So we have a final
16 rule in place by January 2015. That would
17 give a 1-year notification to those foreign
18 operators who might be using this for
19 basically coming into compliance with that
20 effective date if that makes sense.

21 MS. SONNABEND: This is what I was
22 just about to say also. We chose that date

1 because it's comfortable enough for the NOP to
2 go through rulemaking and yet unlike not
3 putting a date in there it gives a time
4 certain right now for the users to start
5 getting ready to expire. Because if we just
6 put when it's done with rulemaking that takes
7 variable amounts of time and is not as clear
8 to the end users as if we put a certain date
9 in it.

10 MR. FELDMAN: Other questions?

11 John.

12 MR. FOSTER: So I think that the -
13 - I think the health information is pretty
14 compelling actually and probably is going to
15 sway me on this. As you all know I'm not a
16 big fan of taking tools out of the organic
17 grower's toolbox. I think this might be a
18 reasonable time to do that.

19 But just for -- to make sure it's
20 on the table as part of the discussion. I'm
21 not sure I like the optics of 15 North
22 Americans telling what South Americans can and

1 can't use in production right now.

2 And since it is not through
3 anyone's fault, it just works out history is
4 such that it's used there. It's pretty
5 important it sounds like for some things
6 there. I just don't want to let the
7 conversation go on without recognizing that
8 this is one of the outcomes when organic
9 becomes a global thing.

10 And back in the day when
11 regulations, certainly the precursors to the
12 regulation and precursors to OFPA were in
13 discussion this really wasn't part of the
14 thought process in like 1982 for example. So
15 this is one of the outcomes of having a lot of
16 success. And I don't want to let that moment
17 pass without recognizing that with that
18 success comes some much more hard decisions to
19 be made. This is one of them I think.

20 And I didn't want to let that
21 moment pass. I think it's important to note
22 particularly with respect to various

1 anniversaries coming up right now that these
2 are bigger questions, they have more global
3 implications and we should recognize that.
4 That's all.

5 MR. FELDMAN: Jennifer?

6 MS. TAYLOR: I'm wondering, Zea
7 and Jay, if in your review of the literature
8 were you able to determine if the letters that
9 were coming from representative countries in
10 South America, if they were aware of the
11 health risk to the users.

12 MR. FELDMAN: You know, they saw
13 the same public documents that we see here so
14 we're assuming they were aware of the
15 literature which was cited in the document
16 that we put in the Federal Register, or
17 published. But I didn't see any comment on
18 the health effects.

19 MS. SONNABEND: Well, yes. All of
20 the commenters said we have not seen any
21 health effects from it. But that, I believe
22 we'll have at least one commenter on this and

1 maybe it's a good question to ask them.

2 MR. FELDMAN: Nick was just saying
3 we're talking about a chronic, long-term
4 effect.

5 John is raising really important
6 points I think that really serve as the basis
7 for a larger discussion especially as we all
8 recognize we live in a global economy. And of
9 course we know that the program is constantly
10 dealing with international agreements and
11 trying to create uniformity across those
12 agreements.

13 We, you know, I hope we have an
14 opportunity to explore the issues you've
15 raised in more depth when we have more time.
16 But bioplastics is awaiting, so. Any other
17 discussion? Yes.

18 MR. STONE: I just want to make
19 sure kind of along that line of importance
20 that John raised that we sort of arbitrarily
21 picked 3 years because it's a year after
22 rulemaking. But if the industry is having

1 trouble with alternatives that they have time
2 to adapt and it doesn't arbitrarily pull the
3 rug a little quicker than they can adapt.

4 MR. FELDMAN: Are you suggesting
5 another time frame? We can ask the
6 representatives. Yes, great. Thank you. Any
7 other questions? Okay.

8 Sulfuric acid is up next. John is
9 managing this and we'll hear from Lisa first
10 on the petition. Thank you.

11 MS. BRINES: Thanks, Jay. This
12 petition for sulfuric acid was received on
13 March 27, 2012 and was submitted by BioStar
14 Systems, LLC. The petition requests the
15 addition of sulfuric acid to Section 205.601
16 of the National List for use as a pH adjuster
17 for anaerobically digested poultry manure.

18 In support of its review the Crops
19 Subcommittee utilized a technical report that
20 was developed in 2006 in response to another
21 petition for sulfuric acid for crop use that
22 was submitted in 2005. So there was no new

1 technical report that was developed in
2 response to this petition.

3 Both the petition and the 2006
4 technical report were posted on the NOP
5 website in advance of the opening of the
6 public comment period for this meeting.
7 Thanks.

8 MR. FELDMAN: Thank you, Lisa.
9 John?

10 MR. FOSTER: Thank you. So, I'll
11 move as quickly as I can on this. The
12 discussion focused around the petitioners
13 asking that this is kind of the only hurdle
14 that's left to be cleared in order to use it.
15 OMRI and others have limited the use of this
16 material in the context of poultry manure
17 stabilization.

18 This is, as most of you know
19 there's an allowance for use with fish-based
20 products. So there's some parity questions
21 here, why would it be good for one versus --
22 and not for another. That was part of the

1 discussion.

2 There's also -- the claim was that
3 other acids, while other acids can be used the
4 claim was that that was insufficient to get
5 the pH to where it needed to be to create a
6 marketable, a commercially viable shelf-stable
7 product.

8 And let's see. Crops Subcommittee
9 agreed with the 2006 vote as Melissa described
10 because of various adverse environmental and
11 health impacts, lack of essentiality and
12 incompatibility with organic principles. The
13 vote was unanimous, 6-0, 2 absent, that it was
14 synthetic and that the listing motion was not
15 adopted by a vote of 6 against and 2 absent.

16 My count was five public comments
17 were submitted on this. I should say five
18 specific comments that were about sulfuric
19 acid in this petition specifically. There
20 were other general comments that could be
21 interpreted to apply, as in keep synthetics
22 out of organic, kind of that vein.

1 But five specifics. Four were
2 from individuals, one was from an
3 environmental organization. And the claims
4 were along the lines I mentioned earlier,
5 essentiality, compatibility and concern about
6 environmental consequences.

7 I have some comments outside of
8 that encapsulation that I throw in whenever
9 it's appropriate.

10 MR. FELDMAN: Thank you, John. So
11 John, I'll call on you for starting the
12 discussion.

13 MR. FOSTER: Thank you. So this
14 is very interesting to me. I'm a big fan of
15 parity. I'm okay with this material in this
16 context. I'll be voting for it for a number
17 of reasons, but among them are ones that
18 didn't come up in the discussion that I wasn't
19 able to participate in some of those, but that
20 my experience particularly over the last year
21 with respect to farm inputs is that my -- on
22 commercial scale organic production there's

1 starting to be a constriction of what organic
2 producers used to be able to use irrespective
3 of what conventional ag was using.

4 And that in my experience started
5 to turn pretty dramatically about a year ago.
6 And that was when I noticed that the supply of
7 compost that was compliant and able to be used
8 in organic ag started being used in very large
9 volumes by conventional vegetable and row crop
10 producers, particularly in southern California
11 and Arizona.

12 And some of the growers that we
13 work with were starting to report significant
14 problems in getting enough compost. And like,
15 that's a great problem to have, right? But
16 still it's not -- I don't want to make it
17 sound like it's the end of the world because
18 it's not, but I do want to be mindful that as
19 organic grows, as conventional production
20 systems evolve, adopt more what we would call
21 organic practices there's going to be a point
22 where organic producers are competing for the

1 same inputs as conventional. We're not used
2 to thing about that and I think we should get
3 ready for that.

4 This is one of the areas where I
5 think there's, for now there's a waste
6 product, poultry manure. If there's a way to
7 utilize that more fully, keep it out of places
8 it shouldn't be, I think that has
9 environmental benefits. If this is a
10 processing aid that helps that happen on the
11 whole I think that's a positive thing.

12 Yes, I'll leave it there. Thanks.

13 MR. FELDMAN: Thank you. Any
14 other questions or comments? Okay, thank you.
15 We'll move onto the next item which is the
16 proposed biodegradable mulch film from
17 bioplastics petition. And Lisa will cue us
18 up. Thank you.

19 MS. BRINES: Thanks, Jay. This
20 petition was received originally on January
21 20, 2012 and there was an update to the
22 petition that was submitted on March 26th.

1 The petition was submitted by the
2 Biodegradable Products Institute and it
3 requests the addition of biodegradable mulch
4 film made from bioplastics to Section 205.601
5 of the National List for use as a
6 biodegradable mulch. Related listings for
7 mulch on the National List appear at
8 205.601(b).

9 In support of its review the Crops
10 Subcommittee requested the development of a
11 technical report for this material. Both the
12 technical report and the revised petition were
13 posted on the NOP website and available to the
14 public in advance of the opening of the public
15 comment period.

16 And a representative of the
17 petitioner is signed up for in-person public
18 comment for later this afternoon. Thanks.

19 MR. FELDMAN: Thank you, Lisa.
20 And we're very grateful to Carmela for
21 shepherding through this process with Zea. So
22 I'll turn it over to you, Carmela. Thanks.

1 MS. BECK: All right. So Zea and
2 I are going to be tag-teaming on this
3 presentation the entire time. So, all right.

4 All right. So biodegradable mulch
5 film made from bioplastics is petitioned to
6 Section 205.601 of the National List for use
7 in organic crop production. This is an
8 alternative to petroleum-based plastic mulches
9 that do not biodegrade. And the byproducts of
10 completely biodegraded bioplastics are carbon
11 dioxide, water and soil biomass.

12 Here's the public -- so, here's
13 the summary of the public comment. The total
14 in favor of adding biodegradable mulch film is
15 163. Of that 163, 38 were farmers, 114 were
16 consumers and 11 were organizations. The
17 total number of those opposed to listing
18 biodegradable mulch film were four. They were
19 zero farmers, one consumer and three
20 organizations. There were also three
21 organizations that were requesting
22 clarification, annotation changes or further

1 research.

2 I'm going to go ahead and read
3 this whole annotation so bear with me. So,
4 the list on 205.601(b)(2). Okay.
5 Biodegradable bio-based bioplastic mulch
6 meeting the following criteria: completely
7 biodegradable as shown by, 1) meeting the
8 requirements of ASTM Standard D6400 or D6868
9 specifications or of other international
10 standard specifications with essentially
11 identical criteria, that is to say, EN 13432,
12 EN 14995, ISO 17088; and 2) showing at least
13 90 percent biodegradation absolute or relative
14 to microcrystalline cellulose in less than 2
15 years in soil, tested according to ISO 17556
16 or ASTM 5988; (b) bio-based certified using
17 the ASTM D6866 method; (c) must be produced
18 without excluded methods; (d) must be produced
19 without engineered nanomaterials; and (e)
20 grower must take the appropriate actions to
21 ensure complete degradation at the end of each
22 growing or harvest season. So that's our

1 current Crops Subcommittee recommended
2 annotation.

3 So the next seven slides are
4 actually just going to be each of the seven
5 sections within the annotation. We listed the
6 public comments there and I'll just comment on
7 one or two of them. You all can read the
8 rest.

9 So with regards to the name, BPI
10 has requested the following name change to
11 biodegradable mulch film. Section A thought
12 it was important to point out OMRI's comments
13 where they state that meeting the requirements
14 of ASTM versus bio-based certified using ASTM
15 mean two different things.

16 OMRI interpreted A(1) to mean that
17 the product must meet the requirements of the
18 specific standard but not necessarily be
19 independently certified to those standards.
20 If it is the NOSB intent to require a
21 certification to each cited method the
22 language should read "certified to ASTM

1 standard."

2 Let's see. They also stated that
3 they felt that the ASTM reference in A(2) is
4 more applicable in comparison to the ASTM
5 standard references in this section. Other
6 commenters, several commenters suggested that
7 there were way too many standards cited in our
8 annotation.

9 So in A(2) BPI made a
10 clarification and said that the terms
11 "biodegradation" and "mineralization" are
12 different. As you can see it says the 90
13 percent threshold value required by the
14 petition and ASTM test methods refer to
15 mineralization. So a complete biodegradation
16 is inferred when a mineralization level of 90
17 percent is reached.

18 OMRI points out that 5988 is a
19 testing method rather than a standard to which
20 certification can be obtained. PCO stated
21 that there again are too many standards
22 referenced in the annotation.

1 In Section B CFS points out that
2 the ASTM standards are based on laboratory
3 testing protocols and they're not field
4 tested. OMRI points out that ASTM 6866 is a
5 testing method and it's not a certification.

6 Section C. CCOF provided the
7 suggested change to this annotation. They
8 said that "must be produced without organisms
9 derived from excluded methods." Other
10 commenters wanted to -- stated that the
11 feedstock and microbial fermentation processes
12 should both be free from GE products.

13 The OTA said that in general
14 there's a prohibition on excluded methods and
15 they express concern over this general
16 prohibition in a specific annotation and they
17 wanted to know what the opinion of the program
18 was with regards to this inclusion.

19 D, both OMRI and OTA expressed
20 concern over the lack of a legal definition of
21 "engineered nanomaterials." And the OTA again
22 wanted to know what the opinion of the NOP was

1 with regards to including this in the
2 annotation.

3 Section E. Both BPI and CCOF
4 offered alternatives or additions to this
5 portion. BPI suggested that we put in there
6 "as recommended by the manufacturer." CCOF
7 included methods by which the biodegradation
8 would occur.

9 CROPP asked what exactly were the
10 grower practices that would achieve the 2-year
11 biodegradability annotation. Organically
12 Grown asked for a definition of "complete
13 degradation." So did PCO, and PCO also
14 specified that we shouldn't be able to use the
15 2 years consecutively in the same field.

16 MS. SONNABEND: Okay. Just --
17 yes. These were additional concerns that were
18 raised by points that weren't exactly part of
19 our annotation. They have to do with short-
20 and long-term impact of pigments on the
21 ecosystem metal catalyst building up in the
22 soil, other additives and processing aids.

1 And then how will growers and certifiers know
2 when the mulch is completely degraded? And
3 then the comments, insufficient studies to
4 verify biodegradability and effect on the
5 environment.

6 So before we get into how -- where
7 we're going with this I want to go back
8 through some of the slides to talk about how
9 we are digesting the information that has come
10 in and what our thinking is on this.

11 So starting back with slide 6.
12 The questioning of why there are so many
13 standards referred to and in particular two
14 standards for ASTM. We have received
15 information about those standards that the
16 first of the ASTM standards is a high-
17 temperature standard in which conditions
18 similar to composting are being applied.

19 The first test provides an initial
20 rejection point much earlier in the time line
21 of review of the material. The ASTM 6400
22 which is the first one talks about a few weeks

1 of composting activity, but it also confirms
2 the absence of ecotoxic effect being via plant
3 growth and seedling germination tests in soils
4 treated with the mulch.

5 The second test, the ASTM D6868,
6 measures biodegradation under lower
7 temperature conditions. The film would have
8 to meet both specifications of higher and
9 lower temp degradation to be considered
10 appropriate.

11 Now, we recognized at the outset
12 of public comment that we were trying to do
13 two things with our annotation. One is to
14 make an annotation so that reviewers can
15 review products that they would be suitable to
16 biodegrade enough, and the reviewers being
17 MROs and certifiers who do materials review.

18 And then the second part is what a
19 grower would have to do and a certifier would
20 have to do to comply -- to verify what the
21 grower was doing. So we are going to try and
22 separate those out in a revised annotation

1 because going forward we don't want a grower
2 to think that they have to meet a 90 percent
3 breakdown compared to microcrystalline
4 cellulose, you know, that part. And if we can
5 go to the next slide.

6 This is designed for MROs who are
7 reviewing products, not for growers to have to
8 comply with. And so we will talk about this
9 going forward in the two different facets,
10 what an MRO/certifier reviewing the products
11 versus what a grower and certifier verifying
12 the product use has to do.

13 Okay. So -- okay. BPI explains
14 the 90 percent which we got questions of in
15 their comments, that there's a certain amount
16 of mineralization and the distinction between
17 mineralization and degradation is -- comes
18 into play.

19 There are also questions raised
20 about the need for certification for a
21 standard, these ASTM standards, which are only
22 standards but don't have a certification

1 behind them. I think we will hear more about
2 this in the public comment coming up and so we
3 will defer talking about that exact point at
4 the moment.

5 The next slide. We realize that
6 we made incorrect terminology here and that
7 the ASTM D6866 is a testing protocol, not a
8 certification.

9 BPI suggests bio-based content
10 will be determined and disclosed using the
11 ASTM method, but then we have to of course
12 have a way, either a certification or an
13 endpoint so that the MRO can determine what
14 amount of bio-based content is sufficient or
15 desirable in a product. Next slide.

16 Okay. So, our thinking on
17 excluded methods is this. We realize that
18 excluded methods is in the rule and is
19 supposed to apply to everything in the rule.
20 However, the excluded methods in the rule
21 refers to field application of inputs and then
22 things in processed foods.

1 We've heard the reasoning already
2 from people that these mulches are not going
3 to be -- they maybe have genetically
4 engineered organisms used to make the mulch,
5 but those organisms are not released into the
6 field. They're in a building that they're
7 manufacturing it in and therefore the excluded
8 method wouldn't apply to this and genetically
9 engineered bacteria could be used to produce
10 this mulch.

11 We reject that contention and we
12 believe that we should do everything possible
13 to keep sources of GMOs out of our stream at
14 any point. And therefore we feel like
15 although it may seem redundant to some we need
16 to put it should not be used with organisms --
17 it should not be made from genetically
18 engineered bacteria or organisms.

19 The feedstock issue is more
20 complicated because right now there's nothing
21 in the rule or in most certifiers'
22 interpretation of it that would prevent you

1 from going into your neighbor's GMO cornfield,
2 cutting down some corn stalks and bringing
3 them into your farm and mulching with them.
4 There's no prohibition specifically on GMO
5 content of any soil inputs per se. And so
6 it's very -- there is a lack of a
7 comprehensive policy on this.

8 People have -- and when I say
9 "people" I mean certifiers and MROs primarily
10 have developed their own policies and they
11 differ somewhat. It's clearly on the work
12 plan for the GMO Ad Hoc Subcommittee to work
13 on making these policies more consistent and
14 to work on a structure and a protocol for
15 evaluating GMO inputs.

16 Therefore our inclination is to
17 not make a statement in this annotation about
18 the feedstock with the acknowledge that we
19 don't like GMOs and we want to keep them out
20 of our chain, but we'd rather have a
21 comprehensive policy that addresses all the
22 GMOs and all the inputs if possible at some

1 point in the future, and possibly within the
2 2 years that it takes for this rule to be --
3 which it's likely to take for this rule to
4 come out.

5 We are still -- we don't have a --
6 none of these points I am discussing have been
7 voted by our subcommittee yet but I'm just
8 telling you what our discussion points are and
9 I'm sure you can help address them in
10 comments.

11 As far as the nanomaterials, we
12 were -- we totally agree that nanomaterials do
13 not belong in organics in any way. And the
14 question becomes whether we need to say this
15 again or whether it's sufficient in the
16 annotation -- to not have it in the annotation
17 but to be clear from the existing NOSB
18 recommendation with NOP affirmation of it that
19 they would be out anyway.

20 We did hear quite a bit of
21 comments, especially from the people in the
22 field who have to deal with enforcing the

1 annotation that shorter is better for our
2 annotation. And so we are -- we're thinking
3 that we maybe do not need this clause to go
4 forward.

5 And then lastly, the grower must
6 take appropriate actions. We acknowledge the
7 comment that it's too confusing to put growing
8 season or harvest season language in that but
9 we feel very strongly that this is the main
10 clause that affects growers and that those
11 appropriate actions are still being determined
12 through research on the material.

13 The appropriate actions would be
14 things like proper soil incorporation, enough
15 moisture, enough sunlight and like that. But
16 if we make the annotation a lot longer by
17 including it we're not going to cover
18 everything and we're not going to give clear
19 guideline for certifiers of how to assess that
20 those appropriate actions are being followed.

21 So we've discussed with the
22 Department about this and they concur that

1 while the rulemaking process is going on if we
2 just leave it at appropriate actions we can
3 then develop a guidance that the NOSB will
4 recommend for and the NOP will cooperate with
5 on exactly what those appropriate actions are,
6 what conditions the mulch may or may not be
7 appropriate from because we think there may be
8 some environmental conditions, soil conditions
9 and the like that these mulches have not been
10 shown to break down properly and the research
11 is still ongoing.

12 But it would enable us to put all
13 that in guidance along with what a certifier
14 would do to verify that the mulch was
15 completely broken down or that the appropriate
16 actions were being taken. That's it. Oh
17 wait, no, one more slide. Sorry.

18 The additional concerns slide to
19 the chart because we don't want to leave
20 without addressing the additional concerns.
21 Okay, the short- and long-term impact of
22 additives. The only additives that are being

1 clearly added in the TR and especially
2 pigments or titanium dioxide in carbon black.

3 Titanium dioxide is non-synthetic
4 and would be allowed anyway, and carbon black
5 is pure carbon. And although it's synthetic
6 it's in effect already allowed as the main
7 component of the ink in newspaper mulch. Any
8 other pigments would have to be petitioned in
9 the future because this is what is in the TR
10 that we're dealing with right now.

11 As far as the other components an
12 important part of meeting the ASTM 6400
13 standard above is to verify that any
14 substances break down completely along with
15 the other ingredients, and those additives
16 will be tested in the course of complying with
17 a standard, either by the MRO or the
18 manufacturer of the materials.

19 I should add that very recently we
20 were given research out of Europe which
21 they've done considerably more research than
22 we have where they've tested for ecotoxicity

1 of all the possible chemicals after several
2 years of using the material and no ecotoxic
3 residues were found of anything.

4 Okay, the processing aids are the
5 same comment as above. The one manufacturer
6 of PLA bioplastic stated that the TR was
7 inaccurate in what solvents they used and they
8 do not use any solvents to produce PLA.

9 How do we know if the mulch is
10 degraded will be covered in the guidance. And
11 insufficient studies to verify
12 biodegradability. Well, there can always be
13 more studies, we know that. We know that it's
14 a relatively new product in the scheme of
15 things and we are to some extent taking a
16 risk.

17 We feel that we have roughly a 2-
18 year window because the NOP has to -- in the
19 rulemaking process has to address the clauses
20 in I think it's 205.206 about removing mulch
21 and so it will probably take a little longer
22 than your average thing.

1 If any problems emerge during that
2 period we will reserve the right to take it up
3 again and reconsider, but we feel that getting
4 the process started because not only will
5 there be at least the 2-year rulemaking
6 process but then the people who are already
7 using it will have used a prohibited material
8 and may have to wait 3 years to get
9 certification back. And so we feel that we'd
10 like to get started with this now and that we
11 can write a good annotation that will satisfy
12 most of the concerns of the whole organic
13 community. Thank you.

14 MR. FELDMAN: Thank you. We are
15 now at 11 o'clock. We started this session 10
16 minutes late so I defer to the chair as to how
17 we should proceed. Our next segment of this
18 session starts at 11 o'clock. So if we could
19 steal a little more time, ask if there are any
20 questions that would be my preference and then
21 move on from there. Okay, just 5 or 10
22 minutes. Any questions from the board on

1 this?

2 Just so you all know, our thinking
3 right now as a committee is that we would hold
4 this over till Thursday to have a vote. So
5 don't feel too much pressure but feel some
6 pressure. Go ahead, John.

7 MR. FOSTER: Thank you. So, no
8 surprise to anyone on the board. So I've kind
9 of evolved my position a little bit on the
10 ASTM. We had a pretty good discussion in
11 previous sessions on that so I've evolved
12 around a little. I can get my head around the
13 ASTM thing now better.

14 So, but I think more precautionary
15 just that every annotation makes a material
16 that much harder to employ. And while in
17 general I think that can be a fine thing if it
18 serves to get in the way of utilizing a better
19 material which I think this, you know,
20 bioplastics, biofilms, I'm not quite sure
21 where we're going to settle on the name but
22 this stuff seems like it's better than the

1 current stuff.

2 And I really don't want to see
3 annotations get in the way or provide any
4 degree of disincentive to a grower
5 particularly to make something better. It's
6 not perfect, we do -- I hate to break it to
7 everyone, but we're not living in a perfect
8 world. We're just trying to make it a little
9 better, at least that's my approach. I think
10 this is an opportunity to do that.

11 I'd like to provide as many
12 incentives as possible to make it
13 incrementally better. I think that's about
14 all we can hope for and I want to throw it out
15 there. I know you're used to hearing it from
16 me so I'll just stop there. That's my main
17 point.

18 MR. FELDMAN: Any other comments?
19 Mac.

20 MR. STONE: In conversation it was
21 discussed is this a plastic or does it fit the
22 definition of plastic? Are we going to hear

1 from commenters, or is this a starch film?

2 And does that have sort of a trickle-down and
3 not go viral in the rulemaking process by
4 semantics?

5 MR. FELDMAN: So that's a question
6 we want to pose to folks in the comment
7 period. Any other comments? Colehour.

8 MR. BONDERA: Thank you and thank
9 you, Zea and Carmela, for the presentation.

10 I want to just let people know
11 that I actually, if you look at the record I
12 actually abstained from the listing motion on
13 this in the Crops Subcommittee because the
14 truth is that from my perspective at that
15 point in time there were lots of unclear and
16 unanswered questions. And I think like John
17 suggested it's not a perfect world but for me
18 when I don't know then I get concerned.

19 I wanted to just say that as an
20 introduction because I did while this
21 presentation was happening write down some
22 questions and I want to ask at least one of

1 them back to you, Zea, to sort of go on a
2 little bit more about. Maybe we can ask some
3 people when they're testifying this same
4 question.

5 But it's a little bit confusing to
6 me from listening to people. If this product
7 is tilled in in the field then doesn't that
8 make it a field application? And it's not
9 removable? And so I just -- that line between
10 whether or not it's a field application and
11 this issue related to the word plastic and how
12 it fits into regulation is confusing to me.

13 But if the recommended or the
14 actual use includes tilling the product in
15 then that becomes a field application. And so
16 if we're going to refer to field application
17 then I wonder if you can clarify or address
18 that a little bit. Thank you.

19 MS. SONNABEND: Yes, it is tilled
20 in and it is a field application.

21 MR. FELDMAN: Other questions that
22 you want to raise now? Okay. Then with that,

1 Mr. Chairman, I guess we're moving onto the
2 next session which is still under the Crops
3 Committee so should we just segue way to that
4 right now? Okay.

5 Thank you all for moving through
6 this so quickly. We really appreciate it.
7 Really good job helping us move this along.
8 And with that we close this, the review of
9 proposals and petitions and so forth.

10 And now we're moving into the 11
11 o'clock session where we will do three things.
12 We will update the board from the Tree Fruit
13 Working Group with David Granatstein. We've
14 allocated 25 minutes to that including Q&A.
15 And then we'll hear from Urvashi Rangan with
16 Consumers Union, 25 minutes including Q&A,
17 again on issues related to tetracycline and
18 streptomycin. And then end with Kiki Hubbard
19 from the Organic Seed Alliance, 25 minutes
20 with Q&A. So we have a full hour and 15
21 minutes until lunch. And why don't we call
22 Dr. Granatstein up to the podium for his

1 presentation and begin this session.

2 I'd like to welcome you. Thank
3 you for coming. I'm going to do a little bit
4 of an introduction so folks have background.
5 I know many folks in the room already know you
6 and appreciate your long career and
7 contribution to organic production.

8 David Granatstein is sustainable
9 agriculture specialist with Washington State
10 University's Center for Sustaining Agriculture
11 and Natural Resources. He has worked with
12 organic farming since 1975 in many different
13 capacities and provides significant support
14 for the organic tree fruit sector in
15 Washington State.

16 He serves on the state organic
17 advisory board and on the board of directors
18 of Oregon Tilth and is chair of the
19 International Society for Horticultural
20 Science Organic Fruit Tree Group. David is
21 based in Wenatchee, Washington.

22 Welcome, Dr. Granatstein. Thank

1 you so much for coming.

2 DR. GRANATSTEIN: Thank you, Jay,
3 and thank you to the entire board for asking
4 for this update.

5 So I'm going to start out just
6 with a little bit of context for those on the
7 board that aren't familiar with the history of
8 our group. This group came about after the
9 Seattle meeting a year and a half ago where
10 the issue of antibiotics and fire blight was
11 discussed.

12 And the general call was put out
13 can we form a group to kind of find out where
14 we are in terms of progress on this issue, on
15 alternatives, on the needs of the industry, et
16 cetera.

17 So we put a group together with
18 our purpose being broader than just looking at
19 the single issue of antibiotics and fire
20 blight, anticipating there are going to be
21 issues for tree fruit into the future. And we
22 wanted a group of folks ready to address those

1 and work with the NOSB in terms of providing
2 the best possible information.

3 So our goal is to create the
4 healthiest, most sustainable organic tree
5 fruit system. That's really what our group is
6 attempting to do. To do this by communicating
7 science-based information and grower
8 experience to you, the NOSB, and help inform
9 deliberations that go on here.

10 Our group has about 17 people from
11 a range of different backgrounds and different
12 parts of the country. We are an industry
13 group representing more the growing and
14 handling side, not a group that includes all
15 stakeholders. So that's one thing I want to
16 make clear.

17 So to start out I just wanted to
18 show where we are in terms of organic tree
19 fruit. It is still growing. These data are
20 some that we've been tracking now for a number
21 of years. And you can see the growth from
22 2010 to `11 we had 6 percent increase in sales

1 of organic apples at this point in the growing
2 season, 8 percent for pears. In this next
3 year, 11 to 12, 27 percent increase and 43
4 percent for pears. So dramatic increase in
5 the growth of sales which says consumers want
6 these products and they want them even more
7 than they did a year ago. So that is an
8 indication of consumer demand.

9 We also can see here in the graph,
10 the blue line represents the price for organic
11 gala apples. The red line is conventional
12 gala apples. And therefore the market has
13 provided a consistent premium price for
14 organic growers over the long haul.

15 Fire blight is kind of the disease
16 of concern here. That's why people are using
17 antibiotics when they do. It's a very
18 complicated disease. I'm not going to go into
19 it. We did talk about this a year ago when I
20 did my previous presentation, but probably the
21 main point is that fire blight control depends
22 on prevention, not cure. And so everything

1 we're talking about is how to prevent
2 infection. Once trees are infected the only
3 cure is the chainsaw essentially, cutting out
4 limbs or cutting down trees and burning the
5 material. So that's what we're talking about
6 here. Antibiotic use is not a curative like
7 it is when we use it for medical reasons.
8 It's a very different situation.

9 Growers use a range of management
10 practices for fire blight. This is a list of
11 many of them. We start with genetic tolerance
12 but this is limited in terms of what varieties
13 of apples and pears are commercially viable.
14 So we have partly a discussion around scale.
15 Small growers have a much larger range of
16 materials to choose from. They can develop
17 relationships with their consumers who will
18 accept the certain characteristics of those
19 fruit that may or may not store very well, may
20 not ship well, may not hold up in a retail
21 environment. But for larger growers those are
22 key considerations as to which varieties they

1 can use.

2 We've talked about the Geneva root
3 stocks and I'll mention those in a minute.
4 There is good progress happening there. But
5 bottom line, when it comes down to a risk of
6 infection as determined by the weather
7 conditions, driven by the computer models that
8 growers use, growers will turn to a material
9 to intervene and try to prevent infection.

10 And to give some perspective on
11 current use, from 2001 to 2011 the percent of
12 bearing acres treated by antibiotics in the
13 U.S. for apples, for tetracycline it was 9.7
14 percent, about 10 percent in a given year were
15 treated, for streptomycin about 17 percent.
16 When we look at pears it's about 34 percent
17 for tetracycline and 28 percent for strep.

18 So right away you see those two
19 crops have different intensity of use factors.
20 Pears tend to be more susceptible and are
21 treated on average more often.

22 We can also look at plant use of

1 antibiotics relative to, for example, use in
2 animal agriculture. And the EPA has
3 determined that a typical pharmaceutical use
4 of tetracycline, when we take it to control an
5 infection in our body, that exposure is 50,000
6 to 200,000 times greater than the maximum
7 theoretical dietary exposure from use of
8 antibiotics in plant agriculture. Just to put
9 things in some perspective.

10 So really the crux of our
11 discussion is around what are the
12 alternatives, how are we progressing. We've
13 heard about Blossom Protect. That's a new
14 material that was registered in early 2012 so
15 it was the first chance for growers to
16 actually use it on a commercial scale.

17 This is a product interestingly
18 enough that was originally isolated in
19 Wenatchee where I live by a USDA researcher,
20 picked up by some Germans, used for another
21 purpose first and then applied as a potential
22 control for fire blight. And it is looking

1 very promising. But again, 2012, the first
2 year for growers to use it and there was
3 limited amount of material available, about
4 enough for 2,000 acres.

5 Two thousand and twelve was a
6 severe fire blight year in Washington State,
7 very, very severe. And it was a very odd year
8 in that the bloom period when we're treating
9 for this disease was extremely compressed. So
10 while the grower reports of efficacy are
11 generally positive there were issues around
12 timing, how to integrate the use of that
13 material with the other activity going on then
14 which is thinning of the blossoms to control
15 the crop load. So this is one area where we
16 clearly need some more work such that the
17 growers have good guidance on how to integrate
18 this new product into an overall management
19 program.

20 The material is only registered
21 for use on bloom so it will not be allowable
22 during other times of the year such as the

1 summer if there's a hailstorm. And certainly
2 in the Midwest and the Eastern states often
3 this is a bigger issue for fire blight
4 infection than bloom time. In the Pacific
5 Northwest our primary concern is during the
6 bloom. So different regions are going to
7 experience different possibilities with this
8 particular material.

9 There's some new materials being
10 developed, some copper materials that are more
11 active than current materials, probably will
12 allow lower rates of actual copper to be used
13 which is good because there are long-term
14 concerns about buildup in the soil. These
15 aren't registered yet and it's not clear if
16 they will be submitted for OMRI or other
17 material review approval. But they are in the
18 pipeline and they are showing good efficacy.

19 And then finally there's work
20 going on with integrated control. So rather
21 than just replacing an antibiotic with one
22 material that's expected to substitute for it

1 how do we start to mix and match the different
2 options that are out there? Some work better
3 on a certain part of the flower, the stigma
4 versus the nectarie. Getting an understanding
5 of that, the sequencing of these materials,
6 integrating with thinning programs. Many of
7 the thinning materials are toxic to these
8 biological control agents so we're still in
9 the process of trying to put all that
10 together. But that is the type of research
11 that is underway.

12 So here's a quick example of some
13 of the work that's been going on. These are
14 2012 results similar to results from the past
15 several years showing on the top bar
16 streptomycin typically is our standard against
17 which we measure the efficacy of other
18 controls. In the green bars we see -- the
19 green bars are the Blossom Protect. So not
20 quite as good as the streptomycin but right up
21 there in terms of very good efficacy. Some of
22 the new copper materials are next in the blue

1 bar. So the data have been pretty consistent
2 showing that these are performing well over
3 different years.

4 These results come from Ken
5 Johnson and the OREI-funded project. This
6 project was started, the first field season in
7 2012, and will run through 2016. And of
8 course this is just a really great addition to
9 our ability to transition from the use of
10 antibiotics. So again, they're testing
11 different materials and a lot of testing of
12 different combinations of materials to see how
13 they hold up over time.

14 In this case, again, streptomycin
15 down here is sort of the standard and we see
16 the lime sulfur plus fish oil. That's a
17 standard thinning program that also has
18 activity against the fire blight bacteria
19 followed by the Blossom Protect is doing as
20 well as the streptomycin. So this has been a
21 result that's been pretty consistent as shown
22 here by Ken Johnson.

1 These are data from three
2 different growing seasons now in Corvallis,
3 Oregon, western Oregon. And the yellow bar
4 with the star represents that treatment of the
5 organic thinning sprays followed by the
6 Blossom Protect and they are doing as well as
7 those treatments with antibiotics.

8 So again we're starting to see
9 some consistency in the efficacy of use here.
10 But these are all inoculated trials, these are
11 all researcher trials. These aren't yet the
12 large-scale field trials where growers are
13 using these out in the real world, and that's
14 one of the gaps I think that we still face.

15 Another example of work from the
16 OREI project. This comes from California,
17 northern California where they're looking at
18 the use of coppers pre-bloom to try to knock
19 down the inoculum level of fire blight in the
20 orchards. And in this case they were just
21 comparing the use of oil which is a standard
22 delayed dormant treatment for a number of

1 insects and some diseases to the copper plus
2 the oil. So the gap between them is the
3 reduction in fire blight by the addition of
4 copper. So, again, very promising
5 developments there.

6 And this is being accompanied with
7 some new work called LAMP. LAMP is a
8 detection technology using molecular methods
9 to actually be able to go out, sample blossoms
10 from the orchard and see how much fire blight
11 exists and when does it exist, when does it
12 start building up.

13 Because it may be that the fire
14 blight model says you are in a high-infection
15 period. At this point in time a grower would
16 respond by treating with an antibiotic, with
17 a biological, whatever material they were
18 using. But it could be that there's not
19 enough organisms in the orchard to even
20 warrant that. And we have yet to have a good
21 diagnostic test that a grower can use in that
22 kind of realtime fashion. This LAMP

1 technology is being developed, is coming along
2 and I think will be a very, very important
3 complement to a non-antibiotic and a more
4 precise fire blight management program in
5 general. So that is also part of the OREI
6 project that's underway.

7 We've talked a lot in the past
8 about genetic resistance and how this should
9 really be our first line of defense and some
10 of the struggles of working with this.

11 So, I just completed a survey, I
12 did a phone survey of a number of the major
13 fruit tree-producing nurseries to find out
14 where they are at. And the first question was
15 around the Geneva root stocks. That's
16 something we've talked about before. Those
17 are moving along but if I wanted to order
18 trees today on Geneva root stock it would be
19 4 to 5 years until I could get those trees.
20 That's how far the backlog is, that's how slow
21 the reproduction of that clonal material is.
22 They are optimistic that it's going to improve

1 but it's still quite a ways out if I wanted to
2 start today.

3 And we would compare that to my
4 ordering trees on the M.9 root stock which is
5 highly susceptible to fire blight, 2-year
6 turnaround, no problem. So there's still a
7 bit of a gap between what growers can get
8 through the standard channels versus the
9 Geneva root stocks. But they are looking very
10 promising as far as their fire blight
11 resistance.

12 And in fact, it does appear from
13 some current research, some very recent
14 research that the Geneva root stock helps the
15 scion that's grafted on top of it to resist
16 the spread of infection a bit more than had
17 been anticipated. So it doesn't slow the
18 infection or reduce the infectability, but if
19 a tree does get infected it appears that
20 there's some nutrient interactions with the
21 root stock that make the infection less
22 damaging. And that's brand new information

1 from Gennaro Fazio in Geneva, New York.

2 Resistant cultivars. All the
3 nurseries I talked to, no one could say ah,
4 there's a fire blight-resistant apple coming
5 down the line that's got real promise. Not
6 one could tell me that. Same for pears. So
7 we're still in that dilemma of things being
8 driven by the commercialization
9 characteristics and the breeding specifically
10 for fire blight still is lagging behind.

11 One example of some promise though
12 is a pear that's being tested at Hood River,
13 Oregon. This is a selection done by USDA
14 that's been tested there now for 10 years that
15 still has not been released, so it's not a
16 named variety yet. It probably will be within
17 the next year. And at that point they plan to
18 plant about a six-tenths of an acre
19 demonstration in Hood River at Oregon State
20 University to begin the whole process of
21 grower evaluation. They need enough fruit for
22 the growers to see how it will work, for the

1 packing houses to test how it's going to
2 handle and store, and for consumers to get
3 used to it. And that's at least another 5-
4 year process. So that gives you a feeling for
5 the time frame of actually getting these
6 materials out there once they're proven to
7 have some value for resistance.

8 There's a new project in
9 Washington and with ARS specifically taking
10 traits from another apple species, malus
11 sieversii. This is a wild relative of apple
12 but it's the strain or it's the species that
13 has the more desirable fruit characteristics.
14 Many of the past efforts for fire blight
15 breeding used different malus species for
16 which the fruit quality never transferred
17 across to varieties that were going to be
18 acceptable to consumers.

19 So they're going to try to bring
20 those genes into the crop reference set that
21 they've developed and using marker-assisted
22 breeding start to understand where they're

1 getting the fire blight resistance. And it
2 looks like there's at least five different
3 locations of fire blight resistance. It's not
4 a single gene or single cluster kind of
5 relationship. So fairly complicated but
6 that's a very promising project that's just
7 starting.

8 And then there's been some new
9 field screening, unpublished data so far by
10 Gennaro Fazio and colleagues looking at some
11 of our modern varieties and trying to see
12 where we are. Again, these weren't bred for
13 fire blight resistance but the question is do
14 they have any. And here's our Geneva root
15 stock G.41, zero infection compared to M.9
16 right below it, up to 100 percent infection.
17 So clearly the Geneva series are progress.

18 Then here's another example of a
19 scion. This is a Sonya apple out of New
20 Zealand. I called the North American nursery
21 that's producing this. They had no idea it
22 had any fire blight resistance. So again, it

1 wasn't bred for that, it really wasn't
2 actively screened for it, but it turns out
3 that it actually may have some very good
4 resistance. Unfortunately this is a patented
5 club variety and it's currently restricted to
6 400 acres of planting in the U.S.A. So it's
7 not a panacea, not -- most people will not be
8 able to grow this. So those are some of the
9 dilemmas around utilizing genetic resistance.

10 Extension activities, there have
11 been a number of things done over this past
12 year. Probably the most exciting was an e-
13 organic webinar done nationally by Ken Johnson
14 on antibiotic control. And some 250 people
15 attended that webinar.

16 But what they're finding with
17 these e-organic webinars, because they post
18 them online many more people come after the
19 fact. So I don't know, it's probably up to
20 thousands of people have been utilizing this
21 information. So a very, very powerful way to
22 get the information out there.

1 I've continued with my surveys of
2 organic tree fruit growers in Washington to
3 try to get a sense of what they think they'll
4 do as the rule change comes into effect. So
5 now this is the third year we've asked them
6 these questions.

7 How will the loss of antibiotics
8 for fire blight control impact your operation?
9 And what we've seen is a shift where we had
10 more people in the little to no effect, that's
11 the most lefthand bar. That used to be 10,
12 12, 15 percent. Now it's down to 7 percent so
13 people's concern level is rising. And nearly
14 90 percent are saying it's going to impact my
15 production or maybe even force me to exit
16 organic apple or pear production. So that's
17 from Washington State growers.

18 A colleague on our committee
19 surveyed some of his folks in the Northeast,
20 small organic growers. They had the opposite.
21 They said in general it probably won't change
22 what we do very much. So it's going to be a

1 different reaction depending on the part of
2 the country you're in and the size of your
3 operation.

4 We also asked them if you tried a
5 non-antibiotic control regime and
6 interestingly enough 73 percent had tried it.
7 That surprised me. We then asked them if it
8 was successful. Thirty-three percent said
9 yes, 67 percent said no. But this was prior
10 to people being able to use the Blossom
11 Protect product that came out this year. So
12 it will be interesting to see if after this
13 year that answer might change.

14 And then we asked them flat out do
15 you support extending the phase-out date and
16 93 percent said yes.

17 So as far as next steps, the
18 feeling that our group has is to develop a
19 rational plan for phase-out. Our group
20 totally supports phase-out. Our growers
21 understand that phase-out is the future, let's
22 get ready for it. But they feel they do need

1 more time to minimize disruption to the
2 growers, to the actual volume of production
3 and to the market and the consumers who as you
4 saw really want these products. So we believe
5 consideration of an extended expiration date
6 does make a lot of sense.

7 In the meantime we're going to
8 have the continued testing. Let's let the
9 OREI project come to completion, that will be
10 2016. It should produce a wealth of
11 information. We've got to transfer that
12 research experience then to good extension
13 materials and good education with growers.

14 The number one barrier right now
15 is confidence-building. Fire blight is a
16 very, very high-risk proposition and people
17 are not going to bet the farm on it without
18 knowing with a high level of certainty that
19 these alternatives will deliver under the
20 different conditions in different locations
21 that they're facing.

22 We will have new products like the

1 copper is coming down the pike to help. More
2 testing of the integration is going to help
3 people figure out how to use these.

4 Some of the more novel research is
5 beyond the scope of the time frame we're
6 looking at but we believe that will help as
7 well into the future. And again, right now
8 you can't go and find a published extension
9 bulletin on science-based non-antibiotic fire
10 blight control and we need to get to that
11 point. That's what growers want to find for
12 their confidence-building. So we have more
13 information on the website that's listed there
14 and we'll plan to put more information online
15 as we get it.

16 Probably one of the biggest things
17 to consider as I close here is that the reason
18 we in Washington have had so many people,
19 about 20-some percent of our growers in the
20 European Union program which does not allow
21 antibiotics is because if they hit a situation
22 where it's an extreme year and they are not

1 comfortable with their control program they
2 can use antibiotics, leave the EU program, but
3 remain certified organic. And so the irony is
4 that the availability of the antibiotic
5 control is probably the reason we have such a
6 high number of people not using antibiotics.
7 So, the risk factor is really huge in terms of
8 the growers and we've got to make sure that we
9 address that.

10 So at this point I'll close just
11 by saying we are working on some documents
12 looking at the published science on antibiotic
13 residues in tree fruit systems and the risk of
14 antibiotic resistance transferring to human
15 pathogens from use in tree fruit as well.
16 With that I'll close and try to answer any
17 questions that I can.

18 MR. FELDMAN: Thank you very much.
19 Questions from the board? Go ahead, Nick.

20 MR. MARAVELL: Yes, thank you for
21 an excellent presentation. I have two
22 questions and you don't have to answer both if

1 we're short on time.

2 One question is is there
3 sufficient research taking place in the
4 various -- in your opinion is there sufficient
5 research taking place in the various regions
6 of the country so that we will be able to give
7 that level of confidence to growers Northeast,
8 Midwest, West.

9 And my second question so you can
10 judge your timing on the response is in your
11 research with the LAMP system where you're
12 taking measurements in specific site locations
13 for the presence of the fire blight is your
14 research built such that that will have a
15 feedback loop to your current predictive
16 models? Is it possible that you might
17 actually be modifying your predictive models
18 based on that data?

19 DR. GRANATSTEIN: First question,
20 the answer is no. Most of the research right
21 now, the OREI project is focused on Oregon,
22 Washington and California. That's what it was

1 funded for. Some folks in Michigan did put in
2 a proposal to OREI to carry on some very
3 similar working the Midwest. That proposal
4 was not funded. So unfortunately that eastern
5 part of the country does not have the same
6 level of activity.

7 I'm not sure how many people are
8 testing these materials. I know folks at
9 Michigan State were testing them on their own.
10 I'm not sure how they were being funded but
11 they don't have a nice well thought through
12 and integrated project like we do in the West.
13 So that is definitely a gap that's out there.

14 As far as the LAMP currently the
15 models are not based on, quote, "scouting"
16 because there hasn't been a technique. So
17 they would have to figure out how they'd build
18 that in there and I assume they would try to
19 do that. But to date that has not been part
20 of the package.

21 One thing that's been noticed on
22 the use of the models, the models were

1 designed in many ways for growers to wait
2 until the last minute to act such that they
3 weren't using these materials in an
4 unwarranted situation based on essentially
5 weather conditions.

6 But because the non-antibiotic
7 control regimes require more time for
8 everything to begin to work it's probably
9 going to be necessary to back off and act
10 earlier than growers now do, and therefore
11 more risk of acting when there was no need to
12 act based on the ultimate play-out of the
13 weather. So that's one of the challenges of
14 trying to figure out how to use the model with
15 these new tools and that was something people
16 found this year.

17 The real advantage to the LAMP
18 will be to say the model may predict risk but
19 my level of organisms in the orchard is so low
20 that I just don't need to treat and that would
21 be a huge breakthrough.

22 MR. FELDMAN: Thank you so much.

1 We will call you back up if that's okay at the
2 end of the session if we have time for more
3 questions. Thank you very much.

4 DR. GRANATSTEIN: Thank you for
5 having me.

6 MR. FELDMAN: And just to make
7 sure everybody on the board knows why we're
8 doing this specifically on the streptomycin,
9 tetracycline. The board back in Seattle which
10 was spring of 2011 voted to adopt an
11 expiration date of October 2014 which means
12 this issue will be on the agenda in the spring
13 of 2013. So we as a board will be voting.
14 That's why Dr. Granatstein had that expiration
15 date, request for an expiration date extension
16 up there on the slide.

17 So now we're honored to have
18 Urvashi Rangan from Consumers Union. I'll
19 give a little bit of an introduction of Dr.
20 Rangan who has a Ph.D. in environmental health
21 sciences from Johns Hopkins.

22 She heads up the Consumer Safety

1 and Sustainability Group for Consumer Reports,
2 is responsible for managing risk analysis,
3 policy assessments, label evaluations and
4 consumer advice for tests, reports. You all
5 know what Consume Reports does.

6 Urvashi joined the organization in
7 1999 and developed the rating system database
8 and website. You're familiar with
9 ecolabels.org for evaluating environmental and
10 food labels.

11 In 2005 she managed the launch of
12 GreenerChoices.org which covers green aspects
13 over a wide range of products and services.
14 She testifies before Congress, has two young
15 children and is generally recognized to be a
16 super woman. So thanks for joining us.

17 DR. RANGAN: Thanks, Jay, that's
18 really nice. Thanks, everybody. It's good to
19 be here, I haven't been here in a little
20 while. So with that introduction, thanks. I
21 haven't met a lot of the new members on the
22 board but it's a pleasure to be here.

1 I am a scientist that works for
2 Consumer Reports. We've been educating
3 consumers about what organic is and what it
4 isn't and what it should be and what the value
5 is for consumers for quite a long time.

6 And so I'm here today to talk a
7 little bit about the consumer perspective with
8 regard to antibiotic use on apples and pears.
9 And really I think kind of what roots what
10 consumers don't know at this point.

11 And I think Dave gave an excellent
12 presentation and I've had an opportunity to
13 hear his talk before on the alternatives.
14 It's a real problem. We'll definitely give
15 you that, it's a real problem. But I think
16 when it comes to consumers and organic they
17 don't know that antibiotics are being used on
18 apples and pears. We have not had that public
19 discussion.

20 And so while it may appear that
21 there is a growing demand for this organic
22 commodity and even other organic commodities

1 that don't quite meet the standard the demand
2 is a little bit hollow in that consumers
3 actually don't know.

4 And I'm going to mea culpa, we're
5 part of the problem. We haven't talked about
6 this issue in the public and when we learned
7 about it in 2005 or '06 we were hoping for
8 sunset within that period of time and then
9 things just got re-listed. And so we as a
10 consumer group are part of this problem, that
11 we haven't had a public dialogue about it.
12 And now we're standing here in 2012 and we're
13 still having this same discussion.

14 So I'm going to get into the ins
15 and outs of why this is a problem. And I
16 think we all need to sort of take stock of the
17 fact that we're going to have to prepare to
18 have a public dialogue about this so that
19 consumers can truly understand what it is the
20 problem is. And I think we all need to think
21 about solutions in the short and long term.

22 So the first thing I want to get

1 into is the law itself. And the OFPA
2 specifically states that organic is about the
3 reduction of external and off-farm inputs, and
4 elimination of synthetic pesticides and
5 fertilizers and other materials such as
6 hormones and antibiotics. And that's just the
7 law so that's what underwrites all these
8 things. We go back to that often when we're
9 trying to talk to consumers about what organic
10 means, what it should mean, what the basis is,
11 what the principles are.

12 And just oddly, I was sort of
13 Googling around to prepare for this
14 presentation and I came across our own
15 comments from May 2000 before the rule had
16 been implemented. And we actually noted this
17 very problem. And this was before anything
18 was put on the National List. But we had
19 concerns about the fact that there was an
20 explicit prohibition of antibiotics for
21 livestock production and yet that didn't apply
22 to crop production. And we found that to be

1 inconsistent and could potentially mislead
2 consumers if antibiotics were to ever be
3 approved for crop production. And so they
4 were.

5 In terms of the science there's a
6 lot of science behind it. I think -- I'm
7 sorry, this is terrible, it's a little bit too
8 small but let me just read this to you. I
9 think we're in a race to the bottom with
10 antibiotic use in the apple and pear industry.
11 And it's a race to the bottom it seems like
12 not just for organic apples and pears but for
13 the whole industry.

14 And we've essentially created a
15 super blight. We have blight that is now
16 resistant to a lot of these antibiotics. And
17 it's not unlike a super bug on the farm. It's
18 a growing problem, it's an industry-wide
19 problem. It seems like a problem. I think
20 we've been adequately convinced of that.

21 Plans to approve other antibiotics
22 like gentamicin have been blocked due to

1 public health concerns and the CDC has voiced
2 that explicitly. The World Health
3 Organization has actually declared the use of
4 streptomycins and tetracyclines to be both
5 critically important, that's Tier 1
6 classification of those, and that high-
7 frequency of any use of these antimicrobials
8 regardless of indication can result in
9 pressure for resistance.

10 Plasmids from gram negative
11 bacteria of which the blight is can transfer
12 resistance. It may be slightly lower in this
13 particular application but the notion that it
14 can transfer resistance is definitely there
15 and rooted in science. And we know that
16 recently introduced varieties over the last
17 decade are more prone to blight.

18 And so while antibiotic resistance
19 is a major issue there is the minor issue of
20 antibiotic residues. We tend not to focus on
21 that when we talk about animal welfare and
22 antibiotic use in that because it's a more

1 minor concern.

2 However, there is a study and I've
3 cited it here that shows streptomycin residues
4 found on some apple and pear samples that were
5 treated 4 to 6 months after application in the
6 fruit itself. And I think that's just yet
7 another problem. It isn't the only problem
8 but it is yet another one. So, we've got
9 scientific issues that consumers can get their
10 heads around.

11 We have a whole campaign, by the
12 way, called "Meat on Drugs" which is all about
13 antibiotics and the meat production industry
14 trying to get the conventional industry to
15 move toward prudent use of antibiotics and
16 trying to move the market toward getting rid
17 of antibiotics in that production system. It
18 isn't unlike this particular system, it's just
19 that consumers really don't know a whole lot
20 about it.

21 I think where consumer demand is
22 when it comes to organics is in the integrity

1 of it. And I hear a lot of discussion over
2 the years about consumer demand, the drive to
3 grow the market, the drive to meet that
4 demand. But when you compromise integrity to
5 meet demand you do something very damaging in
6 the short term and the long term. You do
7 something damaging not only to the particular
8 commodity where standards are being lowered
9 but you do something to the overall integrity
10 of the organic industry and people will
11 extrapolate.

12 And if the Stanford study isn't
13 proof of that I don't know what is. People
14 extrapolate lack of benefit, lack of value
15 when they feel cheated, when they feel like
16 the threads are sort of coming loose even
17 though maybe from the whole system that's not
18 the problem.

19 So the importance of organic
20 remaining a credible, commercially viable
21 model of how sustainable ag practices can
22 succeed in a market is really important. It's

1 important to us too, that's why we spend time
2 educating people about this.

3 The primary goal for the NOP as a
4 program, for you as a board is to hold the
5 standards strong and strengthen it over time,
6 not to grow a market for sub-par organic
7 products. And that applies to whether we're
8 approving synthetics ad nauseam, or whether
9 we're talking about aquiculture that doesn't
10 meet the standard. We run into this issue
11 over and over and over again.

12 And so I always wonder is organic
13 going to be a floor or a ceiling. And I have
14 this existential discussion with lots of
15 people. Maybe it's not going to be a ceiling
16 because there's other labels out there that
17 are exceeding organic in lots of different
18 ways and they're going to compete with
19 organic. And in the end the better ones will
20 win out.

21 And there are other labels like
22 the sustainable label which is going to come

1 and try and compete directly with this
2 program. So the more the standards start to
3 get chipped away in organic the more equivocal
4 you sort of make it with programs that really
5 aren't going to go all the way to the gold
6 standard. And that is going to be the
7 beginning of really I think the undermining of
8 what organic means to consumers in terms of it
9 being a gold standard.

10 If it's going to remain a floor at
11 least we need to keep it nailed in. We can't
12 start taking out the boards and having it not
13 have a floor. So the floor that is there
14 needs to exist, it needs to be solid, it needs
15 to be maintained. We'd argue you need to
16 increase the standards over time, but at the
17 very least the floor has to be maintained.

18 The allowance of antibiotics is
19 just not in line with what organic means for
20 most foods and consumers don't expect it. And
21 the industry is marketing itself as no
22 antibiotics. You just have to take a trip

1 through the store aisle and start reading
2 boxes of Nature's Path cereal or whatever else
3 you want to pick up. This industry is
4 marketing itself as providing value-added by
5 not using those materials.

6 So this isn't just a consumer
7 issue. It's not just about consumers don't
8 get it. This is an industry that has staked
9 itself on these principles and yet they're
10 sort of being chipped away. So the honesty
11 and the added value that organic conveys is
12 constantly under scrutiny.

13 I get calls all the time from
14 reporters and I'm going to get into some of
15 those questions as to how it compares in the
16 marketplace, how is it doing compared to other
17 labels out there. And as the market grows for
18 this industry the scrutiny will also grow.
19 And when the value is compromised so is
20 consumer trust. And that's a very simple
21 equation. It doesn't just apply to organics,
22 it applies across the board.

1 And as I mentioned before there
2 are other labels on the market that are
3 offering better choices in certain cases and
4 in some cases worse, right? Natural is still
5 constantly confused with organic. And yet
6 chipping away at these standards starts to
7 move it toward natural. And so people who buy
8 natural and even pay more for natural are not
9 going to be enticed to go to organic because
10 it won't be that much of a difference in their
11 minds.

12 And so this is the long-term
13 ramifications of chipping away at standards
14 slowly where it's confusing as to what the
15 principles are. It isn't always the case that
16 something is prohibited. And so it starts to
17 get dumbed down. And natural is a dumb label.
18 And we don't want to see organic dumbed down
19 to natural.

20 So, fair competition. You have a
21 whole sector of this industry that's not
22 allowed to use antibiotics and that's really

1 hard for them. The livestock and dairy
2 industry conventionally uses tons of
3 antibiotics. And as I mentioned it's the
4 subject of a massive marketplace campaign we
5 have going on.

6 You have a sector that is going
7 over and beyond to not use antibiotics and
8 makes lots of claims about that too in their
9 marketing materials. And yet why should a
10 sector now in organics be able to use it? It
11 is unfair in terms of the competition even
12 within organics itself.

13 I guess the one advantage of the
14 controversy in all of this is that we finally
15 have some research and development going on
16 and that's a really good thing because it
17 seems like this industry is in a bit of dire
18 straits when it comes to useful tools to fight
19 the diseases that they have going on. And
20 that's a really good thing.

21 We know Europe organic doesn't --
22 you can't send those fruits to Europe if

1 they've been treated with antibiotics. So
2 there's some feasibility here. And as Dave
3 was sort of explaining it's slow but we're
4 starting to get there. And it certainly seems
5 like we can do it at times, we can do it with
6 certain varieties and it is feasible for some
7 of this market to move ahead that is truly
8 organic.

9 You also have regions where
10 resistance to these drugs is completely
11 persistent so they're at a disadvantage,
12 aren't they, from being able to use this tool
13 to fight those diseases. So even within the
14 organic apple and pear industry sector there
15 is sort of unfair competition going on with
16 the allowed use of these antibiotics. So that
17 kind of covers the fair competition question.

18 One thing I want to get into here
19 is what we have to field from the media all
20 the time. And here are just some -- here we
21 go again, sorry about this. I'm going to read
22 them.

1 So, here are some questions we get
2 in the media. What was the purpose of
3 creating an organic law and federal program?
4 Why did we do it? Why did we go to all the
5 trouble? Our answer is generally to impart
6 consistency into what organic meant for
7 consumers and farmers and to minimize
8 confusion in the marketplace. That's why we
9 did it. So why are we creating all these
10 inconsistencies as we move forward? But that
11 is what this is, this is an example of that.

12 Another question we get, organic
13 food, is it worth it? What does it mean?
14 Often the title -- and it's often the title of
15 a lot of articles. And then we end up with
16 this crazy answer of most organic foods meet
17 certain standards and principles but there are
18 exceptions. And organic foods with the most
19 value are produced without synthetic materials
20 or antibiotics but others aren't. Or the
21 standards that apply to most food don't apply
22 to other foods. Or some animals go outside

1 but some may not. Or there's inconsistency in
2 the meaning which is why we went to the
3 trouble of creating the federal program in the
4 first place. So we end up with completely
5 convoluted answers for the media to talk about
6 what organic was meant to be, what it is now.

7 You can start to understand why
8 consumers are going what? What do you mean?
9 I thought that wasn't allowed? Now you're
10 saying it is allowed. I don't get it. And
11 when consumers start to feel cheated, that's
12 when the bottom starts to fall out.

13 I just, I want to go quickly here
14 into consumer understanding. And I just want
15 to talk very quickly here. This is Organic
16 Valley. Organic means no antibiotics, that's
17 their marketing materials on here. So anyway,
18 suffice to say there's a lot of ads going on.

19 In terms of moving forward we've
20 got to prepare for the public conversation
21 about this. We have to have a public
22 conversation about this. People don't know

1 about it. We don't think apples and pears
2 that are treated with antibiotics should be
3 called organic.

4 And I'm sorry, it's -- that is not
5 something that is easy for us to come here and
6 say. I think we feel like there is a lot of
7 hard work going on in this industry and we
8 have a lot of sympathy for this industry. It
9 seems to be in trouble in terms of the tools
10 it has. It still shouldn't be called organic.

11 Alternative labels, maybe
12 transitional and conversion should be
13 considered. And truly organic apples and
14 pears that are produced without antibiotics
15 should be able to honestly differentiate
16 themselves in the marketplace. They can't do
17 that right now.

18 And I think the industry has got
19 to stop pledging the use of antibiotics. We
20 can't have any more exemptions to this. We
21 don't think it should be re-listed. And we
22 think there needs to be a public education

1 campaign. And we have a role to play in that
2 too in terms of which varieties don't -- are
3 more resistant to fire blight than others.
4 And we think this increased transparency in
5 the marketplace are going to help consumers
6 and farmers get on the right track.

7 Consumers want to know you're
8 going to hold the integrity of this label
9 high. So if you say we're just not going to
10 have as many apples and pears on the market
11 for the next 5 years because we've got to get
12 our act together so that we can meet the high
13 standard that you've come to expect then
14 that's what we have to do. Because your job
15 in holding that standard high is more
16 important than creating a short-term market
17 for sub-par organic goods now.

18 And so we really urge you to move
19 in that direction. Let's have an honest
20 dialogue with the public and let's find
21 solutions so that we can eventually have an
22 organic apple and pear industry and do it

1 right where it truly means what consumers
2 expect from other organic food. Thank you.

3 MR. FELDMAN: Thank you, Urvashi.
4 A minute for questions.

5 MS. SONNABEND: Thank you,
6 Urvashi, that was a good presentation. I
7 think all of us on any stakeholder side of
8 this issue agree that part of the reason we
9 got stuck here is because there was no real
10 way to spur more research into the very badly
11 needed alternatives to the antibiotic
12 substances.

13 And so I'm wondering if you have
14 any suggestions for us on how we can encourage
15 and inspire more research and ways that
16 consumers could help out the growers in trying
17 to put on pressure for more research to be
18 done on this.

19 DR. RANGAN: Well Zea, I think
20 that's a great question. And I think again in
21 trying to have a transparent public dialogue
22 about it we have to talk about the fact that

1 we've been stuck in this corner of this box,
2 and that research and development hasn't
3 really taken place. And we need to do that.

4 And I think hopefully with
5 consumer demand for that and pressure to push
6 back so that we do even increase the amount of
7 R&D that's going on, I think we need to do
8 that. Should they be called organic in the
9 meantime? I think that's where we disagree.

10 And I think something to
11 demonstrate that there is movement in this
12 direction, that there is clearly some value to
13 be had in the production practices that are
14 going on compared to conventional, we need
15 something different to call them. And is it
16 in conversion? Is it transition? I don't
17 know, but it's not organic.

18 MR. FELDMAN: Thank you, Urvashi.
19 I wish we had more time for this. We will see
20 if we have more time for questions at the end
21 of this session.

22 DR. RANGAN: Okay, thanks.

1 MR. FELDMAN: Thanks again. Kiki.

2 Is Kiki in the house? Yes.

3 I'd like to introduce our next
4 speaker. And the presentation from Kiki will
5 be on organic seeds. She is a director of
6 advocacy, Kiki Hubbard, the director of
7 advocacy and communications for the Organic
8 Seed Alliance, a national organization that
9 advances the ethical development and
10 stewardship of seed.

11 She's worked for a decade as an
12 organizer, researcher and writer on projects
13 involving agricultural biotechnology and
14 antitrust issues in the seed industry.

15 She was awarded a Doris Duke
16 Conservation Fellowship to examine the
17 implications of genetically engineering
18 alfalfa and has taught at the University of
19 Montana.

20 She's a resident of Montana and
21 serves on the board of directors for the
22 Montana Department of Agriculture's Organic

1 Commodity Advisory Council and Alternative
2 Energy Resources Organization. Thanks so much
3 for making the trip and coming here. Thanks.

4 MS. HUBBARD: Thanks, Jay, and
5 thank you to the board members and NOP staff
6 for inviting me. This is actually my first
7 NOSB meeting and I feel really honored to be
8 participating as a presenter.

9 Organic Seed Alliance as Jay said
10 works to advance the ethical development and
11 stewardship of seed. We believe that seed is
12 a part of our common cultural heritage and
13 demands careful management. And so to that
14 end we work closely with organic farmers and
15 other seed professionals to support the
16 ongoing growth of organic seed systems through
17 research, education and advocacy programs.

18 Our vision is for us to have here
19 in the U.S. and organic food system built on
20 the foundation of seed that is well adapted to
21 organic conditions and provides diverse
22 options for farmers when it comes to their

1 regional and market needs.

2 Today I'm going to talk a bit
3 about an ongoing project of OSA called "The
4 State of Organic Seed." Each of you board
5 members receive a copy of the State of Organic
6 Seed Report I believe last year. I'm going to
7 talk a bit about the findings today and talk
8 about some of our work since publishing this
9 report through diverse working groups to move
10 forward some of the recommendations that were
11 identified in this project.

12 So "The State of Organic Seed" is
13 an ongoing project as I mentioned to monitor
14 opportunities and challenges in building the
15 organic seed sector. There's a real need for
16 this because as you know despite impressive
17 growth in the organic food industry the
18 organic seed sector has simply not kept up
19 with this demand. And we're facing limited
20 availability of appropriate organic seed for
21 a number of reasons, one of which is the lack
22 of clarity when it comes to how to enforce the

1 organic seed requirement as I'll talk about a
2 bit later.

3 But there are other reasons as
4 well, including consolidation in the seed
5 industry where companies who were providing
6 organic seed or looking to invest in organic
7 seed were either merging or bought out by
8 companies with no interest in organic. We've
9 seen a decrease in public funding of plant
10 breeding as well as fewer investments both
11 publicly and privately in organic plant
12 breeding in general among other reasons.

13 The lack of organic seed we
14 believe is a barrier to the organic food
15 industry. And I think we can all agree that
16 organic food integrity starts with organic
17 seed integrity, whether we're talking about
18 the problem of GMOs or simply the commercial
19 availability of organic seed.

20 So we set out to look at the
21 challenges in organic seed systems, published
22 the report that you all have a copy of and

1 then as I mentioned before facilitate some
2 working groups to move some of the solutions
3 forward.

4 And the assessment tools we used
5 to conduct this analysis included a producer
6 survey. We sent out a survey to certified
7 organic crop growers across the U.S. which
8 I'll talk about in a minute. We looked at
9 organic seed funding both in the public and
10 private sector to see where we're at in terms
11 of investments in improving crops for organic
12 systems.

13 We hosted an organic seed
14 symposium in 2010 with more than 100 organic
15 stakeholders to look at the preliminary data
16 we had collected and talk about next steps and
17 recommendations which we then published last
18 year in our State of Organic Seed Report.

19 So, the farmer survey that we
20 conducted, the goal of that was to assess
21 organic farmers' current attitudes and
22 perceptions toward organic seed and to look at

1 what some of the challenges were or barriers
2 to accessing or using organic seed.

3 At the time and still today
4 there's a lot of anecdotal evidence as to why
5 more organic seed isn't used in certified
6 operations, but we wanted to go to growers
7 directly and ask very specific questions
8 ranging from usage to challenges to needs and
9 potential in organic plant breeding.

10 I want to mention that a total of
11 25 agencies, organizations and businesses
12 helped us distribute this survey. And we'll
13 comfortable saying that it represents about 10
14 percent of certified organic crop growers in
15 the U.S. And so while we believe it's a very
16 useful discussion tool we do acknowledge that
17 it's not an exact measurement. We do plan to
18 continue this project and update the survey
19 and report every few years or so.

20 So I can only provide a snapshot
21 of the data today. I encourage board members
22 as well as those in the audience to go to

1 SeedAlliance.org and access our State of
2 Organic Seed Report. You will find pages and
3 pages of useful data representing the survey
4 we conducted with farmers.

5 One of our goals was to capture
6 demographics that reflect the diversity of
7 certified organic producers in the U.S. when
8 it came to crop type, geography and scale or
9 size of acreage. You'll see here that 43
10 percent of the producers who responded to our
11 survey were -- grew some vegetables, 60
12 percent grew some fuel crops and 48 percent
13 grew some forage crops.

14 Overall about 20 percent of
15 farmers who responded to the survey indicate
16 that they are using 100 percent organic seeds.
17 So this should not be read as only 20 percent
18 of farmers are using some organic seed.
19 Twenty percent indicate that they are sourcing
20 all organic seed for their operations. Seven
21 percent indicated they use no organic seed.
22 And then you'll see there some numbers

1 regarding total acreage of vegetables, fuel
2 crops and forage that are planted to certified
3 organic seed again based on our data set that
4 I described earlier.

5 Vegetable crops clearly lag behind
6 according to our data when it comes to
7 availability and usage with only 69 out of 437
8 vegetable producers using all organic seed.

9 Some encouraging data that I want
10 to share today is that over the last 3 years
11 we asked organic farmers if they have
12 increased the percentage of organic seed that
13 they use over the last 3 years and many of
14 them as you can see here, the majority of them
15 indicated that yes, they have increased their
16 use and sourcing of organic seed. About 20
17 percent have been using 100 percent certified
18 organic seed for at least 3 years.

19 Another encouraging point is that
20 we asked if their certifiers have been
21 encouraging them to take extra measures to
22 source organic seed, "extra measures" meaning

1 going beyond three seed catalogs or sources of
2 organic seed or conducting variety trials on
3 their farm to see which organic varieties
4 might be optimal in their systems and replace
5 untreated conventional varieties that they're
6 relying on.

7 And here we see that more than 60
8 percent responded yes, that their certifiers
9 were indeed encouraging them to take extra
10 measures to source organic seed. Not
11 surprisingly, lo and behold, when farmers were
12 encouraged to take extra measures to source
13 organic seed they responded by planting more
14 organic seed which I think is very useful in
15 terms of recommendations to the NOP to support
16 certifiers' role in supporting again the
17 increased use of organic seed.

18 When it came to challenges in
19 sourcing or using organic seed we see that
20 more than half of the farmers responding to
21 our survey indicated that the availability of
22 certain varieties was a significant factor.

1 Seventy-nine percent indicated that it was a
2 moderate or significant factor.

3 The lack of availability of
4 certain varieties was more of an issue with
5 vegetable growers according to our data than
6 fuel crop and forage growers. And then more
7 than 40 percent indicated that price was a
8 factor. And we know that price is not allowed
9 to be a factor when choosing not to use
10 organic seed, and yet we see that again more
11 than 40 percent indicated that this was a
12 challenge for them.

13 We were surprised that distrust of
14 organic seed quality was not more of an issue
15 among our responses. Here we see that with
16 the question when we asked if there was some
17 distrust of organic seed quality that only 10
18 percent indicated it was a moderate factor and
19 even fewer indicated that it was a moderate or
20 significant factor, more than a moderate
21 factor.

22 So, furthermore we asked farmers

1 if they had more, less, or about the same
2 degree of quality issues in organic seed
3 versus conventional and treated seed. And we
4 found that 73 percent of respondents had about
5 the same experience with both types of seed
6 and 23 percent had more problems with organic
7 seed.

8 We asked some questions about
9 genetic integrity issues which is especially
10 appropriate for today's conversation. More
11 than 70 percent of farmers responding to the
12 survey agreed that seed companies should be
13 testing for the unwanted presence of
14 genetically engineered material. This should
15 come as no surprise I'm sure.

16 And the majority of farmers
17 responding also indicated that they don't
18 believe the current regulatory framework in
19 place -- governing genetically engineered
20 crops I want to specify -- do not believe that
21 this current framework is strong enough to
22 protect organic integrity.

1 For those of you not familiar with
2 the coordinated framework for biotechnology
3 there has never been a new law created to
4 address the unique concerns of genetically
5 engineered organisms and instead our
6 government relies on a patchwork of existing
7 laws, some of which predate the technology, to
8 govern the oversight and regulation of
9 genetically engineered crops. And I think
10 this response again reiterates that there's a
11 lot of concern in our farm field and in our
12 farming communities especially among organic
13 farmers that we need better oversight and
14 regulations to protect the integrity of
15 organic.

16 More than 40 percent indicated
17 that their farms are at risk from seed
18 contamination or GE contamination of their
19 seed while 30 percent were neutral.

20 We asked questions about farmers'
21 perspectives on the value of organic seed in
22 breeding. We were pleased to see that the

1 majority of those responding agreed that
2 organic seed is important to maintaining the
3 integrity of organic food production and that
4 more than 80 percent agreed that varieties
5 bred for organic systems are important to the
6 overall success of organic agriculture.

7 And then more than half of the
8 farmers responding said they had some interest
9 in engaging in organic seed production
10 commercially, especially if there was economic
11 value and conducting on-farm crop improvement
12 projects.

13 Organic Seed Alliance sees a ton
14 of potential for participatory plant breeding
15 projects and on-farm variety trial networks in
16 order to strengthen and increase availability
17 of organic seed. It's a major program goal of
18 ours and our research and education if you
19 want to learn more about that.

20 But at the end of the day we just
21 believe that farmers are central to expanding
22 crop diversity and expanding innovation in

1 seed in our farm fields.

2 We also asked farmers just as a
3 quick side note which crop types they thought
4 were in most need of attention when it came to
5 improvements for organic systems. I have not
6 shared this data today but that is in the
7 report as well.

8 We looked at, as I mentioned
9 earlier, some of the investments in research
10 to support the growth of organic seed systems.
11 Since 1996 there have been 57 projects working
12 directly on organic seed projects. More than
13 \$9 million have been invested in these
14 projects. The largest contributors have been
15 USDA's OREI grant program as well as SARE
16 grants. And the crops that have received the
17 most attention include wheat and vegetables.
18 And regionally the Midwest has received the
19 majority -- not the majority, but more funds
20 than other regions.

21 I think it's pretty safe to say
22 that this is a modest investment in organic

1 plant breeding and seed system development
2 given that the organic food sector is now
3 worth more than \$30 billion.

4 So, some conclusions. Just to
5 wrap up some of what I've already said,
6 organic seed use is improving. We have seen
7 improvements with farmers attempting to source
8 more organic seed and pressure from certifiers
9 to do so. But we do believe that there needs
10 to be increased attention and resources given
11 to organic seed system development. And there
12 does seem to be a clear link as I indicated
13 earlier between certifiers encouraging farmers
14 to take extra measures to source organic seed
15 and farmers responding and sourcing more
16 organic seed.

17 Farmers clearly want organic seed
18 protected from genetically engineered traits.
19 There's a need to improve information-sharing
20 which I'll talk about in a second in the areas
21 of organic seed availability.

22 And as some of the data indicated

1 farmers see organic plant breeding and organic
2 plant breeding important to organic farmers
3 and their success to the broader organic
4 industry. And there's a need as I mentioned
5 to create opportunities for organic farmers to
6 work with professionals in on-farm trials and
7 on-farm crop improvement projects.

8 So, one of the most important
9 outcomes from this project has been that
10 there's a general agreement among stakeholders
11 that we need collaborative and comprehensive
12 solutions. So last year Organic Seed Alliance
13 initiated and facilitated four working groups
14 in the areas of organic plant breeding, seed
15 industry concentration, information-sharing
16 and seed integrity.

17 I'm not going to talk about all
18 these working groups, I doubt I have time, but
19 the Organic Plant Breeding Working Group is
20 comprised of about a dozen public plant
21 breeders who are actually in the process of
22 creating a research agenda for organic plant

1 breeding which is pretty exciting. They have
2 also been involved in communicating to the
3 USDA the need to bolster support for classical
4 plant breeding that results in public
5 cultivars that meet the regional needs of
6 farmers including organic farmers.

7 I'm going to try to touch on the
8 Information Working Group activities and the
9 Seed Integrity Working Group activities. One
10 of the working groups that we've been working
11 closely with has had the objective of
12 improving organic producers' ability to meet
13 the NOP requirement to use organic seed.

14 I'm pleased to say that this
15 working group has successfully helped launch
16 a new organic seed database as of this month.
17 It is called Organic Seed Finder. We have met
18 monthly, at times more frequently, since March
19 of 2011 to develop and implement a new organic
20 seed database working with OMRI to learn about
21 their experience and develop a model that is
22 sustainable and again meets the needs of all

1 organic industry members.

2 This is a snapshot of Organic Seed
3 Finder. It is hosted by AOSCA, the official -
4 - the Association of Official Seed Certifying
5 Agencies. AOSCA has wonderful in-house seed
6 expertise. Organic Seed Alliance and our
7 partners has provided the necessary support on
8 behalf of the organic community to ensure that
9 this database is successful since AOSCA before
10 did not have any real ties with the organic
11 community.

12 The database is user-friendly.
13 AOSCA is encouraging feedback from all
14 stakeholders. It is free and open to farmers
15 and certifiers and others looking to source
16 organic seed. And it is funded through seed
17 vendor fees as well as sponsorships.

18 We've had some great response from
19 the organic food industry in wanting to
20 sponsor this database through small and large
21 contributions simply to showcase their support
22 of the organic seed industry and recognize

1 that food starts with seed and we need good
2 organic seed in order to have good organic
3 food.

4 I included this red arrow up there
5 because one neat feature of this database is
6 that there's an opportunity for farmers to
7 document and share which varieties they're
8 looking for in an organic farm but can't find.
9 So this creates a feedback loop to the organic
10 seed industry, to organic plant breeders
11 through our working group and others so that
12 we can identify what the needs are among
13 farmers around the country.

14 This is the website for finding
15 Organic Seed Finder. If you have questions
16 you can contact AOSCA at this email address.

17 And then quickly, I've already
18 shared a bit this morning in my seed purity
19 comments some work from the Seed Integrity
20 Working Group. And this is a group that
21 looked at some opportunities in protecting the
22 genetic integrity of seed use in organic

1 systems.

2 We first sent a letter to the NOSB
3 and NOP asking them to make the GMO issue more
4 of a priority and thankfully as we've learned
5 today they have and we're very grateful for
6 that. We have also had discussions about a
7 seed purity standard some of which is
8 reflected in the questions I included in my
9 written comments.

10 And then this working group
11 informed the survey that I mentioned earlier
12 today where we discussed some of the risk
13 points for the organic seed industry at the
14 time to inform comments that I provided to the
15 AC21 committee. Again, that's the USDA's
16 Advisory Committee on Biotechnology. And we
17 are tentatively planning a meeting to further
18 this discussion in February.

19 I think I'm just going to wrap it
20 up here. These were a few more findings from
21 the survey. You can find the survey findings
22 at our website, again, SeedAlliance.org.

1 But we did ask these seed
2 companies that we talked to many more
3 questions beyond can you meet a genetic purity
4 standard. We wanted to get a sense of were
5 they experiencing financial harm, were they
6 facing barriers to eradicating genetically
7 engineered material.

8 The last thing I want to mention
9 is that the issue of concentration in the seed
10 industry is very tightly linked to the issue
11 of protecting seed integrity in that our plant
12 genetic resources are often in many cases such
13 as hybrid breeding lines, hybrid corn breeding
14 lines concentrated in the hands of a few.

15 And seed companies who are looking
16 to provide for the organic industry often have
17 a hard time licensing untreated germ plasm to
18 use for organic seed production. At times
19 these licensing agreements even come with
20 restrictions on testing for genetically
21 engineered material. Again, these are players
22 who are looking to provide seed to the organic

1 community that meets our standards including
2 not having excluded methods in the end
3 product.

4 And these were our recommendations
5 that I've already provided in written form
6 regarding the draft guidance document on the
7 commercial availability of organic seed. I've
8 already mentioned some of them. I guess I
9 should stop because I don't have more time
10 unless you want me to take 30 seconds.

11 MR. FELDMAN: Thank you so much.

12 MS. HUBBARD: You're welcome.

13 MR. FELDMAN: Really comprehensive
14 and helpful. Thank you. Are there any
15 questions from board members? John.

16 MR. FOSTER: Thanks, Kiki. As you
17 know we all appreciate that work you're
18 continuing to do there.

19 My question is kind of focused on
20 the difference between varietal, limitations
21 on variety versus performance characteristics.
22 And in that survey was the term "variety" used

1 to mean also performance characteristics? Or
2 was the interpretation on the people who were
3 filling it out more that when you said variety
4 you meant marathon broccoli, for example?

5 And as you know, there are many
6 different varieties that may have the same
7 performance characteristics. So my question
8 is more about do you think the survey was
9 filled out with that broader kind of idea
10 about other varieties that might also fit the
11 bill, or did most people read it as in I
12 wanted marathon broccoli and I couldn't find
13 marathon broccoli so that's where I stopped.

14 MS. HUBBARD: John, I prefer it
15 was -- I believe it was the former. I
16 actually was not with Organic Seed Alliance
17 when the survey was first put together. The
18 State of Organic Seed Report does detail the
19 methodology including how the questions were
20 put together. In fact, copies of the
21 questions are in the report. So I'm sorry I
22 can't give you an answer for certain but I

1 believe it's the first thing you mentioned,
2 just the variety and not performance traits.

3 MR. FELDMAN: One last quick
4 question.

5 MR. MARAVELL: You were talking
6 about going forward on farm trials,
7 cooperation with plant breeders for classical
8 plant breeding. And then you mentioned
9 something called public varieties. I was
10 wondering if you could expand a little bit and
11 whether or not there was anything in your
12 survey about how farmers, what sort of
13 varieties they are looking for in terms of
14 public and sometimes called public domain type
15 varieties.

16 Could you say -- would that be
17 something that organic farmers should continue
18 to desire? Or is that a pipe dream that we
19 will have varieties in the future in the
20 public domain?

21 MS. HUBBARD: That's a great
22 question, Nick, and it's something we talk a

1 lot about. Right now when it comes to demand
2 for public varieties I really can only rely on
3 anecdotal evidence through my conversations
4 with farmers who lament the fact that they no
5 longer have as much access to seed held in the
6 public domain. This is especially true in
7 soybeans as I understand it with past research
8 that I've done.

9 I hope it's not a pipe dream. I
10 think the public sector has an important role
11 to play. It's an important form of
12 competition in the seed industry to have
13 public seed available. It's the 150th
14 anniversary of USDA and when they started one-
15 third of their budget went to germ plasm
16 collection and distribution.

17 I mean, it's a principle of the
18 Department of Ag and our land grant university
19 system. So we really hope to see funds going
20 toward projects that -- breeding projects that
21 result in cultivars that are held in the
22 public domain.

1 It's a complicated issue that
2 includes different laws like the 1980 Bayh-
3 Dole Act that allows public research to be
4 patented. It's complicated.

5 MR. FELDMAN: Thank you. We
6 depend on Nick to raise complicated issues for
7 us. So with that thank you so much.

8 MS. HUBBARD: Thank you.

9 MR. FELDMAN: We really appreciate
10 it. We'd like to ask all the presenters
11 today, why don't we give them a round of
12 applause, everybody.

13 (Applause)

14 MR. FELDMAN: We'd like to ask if
15 all the presenters could share with us their
16 written documents or written, printed
17 documents of the presentations if that's
18 possible. Could we find that out somehow,
19 Michele, or do you know? Okay. Thank you.

20 Well, I hand the gavel back to the
21 chairman of the board. Thank you very much.

22 CHAIRPERSON FLAMM: Thank you very

1 much. Those were excellent presentations.
2 We're about 5 minutes past our break time so
3 let's get back together at 1:20.

4 (Whereupon, the foregoing matter
5 went off the record at 12:19 p.m. and went
6 back on the record at 1:39 p.m.)

7 CHAIRPERSON FLAMM: The meeting is
8 back in order and we'll continue with the
9 Crops Committee and public comment. I'll turn
10 it back over to Jay Feldman.

11 MR. FELDMAN: Thank you. Welcome
12 back from lunch. I know everybody is
13 energized by their nutritious meals.

14 So I wanted to, Barry, take just a
15 minute to correct the record on some of our
16 reporting on the public comments. I just want
17 to update the record for the record on the
18 Crops Subcommittee there were some comments
19 that may not have been fully captured in our
20 biodegradable bioplastic mulch film
21 discussion.

22 What we try to do in that as you

1 know, what we try to do when we present this
2 information is give you, give the community,
3 give the board a summary of who said what and
4 how many people weighed in on what side of the
5 issue, et cetera.

6 And I guess what happened is
7 Cornucopia got left off so we need to make
8 sure the record reflects that they suggested
9 that we as a board did not have sufficient
10 information and need separate petitions on the
11 individual synthetic plastic film ingredients.
12 So they're suggesting that they be
13 individually reviewed. And I guess we'll hear
14 more about this from Pam when she speaks
15 during this session.

16 Similarly we neglected to include
17 during the GMO discussion a comment of
18 Cornucopia on their really strong belief that
19 when we're looking at this question of GMO
20 that we include an equal look at both organic
21 growers' use -- or an especially important
22 focus on organic growers' use of conventional

1 seed and the GMO implications associated with
2 that.

3 Again, we try to be as thorough as
4 we can with this process and sometimes we miss
5 the mark a little bit. And those that -- many
6 of you are out there are scrutinizing us
7 closer than others, that's all I can say. So
8 we want to make sure that the record reflects
9 all the hard work that you all put into this
10 process and all the resources that you expend
11 to get to this meeting and prepare for it.

12 So with that, Barry, I will now
13 turn to the public comment period.

14 MR. ARNOLD: My name is Paul
15 Arnold. I'm with Pleasant Valley Farm out of
16 Argyle, New York. It's about an hour
17 northeast of Albany. We're about 4 hours away
18 from here. I took the trip down to make some
19 comments.

20 We're a 7-acre diverse fruit and
21 vegetable farm that sells to farmers markets
22 52 weeks a year. We've made our living at

1 farming for 25 years. It's our sole source of
2 income. We've been using BioTelo for 4 years
3 and we use about four rolls per year which
4 equals about 3 miles of that. We previously
5 did not use any black plastic.

6 Before that we just did not want
7 to get into the labor of removing it and the
8 disposal of it. I had worked on farms before
9 that and been acquainted with it.

10 Some of our want to use this
11 product is the fact that it does break down
12 quickly. And this helps a lot with the fact
13 that once crops are done we are more inclined
14 to get it turned under right away and put
15 cover crops down immediately which helps us
16 instead of in the summer it's harder to think
17 about taking labor to pick up plastic and then
18 get a cover crop down. So it's helped us a
19 lot in that way.

20 For us it's an excellent product
21 that's doing exactly what they say it's going
22 to do. Whether we use it for products like

1 onions in the spring and peas, and then get
2 turned under in July when we're done, the
3 product is gone. Or we use it for products
4 like Brussels sprouts that are going to be
5 there the whole season and will get turned
6 under in the fall, late fall, when they get
7 harvested. That product is always there, it's
8 always good for us.

9 We also use it for strawberries,
10 planting them in the fall and then harvesting
11 in the spring. And then we turn under the
12 strawberry crop. The plastic is then gone.
13 So it's worked well for us.

14 It breaks down easily. There is
15 no residual left that we have seen at any
16 time. We do have some pictures. I think you
17 see the one up here now, it's onions. And
18 then there will be another picture that will
19 come up that is actually not that one but it's
20 another one. That's it right there. That's
21 after turning the onions down in August. So
22 that first picture of onions was in April, the

1 second -- or May, and then that second picture
2 then was in August. So you see it breaks down
3 completely.

4 It rototills easily with no
5 wrapping. It disappears completely whenever
6 it's put in. I also want to say that we also
7 use it in our high tunnels which is you might
8 say on a dry farm situation in the sense of
9 because we're using drip irrigation that it --
10 there is no real water in there to break this
11 plastic down.

12 What we do with it, because it's
13 in there for 6 months because we do summer
14 crops with tomatoes and cucumbers, then we
15 also do winter crops with Swiss chard and
16 kale, that we remove it at the end of the
17 season and it gets composted out in our fields
18 along with all the other sheet composting that
19 we do on our farm. Again, there's just
20 nothing left. It takes a very short time for
21 it to break down and it's just not there.

22 So all our workings with it so far

1 is positive. It lays down easily. It breaks
2 down easily. It's actually allowed us to do
3 a lot more adding of organic matter because
4 between the plastic we use straw and that
5 allows us to add organic matter.

6 We rotate it around our fields and
7 that helps us too. So it's not in one field
8 every year, it's moved around, and that's how
9 we add organic matter to our farm because
10 we've been doing this for 25 years. That's
11 our system so far.

12 MR. FELDMAN: Thank you.

13 Questions from the board? Mac.

14 MR. STONE: Does it hold up well
15 enough during the season as far as running
16 transplanters over it, having workers stepping
17 on it when they're harvesting or hand-weeding
18 in the holes? Does it hold up well enough for
19 production purposes?

20 MR. ARNOLD: It holds up more than
21 well enough. We really don't have anything
22 negative to say about it. The only thing you

1 learn to work with it is the fact that after -
2 - if you lay it down you need to be
3 transplanting into it within the first 2 or 3
4 weeks or it starts to get brittle and fall
5 apart.

6 MR. FELDMAN: Zea.

7 MS. SONNABEND: When you first
8 decided to start using it what level of
9 investigation did you do, or did you even
10 think about the concerns of whether it left
11 chemical residues behind from the components
12 that made it?

13 MR. ARNOLD: We looked into the
14 fact that it was already established for use
15 in Europe. And if they had already done the
16 background in it we weren't really chemists
17 enough to know all that background. But as
18 long as it was good for them then we decided
19 we were going to try a small amount.

20 Our farm is known for doing lots
21 of trials of a lot of different products and
22 keeping up with universities. So this was a

1 small amount, put it down, one roll, find out
2 what it does and then from there we started
3 using it more when we found it did do what we
4 wanted it to.

5 I guess the concern was still the
6 fact that someone had approved it in Europe
7 and so we were okay to use it here.

8 MR. FELDMAN: Other questions?
9 This is your chance. Harold.

10 MR. AUSTIN: In your various
11 trials you were talking about your irrigation,
12 drip irrigation in the various trials. Do you
13 have any other form of irrigation besides
14 drip?

15 MR. ARNOLD: Our farm uses
16 overhead irrigation on all of our acreage
17 outside that we grow crops on is overhead
18 irrigation. Where we use drip irrigation is
19 in the high tunnels and things like
20 blueberries in any permanent crop.

21 MR. AUSTIN: Okay. Along with
22 your -- the irrigation then what's your normal

1 amount of annual rainfall? And then how much
2 -- in the course of your crop year how many
3 acre feet or inches of irrigation water are
4 you applying?

5 MR. ARNOLD: We are -- I'm not
6 going to be able to tell you how many inches
7 we normally get. I'm not versed on that.
8 What I'm watching for as a farmer is what is,
9 you know, is there enough water going down for
10 the transplants and the crops.

11 So we're looking at an inch to an
12 inch and a half a week depending on how hot
13 and dry it is during the summer. In May
14 you're not using as much as you are in July
15 when it's hotter and the plants are bigger and
16 need more. So we have a full irrigation
17 system with unlimited water and so we irrigate
18 as much as the crops need to bring them to
19 their potential. So it's often.

20 MR. FELDMAN: Other questions?
21 Jennifer.

22 MS. TAYLOR: Can you tell me if

1 you have discovered a financial benefit in
2 using this type of mulch versus your previous
3 one that you had? Or what are your benefits,
4 please?

5 MR. ARNOLD: What are our
6 benefits? Well, we were not doing any black
7 plastic before this so it wasn't a strict one-
8 for-one going from one to the other.

9 We were doing a lot of mulch, just
10 strictly mulch, putting it down instead of
11 using the black plastic. And what we found
12 was that a lot of crops that liked heat were
13 being held back because this made things too
14 cool for them. So the black plastic made it
15 a little warmer for a lot of the heat crops
16 that you're using as an all-summer crop like
17 cucumbers and zucchini and tomatoes benefitted
18 from earlier pickings on that, a longer
19 season.

20 The only other thing that was a
21 real benefit was of course at the end of the
22 season there was no residuals that we had to

1 break up and we could get our cover crops down
2 faster which is what was really important to
3 us.

4 MR. FELDMAN: Other questions?
5 Thank you, Mr. Arnold. We appreciate it.
6 Steve Mojo?

7 MR. MOJO: That's correct. Good
8 afternoon. My name is Steve Mojo. I'm the
9 executive director of the Biodegradable
10 Products Institute. I represent the major
11 manufacturers of biodegradable films in the
12 U.S. and Canada.

13 The BPI or Biodegradable Products
14 Institute is a professional trade association
15 with over 150 key individuals and groups from
16 government, industry and academia. And we
17 promote the use and recovery of biodegradable
18 materials. My comments today are on behalf of
19 the petition that we submitted and we greatly
20 appreciate the support of the Crops Committee
21 and agree with the overall decision that this
22 material will benefit the organic community.

1 Rather than comment on the
2 annotations which I understand may be modified
3 I'd like to spend my time to talk about
4 responses to the public comments that were
5 submitted in the Federal Register.

6 First, I appreciate the overall
7 widespread support from the farming community
8 and at the same time I realize that some
9 participants have legitimate concerns. And
10 I'd like to deal with three fundamental
11 issues, one being why we recommended both 6400
12 and the use of 5988 at the soil test.

13 ASTM D6400 provides an initial
14 rejection point much earlier in the
15 developmental time line so that we understand
16 if a material has the ability to reach the 90
17 percent threshold under accelerated aerobic
18 conditions frequently called composted.
19 Importantly, 6400 provides an ecotoxicity test
20 at the end of it so that we know that those
21 materials aren't going to harm plant growth.

22 Then if a material meets ASTM 6400

1 in anywhere from 3 to 6 months then it can go
2 onto the longer term development, the longer
3 term soil test to confirm how long it's going
4 to take to go away under real world conditions
5 or laboratory conditions that simulate the
6 real world. So hopefully that clears up why
7 we have two test methods.

8 Some commenters suggested the
9 materials not only meet these requirements but
10 they also be certified so that the ACAs and
11 MROs can easily determine compliance with the
12 standards. The BPI is willing to establish
13 such a certification program with NSF, an
14 internationally known third party
15 accreditation agency if that's something you
16 would like us to do to make it easier to
17 identify these materials.

18 Third, I want to take the
19 opportunity to clarify the confusion that
20 seems to exist, or the difference that seems
21 to exist between the terms "biodegradable" and
22 "mineralization." While they're often used

1 interchangeably, fundamentally they are
2 technically different.

3 Biodegradation is the process
4 whereby living organisms break down foods,
5 assimilate them and convert them into energy
6 to sustain their lives. The process is
7 fundamentally the same for you and I and the
8 soil microbes, they're just eating different
9 foods. The end products of biodegradation are
10 biomass, water and carbon dioxide.

11 Conversion to the carbon dioxide
12 is the final step of the process. It's
13 mineralization. We know that when things are
14 converted to carbon dioxide they're removed
15 from the soils and they're put into the
16 atmosphere as an inert material.

17 The test approach that we're
18 proposing and the standards that we're using
19 consider CO2 evolution as the final measure of
20 biodegradation. So we know that these
21 materials have been broken down by the
22 microbes, assimilated, used as a food source

1 and then respired out into the atmosphere.
2 It's the same thing that happens for you and
3 I now that we're eating lunch. We're breaking
4 down our foods, we're breathing, we're moving
5 and sooner or later that's going to be
6 expelled as CO2. So by reaching 90 percent it
7 can be said materials reach complete
8 biodegradation.

9 I have one other thought that I'd
10 like to stress, is that in our submission we
11 originally brought in 12 published studies
12 dating all the way back to about 2005.
13 Additionally, we have referenced more recently
14 European studies that go back all the way to
15 2001. So these materials and these chemicals
16 have been looked for over a decade and they
17 have demonstrated their safety in the
18 environment.

19 So with that I'd like to thank the
20 NOSB for the time and if there are any
21 questions I'll be happy to answer them.

22 MR. FELDMAN: Thank you very much.

1 Questions? Zea.

2 MS. SONNABEND: Thank you. I have
3 about 42 questions but I'll start with 1.

4 MR. MOJO: I've got 8 hours. I'm
5 ready.

6 MS. SONNABEND: In our technical
7 report it was explained that there are I
8 believe four different types of materials that
9 fall under this potential category. And what
10 I'm wondering is if by the way we referred to
11 it in the name of saying bio-based bioplastic
12 or by the standards for bio-based content and
13 degradation that we adopted are we excluding -
14 - are we including all four of those types of
15 products in that annotation or are we ruling
16 out the one that started with petroleum
17 originally or any of the other ones?

18 MR. MOJO: In the petition we
19 referenced four materials, you're right. The
20 standards that we're recognizing will allow
21 all four materials because all of those
22 materials meet the specs. And understand

1 those materials aren't necessarily used in
2 isolation with one another, but they can be
3 blended together in such a way to give the
4 properties that the farmers need so that these
5 materials can last on the fields as long as
6 they need. Does that address your question?

7 MS. SONNABEND: Okay. Yes. And
8 then how about the clause about GMO organisms.
9 Does that affect all four of those types of
10 materials or only certain ones?

11 MR. MOJO: They would only affect
12 potentially certain ones. They wouldn't
13 affect the petroleum ones, for example,
14 because GMO has not been highlighted as part
15 of that.

16 MS. SONNABEND: Okay, thank you.

17 MR. MOJO: And there are materials
18 that can be made without GMO I believe, so.

19 MR. FELDMAN: Other questions?
20 John.

21 MR. FOSTER: So there are
22 materials that can be made without GMOs? What

1 does that do to the price point to the grower?

2 MR. MOJO: I don't honestly know
3 the pricing but I would -- a gentleman from
4 BioTelo is going to speak so you can certainly
5 talk to him about that.

6 And Zea, I'll be happy to answer
7 any and all of your questions at some --
8 whenever you'd like.

9 MS. SONNABEND: And will you be
10 around the whole time if we want to call you
11 back?

12 MR. MOJO: I'm going to be -- I'll
13 be back here Thursday morning if that's all
14 right. I'll be here all day today and then
15 back Thursday morning.

16 MR. FELDMAN: Follow-up or is
17 that? Okay. Other questions? Mac.

18 MR. STONE: I'm back to my
19 semantic question of plastic. When does
20 something become a plastic versus some other
21 something that looks like plastic?

22 MR. MOJO: A plastic is a

1 technical definition that talks about products
2 that are formed with heat. So the molding of
3 a material makes it a plastic. So cellulose
4 was the very first plastic naturally based.
5 So plastic has -- in fact the very first
6 plastics as the USDA will tell you were based
7 on products like soybeans and used in your
8 Model A Fords. So it's -- really the process
9 of making something does not make it a
10 plastic. It doesn't necessarily have to be
11 petroleum-based. Does that help?

12 I mean, it looks and -- I mean
13 these materials will look and feel like
14 plastic but they have different components and
15 all of those components can be consumed by the
16 microbes in the soil.

17 MR. FELDMAN: Other questions?
18 Okay, I have a few questions. Thanks again
19 for being here. I have several questions.
20 One goes to the international standard, what
21 Canada is doing and what your understanding is
22 about what is allowed in Canada versus what

1 would be allowed under the annotation that has
2 been proposed, at least passed by the Crops
3 Committee.

4 And then I wanted to get a little
5 sense -- some sense from you as to the
6 different plasticizers, the PLA, what's the
7 other one, the PHA and the requirements for
8 one or other. You talk about a blending and
9 to what extent are we limited in restricting
10 the plasticizers given the necessity to blend.
11 So let's start with those two if you could.
12 That would be great.

13 MR. MOJO: Okay. In terms of
14 what's being done -- the European standards
15 and the U.S. standards as well as those used
16 in Canada revolve around four fundamental
17 criteria when it speaks to composting. One is
18 that the material disintegrates rapidly,
19 within a 12-week time frame. Two is it fully
20 biodegrades within 180 days and that's
21 conversion to CO₂, the 90 percent number.
22 Three is there's no ecotoxic effects from that

1 process. And fourth, that there's regulated
2 metals levels for cadmium, chromium, and all
3 those other things that are dictated by either
4 the Code of Federal Register or the Canadian
5 authorities or the European adolescents.

6 So those four fundamental criteria
7 are the same throughout Europe and North
8 America. There are some minor differences on
9 the metals levels based on what's regulated
10 according to the 503 sludge regs versus what's
11 done in Europe. Hopefully that addresses your
12 questions there.

13 MR. FELDMAN: To follow up on the
14 international, you're familiar with their reg
15 up there 1.4.1 which lays out the specific
16 restrictions on colorants and ingredients such
17 as GMO, et cetera. We're just -- because we
18 were told by one of the earlier presenters
19 that we were, in adopting this listing, this
20 annotation, we were bringing ourselves into
21 uniformity essentially with Canada.

22 We're trying to answer that

1 question, if that in fact is the case given
2 what you know about what's going on through
3 that 1.4.1 and what would be happening here in
4 the U.S. under this standard the Crops
5 Committee has proposed.

6 MR. MOJO: Well, these materials
7 are allowed in Canada and Europe today. And
8 in fact the crops that are grown in Europe and
9 Canada today can be imported into the U.S. as
10 organic today. So they compete with the very
11 same people --

12 MR. FELDMAN: So that's all the
13 four materials you're talking about.

14 MR. MOJO: Yes.

15 MR. FELDMAN: Because we haven't
16 been able to confirm that. That's why we're
17 trying to nail that down.

18 MR. MOJO: Well, to the best of my
19 knowledge absolutely. And I mean, these
20 materials are a class of material much in the
21 same way as newspaper is a class of material.
22 I mean, newspapers differ depending on where

1 you get them off the roll which I think gets
2 us back to why we want -- recommend changing
3 this from bioplastic biodegradable mulch films
4 to a biodegradable mulch film. Because these
5 materials perform much the same way as
6 newspaper does or craft paper does when it's
7 applied to the fields. So we see that as the
8 logical nomenclature for these types of
9 materials.

10 MR. FELDMAN: Okay. Thank you.

11 And on the plasticizer issue, the different
12 types of plasticizer.

13 MR. MOJO: I mean, all of the
14 materials that are used in the -- all of the
15 additives that are used in these materials if
16 they're not minerals such as TiO_2 , all of
17 these materials, no more than 1 percent can go
18 in there and not be proven to be
19 biodegradable. So any of the additives that
20 are in there are biodegradable if they're used
21 in more than 1 percent.

22 And there's no more than five of

1 those additives allowed. And most people
2 don't use them. And in fact, some of the
3 materials that are used at less than 1 percent
4 may be fully biodegradable also.

5 MR. FELDMAN: Miles.

6 MR. MCEVOY: Yes, we've asked the
7 European Commission and the Canadian Organic
8 Office to weigh in on the biodegradable mulch.
9 And from the European Commission they're going
10 to send us a more formal reply but what they
11 said was that from what they can see it
12 appears that biodegradable mulch has not been
13 allowed to date. And they're asking their
14 colleagues for a more complete assessment.

15 The questions that they have
16 looked at is the composition and origin of all
17 components of the mulch that are not
18 mechanically removed which would, they
19 believe, have to meet the requirements in
20 their annex on fertilizer, soil conditioners
21 and nutrients that's in Article 3(1) and
22 6(d)(2) of Regulation 889/2008 as amended. So

1 that would be that the components of the
2 biodegradable mulch would not be allowed to be
3 genetically modified. So they're going to
4 provide more information on that.

5 For the Canadian Organic Office
6 it's a much more lengthy response. They
7 reference the 1.4.1 standard that you referred
8 to. And then they have a question and answer
9 on their Standards Interpretation Committee.

10 I can forward this onto you, Jay.
11 Can you clarify the requirements for removal
12 of plastic mulch films. The annotation for
13 plastic mulches in Table 4.3 of the Prevented
14 Substances List is clearly intended to
15 prohibit the incorporation into the soil for
16 any material other than fully biodegradable
17 films compliant with Section 1.4.1. Where
18 there is any risk of contamination plastic
19 mulch must be removed from the soil.

20 The distinction between annual and
21 perennial crops is made on the premise that
22 following an annual crop tillage will occur in

1 preparation for the next year, but this
2 distinction is not essential to fulfilling the
3 intent of the standard which is to avoid
4 contamination of the soil. In situations
5 where the mulch will not be incorporated into
6 the soil then it may be left on.

7 Are bioplastic mulches made from
8 corn accepted as fully biodegradable films as
9 the term is used in the annotation for mulches
10 Table 4.3 of the Prevented Substances List?

11 The answer: a bioplastic mulch could be
12 accepted as fully biodegradable provided that,
13 one, the mulch is not made using GMO plant
14 material, and two, there are no substances
15 prohibited under 1.4.1 present.

16 So that's a lot of detail there
17 and I can forward this onto the board for your
18 review.

19 MR. FELDMAN: Thank you.

20 MR. MOJO: Thank you, Miles. But
21 I do know there are materials that satisfy
22 that requirement and the gentleman from

1 BioTelo will come forward and talk about that.

2 MR. FELDMAN: Is that your
3 understanding, Miles, that there are approved
4 materials in Canada?

5 MR. MCEVOY: Yes, it's our
6 understanding that there are approved
7 materials in Canada that are currently being
8 used.

9 MR. FELDMAN: Thank you. Other
10 questions? Comments? John.

11 MR. FOSTER: So this is more a
12 question of clarification. Hey Marty, it's
13 more of a clarification from the program.
14 Maybe Miles. I just want to clarify something
15 you said about as long as. I think I heard
16 you say something, as long as the material is
17 not from bio?

18 MR. MCEVOY: Right.

19 MR. FOSTER: Right? So I'm
20 wondering about consistency on that from other
21 inputs that are applied to the soil that may
22 be derived from I thinking corn gluten meal

1 for example. What's the thinking? If I heard
2 you incorrectly, tell me, but what's the
3 thinking about as long as the material is not
4 derived from genetically engineered material?

5 MR. MCEVOY: Right, that's the
6 specific reference for what they term
7 bioplastic mulches under the Canadian
8 standard.

9 MR. FOSTER: Under the Canadian
10 standard. Okay.

11 MR. MCEVOY: Right.

12 MR. FOSTER: Got it.

13 MR. MCEVOY: So we did not ask
14 them the question on GM material in general
15 but for bioplastic mulches they have a
16 specific answer for that.

17 MR. FOSTER: Okay. Then Jay, a
18 quick follow-up to that. Does anyone on the
19 board have knowledge of what Canada's position
20 is on, say, corn gluten meal with respect to
21 genetically engineered components? That would
22 be -- that would help me understand, kind of

1 guide me a little better if we can get that.

2 Thanks.

3 MR. FELDMAN: Others? Thank you
4 so much. And we look forward to seeing you on
5 Thursday.

6 MR. MOJO: Absolutely, and if need
7 be I'll come back tomorrow.

8 MR. FELDMAN: Okay, thank you.
9 Dave Rogers, thank you. And let me say that
10 Eric Menard is up next.

11 MR. ROGERS: Thank you. I'm Dave
12 Rogers. I'm policy advisor with the Northeast
13 Organic Farming Association of Vermont. And
14 my comments are on behalf of NOFA Vermont and
15 Vermont Organic Farmers which is our USDA
16 accredited certifier representing 545
17 certified processors and growers or farmers,
18 including 132 certified vegetable growers.

19 We really appreciate the
20 opportunity to comment on this petition and
21 we're strongly in favor of approval of these
22 products and our farmers are as well.

1 In Vermont as in the rest of the
2 country black plastic mulch is an important
3 production tool for a lot of growers. As you
4 well know they help warm up the cool soils in
5 spring and suppress weed growth, conserve
6 moisture. And these are all benefits to crop
7 production and marketing and really farmers'
8 bottom line as well.

9 And we regularly hear from
10 certified growers who question or oppose the
11 current rule that only allows them to use
12 petroleum-based polyethylene films or mulches
13 that have to be removed and disposed of. It's
14 costly, it's labor-inefficient and it's
15 environmentally irresponsible. Our farmers
16 really feel badly about having to do that.
17 Dumpsters and dumpsters full being hauled off
18 to the landfills.

19 Non-certified growers I've spoken
20 with report and the literature confirms that
21 the performance of these mulch films are
22 comparable to polyethylene mulches in terms of

1 plant growth and production, weed suppression
2 and such. These growers have found that with
3 light tilling they degrade fully with no
4 visible traces in less than a year and often
5 much less depending on soil and moisture
6 conditions.

7 One grower with whom I had a
8 conversation yesterday talked about one
9 product he used persisted well into the second
10 year but it was gone by the end of that
11 season. And that was fine with him, it didn't
12 interfere with his farming practices.

13 So for these reasons the approval
14 of these biodegradable mulch films in organic
15 production is a big deal for many growers in
16 Vermont. And again, many of them submitted
17 written comments to that effect. And indeed,
18 like the Normans yesterday from One Straw Farm
19 we hear from farmers who choose not to become
20 certified organic because they can't use these
21 products.

22 So finally a couple of words,

1 thoughts about degradation that sort of stem
2 from my own personal work over a number of
3 years as a microbiologist. These are simple
4 polymers really that have been shown to break
5 down fully to carbon dioxide and water and
6 microbial biomass. And I haven't seen any
7 evidence and there's no reason to think really
8 that the degradation occurring in fields is
9 any less complete. The microbes really jump
10 on this stuff. And there are dozens of
11 species of bacteria and fungi that have been
12 identified in the technical information that's
13 been submitted whose growth is stimulated as
14 they get to work on these products.

15 As I see it there's really no
16 biochemical reason for them to stop
17 metabolizing this stuff until it's fully
18 mineralized or degraded. And of course there
19 are soil and climatic factors that affect the
20 rate.

21 For these reasons we don't see any
22 reason to think that there are stable

1 intermediate breakdown products or residues
2 that will be produced that could be of
3 consequence and concern. And we think that
4 this recommendation should move forward.
5 There's no reason to table it. We think the
6 information we have is sufficient to justify
7 approval. Thank you.

8 MR. FELDMAN: Thank you. Any
9 questions? Thank you very much, David.

10 MR. ROGERS: Okay, thank you.

11 MR. FELDMAN: And Eric Menard with
12 Matt Cotton on deck. Welcome.

13 MR. MENARD: Good afternoon,
14 everyone. My name is Eric Menard. I'm from
15 Canada. I'm a business development manager at
16 Dubois Agrinovation for 17 years. I'm selling
17 BioTelo mulch film everywhere in the United
18 States and Canada for the past 7 years.

19 And everyone who use the BioTelo,
20 they never come back on plastic mulch again.
21 They go forward with the biodegradable mulch.

22 So I'm here today to explain you

1 much more about the BioTelo, the product. The
2 BioTelo has been first introduced in a wrap
3 about 15 years ago. It is made of Mater-Bi.
4 It's a non-GMO cornstarch. And the film
5 degrades with the microbial activity in the
6 soil. It's very important. The sunlight
7 doesn't have any effect on the film, it's the
8 microbial activity in the ground.

9 And many study has been done on
10 BioTelo by many universities as Penn State,
11 Cornell, Tennessee, Washington State to McGill
12 in Canada and many other universities all over
13 the world.

14 So the BioTelo has the same
15 properties as the plastic mulch but the big
16 advantage is that it doesn't have to be
17 removed from the ground. So when it breaks
18 down it decomposes without leaving any
19 toxicity or residue over time. BioTelo
20 reduces the amount of CO2 per hectare of
21 mulching by over 60 percent compared to
22 traditional plastic film. So BioTelo is a

1 great ecological and responsible alternative
2 to plastic mulch.

3 So here you can see the processing
4 of the degradation over the time for one
5 season. So you see the summer onions, you see
6 the film starting to get small holes in it.
7 After the tillage you have very small residue
8 left in the ground. And in some case in the
9 fall you don't see anything. In early spring
10 it's practically all gone.

11 This is conventional plastic
12 mulch. The use of plastic mulch in the USA
13 exceeds 110 millions of pounds every year, and
14 it's a repeat every year. And that data comes
15 from 1987 so probably today it's more than
16 that.

17 And the plastic have been disposed
18 of routinely by burning, burial or dumping in
19 landfills. So that's what it looks like and
20 that's what I don't like to see. And I'm here
21 today to be -- to solve that big problem here.

22 And why using biodegradable? It's

1 avoiding the soil contamination. And it's
2 certified in European region. Also, it's no
3 disposal issues. It's saving time and labor
4 a lot. Its ability to handle with current
5 commercial equipment and systems with only
6 minor adjustment. Weed suppression, water
7 retention, crop quality and yields comparative
8 to those currently provided by standard
9 polyethylene mulch film in the market.

10 The use of raw material from
11 renewable source rather than fossil fuels.
12 Economic viability. And it's a clean and
13 innovative technology to protect our
14 environment for now and for future generation.

15 So, I'm here today not for
16 business, for myself and for my son and for
17 the next generation. It's time to do
18 something to move and go forward with this
19 technology that exists today. And that's a
20 good alternative.

21 MR. FELDMAN: Thank you.

22 MR. MENARD: Any question?

1 MR. FELDMAN: Any questions?

2 That's what I was going to say. John?

3 MR. FOSTER: So my earlier
4 question was about cost but maybe it's an
5 irrelevant question if all -- are all
6 biodegradable plastics from non-GMO sources?

7 MR. MENARD: I'm not aware about
8 too much the other kind of biodegradable but
9 I can tell you about the BioTelo. It's non-
10 GMO sourced. It can be done with GMO source.
11 It will do the same material basically.

12 MR. FOSTER: But your company
13 doesn't do --

14 MR. MENARD: No, this is
15 manufactured in Italy.

16 MR. FOSTER: Okay.

17 MR. MENARD: It's not manufactured
18 yet in North America.

19 MR. FOSTER: Got it. Thank you.

20 MR. MENARD: It will be and if it
21 has to be the raw material will come from
22 Italy.

1 MR. FELDMAN: Go ahead.

2 MS. SONNABEND: Thank you. Do you
3 have a preference of how you think the
4 material should be referred to? I mean,
5 biodegradable mulch film versus bio-based
6 bioplastic and those type of things we
7 mentioned earlier?

8 MR. MENARD: Yes, I think because
9 this product, it's used and it's very
10 important -- I think for myself it's
11 compostable. It's the word, the terminology,
12 I think it's important in that case to be very
13 -- I think compostable, biodegradable. But
14 the word "compostable" means much more I
15 think, my point of view, of for it goes in the
16 ground, it's organic matter, and it's
17 composting inside the ground. And if it's
18 compost it means it's ecologic.

19 MS. SONNABEND: Well, so you would
20 rather not have it be called bioplastic?

21 MR. MENARD: Well, I don't like
22 the plastic. You know, I'm a guy who has been

1 selling plastic mulch for 17 years so you're
2 talking to a plastic guy who are still selling
3 plastic mulch. But I'm convert today to the
4 compostable mulch or biodegradable mulch film.
5 I'm not using any plastic words anymore for
6 that. So I'm convert and that's I think.

7 And it's not only myself who say
8 that. I talk to Dr. Michael Orzolek from Penn
9 State and he say to me, and he's a plastic guy
10 like me but much older, and he say to me, he
11 say the future 20 years from now is going to
12 be biodegradable and compostable mulch film.
13 It won't have any more plastic mulch film in
14 the industry from now, I mean in 20 years. So
15 I think compostable biodegradable mulch film
16 should be more than bioplastic.

17 MR. FELDMAN: Jennifer.

18 MS. TAYLOR: Thank you. Could you
19 please give us some information about the
20 optimal soil environment that would enhance
21 the breakdown?

22 MR. MENARD: Okay, that's a good

1 question. The breakdown is first of all in
2 the product we have different thickness. We
3 have different thickness so the thickness
4 makes the degradation faster or longer
5 depending also the type of soil you have. So
6 more your soil have organic matter it's going
7 to degrade faster. So if it's sandy soil it
8 degrades over time but it's going to be
9 longer. But there's -- that's answer your
10 question? So the clay soil, clay will degrade
11 faster than sandy. But sandy soil will
12 eventually degrade.

13 And the good thing of it is over
14 the years I never -- I sold over for right now
15 it's over 1,000 acres in the United States and
16 I didn't have any complaints about this
17 product. So the degradation, what we say,
18 it's what you get. So if your type of soil,
19 it's clay soil, we're going to suggest you a
20 thicker mulch so it's going to degrade after
21 the season perfectly.

22 So that's interesting. As a

1 product we don't have any complaint. Because
2 if I had complaint I won't be here today to --
3 talking to you about this product.

4 MS. TAYLOR: And also -- the
5 different types of varieties, or no, the
6 different types of plants that you're planting
7 would determine the thickness of the mulch
8 itself.

9 MR. MENARD: Yes. Yes, exactly.
10 So the crops also, if it's short-term crops
11 we're going to go with thinner film. Like for
12 cucumbers we can use a 0.5 mil thickness so it
13 will last like 3-4 months under sandy loam
14 condition. So we have different -- with the
15 type of crops.

16 But obviously like strawberries
17 for 2 years that product, it doesn't last 2
18 years. The maximum we have right now, it's
19 about 1 year, one season. So we don't have
20 any product for a long term yet.

21 MR. FELDMAN: Go ahead, Harold.

22 MR. AUSTIN: You mentioned that

1 sunlight really doesn't have an effect on the
2 breakdown of the material but its true
3 breakdown and degradation is by microbial
4 activity.

5 MR. MENARD: Yes. The sunlight
6 effect doesn't have any impact. Basically
7 it's the warm of the soil, it does. So that's
8 make the warming the soil, but the sunlight
9 doesn't have an impact like the
10 photodegradable or the oxodegradable film.
11 It's more with the microbial activities in the
12 ground. So you have -- that's why you have to
13 tilling the soil, the film after the season
14 and it will degrade faster. But the sunlight
15 doesn't have any impact directly.

16 MR. FELDMAN: Any other questions?
17 Before you go could you just tell us the
18 products that are used and approved in Canada.
19 Your product is in use in Canada?

20 MR. MENARD: Yes, it's used in
21 Canada by the organic growers. They're using
22 it since the beginning.

1 MR. FELDMAN: Do you know of other
2 products besides your own that are used under
3 the organic standard in Canada?

4 MR. MENARD: There's another one
5 who is approved also.

6 MR. FELDMAN: Okay.

7 MR. MENARD: You want I give you
8 the name?

9 MR. FELDMAN: Sure.

10 MR. MENARD: It's Bio Neuve. It's
11 my competitors. It's made in France and my
12 product right now it's made in Italy. But
13 we're looking to make the product here in
14 North America, in Montreal in the near future.

15 MR. FELDMAN: Okay. Merci and ...
16 bientôt.

17 MR. MENARD: Merci beaucoup.
18 Thank you.

19 MR. FELDMAN: I have Matt up, Matt
20 Cotton, and Kyla Smith on deck.

21 MR. COTTON: Mr. Chair, members of
22 the board, thank you very much. My name is

1 Matt Cotton. I'm a technical consultant to
2 BPI on this issue.

3 I'm going to be brief. I'm really
4 filling in for one of our scientists who
5 couldn't be here from Italy. I do urge you to
6 positively consider the biodegradable mulch
7 petition. Although I'm not a grower I'm
8 extremely familiar with these materials and
9 biodegradable and compostable materials
10 through the work I do with composters and
11 those that buy compost.

12 On the West Coast our biggest
13 market for compost is agriculture,
14 particularly, not exclusively, but certainly
15 organic agriculture is part of that. I
16 certainly appreciate there are lots of
17 questions and concerns and it's a confusing
18 and somewhat a magical product in a lot of
19 ways. You want it to perform exactly like a
20 plastic mulch and then somehow clap your hands
21 and have it degrade.

22 Although I've heard a lot of

1 testimony today I really don't hear a lot of
2 complaints from growers that it's not
3 performing although I know it doesn't work in
4 every situation. It was interesting to me
5 that we had only support from growers and no
6 opposition from growers to the petition.

7 And it's a needed tool for
8 growers. Is it going to work in every
9 situation? No. I'm trying to anticipate
10 Jennifer's question about the types of soil
11 and there was some discussion yesterday about
12 where this is going to work and not going to
13 work. If it's not going to work for a grower,
14 maybe it's in Arizona, maybe it's too dry, too
15 hot. They're probably not going to use it.
16 But clearly what we've heard, testimony
17 yesterday and today from growers that use it
18 is it works fine. There are some real
19 benefits to it.

20 And ironically I think if this
21 were 20 years ago and these materials had been
22 available I think they would have been

1 approved whereas polyethylene mulch which
2 really is a strange contradiction looking at
3 it from my outsider perspective to the organic
4 world, a bit of a contradiction that that's
5 allowable compared to these.

6 In certain places obviously the
7 growers and the certifiers will figure out the
8 best management practices. Obviously this
9 will be part of a crop plan reviewed by the
10 certifiers. I understand there's some
11 questions there. We've worked to try to
12 address those. I believe it's quite clear
13 there's adequate and sufficient data to
14 determine that there are no negative soil
15 impacts of these materials.

16 More study is -- what is needed
17 and ironically if we approve, if you see fit
18 to approve these materials there will be study
19 because that's how it goes. We don't have a
20 lot of history of using these materials
21 because they're not allowed. And the
22 professors I work with like to use materials

1 that people are actually using so their
2 research has benefits. Field experience will
3 continue to inform best practice.

4 And getting to the question, the
5 linguistic question to some extent, I believe
6 biodegradation should be seen as a type of
7 removal. I think we're living in a fantasy
8 world if we think that 100 percent of all the
9 polyethylene mulch that's used in fields is
10 removed. Biodegradation is a much more
11 efficient of removing, truly removing these
12 materials from that environment.

13 Ask any farmer, ask the folks from
14 NOFA Vermont, anyone who's used these
15 materials in the soil how well that material
16 is removed, how completely polyethylene mulch
17 gets removed from the soil after a year of
18 being on a crop in the sun. I think you'll
19 find that there's -- hard to find a place that
20 uses that mulch that doesn't have little
21 shards of plastic throughout the soil and that
22 could be studied.

1 Fundamentally the use and
2 certification to ASTM standards is something
3 that we work with in the composting industry.
4 We're already comfortable with it. We've used
5 the ASTM standards and we think that's a good
6 way to go.

7 With that I'd be happy to answer
8 any questions.

9 MR. FELDMAN: Thank you.
10 Questions? Mac.

11 MR. STONE: How fast is
12 conventional growers adopting this technology?

13 MR. COTTON: I'm sorry?

14 MR. STONE: How fast are
15 conventional growers adopting this technology?

16 MR. COTTON: That's a great
17 question for Eric. I don't know.

18 MR. FELDMAN: Other questions?
19 Okay, Zea.

20 MS. SONNABEND: My question which
21 sort of just occurred to me now I might not be
22 able to word in the right way. But in reading

1 the European studies, the one from Italy
2 particularly they tested biodegradable row
3 covers as well as mulch films. And the row
4 cover is biodegradable but it will last long
5 enough in a season, but then of course as a
6 row cover you would remove it and
7 theoretically compost it. Are there issues
8 there or would it be okay to compost it
9 because you're assured by the same ASTM
10 standards that a row cover would also degrade
11 in composting.

12 MR. COTTON: That's a great
13 question. To be fair I don't have the
14 experience to answer that question. I believe
15 the gentleman who testified earlier from
16 upstate New York does some row tunnel growing
17 and composts that material on the farm for use
18 on the farm. So actually I would guess these
19 materials would compost quite readily. Eric
20 had some samples. I hope he passed them
21 around.

22 It's a relatively thin material.

1 And you may have heard there is some
2 controversy of some of the compostable stuff,
3 maybe you've seen it in the cafes around here,
4 as you get to bigger and bigger thicknesses.
5 But almost every composter will say the bags
6 work just fine. So thin sheets of this stuff
7 allow a lot of surface area for microbes to
8 attack that. So I have not heard of any
9 issues with that whatsoever. It composts
10 great.

11 MR. FELDMAN: Questions? Are you
12 able to tell us what the time to degradation,
13 complete degradation is?

14 MR. COTTON: No. That's a
15 question -- we can certainly -- I can
16 absolutely get you that answer.

17 MR. FELDMAN: Okay.

18 MR. COTTON: I think that will
19 vary to some extent clearly by the thickness
20 and to some extent material by material. But
21 I'm sure we can provide that, be happy to.

22 MR. FELDMAN: Okay, thank you.

1 Thanks a lot.

2 MR. COTTON: Thank you.

3 MR. FELDMAN: Kyla Smith. And we
4 have Jim Munger on deck.

5 MS. SMITH: Okay, good afternoon.
6 My name is Kyla Smith. I am the certification
7 program director for Pennsylvania Certified
8 Organic. PCO is an NOP-accredited non-profit
9 certifying agent that certifies about 650
10 operations in the mid-Atlantic region. I'd
11 like to comment on the recommendation to add
12 biodegradable mulch film made from bioplastics
13 to the National List.

14 PCO does not have a position for
15 or against this specific material. We realize
16 the desire for farmers to want more options
17 for weed control. However, the current
18 version of the recommendation prevents
19 challenges for certifier verification.

20 It is difficult to enforce parts
21 of the regulations, including annotations that
22 leave room for interpretation among producers

1 and certifiers. We recognize that there will
2 be changes to the annotation prior to voting.

3 PCO asks that you consider the
4 following requests for clarification to
5 provide clear measurability by certifiers, to
6 ensure compliance of farmers' organic system
7 plans with the USDA organic regulations. We
8 hope these comments prove useful in your
9 deliberations.

10 The current recommendation defines
11 biodegradable mulch film as showing at least
12 90 percent biodegradation absolute or relative
13 to microcrystalline cellulose in less than 2
14 years and simultaneously requires the grower
15 ensures complete degradation at the end of
16 each growing or harvest season. That is
17 consistent with Section 205.206(c)(6) which
18 requires that plastic or other synthetic
19 mulches be removed from the field at the end
20 of the growing or harvest season.

21 We appreciate the clarification
22 regarding the intent of portions of the

1 annotation were specifically included for MROs
2 and certifiers to evaluate these materials as
3 opposed to the portions that were specifically
4 included for producers.

5 The question still remains that
6 since this is a synthetic material it must be
7 removed from the field at the end of the
8 growing or harvest season, and we are seeking
9 further clarification on how we are to enforce
10 that when typically growing or harvest seasons
11 are less than 2 years and this material could
12 take up to 2 years to biodegrade. Guidance
13 for certifiers to verify that growers have
14 taken measures to ensure complete degradation
15 annually is crucial for consistency throughout
16 the organic industry.

17 Instead of removal from the field
18 the subcommittee's recommendation requires
19 that synthetic bioplastic degrades by the end
20 of the growing or harvest season. If the
21 subcommittee's recommendation infers that
22 degradation equals removal this needs to be

1 more clearly stated.

2 We encourage the board to ask the
3 program to develop guidance that will provide
4 further clarification to certifiers and
5 producers regarding the following. What does
6 complete degradation mean and how is complete
7 degradation expected to be verified? By
8 visual confirmation or testing by the
9 certifier, inspector or producer? If the
10 expectation is that the inspectors will verify
11 complete degradation of the product this may
12 not be able to be verified until the following
13 year as many inspections occur prior to the
14 end of the growing season.

15 We also support the idea of the
16 development of a certification program to the
17 ASTM standards. This will assist MROs and
18 certifiers that may not have the expertise to
19 make these determinations without additional
20 time and resources.

21 Lastly, the technical evaluation
22 report highlights several sub-ingredients like

1 titanium dioxide and carbon black that are
2 used in the production of biodegradable mulch
3 film. In future production there could be
4 other pigments that are used and these could
5 potentially be synthetic.

6 We appreciate the clarification
7 that was provided during the subcommittee's
8 presentation that stated if other synthetics
9 are present in future formulations these must
10 be specifically petitioned for inclusion on
11 the National List.

12 PCO is unclear if there are
13 synthetic forms of titanium dioxide that are
14 used in biodegradable mulch materials. We
15 understand that titanium dioxide is a mined
16 mineral. However, it may undergo synthetic
17 processes. As a certifier that does material
18 review it is critical that the addition of any
19 synthetic materials to the National List is
20 restricted in the same and consistent manner
21 as similar materials already listed on the
22 National List.

1 PCO needs to know if it is our
2 responsibility to confirm if a sub-ingredient
3 such as titanium dioxide is mined.

4 Restrictions such as this are typically
5 annotated. PCO supports putting tools in the
6 farmer's toolbox. However, we must do so in
7 a consistent and clear manner. We think it's
8 imperative that the board must address these
9 concerns. And thank you for your time and
10 effort.

11 MR. FELDMAN: Thank you.

12 Questions? Zea.

13 MS. SONNABEND: Thank you for that
14 input. If you heard us this morning, I'm sure
15 you did, the direction that we are going is
16 trying to have separate sets of the annotation
17 that are oriented for growers and certifiers,
18 and oriented for MROs.

19 If we put the onus of assuring
20 complete degradation onto the MRO side of the
21 equation so to speak so that before the
22 product is approved we have to know that in

1 the right conditions they sufficiently break
2 down. Then all the certifier's role would be
3 is to verify that the appropriate actions as
4 spelled out in the guidance had been taken to
5 assure that it is breaking down in the field.
6 And then one of the ways of verifying that
7 would be to look at the field and see if it
8 hadn't really been broken down and then to see
9 what appropriate actions.

10 We feel this is somewhat more
11 consistent with a process standard approach to
12 the whole thing. I'm wondering do you feel
13 okay with that if that's the way that we're
14 going.

15 MS. SMITH: We totally support a
16 process-based standard. I think clarification
17 -- inspectors may view "complete" differently
18 and so if they are onsite evaluating a field
19 I may, I don't know, see little bits or a few
20 bits here and there and may evaluate that
21 differently than a different inspector. So I
22 think that further clarification in that

1 regard may be helpful.

2 MS. SONNABEND: Okay. They would
3 not have to evaluating complete. They would
4 have to be evaluating appropriate and then
5 just reporting on what they saw in the field.

6 MS. SMITH: Yes, that would be
7 helpful.

8 MS. SONNABEND: Okay.

9 MS. SMITH: We would -- we would
10 be down with that.

11 MR. FELDMAN: Other questions? I
12 had a question about your comment in your
13 written testimony about essentiality which I
14 found interesting. Could you tell us where
15 you think this decision or what factors you
16 think should be brought to the question of
17 essentiality of this material in organic
18 systems?

19 MS. SMITH: I didn't write the
20 written comment. Our policy director did and
21 she's not here so I'll try to address that
22 from conversations with her.

1 We, most of our producers that
2 obviously use the black plastic and we
3 understand that there's a concern that it does
4 end up in landfills. We do have extensive
5 lists of recycling centers that we have found
6 that take the plastic. I don't know what
7 happens to it after they take it. And so we
8 haven't had a big outcry from our producers to
9 use this product. We've had a few requests.
10 So in regards to whether or not our producers
11 find it essential I'm not sure. I don't know
12 if that really answers your question very
13 well.

14 MR. FELDMAN: Thank you. Thank
15 you very much.

16 MS. SMITH: Thanks.

17 MR. FELDMAN: Jim Munger, is he?
18 Thank you. And Lindsay Fernandez-Salvador is
19 up next.

20 MR. MUNGER: Hello, I'm Jim
21 Munger. Being here reminds me of coming here
22 in 1970. I had just celebrated the first

1 Earth Day at the University of the Pacific and
2 came to Roger Williams University and taught
3 environmental chemistry for 30 years. I'm now
4 a farmer and growing things primarily by
5 hydroponics.

6 I'm a member of the Cornucopia
7 Institute and here as a citizen lobbyist. I
8 know that "lobbyist" can sometimes be sort of
9 a dirty word but I guess it's a necessity to
10 make sure that we get all sides of the
11 positions.

12 I'll talk today about four
13 materials, ferric phosphate, oxidized lignite,
14 propylene glycol and rotenone. I have grown
15 chrysanthemums and rotenone is actually made
16 from chrysanthemums.

17 Ferric sulfate, we support the
18 proposal to remove ferric sulfate from the
19 list of synthetic substances allowed for use
20 in organic crop production. Ferric sulfate --
21 phosphate currently is allowed to be used to
22 kill slugs.

1 All commercial products that
2 contain ferric sulfate also include EDTA.
3 Ferric phosphate was initially allowed because
4 EDTA was considered an inert ingredient. The
5 recent reviews suggest that EDTA is not inert
6 and is required to ensure efficiency of the
7 product.

8 This indicates that EDTA must be
9 evaluated as an active ingredient. Previous
10 NOCSB reviews of ferric phosphate with EDTA
11 have shown that EDTA may be harmful to the
12 environment, EDTA may persist in the
13 environment and that EDTA has potential for
14 mammalian toxicity. Products containing
15 ferric phosphate with EDTA should be
16 prohibited.

17 Oxidized lignite. Cornucopia
18 recommends that you reject the proposal to
19 allow hydrogen peroxide-extracted humic acid
20 derivatives, also called oxidized lignite.
21 These humic acids are a product of coal-mining
22 which is harmful to the workers and the

1 environment. The TER stated that these coal
2 derivatives may be toxic. The manufacturing
3 process is not known because it was removed
4 from the petition.

5 Most important, synthetic humic
6 acids are not essential. The same humic acids
7 can be added to the soil through natural
8 methods such as mulches, compost or cover
9 crops.

10 Propylene glycol monolaurate
11 (PGML). Cornucopia recommends that you reject
12 the proposal to add propylene glycol
13 monolaurate to the National List. PGML was
14 petitioned for use as a miticide although it
15 has broad-spectrum activity against mites,
16 fungi and bacteria.

17 The broad-spectrum activity can
18 reduce biodiversity. Organic farmers have
19 found that maintaining a diverse, balanced
20 ecosystem approach to guideline will prevent
21 or minimize mite damage on their crops. A
22 broad-spectrum miticide is not only

1 unnecessary but actually upsets the balance of
2 the ecosystem.

3 And I make a comment on rotenone,
4 and basically we are suggesting that rotenone
5 be prohibited as a natural substitute. I
6 heard the bell so I --

7 MR. FELDMAN: Yes.

8 MR. MUNGER: -- it up.

9 MR. FELDMAN: Unfortunately.

10 Thank you very much. Any questions? Thank
11 you, sir. Lindsay, you're up. And on deck
12 is, excuse me, Bill Wolf is on deck. Thank
13 you.

14 MS. FERNANDEZ-SALVADOR: Good
15 afternoon, I'm Lindsay Fernandez-Salvador from
16 OMRI. I'd like to focus the majority of my
17 comments today on the biodegradable mulch
18 films.

19 We sincerely appreciate the
20 subcommittee's serious consideration of our
21 comments, our written comments. Much of our
22 concerns were addressed in the subcommittee's

1 presentation of these materials. Thus I want
2 to spend some time here indicating to the NOSB
3 what we agree with to this point and what
4 continues to need further clarification and
5 consideration.

6 For the definition of
7 biodegradability we understand that the ASTM
8 6400 is a standard that serves two purposes,
9 both a practical one for the mulch
10 manufacturer to be able to test on a shorter
11 time frame whether it's worth it to pursue
12 certification to the ASTM 5988 and as a test
13 for ecotoxicity of the components as they
14 degrade in a composting condition.

15 We did question the need for
16 verifying both standards for our purposes but
17 accept this explanation going forward. The
18 one thing I would suggest, however, is to make
19 sure that the subcommittee and the NOSB in its
20 entirety fully understands this argument and
21 evaluates if indeed the certification to ASTM
22 6400 is needed for verifying the intent of the

1 NOSB's requirements for the allowance of these
2 films.

3 We are happy to see the
4 clarification that you intend to require third
5 party certification to the various standards.
6 Although OMRI could verify the various
7 standards independently it would not make me
8 happy to have to do so.

9 In regards to the clarification
10 for excluded methods and the use of them in
11 the source and manufacture of such substances
12 we appreciate the clarification that it is the
13 intent to prohibit the use of excluded methods
14 in the organisms or microbes that may carry
15 out the manufacture of these biodegradable
16 plastics.

17 This clarification offered in the
18 presentation concurs with OMRI's policy on the
19 use of GMOs in input products. We're up to
20 date with advances in this technology and it
21 does include GMO microbes that produce
22 biodegradable plastics in their cell walls so

1 it will potentially become a reason for
2 denying OMRI listing in the future.

3 A few clarifications. We're
4 concerned about the additives in the mulch
5 films. My previous research indicates that
6 patents for mulch films include other types of
7 additives such as colorants like red
8 colorants, resins to prevent breakdown,
9 fungicides, et cetera. So, we're concerned
10 about whether or not the intent is to limit it
11 to both carbon black and titanium dioxide, or
12 that we would allow any other additives that
13 might come in future petitions or future
14 products.

15 And finally we want the
16 subcommittee to clarify that by indicating
17 that the mulches should be bio-based that
18 those biodegradable plastics created by
19 microbes are included or excluded from this
20 definition. The subcommittee's recommendation
21 indicates that bio-based is organic material
22 in which carbon is derived from a renewable

1 resource via biological processes. So does
2 this definition for you include bioplastics
3 made by microbes fermenting on methane gas
4 generated from food waste or plant-based
5 media? We'd like to understand more about
6 your understanding of bio-based.

7 We know this is a complicated
8 issue. The petition was very thorough but my
9 experience indicates the technology for
10 bioplastics is moving fast and becoming more
11 innovative. OMRI's goal is to ask the
12 question as to whether the NOSB has all the
13 information about what's coming in this
14 technology.

15 We are concerned that there will
16 be a pressure on OMRI to prove any and all of
17 these materials because there is such a huge
18 demand for them. Thank you.

19 MR. FELDMAN: Thank you.
20 Questions? John.

21 MR. FOSTER: If I had all the
22 information about all the products that might

1 be coming down the pipeline I'd be in a
2 totally different line of work. So given that
3 we will not have that information, we just, we
4 won't, ever, what's the best you see we can do
5 with the information we are likely to be able
6 to have? Because we won't have it all, we
7 never will. So what's the best we can do with
8 what we have? In that regard. You know,
9 preparing and gathering information, what do
10 you --

11 MS. FERNANDEZ-SALVADOR: Totally.

12 MR. FOSTER: -- yes.

13 MS. FERNANDEZ-SALVADOR: Well, I
14 would look at the current technologies right
15 now. The petition outlines several different
16 types of biodegradable plastics that are out
17 there. So I would first go to that and I
18 would make sure that you all understand what
19 those technologies are and understand what
20 you're approving.

21 I would go back to the source. Do
22 you care about that it's made from cornstarch?

1 Do you care that it's made by a microbe on
2 fermentation? These are the things that we
3 want to understand from you.

4 We also want to understand whether
5 or not the additives that are declared in the
6 petition are the only additives that you are
7 going to allow or want to allow. Because
8 going forward we know that manufacturers will
9 put more things because it enhances their
10 product. So we just need to know based on the
11 information that you have today what you're
12 limiting it to and what you're not limiting it
13 to.

14 MR. FELDMAN: Thank you. Zea?

15 MS. SONNABEND: Thank you,
16 Lindsay. I'd like you to help me understand
17 your comment about the "bio-based" word. Was
18 it sort of -- was it similar to my question
19 from the BPI gentleman about whether bio-based
20 would include products that had originally
21 stemmed from petroleum versus plant materials,
22 or is it a different point than that?

1 MS. FERNANDEZ-SALVADOR: No. My
2 main concern here is that there's
3 biodegradable plastics that are derived with
4 feedstocks from plant materials and then
5 there's also biodegradable plastics that are
6 derived by microbes through fermentation of
7 methane gas from food waste facilities and/or
8 plant media.

9 And so my understanding is that
10 the test that the petitioner proposed for this
11 would test that it was in fact bio-based. But
12 I wanted to understand whether or not you guys
13 understood what bio-based was and if your
14 intent was just that the feedstocks need to be
15 bio-based or if it can also be created by a
16 microbe via fermentation.

17 MS. SONNABEND: I don't recall
18 seeing the methane gas origin in our petition
19 or TR.

20 MS. FERNANDEZ-SALVADOR: Right.
21 And so this is where I introduce other
22 technology that's out there. I attended a

1 presentation by a company that was developing
2 this as we speak so that's where I was trying
3 to seek clarification.

4 MR. FELDMAN: Questions? Has OMRI
5 been asked to approve this material up to this
6 point?

7 MS. FERNANDEZ-SALVADOR: No.

8 MR. FELDMAN: Okay. Okay, thank
9 you, Lindsay. Another question.

10 MR. FOSTER: To what extent do you
11 feel it's necessary to address the GMO issue
12 on this material relative to the greater
13 context of GMO policies kind of already in
14 place? And I'd also be interested, if NOP has
15 a thought on that I would be interested in
16 that too. But I want to hear what you have to
17 say.

18 MS. FERNANDEZ-SALVADOR: Sure.
19 Well, that same presentation that I attended
20 where the microbes were in fact creating the
21 biodegradable plastics in their guts, in their
22 cell walls, the presenter indicated that there

1 were GMO microbes being developed that could
2 produce them faster with different properties.

3 And according to our current OMRI
4 policy we would not allow biodegradable
5 plastics from that type of genetically
6 modified microbe, the same as we wouldn't
7 allow citric acid derived from genetically
8 modified aspergillus. So I think what has
9 been presented by the subcommittee and what I
10 understand as the changes would then come in
11 concurrence with OMRI's current policy.

12 So we would -- we do understand
13 that genetically -- cornstarch from, for
14 example, genetically modified corn would be an
15 allowed feedstock and that would also be in
16 concurrence with our current policy.

17 MR. FELDMAN: Do you want some
18 clarification from the program?

19 MR. FOSTER: If they're
20 interested. I would be interested in hearing
21 the relative need to review or to consider the
22 GMO issue with respect to this material given

1 that there's a larger context of excluded
2 methods. That's what I was interested in. Do
3 we need to do it now would be one way of
4 asking that question.

5 MR. FELDMAN: Should we postpone
6 that till later? Because we'll be back at
7 this.

8 MS. BAILEY: Was there a question
9 in there? I thought that was more of a
10 statement.

11 MR. FELDMAN: He's looking -- he's
12 desperately looking for advice.

13 MR. FOSTER: Well, I'm -- what I'm
14 interested in is what is the perceived need to
15 deal with GMO issue with regard to this
16 specific material given that there is a
17 larger, more what I would consider broader
18 scope approach to GMOs that's evolving and I
19 think getting more refined. But what is the
20 need to do it within the context of this
21 material deliberation.

22 MR. MCEVOY: Okay, so the question

1 is should you deal with it now or later. We
2 would like a consistent approach to how you
3 look at 205.105, the excluded methods, what's
4 the use of excluded methods. When is it a use
5 of excluded methods and when it is not.

6 And in the past the NOP in the
7 questions and answers said that GM crop
8 residue, GM soybean meal as a fertility input
9 was not a use of an excluded method. We don't
10 have those questions and answers up anymore
11 but we're looking for the board to take a look
12 at this through the GMO Ad Hoc Committee and
13 provide us with a recommendation.

14 So a consistent approach to
15 looking at those types of substances and how
16 they're used or not used in organic
17 agriculture is what we would like to see, a
18 consistent approach. And you have a substance
19 in front of you that you're taking a look at.
20 So you have to make a determination of whether
21 it makes sense to wait and do it as a group or
22 to look at it on a case-by-case basis.

1 MR. FELDMAN: Thank you. Other
2 questions? Lindsay, one quick question on
3 ASTM 6400 and the ecotoxicity testing. How
4 does that align with the board's
5 responsibility to evaluate long-term or short-
6 and long-term effects on ecotoxicity, on
7 ecosystems.

8 MS. FERNANDEZ-SALVADOR: OMRI's
9 responsibility?

10 MR. FELDMAN: Well, the board, as
11 you would see the board in doing its review
12 before listing something.

13 MS. FERNANDEZ-SALVADOR: Oh.
14 Well, in relation to my comment there what I
15 was really getting at was that because OMRI is
16 going to have to verify this. So we're going
17 to have to get two different certificates for
18 6400 and 5998.

19 My initial understanding was that
20 6400 was really a test for the manufacturer to
21 make sure that they're going to get through
22 the 2-month period of time in a composting

1 facility and that would indicate to them
2 whether or not it was worth it to pursue the
3 5998.

4 And for OMRI I would prefer not to
5 have to verify two standards if I can only
6 verify one. But I understand now that 6400
7 tests both the threshold on timing and also
8 ecotoxicity. So if you feel that is
9 beneficial and you understand that 6400 in
10 fact does something for the NOSB in their
11 review of it and the effectiveness and its
12 effect on the environment then we accept that
13 argument and we're happy to verify that as
14 well.

15 MR. FELDMAN: Are you familiar
16 enough with the ECOTOX review?

17 MS. FERNANDEZ-SALVADOR: That's
18 the first time I'd heard of it.

19 MR. FELDMAN: Okay, thank you.
20 Thank you very much. Bill Wolf is up and on
21 deck is Pam Coleman.

22 MR. WOLF: Hi. I haven't been in

1 front of the board in 2 years and you guys
2 have been doing some great work. I appreciate
3 the opportunity to be here.

4 I'm Bill Wolf with Wolf DiMatteo &
5 Associates. I'm an organic advocate, a
6 farmer, a gardener for 40 years and been
7 involved in organic inputs as well.

8 Regarding mulch film our initial
9 client was Joan and Drew Norman of One Straw
10 Farm as actually as a pro bono support for
11 their efforts, later joined by the
12 Biodegradable Products Institute. And I'm
13 making that statement for transparency
14 purposes.

15 However, as I became involved in
16 looking at this material I actually was a
17 little skeptical and became more and more
18 convinced that it was a useful tool for
19 organic farmers.

20 In 2002 at the first NOSB meeting
21 20 years ago I presented the OFPANA guidelines
22 for organic production as one of the tools for

1 this board to consider in establishing
2 standards and materials review processes.

3 At that time we were all talking
4 about how the standards need to be easy to
5 understand and encourage conversion of more
6 acreage. Organic practices should encourage
7 an increase in earthworms, improve food
8 quality, biodiversity in the environment and
9 help farmers, eaters and the planet.

10 I thought at that time that
11 organic acreage would be over 10 percent by
12 2010 and we even discussed those kinds of
13 goals 20 years ago. But today it's only 1
14 percent worldwide. We have to ask ourselves
15 why and what we can do about it.

16 Today a number of organic farmers
17 are leaving organic, especially the smaller
18 farmers. It has become very complicated and
19 very prescriptive and not very friendly for
20 the smaller farmers. There is a risk that
21 organic may have peaked in some markets and in
22 some uses.

1 Contentious debate rather than
2 consensus-building is now the norm internally.
3 Decisions about what materials should be
4 allowed have always been controversial.

5 On your screen there's a slide
6 that talks about the roots of organic
7 regulations, showing that really we began with
8 the soil. A lot of the principles behind the
9 decisions about organic regulations I jokingly
10 and perhaps not so jokingly say, you know,
11 think like an earthworm when you're making
12 some of these decisions.

13 Decisions about materials not only
14 have been controversial but we have to look at
15 the broader picture. It is useful and needed?
16 Is it better than currently available tools?
17 Is it okay with the earthworms and the
18 beneficials? Let's apply common sense and
19 work together for continuous improvement.

20 Organic was an agricultural
21 standard built from a philosophy rooted in
22 good soil management, not based solely on what

1 the consumer expected who are often influenced
2 by simplified messages from organizations and
3 businesses.

4 On your screen right now are
5 slides from One Straw Farm's use of
6 biodegradable mulch. And I think we did a
7 good job, one of the things I'd like you to
8 consider is that I think we did an excellent
9 job establishing these overarching principles
10 in a system of having an organic system plan
11 and the expectation that inspections verify
12 that farmers are protecting the soil. Let's
13 let that system work rather than being overly
14 restrictive.

15 Here's biodegradable mulch broken
16 down within the same season on One Straw. And
17 here's some of the language about the OSP and
18 farm practices that really manage the process.
19 Remember that growers have to oversee the soil
20 and improve the soil, and that's the case. So
21 please consider biodegradable mulch and
22 approve it. There's a number of bullet points

1 there on the screen that you've heard about.
2 I'm running out of time here so thank you for
3 your time and your efforts.

4 MR. FELDMAN: Thank you.
5 Appreciate it. Any questions from the board?
6 Yes, Wendy.

7 MS. FULWIDER: You made a lot of
8 points about farmers leaving organic and
9 that's certainly been part of the trend,
10 especially with grain farmers. Could you give
11 us some tips on how to make things a little
12 easier to keep farmers in organic and to
13 attract more farmers?

14 MR. WOLF: Well, the areas where I
15 especially see people departing who have been
16 certified are smaller farmers who are doing a
17 good portion of their farming and marketing in
18 local and direct CSAs, farmers markets. I've
19 probably been to 20 farmers markets in the
20 last 2 years where most of the farmers are no
21 longer organic, many of whom I knew and used
22 to be and have just said, you know, the

1 constant doubt of what I'm doing on my farm
2 and all the paperwork has become somewhat
3 overwhelming. And I've met a number of
4 farmers who are also using biodegradable film
5 and saying I got out, I liked it, I'm not
6 using it -- I mean, I'm not going organic.

7 I think there's -- actually
8 there's probably 10 things that we as a
9 community need to look at doing to encourage
10 more acreage. And part of it's education,
11 part of it's research and the research
12 priorities that you are all talking about
13 setting is really important. I think that at
14 the extension level we've seen shift but not
15 as much shift as we need.

16 But I also think that looking at
17 the regulations in terms of being excessively
18 prescriptive is a piece of it. When you
19 mentioned dairy farmers, I know dairy farmers
20 who have looked at -- the pasture rule has
21 actually had a negative influence on some of
22 the smaller farms because they were used to

1 the concept of pasture but they didn't keep
2 track of how many grains of grass.

3 So we get into zero tolerance
4 situations, in other words, we have an
5 incident where there's one bad apple and then
6 we lay down a rule. And I'm not criticizing
7 the pasture rule, I think it was progressive
8 to address those issues of potential CAFOs.
9 But when we deal with a single incident by an
10 umbrella that affects and comes down on
11 everyone it negatively affects the community
12 in many ways. So that's a very good
13 discussion item long-term.

14 MR. FELDMAN: Thank you. Any
15 other questions? Thank you, Bill.

16 MR. WOLF: Thank you.

17 MR. FELDMAN: Pam Coleman is up
18 and Walter Talarek is on deck.

19 MS. COLEMAN: Good afternoon. My
20 name is Pamela Coleman. I'm a farm policy
21 analyst for the Cornucopia Institute. I'm a
22 scientist with a master's degree in vegetable

1 crops, a Ph.D. in plant pathology. I'm also
2 a former inspector and reviewer notably for
3 WSDA.

4 We'll have a slight change of
5 topic because I'd like to congratulate the
6 Crops Subcommittee for developing such a clear
7 and comprehensive proposal for the review of
8 inerts ingredients from EPA Lists 3 and 4.

9 Cornucopia supports this proposal
10 and we believe that the NOSB should expedite
11 the review of these List 3 and List 4 inerts.
12 We'd like to see the review of inerts be given
13 even higher priority than the review of new
14 materials and we're hoping the NOP can support
15 the project.

16 And now back to bioplastic. We
17 also appreciate the work that you've done on
18 bioplastic mulches. The promise of this
19 biodegradable plastic to warm soil and control
20 weeds makes it tempting to approve these
21 materials soon. The challenge though is to
22 verify that they truly are biodegradable and

1 that they don't leave harmful residues in the
2 soil.

3 Cornucopia is requesting that this
4 petition be tabled until the bioplastics can
5 be thoroughly evaluated. The TER was dated
6 August 2, the proposal completed August 15.
7 Yes, the NOSB is a great group but given the
8 challenging technical nature of the review
9 materials we'd like to see that more time is
10 available for all of us to fully evaluate
11 these materials, and especially the breakdown
12 products.

13 You'll notice that I'm calling
14 them bioplastics, not biodegradable, and
15 that's because the petition itself calls them
16 bioplastics. We at Cornucopia are not
17 convinced that they're biodegradable to the
18 degree that is consistent with organic
19 principles, that is to maintain or improve the
20 quality of the soil.

21 The TER also raises concern about
22 the biodegradability in seven different

1 places. I don't have time to read them all
2 but certainly you can ask me more about them
3 in the question and answer period.

4 I would like to read one, though,
5 line 649 from the TER. "Comprehensive studies
6 were not found that described the
7 environmental impacts of the use of bioplastic
8 mulch. Due to the wide variety of potential
9 chemicals released from incomplete degradation
10 of bioplastics this is a data gap."

11 The Crops Subcommittee agreed it
12 might be difficult to separate claims from
13 truth concerning biodegradability. In short,
14 it's clear that synthetic chemicals are used
15 in the manufacture of bioplastics. Therefore,
16 there's a possibility for residues of
17 synthetic chemicals in the soil even after the
18 mulch appears to have degraded.

19 We'd like to see each of these
20 types being reviewed individually and we think
21 that might shed more light on the products of
22 degradation and perhaps clarify things.

1 Please table this petition and I thank you for
2 your attention.

3 MR. FELDMAN: Any questions from
4 the board? Pamela, I'll quickly ask you, you
5 identified data gaps that were identified in
6 the TR. What area -- can you just briefly
7 tell us where those are?

8 MS. COLEMAN: Okay. Do you want
9 me to just read the lines or read the quotes?

10 MR. FELDMAN: Well, if you could
11 read the -- yes, read the quotes quickly if
12 you can.

13 MS. COLEMAN: I'll talk fast and
14 abbreviate. Line 421, "Erucamide binds
15 strongly to soils and sediments in water and
16 is likely to bioconcentrate in aquatic
17 organisms."

18 Line 445, "Studies were not found
19 that specifically assessed ecotoxicity of
20 bioplastics following degradation in the soil
21 and a better understanding of bioplastic
22 degradation is needed."

1 Line 488, "AAC" -- that's the
2 aliphatic aromatic copolymer -- "may leave
3 residues of synthetic chemicals."

4 Line 592, "Researchers have argued
5 for more extensive research into the
6 biodegradation pathways of the various
7 bioplastics."

8 Line 595, "Due to the diversity of
9 bioplastics currently being developed testing
10 is necessary to determine which polymer
11 mixtures are degraded completely and what
12 effects incomplete degradation may have on the
13 agro ecosystem."

14 Line 649 I've already read. Line
15 652, "Reports have shown that bioplastics
16 containing terephthalic acid at concentrations
17 over 50 percent do not completely biodegrade
18 in soil."

19 I will say I noticed that Zea
20 mentioned some studies from Europe. I did not
21 see a scientific citation on that and I would
22 -- I believe that's another reason why we

1 should table this until she can give us the
2 citation and allow the scientific community to
3 review that additional information.

4 MR. FELDMAN: Thank you. Any
5 other questions? Thank you very much.

6 MS. SONNABEND: We did only get
7 those European studies about 3 or 4 days
8 before the meeting. They will be posted to
9 the docket I believe after the meeting is over
10 because they were part of the testimony that
11 was put in today by BPI. And one of the
12 studies has a lot of other citations to
13 further research that we have not had a chance
14 to dig up and look at.

15 MR. FELDMAN: Thank you. Thank
16 you, Pam. Walter Talarek and David Moore is
17 up next.

18 MR. TALAREK: Good afternoon. My
19 name is Walt Talarek and I'm here representing
20 the W. Neudorff company of Emmerthal, Germany.
21 Neudorff is a very small family-owned and
22 operated producer and registrant of pesticide

1 products most of which are considered by EPA
2 to be low-risk pesticides. And many of these
3 registrations that it owns are for products
4 that are approved for NOP and OMRI claims and
5 logos.

6 Two of these products that are
7 approved for NOP and OMRI claims are Sluggo
8 and the slug -- I'm sorry, the Bug-N-Sluggo
9 products. Both of these products contain
10 ferric phosphate as an active ingredient.

11 Back in 2008 Steptoe & Johnson
12 initially submitted its petition to de-list
13 ferric phosphate from the National List. That
14 petition was subsequently modified in 2009.
15 And since that time over the last few years
16 Neudorff has both testified at a couple of
17 these meetings and submitted on numerous
18 occasions to the docket its scientific
19 information and objections to the Steptoe
20 petition.

21 Just recently the Crops
22 Subcommittee came out with a recommendation to

1 reject the Steptoe petition. I'm here today
2 to say that Neudorff the Crops Committee's
3 recommendation. The rationale provided
4 therefore we fully support.

5 And further, we would like to
6 thank the board, the full board, for going
7 back per our request and requesting a
8 supplemental technical report on this
9 petition. And we might note that that
10 petition included most of the scientific
11 information that we submitted but not all of
12 it. And I'll make a couple of comments here
13 as I go on as to what information was not
14 considered.

15 Number one primarily was the
16 initial set of comments that was included in
17 the Neudorff opinion. And that opinion was
18 submitted several times to the docket and that
19 was not considered. Okay.

20 Well, in deciding on the Crops
21 Committee's recommendation we would urge the
22 board to consider in addition the decisions by

1 other regulatory authorities around the world
2 as to what is the active ingredient in
3 Neudorff's two slug baits.

4 EPA as well as other organizations
5 such as the EU, IFOAM, Codex Alimentarius
6 Commission, all of them have decided that
7 there is only one active ingredient and it is
8 ferric phosphate. The European Commission
9 also specifically decided that EDTA was not
10 active and the products do not contain ferric
11 EDTA. So, that information was submitted to
12 the docket also on several occasions.

13 I might like to note that Neudorff
14 slug baits are mixtures. It's not a product
15 that's chemically reacted during production.
16 There's four ingredients all of which are --
17 well, the inert's on List 4 and the active is
18 on the National List right now.

19 MR. FELDMAN: Thank you. Any
20 questions? Thank you very much.

21 MR. TALAREK: Thank you.

22 MR. FELDMAN: David Moore is up

1 and Cam Wilson on deck.

2 MR. MOORE: Good afternoon and
3 thank you for this opportunity to address the
4 board. My name's David Moore. I'm a
5 California licensed agricultural pest control
6 advisor and qualified applicator, and I work
7 for Neudorff.

8 I'm here to encourage each member
9 of this board to affirm the Crops Subcommittee
10 recommendation and vote to reject the petition
11 to de-list ferric phosphate from the National
12 List.

13 Ferric phosphate is the sole
14 active ingredient in our product Sluggo, the
15 only effective molluscicide currently
16 available to organic growers. Assertions that
17 ferric phosphate is not an effective active
18 molluscicide and the implication that our
19 registration is somehow flawed by the presence
20 of an allowed inert fly in the face of
21 regulatory findings the world over and have no
22 basis in science.

1 The finding that ferric phosphate
2 is an active molluscicide is shared by the
3 U.S. EPA, IFOAM, ECOCERT, the EU regulatory
4 body and other regulatory organizations the
5 world round. Neither the supplemental
6 technical report nor the subcommittee
7 recommendation makes any attempt to state a
8 definitive conclusion on this issue because
9 there is no definitive conclusion.

10 The voice of the organic grower
11 has been unanimous in support of ferric
12 phosphate and this voice includes growers that
13 are large and small all around the U.S.
14 growing a wide variety of crops. In some
15 cases these growers are producing a
16 preponderance of the entire U.S. organic
17 production of that crop.

18 These growers have spoken directly
19 to the negative impact that removing ferric
20 phosphate will have on production and
21 availability of certified organic citrus,
22 celery, leafy greens, strawberries and other

1 soft fruits. These are all agronomically
2 challenging high-value crops.

3 I ask you today to please keep in
4 mind the three E's of sustainability. One of
5 these E's is economics and specialty crops
6 grown organically have been a key factor in
7 the economic sustainability of many small
8 farms. The loss of economically sustainable
9 certified production threatens the survival of
10 these farms and will result in fewer acres in
11 certified organic production.

12 Many of these growers will choose
13 not to attempt to compete in the conventional
14 market and these acres may then be lost
15 entirely to agriculture because of the far
16 higher land value when developed for other
17 uses.

18 The removal of the listing for
19 ferric phosphate will place the U.S. organic
20 standards outside the international norm on
21 this material and can have only disruptive
22 effects and will place U.S. growers at a

1 disadvantage.

2 The so-called alternatives cited
3 in the various technical reports do not
4 reflect agricultural reality. There are no
5 field workers in strawberry fields or citrus
6 groves hand-picking snails and slugs at night
7 when the pest is active. A grower cannot
8 exclude a pest from their field if that pest
9 is already present and persistent in the soil
10 fostered by the important practices of cover
11 cropping, fallowing and conservation tillage.

12 The introduction of vertebrate
13 predators such as poultry violates every basic
14 food safety best practice and the soil
15 fertility and crop nutrient standard 203(c)(1)
16 and (2).

17 The report suggests chemical
18 killing solutions that may violate FIFRA if
19 they're not registered pesticides and more
20 importantly, many of the cited materials are
21 not allowed for this use in certified organic
22 agriculture.

1 Lastly, data reflecting large-
2 scale industrial dumping of EDTA in the past
3 is not germane to the agricultural product in
4 use at hand for your vote today.

5 Again, I'd like to encourage every
6 member of this board to affirm the Crops
7 Subcommittee recommendation and reject this
8 petition. The review process developed by the
9 Inerts Working Group and adopted unanimously
10 by the board will address the many allowed
11 synthetic List 4 inert ingredients with due
12 process and proper scrutiny. Thank you very
13 much.

14 MR. FELDMAN: Perfect timing,
15 thank you.

16 MR. MOORE: I tried.

17 MR. FELDMAN: Any questions from
18 the board? Thank you very much.

19 MR. MOORE: Thank you.

20 MR. FELDMAN: Okay, Moore and then
21 we will pick up with the next speaker which is
22 -- I'm sorry, Cam Wilson. We'll pick up with

1 Liane Jenkins after the break. So, thank you.

2 MR. WILSON: Good afternoon, board
3 members. My name is Cam Wilson. I work for
4 the company Neudorff and I'm here to also talk
5 about ferric phosphate. We support the Crops
6 Committee decision to reject the Steptoe
7 petition to de-list and to keep ferric
8 phosphate on the National List.

9 A very important point here is all
10 regulatory bodies worldwide agree on one
11 common fact, that ferric phosphate is the only
12 active ingredient in the Neudorff bait. Here
13 we know it as Sluggo. EDTA is not an active
14 ingredient nor has it ever been identified as
15 an active ingredient anywhere in the world.

16 A similar petition to the Steptoe
17 petition was filed in Europe by a competitor
18 who manufactures metaldehyde baits. Based on
19 this review of this similar document the
20 European authorities concluded the following.
21 And I'd like to quote something from their
22 report.

1 Ferric phosphate is regarded as
2 the active substance. Annex I listing is
3 therefore justified. The coal formulants EDTA
4 or EDDS have no molluscicidal impact.

5 In 2008 the EPA reviewed the
6 Sluggo registration, also confirmed that the
7 active ingredient is solely ferric phosphate.
8 It is not EDTA and it is not iron EDTA.

9 Neudorff has registered ferric
10 phosphate baits in over 30 countries worldwide
11 and the authorities responsible in every one
12 of these countries have determined that ferric
13 phosphate is the only active. None of these
14 countries have determined that the chelate is
15 active. EDTA has no molluscicidal activity
16 and EDTA is a List 4 inert which is compliant
17 with the current organic regulations.

18 It's important to point out that
19 iron phosphate and EDTA do not react in the
20 bait and do not form other substances.

21 Globally, organic certifiers recognize, such
22 as IFOAM, ECOCERT Canada, and OMRI allow

1 ferric phosphate and the Neudorff bait as
2 certified for organic production.

3 Recently it was suggested that
4 ferric phosphate slug and snail baits had
5 adverse effects on earthworms. Neudorff
6 carried out its own extensive studies that
7 determined that the ferric phosphate baits did
8 not harm earthworms. They contracted a third
9 party, Lures Report 2009, that confirmed the
10 same thing, that the ferric phosphate baits do
11 not harm earthworms. This study was done at
12 rates at 4 times the label rate just to
13 challenge the study.

14 In conclusion, we support the
15 rationale of the Crops Committee that ferric
16 phosphate must be considered independently.
17 And other ingredients and inert ingredients in
18 the ferric phosphate bait are currently
19 allowed under Section 205.601(m). The inert
20 ingredients will be addressed separately by
21 the Inerts Working Group.

22 We kindly ask that the NOSB keep

1 ferric phosphate on the National List and
2 remain harmonized with previous decisions and
3 organic certifications worldwide. U.S.
4 organic farmers need iron phosphate baits to
5 stay competitive with other countries. Thank
6 you and I'll leave myself for questions.

7 MR. FELDMAN: Thank you very much.
8 Any questions from the board? Thank you very
9 much.

10 MR. WILSON: Thank you.

11 MR. FELDMAN: So we're going to
12 take a break, folks, 15 minutes. Regroup here
13 at 3:45 on the nose and we will pick up with
14 the five remaining public commenters in the
15 Crops Subcommittee category. And then the
16 board will try to vote on the issues that we
17 figure we can vote on. So we'll let you know.

18 (Whereupon, the foregoing matter
19 went off the record at 3:29 p.m. and went back
20 on the record at 3:44 p.m.)

21 MR. FELDMAN: Okay, the meeting is
22 called to order. Thank you all. So, Liane,

1 go ahead. Thank you.

2 MS. JENKINS: Hello and thank you
3 for this opportunity to present to the board.
4 My name is Liane Jenkins, senior regulatory
5 and compliance specialist at Lonza. Lonza is
6 a technical manufacturer of metaldehyde which
7 is used in formulating a non-organic
8 molluscicide. Metaldehyde competes with
9 Neudorff's ferric phosphate slug and snail
10 killer. Lonza believes in fair competition
11 between these products based on performance.

12 Neudorff markets its ferric
13 phosphate products as organic. However, it
14 misleads organic producers and consumers as
15 ferric phosphate should not be considered
16 organic for three basic reasons.

17 One, ferric phosphate is not an
18 effective molluscicide without adding non-
19 organic EDTA to the formulation. Two, NOSB
20 previously denied organic listing for EDTA and
21 this decision should apply to ferric phosphate
22 products. And three, EDTA does not qualify

1 for organic status under the National Organics
2 Program. I'll briefly elaborate on each of
3 these points.

4 First, ferric phosphate by itself
5 is not an effective molluscicide. The
6 supplemental technical review and USDA's
7 Agriculture Research Service assessment
8 concluded that ferric phosphate by itself has
9 limited effect on snails and slugs. Ferric
10 phosphate must be combined with a chelating
11 agent to be used in controlling these pests.

12 EDTA is what makes the product
13 truly efficacious. EDTA acts as a synergist
14 and only the combination of ferric phosphate
15 and EDTA will there be a toxic effect on these
16 snails and slugs.

17 Neudorff's own patent documents
18 the need for EDTA in their ferric phosphate
19 slug control formulations. The patent shows
20 that ferric phosphate by itself has little to
21 no effect on the pest until combined with
22 EDTA. NOSB should conclude the combination of

1 ferric phosphate and EDTA is a complete active
2 system and this active system is not on the
3 National Organics List.

4 Secondly, NOSB previously assessed
5 sodium ferric hydroxyl EDTA and rejected the
6 petition due to EDTA's behavior in the
7 environment. This assessment stated that EDTA
8 use results in harmful movement of metals in
9 soil and river sediments. EDTA degrades
10 slowly in the environment and EDTA poses a
11 risk to human health.

12 The recent supplemental technical
13 review determined that EDTA used in ferric
14 phosphate molluscicides poses the same risk as
15 the EDTA in previously assessed sodium ferric
16 hydroxyl. Since NOP already assessed the risk
17 of EDTA and deemed it incompatible with
18 organic production then this existing decision
19 should be implemented for ferric phosphate
20 products containing EDTA.

21 Lastly, ferric phosphate as a
22 molluscicide contains the ingredient EDTA

1 which has already been determined to be
2 incompatible with organic production. That
3 means that current ferric phosphate products
4 are not truly organic. It misleads organic
5 producers and consumers of organically grown
6 food when ferric phosphate EDTA products are
7 offered as organic.

8 The organic consumer understands
9 that organically produced foods are not
10 treated with synthetic pesticides, the
11 ingredients do not cause harm to the
12 environment or to themselves or their
13 families. This is not the case when ferric
14 phosphate is used as a molluscicide due to the
15 EDTA in the formulation.

16 Ferric phosphate uses EDTA which
17 is known to have an adverse effect on the
18 environment and humans. Based on this, ferric
19 phosphate products are not a true organic
20 material. NOSB should recommend it to de-list
21 from the National Organics List and USDA's
22 National Organic Program should promptly take

1 the formal step to complete the de-listing.

2 Our written comments to NOSB
3 submitted last month stated the legal standard
4 for a material to be considered organic: 1) it
5 must not be harmful to human health or the
6 environment; 2) it must be necessary to
7 production because of the unavailability of a
8 wholly natural substitute; and 3) it must be
9 consistent with organic farming and handling.

10 As I've discussed, ferric
11 phosphate fails to meet the standard and hence
12 should not be considered organic. We urge the
13 board to vote to de-list ferric phosphate from
14 the National Organics List. Thank you very
15 much for your time and attention.

16 MR. FELDMAN: Thank you. Any
17 board questions? Thank you very much. Luis -
18 - can you pronounce your last name for me?

19 MR. MONEGE: You did it great.

20 MR. FELDMAN: Monege?

21 MR. MONEGE: Yes.

22 MR. FELDMAN: Okay, perfect.

1 Okay, and Marco Castor is on deck.

2 MR. MONEGE: Good afternoon. My
3 name is Luis Monege. I work with organic
4 banana growers in Peru including Colombia.
5 And I'm here today to speak on their behalf.

6 During the last 3 years the
7 organic banana industry in South America has
8 faced a new threat, the red rust, a small
9 insect that reproduces very fast and affects
10 the quality of the fruit, making it non-
11 exportable.

12 The insect damages the fruit when
13 the flowers are still closed. The control of
14 this pest is very difficult and most of the
15 available control alternative has proven to be
16 ineffective.

17 In 2010 on Esperanza Farm in
18 Ecuador, a 15 years old organic banana farm
19 was attacked for the first time by the red
20 rust thrips. The researchers tried all known
21 and reported alternatives such as cultural
22 practices, spraying repellants and approved

1 insecticides applications. Over 15 different
2 substances and treatments were tested.

3 Cultural practices and repellants
4 showed to have low or no effect at all over
5 the pest. Only two substances presented
6 acceptable control, pyrethrins and
7 lonchocarpus roots extract also called
8 rotenone. Both substances are needed in an
9 integrated pest management program in order to
10 avoid resistance issues and to control
11 outbreaks that range from slight to severe.
12 In case of a severe outbreak only rotenone has
13 proven effective.

14 Red rust affected Nueva Esperanza
15 Farm so seriously during 2010 and 2011 that
16 exportable fruit volume was lower on one-sixth
17 of its production, from half a million boxes
18 per year to only 75,000 boxes. This
19 illustrates the severe production decreases
20 that can occur without the use of rotenone,
21 making organic banana production unsustainable
22 and leading to the closing of hundreds of

1 farming operations.

2 Nueva Esperanza Farm is not an
3 isolated case. Thousands of small, medium and
4 large organic banana growers in Peru, Ecuador
5 and Colombia are facing similar situations.

6 The problem is becoming bigger and
7 it has the potential to seriously affect the
8 supply of organic bananas from those countries
9 which represent the 95 percent of the U.S.
10 market supply. Signatures of organic banana
11 growers organization representing more than
12 2,000 organic growers on more than 5,000
13 hectares of organic certified land from Peru,
14 Ecuador and Colombia were submitted to the
15 NOSB stating their opposition to the Crops
16 Subcommittee proposal to add rotenone to
17 205.602 as prohibited natural substance.

18 This is a clear and loud message,
19 an SOS message from the organic growers in
20 Latin America asking this board to keep the
21 use of this natural plant extract as allowed
22 in organic as it currently is. The future of

1 these organic growers and their families may
2 depend on your vote.

3 On the other hand, the organic
4 banana industry in South America is committed
5 on finding new and better alternatives for
6 integrated pest management but it requires
7 time to develop answers to the new challenges.

8 At the present time rotenone is
9 critical in organic banana production in South
10 America for red rust control. There are no
11 other alternatives available and the potential
12 damage of this pest is catastrophic. Please
13 on behalf of all those growers and those
14 families do not prohibit the use of rotenone
15 in organic agriculture. Thank you.

16 MR. FELDMAN: Thank you. Any
17 questions? Nick.

18 MR. MARAVELL: Yes. The damage
19 from the red rust thrip, does that lead to
20 damage -- is that cosmetic or does that lead
21 to spoilage of the fruit itself?

22 MR. MONEGE: It's cosmetic. It's

1 just the skin. If you look at the picture
2 it's just the discoloration on the skin of the
3 fruit. But it's -- there is no internal
4 damage of the fruit. But it is rejected by
5 the market.

6 MR. MARAVELL: Oh, of course. So
7 in other words if it went into storage and was
8 shipped, et cetera, the fruit would still be
9 intact but the customer wouldn't buy it.

10 MR. MONEGE: Correct.

11 MR. MARAVELL: Thank you.

12 MR. FELDMAN: Thank you. Mac.

13 MR. STONE: Luis, is there a
14 relationship to weather patterns or other
15 factors that create the thrips thrive in
16 certain microclimates rather than others? And
17 kind of related to that, you heard this
18 morning that this group is pretty hard on the
19 apple growers, the poultry growers are being -
20 - the methionine issue and so you don't take
21 this personally, but the 3-year sort of window
22 that was discussed earlier to find an

1 alternative, how scary is this 3-year
2 alternative to you?

3 MR. MONEGE: The most appropriate
4 answer I can give you right now is I don't
5 know. Three years from now sounds like a
6 whole bunch of time to develop alternatives
7 but the things in Latin America move a lot
8 slower than here.

9 We have been investigating into
10 the literature about alternatives and we know
11 that the spinosad is something that has some
12 control in other crops in other regions of the
13 world over thrips similar to the thrips that
14 cause the red rust. But we don't know what is
15 going to happen in a banana plantation in the
16 tropical part of the world.

17 And the first thing that we have
18 to do is try to convince the manufacturer of
19 the molecule to go to Latin America to each
20 individual country to get the registration so
21 we can use it. So, is 2016 a good period of
22 time? I don't know. But I will say that if

1 it is a period of time for you in the States
2 to get through the whole paperwork and all the
3 bureaucracy it could be even worse in Latin
4 America.

5 MR. FELDMAN: Any other questions?
6 John.

7 MR. FOSTER: Typically how many
8 applications in a given year would you apply
9 to the crop?

10 MR. MONEGE: Well, it depends
11 because it's not all year round, right? I
12 mean we have our seasons. It depends on the
13 rainfall during the year. But it could be
14 every other week in a short period of time and
15 alternate with pyrethrins. But worst case
16 scenario will be every other week.

17 MR. FOSTER: Quick clarification
18 on that. Every other week for how long? For
19 3 months or 6 months? I know it's going to
20 vary from time to time, just typically.

21 MR. MONEGE: I would say worst
22 case scenario would be every other week during

1 the whole year.

2 MR. FOSTER: Okay. Thanks.

3 MR. FELDMAN: Thank you, Luis.

4 Luis, what about spinosad? Is it registered
5 for use in any of those countries or have you
6 looked at it all --

7 MR. MONEGE: It's not.

8 MR. FELDMAN: -- for this
9 particular species of thrip?

10 MR. MONEGE: No, it's not
11 registered. We are very close to the
12 manufacturer of the Entrust which is the most
13 popular formulation of a spinosad. But they
14 are reluctant to go through Peru, Ecuador and
15 Colombia and get the registration. The
16 process of get registered in those countries
17 is really difficult.

18 MR. FELDMAN: Thank you.

19 Jennifer. One other question.

20 MS. TAYLOR: Thank you. What kind
21 of health issues have the workers reported in
22 regard to using this product?

1 MR. MONEGE: Well, thank you,
2 Jennifer. This is a natural plant extract,
3 right? This substance is coming from pre-
4 Hispanic times. Since then, since the Native
5 Americans use it for different purposes.

6 We have no registered events
7 related with human health. I mean, there is
8 no negative -- how you call it -- events I
9 will say regarding the use of rotenone. We
10 have no records in Latin America that
11 something like that happened.

12 MS. TAYLOR: But with the
13 knowledge now that, you know, it's a
14 possibility that it does happen in other
15 places --

16 MR. MONEGE: Well, yes.

17 MS. TAYLOR: -- how will you use
18 that knowledge with?

19 MR. MONEGE: Rudy Amador, my
20 colleague, is going to refer to that topic
21 specifically. I will prefer that he, as he is
22 the expert in that area he will answer that

1 question. Gracias.

2 MR. FELDMAN: Gracias. Marco and
3 Jack Manix on deck.

4 MR. AMADOR: Good afternoon. My
5 name is Rudy Amador. I'm replacing Marco who
6 unfortunately could not be here today.

7 I'm director of environmental
8 affairs for Dole in Latin America. We're
9 based in San Jose, Costa Rica. And we
10 appreciate the opportunity to come and speak
11 with you today. I will be speaking in favor
12 of maintaining rotenone on the NOP list for
13 some additional reasons as those given by
14 Luis.

15 I don't have a lot of time to go
16 through risk management theory but if you take
17 a look at this picture we can all agree that
18 it is dangerous to jump off a building. You
19 can have a problem with the cement down below.
20 If you don't manage the exposure side of the
21 risk management equation which is hopefully
22 you will put on a bungee cord which is UL-

1 tested or an air mattress down below. But
2 basically the point is, and it applies not
3 only to rotenone but anything, any pesticide
4 or actually any farm input is that you need to
5 manage the exposure side of the equation.

6 Out of the EPA's RED from 2007 I
7 extracted basically the two dangers of
8 rotenone. The first one being acute toxicity
9 for human health, especially inhalation, and
10 the second one being infested environment
11 being very highly toxic to marine organisms.
12 Again, we can manage that risk by decreasing
13 exposure.

14 This is to answer a little bit of
15 the questions that Luis got, this is the
16 personal protective equipment that's actually
17 on the rotenone label down in Peru. Also the
18 same engineering controls accepted by the RED
19 that the EPA put out in 2007 in order to
20 reduce that risk to acceptable levels. That's
21 regarding the health risk mitigation.

22 And on the environmental side

1 similarly there's good air culture practices
2 that are applied. In the case of rotenone
3 it's a liquid. It's applied only to the
4 pseudostem. This is the banana plant. There
5 is -- solids are not applied.

6 Also, it's applied in areas that,
7 since it's organic bananas, in very low
8 rainfall areas and therefore very difficult
9 for the product to get to waterways and
10 produce an environmental effect. In addition
11 to that obviously we do not allow or permit
12 applications directly to water or drainage
13 canals or anything similar to that.

14 I wanted to present very quickly a
15 label. This is a label, the registered
16 product in Peru. Four things to point out
17 here. In addition to the local registration
18 that is required for any product and which
19 takes time to achieve for any alternative that
20 is found in that time will need to transpire
21 into the countries where we operate in. The
22 label specifically says, again, those risk

1 mitigation measures, not contaminating water,
2 using the appropriate personal protective
3 equipment.

4 In addition, I wanted to point out
5 that there's other crops. We're here
6 representing organic bananas but there are
7 other crops that apparently are using this.
8 This label mentions asparagus, cotton and
9 citrus.

10 The other very important point to
11 discuss here is the issue on international
12 regulatory scenario with rotenone. As early
13 as 2009 the Codex delegation was not
14 supporting the deletion of rotenone from the
15 Codex Practices on Organic Agriculture. And
16 on the most latest Codex list rotenone is
17 listed.

18 What they did there after 4 years
19 of discussion was that they were concerned
20 about effect on aquatic organisms. So they
21 added a restriction which is the substance
22 should not be used in such a way as to prevent

1 -- or should be used in a way to prevent
2 flowing into waterways.

3 Similarly in the EU it is
4 registered and on the organic list. I'll end
5 up here, but very important for you to know
6 just 3 weeks ago here in the United States the
7 EPA decided not to revoke the tolerance
8 exemptions that it had proposed to do so
9 earlier in the year citing the need for
10 imported produce of this substance.

11 My time is over. I appreciate
12 your questions if you have any.

13 MR. FELDMAN: Thank you.
14 Questions? John.

15 MR. FOSTER: So, the -- as
16 probably everyone knows I kind of have mixed
17 emotions about this particular material. How
18 effective or how useful would it be to imagine
19 a world where rotenone was on 602 with some
20 limiting annotations that would minimize its
21 per-year usage or crop usage? You're here
22 representing bananas so if it were only used

1 on bananas, I don't know, twice a year and
2 only in rotation with other materials would
3 that be useful or not effective?

4 MR. AMADOR: I think we favor any
5 limitation that will minimize worker exposure
6 or exposure to the environment regarding good
7 agricultural practices. I do not think it's
8 a good agricultural practice to limit
9 applications to two times a year. That could
10 produce outbreaks that would have to be
11 controlled with other means that may not be as
12 effective as rotenone.

13 And in some cases as the graph
14 that Luis mentioned we basically had to --
15 were on the verge of closing the farm until we
16 found this alternative. So we do not favor
17 restricting frequency. We do favor good
18 agricultural practices and establishing
19 mechanisms in which to protect workers and
20 water which are the two main issues.

21 MR. FELDMAN: Yes, Mac.

22 MR. STONE: Is rotenone used on

1 any other tropical fruits?

2 MR. AMADOR: We are unfortunately
3 not very aware of that. We're basically
4 involved in the pineapple and banana business
5 out of Latin America. And I put that label
6 there on purpose because we found that one
7 that was listing those other four crops,
8 asparagus, cotton and there's one other there.
9 But we were unaware of the use.

10 We do know, as Luis mentioned in
11 the organic banana industry this could be
12 basically a catastrophe if growers are not
13 allowed to use it as we have not been able to
14 find an alternative. And we continue to look
15 for alternatives, by the way. There's not a
16 better way to look for alternatives than if
17 you have your farm infested with this and you
18 make a decision in a few weeks' time. And we
19 were basically weeks away from closing our
20 farm. We were able to determine that rotenone
21 was effective and began applying it and
22 teaching our growers on how to do so

1 appropriately.

2 MR. AUSTIN: In one of your slides
3 it showed the bunches, it showed the guy with
4 the PPE equipment and stuff and it looks like
5 your guys have been well trained. Go back one
6 now. That one.

7 Okay, so the method of application
8 is not to the entire plant specific but it's
9 to a very specific, it's to the fruit itself,
10 correct? Or am I misinterpreting what's
11 taking place there?

12 MR. AMADOR: Yes, it could be in
13 two different places. We call it the
14 pseudostem which is the trunk of the banana
15 plant. That is a place where this pest is
16 harbored. And also if you see infestation
17 around the fruit you need to do that too. So
18 in this case what the worker is doing is he's
19 lifting the plastic that's protecting the
20 fruit to make an application within the
21 developing banana stem.

22 Luis mentioned this but we've

1 tried oils. One of the things that you see
2 with this is that the other products do not
3 get into contact effectively with the insect
4 and has left only rotenone as the alternative.
5 But yes, the picture basically is showing
6 complete personal protective equipment which
7 is recommended by the product label and also
8 recommended as an engineering control by EPA.

9 MR. FELDMAN: Other questions?

10 Thank you very much. I'm sorry, Calvin. Go
11 ahead.

12 MR. WALKER: Could you share with
13 us your last statement about conditional
14 approval?

15 MR. AMADOR: Yes, I was trying to
16 make a reference to what happened in the Codex
17 process. You know, they went through 4 years
18 of discussions and finally they decided well,
19 we're going to put in a restriction referred
20 to water. And you know, just the thought that
21 you could have an approval for renewable with
22 a conditional use wording to improve good

1 agricultural practices, including worker
2 protection requirements and protecting
3 waterways.

4 MR. FELDMAN: Other questions?

5 Thank you. Thank you very much.

6 MR. AMADOR: You're welcome, thank
7 you.

8 MR. FELDMAN: So Jack Manix and
9 Skip Paul is up on deck. Thank you.

10 MR. MANIX: Thank you. I'd like
11 to thank you for allowing me the opportunity
12 to get my 2 cents in on biodegradable mulch,
13 specifically BioTelo. My name is Jack Manix
14 and I'm a certified organic grower. I've
15 traveled from downtown East Dummerston,
16 Vermont to Providence on a beautiful sunny day
17 to try to help persuade you to approve this
18 product which I think is essential for organic
19 growers.

20 In 1993 14 towns in our county
21 tried to site a landfill and dump on our farm
22 and a KOA campground next to us and take some

1 of the land by eminent domain. While I'm
2 talking to you I'm going to pass around this
3 highly offensive picture. I'm glad to see
4 there's no young adults on the board. It's a
5 dumpster full of black plastic.

6 And on our farm we eventually
7 fought that battle from 1993 to 1996 and won
8 the battle. And they gave up the siting of
9 the landfill. So the results of that is that
10 I hate trash. And on our farm which is a
11 family farm, been in my family since 1770 we
12 do everything possible to reduce, reuse and
13 recycle.

14 Right now I produce about three
15 dumpsters' worth of black plastic. I have one
16 sitting on our property right now that's due
17 to be picked up tomorrow morning. It's
18 embarrassing and I think as an organic grower
19 where we try to do what's right for the Earth
20 it makes it difficult to have that as part of
21 our operation.

22 But we need to use mulch plastics.

1 We've used black plastic because, well, the
2 global climate extremes have been a large
3 reason. This past summer the extreme heat has
4 kept, you know, we need that to retain soil
5 moisture. When it's raining we need it to
6 drain the moisture off the crops so that the
7 roots don't get too soggy. So we've tried
8 using hay and straw mulches and we do use a
9 lot of those also but they're costly, they're
10 difficult to apply mechanically and in the
11 long run small growers and large growers alike
12 find the costs involved with mulches worth the
13 effort in producing a product that you can
14 sell competitively, organically to families
15 and neighbors.

16 I'm a member of NOFA Vermont board
17 of directors, the Vermont Vegetable and Berry
18 Growers Association, Vermont Association of
19 Professional Horticulturalists, the Vermont
20 State Farm Bureau. And I come in contact with
21 a lot of young growers. And one of the
22 previous speakers mentioned that we're losing

1 organic growers and yes, we are losing some
2 organic growers. I feel a large part of that
3 is because we don't market organics nearly
4 well enough. The only time I see organics is
5 in magazines that are directed toward organic
6 people. I don't see it on Fox News and I
7 don't see it in a lot of periodicals that we
8 should be approaching for our market.

9 But one of the reasons we're also
10 losing organic growers is because they don't
11 understand the logic of not being able to use
12 these BioTelo mulches. We keep trying to
13 reinvent the wheel. They're being used in
14 Europe and Canada for a long time. I know a
15 lot of growers in New York State and
16 Massachusetts that don't become certified
17 because they need to use these organic
18 mulches.

19 On our farm it's really essential
20 for reducing the label and the use of fossil
21 fuels. So I urge you to consider the approval
22 of these organic mulches for organic farmers.

1 Thank you.

2 MR. FELDMAN: Thank you. Any
3 questions? Thanks for coming down on a
4 beautiful day.

5 MR. MANIX: Thank you.

6 MR. FELDMAN: Skip Paul, please.

7 MR. PAUL: I wanted to thank the
8 board for allowing a few farmers to get away
9 from picking up plastic mulch and come down
10 here and talk to you about what we really want
11 to do is harrow in BioTelo mulch.

12 My name is Skip Paul and I'm from
13 -- actually a Rhode Island farmer. I'm from
14 Little Compton, Rhode Island which is just as
15 the crow flies about 50 miles down that way.
16 Wishing Stone Farm has been growing
17 organically since 1982. We were one of the
18 first organic farms certified in Rhode Island.
19 Right now our acreage is over 38 acres
20 representing seven small diversified farms
21 near our home farm.

22 To manage these farms

1 successfully, and some of them are over 3
2 miles away, we have come to rely on plastic
3 mulch to control weeds, to retain moisture and
4 manage water efficiency in our crops, and
5 three, to give and add heat to -- as in soil-
6 warming for early crops and even late-season
7 crops. Quite often we'll put broccoli late,
8 or hail Mary broccoli we call it on plastic
9 mulch just because it actually gives us the
10 heat to drive it into December.

11 At this stage in our evolution we
12 are covering I'm ashamed to say over 40
13 percent of our crop lands with plastic mulch
14 of some form or another. My family's sole
15 income comes from farming so our marketing is
16 30 percent farmers markets, 20 percent
17 wholesale and 50 percent CSA which represents
18 over 385 families some of which have been with
19 us for over 20 years.

20 We are year-round growers which
21 means we grow and cultivate crops over 365
22 days a year. We are constantly in

1 communication with our patrons and develop
2 deep relationships with not only our CSA
3 members which we have contact with longer but
4 with over 3,000 farmers market patrons which
5 visit us weekly at our farmers market in
6 Providence.

7 We are continually in
8 communication with our patrons about issues
9 facing us as farmers, how to do a better job,
10 but also issues facing us as fellow human
11 beings on this planet. Since the arrival of
12 BioTelo on the ag stage more and more
13 conversations have spontaneously developed
14 around what it is and how does it work.

15 An earlier farmer that came up,
16 Paul and Sandy Arnold, have been valuable
17 pioneers in working and evaluating the
18 BioTelo's effectiveness and biological safety
19 of this product, not to mention reams of
20 papers and articles that have been penned in
21 Europe and Canada and elsewhere extolling its
22 biological virtues.

1 These conversations are going on
2 with our CSA members and farmers market
3 customers too. As they are getting better and
4 better informed about the safety and
5 effectiveness of BioTelo they are asking the
6 same question as we farmers are. What is the
7 biological rationale of putting tons of oil-
8 based completely synthetic plastic into our
9 nation's landfills when we could be using
10 BioTelo?

11 I feel BioTelo will save us energy
12 because it's less tractors work going over,
13 taking up plastic and doing other things. It
14 will keep the fields adjacent to us cleaner
15 and more sanitary. It will help us get cover
16 crops more quickly and more efficiently,
17 capturing nutrients left over from other crops
18 and helping keep disease pressure down by more
19 quickly being able to destroy diseased crops.
20 This was particularly important this year with
21 late blight on tomatoes and other things.

22 Pulling black plastic up, you have

1 to remove the plants by hand first. You can't
2 -- no machine will take that up and so there's
3 a lot more labor in pulling up black plastic
4 mulch.

5 This issue has come to the
6 forefront at our farm and has now gained such
7 an importance that our members who are
8 informed about this subject are urging us to
9 drop certification on CSA plastic mulch
10 acreage so we can use BioTelo and be more
11 biologically responsible.

12 MR. FELDMAN: Thank you very much.
13 Any questions from the board? Well -- oh, I'm
14 sorry. Go ahead.

15 MR. FOSTER: How have you found
16 its -- you know what, never mind. It's not
17 going to be a relevant question for you.

18 MR. FELDMAN: Okay. Thank you so
19 much for participating in this process.

20 MR. PAUL: Thank you.

21 MR. FELDMAN: And we thank
22 everybody that participated in the comment

1 process today, public comment process.

2 We will now try to segue way in
3 the next half hour or so to some of the votes.
4 The Crops Committee came together briefly to
5 get a sense of whether people felt comfortable
6 voting on some of these materials. And we
7 decided, or I didn't hear any objections to
8 moving ahead with at least some of these votes
9 and see how far we get.

10 It may be after we heard the
11 rotenone discussion we should discuss that
12 more? It's up to you all. But we could start
13 at the top of the list, ferric phosphate, and
14 work our way down if that's okay. Any
15 objections to doing that? Okay. Okay, thank
16 you.

17 CHAIRPERSON FLAMM: So you're
18 prepared to move forward on ferric phosphate.
19 Is there a motion? And I need something in
20 writing so I can make sure that the motion is
21 in order. Okay, thank you. I've got it.

22 You wish to proceed with making a

1 motion?

2 MS. BECK: All right, so I'd like
3 to make the motion to remove ferric phosphate
4 from Section 205.601(h).

5 CHAIRPERSON FLAMM: Is there a
6 second to the motion?

7 MR. BONDERA: I'll second that.

8 CHAIRPERSON FLAMM: The motion has
9 been seconded to remove ferric phosphate from
10 Section 205.601(h). Discussion? Zea?

11 MS. SONNABEND: Thank you, Barry.
12 I just want to make a very brief
13 clarification. I hope everyone realizes this,
14 but a vote yes will remove it from the list
15 and a vote no will leave it on the list. It's
16 a little backwards for some of our other
17 votes.

18 CHAIRPERSON FLAMM: Any other
19 discussion, comments? If not we'll proceed
20 with a vote starting with Jay.

21 MR. FELDMAN: Yes.

22 MS. SONNABEND: No.

1 MR. STONE: No, sir.

2 CHAIRPERSON FLAMM: No.

3 MS. FAVRE: No.

4 MR. AUSTIN: No.

5 MS. BECK: No.

6 MS. RICHARDSON: No.

7 MR. FOSTER: No.

8 MR. DICKSON: No.

9 MS. FULWIDER: No.

10 MR. WALKER: No.

11 MR. BONDERA: Yes.

12 MS. TAYLOR: Yes.

13 MR. MARAVELL: No.

14 CHAIRPERSON FLAMM: The vote is 3
15 yeses, 12 nos. The motion fails to pass.

16 Does the Crops Committee have
17 another proposal that they wish to move on?

18 MR. FELDMAN: Proposal to the
19 petition on oxidized lignite which you'll
20 state I guess, is that right?

21 MS. SONNABEND: So the oxidized
22 lignite recommendation is the same as in the

1 posted document, no changes. And once again -
2 - well --

3 CHAIRPERSON FLAMM: Zea, please
4 just state the motion and we'll get discussion
5 afterward.

6 MS. SONNABEND: Yes, I'm waiting
7 for Michelle to put it up. Okay. To add --
8 okay.

9 This has two motions, a
10 classification motion and a listing motion.
11 The classification motion is that humic acids
12 that are hydrogen peroxide-extracted are
13 synthetic.

14 MR. FOSTER: I'll second that.

15 CHAIRPERSON FLAMM: Okay, the
16 motion has been made and seconded to classify
17 hydrogen peroxide-extracted as synthetic. We
18 need to take a vote on this. I'll ask if
19 there is any discussion. Any discussion on
20 classification of this material?

21 We never did the beginning of your
22 committee. You were supposed to do the -- so

1 we've got a policeman in the court. So we
2 apologize for not doing that earlier but I
3 think for simplicity I'll just do it now and
4 ask if anybody has anything that they want to
5 reveal or discuss or ask an opinion on in
6 terms of their ability to vote on this and any
7 other materials we'll be voting on. And I
8 want to make this retrospective if there was
9 anything regarding ferric phosphate. I
10 apologize. Jay.

11 MR. FELDMAN: I just want to share
12 with the board what I shared with the program.
13 I'll just read what I sent the program. I do
14 not believe that I have any conflicts of
15 interest regarding upcoming votes of the NOSB.
16 However, the organization that employs me may
17 have members who use or may use petitioned
18 materials under consideration by the NOSB.
19 Similarly, the organization I work for may
20 receive contributions to support the
21 organizations national forum from companies
22 that use or may use materials before the NOSB.

1 CHAIRPERSON FLAMM: Okay. Jay has
2 disclosed that interest. Is there any comment
3 by anyone on that? Including if the program
4 feels that they wish to speak up. If not we
5 can move on to Zea.

6 MS. SONNABEND: I wish to make a
7 voluntary disclosure of my interest also. I
8 do not believe I have any conflicts with any
9 of the items on the agenda and have asked the
10 Department for that ruling and they have said
11 I do not need to recuse myself.

12 However, I am a farmer who
13 certainly uses things with inert ingredients
14 in it and work for an organization that is a
15 certifier that may certify anything that gets
16 approved for the National List as well as
17 being affiliated with three other non-profit
18 entities who may or may not submit comments on
19 anything at any particular time.

20 I get no financial gain directly
21 from any of those activities except hopefully
22 farming sometime. But not from direct use of

1 the products on the list.

2 CHAIRPERSON FLAMM: Board members,
3 you've heard the disclosure by Zea. Any
4 thoughts? Any comments by anybody including
5 the program? And Zea has already indicated
6 that she's run that by the program. We'll
7 move on. John?

8 MR. FOSTER: So I too, a number of
9 the contract growers -- this will be true for
10 handlers too -- may use some of these
11 materials. I don't -- may want to use them.
12 I'm sure some will. But I don't have any
13 direct financial gain from any of the
14 companies involved.

15 I'm sure they're somewhere in our
16 supply -- in Earthbound's supply chain but --
17 or going to be, but that's the limit of it.
18 And that's what I declared in writing to the
19 program, I don't know, whenever it was, a
20 couple of weeks ago.

21 CHAIRPERSON FLAMM: Thank you for
22 that, John. Any comments on John's disclosure

1 of his activities which was previously
2 disclosed? I don't believe any comment from
3 the program. Any other? If not we can -- I
4 think we can proceed and thank you, Tracy, for
5 being our watchdog. Thank you.

6 I believe -- I'd ask whether or
7 not there was any discussion on the
8 classification of this material. Hearing none
9 I believe we can begin with the voting I think
10 starting with Zea.

11 MS. SONNABEND: Yes, oxidized
12 lignite is synthetic.

13 MR. STONE: Yes, sir.

14 MS. FULWIDER: Yes.

15 MR. AUSTIN: Yes.

16 MS. FAVRE: Yes.

17 MS. BECK: Yes.

18 MR. DICKSON: Yes.

19 MR. FOSTER: Yes.

20 MS. RICHARDSON: Yes.

21 MR. WALKER: Yes.

22 MR. BONDERA: Yes.

1 MS. TAYLOR: Yes.

2 MR. MARAVELL: Yes.

3 MR. FELDMAN: Yes.

4 CHAIRPERSON FLAMM: And the chair
5 votes yes. Now we can entertain a motion on
6 the listing of the material.

7 MS. SONNABEND: The motion is to
8 change the listing in 7 C.F.R. 205.601(j)(3)
9 to humic acids, naturally occurring deposits,
10 water, alkali and hydrogen peroxide extracts
11 only to expire in 2017.

12 CHAIRPERSON FLAMM: All right. Do
13 we have a second to that motion?

14 MR. FELDMAN: Second.

15 CHAIRPERSON FLAMM: We have a
16 second to the motion to change the listing in
17 7 C.F.R. 205.601(3) to humic acids, naturally
18 occurring deposits, water, alkali and hydrogen
19 peroxide extracts only to expire in 2017.
20 Discussion on the motion?

21 MS. BAILEY: Excuse me -- thanks.
22 So just a clarification. So the annotation

1 that you have there says to expire in 2017.
2 We would advocate that you put the actual date
3 for sunset in 2017 there so that it says
4 October, I believe it's October 21, 2017.

5 MS. SONNABEND: Oh, I accept that
6 amendment as the motion-maker. Does the
7 second accept it?

8 MR. FELDMAN: Yes, he does.

9 CHAIRPERSON FLAMM: We have a
10 proposed amendment to the motion. Could you -
11 - is it acceptable to the person making the
12 motion and the second?

13 MS. SONNABEND: Yes.

14 MR. FELDMAN: Yes.

15 CHAIRPERSON FLAMM: Okay. Could
16 you please -- as the originator of the
17 original motion would you state the -- restate
18 the amended motion? Oh, okay.

19 MS. BROWN-ROSEN: Sorry. Yes, the
20 previous sunset date in the proposed rule was
21 October 21, 2017 but when we issued the final
22 rule for sunset 2012 the sunset date for the

1 current listing for humic acids was moved up
2 to June 27, 2017. So June 27 would be the
3 date that we would recommend to include.
4 Sorry for the confusion.

5 MS. SONNABEND: June what?

6 MS. BROWN-ROSEN: Twenty-seven.

7 CHAIRPERSON FLAMM: Okay. Just so
8 we get the right date.

9 MS. SONNABEND: So, the full
10 motion is to change the listing in 7 C.F.R.
11 205.601(j)(3) to humic acids, naturally
12 occurring deposits, water, alkali and hydrogen
13 peroxide extracts only to expire on June 27,
14 2017.

15 CHAIRPERSON FLAMM: And that
16 change of date is accepted by the person
17 seconding the motion?

18 MR. FELDMAN: Yes.

19 CHAIRPERSON FLAMM: Okay. So the
20 motion was amended to change the date to June
21 22 -- 27, 2017. Discussion on the motion?
22 Any discussion on the motion? If not we can

1 proceed with the vote beginning with Mac.

2 MR. STONE: Yes, sir.

3 MS. FULWIDER: Yes.

4 MR. AUSTIN: Yes.

5 MS. FAVRE: Yes.

6 MS. BECK: Yes.

7 MR. FOSTER: Yes.

8 MR. DICKSON: Yes.

9 MS. RICHARDSON: Yes.

10 MR. WALKER: No.

11 MR. BONDERA: No.

12 MS. TAYLOR: No.

13 MR. MARAVELL: No.

14 MR. FELDMAN: No.

15 MS. SONNABEND: No.

16 CHAIRPERSON FLAMM: And the chair

17 votes no. So we've got to do a tally here.

18 The vote was 8 yes, 7 no. The motion failed.

19 Jay, do you have another?

20 MR. FELDMAN: The next proposal is

21 the petition on PGML.

22 MR. BONDERA: So I would like to

1 suggest that we entertain two motions on PGML.
2 And the first one is classification and I
3 would like to myself make that motion that
4 PGML is synthetic.

5 MR. FELDMAN: Second.

6 CHAIRPERSON FLAMM: I don't have
7 the material here. The motion has been made
8 and seconded to classify PGML as a synthetic.
9 Is there discussion on the motion? Hearing no
10 need for further discussion we can begin the
11 voting on the classification of PGML beginning
12 with Wendy.

13 MS. FULWIDER: Yes.

14 MR. AUSTIN: Yes.

15 MS. FAVRE: Yes.

16 MS. BECK: Yes.

17 MR. FOSTER: Yes.

18 MR. DICKSON: Yes.

19 MS. RICHARDSON: Yes.

20 MR. WALKER: Yes.

21 MR. BONDERA: Yes.

22 MS. TAYLOR: Yes.

1 MR. MARAVELL: Yes.

2 MR. FELDMAN: Yes.

3 MS. SONNABEND: Yes.

4 MR. STONE: Yes, sir.

5 CHAIRPERSON FLAMM: And the chair
6 votes yes. I believe the count is 15 yes,
7 zero no. The motion passes. Do we have a
8 motion on the listing of this material? The
9 PGML.

10 MR. BONDERA: Yes, thank you. I
11 would like to make that motion to add PGML to
12 the National List 205.601(e) as an acaricide.

13 CHAIRPERSON FLAMM: Do we have a
14 second to the motion?

15 MR. FOSTER: I'll second.

16 CHAIRPERSON FLAMM: Who seconded?
17 Okay, John. It's been moved and seconded to
18 add PGML to the National List 205.601(e) as an
19 acaricide. Discussion? Any discussion on the
20 motion? Harold.

21 MR. AUSTIN: Yes, I think I would
22 like to just mention that, you know, this is

1 a material as we look to vote on it. A lot of
2 the materials that we look at deal with
3 essentiality and we have to discern whether or
4 not the other materials that are listed as
5 alternative materials are in fact truly what
6 they're claimed to be. Are they actually
7 alternative, are they effective alternative
8 materials. Do they have the proper efficacy?
9 Do they have the proper control? Are they as
10 environmentally friendly as what we think they
11 are?

12 I look at this material, I look at
13 the alternatives that have been listed and I
14 have some of the same concerns with those
15 materials as some of the board members have
16 with this particular material, whether to list
17 it or not list it as far as their impact on
18 the environment, their impact on the
19 predacious insects.

20 I'm going to vote in favor of this
21 but because I think the organic growers need
22 a material that is effective at a time when

1 it's needed. A lot of the products that are
2 out there right now are not immediately
3 effective if a grower finds himself into a
4 mite situation, a flare-up, there's not viable
5 materials out there, especially in tree fruit
6 and stuff that will really bail them out of a
7 hot spot if they really, truly get into a
8 difficult time. So being able to take and put
9 a material, another tool out there that our
10 organic growers could utilize, I think there's
11 value to that.

12 CHAIRPERSON FLAMM: Further
13 comments, discussion on this material? PGML.
14 John?

15 MR. FOSTER: I would add to that -
16 - I agree with Harold -- add to that that I
17 continue to have faith in the expectation that
18 205.206 and that kind of mandatory IPM system
19 would necessitate a pretty good look at an
20 appropriate record that other practices, other
21 alternatives have been ineffective. And I
22 want to keep driving that point home because

1 I don't think it hits the discussion table
2 often enough. So I continue to have faith in
3 that process and the rest of the regulation
4 and how it's implemented. And I think in that
5 context this is an appropriate material.

6 CHAIRPERSON FLAMM: Further
7 discussion? Mac?

8 MR. STONE: Just as a tally-taker
9 helping Wendy to make sure, remind everybody
10 that there's no rush to convey your vote so
11 that we can accurately tally. So when it
12 comes your turn there's no rush to vote.

13 CHAIRPERSON FLAMM: Any further
14 discussion on this proposed -- this petition
15 material to be listed? All right, I believe
16 we can then proceed with a vote starting with
17 Harold.

18 MR. AUSTIN: Yes.

19 MS. FAVRE: No.

20 MS. BECK: Yes.

21 MR. FOSTER: Yes.

22 MR. DICKSON: Yes.

1 MS. RICHARDSON: No.

2 MR. WALKER: No.

3 MR. BONDERA: No.

4 MS. TAYLOR: No.

5 MR. MARAVELL: No.

6 MR. FELDMAN: No.

7 MS. SONNABEND: No.

8 MR. STONE: No, sir.

9 CHAIRPERSON FLAMM: And the chair
10 votes no. Oh, I did it. You're next,
11 Jennifer. Okay, I retract my vote.

12 MS. FULWIDER: I vote yes.

13 CHAIRPERSON FLAMM: The chair
14 votes no. The vote is 5 yes, 10 nos. The
15 motion fails. Does the Crops Committee have
16 another proposal for consideration?

17 MR. FELDMAN: The review of inert
18 ingredients.

19 MS. SONNABEND: On this one it's a
20 little different than a petitioned item or
21 anything because what -- the reason that we
22 need a vote is to move forward with the whole

1 procedure. And so when we're voting for this
2 we're not voting for exactly what's in each
3 group of inerts or exactly what regulatory
4 language is going to be or be locked into the
5 details, but just to set in motion the things
6 we need to set in motion in order for the
7 procedure to move forward.

8 And so therefore the motion is the
9 whole procedure but in terms of making it
10 feasible for the voting sheet we're going to
11 just say the motion to adopt the proposed
12 Policy and Procedure Proposal on other inert
13 ingredients in pesticide formulations on the
14 National List.

15 MR. FELDMAN: I'll second.

16 CHAIRPERSON FLAMM: There's -- the
17 motion has been made and seconded to adopt the
18 proposed Policy and Procedures Proposal on
19 other inert ingredients in pesticide
20 formulation on the National List which is I
21 think we should reference the document or the
22 date some way.

1 MS. SONNABEND: Well, that's the
2 title of the document that I read into the
3 motion.

4 CHAIRPERSON FLAMM: Okay, this has
5 been read into the record and it was posted on
6 -- properly posted. Is there any question by
7 the board about understanding what the motion
8 is and what we're voting on? If there's any
9 doubt please speak up, otherwise I'll proceed
10 with the discussion.

11 Any discussion on this document?
12 Procedural document. Any discussion? Hearing
13 none I believe we should proceed with a vote.
14 I think, Tracy, you are first off.

15 MS. FAVRE: Yes.

16 MS. BECK: Yes.

17 MR. FOSTER: Yes.

18 MR. DICKSON: Yes.

19 MS. RICHARDSON: Yes.

20 MR. WALKER: Yes.

21 MR. BONDERA: Yes.

22 MS. TAYLOR: Yes.

1 MR. MARAVELL: Yes.

2 MR. FELDMAN: Yea.

3 MS. SONNABEND: Yes.

4 MR. STONE: Yes, sir.

5 CHAIRPERSON FLAMM: Wendy?

6 MS. FULWIDER: Yes.

7 MR. AUSTIN: Yes.

8 CHAIRPERSON FLAMM: And the chair
9 votes yes. Fifteen yeses, zero nos, the
10 motion passes. Does the Crops Committee have
11 any other proposals they wish to be considered
12 at this time?

13 MR. FELDMAN: I'd like to skip to
14 sulfuric acid and do that one. So John, I
15 turn that over to you.

16 MR. FOSTER: We have two motions
17 regarding sulfuric acid. The first one will
18 be a classification motion. The motion would
19 be to consider sulfuric acid as synthetic. I
20 would move that.

21 MR. BONDERA: I'll second that.

22 CHAIRPERSON FLAMM: It's been

1 moved and seconded to classify -- read what
2 you said -- sulfuric acid as synthetic.
3 Discussion on the motion? Hearing none we can
4 proceed with a vote beginning with Carmela.

5 MS. BECK: Yes.

6 MR. FOSTER: Yes.

7 MR. DICKSON: Yes.

8 MS. RICHARDSON: Yes.

9 MR. WALKER: Yes.

10 MR. BONDERA: Yes.

11 MS. TAYLOR: Yes.

12 MR. MARAVELL: Yes.

13 MR. FELDMAN: Yes.

14 MS. SONNABEND: Yes.

15 MR. STONE: Yes, sir.

16 MS. FULWIDER: Yes.

17 MR. AUSTIN: Yes.

18 MS. FAVRE: Yes.

19 CHAIRPERSON FLAMM: And the chair
20 votes yes. I believe we have 15 yeses and
21 zero nos. We can proceed with a motion on the
22 listing of this material.

1 MR. FOSTER: The second of two
2 motions, that would be to list on 205.601(j)
3 sulfuric acid for stabilization of digested
4 poultry manure to a pH under 4.5 but not below
5 3.5. I would so move.

6 CHAIRPERSON FLAMM: Do we have a
7 second to that motion?

8 MR. AUSTIN: Second it.

9 CHAIRPERSON FLAMM: We have a
10 motion which has been seconded to list on
11 205.601 sulfuric acid for stabilization of
12 digested poultry manure to a pH under 4.5 but
13 not below 3.5. Discussion on the motion?
14 Hearing no desire for discussion we can
15 proceed with a vote and I believe, John,
16 you're the one to start it off.

17 MR. FOSTER: Yes.

18 MR. DICKSON: Yes.

19 MS. RICHARDSON: No.

20 MR. WALKER: No.

21 MR. BONDERA: No.

22 MS. TAYLOR: No.

1 MR. MARAVELL: No.

2 MR. FELDMAN: No.

3 MS. SONNABEND: No.

4 MR. STONE: No, sir.

5 MS. FULWIDER: No.

6 MR. AUSTIN: Yes.

7 MS. FAVRE: No.

8 MS. BECK: No.

9 CHAIRPERSON FLAMM: And the chair
10 votes no. Three yeses, twelve nos. The
11 motion failed.

12 MR. FELDMAN: Mr. Chair, unless
13 there are any objections from the subcommittee
14 I'd like to propose postponing the additional
15 two material petitions until -- or motions and
16 petitions until Thursday.

17 CHAIRPERSON FLAMM: No objection?
18 The remaining two proposals will be dealt with
19 on Thursday. I believe that concludes the
20 Crops Subcommittee work and we can move
21 directly to Materials Committee.

22 Jennifer, if you would like to

1 take over. The gavel is passed to you for
2 now. Symbolically, that's okay. Or you could
3 have it for real.

4 MS. TAYLOR: Audience, please sit
5 down. Please sit down. We're ready now.
6 Thank you. Thank you for your patience.

7 I thought it would be good to
8 start with some of the public comments, the
9 written comments that we have received.

10 MS. ARSENAULT: Could you move
11 your mike closer?

12 MS. TAYLOR: I thought it would be
13 good to start with some of the public
14 comments, our written comments that we
15 received in the general docket that are often
16 foundational to the purposes of many of us
17 here as well as the proposal that we will
18 introduce.

19 I support having in place the
20 strongest possible standards for organic foods
21 products to protect consumers, to help protect
22 the resources of our planet and to keep us all

1 safe. Having choices is as important to
2 consumers as keeping our food supply safe and
3 it is information, that is transparency, that
4 helps -- can we move to the first slide
5 please, Michelle? Thank you.

6 I support having in place the
7 strongest possible standards for organic
8 foods, products to protect consumers, to help
9 protect the resources of our planet, and to
10 keep us all safe. Having choices is as
11 important to consumers as keeping our food
12 supply safe and it is information, that is
13 transparency, that helps assure both.

14 Please consider chemical additives
15 and processes that harm people, animals and
16 the environment as the enemy and preserve the
17 organic methods of farming, production and
18 living as safeguards of our society by
19 preventing these substances and methods from
20 infiltrating our atmosphere, water, soil and
21 food.

22 Another written comment. Please

1 keep the purity of the organic label and do
2 not allow the proposed or any other synthetic
3 substances under the organic label. Please
4 keep synthetics and chemicals out of organic
5 food and products for the good of all.

6 Another written comment from the
7 general docket. Paying a premium for an
8 honest product is okay with me, but if the
9 organic seal has been compromised in my eyes
10 I see no point in preferably selecting those
11 products.

12 Another comment. Please keep
13 organics safe.

14 The members of the National
15 Organic Standards Board Materials Subcommittee
16 include Jay Feldman who is also chair of the
17 Crops Committee, Calvin Walker who is also co-
18 chair of the Policy Development Subcommittee,
19 Wendy Fulwider, co-chair -- I'm sorry, chair
20 of the Livestock Subcommittee, John Foster who
21 chairs the Handling Committee -- I'm saying
22 committee and I mean subcommittee, okay? Zea

1 Sonnabend who is co-chair of this committee,
2 the Materials Committee, as well as the chair
3 of the GMO Ad Hoc Subcommittee and myself.

4 The document that you have before
5 you represents the board's research priorities
6 for the year 2013. And Zea and Calvin as
7 leaders of -- key people and leaders in the
8 development of the document will discuss the
9 comments that we received and also the impact,
10 the potential impact that we see that this
11 document will have on the organic research
12 agenda.

13 MS. SONNABEND: Should we go ahead
14 and do it without slides? Because I believe
15 Calvin and I each have a copy of it and we
16 could just read through it. It's only six
17 slides. It could be short.

18 Okay, our slides are to summarize
19 the public comment that we received on the
20 research priorities. I want to make clear
21 that in our research priorities framework we
22 stated that the priorities would be collected

1 over the past year and presented each fall at
2 each fall NOSB meeting.

3 So you will not see anything in
4 our posted document of research questions that
5 arise during this meeting such as
6 biodegradable mulch. Those will be in our
7 next cycle of research priorities. But what
8 is on this research priorities collection is
9 the ones from the last two NOSB meetings
10 roughly, priorities that have been collected
11 over that time.

12 The criteria for research topics
13 are -- there we go. So the second slide.
14 Well, it's on there, it's not on there. Okay,
15 the criteria for deciding what research topics
16 to include, and I've shortened these.

17 Everyone can read them in our posted document,
18 but topics that are persistent and chronic,
19 challenging, controversial, nebulous, lacking
20 in primary research and relevant to assessing
21 the need for alternative cultural, biological
22 and mechanical controls to materials on the

1 National List.

2 Okay, Calvin, do you want to talk
3 about the public comment? You want me to keep
4 going? Are you sure? All right.

5 This is the public comments that
6 we received. We received 11 commenters and
7 this is in the regulations.gov docket. All of
8 them supported the research document. None of
9 them were opposed. Some of them had concerns
10 and suggestions. Then in addition after the
11 docket comment period closed we received two
12 more directly which we will talk about at the
13 end.

14 Okay, so these are the main points
15 that were brought up in the comments.
16 Research needs for organic farmers and
17 processors continue to be significant.
18 Feedback to researchers, research institutions
19 and particularly the USDA, NIFA and the ARS on
20 needs of organic sector is incredibly
21 valuable.

22 Two, methionine should be listed

1 as a priority research topic. However, we do
2 not support the inclusion of animal byproducts
3 as an acceptable alternative. We request this
4 focus area be removed.

5 Three, methionine research should
6 focus on the viability of potential
7 alternatives and explore plant materials,
8 products of microbial fermentation, marine
9 species, insects, worms and other
10 invertebrates.

11 Four, organic farmers are
12 innovators and solutions developed on farms do
13 not always fit in the typical research
14 framework. And research on whole farm
15 management methods progresses from farms to
16 research institutions and back to farms these
17 systems questions need to be integrated into
18 research proposals.

19 Five, the NOSB needs to carefully
20 consider evidence available in the independent
21 scientific literature.

22 Six, proposed areas of research

1 must be challenging and based on controversial
2 NOSB decisions is okay. However, research
3 needs that is persistent, lacking in primary
4 research and difficult to identify needs to be
5 a priority. For example, improved organic
6 weed control methods. We encourage concerned
7 citizens to include their own comments on
8 areas where they think organic production
9 needs further research.

10 Seven, research projects that
11 focus on the integration of farm systems are
12 extremely important because much research on
13 farm systems has tended to focus on isolated
14 aspects of farming practice. This methodology
15 limits the scope of the research question so
16 the results can be more easily analyzed and
17 understood. However, organic farming is
18 system-based and the methods used to study it
19 must follow suit if they are to open our view
20 to the interactions between different parts of
21 the system that make up a farm.

22 We request a change to the

1 following language which we suspect will be
2 used in the future. Controversial, i.e.,
3 topics on which there are widely differing
4 perspectives in the independent scientific
5 community or for which there has been very
6 close NOSB votes, the addition being in the
7 yellow there.

8 Nine, we urge the board to remove
9 carrageenan from the list of research topics
10 for the simple reason that researchers funded
11 by the NIH and Veterans Administration already
12 provide answers to these questions.

13 Ten, we urge the board to add the
14 following language to the research priorities
15 proposal. When researchers answer the NOSB's
16 call to perform primary research on topics
17 that are listed as priorities the NOSB will
18 consider this research in its decision-making
19 process. NOSB members in their deliberations
20 will also take into consideration the funding
21 source of research that is presented,
22 especially when research is funded by entities

1 with a financial stake in the outcome of the
2 research.

3 Eleven, organic farmers are faced
4 with serious, on-the-ground problems that must
5 be addressed by research. If the board is
6 committed to encouraging research funding it
7 needs to make a systematic attempt to poll
8 farmers on the ground about what they consider
9 to be research priorities.

10 Now, Michelle, I guess I gave you
11 the version that's one slide short of what I
12 made yesterday which means it's lost in the
13 drop box thing. So I'll just verbally state
14 the last slide but we don't have a slide for
15 it.

16 We received two additional
17 comments after the docket closed and I want to
18 read them into the record. One of them was
19 from the FMC Company. We urge the board to
20 remove carrageenan from the list of research
21 topics for the simple reason that researchers
22 have already provided the answers to all the

1 questions and found carrageenan to be
2 perfectly safe.

3 The next one that was verbal
4 comments from our colleague Mark Lipson on our
5 conference call was that the research topics
6 would be more useful to funders of organic
7 research if we provided direct links for each
8 topic to which of the criteria they addressed
9 so that funders who have set criteria can say
10 here is a direct link from this criteria to
11 this topic.

12 And then additionally that we
13 prioritize the topics within -- we ask each
14 committee to prioritize the topics and then we
15 put the whole list of committee priorities
16 together as one. But he suggested we
17 prioritize within the committee's top
18 priorities.

19 So those are the main public
20 comment that we received. Thank you.

21 MS. TAYLOR: Are there any
22 comments or any discussion? Nick?

1 MR. MARAVELL: Yes, on comment
2 number 11 about hearing from farmers on the
3 ground as to their research priorities. I was
4 wondering if that type of information is
5 available through OFRF. I was, well, thinking
6 that perhaps the committee may have looked
7 into that. Or perhaps anyone in the audience
8 or anyone else? I mean, OFRF in the past has
9 asked about research priorities. I was just
10 wondering if that was part of -- no? Okay.
11 End of question.

12 MS. SONNABEND: I think it is
13 appropriate to ask the board if based on any
14 of this public comment we want to make any
15 changes to our posted document, such as the
16 suggestion to remove methionine research on
17 meat byproducts or such as to add that yellow
18 clause into our criteria. Well, yes, we
19 received comment on both sides of carrageenan.

20 MS. TAYLOR: John, go ahead.

21 MR. FOSTER: I have a question.
22 What do you think about the research that

1 someone says is already done around
2 carrageenan? Zea, what do you think about
3 that?

4 MS. SONNABEND: I think the fact
5 that we heard exactly almost to the word the
6 same thing from both sides, that all the
7 research questions were answered one way and
8 all the research questions were answered the
9 other way indicates it should stay on the list
10 of research topics because not everyone agrees
11 on the answers.

12 MR. FOSTER: Or rather everyone
13 agrees on the advice but in a totally opposite
14 direction, right? Okay.

15 I do have one more, actually. All
16 the conversations we had -- you know what?
17 I'm going to stop myself again. I'm good.
18 I'm getting better at that. I think it's a
19 function of getting older, actually. It's the
20 only good thing I can find. So I'm going to
21 hold off on that. Thank you.

22 MS. TAYLOR: Okay, so we will

1 introduce the motion. Okay. Yes, I'm sorry,
2 Colehour.

3 MR. WALKER: Thank you and thank
4 you for your work. I guess I want to for the
5 sake of this being in the record just comment
6 about my own personal perspective. I haven't
7 been directly involved in this.

8 And I guess since this is a new
9 conceptualization which I actually think is a
10 very good idea and a much-needed idea for us
11 to be making use of. I don't at all mean to
12 come across negatively but I want to ask if
13 it's discovered as was referred to and as is
14 being raised after the NOSB has made a
15 decision about a topic, it's identified that
16 perhaps we don't have the research in place,
17 and realistically and honestly that means it
18 wasn't in place to have made a decision, then
19 it's a little bit confusing that therefore
20 we're going to decide that we need research
21 which from my understanding of a precautionary
22 principle we should have had in place before

1 we made a decision.

2 So I don't think it's a catch-22
3 commentary but I do want to raise that and ask
4 -- I mean, it relates back to some of these
5 topics that are on this current list. But I
6 think from a perspective of coming up with a
7 system that is functional for making use of
8 this idea of annually doing this I would like
9 to understand how we can address that or
10 incorporate that. And I'd like whatever the
11 subcommittee has internally discussed about
12 that shared. Thank you.

13 MS. TAYLOR: Go ahead, Zea.

14 MS. SONNABEND: Okay. Michelle
15 found the lost slide version and there's one
16 semi-housekeeping change to our posted
17 document that I would like to bring up.

18 When the Materials Committee
19 originally passed the document we had an
20 additional bullet point for carrageenan that
21 was suggested within our handling committee by
22 Jean although she missed the call when we

1 voted on it. But we would like to -- because
2 this was already voted as a research topic we
3 would like to add it to our final document,
4 and that is what are the ecological impacts of
5 seaweed cultivation and harvest in species
6 used for carrageenan.

7 MS. TAYLOR: Okay, thank you. So
8 do we have a motion to adopt the proposal on
9 the NOSB research priorities with the
10 recommended change? Yes, Zea.

11 MS. SONNABEND: I'll move to adopt
12 the recommended research priorities. Oh,
13 sorry.

14 CHAIRPERSON FLAMM: Jennifer, we
15 also failed. We're supposed to by each
16 subcommittee to do our recusal thing and we
17 didn't do it.

18 MS. TAYLOR: Okay, you're right.

19 CHAIRPERSON FLAMM: I'll let you
20 conduct that before we move to the motion.

21 MS. TAYLOR: Are there any
22 conflicts of interest here? Okay, none being

1 reported let us proceed.

2 CHAIRPERSON FLAMM: Okay. Thank
3 you, Jennifer. The Materials Committee has a
4 proposal by the consideration of the full
5 board. Is there a motion that the Materials
6 Committee would like us to entertain?

7 MS. SONNABEND: Well, I'll make
8 the motion but it's the wording in the posted
9 proposal that I don't have in front of me.

10 CHAIRPERSON FLAMM: And are you
11 going to -- the motion, will that include the
12 amendment that you just gave?

13 MS. SONNABEND: Yes.

14 CHAIRPERSON FLAMM: Okay.

15 MS. SONNABEND: The motion is to
16 adopt the proposal on NOSB research priorities
17 with the amendment to add a bullet point to
18 carrageenan saying what are the ecological
19 impacts of seaweed cultivation and harvest in
20 species used for carrageenan.

21 CHAIRPERSON FLAMM: Is there a
22 second to the motion?

1 MR. WALKER: Second.

2 CHAIRPERSON FLAMM: The motion has
3 been seconded. The motion is accept the
4 proposal on NOSB research priorities that's
5 been -- as amended as read by Zea, if that's
6 satisfactory. I don't have the exact language
7 in front of me but is everybody clear on what
8 the motion is? Any questions about what the
9 motion is?

10 Okay, the motion has been made and
11 seconded. Discussion on the motion? John.

12 MR. FOSTER: Just, I'm fine with
13 the language of this but when it comes up kind
14 of with an eye towards traditional
15 sustainability criteria I would just ask that
16 the conversation at some point drift around to
17 also the economic impact of seaweed
18 cultivation and harvest in those areas. It
19 seems appropriate to me not -- I don't want to
20 change the language, I'm fine with that, but
21 that was something that wasn't particularly
22 well discussed. Actually it wasn't discussed

1 at all as far as I can recall in our
2 discussions.

3 And when we were talking about
4 adding this component to the research
5 priorities I think it's reasonable to in our
6 discussion have the conversation, what is the
7 economic impact of these activities,
8 particularly because they're not generally
9 well covered in our checklists either going
10 forward. I just think it's fair, that's all.

11 What does it do for the community
12 economically. It may not be critical for this
13 particular topic but it can be for other
14 materials in front of the board.

15 CHAIRPERSON FLAMM: Sounds like
16 something that you're suggesting for future
17 research?

18 MR. FOSTER: No, just on this
19 particular issue there's ecological impacts to
20 the cultivation and harvest. I think we need
21 further exploration on that. But I would hope
22 that the conversation would also include a

1 discussion of the economic value of that
2 activity to those as well when we talk about
3 it. I don't want to add it, I don't want to
4 go through that process, but I want to be
5 mindful that there's many sides to every
6 activity and economics is one of them.

7 CHAIRPERSON FLAMM: Any other
8 comments, discussion? Hearing none we can
9 proceed with the voting beginning with Joe.

10 MR. DICKSON: Yes.

11 MS. RICHARDSON: Yes.

12 MR. WALKER: Yes.

13 MR. BONDERA: Yes.

14 MS. TAYLOR: Yes.

15 MR. MARAVELL: Yes.

16 MR. FELDMAN: Yes.

17 MS. SONNABEND: Yes.

18 MR. STONE: Yes, sir.

19 MS. FULWIDER: Yes.

20 MR. AUSTIN: Yes.

21 MS. FAVRE: Yes.

22 MS. BECK: Yes.

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MR. FOSTER: Yes.

CHAIRPERSON FLAMM: And the chair
votes yes. That's 15 yes, zero no. The
motion passes.

I believe that concludes our
meeting for today and we can recess until 8
o'clock tomorrow morning. Thank you,
everyone.

(Whereupon, the foregoing matter
went off the record at 5:30 p.m.)

A				
AAC 309:1	access 9:12 53:1 54:12 73:19 74:5 74:11 201:1 219:5	47:18 87:8 90:5 173:2,9,12 192:12 220:3	370:15,16 387:13 390:17 394:3 395:17 398:3	32:1 135:21 242:11
abbreviate 308:14	accessible 74:2	acting 173:11	added 81:3 139:1 185:11 283:7 340:21	addressing 138:20
ability 80:7 101:20 157:9 211:12 233:16 257:4 359:6	accessing 24:1 200:2	action 38:8 107:5	adding 13:15 78:13 78:16 104:19 124:14 227:3 323:18 397:4	adequacy 53:17
able 5:3 7:13 37:16 63:1 78:19 96:3 107:6 115:8 120:19 121:2,7 129:14 159:9 165:8 167:10 171:6 187:10 188:12 191:15 230:6 243:16 269:22 271:12 275:12 285:10 289:5 343:13,20 349:11 353:19 370:8	accompanied 52:21 159:6	actions 23:21 38:9 125:20 137:6,11 137:13,20 138:2,5 138:16 278:3,9	addition 76:13 82:16 87:14 117:15 123:3 157:8 159:3 276:18 312:22 339:10,17 340:4 384:10 387:6	adequate 13:4 18:8 267:13
absence 49:8 131:2	accomplished 22:19	active 68:5,8 74:21 75:5,6,15 87:2 155:11 282:9 311:10 313:2,7,10 313:17 314:14,17 315:2 317:7 319:12,13,15 320:2,7,13,15 325:1,2	additional 11:7,8 11:15 43:13 48:17 67:11 73:12 129:17 138:18,20 275:19 310:3 337:13 378:14 388:16 393:20	adequately 26:20 179:20
absent 119:13,15	accreditation 234:15	actively 165:2	activities 165:10 211:8,9 263:11 360:21 362:1 397:7	adjuster 19:7 353:14
absolute 125:13 273:12	accredited 42:1 250:16	activity 72:6,17,18 72:20 73:1 131:1 154:13 157:18 172:6 255:5,8 263:4 283:15,17 320:15 398:2,6	additions 129:4	adjustment 257:6
absolutely 11:11 17:16 54:11 243:19 250:6 271:16	accurate 76:2	acts 324:13	additives 129:22 138:22,22 139:15 244:15,19 245:1 287:4,7,12 290:5 290:6 380:14	administered 18:6
abstained 144:12	accurately 371:11	actual 7:19 75:12 145:14 155:12 168:2 364:2	address 9:16 12:20 89:5,17,18 98:7 136:9 140:19 145:17 148:22 170:9 206:4 213:16 238:6 267:12 277:8 279:21 292:11 304:8 314:3 318:10 393:9	Administration 387:11
ACA 19:1	achievable 33:11	acute 338:8	addresses 19:15	Administrator 2:10,22
academia 232:16	achieve 39:3 129:10 339:19	AC21 5:16 59:4 214:15		adolescents 242:5
acari 83:19	acid 3:12 76:18 77:7,9 78:9,12 81:5 117:8,12,15 117:21 119:19 282:19 293:7 309:16 375:14,17 375:19 376:2 377:3,11	ad 3:2 4:6,20 21:15 51:5 135:12 183:8 295:12 382:3		adopt 91:10 121:20 174:10 373:11,17 394:8,11 395:16
acaricide 82:19 83:18 368:12,19	acids 76:20 78:14 79:1 119:3,3 282:21 283:6,6 358:11 363:9,17 365:1,11	adapt 117:2,3		adopted 95:2 119:15 237:13 318:9
ACAs 234:10	acknowledge 8:13 56:17 135:18 137:6 200:16	adapted 196:20		adopting 242:19 269:12,15
accelerated 233:17	ACOAs 8:14,22	add 69:7 79:12 83:16 108:1 139:19 227:5,9 272:11 283:12 330:16 351:5 358:7 368:11,18		Adoption 42:17
accept 33:12 92:3 151:18 285:17 297:12 364:5,7 396:3	acquainted 224:9			adopts 109:9
acceptable 163:18 329:6 338:20 364:11 385:3	acre 162:18 230:3			ads 190:18
accepted 73:16 103:5 247:8,12 338:18 365:16	acreage 201:9 202:1 229:16 299:6,11 303:10 350:19 354:10			adults 347:4

advisement 6:12	361:20	aid 122:10	246:2 267:21	328:7 330:20
advisor 250:12	agree 9:13 18:13	aids 129:22 140:4	281:19,21 282:3	331:4,10 333:7,19
314:6	51:15 63:1 136:12	aiming 38:21	293:15 300:4	334:4 336:10
advisory 2:12 59:3	193:8 198:15	air 338:1 339:1	314:20 317:21	337:8 343:5
67:8 147:17 196:1	232:21 285:3	aisle 185:1	318:10 321:19	American 16:1
214:16	319:10 337:17	Albany 223:17	330:21 343:13	39:13 164:20
advocacy 50:21	370:16	Albuquerque 4:19	allowing 346:11	Americans 113:22
195:6,7 196:17	agreed 17:12 119:9	alcohol 93:13	350:8	113:22 336:5
advocate 298:5	205:12 207:1,4	alfalfa 195:18	allows 220:3 227:5	America's 29:21
364:2	307:11	align 95:7 296:4	251:11	amount 52:6 98:11
aerobic 233:17	agreement 99:11	alike 348:11	all-summer 231:16	132:15 133:14
affairs 337:8	210:10	Alimentarius 313:5	alternate 334:15	154:3 194:6
affect 89:8 109:11	agreements 116:10	aliphatic 309:2	alternating 105:21	228:19 229:1
109:15 238:9,11	116:12 215:19	alkali 76:21 78:15	alternative 70:4	230:1 255:20
238:13 253:19	agrees 10:14	78:17 79:1,4	84:11 124:8	amounts 113:7
330:7	391:10,13	80:21 81:4 82:2,3	191:11 196:1	AMS 1:1
affiliated 360:17	agricultural 2:18	93:13,13 363:10	256:1 257:20	anaerobically
affirm 314:9 318:6	52:8 62:7 195:13	363:18 365:12	328:15 333:1,2	117:17
affirmation 136:18	300:20 314:5	alkoxylates 93:13	339:19 342:16	analysis 11:17
afford 37:12 62:11	317:4 318:3 342:7	Alliance 3:17 9:5	343:14 345:4	175:2 199:5
63:1	342:8,18 346:1	13:9 17:18 50:18	369:5,7,7 383:21	analyst 304:21
affordable 12:17	agriculture 1:1,1	50:22 146:19	385:3	analytical 13:3
afforded 52:8	25:16 30:15 31:12	195:8 196:9	alternatives 69:15	analyzed 386:16
afternoon 123:18	57:3 70:3 79:19	207:13 210:12	84:19 106:5,7	and/or 291:7
232:8 254:13	85:4 91:8 147:9	212:6 217:16	107:14 108:5	anecdotal 200:4
272:5 284:15	147:10 153:2,8	allocated 65:19,21	117:1 129:4	219:3
304:19 310:18	207:6 265:13,15	146:14	148:15 153:12	animal 62:6 153:2
314:2 319:2 328:2	295:17 316:15	allow 17:3 89:18	168:19 176:13	180:21 385:2
337:4	317:22 324:7	155:12 169:20	193:11 317:2	animals 189:22
afterward 358:5	331:15 340:15	237:20 271:7	328:21 331:5,11	380:15
ag 9:9 121:3,8	Agriculture's	282:19 287:12	333:6,10 343:15	annex 245:20 320:2
182:21 219:18	195:22	290:7,7 293:4,7	343:16 369:13	anniversaries
352:12	Agrinovation	310:2 320:22	370:21 385:7	115:1
agencies 39:21	254:16	339:11 381:2	Amador 336:19	anniversary 219:14
200:11 212:5	agro 309:13	allowable 109:10	337:4,5 342:4	annotated 277:5
agency 8:16 16:11	agronomic 80:22	154:21 267:5	343:2 344:12	annotation 71:12
40:13 234:15	agronomically	allowance 76:19	345:15 346:6	124:22 125:3
agenda 66:19 92:4	316:1	89:9 118:19	amended 245:22	126:2,5 127:8,22
174:12 210:22	ah 162:3	184:18 286:1	364:18 365:20	128:7,16 129:2,11
360:9 382:12	ahead 70:22 100:13	allowed 69:3,8	396:5	129:19 131:13,14
agent 78:8 83:22	125:2 142:6	85:17 87:12,14	amending 107:22	131:22 135:17
272:9 324:11	170:19 188:7	104:17 111:5,10	amendment 76:15	136:16,16 137:1,2
agents 156:8	259:1 262:21	139:4,6 186:22	80:13,17 364:6,10	137:16 141:11
ago 121:5 148:9	323:1 345:11	188:16 190:9,10	395:12,17	142:15 237:15
150:7,19 255:3	354:14 355:8	204:8 227:2	America 105:11,15	241:1 242:20
266:21 298:21	382:13 390:20	240:22 241:1	115:10 242:8	246:12 247:9
299:13 341:6	393:13	243:7 245:1,13	258:18 264:14	273:2 274:1

277:16 363:22 annotations 143:3 233:2 272:21 341:20 announcement 91:11 annual 230:1 246:20,22 annually 274:15 393:8 answer 26:19 37:18 46:9 102:2 167:13 170:16,22 171:20 189:5,16 217:22 236:21 239:6 242:22 246:8 247:11 249:16 261:9 269:7 270:14 271:16 307:3 333:4 336:22 338:14 387:15 answered 26:21 391:7,8 answers 14:5 34:5 68:12 190:5 280:12 295:7,10 331:7 387:12 388:22 391:11 antibiotic 151:6 155:21 159:16 165:14 170:4,12 170:14 176:8 179:10 180:18,20 180:22 193:11 antibiotics 148:10 148:19 150:17 152:12 153:1,8 157:10 158:7 166:7 169:21 170:2,6 176:17 178:6,20 179:2,16 179:21 181:13,15 181:17 184:18,22 186:22 187:3,7 188:1,16 189:20 190:16 191:2,14	191:19 anticipate 266:9 anticipated 90:16 161:17 anticipating 148:20 antimicrobial 83:21 antimicrobials 180:7 antitrust 195:14 anybody 359:4 361:4 anybody's 36:17 anymore 260:5 295:10 anyone's 114:3 anytime 28:3 anyway 108:18 136:19 139:4 190:17 AOSCA 16:5,7,9 16:12 19:3 39:21 212:3,5,9,13 213:16 apart 228:5 apologize 7:15 66:8 359:2,10 apparent 62:17 apparently 340:7 appealing 57:10 appear 78:2 123:7 161:12 176:20 appears 16:21 45:22 80:20 161:19 245:12 307:18 applaud 51:8 applause 220:12,13 apple 162:4 163:10 163:11 164:19 166:16 179:10 181:4 188:14 192:22 304:5 332:19 apples 150:1,11,12 151:13 152:13 176:8,18 179:12	191:1,13 192:10 applicable 9:2 127:4 application 133:21 145:8,10,15,16,20 180:13 181:5 344:7,20 applications 329:1 334:8 339:12 342:9 applicator 314:6 applicators 104:10 applied 75:6 130:18 153:21 244:7 248:21 339:2,3,5,6 applies 183:7 185:22 338:2 apply 9:6 17:19 32:17 119:21 133:19 134:8 178:21 185:21 189:21,21 300:18 323:21 334:8 348:10 applying 31:9 57:11 230:4 343:21 appreciate 44:10 95:16 98:19 146:6 147:6 216:17 220:9 232:5,20 233:6 250:19 265:16 273:21 276:6 284:19 286:12 298:2 302:5 305:17 337:10 341:11 approach 19:5,14 30:18 39:22 143:9 235:17 278:11 283:20 294:18 295:2,14,18 approaching 349:8 appropriate 14:7 53:2 59:5 91:12 91:18 111:21	120:9 125:20 131:10 137:6,11 137:13,20 138:2,5 138:7,15 197:20 205:10 278:3,9 279:4 333:3 340:2 370:20 371:5 390:13 396:19 appropriately 344:1 appropriateness 16:13 approval 155:17 250:21 252:13 254:7 345:14,21 349:21 approve 179:21 267:17,18 292:5 301:22 305:20 346:17 approved 90:6 179:3 229:6 248:3 248:6 263:18 264:5 267:1 277:22 311:4,7 328:22 360:16 approving 183:8 289:20 April 82:13 225:22 AP/LLP 43:9 aquatic 308:16 340:20 aquiculture 183:9 arbitrarily 116:20 117:2 area 31:11 40:15 56:8 154:15 271:7 308:6 336:22 385:4 areas 34:7 61:9 122:4 209:20 210:14 302:14 339:6,8 385:22 386:8 396:18 arenas 33:16 argue 184:15 argued 309:4	argument 70:9,12 285:20 297:13 Argyle 223:16 Arizona 121:11 266:14 Arnold 223:14,15 227:20 228:13 229:15 230:5 231:5 232:5 352:16 aromatic 309:2 arrival 352:11 arrow 213:4 ARS 70:7 74:4 163:9 384:19 ARSENAULT 2:12 379:10 article 57:1 245:21 articles 189:15 352:20 ashamed 351:12 aside 80:19 asked 44:19 73:21 73:22 74:4 129:9 129:12 166:5 167:4,7,14 202:11 202:20 204:16,22 205:8 206:20 208:2 245:6 292:5 360:9 390:9 asking 28:12 33:22 60:7 93:17,18 118:13 148:3 214:3 245:13 294:4 330:20 353:5 asks 273:3 asparagus 340:8 343:8 aspects 15:21 47:5 47:20 175:12 386:14 aspergillus 293:8 Assertions 314:16 assess 15:16 94:14 137:19 199:20 assessed 308:19
--	--	---	--	---

325:4,15,16	attempting 149:6 209:7	avoid 17:7 106:2 247:3 329:10	283:16	92:10 108:7 128:2
assessing 383:20	attended 165:15 291:22 292:19	avoiding 32:18 257:1	bad 81:18 304:5	147:21 171:18
assessment 41:7,8 199:4 245:14 324:7 325:7	attention 5:3 208:4 208:17 209:10 308:2 327:15	awaiting 116:16	badly 193:10 251:16	172:15 173:4,12 202:3 240:4,6 242:9 290:10
assessments 175:3	attitudes 199:21	awarded 195:15	bag 28:16	300:22 319:18 323:11 326:18 337:9 353:8 386:1 390:13
assimilate 235:5	attract 302:13	aware 41:22 103:7 107:19 115:10,14 258:7 343:3	bags 271:5	basic 39:18 317:13 323:16
assimilated 235:22	at-risk 53:6	awareness 64:13	bail 370:6	basically 78:4 88:17 112:19 258:11 263:6 284:4 338:2,7 342:14 343:3,12 343:19 345:5
assist 275:17	audience 4:13 81:15 200:22 379:4 390:7	awhile 35:3 112:13	BAILEY 2:14 112:8 294:8 363:21	basis 32:15 43:6 101:9 116:6 178:10 295:22 314:22
Associate 2:20	August 110:8 225:21 226:2 306:6,6	A(1) 126:16	bait 67:4 319:12 320:20 321:1,18	battle 347:7,8
associated 5:13 49:18 50:12 101:7 223:1	AUSTIN 1:15 229:10,21 262:22 344:2 357:4 362:15 366:4 367:14 368:21 371:18 375:7 376:17 377:8 378:6 398:20	A(2) 127:3,9	baits 313:3,14 319:18 320:10 321:4,7,10 322:4	Bayh 220:2
Associates 298:5	authorities 242:5 313:1 319:20 320:11	A-G-E-N-D-A 3:1	balance 16:21 30:7 284:1	bear 11:22 29:12 125:3
association 16:2,3 39:14,20 42:18 60:16 93:20 212:4 232:14 250:13 348:18,18	availability 13:13 54:3 70:3 170:4 197:20 198:19 202:7 203:21 204:3 207:16 209:21 216:7 315:21	a.m 1:10 4:2 65:10 65:11	balanced 283:19	bearing 152:12
associations 40:12	available 22:20 41:17 52:20 61:20 67:6,15,16 77:5 78:9 98:16 106:7 107:9 123:13 154:3 219:13 266:22 300:16 306:10 314:16 328:15 331:11 385:20 390:5	<hr/> B <hr/>	ban 109:5	beaucoup 264:17
assume 172:18		b 125:16 128:1	banana 105:8,12 328:4,7,18 329:21 330:4,10 331:4,9 333:15 339:4 343:4,11 344:14 344:21	beautiful 346:16 350:4
assuming 115:14		back 4:14 27:17 46:19 47:9,14 56:6 65:10,12 81:19 86:21 88:9 111:4 114:10 130:7,11 141:9 145:1 173:9 174:1 174:9 178:8 194:6 220:20 221:3,6,8 221:10,12 231:13 236:12,14 239:11 239:13,15,18 244:2 250:7 254:20 289:21 294:6 305:16 311:11 312:7 322:19 344:5 385:16 393:4	bananas 105:10 107:10 330:8 339:7 340:6 341:22 342:1	BECK 1:15 25:10 68:2 124:1 356:2 357:5 362:17 366:6 367:16 371:20 374:16 376:5 378:8 398:22
assurance 12:22		background 66:17 86:14,18 147:4 228:16,17	Band-Aids 31:10	becoming 62:15 288:10 330:6
assure 278:5 380:13		backgrounds 149:11	banning 109:3	beet 32:19
assured 270:9		backlog 160:20	bar 156:15 157:1 158:3 166:11	began 300:7 343:21
assuring 277:19		backwards 356:16	barn 110:16 111:4	beginning 88:17 184:7 263:22 358:21 366:1 367:11 376:4 398:9
Asta 11:5,14 16:1 39:9 40:21		bacteria 83:22 134:9,18 157:18 180:11 253:11	barrier 168:14 198:14	behalf 58:22 212:8 232:18 250:14
ASTM 125:8,16,17 126:14,14,22 127:3,4,14 128:2 128:4 130:14,16 130:21 131:5 132:21 133:7,11 139:12 142:10,13 233:13,22 269:2,5 270:9 275:17 285:7,12,21 296:3			barriers 200:1 215:6	
atmosphere 235:16 236:1 380:20			Barry 1:12,14 4:9 65:16 221:14 223:12 356:11	
attachments 73:17			bars 156:18,19	
attack 106:19 271:8			base 31:12 46:18 46:20 47:1	
attacked 328:19			based 11:19 16:14 17:1 25:3 38:9 39:22 42:4 92:2	
attempt 315:7 316:13 388:7				

328:5 331:13	best 26:14 38:19	biodegradable 3:12	125:5 140:6	bits 278:19,20
behavior 325:6	50:11 52:15 58:6	122:16 123:2,3,6	221:20 237:11	black 139:2,4 224:5
behold 203:11	96:12 149:2	124:4,14,18 125:5	244:3 247:7,11	231:6,11,14 251:2
beings 352:11	243:18 267:8	125:7 126:11	249:7,15 259:6,20	276:1 280:2
belief 222:18	268:3 289:4,7	221:20 232:9,11	260:16 274:19	287:11 347:5,15
believe 9:17 11:5	317:14	232:13,17 234:21	305:16,18 307:7	348:1 353:22
16:19 20:5 21:19	bet 168:17	244:3,4,19,20	308:21	354:3
23:17,19 24:11	Beth 21:9,11 25:7	245:4,8,12 246:2	bioplastics 3:13	blend 241:10
25:13 28:19 32:7	25:10 26:2 28:2	246:16 247:8,12	116:16 122:17	blended 238:3
51:14 52:17 53:5	29:2 44:19	252:14 254:21	123:4 124:5,10	blending 241:8
57:11 58:4 59:12	better 14:20 16:19	256:22 258:6,8	142:20 272:12	blight 148:10,20
61:16,21,22 63:5	52:11 56:15 82:5	259:5,13 260:4,12	288:2,10 306:4,14	150:15,21 151:10
72:14 74:8,13	84:14 99:10 100:4	260:15 265:6,9	306:16 307:10,15	153:22 154:6
115:21 134:12	137:1 142:13,18	270:2,4 272:12	308:20 309:7,9,15	155:3 157:18
168:4 169:6	142:22 143:5,9,13	273:11 276:2,14	BioStar 117:13	158:19 159:3,10
196:11 197:6	156:2 183:19	284:17 286:15,22	biotech 57:5,6	159:14 160:4
198:14 200:15	186:3 206:13	287:18 289:16	biotechnology	161:5,10 162:10
205:18,20 207:21	250:1 300:16	291:3,5 292:21	57:18 59:3 195:13	163:14 164:1,3,13
209:9 217:15	308:21 331:5	293:4 298:12	206:2 214:16	164:22 166:8
218:1 237:8	343:16 352:9	301:6,15,21 303:4	BioTelo 224:2	168:15 169:10
238:18 245:19	353:3,4 391:18	305:19,22 306:14	239:4 248:1	171:13 179:15,15
267:12 268:5	beyond 6:17 10:6	306:17 346:12	254:17,19 255:1,2	180:11,17 192:3
270:14 305:10	169:5 187:7 203:1	383:6	255:10,14,19,22	353:21
309:22 310:9	215:3	biodegradation	258:9 346:13	blight-resistant
359:14 360:8	bient“t 264:16	125:13 127:11,15	349:12 350:11	162:4
362:2,6,9 364:4	big 113:16 120:14	129:7 131:6 235:3	352:12 353:5,10	blocked 179:22
368:6 371:15	252:15 255:15	235:9,20 236:8	353:11 354:10	bloom 154:8,21
374:13 376:20	256:21 280:8	268:6,10 273:12	BioTelo's 352:18	155:4,6
377:15 378:19	bigger 115:2 155:3	309:6	bio-based 125:5,16	Blossom 153:13
382:14 399:5	230:15 271:4,4	biodegrade 124:9	126:14 133:9,14	156:19 157:19
believes 9:5 13:1,9	330:6	131:16 274:12	237:11,12 259:5	158:6 167:10
101:7 323:10	biggest 169:16	309:17	287:17,21 288:6	blossoms 154:14
bell 284:6	265:12	biodegraded	290:17,19 291:11	159:9
belong 136:13	bill 217:11 284:12	124:10	291:13,15	blue 8:1 12:6 17:15
belongs 72:3	297:20 298:4	biodegrades	bit 7:22 10:15 20:8	19:17 150:10
beneficial 85:7	304:15	241:20	34:22 48:17 64:19	156:22
297:9	billion 209:3	biodiversity 85:12	73:17 136:20	blueberries 229:20
beneficials 300:18	Biltmore 1:10	283:18 299:8	142:9 145:2,5,18	blunt 112:1
benefit 85:2 182:14	binds 308:14	biofilms 142:20	147:3 148:6 161:7	board 1:5,10 2:12
231:1,21 232:22	bio 248:17 264:10	biological 84:20	161:16 174:19	3:20,23 5:2 25:8
benefits 8:10 10:1	biochemical 253:16	156:8 159:17	176:7 177:2 179:7	26:4 29:21 34:12
122:9 231:3,6	bioconcentrate	288:1 352:18,22	187:17 197:2,7	34:13 39:14 44:9
251:6 266:19	308:16	353:7 383:21	198:2 213:18	59:13,17 64:10
268:2	biodegradability	biologically 354:11	218:10 223:5	65:20 73:9 75:4
benefitted 231:17	129:11 130:4	biomass 124:11	267:4 338:14	81:8,11 86:2
benign 80:20	140:12 285:7	235:10 253:6	392:19	88:14 91:16 95:2
Berry 348:17	306:22 307:13	bioplastic 66:1	bite 28:4	97:10 98:22

101:19 103:21	104:1	211:1,4 215:13,13	196:19 300:21	191:3,10 194:8
108:11 109:9	bottom 152:5 179:9	218:8 219:20	bullet 301:22	197:3 211:17
112:10 141:22	179:11 190:12	brief 34:7 265:3	393:20 395:17	218:9,14 233:18
142:8 146:12	251:8	356:12	bulletin 169:9	259:20 282:20
147:17,17 148:3,7	bought 198:7	briefly 308:6 324:2	bunch 333:6	322:22 329:7
170:19 174:7,9,13	box 194:1 388:13	355:4	bunches 344:3	calling 306:13
175:22 183:4	boxes 185:2 329:17	BRINES 2:16	bungee 337:22	calls 103:11 185:13
185:22 195:21	329:18	66:18 74:9 76:9	burden 11:8 13:7	306:15
196:5 197:4	BPI 126:9 127:9	82:12 83:8 117:11	26:6 27:10 45:1	Calvin 1:22 73:10
200:21 216:15	129:3,5 132:13	122:19	48:19 53:20 55:14	345:10 381:17
220:21 222:3,9	133:9 232:13	bring 8:21 59:20	burdensome 12:4	382:6,15 384:2
227:13 247:17	234:12 265:2	163:19 230:18	Bureau 348:20	Cam 314:1 318:22
249:19 264:22	290:19 310:11	393:17	bureaucracy 112:1	319:3
275:2 277:8	brand 161:22	bringing 135:2	334:3	campaign 181:11
295:11 296:10,11	brands 21:14	242:20	burial 256:18	187:4 192:1
298:1 299:1 302:5	break 60:6 65:7	brittle 228:4	burning 151:4	campground
308:4 312:6,6,22	138:10 139:14	broad 85:6	256:18	346:22
314:4,9 318:6,10	143:6 221:2	broader 148:18	business 14:15 33:7	Canada 232:12
318:18 319:2	224:11 226:10,21	210:3 217:9	73:18 74:12	240:21,22 241:16
322:8,16 323:3	232:1 235:4 253:4	294:17 300:15	254:15 257:16	242:21 243:7,9
327:13,17 330:20	278:1 319:1	broadly 9:1	343:4	248:4,7 254:15,18
347:4 348:16	322:12	broad-spectrum	businesses 200:11	255:12 263:18,19
350:8 354:13	breakdown 132:3	83:21 85:18	301:3	263:21 264:3
359:12 361:2	254:1 260:21	283:15,17,22	buy 62:11,12 186:7	320:22 349:14
369:15 374:7	261:1 263:2,3	broccoli 217:4,12	265:11 332:9	352:21
381:15 387:8,13	287:8 306:11	217:13 351:7,8	buyers 8:17	Canada's 249:19
388:5,19 390:13	breakfast 29:22	broken 138:15	byproducts 124:9	Canadian 242:4
395:5 397:14	breaking 236:3	235:21 278:8	385:2 390:17	245:7 246:5 249:7
boards 184:12	278:5	301:15		249:9
board's 296:4	breaks 225:14	brought 88:7,12	C	canals 339:13
382:5	226:2 227:1	236:11 279:16	c 125:17 128:6	cancellation 103:6
bodies 41:1 319:10	255:17	384:15	cadmium 242:2	110:1
body 88:8 153:5	breakthrough	BROWN-ROSEN	cafes 271:3	canola 32:19
315:4	173:21	2:18 364:19 365:6	CAFOs 304:8	capable 12:14
boiled 71:15	breathing 236:4	Brussels 225:4	California 121:10	capacities 147:13
bolster 211:3	bred 64:7 164:12	budget 219:15	158:16,17 171:22	capture 7:16 64:16
BONDERA 1:16	165:1 207:5	bug 179:17	314:5	201:5
83:12 144:8 356:7	breeders 210:21	bugs 106:20	call 5:3 78:12 100:9	captured 221:19
357:11 362:22	213:10 218:7	Bug-N-Sluggo	120:11 121:20	capturing 353:17
366:11,22 367:21	breeding 11:2	311:8	146:21 148:12	carbon 124:10
368:10 372:3	13:17 40:9 46:18	build 24:8 172:17	174:1 194:15	139:2,4,5 235:10
374:21 375:21	46:20 48:6 52:12	building 106:2	239:10 336:8	235:11,14 253:5
376:10 377:21	54:7 162:9 163:15	129:21 134:6	344:13 351:8	276:1 287:11,22
398:13	163:22 198:10,12	159:12 197:14	387:16 389:5	care 32:10 42:6
bono 298:10	200:9 206:22	337:18	393:22	289:22 290:1
botanical 106:13	207:14 209:1	buildup 155:14	called 77:16 159:7	career 147:6
botanicals 103:11	210:1,2,14,19	built 31:8 171:14	164:20 181:12	careful 196:13

carefully 39:5 385:19	CCOF 11:11 128:6 129:3,6	29:22 43:2 48:21 109:12 125:16 126:14,19,22 170:3 199:6 200:5 200:14 201:7 202:2,17 234:10 250:17,18 251:10 252:20 257:2 272:7 302:16 315:21 316:9,11 317:21 321:2 330:13 346:14 349:16 350:18	366:16 368:5 372:9,13 375:8 376:19 378:9,12 381:16,18,19 382:2 399:2	changes 45:17 124:22 273:2 293:10 358:1 390:15
cares 32:9	CDC 180:1	celebrated 280:22	chairman 146:1 220:21	changing 244:2
Carmela 1:15 25:9 66:14 68:1 123:20 123:22 144:9 376:4	ceiling 183:13,15	celery 315:22	Chairperson 1:12 1:14 4:3 65:12 220:22 221:7 355:17 356:5,8,18 357:2,14 358:3,15 360:1 361:2,21 363:4,12,15 364:9 364:15 365:7,15 365:19 366:16 367:6 368:5,13,16 370:12 371:6,13 372:9,13 373:16 374:4 375:5,8,22 376:19 377:6,9 378:9,17 394:14 394:19 395:2,10 395:14,21 396:2 397:15 398:7 399:2	channels 161:8
carrageenan 387:9 388:20 389:1 390:19 391:2 393:20 394:6 395:18,20	cell 286:22 292:22	cellulose 125:14 132:4 240:3 273:13	chairs 381:21	chapter 60:16
carrageenan 387:9 388:20 389:1 390:19 391:2 393:20 394:6 395:18,20	cellulose 125:14 132:4 240:3 273:13	cement 337:19	challenge 204:12 305:21 321:13	characteristics 151:18 162:9 163:13 216:21 217:1,7
carried 70:12 321:6	Center 147:10	Center 147:10	challenges 173:13 197:14 198:21 200:1,8 203:18 272:19 331:7	characterization 40:9 48:12
carries 9:20	centers 280:5	central 207:21	challenging 306:8 316:2 383:19 386:1	chard 226:15
carry 172:2 286:14	cents 346:12	cereal 29:22 185:2	chambers 40:7	charge 74:18
case 16:12 26:14 109:10 157:14 158:20 186:15 243:1 256:8 259:12 301:20 326:13 329:12 330:3 334:15,22 339:2 344:18	certain 38:9 87:15 113:4,8 132:15 151:18 156:3 186:3 188:6 189:17 203:22 204:4 217:22 238:10,12 267:6 332:16	certainly 8:20 21:3 27:22 42:10 44:9 45:11 114:11 155:1 188:4 239:4 265:14,16 271:15 302:9 307:2 360:13	chance 82:7 153:15 229:9 310:13	charged 59:4
cases 101:15 186:3 186:4 215:12 315:15 342:13	cases 101:15 186:3 186:4 215:12 315:15 342:13	case-by-case 295:22	change 26:6 126:10 128:7 166:4,21 167:13 305:4 363:8,16 365:10 365:16,20 386:22 393:16 394:10 396:20	chart 39:18,18 40:17 44:3 138:19
case-by-case 295:22	Castor 328:1	catalogs 203:1	changed 106:14	cheated 182:15 190:11
Castor 328:1	catalogs 203:1	catalyst 129:21		checking 45:14
catalogs 203:1	catalyst 129:21	catastrophe 343:12		checklists 397:9
catalyst 129:21	catastrophe 343:12 331:12	catastrophic 331:12		chelate 320:14
catalyzed 80:11	catch-22 393:2	categories 93:12		chelating 324:10
category 79:6 80:17 81:8 85:17 87:12 90:3 98:18 101:1 102:10 237:9 322:15	categories 93:12	categorized 80:11		chemical 5:7 228:11 317:17 380:14
cause 83:22 105:19 326:11 333:14	certainty 168:18	certificates 296:17		chemically 313:15
causing 38:11	certification 8:16 11:17,19 12:2 39:21 40:13 42:19 42:22 126:21 127:20 128:5 132:20,22 133:8 133:12 141:9 234:13 269:2 272:6 275:16 285:12,21 286:5 354:9	certification 8:16 11:17,19 12:2 39:21 40:13 42:19 42:22 126:21 127:20 128:5 132:20,22 133:8 133:12 141:9 234:13 269:2 272:6 275:16 285:12,21 286:5 354:9		chemicals 90:12,15 140:1 236:15 307:9,14,17 309:3 381:4
caution 53:7	certifications 54:9 322:3	certified 16:9 21:22		chemistry 281:3
	certified 16:9 21:22			chemists 228:16
				children 175:15
				chime 86:16
				chipped 184:3 185:10
				chipping 186:6,13
				choice 8:4 13:18 75:19
				choices 186:3 380:1 380:10
				choose 99:19 151:16 252:19 316:12
				choosing 204:9

chose 112:22	218:7	387:6	combinations	83:3 93:16 94:17
Chris 95:13	classification 85:19	closed 72:13	157:12	98:19 104:21,22
chromium 242:2	180:6 358:10,11	328:13 384:11	combined 70:20	115:17 118:6
chronic 116:3	358:20 362:8	388:17	72:21 324:10,21	123:15,18 124:13
383:18	367:2,11 375:18	closely 196:14	come 4:4 45:11	126:6 131:12
chrysanthemums	classify 358:16	211:11	60:19 97:22	133:2 137:7 140:5
281:15,16	367:8 376:1	closer 83:8 223:7	100:19 103:1	144:6 221:9
citation 309:21	clause 72:11	379:11	120:18 130:9	222:17 223:13
310:2	101:17 137:3,10	closing 329:22	136:4 157:4	233:1 250:20
citations 110:10	238:8 390:18	342:15 343:19	165:18 168:9	272:11 279:12,20
310:12	clauses 140:19	clout 28:9	183:22 191:5	284:3 290:17
cited 68:20 69:15	clay 261:10,10,19	club 165:5	192:13 205:15	296:14 354:22
70:1 115:15	clean 21:19 22:4,8	cluster 93:3 164:4	215:19 225:19	355:1 360:2 362:2
126:21 127:7	22:11,18 23:13	clusters 90:12,17	248:1 250:7	380:22 381:6,12
181:3 317:2,20	24:1 257:12	92:22 93:2	254:20 258:21	382:19 384:3,11
cites 9:22	cleaner 353:14	coal 283:1 320:3	287:13 293:10	389:20 390:1,14
citing 341:9	cleaners 29:9	Coalition 51:1	337:10 348:20	390:19 392:5
citizen 281:7	cleaning 37:17	coal-mining 282:21	350:9 351:2 354:5	commentary 393:3
citizens 386:7	cleanup 32:11	Coast 265:12	392:12	commenter 60:9
citric 293:7	clear 12:13 87:3	Code 242:4	comes 46:14 75:10	115:22
citrus 6:21 315:21	103:17 104:18	Codex 313:5	92:20 114:18	commenters 10:6
317:5 340:9	113:7 136:17	340:13,15,16	132:17 152:5	21:5 70:15 76:1
claim 119:2,4	137:18 149:16	345:16	158:16 166:4	85:9 94:9 115:20
claimed 75:2 369:6	155:15 209:12	coexistence 40:21	176:16 181:22	127:6,6 128:10
claims 120:3 187:8	267:12 273:5	40:22 41:3 63:5	187:18 196:22	144:1 234:8
307:12 311:4,7	277:7 305:6	Colehour 1:16	197:22 202:6	322:14 384:6
clap 265:20	307:14 330:18	83:10 144:7 392:2	219:1 256:14	comments 3:3,6,22
clarification 8:18	382:20 396:7	Coleman 297:21	304:10 351:15	6:14,19 7:3,5,10
74:7 76:1 93:17	cleared 118:14	304:17,19,20	371:12 396:13	7:21 14:19 19:12
112:9 124:22	clearer 5:11,11	308:8,13	comfortable 113:1	23:15 34:8 40:20
127:10 248:12,13	clearest 78:18	collaborative	170:1 200:13	51:1,20 53:14
273:4,21 274:9	clearly 20:10 72:16	210:11	269:4 355:5	55:4 58:1 71:19
275:4 276:6	82:2 135:11 139:1	colleague 166:18	coming 5:1 59:2	72:9 73:16 79:16
278:16,22 285:4	154:16 164:17	336:20 389:4	89:12 94:10,22	79:19 100:15
286:4,9,12,17	194:12 202:5	colleagues 164:10	98:6 112:19 115:1	105:1,3,12 119:16
292:3 293:18	209:17 246:14	245:14	115:9 133:2 147:3	119:18,20 120:7
334:17 356:13	266:16 271:19	collect 34:16 52:15	148:1 160:1 162:4	122:14 126:6,12
363:22	275:1	collected 199:16	169:1 182:16	130:3 132:15
clarifications 287:3	clears 234:6	382:22 383:10	196:3 280:21	136:10,21 143:18
clarify 145:17	client 298:9	collection 219:16	288:13 289:1	144:7 178:15
234:19 246:11	clients 80:2	383:8	336:3 350:3 393:6	213:19 214:9,14
248:14 287:16	climate 348:2	Colombia 328:4	comment 3:4,19	221:16,18 223:19
307:22	climatic 253:19	330:5,14 335:15	6:8,11 7:14 8:13	232:18 233:4
clarity 197:22	clip 66:7	colorants 242:16	21:8 23:4 28:15	248:10 250:14
class 92:17 243:20	clonal 160:21	287:7,8	39:15 44:1,3,5	252:17 273:8
243:21	close 146:8 169:17	combination 10:8	67:18,19,22 68:14	284:17,21,21
classical 211:3	170:10,16 335:11	15:19 324:14,22	74:17 79:15 82:1	312:12,16 327:2

356:19 360:18 361:4,22 370:13 379:8,9,14,14 382:9 384:5,15 386:7 388:17 389:4,22 398:8 commerce 110:3 commercial 25:2 40:16 54:2 120:22 153:16 198:18 216:7 257:5 282:1 commercialization 162:8 commercially 119:6 151:13 182:20 207:10 commission 91:15 91:19 245:7,9 313:6,8 commit 96:8 commitment 22:8 committed 30:3 331:4 388:6 committee 14:12 14:18 28:1 59:3,4 59:18,22 73:6 77:14 79:8,9,11 80:19 86:17 88:12 89:12,13 90:9,18 92:3 95:19 104:19 107:21 108:6 142:3 146:3 166:18 214:15,16 221:9 232:20 241:3 243:5 246:9 295:12 319:6 321:15 355:4 357:16 358:22 372:15 375:10 378:21 381:17,21 381:22 382:1,2 389:14,15 390:6 393:18,21 395:3,6 committee's 312:2 312:21 389:17 commodities 176:22	commodity 176:22 182:8 196:1 common 89:19 99:11 196:12 300:18 319:11 commonly 15:1 77:16 105:10 communicating 149:6 211:2 communication 352:1,8 communications 50:21 195:7 communities 206:12 community 5:14,19 12:15 17:21 18:3 20:1,18 22:21 23:22 24:7 25:3 26:13 52:9 56:19 59:1 64:12 86:10 87:4 101:6 141:13 212:8,11 216:1 222:2 232:22 233:7 303:9 304:11 310:2 387:5 397:11 community's 51:11 companies 19:22 22:14 23:10,14 25:1,1 26:10,12 27:17,19 28:16 54:18,20 55:6,10 55:15 58:2,9,11 58:19 99:18,20 198:5,8 205:12 215:2,15 359:21 361:14 company 26:12 39:12 106:14 258:12 292:1 310:20 319:4 388:19 comparable 251:22 comparative 257:7 compare 161:3 compared 132:3	164:15 185:16 194:14 255:21 267:5 compares 185:15 comparing 158:21 comparison 127:4 compatibility 120:5 compelling 113:14 compensation 18:8 58:16 59:5 63:14 compete 183:18 184:1 243:10 316:13 competes 323:8 competing 121:22 competition 186:20 187:11 188:15,17 219:12 323:10 competitive 322:5 competitively 348:14 competitor 319:17 competitors 264:11 complaint 262:1,2 complaints 261:16 266:2 complement 160:3 complete 89:21 125:21 127:15 129:12 236:7 245:14 253:9 271:13 273:15 274:14 275:6,6,11 277:20 278:17 279:3 325:1 327:1 345:6 completed 54:17 112:3 160:11 306:6 completely 124:10 125:6 130:2 138:15 139:14 188:10 190:4 226:3,5 268:16 309:11,17 353:8 completion 90:21	168:9 complex 35:4 96:20 compliance 41:13 112:19 234:11 273:6 323:5 compliant 121:7 246:17 320:16 complicated 96:17 134:20 150:18 164:5 220:1,4,6 288:7 299:18 comply 131:20 132:8 complying 139:16 component 21:20 34:2 139:7 397:4 components 139:11 228:11 240:14,15 245:17 246:1 249:21 285:13 composition 245:16 compost 121:7,14 259:18 265:11,13 270:7,8,19 283:8 compostable 259:11,13,14 260:4,12,15 265:9 271:2 composted 226:17 233:18 composter 271:5 composters 265:10 composting 130:18 131:1 226:18 241:17 259:17 269:3 270:11 285:14 296:22 composts 270:17 271:9 compounds 107:3 comprehensive 10:9 17:22 18:5 19:13 135:7,21 210:11 216:13 305:7 307:5 compressed 154:9	comprised 210:20 compromise 182:4 compromised 185:19 381:9 Compton 350:14 computer 44:12 152:7 concentrated 215:14 concentration 210:15 215:9 concentrations 309:16 concept 304:1 conceptualization 392:9 concern 44:21 46:22 59:1 61:18 64:13 84:12 87:9 87:17 88:18 92:20 94:10,11 99:8 106:4 120:5 128:15,20 150:16 155:5 166:13 181:1 206:11 229:5 254:3 280:3 291:2 306:21 concerned 11:14 13:12,15,20 15:14 28:8 32:10 38:11 53:9,19 54:1 61:7 61:13,14 96:7 144:18 287:4,9 288:15 340:19 386:6 concerning 307:13 concerns 7:12 51:11,19 55:12 97:8 129:17 138:18,20 141:12 155:14 178:19 180:1 206:4 228:10 233:9 265:17 277:9 284:22 369:14 384:9 conclude 65:3
---	--	--	--	--

324:22	conflicts 359:14	151:22	38:16 43:14 62:8	Contentious 300:1
concluded 319:20	360:8 394:22	considered 8:8	68:17 69:21	context 18:4 99:1,4
324:8	confront 57:14	47:12 68:6 131:9	124:16 146:16	99:9,10 118:16
concludes 21:6	confused 78:1	191:13 282:4	150:5 151:17	120:16 148:6
60:2 65:6 378:19	186:5	311:1 312:14,19	163:2,18 168:3	292:13 294:1,20
399:5	confusing 77:13	321:16 323:15	174:18 176:3,5,10	371:5
conclusion 43:18	137:7 145:5,12	327:4,12 375:11	176:16 177:2,19	continually 352:7
315:8,9 321:14	186:14 265:17	considering 92:10	178:9 179:2 181:9	continue 22:4,13
conclusions 209:4	392:19	consist 16:15	181:19 184:8,20	22:21 27:21 57:21
concur 137:22	confusion 189:8	consisted 79:15	185:7 189:7 190:8	71:1 200:18
concurrence	234:19 365:4	consistency 158:9	190:11 192:5,7	218:17 221:8
293:11,16	congratulate 305:5	189:6 248:20	193:1,16 323:14	268:3 343:14
concur 286:18	Congress 175:14	274:15	326:5 379:21	370:17 371:2
condition 262:14	conscience 104:17	consistent 13:2	380:2,8,11	384:17
285:14	conscious 4:15	32:15 85:5 108:19	contact 104:11	continued 166:1
conditional 345:13	consecutively	135:13 150:13	213:16 345:3	168:8
345:22	129:15	157:1,21 273:17	348:20 352:3	continues 285:4
conditioners	consensus 21:2	276:20 277:7	contain 107:2	continuing 91:4
245:20	25:4	278:11 295:2,14	282:2 311:9	216:18
conditioning 49:19	consensus-buildi...	295:18 306:18	313:10	continuous 12:15
conditions 130:17	300:2	327:9	contained 40:6	300:19
131:7 138:6,8,8	consequence 254:3	consistently 55:11	containing 282:14	contract 361:9
152:7 168:20	consequences	consolidation	309:16 325:20	contracted 321:8
173:5 196:21	53:11,12,18 69:17	198:4	contains 22:10	contractor 73:19
233:18 234:4,5	120:6	constant 37:10	325:22	74:11
252:6 278:1	conservation	303:1	contaminants 20:2	contradiction
conduct 4:7 40:5	195:16 317:11	constantly 116:9	contaminated 6:1	267:2,4
58:11 199:5	conserve 251:5	185:12 186:5	19:19 31:18	contribution 147:7
394:20	consider 5:5 7:5	351:22	contaminating	contributions
conducted 199:20	8:3 11:13 43:3	constitutes 15:6	63:21 340:1	212:21 359:20
201:4	45:8 92:20 107:22	constriction 121:1	contamination	contributors
conducting 203:2	169:17 235:19	construed 51:20	10:9,18 13:5 14:6	208:14
207:11	265:6 273:3	consult 91:6	15:5 18:1,12 19:7	control 27:5 70:4
conference 389:5	293:21 294:17	consultant 265:1	19:16 22:6 23:9	83:22 84:9 85:11
confidence 17:9	299:1 301:8,21	Consume 175:5	26:1 30:19,22	105:18,20 150:21
30:11 38:16 171:7	312:22 349:21	consumed 240:15	31:6,14 32:5,8,18	153:4,22 154:14
confidence-build...	375:19 380:14	consumer 11:10	33:15,18 36:13,21	155:20 156:8
168:15 169:12	385:20 387:18	30:4,11 93:20	38:22 41:5,18	165:14 166:8
confidential 72:11	388:8	104:13 124:19	52:12 54:22 55:13	167:5 169:10
73:18 74:12	considerably	150:8 174:22	56:20 57:15,19	170:1,5 173:7
confirm 234:3	139:21	175:1,4 176:2,7	58:5 61:11,21,22	272:17 305:19
243:16 277:2	consideration 12:5	177:10 181:21	62:3 63:12,18	314:5 324:19
confirmation 275:8	45:5 168:5 284:20	182:2 185:6,20	206:18,18 246:18	328:13,15 329:6
confirmed 320:6	285:5 359:18	190:14 194:5	247:4 257:1	329:10 331:10
321:9	372:16 387:20	301:1 326:8	content 133:9,14	333:12 345:8
confirms 131:1	395:4	consumers 3:16	135:5 237:12	351:3 369:9 386:6
251:20	considerations	21:21 32:10 33:10	contention 134:11	controlled 342:11

controlling 324:11	cooperate 138:4	costly 251:14 348:9	covers 175:12	229:20 230:2
controls 72:19	cooperation 22:3	costs 11:9 14:3 18:9	188:17 270:3	231:16 246:22
84:20 106:11	24:7,13 218:7	43:13 48:17 49:1	co-chair 381:19	251:6 257:7 267:9
156:18 338:18	cooperative 9:14	50:4,4 58:17	382:1	268:18 281:20
383:22	21:11,12 25:5	348:12	co-ops 8:18	295:7 315:17
controversial 300:4	coordinate 91:16	cotton 32:19	CO2 235:19 236:6	317:15 334:9
300:14 383:19	coordinated 206:2	254:12 264:20,21	241:21 255:20	341:21 351:13
386:1 387:2	copied 6:17	265:1 269:13,16	craft 244:6	CROPP 21:11
controversy 187:14	copies 217:20	270:12 271:14,18	crazy 189:16	129:9
271:2	copolymer 309:2	272:2 340:8 343:8	create 12:7 23:1	cropping 317:11
convened 1:10	copper 155:10,12	Council 196:1	38:15 77:21	cropps 3:5 18:6 22:6
conveniences 30:10	156:22 159:1,4	count 105:6 119:16	116:11 119:5	37:9 43:7 47:4
convention 12:21	169:1	368:6	149:3 210:5	57:7 61:6,15,19
conventional 11:1	coppers 158:18	countries 105:11	332:15	61:20 62:22 63:10
14:1 31:19 43:4	copy 197:5 198:22	105:22 106:9	created 78:3 93:2	65:13 66:19 68:2
121:3,9,19 122:1	382:15	107:10 109:5	179:14 206:3	70:18 71:3 77:1
150:11 181:14	cord 337:22	115:9 320:10,12	287:18 291:15	82:21 84:3,16
194:14 203:5	core 31:9	320:14 322:5	creates 78:8 213:9	88:12 89:6,11,13
205:3 222:22	corn 31:16 32:18	330:8 335:5,16	creating 189:3,9	92:3 95:18 107:21
256:11 269:12,15	48:21 53:6 61:10	339:21	190:3 192:16	108:5 117:18
316:13	61:12 135:2	country 106:6,11	210:22 292:20	119:8 123:9 126:1
conventionally 6:3	215:13 247:8	109:17 149:12	creation 103:12	144:13 146:2
187:2	248:22 249:20	167:2 171:6 172:5	creative 101:18	152:19 199:11
conversation 27:19	293:14	213:13 251:2	credible 182:20	201:12,13 202:2,5
29:12 33:14 55:19	Cornell 255:11	333:20	creeping 25:22	205:20 206:9
71:1 114:7 143:20	corner 194:1	county 346:20	criteria 125:6,11	208:16 221:9,18
190:20,22 205:10	cornfield 135:1	couple 33:2 88:5	241:17 242:6	224:13,15 226:14
252:8 396:16	cornstarch 255:4	94:3 107:7 252:22	383:12,15 389:8,9	226:15 229:17
397:6,22	289:22 293:13	311:16 312:12	389:10 390:18	230:10,18 231:12
conversations	Cornucopia 222:7	361:20	396:15	231:15 232:1,20
23:21 219:3	222:18 281:6	course 7:19 8:9	critical 8:2 21:20	241:2 243:4,8
279:22 352:13	282:17 283:11	32:21 46:13 62:13	27:20 28:17	246:21 262:10,10
353:1 391:16	304:21 305:9	88:19 103:18,20	276:18 331:9	262:15 283:9,21
conversion 191:12	306:3,16	116:9 133:11	397:12	305:1,6 307:11
194:16 235:11	correct 71:11 75:17	139:16 157:8	critically 180:5	311:21 312:2,20
241:21 299:5	221:15 232:7	230:2 231:21	criticizing 304:6	314:9 315:14
convert 235:5	332:10 344:10	253:18 270:5	crop 16:14 45:2	316:2,5 318:6
260:3,6	correctly 111:7	332:6	58:10 59:11 61:4	319:5 321:15
converted 235:14	Corvallis 158:2	court 359:1	64:21 65:7 84:9	322:15 330:15
convey 371:10	cosmetic 331:20,22	cover 55:12 58:17	117:21 121:9	333:12 340:5,7
conveys 185:11	cost 11:15,22 33:15	137:17 224:15,18	124:7 154:15	343:7 348:6 351:4
convince 333:18	34:3,3 43:10,11	232:1 270:4,6,10	163:20 178:22	351:6,7,21 353:16
convinced 22:18	43:11,12 49:2,9	283:8 317:10	179:3 199:7	353:17,19 355:4
179:20 298:18	49:12,18,21 50:2	353:15	200:14 201:8	357:16 372:15
306:17	50:8,10,11,12	covered 140:10	204:6 207:11,22	375:10 378:20
convoluted 190:5	54:9 64:14 258:4	397:9	208:3 210:7	381:17
cool 231:14 251:4	Costa 337:9	covering 351:12	224:18 225:12	crop-by-crop 43:5

cross 46:20	151:4	dating 236:12	386:2	263:14 265:21
crow 350:15	cycle 383:7	Dave 39:10 176:11	decision-making	270:10 285:14
crucial 274:15	C.F.R 363:8,17	188:2 250:9,11	387:18	degraded 130:2
crux 153:10	365:10	David 3:14 146:13	deck 254:12 264:20	140:10 253:18
CSA 351:17 352:2	D	147:8,20 254:9	272:4 284:11,12	307:18 309:11
353:2 354:9	d 125:18 128:19	310:16 313:22	297:21 304:18	degrades 255:5
CSAs 61:3 302:18	Dag 29:15,17 34:10	314:4	314:1 328:1 337:3	261:8 274:19
cucumbers 226:14	39:6	day 114:10 207:20	346:9	325:9
231:17 262:12	dairy 187:1 303:19	239:14 281:1	declared 180:3	degree 80:8,10 84:4
cue 82:11 86:5	303:19	346:16 350:4	290:5 361:18	143:4 205:2
102:17 122:17	damage 85:1	days 44:14 241:20	decomposes 255:18	304:22 306:18
culpa 177:4	283:21 331:12,18	310:7 351:22	decrease 198:9	delayed 158:22
cultivars 162:2	331:20 332:4	deal 22:5 31:5,17	decreases 329:19	delegation 340:13
211:5 219:21	damages 328:12	34:14,15 41:3	decreasing 26:5	deletion 340:14
cultivate 351:21	damaging 161:22	63:13,15 96:3	338:12	deliberation 99:14
cultivation 394:5	182:5,7	136:22 233:10	deemed 41:9	294:21
395:19 396:18	danger 104:12	252:15 294:15	325:17	deliberations 149:9
397:20	dangerous 337:18	295:1 304:9 369:2	deep 352:2	273:9 387:19
cultural 70:4 84:19	dangers 338:7	dealing 31:9 35:4	defense 160:9	delineated 91:21
196:12 328:21	data 9:12 17:22	86:19 116:10	defer 133:3 141:16	deliver 168:19
329:3 383:21	20:8 37:15 52:10	139:10	deference 41:4	demand 9:21 32:11
culture 339:1	52:15,17,20	dealt 30:22 378:18	defined 41:19	150:8 176:21
curative 151:6	100:22 149:19	Dear 29:20	defines 273:10	177:1 181:21
cure 150:22 151:3	157:1 158:1 164:9	death 62:15	definitely 9:13	182:2,4,5 194:5
current 47:11 57:5	171:18 199:15	debate 300:1	25:14 172:13	197:19 219:1
57:6 62:4 76:19	200:21 201:3	decade 180:17	176:14 180:14	288:18
126:1 143:1	202:3,6,9 204:5	195:11 236:16	definition 45:17	demands 196:13
152:11 155:11	208:6 209:22	decay 84:1	48:9 49:5 86:20	demographics
161:13 171:15	256:14 267:13	December 351:10	86:22,22 87:1	201:6
199:21 205:18,21	307:10 308:5	decide 54:8 79:11	128:20 129:12	demonstrate 34:3
251:11 257:4	318:1	392:20	143:22 240:1	194:11
272:17 273:10	database 175:7	decided 78:10	285:6 287:20	demonstrated
289:14 293:3,11	211:16,20 212:9	87:19 103:9 228:8	288:2	236:17
293:16 320:17	212:12,20 213:5	228:18 313:6,9	definitions 5:12	demonstration
326:3 365:1 393:5	date 52:8 67:12	341:7 345:18	definitive 315:8,9	162:19
currently 57:16	88:2 108:18,19,22	355:7	degradation	denied 70:11 75:5
67:3 69:6 76:16	109:5 110:19	deciding 312:20	125:21 129:13	323:20
84:14 90:8 165:5	111:1,4,10,13,21	383:15	131:9 132:17	denying 287:2
172:14 248:7	112:20,22 113:3,8	decision 51:9 94:21	237:13 253:1,8	departing 302:15
257:8 281:21	167:15 168:5	98:12 232:21	256:4 261:4,17	department 1:1
300:16 309:9	172:19 174:11,15	279:15 319:6	263:3 271:12,13	20:14 91:7 137:22
314:15 321:18	174:15 245:13	323:21 325:18	273:15 274:14,22	195:22 219:18
330:22	286:20 364:2,20	343:18 392:15,18	275:6,7,11 277:20	360:10
customer 40:19	364:22 365:3,8,16	393:1	307:9,22 308:20	departure 9:18
50:9 332:9	365:20 373:22	decisions 114:18	308:22 309:12	depend 220:6
customers 353:3	dated 306:5	300:3,9,12,13	degrade 252:3	331:2
cutting 135:2 151:3		312:22 322:2	261:7,10,12,20	dependent 11:19

85:14	determine 69:5	diagnostic 159:21	difficult 14:11 22:5	disappointing 8:6
depending 15:14	91:18 107:13	diagram 44:7	37:5 272:20	discern 369:3
167:1 230:12	115:8 133:13	dialogue 43:17	307:12 328:14	disclose 99:19,22
243:22 252:5	234:11 262:7	64:15 177:11,18	335:17 339:8	100:3 102:10
261:5	267:14 309:10	192:20 193:21	347:20 348:10	disclosed 133:10
depends 150:21	343:20	DICKSON 1:17	370:8 386:4	360:2 362:2
334:10,12	determined 15:17	357:8 362:18	dig 310:14	disclosure 48:20
deposits 76:21	133:10 137:11	366:8 367:18	digested 117:17	100:10 101:13
78:15 363:9,18	152:6 153:3	371:22 374:18	377:3,12	102:4,7,14 360:7
365:12	320:12,14 321:7	376:7 377:18	digesting 130:9	361:3,22
depth 116:15	325:13 326:1	398:10	dilemma 162:7	discoloration 332:2
Deputy 2:10,20	detrimental 69:16	dictated 41:12	dilemmas 165:9	discourage 13:16
derivative 76:18	develop 63:13	242:3	DiMatteo 94:5,16	53:21 54:5
78:9,12	138:3 151:16	dietary 153:7	298:4	discourages 32:5
derivatives 77:9	167:18 211:19,21	differ 135:11	diminishing 13:18	discovered 231:1
80:21 282:20	275:3 331:7 333:6	243:22	dioxide 124:11	392:13
283:2	352:1	difference 75:11	139:2,3 235:10,11	discovering 32:4
derived 46:14	developed 30:21	186:10 216:20	235:14 253:5	discuss 24:4 59:19
128:9 248:22	53:13 64:7 83:1	234:20	276:1,13,15 277:3	66:6 80:16 340:11
249:4 287:22	88:10 117:20	differences 242:8	287:11	355:11 359:5
291:3,6 293:7	118:1 135:10	different 40:22	dire 187:17	382:8
described 13:11	155:10 160:1	43:6 61:2 63:9	direct 46:3 302:18	discussed 137:21
56:12 119:9 202:4	163:21 175:7	107:2 126:15	360:22 361:13	143:21 148:11
307:6	293:1 309:9	127:12 132:9	389:7,10	214:12 299:12
description 49:5	316:16 318:8	147:12 149:11,11	directed 349:5	327:10 332:22
deserves 12:22	352:13 385:12	151:8 152:19	direction 63:22	393:11 396:22,22
design 20:2	developing 31:12	155:6,7 156:1	64:5 192:19	discussing 65:22
designed 85:3	61:15 64:3 292:1	157:3,11,12 158:2	194:12 277:15	93:11 136:6
132:6 173:1	305:6 344:21	163:15 164:2	391:14	discussion 5:18
desirable 133:15	development 10:7	167:1 168:20,20	directly 61:16	8:15 17:2,15 23:6
163:13	24:16,19 45:21	183:17 194:15	109:7 184:1 200:7	24:4,21 51:7 58:8
desire 218:18	46:2 77:2 82:22	217:6 220:2	208:12 263:15	59:14,19,20 64:13
272:16 377:14	108:5 123:10	228:21 235:2,8	315:18 339:12	66:1,3 73:9 80:9
desperately 294:12	187:15 194:2	237:8 240:14	360:20 378:21	80:10,13 86:2
despite 58:6 197:16	195:9 196:10	241:6 244:11	384:12 392:7	88:8,13,15 113:20
destroy 353:19	209:1,11 234:2	261:2,3 262:5,6	director 2:14 39:11	114:13 116:7,17
detail 98:11 100:6	254:15 275:16	262:14 278:21	50:20 195:5,6	118:12 119:1
217:18 247:16	381:18 382:8	289:2,15 290:22	232:9 272:7	120:12,18 136:8
detailed 34:5	developmental	293:2 296:17	279:20 337:7	142:10 151:14
details 34:20 373:5	233:15	306:22 329:1	directors 147:17	153:11 176:19
detectable 15:8	developments	336:5 344:13	195:21 348:17	177:13 182:1
detection 15:10,13	159:5	372:20 386:20	dirty 281:9	183:14 200:16
17:4 159:8	de-list 311:12	differentiate	disadvantage	214:18 221:21
determination	314:11 319:7	191:15	188:11 317:1	222:17 266:11
295:20	326:20 327:13	differently 278:17	disagree 194:9	304:13 340:19
determinations	de-listing 69:19,22	278:21	disagreement 75:1	355:11 356:10,19
275:19	327:1	differing 387:3	disappears 226:5	358:4,19,19 362:7

363:20 365:21,22 367:9,10 368:19 368:19 370:13 371:1,7,14 374:10 374:11,12 376:3 377:13,14 389:22 396:11 397:6 398:1,8 discussions 65:8 214:6 345:18 397:2 disease 103:2 104:9 104:15 150:15,18 154:9 353:18 diseased 353:19 diseases 159:1 187:19 188:13 disincentive 143:4 disintegrates 241:18 dispensers 87:15 95:9 disposal 224:8 257:3 disposed 251:13 256:17 disqualify 38:3 disruption 168:1 disruptive 316:21 distance 49:17 distinct 7:7 distinction 132:16 246:20 247:2 distinguished 87:2 distribute 200:12 distribution 40:17 219:16 distrust 204:13,17 dive 35:6 diverse 58:1 196:21 197:9 223:20 283:19 diversified 350:20 diversity 201:6 207:22 309:8 diverting 58:13 divided 84:4 85:21	Division 2:14,16 doable 28:19 docket 14:18 72:13 72:14 310:9 311:18 312:18 313:12 379:15 381:7 384:7,11 388:17 document 5:19 6:6 17:15 24:4,21 51:7 58:8 59:21 88:8,13,15 90:9,9 103:3 115:15 213:7 216:6 319:19 358:1 373:21 374:2,11 374:12 382:4,8,11 383:4,17 384:8 390:15 393:17,19 394:3 documented 70:5 documents 91:21 115:13 170:11 220:16,17 324:17 doing 27:20 36:9 40:18 48:9,15 56:19 58:5 100:10 111:20 131:21 157:19 158:6 174:8 185:16 224:21 227:10 228:20 231:6,9 240:21 296:11 298:2 302:16 303:1,9 344:18 353:13 355:15 359:2 393:8 Dole 220:3 337:8 dollars 58:20 domain 218:14,20 219:6,22 347:1 domestic 109:13 domestically 109:17 door 24:18 Doris 195:15 dormant 158:22	Dorrance 1:11 doubled 50:8 doubt 210:18 303:1 374:9 downtown 346:15 dozen 210:20 dozens 253:10 do-nothing 51:21 Dr 3:17 60:5 65:5 146:22 147:22 148:2 171:19 174:4,14,19 175:17 193:19 194:22 260:8 draft 216:6 drafts 100:7 drain 348:6 drainage 339:12 dramatic 150:4 dramatically 121:5 draw 5:12 dream 218:18 219:9 Drew 298:9 drift 396:16 drill 71:20 drip 226:9 229:12 229:14,18 drive 102:13 182:2 182:3 351:10 driven 152:7 162:8 driving 87:6,16 370:22 drop 62:22 354:9 388:13 dropped 61:10 drugs 181:12 188:10 dry 226:8 230:13 266:14 Dubois 254:16 due 70:10,11 179:22 307:8 309:8 318:11 325:6 326:14 347:16 Duke 195:15	dumb 186:17 dumbed 186:17,18 Dummerston 346:15 dump 346:21 dumping 256:18 318:2 dumpster 347:5 dumpsters 251:17 251:17 347:15 duplicative 7:4 Dupont 39:11 D6400 125:8 233:13 D6866 125:17 133:7 D6868 125:8 131:5 <hr/> E <hr/> e 125:19 129:3 165:12 earlier 40:21 42:3 51:9 54:17 94:6 94:14 120:4 130:20 173:10 202:4 208:9 209:13 214:11 231:18 233:14 242:18 258:3 259:7 270:15 332:22 341:9 352:15 359:2 early 20:5 30:20 153:14 256:9 340:12 351:6 Earth 281:1 347:19 Earthbound's 361:16 earthworm 300:11 earthworms 70:6 299:7 300:17 321:5,8,11 easier 234:16 302:12 easily 28:8 225:14 226:4 227:1,2 234:11 386:16	East 346:15 eastern 155:2 172:4 easy 37:13 53:10 191:5 299:4 eaters 299:9 eating 104:13 235:8 236:3 echoes 12:8 ECOCERT 315:3 320:22 ecolabels.org 175:9 ecologic 259:18 ecological 69:17 256:1 394:4 395:18 397:19 economic 20:16 59:6 69:17 207:10 257:12 316:7 396:17 397:7 398:1 economically 316:8 397:12 economics 316:5 398:6 economy 116:8 ecosystem 129:21 283:20 284:2 309:13 ecosystems 296:7 ECOTOX 92:18 297:16 ecotoxic 131:2 140:2 241:22 ecotoxicity 139:22 233:19 285:13 296:3,6 297:8 308:19 Ecuador 105:13,14 328:18 330:4,14 335:14 EDDS 320:4 EDTA 69:2,3 70:10 70:14,20 72:18,21 72:22 73:3 74:21 282:2,4,5,8,10,11 282:12,13,15
--	--	--	--	--

313:9,11 318:2 319:13 320:3,8,8 320:15,16,19 323:19,20,22 324:12,13,15,18 324:22 325:1,5,7 325:9,10,13,15,17 325:20,22 326:6 326:15,16 EDTA's 325:6 educating 176:2 183:2 education 8:18 168:13 191:22 196:17 207:18 303:10 effect 47:15 54:2 69:1 72:4 89:19 104:18 108:3 116:4 130:4 131:2 139:6 166:4,10 252:17 255:7 263:1,6 297:12 324:9,15,21 326:17 329:4 339:10 340:20 effective 62:1 69:14 70:19 112:20 314:15,17 323:18 324:5 329:13 341:18 342:3,12 343:21 369:7,22 370:3 effectively 30:22 345:3 effectiveness 297:11 352:18 353:5 effects 5:5 92:21 103:17 115:18,21 241:22 296:6 309:12 316:22 321:5 efficacious 324:13 efficacy 75:13 154:10 155:18 156:17,21 158:9	369:8 efficiency 282:6 351:4 efficient 268:11 efficiently 353:16 effort 95:14 277:10 348:13 efforts 46:19 51:22 52:2 55:19 58:6 163:14 298:11 302:3 Eight 6:19 69:13 Eight-five 6:14 either 46:7 68:7 72:18 75:18 80:18 85:5 106:3 133:12 139:17 198:7 242:3 397:9 elaborate 48:16 324:2 element 87:16 92:5 elements 94:14 elevate 56:14 92:16 Eleven 388:3 elimination 178:4 elite 12:15 else's 7:5 email 213:16 embarrassing 347:18 embraced 32:16 emerge 141:1 Emily 2:18 95:11 eminent 347:1 Emmerthal 310:20 emotions 341:17 employ 142:16 employs 359:16 EN 125:11,12 enable 9:22 63:15 138:12 encapsulation 120:8 encounter 33:7 encourage 10:20 12:6 13:21 55:2 193:14 200:21	275:2 299:5,6 303:9 314:8 318:5 386:6 encouraged 203:12 encouraging 202:9 202:19,21 203:9 209:13 212:13 388:6 endorse 10:7 endpoint 133:13 enemy 380:16 energized 221:13 energy 64:4 196:2 235:5 353:11 enforce 197:22 272:20 274:9 enforcement 10:10 10:11 56:11 enforcing 136:22 engage 24:22 37:4 58:1 engagement 28:1 28:18 engaging 27:18 207:9 engineered 51:12 52:3 59:7 125:19 128:21 134:4,9,18 205:14,19 206:5,9 209:18 215:7,21 249:4,21 engineering 15:5 195:17 338:18 345:8 England 60:18 enhance 260:20 enhanced 48:8,10 enhances 290:9 enroll 31:22 ensure 10:22 25:5 25:22 40:15 49:7 49:14 53:1 125:21 212:8 273:6 274:14 282:6 ensures 24:9 273:15 entertain 363:5	367:1 395:6 enticed 186:9 entire 124:3 148:3 315:16 344:8 entirely 316:15 entirety 285:20 entities 360:18 387:22 Entrust 106:12 335:12 entry 37:13,22 environment 26:9 130:5 151:21 236:18 257:14 260:20 268:12 282:12,13 283:1 297:12 299:8 325:7,10 326:12 326:18 327:6 338:10 342:6 369:18 380:16 environmental 76:11 84:10,22 85:1 119:10 120:3 120:6 122:9 138:8 174:20 175:9 281:3 307:7 337:7 338:22 339:10 environmentally 251:15 369:10 envision 101:20 EPA 41:8 69:10 86:21 87:19 88:1 88:4 90:4 95:13 96:11 103:4 110:6 110:15 153:2 305:8 311:1 313:4 315:3 320:5 338:19 341:7 345:8 EPA's 338:6 epoxy 97:13 equal 222:20 equals 224:4 274:22 equation 185:21 277:21 337:21	338:5 equipment 257:5 338:16 340:3 344:4 345:6 equivalent 17:8 equivocal 184:3 eradicate 9:11 eradicating 215:6 Eric 250:10 254:11 254:14 269:17 270:19 err 42:4 error 42:5,6,8,12 42:12 ERS 52:16 Erucamide 308:14 especially 52:17 53:6 59:17 62:20 116:7 136:21 139:1 205:9 206:12 207:10 219:6 222:21 299:17 302:10,15 306:11 338:9 370:5 387:22 Esperanza 328:17 329:14 330:2 essential 34:1 85:14 247:2 280:11 283:6 346:18 349:19 essentiality 69:13 70:2 119:11 120:5 279:13,17 369:3 essentially 5:7 125:10 151:3 173:4 179:14 242:21 establish 10:4,21 11:6 17:20 45:6 90:1 234:12 established 12:19 13:6 25:18 33:4 37:14 228:14 establishing 9:1 22:1 24:11 36:15 49:3 299:1 301:9
--	--	---	--	--

342:18	354:22 371:9	excluded 13:5	270:14 288:9	extensive 280:4
establishment	396:7	45:16,17 125:18	experiencing 215:5	309:5 321:6
35:21 36:1 64:14	everybody's 110:16	128:9,14 133:17	expert 106:22	extent 4:16 140:15
et 92:13 148:15	evidence 55:5	133:18,20 134:7	336:22	241:9 268:5
222:5 242:17	200:4 219:3 253:7	216:2 286:10,13	expertise 212:6	271:19,20 292:10
287:9 332:8	385:20	287:19 294:1	275:18	external 178:3
ethical 195:9	evolution 235:19	295:3,4,5,9	experts 15:9	extolling 352:21
196:10	351:11	excluding 237:13	expiration 168:5	extra 49:14 202:21
ethoxylate 97:13	evolve 121:20	exclusively 265:14	174:11,14,15	202:22 203:9,12
ETS 39:22	evolved 142:9,11	excuse 23:3 284:12	expire 113:5	209:14
EU 170:2 313:5	evolving 294:18	363:21	363:11,19 364:1	extract 80:1,11
315:3 341:3	exacerbate 85:15	executive 232:9	365:13	329:7 330:21
Europe 46:13	exact 133:3 200:17	exemptions 79:6	explain 10:5 66:16	336:2
139:20 187:21,22	396:6	191:20 341:8	254:22	extracted 79:1 81:5
228:15 229:6	exactly 37:20 77:15	exist 159:11 184:14	explained 237:7	82:3,3 338:7
242:7,11 243:7,8	129:9,18 138:5	234:20,21	explaining 188:3	extracts 76:21
309:20 319:17	224:21 262:9	existential 183:14	explains 132:13	78:16,17 79:4
349:14 352:21	265:19 373:2,3	existing 32:4 77:7	explanation 285:17	363:10,19 365:13
European 169:20	391:5	110:1,7,19 136:17	explicit 178:20	extraordinary
236:14 241:14	examine 195:16	206:6 325:18	explicitly 180:2	95:14
242:5 245:7,9	examined 53:9	exists 159:11	exploration 397:21	extrapolate 182:11
257:2 270:1 310:7	example 27:13 41:1	257:19	explore 52:14	182:14
313:8 319:20	81:18 114:14	exit 166:15	57:21 116:14	extreme 169:22
evaluate 274:2	153:1 156:12	expand 106:15	385:7	348:3
278:20 296:5	158:15 162:11	218:10	explored 53:9	extremely 154:9
306:10	164:18 189:11	expanding 207:21	exploring 22:22	265:8 386:12
evaluated 90:17	217:4 238:13	207:22	59:4	extremes 348:2
95:16 282:9 306:5	249:1 293:14	expect 21:21	exportable 328:11	eye 396:14
evaluates 285:21	386:5	184:20 192:13	329:16	eyes 381:9
evaluating 75:17	examples 15:20	193:2	exposed 47:2	E's 316:4,5
135:15 175:9	90:13	expectation 99:12	104:14	e-organic 165:17
278:18 279:3,4	exceed 49:2	275:10 301:11	exposure 31:5	
352:17	exceeding 183:17	370:17	153:5,7 337:20	F
evaluation 162:21	exceeds 58:13	expectations 9:21	338:5,13 342:5,6	face 158:14 314:20
275:21	256:13	30:3	express 128:15	faced 328:8 388:3
evaluations 175:3	Excellence 40:1	expected 19:1	expressed 94:10	facets 132:9
event 46:11 47:15	excellent 21:17	31:20 155:22	105:17 128:19	facilitate 23:22
events 336:6,8	170:21 176:11	275:7 301:1	expressions 17:8	199:1
eventually 47:3	221:1 224:20	expedite 305:10	17:10	facilitated 210:13
87:11 100:19	301:8	expelled 236:6	extemporaneous	facilitating 28:1
192:21 261:12	exceptions 97:18	expend 223:10	23:4	facilities 40:7 291:7
347:6	189:18	expense 18:3 54:15	extend 105:4	facility 297:1
everybody 28:20	excess 79:4	experience 31:15	extended 168:5	facing 54:20
28:22 36:18,20	excessively 303:17	34:22 35:3 120:20	extending 167:15	168:21 197:19
65:17 94:11 95:14	exciting 165:12	121:4 149:8 155:7	extension 165:10	215:6 330:5 352:9
174:7 175:18	211:1	168:12 205:5	168:12 169:8	352:10
220:12 221:12	exclude 317:8	211:21 268:2	174:15 303:14	fact 5:4 21:1,22

31:10 40:22 47:1 56:21 63:14 70:11 75:8 78:22 87:19 98:17 161:12 165:19 177:17 178:19 193:22 217:20 219:4 224:11,12 228:1 228:14 229:6 240:5 243:1,8 245:2 291:11 292:20 297:10 319:11 369:5 391:4 factor 170:7 203:22 204:2,8,9,18,20 204:21 316:6 factors 152:19 253:19 279:15 332:15 failed 366:18 378:11 394:15 fails 9:15 327:11 357:15 372:15 fair 186:20 188:17 270:13 323:10 397:10 fairly 20:4 107:11 107:17 108:19 110:6 164:5 faith 370:17 371:2 Falk 29:15,17,17 34:21 36:4,8 37:11 38:5 39:7 fall 27:14 88:9 190:12 225:6,6,10 228:4 237:9 256:9 383:1,2 fallowing 317:11 falls 101:1 false 42:14 falsely 17:10 familiar 148:7 175:8 206:1 242:14 265:8 297:15 families 326:13	331:1,14 348:14 351:18 family 105:15 347:11,11 family's 351:14 family-owned 310:21 fan 113:16 120:14 fantasy 268:7 far 49:2 61:1 106:10 109:1 136:11 139:11 160:20 161:10 164:9 167:17 172:14 226:22 227:11,15 316:15 355:9 369:17 397:1 farm 61:3 120:21 135:3 168:17 179:17 203:3 206:11 208:1 213:8 218:6 223:15,21 226:8 226:19 227:9 228:20 229:15 252:18 270:17,18 298:10 301:18 303:1 304:20 328:17,18 329:15 330:2 338:4 342:15 343:17,20 346:21 347:6,10 347:11 348:20 349:19 350:16,21 354:6 385:14 386:11,13,21 farmer 12:22 21:11 40:18 111:3 199:19 230:8 268:13 281:4 298:6 350:13 352:15 360:12 farmers 8:4 10:1 11:8,9 13:8 18:9 22:15 32:6 33:6 33:17,19 37:3	38:12 53:20 54:5 54:8,12,15 56:18 59:11 60:20 61:3 61:9,18 62:19,21 63:15,19 68:17 69:21 84:13 110:22 124:15,19 189:7 192:6 196:14,22 199:21 201:4,15,18 202:11 203:11,20 204:22 205:11,16 206:13,20 207:8 207:21 208:2 209:7,13,15,17 210:1,2,5 211:6,6 212:14 213:6,13 218:12,17 219:4 223:21 238:4 250:15,17,22 251:7,15 252:19 272:16 273:6 283:18 298:19 299:9,16,18,20 301:12 302:8,10 302:12,13,16,18 302:19,20 303:4 303:19,19 322:4 349:22 350:8 351:16 352:4,5,9 353:2,6 384:16 385:11 388:3,8 390:2 farmer's 277:6 farming 60:16 61:1 64:7,19,21 147:12 206:12 224:1 233:7 250:13 252:12 302:17 327:9 330:1 351:15 360:22 380:17 386:14,17 farms 19:8 85:13 206:17 224:8 303:22 316:8,10 350:18,20,22 385:12,15,16	Farm's 301:5 fashion 159:22 fast 12:4 20:20 21:4 269:11,14 288:10 308:13 328:9 faster 100:2 232:2 261:4,7,11 263:14 293:2 fault 114:3 favor 68:15,19 69:19,22 71:3 85:22 124:14 250:21 337:11 342:4,16,17 369:20 FAVRE 1:17 357:3 362:16 366:5 367:15 371:19 374:15 376:18 378:7 398:21 Fazio 162:1 164:10 FDA 41:8 feasibility 15:22 16:22 52:18 96:3 188:2 feasible 38:20 39:2 89:1 188:6 373:10 feature 213:5 February 214:18 federal 41:12,14 42:16 47:18 62:2 81:2 90:4 115:16 189:3 190:3 233:5 242:4 feed 62:6,11,13,14 feedback 7:11 171:15 212:13 213:9 384:18 feedstock 128:11 134:19 135:18 293:15 feedstocks 291:4 291:14 feel 11:7 27:15,16 36:14 43:17 70:15 76:2 86:15 101:22 103:3 108:6	134:14 137:9 140:17 141:3,9 142:5,5 167:22 182:15,15 190:11 191:6 196:7 240:13 251:16 278:10,12 292:11 297:8 349:2 353:11 feeling 163:4 167:18 feels 9:15 360:4 fees 212:17 feet 230:3 Feldman 1:18 56:3 65:15,16 68:1 73:9 74:16 77:11 80:4 82:6 83:5,10 86:2 91:2 98:13 99:7 100:12,20 102:15 108:10 109:8,19 110:13 112:5 113:10 115:5,12 116:2 117:4 118:8 120:10 122:13 123:19 141:14 143:18 144:5 145:21 170:18 173:22 174:6 193:3 194:18 195:1 216:11,13 218:3 220:5,9,14 221:10,11 227:12 228:6 229:8 230:20 232:4 236:22 238:19 239:16 240:17 242:13 243:12,15 244:10 245:5 247:19 248:2,9 250:3,8 254:8,11 257:21 258:1 259:1 260:17 262:21 263:16 264:1,6,9,15,19 269:9,18 271:11
--	---	--	---	---

271:17,22 272:3	311:10,13 313:8	figured 93:5	Finder 211:17	375:17 380:4
277:11 279:11	313:10 314:11,13	figuring 28:21	212:3 213:15	fish 157:16
280:14,17 284:7,9	314:17 315:1,11	filed 319:17	finding 165:16	fish-based 118:19
288:19 290:14	315:19 316:19	filled 217:9	213:14 315:1	fit 90:1 143:21
292:4,8 293:17	319:5,7,11 320:1	filling 217:3 265:4	331:5	217:10 267:17
294:5,11 296:1,10	320:7,9,12 321:1	film 3:12 122:16	findings 55:3,4	385:13
297:15,19 302:4	321:4,7,10,15,18	123:4 124:5,14,18	197:7 214:20,21	fits 145:12
304:14,17 308:3	322:1 323:9,12,15	126:11 131:7	314:21	five 69:9 79:13
308:10 310:4,15	323:17,21 324:4,8	144:1 221:20	finds 370:3	119:16,17 120:1
313:19,22 318:14	324:9,14,18,20	222:11 244:4	fine 142:17 252:11	164:2 244:22
318:17,20 322:7	325:1,5,13,15,19	254:17 255:4,7,22	266:18 271:6	322:14 385:19
322:11,21 327:16	325:21 326:3,6,13	256:6 257:9 259:5	396:12,20	Flamm 1:12,14 4:3
327:20,22 331:16	326:16,18 327:10	260:4,12,13,15	finished 32:20	65:12 220:22
332:12 334:5	327:13 355:13,18	262:11 263:10,13	fire 148:10,19	221:7 355:17
335:3,8,18 337:2	356:3,9 359:9	272:12 273:11	150:15,21 151:10	356:5,8,18 357:2
341:13 342:21	fertility 80:12,17	276:3 298:8 303:4	153:22 154:6	357:14 358:3,15
345:9 346:4,8	295:8 317:15	films 232:11 244:3	155:3 157:18	360:1 361:2,21
350:2,6 354:12,18	fertilizer 80:12	246:12,17 247:8	158:19 159:3,10	363:4,12,15 364:9
354:21 356:21	245:20	251:12,21 252:14	159:13 160:4	364:15 365:7,15
357:18 359:11	fertilizers 79:7	270:3 284:18	161:5,10 162:4,10	365:19 366:16
363:3,14 364:8,14	80:8 178:5	286:2 287:5,6	163:14 164:1,3,13	367:6 368:5,13,16
365:18 366:14,20	fewer 198:10	final 43:15 108:16	164:22 166:8	370:12 371:6,13
367:5 368:2 372:6	204:19 316:10	111:15,17,17	168:15 169:9	372:9,13 373:16
372:17 373:15	field 8:19 18:8 40:8	112:10,14,15	171:13 192:3	374:4 375:5,8,22
375:2,13 376:13	57:19 128:3	235:12,19 364:21	firms 54:6	376:19 377:6,9
378:2,12 381:16	129:15 133:21	394:3	first 20:11 21:20	378:9,17 394:14
398:16	134:6 136:22	finalize 91:5 95:3	22:1 25:14 33:5	394:19 395:2,10
fellow 352:10	145:7,8,10,15,16	finally 72:12	35:8,16 39:16	395:14,21 396:2
Fellowship 195:16	145:20 157:6	108:15 155:19	40:4 51:14 56:16	397:15 398:7
felt 73:6 79:5 127:3	158:12 164:9	187:14 252:22	60:17 66:13,16,19	399:2
355:5	188:19 206:11	287:15 345:18	72:9 76:7 77:14	flare-up 370:4
fermentation	227:7 268:2	financial 55:14	92:11 112:7 117:9	flat 167:14
128:11 290:2	273:19 274:7,17	58:15 215:5 231:1	130:16,19,22	flawed 314:19
291:6,16 385:8	278:5,7,18 279:5	360:20 361:13	153:15,21 154:1	flies 350:15
fermenting 288:3	317:5,8	388:1	157:6 160:9,14	flip 74:18
Fernandez-Salva...	fields 52:4 208:1	financially 27:9	171:19 177:22	floor 183:13 184:10
280:18 284:14,15	226:17 227:6	find 5:18 17:13	190:4 196:6 214:2	184:13,13,17
289:11,13 291:1	238:5 244:7 253:8	20:17 22:14 38:19	217:17 218:1	flow 39:17,18 44:2
291:20 292:7,18	268:9 317:5	50:6 62:6 72:8	225:22 228:3,7	flower 156:3
296:8,13 297:17	353:14	148:13 160:13	233:6 240:4,5	flowers 328:13
ferric 3:8 66:14,20	FIFRA 317:18	169:8,11 192:20	255:2 261:1	flowing 341:2
67:2 68:4,6,16,19	Fifteen 375:9	201:2 213:8	280:22 289:17	fly 314:20
68:22 69:11,20	fight 187:18 188:13	214:21 217:12	297:18 298:20	FMC 388:19
70:1,18 71:4 72:3	figure 22:5 88:22	220:18 229:1	324:4 328:19	focus 8:11 31:11
72:16,20 73:7	100:8 169:3	268:19,19 280:11	333:17 338:8	87:9 180:20
281:13,17,18,20	172:17 173:14	332:22 343:14	350:18 354:1	222:22 284:16
282:2,3,10,15	267:7 322:17	348:12 391:20	367:2 374:14	385:4,6 386:11,13

focused 80:10 103:9 118:12 171:21 216:19	112:17 foresee 26:4 forever 48:10,15 forget 16:7 form 148:13 216:5 219:11 229:13 320:20 351:14	Foster 1:18 26:2,21 35:19 36:6 43:22 44:6,13,17 64:11 80:6 81:4,10,13 81:16 98:20 99:8 113:12 118:10 120:13 142:7 216:16 238:21 248:11,19 249:9 249:12,17 258:3 258:12,16,19 288:21 289:12 292:10 293:19 294:13 334:7,17 335:2 341:15 354:15 357:7 358:14 361:8 362:19 366:7 367:17 368:15 370:15 371:21 374:17 375:16 376:6 377:1,17 381:20 390:21 391:12 396:12 397:18 399:1	210:13 224:3 237:8,14,19,21 238:9 241:16 242:6 243:13 281:12 313:16 339:16 343:7 385:11 fourth 40:11 242:1 Fox 349:6 frame 89:2 94:15 96:9 97:4 117:5 163:5 169:5 241:19 285:11 framework 18:5 57:6 205:18,21 206:2 382:21 385:14 France 264:11 free 31:13 86:15 128:12 212:14 frequency 16:14 180:7 342:17 frequently 34:19 211:18 233:18 friendly 299:19 369:10 front 5:2,2 295:19 298:1 395:9 396:7 397:14 fruit 3:14 84:1 146:12 147:14,20 148:21 149:5,19 151:19 160:13 162:21 163:13,16 166:2 170:13,15 181:6 223:20 328:10,12 329:16 331:21 332:3,4,8 344:9,17,20 370:5	fulfilling 247:2 full 15:12 48:20 90:14 101:8,13 102:6,14 146:20 230:16 251:17 312:6 347:5 365:9 395:4 fully 51:21 57:14 122:7 221:19 241:19 245:4 246:16 247:8,12 252:3 253:5,17 285:20 306:10 312:4 Fulwider 1:19 302:7 357:9 362:14 366:3 367:13 372:12 375:6 376:16 378:5 381:19 398:19 function 70:21 78:7 391:19 functional 99:13 393:7 fundamental 233:10 241:16 242:6 fundamentally 235:1,7 269:1 funded 172:1,4,10 212:16 387:10,22 funders 389:6,9 funding 198:9 199:9 387:20 388:6 funds 208:19 219:19 fungi 83:22 253:11 283:16 Fungicide 90:5 fungicides 287:9 further 13:16,22 22:7 24:3 45:21 57:4,11 74:4 124:22 214:17 274:9 275:4
follow 20:1 35:20 98:2 100:14 242:13 386:19	formal 245:10 327:1 format 91:18 formed 88:4 240:2 former 217:15 305:2 forming 4:20 forms 276:13 formula 106:14 formulants 320:3 formulated 71:13 formulating 323:7 formulation 75:12 92:5,6 99:2 101:9 323:19 326:15 335:13 373:20	fostered 317:10 fought 347:7 found 12:10 22:16 30:7 87:5 103:21 106:10 140:3 173:16 178:22 181:4 205:4 229:3 231:11 252:2 279:14 280:5 283:19 307:6 308:18 339:20 342:16 343:6 354:15 389:1 393:15 foundation 9:19 11:3 23:13 24:1,8 25:15 196:20 foundational 26:16 379:16 four 68:9 69:6 70:5 90:16 105:12 120:1 124:18	fourth 40:11 242:1 Fox 349:6 frame 89:2 94:15 96:9 97:4 117:5 163:5 169:5 241:19 285:11 framework 18:5 57:6 205:18,21 206:2 382:21 385:14 France 264:11 free 31:13 86:15 128:12 212:14 frequency 16:14 180:7 342:17 frequently 34:19 211:18 233:18 friendly 299:19 369:10 front 5:2,2 295:19 298:1 395:9 396:7 397:14 fruit 3:14 84:1 146:12 147:14,20 148:21 149:5,19 151:19 160:13 162:21 163:13,16 166:2 170:13,15 181:6 223:20 328:10,12 329:16 331:21 332:3,4,8 344:9,17,20 370:5	followed 40:14 137:20 157:19 158:5 following 68:21 70:1 125:6 126:10 246:22 273:4 275:5,12 308:20 319:20 387:1,14 follows 41:15 follow-up 37:7 239:16 249:18 food 45:21 57:9 175:10 189:13,21 193:2 196:19 197:17 198:14,16 207:3 209:2 212:19 213:1,3 235:22 288:4 291:7 299:7 317:14 326:6 380:2,11,21 381:5 foods 29:19 87:7 133:22 184:20 189:16,18,22 235:4,9 236:4 326:9 379:20 380:8 forage 201:13 202:2 204:6 force 33:14 166:15 forced 33:19 Fords 240:8 forefront 354:6 foregoing 65:9 221:4 322:18 399:9 foreign 109:4,17
foods 29:19 87:7 133:22 184:20 189:16,18,22 235:4,9 236:4 326:9 379:20 380:8 forage 201:13 202:2 204:6 force 33:14 166:15 forced 33:19 Fords 240:8 forefront 354:6 foregoing 65:9 221:4 322:18 399:9 foreign 109:4,17	formal 245:10 327:1 format 91:18 formed 88:4 240:2 former 217:15 305:2 forming 4:20 forms 276:13 formula 106:14 formulants 320:3 formulated 71:13 formulating 323:7 formulation 75:12 92:5,6 99:2 101:9 323:19 326:15 335:13 373:20 formulations 3:10 70:14 86:13 276:9 324:19 373:13 formulators 94:20 forth 89:2,20 146:9 forthcoming 70:17 forty 58:19 forum 359:21 forward 24:3 52:1 55:17,19 60:1,3 70:13 79:12 92:4 96:13,20 132:1,9 137:4 189:10 190:19 197:10 199:3 218:6 246:10 247:17 248:1 250:4 254:4 254:21 257:18 285:17 290:8 355:18 372:22 373:7 397:10 for-one 231:8 fossil 85:13 257:11 349:20	fostered 317:10 fought 347:7 found 12:10 22:16 30:7 87:5 103:21 106:10 140:3 173:16 178:22 181:4 205:4 229:3 231:11 252:2 279:14 280:5 283:19 307:6 308:18 339:20 342:16 343:6 354:15 389:1 393:15 foundation 9:19 11:3 23:13 24:1,8 25:15 196:20 foundational 26:16 379:16 four 68:9 69:6 70:5 90:16 105:12 120:1 124:18	fulfilling 247:2 full 15:12 48:20 90:14 101:8,13 102:6,14 146:20 230:16 251:17 312:6 347:5 365:9 395:4 fully 51:21 57:14 122:7 221:19 241:19 245:4 246:16 247:8,12 252:3 253:5,17 285:20 306:10 312:4 Fulwider 1:19 302:7 357:9 362:14 366:3 367:13 372:12 375:6 376:16 378:5 381:19 398:19 function 70:21 78:7 391:19 functional 99:13 393:7 fundamental 233:10 241:16 242:6 fundamentally 235:1,7 269:1 funded 172:1,4,10 212:16 387:10,22 funders 389:6,9 funding 198:9 199:9 387:20 388:6 funds 208:19 219:19 fungi 83:22 253:11 283:16 Fungicide 90:5 fungicides 287:9 further 13:16,22 22:7 24:3 45:21 57:4,11 74:4 124:22 214:17 274:9 275:4	

278:22 285:4 310:13 312:5 367:10 370:12 371:6,13 386:9 397:21 furthermore 204:22 future 6:22 12:5 14:13 19:10 24:9 60:4 136:1 139:9 148:21 167:21 169:7 218:19 257:14 260:11 264:14 276:3,9 287:2,13,13 330:22 387:2 397:16	generalist 106:19 generally 87:18,18 154:11 175:15 189:5 397:8 generated 288:4 generation 257:14 257:17 generational 46:2 generations 45:15 generic 68:5 genes 163:20 genetic 11:3 12:18 13:10 14:2 15:4 22:15 23:16 42:17 47:15 52:7,19 53:2,4,18 54:13 55:7 57:8 61:8 62:5 151:11 160:8 165:9 205:9 213:22 215:3,12 genetically 24:10 46:11 47:10,13 48:8,10 51:12 52:3 59:7 61:19 134:3,8,17 195:17 205:14,19 206:4,9 209:18 215:6,20 246:3 249:4,21 293:5,7,13,14 genetics 8:5,6 12:16 25:1 Geneva 152:2 160:15,18 161:9 161:14 162:1 164:14,17 Gennaro 162:1 164:10 genome 48:5 gentamicin 179:22 gentleman 239:3 247:22 270:15 290:19 geography 201:8 germ 46:18,22 47:1 215:17 219:15 germane 318:3 Germans 153:20	Germany 310:20 germination 131:3 getting 18:14 21:4 96:14 100:2 102:20 104:4 113:5 121:14 141:3 156:4 163:5 164:1 181:16 268:4 294:19 296:15 353:3 391:18,19 give 15:20 49:4,5 84:13 96:21 99:17 100:1 108:4 112:17 137:18 152:10 171:6 174:19 176:14 217:22 220:11 222:2,2,3 238:3 260:19 264:7 302:10 310:1 333:4 351:5 given 90:12 108:13 111:21 139:20 152:14 209:2,10 241:10 243:1 289:2 293:22 294:16 305:12 306:7 334:8 337:13 gives 56:1 86:3 113:3 163:4 351:9 giving 111:13 glad 30:13 62:9 347:3 global 114:9 115:2 116:8 348:2 Globally 320:21 gluten 248:22 249:20 glycol 3:9 82:10,17 83:15 281:14 283:10,12 GM 249:14 295:7,8 GMO 3:2 4:6,20 5:5,13,20,21 6:19 6:21 11:12 12:21	19:7 22:6 23:8 30:19,22 31:5,13 31:16,18 32:14,18 35:2 41:5 49:8 51:22 60:3 62:14 63:18 65:3,6 135:1,4,12,15 214:3 222:17,19 223:1 238:8,14,18 242:17 247:13 258:10,10 286:21 292:11,13 293:1 293:22 294:15 295:12 382:3 GMOs 4:22 5:5 6:1 6:4 30:13,20 31:2 51:4 63:5,17 134:13 135:19,22 198:18 238:22 286:19 294:18 go 6:9 15:18 24:3 47:8,14 49:7 56:13 68:11 70:22 81:19 84:2 92:1 92:17 95:1 96:21 100:13 111:15 112:7 113:2 114:7 125:2 130:7 132:5 137:3 142:6 144:3 145:1 149:9 150:18 159:9 169:8 170:19 178:8 184:5 186:9 188:21 189:4,22 190:13 200:6,22 234:1,4 236:14 244:17 254:21 257:18 259:1 262:11,21 263:17 269:6 289:17,21 312:13 323:1 333:19 335:14 337:15 344:5 345:10 354:14 382:13 383:13 390:20 393:13 398:4	goal 89:3 149:3 183:3 199:20 207:17 288:11 goals 201:5 299:13 goes 8:20 27:17 86:21 96:15 103:3 106:11 240:20 259:15 267:19 going 5:20 6:5,7,9 6:10 7:9,13 14:4 14:16 18:17,21 20:13,15,19 26:7 28:10,12 36:10 37:2,4,15 42:7 61:15 62:12,21,22 64:6 66:7,14 68:11 70:22 73:2 81:18 83:13 87:20 91:22 93:14 95:20 96:17 97:1,11,16 97:22 98:14 99:13 102:16 107:22 110:8,22 113:14 121:21 124:2 125:2 126:4 130:7 131:21 132:1,9 134:2 135:1 137:17,18 138:1 142:21 143:22 145:16 147:3 148:5,20 150:18 154:13 155:6,20 156:13 160:22 163:1,17,19 166:14,22 168:7 168:17 169:2 173:9 177:4,14,17 183:13,15,18,22 184:5,6,10 185:14 186:9 187:5,6,15 187:19 188:15,21 190:8,18 191:7 192:5,8,9 194:7 194:14 197:2,6 203:1 210:17 211:7 214:19 218:6 219:19
G				
gain 360:20 361:13 gained 354:6 gaining 22:3 gala 150:11,12 gap 159:2 161:7 172:13 307:10 gaps 158:14 308:5 gardener 298:6 gas 288:3 291:7,18 gather 35:14 gathering 35:12,13 35:22 37:15 289:9 gavel 4:7 65:14 220:20 379:1 GE 9:11 10:9,17 15:9 17:21 18:1,6 18:11 20:2 33:18 34:8 41:7,17,20 55:13 128:12 206:18 gene 164:4 general 10:13 80:16,21 119:20 128:13,15 142:17 148:12 160:5 166:21 198:12 210:10 249:14 379:15 381:7				

224:21 225:4	379:7,13 381:5	ground 255:8,17	45:9 57:17 79:17	grows 121:19
228:19 230:6,9	391:17,20 392:10	256:8 259:16,17	79:20 80:2 105:9	185:17
231:8 233:21	goods 192:17	263:12 388:8	105:12,13,14,14	growth 24:19 40:7
234:3 236:5 239:4	Googling 178:13	390:3	121:12 130:1	53:21 131:3
239:12 243:2	govern 206:8	group 3:14 7:6 69:5	132:7 137:10	149:21 150:5
245:9 246:3 258:2	governing 205:19	70:16 82:15 83:19	150:14 151:9,15	196:16 197:17
260:11 261:6,8,19	government 206:6	87:13 88:4,5,6,10	151:21 152:8,8	208:10 233:21
261:20 262:11	232:16	88:21 89:11 90:14	153:15 154:2,17	251:5 252:1
265:3 266:8,12,12	Gracias 337:1,2	91:5,6,15,20 92:9	158:12 161:7	253:13
266:13,15 277:15	grafted 161:15	146:13 147:20	162:22 166:2,17	guess 34:8 48:19
278:14 285:17	grain 64:21 302:10	148:8,8,13,17,22	166:20 167:20	56:3 60:11 111:19
290:7,8 296:16,16	grains 304:2	149:5,10,13,14	168:2,13 169:11	146:1 187:13
296:21 303:6	gram 180:10	167:18,19 175:1	169:19 170:8	216:8 222:6,13
312:6 322:11	Granatstein 3:14	177:10 210:19	171:7 173:1,10	229:5 270:18
333:15 334:19	60:5 65:5 146:13	211:8,9,15 213:11	193:16 199:7	281:9 357:20
336:20 345:19	146:22 147:8,22	213:20,20 214:10	200:6,14 204:5,6	388:10 392:4,8
347:2 353:1,12	148:2 171:19	295:21 306:7	222:21,22 250:17	guidance 16:11
354:17 361:17	174:4,14	318:9 321:21	250:18 251:3,10	18:20 19:11 138:3
369:20 373:4,10	grant 208:15	332:18 373:3	251:19 252:2,15	138:13 140:10
384:4 391:17,20	219:18	grouping 90:11	263:21 266:2,5,6	154:17 216:6
392:20 395:11	grants 208:16	groupings 89:17	266:8,17 267:7	274:12 275:3
397:9	graph 150:9 342:13	90:14	269:12,15 274:13	278:4
gold 184:5,9	grapple 97:21	groups 19:1 89:19	277:17 301:19	guide 250:1
good 4:10 7:11 9:12	98:14	92:4 197:9 199:2	314:16 315:12,15	guideline 137:19
18:22 20:6 21:10	grappling 99:17	210:13,18 211:10	315:18 316:12,22	283:20
26:2 50:19 81:17	grass 304:2	232:15	328:4 330:4,11,12	guidelines 47:19
83:12 104:16	grateful 51:3	groves 317:6	330:19 331:1,13	89:16 298:21
116:1 118:21	123:20 214:5	grow 25:2 165:8	332:19,19 343:12	guts 292:21
141:11 142:10	grave 97:15,19	182:3 183:6	343:22 346:19	guy 259:22 260:2,9
146:7 152:4	great 54:10 55:15	185:18 229:17	348:11,11,18,21	344:3
154:17 155:13,18	117:6 121:15	351:21	349:1,2,10,15	guys 291:12 298:1
156:20,21 159:20	157:8 193:20	grower 64:12	351:20 361:9	344:5
165:3 168:12,13	212:18 218:21	125:20 129:10	369:21 370:10	G.41 164:15
175:18 187:16,20	241:12 256:1	131:19,21 132:1	grower's 113:17	
193:6 213:1,2	269:16 270:12	132:11 137:5	growing 26:17 31:6	
225:8 228:18	271:10 298:2	143:4 149:7	125:22 137:7	H
232:7 254:13	306:7 327:19	154:10 159:15,21	149:13,19 150:1	hail 351:8
257:20 260:22	greater 153:6	162:21 239:1	158:2 176:21	hailstorm 155:1
261:13 269:5	292:12	252:7 265:7	179:18 270:16	half 148:9 203:20
272:5 284:14	greatly 232:19	266:13 273:14	273:16,20 274:8	207:7 230:12
300:22 301:7	green 156:18,19	315:10 317:7	274:10,20 275:14	329:17 355:3
302:17 304:12,19	175:12	346:14 347:18	281:4 315:14	hand 38:17 87:6
310:18 314:2	GreenerChoices....	370:3	350:16	220:20 318:4
319:2 328:2	175:12	growers 10:1 11:15	grown 6:2,3 107:10	331:3 354:1
333:21 337:4	greenhouse 40:6	16:3 19:21 25:11	129:12 243:8	handle 25:11 163:2
339:1 342:6,8,17	greens 315:22	26:6 27:4,8,14,18	281:14 316:6	257:4
345:22 370:19	grew 201:11,12,13	29:7 44:20,22	326:5	handled 80:14
				handler 80:3

handlers 8:17 361:10	Harold 1:15 229:9 262:21 368:20 370:16 371:17	265:22 266:16 271:1,8 277:14 284:6 297:18 302:1 332:17 355:10 361:3 391:5	Hi 60:10 297:22	hope 52:14 55:2 86:20 116:13 143:14 219:9,19 270:20 273:8 356:13 397:21
handling 149:14 327:9 381:21 393:21	harrow 350:11	hearing 5:1 94:7 143:15 293:20 362:8 367:9 374:12 376:3 377:14 390:2 398:8	high 30:2 31:15 37:12,21 61:5 130:16 168:18 170:6 180:6 192:9 192:12,15 226:7 229:19	hopefully 9:3 37:16 76:2 101:5 194:4 234:6 242:11 337:21 360:21
handout 34:6	harvest 16:15 125:22 137:8	heat 231:12,15 240:2 348:3 351:5 351:10	higher 43:9 131:8 305:13 316:16	hoping 14:9 20:7 177:7 305:14
hands 28:11 106:14 215:14 265:20	harvested 225:7	hectare 255:20	highest 30:8	Hopkins 174:21
hand-picking 317:6	harvesting 225:10 227:17	hectares 330:13	highlighted 238:14	hormones 178:6
hand-weeding 227:17	hate 143:6 347:10	held 219:5,21 231:13	highlights 275:22	Horticultural 147:19
happen 23:20 33:16 54:14 73:5 96:9 122:10 333:15 336:14	haul 150:14	Hello 29:17 280:20 323:2	highly 92:18 161:5 338:11 347:3	Horticulturalists 348:19
happened 222:6 336:11 345:16	hauled 251:17	help 19:3 25:19 36:2 64:2 81:5 136:9 149:8 169:1 169:2,6 192:5 193:16 240:11 249:22 251:4 290:16 299:9 346:17 353:15 379:21 380:8	high-infection 159:14	hosted 199:13 212:3
happening 20:18 144:21 152:4 243:3	hay 348:8	helped 103:14 200:12 211:15 224:18	high-risk 168:16	hot 230:12 266:15 370:7
happens 236:2 280:7	hazard 92:20	helpful 44:7,14,15 63:8 94:17 109:8 216:14 279:1,7	high-value 61:19 316:2	Hotel 1:10
happy 27:22 236:21 239:6 269:7 271:21 286:3,8 297:13	hazardous 105:6	helping 86:15 146:7 353:18 371:9	history 103:4 114:3 148:7 267:20	hotter 230:15
harbored 344:16	hazards 104:14	helps 122:10 161:14 224:12,15 227:7 380:4,13	hit 58:15 169:21	hour 146:20 223:16 355:3
hard 4:14 27:8 71:20 72:7 81:21 82:4 114:18 187:1 191:7 215:17 223:9 268:19 332:18	head 92:16 142:12	heritage 12:21 196:12	hits 371:1	hours 223:17 237:4
harder 142:16 224:16	heads 174:22 181:10	herrings 71:17	Hoc 3:2 4:6,20 21:15 51:6 135:12 295:12 382:3	house 195:2
hardest 97:21	head-nodding 99:5	hesitate 83:13	hold 45:18 60:8 142:3 151:20 157:13 183:4 192:8 227:14,18 391:21	houses 163:1
hardship 34:4 38:11,15	health 62:1 84:22 92:21 103:17 104:18 108:8 113:13 115:11,18 115:21 119:11 174:20 180:1,2 325:11 327:5 335:21 336:7 338:9,21	Hey 248:12	holding 192:15	Hubbard 3:18 50:18,19,20 56:16 146:18 195:6 196:4 216:12 217:14 218:21 220:8
harm 15:6 24:16 34:3 59:6,12 215:5 233:21 321:8,11 326:11 380:15	healthiest 149:4		holds 227:20	huge 98:11 170:7 173:21 288:17
harmful 282:11,22 306:1 325:8 327:5	hear 4:14 6:10 98:21 117:9 133:1 136:20 143:22 146:15 176:13 182:1 222:13 251:9 252:19 266:1 292:16 355:7		holes 227:18 256:6	human 57:3 84:22 170:14 325:11 327:5 336:7 338:9 352:10
harmonized 322:2	heard 4:12 15:1 45:14 55:9 94:3 105:8 106:22 134:1 153:13 248:15 249:1		home 350:21 370:22	humans 48:11 326:18
			honest 58:6 192:19 381:8	humates 77:19 78:4
			honestly 191:15 239:2 392:17	humic 76:18,20 77:7,9 78:9,12,14 79:1 81:5 282:19
			honesty 185:10	
			honored 174:17 196:7	
			Hood 162:12,19	

282:21 283:5,6 358:11 363:9,17 365:1,11 hundreds 329:22 hurdle 118:13 hurt 28:8 101:10 hybrid 39:12 47:11 215:13,13 Hybrids 8:1 hydrogen 78:5,6,17 79:2,3 282:19 358:12,17 363:10 363:18 365:12 hydroponics 281:5 hydroxyl 70:10 75:7 325:5,16	138:21 166:8,14 263:6,9,15 315:19 320:4 369:17,18 382:9,10 396:17 397:7 impacts 84:21 85:1 97:19 98:8 119:11 267:15 307:7 394:4 395:19 397:19 impart 189:5 imperative 277:8 implement 10:22 13:10 211:19 implemented 53:3 108:16 178:16 325:19 371:4 implementing 53:7 implication 314:18 implications 115:3 195:17 223:1 imply 17:10 importance 30:9 116:19 182:19 354:7 important 6:22 8:21 33:13 51:14 52:18 59:13 64:1 75:21 96:22 104:7 114:5,21 116:5 126:12 139:12 160:2 180:5 182:22 183:1 192:16 207:2,5 210:2,8 219:10,11 222:21 232:2 251:2 255:6 259:10,12 283:5 303:13 317:10 319:9 320:18 340:10 341:5 353:20 380:1,11 386:12 importantly 233:19 317:20 imported 243:9 341:10	impossible 99:3 impress 71:18 impressive 197:16 improve 32:15 160:22 209:19 299:7 301:20 306:19 345:22 improved 386:5 improvement 207:11 210:7 300:19 improvements 208:5 209:7 improving 199:11 209:6 211:12 inaccurate 140:7 inadequacy 57:5 inadvertent 48:13 incentive 99:18 100:1 incentives 143:12 inch 230:11,12 inches 230:3,6 incidences 55:13 incident 304:5,9 inclination 135:16 inclined 224:13 include 18:7 94:18 106:11 208:17 222:16,20 282:2 286:21 287:6 288:2 290:20 365:3 381:16 383:16 386:7 395:11 397:22 included 129:7 199:5 213:4 214:8 274:1,4 287:19 312:10,16 includes 6:2 19:14 90:11 91:3 145:14 149:14 220:2 315:12 including 84:19 90:15 129:1 137:17 146:14,16 198:4 211:6 216:1	217:19 237:14 250:18 272:21 328:4 346:1 360:3 361:4 inclusion 128:18 276:10 385:2 income 224:2 351:15 incompatibility 70:2 119:12 incompatible 85:16 325:17 326:2 incomplete 307:9 309:12 inconsistencies 189:10 inconsistency 190:1 inconsistent 179:1 incorporate 393:10 incorporated 76:12 82:15 247:5 incorporation 137:14 246:15 incorrect 110:4 133:6 incorrectly 249:2 increase 26:15 149:22 150:3,4 184:16 194:6 207:16 299:7 increased 49:17 192:4 202:12,15 203:17 209:10 increasing 26:5 36:14 increasingly 61:17 62:6 incredibly 384:20 incrementally 143:13 incurred 11:9 independent 385:20 387:4 independently 126:19 286:7 321:16	indicate 201:15,19 297:1 indicated 43:8 75:8 97:8 201:21 202:15 203:21 204:1,7,11,18,19 205:17 206:16 209:12,22 292:22 361:5 indicates 282:8 287:5,21 288:9 391:9 indicating 47:11 285:2 287:16 indication 150:8 180:8 indicative 92:19 individual 6:13 92:7 94:19 98:9 222:11 333:20 individually 222:13 307:20 individuals 120:2 232:15 industrial 318:2 industries 33:17 industry 5:6 9:21 12:12 14:1 15:7 22:13 24:14,20 28:10 30:17 38:6 38:14 39:19 40:3 41:2,15 43:16 53:22 97:20 102:20 116:22 148:15 149:12 179:10,13 181:13 181:14 182:10 184:21 185:3,8,18 186:21 187:2,17 188:14 191:7,8,18 192:22 195:14 197:17 198:5,15 210:4,15 212:1,19 212:22 213:10 214:13 215:10,16 219:12 232:16 260:14 269:3
I				
idea 63:4 164:21 217:9 275:15 392:10,10 393:8 ideally 52:19 ideas 7:16 27:6 identical 37:8 125:11 identified 53:11,12 87:8 197:11 253:12 308:5,5 319:14 392:15 identifies 19:15 identify 40:2 54:19 63:12 90:19 213:12 234:17 386:4 identifying 56:10 IFOAM 313:5 315:3 320:22 illegal 110:17,18 illustrates 329:19 imagination 36:17 imagine 341:18 immediate 10:16 immediately 224:15 370:2 impact 13:12 26:7 70:6 84:9,10 97:15 129:20				

274:16 328:7 331:4 343:11 industry's 22:3 industry-wide 179:18 ineffective 328:16 370:21 inert 3:10 68:8 69:4 75:3,3 86:12,19 87:1 90:22 91:8 93:4 94:2 95:8 235:16 282:4,5 314:20 318:11 320:16 321:17,19 360:13 372:17 373:12,19 inerts 69:4,5,8,10 70:16 73:3 75:20 86:3 87:8,12,14 87:17,20 88:10,18 88:21 89:15 91:4 91:19 93:1 94:19 96:4,10,11 98:3 99:20 100:5 101:1 305:8,11,12 318:9 321:21 373:3 inert's 313:17 infectability 161:18 infected 151:2 161:19 infection 151:2 152:6,9 153:5 155:4 161:16,18 161:21 164:15,16 infer 105:2 inferred 127:16 infers 274:21 infestation 344:16 infested 338:10 343:17 infiltrating 380:20 infinite 36:17 influence 303:21 influenced 301:1 influx 93:19 inform 20:11 149:8 214:14 268:3	information 14:9 19:1 20:12 34:17 34:18 35:5,12,22 54:12 67:6 71:17 72:1,12 73:12,14 73:18,20,22 74:2 74:12 95:15 98:15 98:18 110:6 113:13 130:9,15 149:2,7 161:22 165:21,22 168:11 169:13,14 211:8 222:2,10 246:4 253:12 254:6 260:19 288:13,22 289:3,5,9 290:11 310:3 311:19 312:11,13 313:11 380:3,12 390:4 information-gath... 36:2 information-shar... 209:19 210:15 informed 214:11 353:4 354:8 ingredient 68:5,7 75:2,4,5,6,14 87:4 282:4,9 311:10 313:2,7 314:14 319:12,14,15 320:7 325:22 ingredients 3:10 31:16,19 32:20,22 86:12,19 87:18 90:7,20,22 94:2 95:8 101:9 102:11 139:15 222:11 242:16 305:8 313:16 318:11 321:17,17,20 326:11 360:13 372:18 373:13,19 inhalation 338:9 inherent 42:14 initial 130:19 233:13 296:19 298:8 312:16	initially 282:3 311:12 initiate 20:13 initiated 210:13 ink 139:7 innocent 28:7 innovation 207:22 innovative 257:13 288:11 innovators 385:12 inoculated 158:10 inoculum 158:19 input 21:3 80:12,17 85:18 277:14 286:19 295:8 338:4 inputs 12:1 120:21 122:1 133:21 135:5,15,22 178:3 248:21 298:7 ins 177:14 insect 328:9,12 345:3 Insecticide 90:4 insecticides 329:1 insects 107:3,5 159:1 369:19 385:9 inserted 48:4,5 inside 259:17 inspections 275:13 301:11 inspector 110:14 275:9 278:21 305:2 inspectors 275:10 278:17 inspire 193:15 instance 25:18 61:10 instances 59:6 Institute 123:2 232:10,14 281:7 298:12 304:21 institutions 384:18 385:16 instrumental 86:17	insufficient 119:4 130:3 140:11 insurance 59:11 63:2,4 intact 332:9 integrate 154:12,17 integrated 155:20 172:12 329:9 331:6 385:17 integrating 156:6 integration 40:10 169:2 386:11 integrity 11:4 13:14 15:7 25:6 30:2 51:5,13 54:4 57:8 181:22 182:4 182:9 192:8 198:16,17 205:9 205:22 206:14 207:3 210:16 211:9 213:19,22 215:11 intend 286:4 intended 246:14 intends 106:15 intensity 152:19 intent 126:20 247:3 273:22 285:22 286:13 287:10 291:14 interactions 98:10 161:20 386:20 intercept 20:2 interchangeably 235:1 interest 48:19 56:9 101:11 198:8 207:8 359:15 360:2,7 394:22 interested 6:6 95:22 292:14,15 293:20,20 294:2 294:14 interesting 63:21 120:14 167:12 261:22 266:4 279:14	interestingly 153:17 167:6 interests 101:3,10 102:1 interfere 77:22 252:12 intermediate 254:1 internal 58:12,13 332:3 internally 300:2 393:11 international 15:9 109:13 116:10 125:9 147:19 240:20 242:14 316:20 340:11 internationally 35:1 234:14 interpretation 134:22 217:2 246:9 272:22 interpreted 119:21 126:16 interpreter 81:1 interrupt 66:9 intervene 152:9 introduce 195:3 291:21 379:18 392:1 introduced 30:20 180:16 255:2 introduction 144:20 147:4 174:19 175:20 317:12 inventory 43:12 50:4,10 invertebrates 385:10 invest 14:2 198:6 invested 208:13 investigate 91:10 investigating 333:9 investigation 35:10 228:9 investing 54:6 investment 208:22
--	--	--	---	--

investments 13:17 198:10 199:11 208:9	174:12 177:6 180:19,19 183:10 185:7 193:8 204:4 204:14 214:3	246:10 249:17 356:20 359:10 360:1 366:19 381:16	journal 57:3 judge 171:10 July 66:21 67:8 225:2 230:14	kind 14:10 27:12 28:6,11 39:17 44:18 99:11 107:16 116:19 118:13 119:22 142:8 148:13 150:15 159:22 164:4 176:9 188:17 216:19 217:9 249:22 258:8 292:13 332:17 335:20 341:16 370:18 396:13
inviting 196:6	215:9,10 220:1 222:5 244:11	Jean 1:20 100:15 393:22	jump 68:13 112:8 253:9 337:18	107:16 116:19 118:13 119:22 142:8 148:13 150:15 159:22 164:4 176:9 188:17 216:19 217:9 249:22 258:8 292:13 332:17 335:20 341:16 370:18 396:13
involve 49:8	265:2 288:8 292:11 293:22	Jenkins 319:1 323:2,4	June 76:10 365:2,2 365:5,13,20	kindly 321:22
involved 43:19 47:4 102:9,18 211:2 298:7,15 343:4 348:12 361:14 392:7	294:15 315:8 332:20 340:11 354:5 397:19	Jennifer 1:22 2:20 29:3 115:5 230:21 260:17 335:19 336:2 372:11 378:22 394:14 395:3	jurisdiction 93:8 justified 320:3 justify 254:6	kinds 61:4 63:9 299:12
involvement 93:22	issued 108:17 364:21	Jennifer's 266:10		Kittredge 60:10,14 60:15 64:17
involving 195:13	issues 4:21 5:13 7:8 23:12 31:9 35:4 41:3 71:21 105:17 116:14 146:17 148:21 154:11 181:9 195:14 205:2,9 220:6 233:11 257:3 270:7 271:9 304:8 322:16 329:10 335:21 342:20 352:8,10	Jim 39:8 272:4 280:17,20	<hr/> K <hr/>	knew 302:21
in-house 25:19 212:5		Joan 298:9	kale 226:16	knock 158:18
in-person 67:21 123:17		job 146:7 192:14 301:7,9 352:9	keep 4:21 5:1,9,10 5:11 8:12 30:1 43:16 49:20 75:21 119:21 122:7 134:13 135:19 184:11 302:12 304:1 316:3 319:7 321:22 330:20 349:12 353:14,18 370:22 379:22 380:10 381:1,4,12 384:3	know 6:14 18:16 21:8 23:17 26:14 27:1,2,7,20 28:14 28:21 36:9,20 38:10 41:10 44:20 45:10,19 46:13,21 48:4 57:10 58:16 60:19 65:20 80:18 83:6 86:20 91:20 92:18 94:11,21 98:2,10 99:4,4,5 100:4 101:1,16 105:7 109:1,10 110:15,15 112:12 113:15 115:12 116:9,13 118:18 128:17,22 130:1 132:4 140:9,13,13 142:2,19 143:15 144:10,18 147:5,5 165:19 172:8 175:5 176:10,17 177:3 180:15 181:19 182:13 187:21 190:22 192:7 194:17
IPM 370:18		Joe 398:9	keeping 6:21 68:19 228:22 380:2,11	
iron 320:8,19 322:4	Italy 258:15,22 264:12 265:5 270:1	John 1:18 26:9 35:18 80:5 99:16 101:14 113:11 116:5,20 117:8 118:9 120:10,11 142:6 144:16 216:15 217:14 238:20 248:10 258:2 288:20 334:6 341:14 361:7,22 368:17 370:14 375:14 377:15 381:20 390:20 396:11	Ken 157:4,22 165:13	
ironically 266:20 267:17	item 71:9,10 107:16 122:15 304:13 372:20	John's 28:6 37:8 100:15 361:22	kept 6:4 50:1 73:7 88:1 102:20 197:18 348:4	
irony 170:3	items 360:9	Johnson 66:22 157:5,22 165:13 311:11	Ken 157:4,22 165:13	
irrelevant 258:5	i.e 387:2	JOSEPH 1:17	key 5:9 14:21 31:11 34:1 71:6,15,21 72:2 151:22 232:15 316:6 382:7	
irreparable 15:6			Kerri 95:13	
irrespective 121:2			key 5:9 14:21 31:11 34:1 71:6,15,21 72:2 151:22 232:15 316:6 382:7	
irresponsible 251:15			Kerri 95:13	
irrigate 230:17			key 5:9 14:21 31:11 34:1 71:6,15,21 72:2 151:22 232:15 316:6 382:7	
irrigation 226:9 229:11,12,13,16 229:18,18,22 230:3,16			Kerri 95:13	
Island 1:11 350:13 350:14,18			key 5:9 14:21 31:11 34:1 71:6,15,21 72:2 151:22 232:15 316:6 382:7	
ISO 16:16 125:12 125:15			Kerri 95:13	
isolated 153:18 330:3 386:13			key 5:9 14:21 31:11 34:1 71:6,15,21 72:2 151:22 232:15 316:6 382:7	
isolation 49:17 238:2			Kerri 95:13	
issue 9:16 37:5,17 43:17 46:13,14 52:1 54:4 55:17 56:14 57:15 61:8 61:11 62:15,16 75:3 86:10 134:19 145:11 148:10,14 148:19 155:3	Jack 60:14 337:3 346:8,13 Jane 97:7 January 108:3 112:3,13,16 122:20 Jay 1:18 65:15 66:18 76:9 82:12 99:6 108:12 115:7 117:11 122:19 148:2 175:17 196:4,9 221:10		key 5:9 14:21 31:11 34:1 71:6,15,21 72:2 151:22 232:15 316:6 382:7	

389:10	listening 145:6	load 154:15	332:1 337:17	190:18 191:6,8
linked 31:2 215:10	listing 68:16 71:4	loam 262:13	343:14,16 369:1,2	200:4 206:11
links 389:7	76:16 77:22 78:1	lobbyist 281:7,8	369:12,12 370:19	219:1 224:12,19
Lipson 389:4	78:18 85:10,20	local 62:7,12	looked 78:20,21	227:3 228:21
liquid 339:3	86:1 90:15 119:14	302:18 339:17	87:10 96:6 199:8	231:9,12,15
Lisa 2:16 66:16	124:17 144:12	locations 164:3	208:8 213:21	247:16 251:3
74:7 76:7 82:11	242:19 287:2	168:20 171:12	228:13 236:16	257:4 265:18,22
95:12 117:9 118:8	296:12 316:18	locked 373:4	245:16 303:20	266:1 267:20
122:17 123:19	320:2 323:20	logic 349:11	335:6 390:6	271:7 272:1 300:8
list 3:10 67:3,9 68:5	343:7 358:10	logical 45:7 98:12	looking 35:9 36:11	302:7 310:12
68:20 69:3,10,12	363:6,8,16 365:1	244:8	43:22 48:18 97:11	333:7 337:15
71:9 72:3 73:7	365:10 368:8	logos 311:5	98:9,22 106:5	348:9,21 349:7,15
76:5,15,17 77:15	376:22	lonchocarpus	148:18 153:22	354:3 369:1 370:1
78:6,11 79:8,13	listings 77:7 123:6	329:7	158:17 161:9	lots 50:6 144:15
80:7 81:20 82:18	lists 87:11 91:8	long 33:21 37:9	164:10 169:6	183:14,17 187:8
86:13 87:13,14,20	280:5 305:8	62:22 71:22	170:12 198:6	228:20 265:16
88:1 89:9,17 90:6	literature 104:7,8	107:11 147:6	212:15 213:8	loud 330:18
90:20 93:6 94:18	115:7,15 251:20	150:14 176:5	215:15,22 218:13	love 62:10 63:3
95:8 96:10,11	333:10 385:21	177:21 182:6	222:19 230:11	low 39:2 173:19
102:13 103:12	little 20:7 48:17	228:18 234:3	264:13 267:2	329:4 339:7
104:20 107:11	64:17,19 104:3,22	238:5 248:15,16	294:11,12 295:11	lower 131:6,9
108:2 111:9,18	117:3 140:21	249:3 262:20	295:15 298:16	155:12 180:12
117:16 123:5,7	141:19 142:9,12	270:4 334:18	303:16	329:16
124:6 125:4	143:8 145:2,5,18	348:11 349:14	looks 11:17 92:11	lowered 182:8
151:10 178:18	147:3 148:6	longer 47:12 87:19	95:5 164:2 239:21	low-level 41:20
246:14 247:10	166:10 174:19	137:16 140:21	240:12 256:19	low-risk 311:2
272:13 276:11,19	175:19 176:7	219:5 231:18	344:4	loxy 97:12
276:22 281:19	177:2 179:7	234:2,2 261:4,9	loop 171:15 213:9	Luis 327:17 328:3
283:13 305:11,11	218:10 223:5	302:21 352:3	loose 182:16	332:13 335:3,4
311:13 313:17,18	231:15 241:4	longstanding 51:11	lose 38:16 54:8	337:14 338:15
314:12 318:11	250:1 268:20	long-term 116:3	losing 348:22 349:1	342:14 343:10
319:8 320:16	278:19 298:17	129:20 138:21	349:10	344:22
322:1 325:3	302:11 324:20	155:13 186:12	loss 166:7 316:8	lumbers 111:22
326:21 327:14	338:14 350:14	296:5,6 304:13	lost 316:14 388:12	lunch 66:11 146:21
337:12 340:16	356:16 372:20	Lonza 323:5,5,10	393:15	221:12 236:3
341:4 355:13	392:19	look 14:12 15:21	lot 15:15 21:3 27:7	Lures 321:9
356:14,15 360:16	live 33:11 116:8	20:15 36:10,16	27:8 35:3 47:3	
361:1 368:12,18	153:19	38:2 39:4 44:7,15	50:11 58:12 66:4	<hr/> M <hr/>
369:16,17 373:14	lives 235:6	52:1 55:17 60:3	71:16 73:13 83:7	Mac 1:21 28:17
373:20 377:2,10	livestock 89:7	84:15 93:18 96:10	88:20 95:15 96:17	143:19 227:13
384:1 387:9	178:21 187:1	144:11 152:16,22	97:12 98:16	239:17 269:10
388:20 389:15	381:20	198:20 199:15,22	102:22 103:15	332:12 342:21
391:9 393:5	living 31:2 143:7	222:20 240:13	114:15 137:16	366:1 371:7
listed 126:5 169:13	223:22 235:4	250:4 278:7	157:11 160:7	machine 354:2
276:21 340:17	268:7 380:18	289:14 295:3,11	168:6 175:21	magazines 349:5
369:4,13 371:15	LLC 117:14	295:19,22 300:14	179:6,16 181:19	magical 265:18
384:22 387:17	lo 203:11	303:9 310:14	182:1 189:15	main 105:20 137:9

139:6 143:16 150:21 291:2 342:20 384:14 389:19 maintain 11:3 87:20 306:19 maintained 96:12 184:15,17 maintaining 30:8 68:15 71:4 207:2 283:19 337:12 major 61:4 160:12 180:19 207:17 232:10 majority 71:2,6 73:6 84:16 202:14 205:16 207:1 208:19,19 284:16 making 48:12 108:14 135:13 196:3 240:9 298:13 300:11 328:10 329:21 355:22 364:11 373:9 392:11 393:7 malus 163:10,15 mammalian 282:14 manage 301:18 337:20 338:5,12 350:22 351:4 managed 175:11 management 151:9 154:18 160:4 196:13 267:8 300:22 329:9 331:6 337:16,21 385:15 manager 29:18 254:15 managing 76:6 117:9 175:2 mandated 56:21 mandatory 370:18 Manix 337:3 346:8 346:10,13 350:5 manner 25:5 31:1	276:20 277:7 manufacture 85:13 286:11,15 307:15 manufactured 258:15,17 manufacturer 75:1 77:17 79:16 101:22 129:6 139:18 140:5 285:10 296:20 323:6 333:18 335:12 manufacturers 27:12 32:7 90:19 91:13 101:2,7 102:9 232:11 290:8 manufactures 319:18 manufacturing 134:7 283:2 manure 117:17 118:16 122:6 377:4,12 map 14:11 88:17 89:5 marathon 217:4,12 217:13 MARAVELL 1:19 37:7,20 47:6 48:16 100:14 108:12 109:21 110:21 111:12,19 112:4 170:20 218:5 331:18 332:6,11 357:13 363:2 366:13 368:1 372:5 375:1 376:12 378:1 390:1 398:15 March 117:13 122:22 211:18 Marco 328:1 337:2 337:5 marine 338:11 385:8 mark 223:5 389:4	marker-assisted 163:21 market 9:20 16:4 23:1 26:18 28:13 30:10,12 43:1 47:5 110:11 150:12 168:3 181:16 182:3,22 183:6 185:17 186:2 188:7 192:10,16 197:1 257:9 265:13 316:14 330:10 332:5 349:3,8 352:4,5 353:2 marketable 119:6 marketing 1:1 2:18 8:17 21:12 23:12 184:21 185:4 187:9 190:17 251:7 302:17 351:15 marketplace 52:5 58:15 185:16 187:4 189:8 191:16 192:5 markets 61:3 223:21 299:21 302:18,19 323:12 351:16 Marty 248:12 Mary 351:8 Massachusetts 60:16 64:18,22 349:16 massive 93:19 187:4 master's 304:22 match 30:2 156:1 material 9:11 17:4 41:20 59:8 65:21 66:13 67:10 75:17 76:5 78:22 79:21 79:22 81:20 82:2 82:9,21 85:4 86:6 92:6 104:11 118:16 120:15	123:11 130:21 137:12 140:2 141:7 142:15,19 151:5 152:8 153:14 154:3,13 154:20 155:8,17 155:22 159:17 160:21 205:14 215:7,21 232:22 233:16,22 235:16 240:3 241:18 243:20,21 246:16 247:14 248:16 249:3,4,14 257:10 258:11,21 259:4 263:2 268:15 270:17,22 271:20 271:20 272:15 274:6,11 276:17 279:17 287:21 292:5,12 293:22 294:16,21 298:16 316:21 326:20 327:4 341:17 358:20 362:8 363:6 367:7 368:8 369:1,12,16,22 370:9,13 371:5,15 376:22 378:15 materials 3:21 65:18 71:7 75:9 84:11 88:20 89:7 89:9,18 92:17 93:5,8 98:16 99:1 109:10 131:17 139:18 151:16 155:9,10,11 156:5 156:7,22 157:11 157:12 163:6 168:13 172:8 173:3 178:5 185:5 187:9 189:19 190:17 232:18 233:21 234:9,17 235:21 236:7,15 237:8,19,21,22 238:1,5,10,17,22	240:13 243:6,13 243:20 244:5,9,14 244:15,17 245:3 247:21 248:4,7 265:8,9 266:21 267:15,18,20,22 268:12,15 270:19 274:2 276:14,19 276:21 281:13 285:1 288:17 290:21 291:4 299:2 300:3,13 305:14,21 306:9 306:11 317:20 342:2 355:6 359:7 359:18,22 361:11 369:2,4,5,8,15 370:5 378:21 381:15 382:2 383:22 385:7 393:18 395:3,5 397:14 Mater-Bi 255:3 Matt 254:12 264:19,19 265:1 matter 28:20 42:8 65:9 88:11 221:4 227:3,5,9 259:16 261:6 322:18 399:9 mattress 338:1 maximum 153:6 262:18 McEVOY 2:10 96:6 108:21 109:14,20 111:8 111:14 112:2 245:6 248:5,18 249:5,11,13 294:22 McGill 255:11 mea 177:4 meal 248:22 249:20 295:8 meals 221:13 mean 36:4 46:15 56:8 72:22 81:16
--	--	--	---	---

81:22 98:11 126:15,16 135:9 178:10 189:13 190:8 217:1 219:17 240:12,12 243:19,22 244:13 259:4 260:14 275:6 303:6 334:12 336:7 381:22 390:8 392:11 393:4 meaning 190:2 202:22 meaningful 15:17 33:4 57:15 means 38:8 52:17 57:13 174:11 178:10 184:8,19 190:16 193:1 259:14,18 326:3 342:11 351:21 388:12 392:17 meant 189:6 190:6 217:4 measurability 273:5 measure 156:17 235:19 measurement 15:17 200:17 measurements 171:12 measures 13:4 18:7 52:22 56:20 70:5 131:6 202:21,22 203:10,12 209:14 274:14 340:1 meat 181:12,13 390:17 mechanical 383:22 mechanically 245:18 348:10 mechanism 44:8 58:16 59:5 91:12 mechanisms 89:19 342:19 media 188:19	189:2 190:5 288:5 291:8 medical 151:7 medium 330:3 meet 12:16,20 23:16 24:15 50:6 55:10 95:5 109:18 126:17 131:8 132:2 177:1 182:3 182:5 183:10 189:16 192:12 211:5,12 215:3 234:9 237:22 245:19 327:11 meeting 1:4 4:3,19 14:2 20:22 58:7 72:14 88:15 94:15 95:3 103:19 112:11 118:6 125:6,7 126:13 139:12 148:9 196:7 214:17 221:7 223:11 298:20 310:8,9 322:21 383:2,5 399:6 meetings 311:17 383:9 meets 22:15 53:2 211:22 216:1 233:22 Melissa 2:14 112:7 119:9 member 50:22 281:6 314:8 318:6 348:16 members 1:13 5:16 22:11 26:4 34:12 63:16 83:19 84:3 97:10 175:21 196:5 197:5 200:21 212:1 216:15 264:21 319:3 352:3 353:2 354:7 359:17 361:2 369:15 381:14 387:19	memo 9:15 Menard 250:10 254:11,13,14 257:22 258:7,14 258:17,20 259:8 259:21 260:22 262:9 263:5,20 264:4,7,10,17 mention 152:3 200:10 215:8 352:19 368:22 mentioned 19:9 39:20 42:2 52:16 56:8 94:4,14 107:9 120:4 186:1 187:3 197:13 199:1 208:8 210:4 214:11 216:8 218:1,8 259:7 262:22 303:19 309:20 342:14 343:10 344:22 348:22 mentions 340:8 Merci 264:15,17 merging 198:7 message 330:18,19 messages 301:2 met 88:5 175:21 211:17 303:3 metabolizing 253:17 metal 129:21 metaldehyde 319:18 323:6,8 metals 242:2,9 325:8 methane 288:3 291:7,18 methionine 332:20 384:22 385:5 390:16 method 15:19 45:16 125:17 126:21 127:19 128:5 133:11 134:8 295:9 344:7	methodology 217:19 386:14 methods 13:5 14:7 15:11 41:10,21 45:18 125:18 127:14 128:9,14 129:7 133:17,18 133:20 159:8 216:2 234:7 283:8 286:10,13 294:2 295:3,4,5 380:17 380:19 385:15 386:6,18 Michael 260:8 Michele 220:19 Michelle 2:12 4:11 7:21 44:11 60:7 79:8 83:14 86:7 358:7 380:5 388:10 393:14 Michigan 172:1,9 microbe 290:1 291:16 293:6 microbes 235:8,22 240:16 253:9 271:7 286:14,21 287:19 288:3 291:6 292:20 293:1 microbial 128:11 253:6 255:5,8 263:3,11 385:8 microbiologist 253:3 microclimates 332:16 microcrystalline 125:14 132:3 273:13 Midwest 155:2 171:8 172:3 208:18 mid-Atlantic 272:10 mid-sized 58:18 mike 29:16 83:9 379:11	mil 262:12 miles 2:10 111:20 224:4 245:5 247:20 248:3,14 350:15 351:2 million 208:13 329:17 millions 256:13 mind 75:21 316:4 354:16 mindful 121:18 398:5 minds 45:12 62:3 186:11 mind-blowing 95:19 mined 276:15 277:3 mineral 276:16 mineralization 127:11,15,16 132:16,17 234:22 235:13 mineralized 253:18 minerals 244:16 minimal 15:16 90:3 minimize 168:1 189:7 283:21 341:20 342:5 minor 180:19 181:1 242:8 257:6 minority 70:18 minute 60:8 106:20 152:3 173:2 193:4 199:8 221:15 minutes 59:17 65:21 73:4 141:16 141:22 146:14,16 146:19,21 221:2 322:12 misheard 36:7 misinterpreting 344:10 mislead 179:1 misleading 41:6 misleads 323:14 326:4
---	--	---	--	---

missed 74:3 393:22	molding 240:2	107:22 119:14	146:1,5,10 160:17	305:18 348:8,12
mission 4:20	molecular 159:8	144:12 355:19,20	190:19 236:4	349:12,18,22
missions 20:11	molecule 333:19	356:1,3,6,8	288:10 355:8	mulching 135:3
mite 85:11 283:21	molluscicidal 320:4	357:15 358:4,10	MRO 27:12 133:13	255:21
370:4	320:15	358:10,11,16	139:17 277:20	multiple 89:18
mites 83:19 85:8	molluscicide	363:5,7,13,16,20	MROs 131:17	multiplication
283:15	314:15,18 315:2	364:10,12,17,18	132:6 135:9	40:12
miticide 82:19	323:8,18 324:5	365:10,17,20,21	234:11 274:1	Munger 272:4
283:14,22	325:22 326:14	365:22 366:18	275:17 277:18	280:17,20,21
mitigation 11:18	molluscicides	367:3,7,9 368:7,8	MRO/certifier	284:8
338:21 340:1	325:14	368:11,14,20	132:10	mutate 107:6
mix 156:1	moment 6:18	372:15 373:5,6,8	much-needed	mutations 48:13
mixed 28:16	105:21 114:16,21	373:11,17 374:3,7	392:10	M.9 161:4 164:15
341:16	133:4	375:10,18,18	mulch 3:12 122:16	
mixtures 309:11	Monege 327:19,20	376:3,21 377:7,10	123:3,6,7 124:4	<hr/> N <hr/>
313:14	327:21 328:2,3	377:13 378:11	124:14,18 125:5	nail 243:17
mode 21:2	331:22 332:10	392:1 394:8,20	126:11 130:2	nailed 184:11
model 159:14	333:3 334:10,21	395:5,8,11,15,22	131:4 134:4,10	name 50:20 60:14
173:14,18 182:21	335:7,10 336:1,16	396:2,3,8,9,10,11	138:6,14 139:7	126:9,10 142:21
211:21 240:8	336:19	399:4	140:9,20 221:20	223:14 232:8
models 152:7	money 81:17	motions 358:9	231:2,9,10 244:3	237:11 254:14
171:16,17 172:15	monitor 197:13	367:1 375:16	244:4 245:8,12,17	264:8,22 272:6
172:22,22	monitoring 17:21	377:2 378:15	246:2,12,19 247:5	304:20 310:19
moderate 204:2,18	18:11 50:5 52:9	motion-maker	247:11,13 251:2	319:3 323:4
204:19,20	53:1	364:6	251:21 252:14	327:18 328:3
modern 45:18	monolaurate 3:9	move 55:19 60:1	254:17,20,21	337:5 346:13
164:11	82:10,17 83:15	66:9 76:3,5 89:7	255:15 256:2,12	350:12
modes 107:4	283:10,13	92:4 102:16	256:12 257:9	named 162:16
modest 208:22	Montana 195:19	118:11 122:15	259:5 260:1,3,4,4	name's 314:4
modification 61:8	195:20,22	141:21 146:7	260:12,13,15	nanomaterials
62:5	month 211:16	181:15,16 186:7	261:20 262:7	125:19 128:21
modified 47:10,13	327:3	188:7 189:10	265:6,20 267:1	136:11,12
61:16,20 97:4	monthly 211:18	192:18 197:9	268:9,16,20 270:3	national 1:2,4,10
233:2 246:3 293:6	months 91:10	199:2 254:4	272:12 273:11	2:10,15,16 3:10
293:8,14 311:14	181:5 226:13	257:18 333:7	276:2,14 284:17	24:6 29:20 51:1
modifying 171:17	234:1 262:13	355:18 357:17	285:9 287:4,6	67:3 68:5,20
module 40:5,7,11	334:19,19	360:5 361:7	298:8 301:6,15,21	69:12 76:15,17
moisture 137:15	Montreal 264:14	372:22 373:7	307:8,18 346:12	78:6 79:13 82:18
251:6 252:5 348:5	Moore 310:16	375:20 377:5	347:22 350:9,11	86:13 87:13 89:9
348:6 351:3	313:22 314:2,4	378:20 379:10	351:3,9,13 354:4	103:12 108:1
Mojo 232:6,7,8	318:16,19,20	380:4 394:11,20	354:9 383:6	111:9,18 117:16
237:4,18 238:11	morning 4:4,10	moved 227:8 365:1	mulches 124:8	123:5,7 124:6
238:17 239:2,12	21:10 26:2 50:19	368:17 376:1	134:2 138:9	178:18 195:8
239:22 241:13	213:18 239:13,15	movement 62:7	246:13 247:7,9	272:13 276:11,19
243:6,14,18	277:14 332:18	194:11 325:8	249:7,15 251:12	276:22 283:13
244:13 247:20	347:17 399:7	moving 11:18 66:7	251:22 273:19	311:13 313:18
250:6	motion 85:20	96:13,20 102:9	283:8 287:17	314:11 319:8

322:1 324:1 325:3 326:21,22 327:14 359:21 360:16 368:12,18 373:14 373:20 381:14 384:1 nationally 165:13 nation's 353:9 Native 336:4 natural 77:20 78:4 85:11 93:10 104:20 105:5 108:2,20 109:11 111:9,11,18 147:11 186:4,7,8 186:8,17,19 283:7 284:5 327:8 330:17,21 336:2 naturally 76:20 78:15 240:4 363:9 363:17 365:11 nature 64:19 77:19 100:22 306:8 Nature's 29:18,21 185:2 nauseam 183:8 near 264:14 350:21 nearly 166:13 349:3 neat 213:5 nebulous 383:19 necessarily 44:21 126:18 238:1 240:10 necessary 18:2 33:11 35:21 43:2 54:11 94:7 173:9 212:7 292:11 309:10 327:6 necessitate 370:19 necessity 241:10 281:9 nectarie 156:4 need 5:8 8:15 9:12 10:4 11:6 19:13 26:13 34:15,17 35:13,14,15 54:12	56:17 65:18 66:15 93:10 96:8,9 98:9 132:20 134:15 136:14 137:3 154:16 162:21 167:22 169:10 173:11,20 177:16 177:20 184:11,15 194:3,7,14 197:15 206:13 208:4 209:19 210:4,11 211:3 213:1 222:7 222:10 228:2 230:16,18 238:4,6 250:6 285:4,15 290:10 291:14 293:21 294:3,14 294:20 299:4 303:9,15 322:4 324:18 338:4 339:20 341:9 344:17 347:22 348:4,5 349:17 355:19 358:18 360:11 367:10 369:21 372:22 373:6 383:21 385:17 392:20 397:20 needed 8:19 17:16 79:20 84:18 92:7 93:18 119:5 193:11 266:7 267:16 285:22 300:15 308:22 329:8 370:1 needs 12:19 17:22 30:7 33:4 43:5 45:8 68:6 97:3,4 148:15 184:14,14 184:14 191:22 197:1 200:8 209:9 211:5,22 213:12 274:22 277:1 384:16,20 385:19 386:3,4,9 388:7 negative 70:5	180:10 227:22 267:14 303:21 315:19 336:8 negatively 304:11 392:12 neglected 95:11 222:16 neighboring 19:8 neighbors 63:21 348:15 neighbor's 135:1 Neither 315:5 nets 55:12 networks 207:15 Neudorff 310:20 310:21 311:16 312:2,17 313:13 314:7 319:4,12 320:9 321:1,5 323:12 Neudorff's 313:3 323:9 324:17 neutral 206:19 Neuve 264:10 never 36:1 37:4 107:1 163:16 206:3 254:20 261:14 289:7 354:16 358:21 new 4:20 16:15 24:19 46:9 60:18 62:16 64:20 73:22 77:3 89:14,22 90:22 106:14 117:22 140:14 153:13 154:18 155:9 156:22 159:7 161:22 162:1 163:8 164:8 164:19 168:22 173:15 175:21 206:3 211:16,19 223:16 270:16 305:13 328:8 331:5,7 349:15 392:8 news 102:22 349:6	newspaper 139:7 243:21 244:6 newspapers 243:22 nice 44:2 60:18 93:21 100:1 172:11 175:18 NICHOLAS 1:19 Nick 37:6 102:2 110:14 116:2 170:19 218:22 220:6 331:17 389:22 NIFA 384:19 night 4:13 317:6 NIH 387:11 nine 69:21 387:8 NOCSB 282:10 NOFA 60:20 250:14 268:14 348:16 nomenclature 244:8 non 35:1 77:17 85:3 94:4 258:9 323:18 328:10 non-antibiotic 160:3 167:5 169:9 173:6 Non-certified 251:19 non-detect 22:1 24:12 non-detectable 17:1 non-disclosure 102:5 Non-GE 17:21 49:20 non-GMO 31:20 31:22 64:3 255:4 258:6 non-organic 13:22 58:14 323:7 non-profit 272:8 360:17 non-synthetic 78:1 93:3,7 139:3	NOP 1:2 9:4,15 32:17 57:7 67:17 70:13 83:2 88:4 91:9,14,18 95:11 96:2 97:7 108:15 113:1 118:4 123:13 128:22 136:18 138:4 140:18 183:3 196:5 203:15 211:13 214:3 292:14 295:6 305:14 311:4,7 325:16 337:12 NOP-accredited 272:8 NOP-required 11:6 norm 300:2 316:20 normal 108:14 229:22 normally 230:7 Norman 298:9 Normans 252:18 North 29:21 113:21 164:20 242:7 258:18 264:14 northeast 60:15 166:19 171:7 223:17 250:12 northern 158:17 Northwest 155:5 nos 357:15 372:14 375:9 376:21 378:10 NOSB 1:5 4:19 9:3 9:6,9 17:18 18:15 30:14,16 51:3 52:14 56:14 57:20 58:22 63:3 69:9 69:11 70:12,15 87:21 88:5,7 91:3 91:5,9,13,17 92:3 92:4,8 94:21 126:20 136:17 138:3 149:1,8 196:7 214:2
--	--	---	---	---

236:20 285:2,19	312:15 361:8	offered 129:4	294:22 297:19	onions 225:1,17,21
288:12 297:10	390:2	286:17 326:7	300:17 308:8	225:22 256:5
298:20 305:10	numbers 28:3,5	offering 186:3	312:19 318:20	online 165:18
306:7 321:22	201:22	Office 245:8 246:5	322:21 327:22	169:14
323:19 324:22	numerous 106:18	official 39:20 42:18	328:1 335:2 344:7	onsite 278:18
325:4 326:20	311:17	212:3,4	354:18 355:14,15	onus 51:15 277:19
327:2 330:15	nurseries 160:13	off-farm 178:3	355:15,21 358:7,8	on-farm 207:11,15
359:15,18,22	162:3	OFPA 23:8 78:21	358:15 360:1	210:6,7
383:2,9 385:19	nursery 164:20	79:7 81:2 103:11	364:15,18 365:7	on-the-ground
386:2 387:6,17,19	nutrient 161:20	114:12 178:1	365:19 368:17	388:4
392:14 394:9	317:15	OFPANA 298:21	372:11 374:4	open 24:18 43:17
395:16 396:4	nutrients 245:21	OFRF 390:5,8	379:2 381:8,22	212:14 386:19
NOSB's 51:8 286:1	353:17	OGC 12:8 79:21	382:18 383:14	opening 67:18 83:3
387:15	nutritious 221:13	oh 29:2 44:17 86:6	384:2,14 386:2	118:5 123:14
nose 322:13		100:13 112:7	390:10 391:14,22	operate 339:21
notably 305:2	O	138:16 296:13	392:1 393:14	operated 310:22
note 104:7 114:21	objection 378:17	332:6 354:13	394:7,18,22 395:2	operation 49:19
208:3 312:9	objections 311:19	364:5,18 372:10	395:14 396:10	166:8 167:3
313:13	355:7,15 378:13	394:12	old 81:19 328:18	347:21
noted 91:15 93:2	objective 38:13	oil 157:16 158:21	older 260:10	operations 64:22
178:16	74:4 211:11	159:2 353:7	391:19	200:6 201:20
notice 111:13	obligation 9:8	oils 32:22 106:18	OMRI 27:13 91:6	272:10 330:1
306:13	57:13	345:1	93:2 94:4 101:16	operators 112:18
noticed 121:6	obtained 127:20	okay 4:18 7:18 8:1	118:15 126:16	opinion 70:18 74:5
172:21 309:19	obviously 62:19	10:3 14:4 21:7	127:18 128:4,19	75:11 80:18
notification 112:17	75:1 86:9 262:16	29:15 37:2 59:15	155:16 211:20	128:17,22 171:4
notified 94:20	267:6,8 280:2	60:13 65:2 66:13	284:16 286:6	312:17,17 359:5
notifying 91:13	339:11	68:2 76:2 81:10	287:2 288:16	opportunities
notion 180:13	occasion 25:22	81:10 86:4 91:2	292:4 293:3	197:14 210:5
novel 169:4	occasions 311:18	100:3,13 109:8,19	296:15 297:4	213:21
NSF 234:13	313:12	117:7 120:15	311:4,7 320:22	opportunity 23:10
Nueva 329:14	occur 8:16 18:4	122:14 125:4	OMRI's 126:12	39:15,17 55:22
330:2	45:11 77:18	129:16 132:13,13	286:18 288:11	58:22 81:20,22
number 7:20 14:14	108:20 129:8	133:16 138:21	293:11 296:8	116:14 143:10
35:21 36:1,5,16	246:22 275:13	140:4 141:21	once 37:14 63:16	176:12 213:6
36:18 37:8,9,11	329:20	145:22 146:4	95:1 151:2 163:6	234:19 250:20
37:14,16,21 38:2	occurred 34:4	174:1 194:22	224:13 358:1	298:3 314:3 323:3
38:2,7,20 39:4	269:21	220:19 229:7,21	ones 93:9 96:17	337:10 346:11
47:13 53:15 62:9	occurring 76:21	238:7,16 239:17	99:22 120:17	oppose 251:10
65:18 71:5 96:4	78:15 253:8 363:9	240:18 241:13	183:19 237:17	opposed 84:17 85:9
120:16 124:17	363:18 365:12	244:10 249:10,17	238:10,12,13	85:22 124:17
149:20 158:22	October 1:8 174:11	250:8 254:10	383:9	274:3 384:9
160:12 165:11	364:4,4,21	258:16 260:22	one-sixth 329:16	opposite 166:20
168:14 170:6	odd 154:7	264:6,15 269:19	ongoing 17:20	391:13
197:21 241:21	oddly 178:12	270:8 271:17,22	32:14 35:2 52:2	opposition 266:6
253:2 299:16	offensive 347:3	272:5 278:13	53:1 55:13 138:11	330:15
301:22 303:3	offer 46:8	279:2,8 292:8,8	196:16 197:3,13	optics 113:21

optimal 203:4 260:20	38:3 42:21 43:4 44:22 45:2,9,22	201:21 202:3,8,11 202:12,16,18,22	330:19,22 331:1,3 331:9,15 339:7	originally 122:20 153:18 236:11
optimistic 160:22	49:20 50:18,21	203:2,3,10,13,14	340:6,15 341:4	237:17 290:20
options 22:22 84:8 84:21 156:2	51:1,5,10,13,17	203:17,19 204:10	343:11 346:14,18	393:19
196:22 272:16	52:13 53:20,21	204:14,17 205:2,6	347:18 349:1,2,5	originator 364:16
orchard 159:10,19 173:19	54:3,4,6,7,8,14,15	205:22 206:12,15	349:10,17,22,22	Orzolek 260:8
orchards 158:20	54:18,21 55:14	206:21 207:2,3,5	350:18 369:21	OSA 12:8 50:22
order 4:4 23:12	56:18,19,21 57:8	207:6,9,13,17	370:10 379:20	197:3
33:3 34:2 37:22	57:13 59:1,10	208:5,10,12,22	380:7,17 381:1,3	OSGATA 10:20
65:13 92:9 118:14	60:15 62:10,11	209:2,6,8,11,14	381:4,9,15 382:11	16:2 19:21 20:4
160:17 207:16	64:7 70:3,14 84:7	209:16,17,21	384:16,20 385:11	OSGATA's 15:4
213:2 221:8	84:13 85:4,5,12	210:1,1,2,3,5,12	386:5,8,17 388:3	OSP 301:17
322:22 329:9	85:16 87:7 92:13	210:14,19,22	389:6	OTA 9:22 13:1
338:19 355:21	93:20 101:6,12	211:6,12,13,16,17	organically 6:2	19:2 128:13,19,21
373:6	102:9 109:2,3,6	211:19 212:1,2,6	48:21 129:11	outbreak 329:12
ordering 161:4	113:16 114:8	212:8,10,16,19,22	316:6 326:5,9	outbreaks 329:11
Oregon 12:18	119:12,22 120:22	213:2,2,8,9,10,15	348:14 350:17	342:10
147:18 158:3,3	121:1,8,19,21,22	213:22 214:13	organics 105:4	outcome 97:19
162:13,19 171:21	124:7 141:12	215:16,18,22	136:13 181:22	388:1
OREI 158:16 160:5	146:19 147:7,12	216:7 217:16,18	185:21 187:10,12	outcomes 114:8,15
168:9 171:21	147:14,16,20	218:17 222:20,22	324:1 325:3	210:9
172:2 208:15	149:4,18 150:1,10	227:3,5,9 232:22	326:21 327:14	outcry 280:8
OREI-funded	150:14 158:5	243:10 245:7	349:3,4 381:13	outlines 289:15
157:5	165:13 166:2,16	246:5 250:13,15	organisms 31:3	outlining 51:10
organic 1:2,4,10	166:20 170:3	252:14,20 259:16	70:6 128:8 134:4	outs 177:15
2:11,15,17 3:17	176:3,16,21,22	261:6 263:21	134:5,16,18	outset 131:11
5:4,6,14,19,22 8:4	178:2,9 179:12	264:3 265:15	159:19 173:19	outside 18:14 33:16
8:7,11 9:5,8,14	182:10,19 183:6	267:3 272:8 273:6	206:5 235:4 238:8	34:8 60:11 99:1
10:22 11:8,9,12	183:12,17,19	273:7 274:16	286:14 308:17	120:7 189:22
11:15 12:9,12,14	184:3,8,19 185:11	279:17 281:20	338:11 340:20	229:17 316:20
12:21 13:7,9,13	186:5,9,18 187:21	283:18 287:21	organization 120:3	outsider 267:3
13:14,17 14:3	188:8,14 189:3,6	295:16 298:5,7,19	175:6 180:3 195:8	overall 53:21 85:2
15:5,7,8 16:3,18	189:12,16,18	298:22 299:6,11	196:2 330:11	154:18 182:9
17:18,21 18:3,8	190:6,15,16 191:3	299:16,17,21	359:16,19 360:14	201:14 207:6
19:2,6,22 20:1,18	191:10,13 192:17	300:6,9,20 301:10	organizations	232:21 233:6
21:12,13,13,22	192:22 193:2	302:8,12,21 303:6	68:18 69:21	overarching 7:20
22:2,9,11,21	194:8,17 195:5,7	306:18 314:16	124:16,20,21	301:9
23:22 24:6,7,12	195:22 196:9,14	315:10,16,21	200:11 301:2	overdue 94:2
24:17,20 25:3,6	196:16,19,21	316:11,19 317:21	313:4 315:4	overhead 229:16
26:11,13,16,17	197:4,5,12,15,17	320:17,21 321:2	359:21	229:17
29:18,20,22 30:1	197:18,20 198:1,6	322:3,4 323:13,14	organizer 195:12	overly 53:20
30:3,8,11,12,17	198:6,8,11,13,14	323:16,19,20	Organocide 106:17	301:13
30:21 31:4,8,12	198:16,16,19,21	324:1 325:18	oriented 277:17,18	override 30:9
31:17 32:2,3,6,11	199:7,9,11,13,14	326:2,4,4,7,8,19	origin 245:16	oversee 301:19
33:16,19 36:13	199:18,21,22	326:22 327:4,9,12	291:18	oversight 206:8,13
	200:2,5,9,14	328:3,7,18 329:21	original 67:7,9	overwhelming
	201:2,7,16,18,20	330:4,8,10,12,13	74:13 77:9 364:17	88:19 303:3

owned 21:12	129:18 131:18	pass/fail 38:7	141:6 144:10	perfectly 261:21
owners 18:10 57:17	132:4 139:12	pasture 303:20	145:3,6 149:10	389:2
owns 311:3	156:3 160:5 167:1	304:1,7	150:16 165:7,14	perform 244:5
oxidized 3:9 76:6	172:5,19 177:5,10	patchwork 206:6	165:18,20 166:10	265:19 387:16
76:14 77:16,18,20	193:8 196:12	patent 324:17,19	167:10 168:16	performance
78:11 281:13	238:14 265:15	patented 165:4	169:3,18 170:6	216:21 217:1,7
282:17,20 357:19	267:9 302:9	220:4	172:7 173:15	218:2 251:21
357:21 362:11	303:10,11 310:10	patents 287:6	182:10,13 183:2	323:11
oxidizing 78:8	333:16 347:20	path 22:14 29:18	183:15 186:7	performing 157:2
oxodegradable	349:2 390:10	29:21 185:2	190:22 217:2,11	266:3
263:10	participants 233:9	pathogens 170:15	222:4 243:11	period 22:10 67:18
oxy 97:12	participate 120:19	pathology 305:1	245:1 268:1	83:4 95:6 100:16
oxygen 79:3	participated	pathways 309:6	302:15 349:6	118:6 123:15
o'clock 141:15,18	354:22	patience 379:6	355:5 380:15	141:2 144:7 154:8
146:11 399:7	participating 196:8	patrons 352:1,4,8	382:7	159:15 177:8
	354:19	patterns 332:14	people's 45:12	223:13 296:22
	participatory	Paul 223:14 346:9	166:13	307:3 333:21
	207:14	350:6,7,12 352:16	perceived 294:14	334:1,14 384:11
	particular 38:12	354:20	percent 17:9,9,17	periodicals 349:7
	75:14 76:17	pay 12:3 186:8	125:13 127:13,17	permanent 229:20
	130:13 155:8	Paying 381:7	132:2,14 149:22	permit 339:11
	180:13 181:18	PCO 8:14 127:20	150:2,3,4 152:11	permitted 67:3
	182:7 335:9	129:13,13 272:8	152:14,14,15,16	90:2 110:4
	341:17 360:19	272:14 273:3	152:17 164:16	peroxide 78:5,6,17
	369:16 397:13,19	276:12 277:1,5	166:12,12,14	79:2 363:10,19
	particularly 114:22	PCR 15:11,20 42:2	167:6,8,9,16	365:13
	120:20 121:10	peaked 299:21	169:19 200:14	peroxide-extracted
	143:5 265:14	pear 162:12 166:16	201:10,12,12,14	282:19 358:12,17
	270:2 353:20	179:10 181:4	201:16,17,19,21	persist 282:12
	384:19 396:21	188:14 192:22	202:17,17 203:8	persisted 252:9
	397:8	pears 150:2,4	204:1,7,11,18	persistent 188:11
	parties 43:19	151:13 152:16,20	205:4,6,11 206:16	317:9 383:18
	partly 97:6 151:14	162:6 176:8,18	206:19 207:4	386:3
	partners 212:7	179:12 191:1,14	233:17 236:6	person 7:6 50:17
	parts 149:12	192:10	241:21 244:17,21	364:11 365:16
	272:20 386:20	peas 225:1	245:3 255:21	personal 80:18
	party 234:14 286:5	peer-reviewed 57:2	268:8 273:12	253:2 338:16
	321:9	Penn 255:10 260:8	299:11,14 309:17	340:2 345:6 392:6
	pass 114:17,21	penned 352:20	330:9 351:13,16	personally 111:2
	347:2 357:15	Pennsylvania	351:16,17	332:21
	passed 11:10 34:6	272:7	percentage 202:12	person's 14:15
	43:13 57:1 81:11	people 4:15 6:17,19	perceptions 199:22	perspective 56:4
	104:3 241:2	7:20 48:18 79:17	perennial 246:21	96:2 144:14
	270:20 379:1	85:22 104:10	perfect 26:9 31:10	152:10 153:9
	393:19	105:1 107:17	80:22 143:6,7	176:7 267:3 392:6
	passes 368:7	111:13 134:2	144:17 318:14	393:6
	375:10 399:4	135:8,9 136:21	327:22	perspectives

206:21 387:4	petitioner 67:21 123:17 291:10	323:9,13,15,17,21 324:4,8,10,14,18 324:20 325:1,14 325:19,21 326:3,6 326:14,16,19 327:11,13 355:13 355:18 356:3,9 359:9	194:3 205:19 268:19 292:14 316:19,22 344:11 344:15 379:19 380:6 392:16,18 392:22	215:17 219:15
persuade 346:17	petitioners 118:12	phosphorus 79:5	places 5:12 38:19 122:7 267:6 307:1 336:15 344:13	Plasmids 180:10
Peru 105:16 328:4 330:4,13 335:14 338:17 339:16	petitions 146:9 222:10 287:13 378:15,16	photodegradable 263:10	plan 10:9,15,17 19:10 20:22 63:4 95:10 112:13 135:12 162:17 167:19 169:14 200:17 267:9 301:10	plastic 124:8 143:21,22 145:11 222:11 224:5,17 225:12 226:11 227:4 231:7,11,14 239:19,20,21,22 240:3,4,5,10,14 246:12,13,18 251:2 254:20 255:15,22 256:2 256:11,12,17 259:22 260:1,2,3 260:5,9,13 265:20 268:21 273:18 280:2,6 305:19 344:19 347:5,15 348:1 350:9 351:2 351:8,13 353:8,13 353:22 354:3,9
per-year 341:21	petition's 70:8	phrase 41:5	planet 299:9 352:11 379:22 380:9	plasticizer 244:11 244:12
pest 314:5 317:7,8 317:8 324:21 328:14 329:5,9 331:6,12 344:15	petroleum 237:16 238:13 290:21	Physical 49:22	planning 10:17 16:16 214:17	plasticizers 241:6 241:10
pesticide 3:10 63:17 83:18 85:18 86:13 94:19 310:22 338:3 373:13,19	petroleum-based 124:8 240:11 251:12	physically 50:1	plans 56:22 179:21 273:7	plastics 240:6 258:6 286:16,22 287:18 289:16 291:3,5 292:21 293:5 347:22
pesticides 6:18 10:6 178:4 311:2 317:19 326:10	PGML 3:9 82:10 82:13 83:16,17,20 84:5 85:10,10 283:11,13 366:21 367:1,4,8,11 368:9,11,18 370:13	Ph.D 174:20 305:1	plant 40:8 63:20 131:2 152:22 153:8 162:18 198:9,11 200:9 207:14 209:1 210:1,2,14,19,20 210:22 211:4 213:10 215:11 218:7,8 233:21 247:13 252:1 290:21 291:4,8 305:1 330:21 336:2 339:4 344:8 344:15 385:7	play 132:18 192:1 219:11
pests 85:12 324:11	pH 117:16 119:5 377:4,12	pick 185:3 224:17 318:21,22 322:13	plantation 333:15	players 215:21
petition 66:16,19 66:21 67:1,6,9,15 68:4 70:10 74:13 74:14 76:8,10,13 77:4 82:13,16 83:2,16,20 84:17 93:21 102:17 107:19 117:10,12 117:14,21 118:2,3 119:19 122:17,20 122:22 123:1,12 127:14 232:19 237:18 250:20 265:7 266:6 283:4 288:8 289:15 290:6 291:18 306:4,15 308:1 311:12,14,20 312:1,9,10 314:10 318:8 319:7,16,17 325:6 357:19 366:21 371:14	PHA 241:7	picked 116:21 153:20 347:17	planted 11:1 52:4 202:2	plays 57:7
pesticides 6:18 10:6 178:4 311:2 317:19 326:10	pharmaceutical 153:3	picking 48:13 350:9	planting 54:13 165:6 203:13 225:10 262:6	play-out 173:12
pests 85:12 324:11	phase-in 22:10	pickings 231:18	plants 230:15 262:6 354:1	Pleasant 223:15
petition 66:16,19 66:21 67:1,6,9,15 68:4 70:10 74:13 74:14 76:8,10,13 77:4 82:13,16 83:2,16,20 84:17 93:21 102:17 107:19 117:10,12 117:14,21 118:2,3 119:19 122:17,20 122:22 123:1,12 127:14 232:19 237:18 250:20 265:7 266:6 283:4 288:8 289:15 290:6 291:18 306:4,15 308:1 311:12,14,20 312:1,9,10 314:10 318:8 319:7,16,17 325:6 357:19 366:21 371:14	phase-out 108:18 108:19,21 109:5 167:15,19,20,21	picture 225:18,22 226:1 300:15 332:1 337:17 345:5 347:3	plant-based 288:4	please 4:4 10:5 29:15 231:4 260:19 301:21 308:1 316:3 331:12 350:6 358:3 364:16 374:9 379:4,5 380:5,14,22 381:3 381:12
petitioned 83:17 86:6 91:1 107:16 107:18 124:5 139:8 276:10 283:14 359:17 372:20	pheromone 87:15	piece 303:18	plasm 46:18 47:1,2	pleased 206:22 211:14
	pheromones 95:9,9	pieces 67:5		
	philosophy 300:21	pigments 129:20 139:2,8 276:4		
	phone 160:12	pike 169:1		
	phosphate 3:8 66:15,20 67:2 68:4,6,16,20,22 69:11,20 70:1,19 71:4 72:3,17,21 73:7 281:13,21 282:3,10,15 311:10,13 313:8 314:11,13,17 315:1,12,20 316:19 319:5,8,11 320:1,7,10,13,19 321:1,4,7,10,16 321:18 322:1,4	pineapple 343:4		
		Pioneer 39:12		
		pioneers 352:17		
		pipe 218:18 219:9		
		pipeline 61:17 155:18 289:1		
		pirate 106:20		
		pitfall 32:4		
		PLA 140:6,8 241:6		
		place 7:10 13:4 20:7,21 34:2 35:11 55:8 58:17 61:21 69:7 112:16 171:3,5 190:4		

pleasure 175:22	pollution 62:3	post-harvest 84:1	114:11,12	176:12 178:14
pledging 191:19	polyethylene	potassium 79:5	predacious 369:19	193:6 195:4 276:8
plus 10:6 157:16	251:12,22 257:9	potential 13:21	predate 206:7	285:1 286:18
159:1	267:1 268:9,16	53:12,17 59:12	predators 85:7,11	292:1,19
podium 146:22	polymer 309:10	69:16 84:10 108:4	106:19 317:13	presentations 3:15
point 11:20 13:15	polymers 253:4	153:21 200:9	predict 173:18	220:17 221:1
28:4 37:13 49:11	poorer 8:5	207:14 230:19	predictive 171:15	presented 90:15
57:4 74:19 75:21	popular 335:13	237:9 282:13	171:17	104:6 293:9
86:16 101:6,13	portion 129:5	304:8 307:8 330:7	prefer 217:14	298:21 329:5
121:21 126:12	302:17	331:11 382:10	297:4 336:21	383:1 387:21
130:20 133:3	portions 273:22	385:6	preferable 78:22	presenter 196:8
134:14 136:1	274:3	potentially 179:1	79:22 81:20 82:2	292:22
143:17 144:15	pose 144:6	238:12 276:5	preferably 38:10	presenters 220:10
150:1,21 159:15	posed 7:19	287:1	381:10	220:15 242:18
162:17 169:11	poses 325:10,14	poultry 117:17	preference 141:20	preserve 380:16
170:10 176:10	position 28:22 51:2	118:16 122:6	259:3	presiding 1:12
202:19 233:14	102:8 142:9	317:13 332:19	preliminary 199:15	pressure 9:7 17:19
239:1 259:15	249:19 272:14	377:4,12	premise 246:21	27:3,4 57:12
285:3 290:22	positions 281:11	pounds 256:13	premium 150:13	142:5,6 180:9
292:6 319:9	positive 8:7 42:19	powerful 165:21	381:7	193:17 194:5
320:18 338:2	122:11 154:11	PowerPoint 86:9	preparation 247:1	209:8 288:16
339:16 340:4,10	227:1	PPE 344:4	prepare 103:14	353:18
370:22 381:10	positively 265:6	practical 22:22	177:17 178:13	pretty 28:8 66:7
393:20 395:17	positives 42:14	69:14 285:9	190:20 223:11	99:3 113:13 114:4
396:16	possession 111:6	practically 256:10	prepared 67:8,13	121:5 142:10
pointed 94:4	possibilities 155:7	practice 9:21 32:17	67:14 77:6,6	157:1,21 208:21
pointing 19:17	possibility 307:16	36:12 268:3	355:18	211:1 332:18
points 33:2 59:19	336:14	317:14 342:8	preparing 38:22	370:19
116:6 127:18	possible 4:17 31:13	386:14	89:15 289:9	prevent 10:9,17
128:1,4 129:18	37:13,22 38:20	practices 9:11	preponderance	13:5 42:20 56:20
136:6,8 214:13	41:1 48:3 64:5	50:12 70:4 84:20	315:16	57:18 134:22
301:22 302:8	134:12 135:22	121:21 129:10	prescriptive 299:19	151:1 152:9
324:3 384:14	140:1 143:12	151:10 182:21	303:18	283:20 287:8
policeman 359:1	149:2 171:16	194:13 252:12	presence 5:13 9:16	340:22 341:1
policies 9:10	220:18 347:12	267:8 299:6	17:11 32:14 41:19	Prevented 246:13
135:10,13 292:13	379:20 380:7	301:18 317:10	41:20 42:20 43:4	247:10
policy 9:15 15:4	possibly 136:1	328:22 329:3	49:16 59:7 171:13	preventing 11:12
22:9 51:21 69:5	post 165:17	339:1 340:15	205:13 314:19	58:4 380:19
86:11 103:9 135:7	posted 4:11 67:17	342:7,18 346:1	present 1:13 2:8	prevention 18:7,10
135:21 175:3	68:10 72:13 83:2	370:20	7:17 222:1 247:15	19:10 20:3 52:22
250:12 279:20	103:3 118:4	Prairie 21:13	276:9 317:9 323:3	56:7 57:16 150:22
286:18 293:4,11	123:13 310:8	pre 336:3	331:8 339:14	preventive 56:10
293:16 304:20	358:1 374:5,6	precautionary	presentation 21:6	prevents 272:18
373:12,18 381:18	383:4,17 390:15	142:14 392:21	56:2 60:2 65:3,6	previous 45:15
politely 33:22	393:16 395:8	precise 160:4	65:22 66:2 124:3	77:4 142:11
poll 388:7	postpone 294:5	precursor 35:22	144:9,21 147:1	150:20 231:2
polluted 33:12	postponing 378:14	precursors 32:21	150:20 170:21	282:9 287:5 322:2

348:22 364:20	166:21 169:16	111:16,22 114:14	280:8,10 323:14	252:1,15 276:2,3
previously 75:4	170:5 173:8	123:21 138:1	326:5	281:20 298:22
77:6 224:4 323:20	256:15 266:15	140:19 141:4,6	producing 43:12	313:15 315:17,20
325:4,15 362:1	302:19 303:8	144:3 156:9	54:5 55:1 61:18	316:9,11 321:2
pre-bloom 158:18	341:16	162:20 163:4	164:21 315:15	325:18 326:2
price 12:17 150:10	problem 27:15	210:21 223:4,10	348:13	327:7 329:17,19
150:13 204:7,8	32:9 55:5 66:12	235:3,6,12 240:8	product 11:18 24:6	329:21 331:9
239:1	71:11,14 87:21	242:1 278:11	33:8 38:3 45:9,22	380:17 386:8
pricing 239:3	92:19 100:21	283:3 301:18	46:12 61:10 69:18	products 11:22
primarily 135:9	121:15 161:6	318:8,12 335:16	75:2,5,12 76:18	18:11 21:12,22
281:4 312:15	176:14,15 177:5	345:17 354:19	77:15 78:3 85:3	22:6 31:22 33:19
primary 25:1 58:2	177:10,15,20	355:1,1 371:3	99:19 101:8	41:6 51:13 57:18
62:4 155:5 183:3	178:17 179:18,19	387:19 398:4	102:11 105:21	76:11 90:3 97:17
383:20 386:3	179:19 181:7,7	processed 133:22	119:7 122:6	98:9 102:7,13
387:16	182:18 198:18	processes 77:20	126:17 132:12	105:5 106:1,3
principle 219:17	256:21 330:6	128:11 276:17	133:15 140:14	109:12,15 118:20
392:22	337:19	288:1 299:2	145:6,14 153:17	123:2 128:12
principles 30:8	problematic 20:14	380:15	154:18 167:11	131:15 132:7,10
119:12 178:11	92:11	processing 122:10	216:3 224:11,20	150:6 168:4,22
185:9 186:15	problems 12:8	129:22 140:4	225:3,7 252:9	175:13 183:7
189:17 300:8	19:17 63:16 85:15	256:3	255:1 259:9 261:2	224:22 225:3
301:9 306:19	108:9 121:14	processors 38:12	261:17 262:1,3,17	228:21 232:10,13
printed 220:16	141:1 205:6 388:4	250:17 384:17	262:20 263:19	235:9 237:15
prior 167:9 273:2	Procedural 374:12	process-based	264:12,13 265:18	240:1,7 250:22
275:13	procedure 86:11	11:16 13:2 23:7	275:11 277:22	252:21 253:14
priorities 303:12	90:10 91:3 94:13	28:5 40:14 278:16	280:9 282:7,21	254:1 263:18
382:5,20,21,22	94:13 95:2,3	produce 14:3 40:15	290:10 313:14	264:2 282:1,14
383:7,8,10 387:14	373:1,7,9,12	134:9 140:8	314:14 318:3	286:19 287:14
387:17 388:9	procedures 40:2	168:10 286:21	324:12 335:22	288:22 290:20
389:15,18 390:3,9	71:7 373:18	293:2 339:10	339:9,16,18 345:7	298:12 306:12
394:9,12 395:16	proceed 34:18 82:8	341:10 342:10	346:18 348:13	307:21 311:1,3,6
396:4 397:5	141:17 355:22	347:14	352:19 381:8	311:9,9 313:10
prioritize 92:9	356:19 362:4	produced 109:15	production 5:22	323:11,13,22
389:13,14,17	366:1 371:16	109:16 125:17,18	11:12 12:12 13:18	325:20 326:3,6,19
priority 92:10,15	374:9,13 376:4,21	128:8 189:19	22:2 24:13 30:7	345:2 361:1 370:1
214:4 305:13	377:15 395:1	191:14 254:2	30:10 41:2 43:10	379:21 380:8
385:1 386:5	398:9	326:9	49:13 50:9 54:7	381:5,11 385:8
private 54:6 199:10	process 9:19 24:1	producer 19:6 30:1	61:5,12 85:6,16	product-based
privately 198:11	35:12 38:1 39:21	42:21 46:1 48:20	87:8 92:13 109:2	23:7
pro 298:10	44:2 46:17,18	48:21 49:6 199:5	109:4,6 114:1	professional
probability 49:15	48:7 65:17 69:7	275:9 310:22	120:22 121:19	232:14 348:19
probably 64:1	75:20 77:19 84:2	producers 8:17	124:7 147:7	professionals
68:12 93:6 96:1	87:6,17 88:11,18	29:8 30:6 45:2	166:15,16 168:2	196:15 210:6
96:16 97:18 98:21	89:8,21 90:22	62:10 121:2,10,22	178:21,22 179:3	professors 267:22
113:14 140:21	92:15 97:2,3	201:7,10 202:8	181:13,17 194:13	profound 52:6
150:20 155:11	100:10,18 102:4	211:12 272:22	207:3,9 215:18	program 1:2 2:11
162:16 165:12,19	102:18 108:14,20	274:4 275:5 280:1	227:19 251:3,7	2:15,17 10:2 24:6

29:18 32:1 103:22 108:13 116:9 128:17 154:19 157:17 160:4 169:20 170:1,2 183:4 184:2 189:3 190:3 207:17 208:15 234:13 248:13 272:7 275:3,16 293:18 324:2 326:22 329:9 359:12,13 360:3 361:5,6,19 362:3 programs 156:6 184:4 196:17 progress 13:19 24:18 107:20 148:14 152:4 164:17 progresses 385:15 progressing 153:12 progressive 304:7 prohibit 70:13 93:11 108:7 246:15 286:13 331:14 prohibited 31:1 69:1 104:20 108:2 110:18 111:9,11 111:18 141:7 186:16 247:15 282:16 284:5 330:17 prohibition 109:11 128:14,16 135:4 178:20 project 31:22 35:2 88:22 96:14 157:5 157:6 158:16 160:6 163:8 164:6 168:9 171:21 172:12 197:3,11 197:13 200:18 210:9 305:15 projects 195:12 207:12,15 208:11	208:12,14 210:7 219:20,20 386:10 promise 162:5,11 305:18 promising 154:1 159:4 161:10 164:6 promote 232:17 promptly 326:22 prone 42:4 180:17 pronounce 97:14 327:18 proof 182:13 proper 71:7 137:14 318:12 369:8,9 properly 13:6 63:20 84:15 138:10 374:6 properties 74:21 75:15 238:4 255:15 293:2 property 347:16 proposal 3:2,6,22 24:5 25:3 67:20 73:3 86:11 88:11 88:13 91:5,11,14 94:1 95:11 96:13 96:22 100:7 172:2 172:3 281:18 282:18 283:12 305:7,9 306:6 330:16 357:17,18 366:20 372:16 373:12,18 379:17 387:15 394:8 395:4,9,16 396:4 proposals 3:8 8:2 51:19 146:9 375:11 378:18 385:18 propose 78:13 378:14 proposed 58:8 91:3 92:22 108:17 111:15 112:14 122:16 241:2 243:5 291:10	341:8 364:10,20 371:14 373:11,18 381:2 385:22 proposing 88:16 89:4,10 104:19 235:18 proposition 168:16 proprietary 100:22 101:3,10 102:1 propylene 3:9 82:9 82:17 83:15 281:14 283:10,12 protect 13:7 24:8 153:13 156:19 157:19 158:6 167:11 205:22 206:14 257:13 342:19 379:21,21 380:8,9 protected 101:2,4 209:18 protecting 30:18 57:8 213:21 215:11 301:12 344:19 346:2 protection 101:17 101:21 346:2 protective 338:16 340:2 345:6 protocol 10:5,8 16:20 40:2 71:8 133:7 135:14 protocols 10:22 20:1 40:14 42:19 52:22 63:13 128:3 prove 273:8 288:16 proven 18:7 52:22 163:6 244:18 328:15 329:13 provide 9:9 12:14 22:14 23:12 24:5 33:6,9,14 37:22 40:19 52:10 143:3 143:11 200:20 215:16,22 246:4 271:21 273:5 275:3 295:13	387:12 provided 53:13 128:6 150:13 212:7 214:14 216:5 247:12 257:8 276:7 312:3 388:22 389:7 Providence 1:11 346:16 352:6 providers 47:19 provides 102:3 130:19 147:13 196:21 233:13,19 providing 21:20 22:4 24:14 149:1 185:4 198:5 prudent 181:15 pseudostem 339:4 344:14 public 3:4,19 5:3 6:8,11 14:18 21:8 44:1 67:18,21 68:14 73:16 79:15 83:3 93:16,22 101:11 104:21,22 115:13 118:6 119:16 123:14,14 123:17 124:12,13 126:6 131:12 133:2 176:18 177:6,11,18 180:1 190:20,21 191:22 192:20 193:21 198:9 199:9 210:20 211:4 218:9,14,14,20 219:2,6,10,13,22 220:3 221:9,16 223:13 233:4 322:14 355:1 379:8,13 382:19 384:3,5 389:19 390:14 publicly 52:20 198:11 published 57:2 115:17 169:8	170:12 198:21 199:17 236:11 publishing 20:4 197:8 pull 117:2 pulling 353:22 354:3 purchase 59:11 purchasing 12:22 pure 13:1 24:10 139:5 purity 5:17 6:20 8:3,15 10:4,7,21 11:6,13 12:7,10 12:18 13:1,6,10 14:2,21 19:14 21:21 22:16 23:16 26:5 41:11,11 42:15,17 44:19 49:3,7 52:7,19 53:2,4,18 54:13 55:7 56:5 213:18 214:7 215:3 381:1 purpose 54:19 148:18 153:21 189:2 343:6 purposes 47:18 64:8 227:19 285:8 285:16 298:14 336:5 379:16 pursue 285:11 297:2 push 194:5 put 4:11 6:19 8:10 14:10 27:4 28:3 56:4 64:4 71:11 79:7,11 81:9 89:4 93:6 95:14 97:14 100:7 111:8,17 113:6,8 115:16 129:5 134:16 137:7 138:12 148:12,17 153:8 156:9 169:14 172:1 178:18 193:17 217:17,20 223:9 224:14
---	--	---	---	---

220:9 222:18	389:20 390:19	records 336:10	regard 42:9 176:8	regulations 9:2
227:21 228:16	receiving 42:21	recovery 232:17	279:1 289:8	11:21 114:11
232:2 240:8	recess 399:6	recusal 394:16	294:15 335:22	206:14 272:21
250:19 251:7,16	recognize 19:19	recuse 360:11	regarded 320:1	273:7 300:7,9
253:4,7,9,15	27:7 30:5 66:15	recycle 347:13	regarding 16:12	303:17 320:17
263:1 265:3 266:1	115:3 116:8	recycling 280:5	30:13 76:17 202:1	regulations.gov
267:2 278:8	212:22 273:1	red 71:17 150:11	216:6 273:22	384:7
280:12 296:15,20	320:21	213:4 287:7 328:8	275:5 298:8 336:9	regulatory 18:5
300:7 301:18	recognized 131:11	328:19 329:14	338:21 342:6	57:6 89:14,22
303:13 335:17	175:15	331:10,19 333:14	359:9,15 375:17	103:4 111:22
349:19 350:10	recognizing 106:6	338:6,18	regardless 180:8	205:18 313:1
370:6,7	114:7,17 237:20	redacted 72:8,10	regards 126:9	314:21 315:3,4
realtime 159:22	recommend 15:10	73:17,20	128:18 129:1	319:10 323:4
reams 352:19	138:4 244:2	reduce 49:15	280:10 286:9	340:12 373:3
reason 32:7 33:3,6	326:20 365:3	161:18 283:18	regime 167:5	reinvent 349:13
39:3 69:15 71:6	recommendation	338:20 347:12	regimes 173:7	reiterates 206:10
169:17 170:5	4:12 20:20 57:11	reduces 85:12	region 61:1,13	reject 134:11
193:8 253:7,16,22	59:9 79:12 94:18	255:20	62:20 257:2	282:18 283:11
254:5 287:1	108:14 112:10,11	reducing 38:21	272:10	312:1 314:10
309:22 348:3	136:18 254:4	349:20	regional 197:1	318:7 319:6
372:21 387:10	272:11,18 273:10	reduction 159:3	211:5	rejected 325:5
388:21	274:18,21 287:20	178:3	regionally 208:18	332:4
reasonable 43:18	295:13 311:22	redundant 134:15	regions 155:6	rejection 33:8
113:18 397:5	312:3,21 314:10	refer 82:10 127:14	171:5 188:9	130:20 233:14
reasoning 134:1	315:7 318:7	145:16 336:20	208:20 333:12	related 6:20 76:16
reasons 8:7 13:11	357:22	reference 88:1	Register 115:16	109:7 123:6
16:4 33:5 42:15	recommendations	127:3 163:20	233:5 242:4	145:11 146:17
43:1 68:21 70:8	9:10 57:4 59:2	246:7 249:6	registered 153:14	332:17 336:7
120:17 151:7	70:17 197:10	345:16 373:21	154:20 155:15	relates 393:4
197:21 198:3,12	199:17 203:15	referenced 127:22	317:19 320:9	relation 296:14
252:13 253:21	216:4	236:13 237:19	335:4,11,16 336:6	relationship 164:5
323:16 337:13	recommended	references 127:5	339:15 341:4	332:14
349:9	126:1 129:6	referred 130:13	registrant 310:22	relationships
reassessment 97:1	145:13 233:11	237:10 246:7	registration 102:4	151:17 352:2
recall 88:8 291:17	345:7,8 394:10,12	259:4 345:19	314:19 320:6	relative 45:1
397:1	recommends 8:22	392:13	333:20 335:15	125:13 153:1
recalling 103:5	12:10 68:3 282:18	refers 133:21	339:17	163:11 273:12
receive 197:5	283:11	refine 24:4 25:3	registrations 311:3	292:12 293:21
359:20	reconsider 141:3	refined 294:19	Regroup 322:12	relatively 96:5
received 6:13 15:2	reconstruct 47:15	reflect 51:2 201:6	regs 242:10	104:22 140:14
28:15 66:21 67:19	record 65:10,11	317:4	regular 107:16	270:22
76:10 82:13	144:11 221:5,6,15	reflected 22:9	regularly 251:9	released 134:5
104:21 110:5	221:17,17 222:8	214:8	regulated 242:1,9	162:15 307:9
117:12 122:20	223:8 322:19,20	reflecting 318:1	regulation 28:3	relevant 354:17
130:14 208:16,18	370:20 374:5	reflects 222:8	62:1 114:12	383:20
379:9,15 382:9,19	388:18 392:5	223:8	145:12 206:8	relies 206:6
384:6,6,11 388:16	399:10	reg 242:14	245:22 371:3	reluctant 335:14

rely 84:14 91:6 219:2 351:2	121:13 123:11,12 197:6,9 198:22	126:10	386:15 387:9,14 387:16,18,21,22	respect 114:22 120:21 249:20
relying 203:6	199:18 200:19	requesting 103:22 124:21 306:3	388:2,5,6,9,20 389:5,7 390:3,9	293:22
remain 51:16 170:3 184:10 322:2	201:2 208:7	312:7	390:16,22 391:7,8 391:10 392:16,20	respects 42:10 48:9 48:14
remaining 59:16 182:20 322:14	217:18,21 237:7 251:20 275:22	requests 67:1 76:13 82:16 117:14	394:2,9,12 395:16 396:4 397:4,17	respirated 236:1
378:18	312:8 315:6 317:17 319:22	123:3 273:4 280:9	researched 106:8 107:12	respond 108:13 159:16
remains 274:5	321:9	require 12:1 35:9 126:20 173:7	researcher 153:19 158:11 195:12	responded 201:10 201:15 203:8,13
remember 66:4 79:10 81:15	reported 107:1 328:21 335:21	286:4	researchers 309:4 328:20 384:18	respondents 205:4
301:19	395:1	required 102:7 127:13 282:6	387:10,15 388:21	responding 203:20 205:11,17 207:1,8
remind 371:9	reporters 185:14	339:18	researching 103:20	209:15
reminds 280:21	reporting 221:16 279:5	requirement 50:7 57:16 89:5 109:18	reserve 90:6 141:2	response 16:18 18:19 31:21 67:9
removable 145:9	reports 67:12,16 77:5 96:16 154:10	198:1 211:13	resident 195:20	67:20 77:3,6 97:7
removal 48:2 67:1 70:9 246:11 268:7	175:1,4,5 176:2	247:22	residual 104:12 225:15	106:4 117:20
274:17,22 316:18	309:15 317:3	requirements 43:9 125:8 126:13,17	residuals 231:22	118:2 171:10
remove 46:11 68:4 69:7 71:9 74:14	represent 60:22 61:2 80:1 232:10	234:9 241:7	residue 23:8,9 255:19 256:7	206:10 212:18 246:6
226:16 270:6	330:9	245:19 246:11	295:8	responses 15:3 18:21 70:8 204:15
281:18 354:1	representative 115:9 123:16	286:1 346:2	residues 140:3 170:13 180:20	233:4
356:3,9,14 387:8	representatives 60:20 117:6	requires 11:21 23:8 273:14,18 274:18	181:3 228:11	responsibility 26:10 33:20 277:2
388:20 390:16	represented 6:16	331:6	254:1 306:1	296:5,9
removed 69:18 235:14 245:18	representing 39:13 105:13 149:13	research 20:16 39:11 40:5 46:9	307:16 309:3	responsible 175:2 256:1 320:11
246:19 251:13	201:3 250:16	46:16 68:21 108:4	resins 287:8	354:11
255:17 268:10,16	310:19 330:11	108:8 125:1	resist 161:15	rest 18:16 34:13,15
268:17 273:19	340:6 341:22	137:12 138:10	resistance 106:2 107:1 160:8	126:8 251:1 371:3
274:7 283:3 385:4	350:20	139:20,21 156:10	161:11 163:7	restate 364:17
removing 140:20 224:7 268:11,11	represents 9:18,18 150:10 158:4	161:13,14 168:12	164:1,3,13,22	restricted 165:5 276:20
315:19	200:13 351:17	169:4 171:3,5,11	165:4,9 170:14	restricting 241:9 342:17
renewable 257:11 287:22 345:21	382:5	171:14,20 187:15	180:9,12,14,18	restriction 340:21 345:19
repeat 256:14	reproduces 328:9	193:10,15,17	188:10 329:10	restrictions 215:20 242:16 277:4
repellants 328:22 329:3	reproducing 31:3	194:2 196:17	resistant 162:2 179:16 192:3	restrictive 301:14
replace 203:4	reproduction 160:21	207:18 208:9	resolve 23:11	result 88:3 157:21 180:8 219:21
replaces 90:7	request 5:16 77:2 82:21 90:21 91:9	210:22 219:7	resource 288:1	316:10
replacing 155:21 337:5	91:14,17 174:15	220:3 268:2 287:5	resources 18:20 96:7 147:11 196:2	resulting 45:9 59:6
reply 245:10	312:7 385:3	303:11,11 309:5	209:10 215:12	results 88:14 92:2
report 67:8,14 70:7 74:10 77:3 82:22	386:22	310:13 324:7	223:10 275:20	
83:1,1 98:6	requested 123:10	382:5,11,20,21	379:22 380:9	
117:19 118:1,4		383:4,7,8,12,15		
		383:20 384:8,16		
		384:18 385:1,5,13		
		385:14,16,18,22		
		386:2,4,9,10,12		

156:14,14 157:4 211:4 325:8 347:9 386:16 retail 151:20 retain 348:4 351:3 retention 257:7 retract 372:11 retrospective 359:8 return 60:6 65:7 reuse 347:12 reveal 359:5 review 71:7 73:5,22 74:1 77:1,9 82:20 88:18 89:6,21 90:2,11,18,21 91:16 92:7 93:7 94:2,6 95:4 100:4 100:18 101:20 103:11,13,15 104:1 115:7 117:18 123:9 130:21 131:15,17 146:8 155:17 247:18 276:18 293:21 296:11 297:11,16 299:2 305:7,11,12,13 306:8 310:3 318:8 319:19 324:6 325:13 372:17 reviewed 100:2 222:13 267:9 307:20 320:5 reviewer 305:2 reviewers 131:14 131:16 reviewing 73:3 132:7,10 reviews 89:15,16 92:9 282:5,10 revised 123:12 131:22 revoke 341:7 revolve 241:16 revolves 17:2 re-listed 69:9,11 177:9 191:21	re-review 104:5,6 Rhode 1:11 350:13 350:14,18 Rica 337:9 RICHARDSON 1:20 95:18 98:1 357:6 362:20 366:9 367:19 372:1 374:19 376:8 377:19 398:11 rid 181:16 right 4:7 16:21 19:18 23:5 36:6,7 44:16 49:10,10 50:16 71:8 93:1 98:4 109:14 110:16,21 111:14 111:20 113:4 114:1 115:1 121:15 124:1,3,4 134:20 139:10 141:2 142:3 146:4 152:18 156:20 164:16 168:14 169:7 171:20 186:4 191:17 192:6 193:1 219:1 224:14 225:20 237:19 239:14 248:18,19 249:5 249:11 261:14 262:18 264:12 269:22 278:1 289:14 291:20 301:4 313:18 333:4 334:11 336:3 347:14,16 347:19 350:19 356:2 357:20 363:12 365:8 370:2 371:15 384:4 391:14 394:18 rigor 16:22 rigorous 10:10 rising 166:13	risk 11:17 13:14,15 31:6,16 33:8 55:14 90:3 115:11 140:16 152:5 170:7,13 173:11 173:18 175:2 206:17 214:12 246:18 299:20 325:11,14,16 337:16,21 338:12 338:20,21 339:22 risks 9:20 54:20 risk-benefits 84:15 river 8:1 12:6 17:15 19:17 162:12,19 325:9 road 56:13 88:17 89:4 101:19 robust 24:17 Rodenticide 90:5 Roger 281:2 Rogers 250:9,11,12 254:10 role 9:1 29:5,6,10 57:7 88:21 192:1 203:16 219:10 278:2 roll 229:1 244:1 rolling 27:6 rolls 224:3 room 4:14 147:5 272:22 root 152:2 160:15 160:18 161:4,9,14 161:21 164:14 rooted 180:15 300:21 roots 176:9 300:6 329:7 348:7 rotate 227:6 rotation 342:2 rotenone 3:11 93:12 102:16,21 103:1,16 104:9,14 105:2,21 108:1 109:1,6 110:2 111:2,3 281:14,15	284:3,4 329:8,12 329:20 330:16 331:8,14 336:9 337:12 338:3,8,17 339:2 340:12,14 340:16 341:19 342:12,22 343:20 345:4 355:11 rototills 226:4 rough 89:20 roughly 10:6 140:17 383:10 round 24:19 220:11 315:5 334:11 routine 18:11 routinely 256:18 row 121:9 270:2,3 270:6,10,16 Rudy 336:19 337:5 rug 117:3 rule 32:17 35:11 78:21 81:2 108:15 108:17 111:17 112:14,16 133:18 133:19,20 134:21 136:2,3 166:4 178:15 251:11 303:20 304:6,7 364:20,22 rulemaking 108:20 111:16 112:12 113:2,6 116:22 138:1 140:19 141:5 144:3 rules 78:14 ruling 237:15 360:10 run 86:8 157:7 183:10 348:11 361:6 running 227:15 302:2 rush 371:10,12 rust 328:8,20 329:14 331:10,19 333:14	Ryania 106:12 R&D 194:7 <hr/> S <hr/> sad 31:21 safe 25:20 33:6 36:16,22 37:3 41:9 208:21 380:1 380:2,10,12 381:13 389:2 safeguard 19:6 safeguards 380:18 safes 16:16 safety 41:7 55:12 62:2 174:22 236:17 317:14 352:18 353:4 sake 392:5 sales 40:17 149:22 150:5 sample 12:11 15:10 15:12 17:1,2,5 20:9 22:17 34:19 43:6 159:9 samples 63:10 181:4 270:20 sampling 42:6,8 San 337:9 sandy 261:7,11,11 262:13 352:16 sanitary 353:15 SARE 208:15 satisfactory 396:6 satisfy 141:11 247:21 save 25:12 38:14 353:11 saving 25:15 257:3 saw 115:12 168:4 279:5 saws 81:19 saying 29:7 36:9 48:2 59:10 79:17 79:20 85:10 116:2 166:14 170:11 190:10 200:13 237:11 303:5
--	---	---	--	---

381:21 395:18	seal 381:9	186:21 187:6,10	13:13,18,22 14:1	209:21 210:12,14
says 17:15 101:5	season 125:22	188:14 197:15,18	14:3,21 15:1,6,7,8	210:16 211:9,13
127:12 150:5	137:8,8 150:2	199:10 209:2	16:1,3,10,11,15	211:16,17,20
159:14 339:22	157:6 225:5	219:10 384:20	17:18 18:12 19:6	212:2,4,5,6,16,16
364:1,3 391:1	226:17 227:15	securing 24:13	19:14,21,21,22	212:22 213:1,2,10
scale 58:19 61:2	231:19,22 252:11	sediments 308:15	21:19 22:2,3,4,8,9	213:15,18,19,22
120:22 151:14	256:5 261:21	325:9	22:12,13,14,15,19	214:7,13 215:1,9
153:16 201:8	262:19 263:13	see 11:16 20:21	22:20 23:10,13,14	215:11,15,18,22
318:2	270:5 273:16,20	21:4 25:8 26:9	24:2,10,12,14,17	216:7 217:16,18
scared 36:18,20	274:8,20 275:14	27:6,10,11 29:5,6	25:1,2,6,20,21	219:5,12,13 223:1
scary 97:9 333:1	301:16	34:12 44:19,22	26:5,10,11,12,12	SeedAlliance.org
scenario 26:15	seasons 158:2	62:9 63:3 64:4	26:16,17 27:13,17	201:1 214:22
334:16,22 340:12	274:10 334:12	79:19 81:1 85:21	27:18,19 28:9,16	seedling 131:3
schedule 95:5	Seattle 148:9 174:9	93:21 95:4 96:15	28:18 29:6,7,9	seeds 8:4 15:15
scheme 140:14	seaweed 394:5	97:2 100:16,17	31:12 32:20 39:12	16:15 24:8 25:12
schemes 63:14	395:19 396:17	115:13,17 119:8	39:13,18,21 40:11	25:15 34:19 42:7
science 147:20	second 69:3 74:14	127:2,12 143:2	40:13,15,16,19	46:2 48:22,22
170:12 179:5,6	131:5,18 171:9	149:21 150:9	41:2,2,11,11,12	64:6 195:5 201:16
180:15 314:22	209:20 226:1,1	152:18 156:18	41:14,14 42:7,9	seed-testing 16:20
sciences 174:21	252:9 338:10	157:12,15 158:8	42:16,18 43:2,5	seeing 250:4
science-based	356:6,7 358:14	159:10 162:22	43:10,12,16 44:19	291:18
149:7 169:9	363:13,14,16	164:11 167:12	45:6,21 47:13,16	seek 292:3
scientific 98:6	364:7,12 367:5	186:18 194:19	47:18,20 48:1,20	seeking 274:8
181:9 309:21	368:14,15 373:15	199:10 201:9,22	48:21 49:3,6,12	seen 33:21 115:20
310:2 311:18	375:21 377:1,7,8	202:14 203:3,7,19	50:18,22 52:3,7	166:9 198:9 209:6
312:10 385:21	383:13 395:22	204:10,15 206:22	52:12 53:2,6 54:3	225:15 253:6
387:4	396:1	210:1 219:19	54:4,6,7,13,18,21	268:6 271:3
scientist 176:1	seconded 356:9	225:17 226:2	54:22 55:14 56:5	303:14
304:22	358:16 367:8	244:7 245:11	58:2,13,14 64:3	sees 207:13
scientists 265:4	368:16,17 373:17	253:15,21 256:3,5	146:19 195:8,10	segment 141:17
scion 161:15	376:1 377:10	256:5,9,20 267:17	195:14 196:9,11	segue 146:3 355:2
164:19	396:3,11	278:7,8,19 286:3	196:11,15,16,20	selecting 381:10
scope 16:13 88:22	seconding 365:17	289:4 295:17	197:4,6,12,15,18	selection 24:15
169:5 294:18	Secondly 325:4	296:11 302:15	197:20 198:1,4,6	48:12 162:13
386:15	seconds 216:10	305:12 306:9	198:7,13,17,19,21	self-insure 59:12
scouting 172:15	Secretary 9:7	307:19 309:21	199:9,13,18,22	sell 25:2 348:14
screen 68:10 83:14	30:14 51:10	344:16 345:1	200:2,5 201:2,18	selling 55:1 254:16
87:1 92:18 300:5	section 67:2 76:14	347:3 349:4,6,7	201:20,21 202:3,8	260:1,2
301:4 302:1	76:19 82:17 90:5	355:9 381:10	202:12,16,18,22	sells 223:21
screened 165:2	104:20 117:15	382:10 383:3	203:1,2,10,13,14	semantic 239:19
screening 89:15	123:4 124:6	seed 3:17 5:17,20	203:17,19 204:10	semantics 144:4
92:15 164:9	126:11 127:5	5:21,22 6:2,3,20	204:14,17 205:2,3	semi-housekeeping
scroll 7:21 79:9	128:1,6 129:3	8:3,8,11,15 9:5,12	205:5,7,12 206:17	393:16
scrutinizing 223:6	246:17 273:17	9:21 10:1,4,7,21	206:19,21 207:2,9	send 51:9 187:22
scrutiny 185:12,18	321:19 356:4,10	11:1,2,3,6,13 12:3	207:13,17 208:1	245:10
318:12	sections 126:5	12:7,10,11,12,20	208:10,12 209:1,6	senior 323:4
se 135:5	sector 147:14	12:20,22 13:1,6,9	209:8,11,14,16,17	sense 31:11 63:11

112:20 166:3	201:20 306:22	344:3,3	197:18 198:18	301:5 344:2
168:6 215:4 226:8	350:20 386:10	showing 44:2 108:8	212:21	382:14,17,18
241:5,5 295:21	seventy 58:20	125:12 155:18	simulate 234:5	slight 305:4 329:11
300:18 355:5	Seventy-nine 204:1	156:15 157:2	simultaneously	slightly 180:12
sensitive 42:3,13	severe 154:6,7	273:11 300:7	273:14	slow 160:20 161:17
sensitivity 42:4	329:11,12,19	345:5	sincerely 284:19	188:3
sent 30:14 44:1	SHAC 76:11	shown 68:21 71:13	single 7:13,14 92:5	slower 333:8
72:9 199:6 214:2	shaking 45:1	105:5 125:7	96:18 148:19	slowly 186:14
359:13	shards 268:21	138:10 157:21	164:4,4 304:9	325:10
separate 49:19,20	share 202:10 213:7	253:4 282:11	sir 284:11 357:1	sludge 242:10
131:22 222:10	220:15 345:12	309:15	362:13 366:2	slug 67:4 311:8
277:16 307:12	359:11	shows 40:18 104:8	368:4 372:8 375:4	313:3,14 321:4
separated 50:1	shared 18:9 208:6	110:14 181:3	376:15 378:4	323:9 324:19
separately 68:7	213:18 315:2	324:19	398:18	Sluggo 311:7
321:20	359:12 393:12	side 74:19 149:14	sit 45:10 98:4 379:4	314:14 319:13
separation 49:22	shed 307:21	193:7 208:3 222:4	379:5	320:6
sequencing 156:5	sheet 226:18	277:20 337:20	site 171:12 346:21	slugs 72:5 281:22
series 89:14 164:17	373:10	338:5,22	siting 347:8	317:6 324:9,16
serious 53:8 55:11	sheets 271:6	sides 71:18 281:10	sitting 28:20	small 15:15 49:12
64:21 284:20	shelf 110:3	390:19 391:6	347:16	58:18 61:5 62:21
388:4	shelf-stable 119:6	398:5	situation 32:16	63:15 151:15
seriously 51:4	shepherding	sieversii 163:11	151:8 169:21	166:20 179:8
329:15 330:7	123:21	signal 15:16	173:4 226:8 266:4	212:20 228:19
serve 78:7 116:6	shift 9:22 166:9	Signatures 330:10	266:9 370:4	229:1 256:6,7
serves 142:18	303:14,15	signed 60:10 67:21	situations 247:4	310:21 315:13
147:16 195:21	ship 151:20	123:17	304:4 330:5	316:7 328:8 330:3
285:8	shipped 332:8	significant 24:18	six 69:10 85:22	348:11 350:20
Service 1:1 20:16	short 8:12 96:5	121:13 147:13	90:16 107:2,4	smaller 299:17,20
324:7	103:4 129:19	203:22 204:2,20	382:16 385:22	302:16 303:22
services 82:15	138:21 171:1	384:17	six-spotted 106:20	Smith 264:20 272:3
175:13	177:21 182:6	sign-ons 93:20	six-tenths 162:18	272:5,6 278:15
session 4:5,8 65:13	226:20 296:5	silver 102:12	size 15:10,15 17:3	279:6,9,19 280:16
141:15,18 146:2	307:13 334:14	similar 19:12	42:9 43:6 167:2	snail 67:4 321:4
146:11 147:1	382:17 388:11	130:18 156:14	201:9	323:9
174:2 194:21	shortcomings 32:2	172:3 276:21	sizes 20:9	snails 69:1 72:4,18
222:15	shortened 383:16	290:18 319:16,19	skeptical 298:17	317:6 324:9,16
sessions 142:11	shorter 137:1	330:5 333:13	skin 332:1,2	snapshot 200:20
set 17:22 35:14	285:10	339:13	skip 346:9 350:6,12	212:2
39:2 63:12 163:20	short-term 192:16	similarly 74:3	375:13	society 147:19
198:20 202:3	262:10	222:16 339:1	slide 39:16 44:2	380:18
312:16 373:5,6	shoulders 51:17	341:3 359:19	130:11 132:5	sodium 70:10 75:7
389:9	show 55:4,5 72:6	simple 185:20	133:5,15 138:17	325:5,15
sets 277:16	103:1 104:11	253:3 387:10	138:18 174:16	soft 316:1
setting 13:1 35:11	149:18	388:21	300:5 380:4	soggy 348:7
39:4 303:13	showcase 212:21	simplicity 359:3	383:13 388:11,14	soil 70:6 76:15
settle 142:21	showed 72:16 93:5	simplified 301:2	388:14 393:15	80:13,17 124:11
seven 69:13 126:3,4	110:10,10 329:4	simply 54:8,9 90:7	slides 126:3 130:8	125:15 129:22

135:5 137:14	34:10 35:18 37:6	157:15 177:16	speaks 222:14	spontaneously
138:8 155:14	39:6,8 43:20	178:12 182:16	241:17	352:13
233:12 234:3	50:14,17 55:20	184:4 185:10	spearheaded 10:12	sporadic 84:8
235:8 240:16	59:15 60:7,13	188:3,15 218:12	special 91:19	spot 370:7
245:20 246:15,19	64:9 65:2 71:2	253:1 269:21	103:11 104:1	sprang 107:16
247:4,6 248:21	73:15 77:12 80:15	281:8 290:18	specialist 2:12,19	sprayed 104:13
252:5 253:19	81:7,14 90:10	332:21	147:9 323:5	spraying 328:22
255:6 257:1	97:6 99:15 102:19	SOS 330:19	specialty 316:5	sprays 158:5
260:20 261:5,6,7	110:5 112:6,21	sound 4:15 121:17	species 163:10,12	spread 161:16
261:10,11,18,19	115:19 129:16	sounds 6:15 81:22	163:15 253:11	spring 88:15 90:16
263:7,8,13 266:10	145:19 193:5	114:5 333:5	335:9 385:9 394:5	91:12 95:3 174:10
267:14 268:15,17	228:7 237:2,6	397:15	395:20	174:12 225:1,11
268:21 283:7	238:7,16 239:9	source 33:17,18	specific 9:9 14:15	251:5 256:9
300:8,22 301:12	259:2,19 269:20	202:22 203:10,12	20:8 105:1 111:1	sprouts 225:4
301:19,20 305:19	277:13 279:2,8	209:7,14 212:15	119:18 126:18	spur 193:10
306:2,20 307:17	290:15 291:17	224:1 235:22	128:16 171:12	squarely 27:11,12
308:20 309:18	310:6 356:11,22	257:11 258:10	200:7 242:15	stabilization
317:9,14 325:9	357:21 358:6	286:11 289:21	249:6,16 272:15	118:17 377:3,11
348:4 351:5	360:6 362:11	387:21	294:16 344:8,9	stable 253:22
380:20	363:7 364:5,13	sourced 258:10	specifically 32:19	staff 2:8 8:17 95:13
soils 131:3 235:15	365:5,9 366:15	sources 19:15	65:20 119:19	96:2 196:5
251:4 308:15	368:3 372:7,19	63:12 134:13	135:4 162:9 163:9	stage 351:11
sold 48:1 52:4,13	374:1 375:3	203:1 258:6	174:8 178:2 274:1	352:12
261:14	376:14 378:3	sourcing 201:19	274:3 276:10	staining 105:19
sole 224:1 314:13	382:1,13 390:12	202:16 203:19	308:19 313:9	stake 388:1
351:14	391:4 393:14	209:15	336:21 339:22	staked 185:8
solely 51:16 300:22	394:11 395:7,13	South 105:11	346:13	stakeholder 21:3
320:7	395:15 398:17	113:22 115:10	specifications	193:7
solid 24:5 184:14	Sonya 164:19	328:7 331:4,9	125:9,10 131:8	stakeholders 52:21
solids 339:5	soon 13:10 20:4	southern 121:10	specifics 120:1	53:16 56:18 58:1
solution 53:10	53:8 305:21	soy 31:16 32:18	specified 129:14	58:2 149:15
solutions 62:18	sooner 236:5	61:12	specify 205:20	199:15 210:10
177:21 192:21	sorry 29:2 60:9	soybean 48:22	specifying 111:12	212:14
199:2 210:12	66:15 100:13	295:8	specs 237:22	stalks 135:2
317:18 385:12	138:17 179:7	soybeans 219:7	spectrum 85:7	stance 30:16
solve 256:21	188:21 191:4	240:7	spelled 278:4	stand 66:10
solvents 140:7,8	217:21 269:13	so-called 86:12	spend 183:1 233:3	standard 8:3 9:17
solves 12:8	311:8 318:22	317:2	285:2	9:19 10:4,21 11:7
somebody 45:7	345:10 354:14	speak 4:16 9:10	spinosad 106:12	11:13 12:7,10,16
110:15,16	364:19 365:4	60:21 63:3 239:4	333:11 335:4,13	12:19 13:2,3,6,11
somewhat 60:22	381:19 392:1	277:21 292:2	spoilage 331:21	13:12,16 14:2,21
77:13 84:11 87:21	394:13	328:5 337:10	spoke 58:10	16:9,10,20,22
135:11 265:18	sort 38:1,18 56:14	360:4 374:9	spoken 251:19	17:3,16 22:1,16
278:10 303:2	74:18 95:19,22	speaker 195:4	315:18	23:16,20 24:12,15
son 257:16	100:14 110:2	318:21	sponsor 212:20	26:5 36:12 41:11
Sonnabend 1:21	111:22 116:20	speakers 348:22	sponsorships	42:17 44:20 52:19
4:9 25:7 29:1,14	144:2 145:1	speaking 337:11	212:17	53:3,5,5,18,19

55:7,10 58:7	148:5 149:17	109:2 155:2 178:2	378:4 398:18	380:7
109:16 125:8,10	151:11 156:1	254:18 261:15	stop 143:16 191:19	strongly 62:8 137:9
126:18 127:1,5,19	159:12 161:2	334:1 341:6	216:9 253:16	250:21 308:15
130:17 132:21	163:22 184:2,12	stating 330:15	391:17	structure 135:14
139:13,17 156:16	185:1 190:7,11	statistical 15:13	stopped 217:13	struggle 38:6
157:15,17 158:21	228:8 237:3	17:7	stop-use 110:19	struggles 160:10
161:8 177:1	241:11 355:12	statistically 15:16	storage 332:7	stuck 38:18 193:9
183:10 184:6,9	377:16 379:8,13	statistics 42:10	store 151:19 163:2	194:1
192:13,15 214:7	started 5:15,17	status 38:4 59:10	185:1	studied 268:22
215:4 240:20	106:5 121:4,8	324:1	straight 68:13	studies 43:8 72:5,7
243:4 246:7 247:3	141:4,10,15 157:6	statute 87:7	straightforward	74:6 102:22 130:3
249:8,10 257:8	219:14 229:2	stay 37:9 322:5	23:11	140:11,13 236:11
264:3 278:11,16	237:16	391:9	strain 47:10 163:12	236:14 270:1
285:8 300:21	starting 20:7	steal 141:19	straits 187:18	307:5 308:18
317:15 327:3,11	120:11 121:1,13	stem 253:1 344:21	strange 267:2	309:20 310:7,12
standards 1:5,10	130:11 158:8	stemmed 290:21	strategies 56:10	321:6
2:14,16 8:15 16:5	164:7 188:4 256:6	step 9:6 35:8,17	strategy 10:10,11	study 72:10,12,15
23:7 29:20 30:1,5	356:20 362:10	45:7 51:14 56:6	19:10 20:3	181:2 182:12
30:21 31:5,8 32:2	371:16	235:12 327:1	straw 227:4 252:18	255:9 267:16,18
43:2 126:19 127:7	starts 141:18 186:6	stepping 80:19	298:9 301:5,16	321:11,13 386:18
127:21 128:2	186:16 190:12	227:16	348:8	stuff 110:17 142:22
130:13,14,15,16	198:16 213:1	steps 5:8,10 49:14	strawberries 225:9	143:1 253:10,17
132:21,22 182:8	228:4	89:14 90:11 91:22	262:16 315:22	271:2,6 344:4
183:5 184:2,16	state 18:1 29:15	167:17 199:16	strawberry 225:12	370:6
186:6,13 189:17	52:7,11 54:21	Stephoe 66:22	317:5	subcommittee 3:2
189:21 216:1	70:9 91:7 126:13	311:11,19 312:1	stream 110:2	3:2,5,6,21,22 4:6
234:12 235:18	147:9,15,16 154:6	319:6,16	134:13	4:21 10:14 17:12
237:12,20 241:14	162:19 166:17	Steve 232:6,8	Street 1:11	21:16 51:6 56:9
241:15 246:9	172:9 197:4,5,12	stewardship 40:1	strengthen 183:5	60:1,3 65:4,8,14
269:2,5 270:10	199:18 201:1	195:10 196:11	207:16	65:15 66:20 68:3
275:17 285:16	217:18 255:10,11	stigma 156:3	strep 152:17	70:18 71:3 77:2
286:5,7 297:5	260:9 315:7	stimulated 253:13	streptomycin	82:21 84:3,17
299:2,4 316:20	348:20 349:15	stock 11:3 110:1,7	146:18 152:15	117:19 119:8
379:20 380:7	357:20 358:4	160:18 161:4,14	156:16,20 157:14	123:10 126:1
381:15	364:17 388:13	161:21 164:15	157:20 174:8	135:12 136:7
standard's 54:2	stated 94:5 106:1	177:16	181:3	144:13 221:18
standing 177:12	127:2,20 128:10	stocks 152:3	streptomycins	285:19 287:16
standpoint 45:4	140:6 275:1 276:8	160:15 161:9	180:4	293:9 305:6
stands 16:6,8 49:22	283:1 325:7 327:3	Stone 1:21 28:2	stress 236:10	307:11 311:22
61:3	382:22	45:13 46:6 116:18	strict 28:5 231:7	314:9 315:6 318:7
Stanford 182:12	statement 43:15	143:20 227:14	stricter 43:9	322:15 330:16
star 158:4	103:21 135:17	239:18 269:11,14	strictly 231:10	378:13,20 381:15
starch 144:1	294:10 298:13	332:13 342:22	strike 16:21	381:18,20,22
start 21:7,17 24:22	345:13	350:16 357:1	strong 104:8 183:5	382:3 393:11
26:17 35:11,13	states 1:1 15:5	362:13 366:2	205:21 222:18	394:16
37:12,15 54:19	64:20 83:20 103:6	368:4 371:8 372:8	stronger 30:16	subcommittee's
107:12,13 113:4	103:9 108:22	375:4 376:15	strongest 379:20	51:22 274:18,21

276:7 284:20,22 287:20 subject 7:1 187:4 354:8 subjects 6:19 submission 236:10 submit 360:18 submitted 66:22 74:1 76:11 82:14 117:13,22 119:17 122:22 123:1 155:16 232:19 233:5 252:16 253:13 311:12,17 312:11,18 313:11 327:3 330:14 subsequent 100:16 100:17 subsequently 311:14 substance 67:7 108:2 111:11 295:18 320:2 330:17 336:3 340:21 341:10 substances 31:2 90:2 96:19 97:5 139:14 193:12 246:14 247:10,14 281:19 286:11 295:15 320:20 329:2,5,8 380:19 381:3 substantive 7:3,6 substitute 155:22 284:5 327:8 substituted 84:18 sub-ingredient 277:2 sub-ingredients 275:22 sub-par 183:6 192:17 succeed 182:22 success 9:8 57:13 58:7 114:16,18 207:6 210:3	successful 167:8 212:9 successfully 58:4 211:15 351:1 SucraShield 106:17 sudden 50:8 suffice 190:18 sufficient 133:14 136:15 171:3,4 222:9 254:6 267:13 sufficiently 278:1 sugar 32:19 suggest 15:18 17:16 34:13,16 261:19 282:5 285:18 367:1 suggested 16:10 46:9 63:17 127:6 128:7 129:5 144:17 222:8 234:8 321:3 389:16 393:21 suggesting 117:4 222:12 284:4 397:16 suggestion 14:20 15:22 390:16 suggestions 7:17 193:14 384:10 suggests 133:9 317:17 suit 386:19 suitable 131:15 sulfate 281:17,18 281:20 282:2 sulfur 157:16 sulfuric 3:12 117:8 117:12,15,21 119:18 375:14,17 375:19 376:2 377:3,11 summarize 6:7,18 7:13 14:4,12 18:18 382:18 summarized 84:5	88:14 summary 3:2,6,22 42:15 85:19 124:13 222:3 summer 155:1 224:16 226:13 230:13 256:5 348:3 sun 268:18 sunlight 137:15 255:6 263:1,5,8 263:14 sunny 346:16 sunset 95:6 177:8 364:3,20,22,22 sunsetting 95:7 super 175:16 179:15,17 supplement 112:6 supplemental 67:13 68:9 70:7 73:21 74:10,20 75:8 312:8 315:5 324:6 325:12 suppliers 22:20 26:17 28:18 supply 12:15 19:16 22:7 24:9,17 25:4 31:18 54:18 121:6 330:8,10 361:16 361:16 380:2,12 supplying 19:22 26:12 54:21 support 7:4 9:8 11:11 25:14 51:22 55:18 82:20 84:5 89:13 96:14,20 117:18 123:9 147:13 167:15 196:15 203:15 208:10 211:3 212:7,21 232:20 233:7 266:5 275:15 278:15 281:17 298:10 305:14 312:4 315:11 319:5	321:14 359:20 379:19 380:6 385:2 supported 62:8 70:8 384:8 supporting 51:21 52:1 93:16 94:1 203:16 340:14 supports 167:20 277:5 305:9 supposed 133:19 358:22 394:15 suppress 251:5 suppression 252:1 257:6 sure 6:10 20:20 42:1 46:4,6 47:7 49:22 98:5 100:10 113:19,21 116:19 136:9 142:20 170:8 172:7,10 174:7 205:15 222:8 223:8 264:9 271:21 277:14 280:11 281:10 285:19 289:18 292:18 296:21 355:20 361:12,15 371:9 384:4 surface 271:7 surprise 26:3 64:11 142:8 205:15 surprised 167:7 204:13 surprisingly 203:11 survey 20:13 54:18 58:10 110:10 160:11,12 199:6,6 199:19 200:12,18 201:3,11,15 203:21 205:12 214:11,21,21 216:22 217:8,17 218:12 surveyed 166:19 surveys 166:1	survival 316:9 susceptible 106:18 152:20 161:5 suspect 387:1 sustain 235:6 sustainability 175:1 316:4,7 396:15 sustainable 85:5 147:8 149:4 182:21 183:22 211:22 316:8 Sustaining 147:10 sway 113:15 Swiss 226:15 Symbolically 379:2 sympathy 191:8 symposium 199:14 synergies 100:19 synergist 70:20 324:13 synergistic 98:8 synergy 98:7,17 99:2,4 synthetic 77:18 78:2 79:4,7 80:7 85:3,17 119:14 139:5 178:4 189:19 222:11 273:18 274:6,19 276:5,13,16,19 281:19 283:5 307:14,17 309:3 318:11 326:10 353:8 358:13,17 362:12 367:4,8 375:19 376:2 381:2 synthetics 79:18 94:5 105:3 119:21 183:8 276:8 381:4 system 16:17 17:20 29:6,9 32:3 52:10 92:10,15 149:5 171:11 175:7 181:17,18 182:17 196:19 209:1,11
--	--	--	---	--

219:19 227:11	379:1 387:20	29:4 115:6 230:22	Ten 387:13	testifies 175:14
230:17 273:6	taken 138:16 194:3	260:18 262:4	tend 152:20 180:20	testifying 145:3
301:10,10,13	274:14 278:4	335:20 336:12,17	tended 386:13	testimony 266:1,16
325:2,2 370:18	takes 15:12 61:21	357:12 363:1	Tennessee 255:11	279:13 310:10
386:21 393:7	112:13 113:6	366:12 367:22	tentative 89:17	testing 9:17 11:19
systematic 388:7	136:2 226:20	372:4 374:22	tentatively 214:17	11:22 12:3 14:6,7
systemic 100:20	339:19	376:11 377:22	TER 283:1 306:5	15:1,11 16:12,13
systems 54:14 85:6	Talarek 304:18	379:4,12 389:21	306:21 307:5	16:14 17:20 18:2
117:14 121:20	310:16,18,19	390:20 391:22	terephthalic	18:4,9 23:8 25:19
170:13 196:16	313:21	393:13 394:7,18	309:16	25:20 26:6 27:7
198:21 199:12	talk 14:17 16:16	394:21 398:14	term 177:21 182:6	27:11,17 32:5,14
203:4 207:5 208:5	20:3 36:21 41:18	teaching 343:22	182:6 216:22	32:16 33:3 35:10
208:10 214:1	56:6 130:8 132:8	technical 15:21	234:2,3 247:9	36:19 41:10,16,17
257:5 279:18	150:19 176:6,13	23:11 67:5,7,12	249:6 262:20	41:21 42:19 43:3
385:17 386:11,13	178:9 180:21	67:14,16 74:10	terminology 133:6	43:11 45:1 48:18
system's 56:22	190:5,15 193:22	77:3,5 82:22	259:11	49:2,9,11 50:5
system-based	197:2,7,7 198:1	89:16 96:16 98:6	terms 8:18 17:10	52:9,21 54:11
386:18	199:8,16 209:20	117:19 118:1,4	56:10 62:18 63:11	56:19 58:11,17
	210:17 218:22	123:11,12 237:6	87:22 89:11 93:22	62:19 63:1,9
	233:3 239:5 241:8	240:1 253:12	96:13 97:22	127:19 128:3,5
T	248:1 260:8	265:1 275:21	100:21 127:10	133:7 157:10,11
table 28:21 58:3	281:12 308:13	306:8 312:8 315:6	148:14 149:1,18	168:8 169:2 172:8
60:11 113:20	319:4 350:10	317:3 323:6 324:6	151:12 156:21	172:9 205:13
246:13 247:10	384:2,12 398:2	325:12	170:7 179:5 184:8	215:20 275:8
254:5 308:1 310:1	talked 4:18 10:14	technically 12:13	187:11 190:19	296:3 309:9
371:1	152:2 160:7,16	22:19 48:3 96:19	191:9 192:2	tests 42:2,2,3,13
tabled 306:4	162:3 177:5 215:2	235:2	199:10 203:15	131:3 175:4 297:7
tag-teaming 124:2	252:8	technique 172:16	218:13 234:21	tetracycline 146:17
take 5:8 6:11 8:22	talking 5:10 23:15	techniques 46:10	241:13 251:22	152:13,17 153:4
20:21 23:22 30:16	26:11 53:15 56:5	technologies	303:17 359:6	174:9
33:20 35:8 38:1,8	61:4 73:4 109:3	289:14,19	373:9	tetracyclines 180:4
39:16,17 41:4	116:3 133:3 151:1	technology 45:16	terrible 179:7	thank 4:9 14:10
47:15 48:6 49:13	151:5 183:9	82:14 159:8 160:1	test 15:19 32:21	21:5,15 25:7 29:2
49:14 55:21 60:6	198:17 218:5	206:7 257:13,19	34:19 127:14	29:5 34:9,10
65:6 102:8 103:10	229:11 243:13	269:12,15 286:20	130:19 131:5	35:18 39:6,7,14
108:3 125:20	260:2 262:3 299:3	288:9,14 291:22	159:21 163:1	43:19,20 50:14,16
136:3 137:6	303:12 347:2	tell 16:6 37:1 162:6	233:12,19 234:3,7	55:16,20 56:3
140:21 141:2	397:3	230:6,22 240:6	235:17 285:10,12	59:15 60:5,17
153:4 177:16	talks 130:22 240:1	249:2 258:9	291:10,11 296:20	64:8,9 65:2,5,16
184:22 202:21	300:6	263:17 271:12	tested 20:8 22:11	66:17,18 68:1
203:9,12 209:14	tally 366:17 371:11	279:14 308:7	22:19 25:17,21	73:8 74:15 77:10
216:10 221:14	tally-taker 371:8	telling 113:22	33:1 125:15 128:4	77:11,12 79:13
234:4,18 274:12	target 85:8	136:8	139:16,22 162:12	80:4 82:7,11
280:6,7 295:11	task 88:19	temp 131:9	162:14 270:2	83:10,12 86:1,3,6
322:12 326:22	taught 195:18	temperature	329:2 338:1	86:7 95:11 97:6
332:20 337:16	281:2	130:17 131:7	testified 270:15	100:12 102:15
346:22 354:2	TAYLOR 1:22	tempting 305:20	311:16	108:9,10 112:4
358:18 370:8				

117:6,10 118:8,10 120:10,13 122:13 122:14,18 123:19 141:13,14 142:7 144:8,8 145:18 146:5 147:2,22 148:2,3 170:18,20 173:22 174:3,4 193:2,3,5 194:18 196:5 216:11,14 220:5,7,8,19,21 220:22 221:11 227:12 232:5 236:19,22 237:2 238:16 244:10 247:19,20 248:9 250:3,8,9,11 254:7,8,9,10 257:21 258:19 259:2 260:18 264:18,22 269:9 271:22 272:2 277:9,11,13 280:14,14,18 284:10,10,12 288:18,19 290:14 290:15 292:8 296:1 297:19,20 302:2,4 304:14,15 304:16 308:1 310:4,5,15,15 312:6 313:19,20 313:21 314:3 318:12,15,18,19 319:1 322:5,7,8 322:10,22 323:1,2 327:14,16,17 331:15,16 332:11 332:12 335:3,18 335:20 336:1 341:13 345:10 346:5,5,6,9,10,11 350:1,2,5,7 354:12,18,20,21 355:15,21 356:11 361:21 362:4,5 368:10 379:6,6	380:5 389:20 391:21 392:3,3 393:12 394:7 395:2 399:7 thankfully 214:4 thanks 67:22 76:9 82:12 83:4,9 117:11 118:7 122:12,19 123:18 123:22 175:16,17 175:18,20 194:22 195:1 196:2,3,4 216:16 240:18 250:2 272:1 280:16 335:2 350:3 363:21 theoretical 153:7 theoretically 270:7 theory 337:16 they'd 172:17 thicker 261:20 thickness 261:2,3,3 262:7,12 271:19 thicknesses 271:4 thin 270:22 271:6 thing 11:14 35:7 38:17 41:21 56:4 62:20 64:2 66:9 71:8,11,13 72:2 97:21 98:13 100:2 114:9 122:2,11 140:22 142:13,17 149:15 172:21 177:22 187:16,20 188:18 215:8 218:1 227:22 231:20 236:2 261:13 278:12 285:18 321:10 333:17 388:13 391:6,20 394:16 things 6:21 7:12 10:18 19:3 20:10 27:2,4 39:19 41:7 42:18 46:10,12,15 49:6 50:1 63:7,20 71:22 85:10 95:4	95:20 97:12 99:16 101:21 107:7,8,12 114:5 126:15 131:13 133:22 137:14 140:15 146:11 153:9 162:7 165:11 169:16 177:9 178:8 229:19 231:13 235:13 242:3 259:6 281:4 290:2,9 301:7 302:11 303:8 307:22 333:7 339:16 345:1 353:13,21 360:13 373:5 think 9:20 20:6 25:20 26:8 27:14 29:12 34:21 35:5 35:7 37:2,11 38:6 43:15 45:3,12 49:11 50:3,10 51:15 56:17 57:20 61:9 62:18 75:20 75:21 79:17 93:10 97:1,7 101:15 105:2 112:2 113:12,13,17 114:19,21 116:6 122:2,5,8,11 132:2 133:1 138:7 140:20 142:14,17 142:19 143:9,13 144:16 158:14 160:2 166:3 176:9 176:11,15 177:16 177:20,20 179:6,9 179:19 181:6,21 184:7 191:1,6,18 191:21,22 192:4 193:7,19,20 194:4 194:7,9,10 198:15 203:14 206:9 208:21 214:19 217:8 219:10 224:16 225:16	228:10 244:1 248:15 253:7,22 254:3,5 259:3,8 259:10,12,13,15 260:6,15 266:20 266:22 268:7,8,18 269:5 271:18 277:7 278:16,22 279:15,16 293:8 294:19 300:11 301:6,8 303:7,13 303:16 304:7 307:20 342:4,7 346:18 347:18 359:3 362:4,9 368:21 369:10,21 370:10 371:1,4 373:21 374:14 386:8 390:12,22 391:2,4,18 392:9 393:2,6 397:5,10 397:20 thinking 56:6 110:22 130:10 133:16 137:2 142:2 248:22 249:1,3 390:5 thinner 262:11 thinning 154:14 156:6,7 157:17 158:5 third 33:13 40:7 74:6 84:12 166:5 219:15 234:14,18 286:4 321:8 Thirty-three 167:8 thorough 41:7 223:3 288:8 thoroughly 306:5 thought 7:12 8:21 21:16 26:22 79:22 114:14 126:11 172:11 190:9 208:3 236:9 292:15 294:9 299:10 345:20 379:7,12	thoughtful 51:6 thoughts 6:9 59:22 84:5 253:1 361:4 thousand 58:20 154:5 thousands 48:14 105:14 165:20 330:3 threads 182:16 threat 51:4,12 63:12 328:8 threatens 316:9 three 33:5 47:6 67:5,16 69:4 70:3 72:5 74:6 79:13 84:6 104:22 124:19,20 146:11 158:1 203:1 233:10 241:22 316:4 323:16,22 333:5 347:14 351:5 360:17 378:10 385:5 threshold 16:5 17:6 17:14 33:4 34:1 35:15 36:4,6 38:8 43:1 45:6,8 127:13 233:17 297:7 thresholds 58:12 58:14 64:14 thrip 106:20 331:19 335:9 thrips 105:18 106:11,17,19 107:4 328:20 332:15 333:13,13 thrive 332:15 throw 28:10 81:17 120:8 143:14 Thursday 142:4 239:13,15 250:5 378:16,19 ticks 83:19 Tier 180:5 ties 212:10 tighten 37:16
--	--	---	---	--

tightly 215:10	369:22 370:8	ton 58:7 207:13	traces 252:4	treat 173:20
till 142:4 294:6	375:12 383:11	tons 187:2 353:7	track 192:6 304:2	treated 131:4
tillage 246:22	times 56:19 58:12	tool 32:17 33:14	tracking 149:20	152:12,15,21
256:7 317:11	153:6 154:22	84:13 85:3 188:12	tractors 353:12	181:5 188:1 191:2
tilled 145:7,19	188:5 211:18	200:16 251:3	Tracy 1:17 362:4	205:3 326:10
tilling 145:14 252:3	215:18 312:18	266:7 298:18	374:14	treating 78:5 154:8
263:13	321:12 336:4	370:9	trade 16:2,3 39:13	159:16
Tilth 12:18 147:18	342:9	toolbox 113:17	232:14	treatment 158:4,22
time 5:1 7:6 31:4	timing 154:12	277:6	traditional 255:22	treatments 158:7
38:15,21 41:3	171:10 297:7	tools 32:13 113:16	396:14	329:2
46:1 55:8 66:5	318:14	173:15 187:18	trailing 83:6	tree 3:14 146:12
86:3 89:1,20	TiO₂ 244:16	191:9 199:4 277:5	trained 63:19	147:14,20 148:21
90:19 94:11,15	tips 302:11	298:22 300:16	344:5	149:4,18 161:19
96:5,9 97:4	titanium 139:2,3	top 156:15 161:15	training 18:20 19:2	166:2 170:13,15
100:16 101:6	276:1,13,15 277:3	355:13 389:17	trait 40:9 47:19	370:5
103:10,15,21	287:11	topic 53:4 83:17	traits 163:10	trees 6:21 151:2,4
104:3,5 112:15	title 189:14,14	95:21 305:5	209:18 218:2	160:18,19 161:4
113:3,7,18 116:15	374:2	336:20 385:1	transcript 103:19	tree-producing
117:1,5 124:3	today 32:12 36:12	389:8,11 392:15	transfer 168:11	160:13
130:20 141:19	39:12 46:16 47:1	394:2 397:13	180:11,14	trend 302:9
144:15 155:4	55:9 66:5,20	topics 34:15,17	transferred 163:16	trespass 5:7 56:12
157:13 159:15	75:19 88:17 89:4	383:12,15,18	transferring	trial 207:15
163:5 168:1 169:5	160:18 161:2	387:3,9,16 388:21	170:14	trials 40:8 158:10
171:1 173:7 174:2	176:6 197:2,7	389:5,13,14	transgene 48:3,4	158:11,12 203:2
176:5 177:8 183:1	200:3,21 202:10	391:10 393:5	transgenic 17:4	210:6 218:6
183:5 184:16	208:6 214:5,12	total 18:3 54:15	46:11,19,20 47:5	228:21 229:11,12
185:13 188:20	220:11 232:18	68:15 69:19	47:21,21 48:7	trickle-down 144:2
194:19,20 200:3	239:14 243:7,9,10	124:13,17 200:10	transgenics 43:7	tried 7:15 71:18
210:18 214:14	254:22 256:15,21	202:1	46:17 47:3	167:4,6 318:16
215:17 216:9	257:15,19 260:3	totally 136:12	transition 157:9	328:20 345:1
221:2 225:16	262:2 266:1,17	167:20 278:15	194:16	346:21 348:7
226:20 233:3,8,15	281:12 284:17	289:2,11 391:13	transitional 191:12	trip 184:22 196:3
236:20 239:10	290:11 299:13,16	touch 211:7	transparency	223:18
241:19 255:19	310:11 312:1	towns 346:20	101:8,12 192:4	tropical 333:16
256:4 257:3,17	316:3 318:4 328:5	toxic 92:18 107:3	298:13 380:3,13	343:1
261:8 271:12	337:6,11 355:1	156:7 283:2	transparent 52:9	trouble 117:1
275:20 277:9	399:6	324:15 338:11	193:21	189:5 190:3 191:9
285:2,11 296:22	today's 205:10	toxicity 255:19	transpire 339:20	TRs 90:18,18
297:18 299:3,10	told 46:3 242:18	282:14 338:8	transplanters	true 99:7,15 219:6
302:2,3 306:9	tolerance 17:7,14	toxicological 87:9	227:16	263:2 326:19
307:1 311:15	151:11 304:3	TR 68:9 70:5,7	transplanting	361:9
327:15 328:19	341:7	73:11,13,19,21	228:3	truly 77:17 97:9
331:7,8 333:6,22	Tom 30:15	74:20 75:7,7	transplants 230:10	177:19 188:7
334:1,14,20,20	tomatoes 226:14	91:15,19 92:2	transportation	191:13 193:1
337:15 339:19,20	231:17 353:21	107:20 139:1,9	29:8	268:11 305:22
341:11 343:18	tomorrow 250:7	140:6 291:19	trash 347:10	324:13 326:4
349:4,14 360:19	347:17 399:7	308:6	traveled 346:15	369:5 370:7

trunk 344:14	twelve 154:5 378:10	ultimate 173:12	285:20 326:8	untreated 203:5 215:17
trust 185:20	Twenty 201:19	ultimately 24:5 64:5	understood 47:8 291:13 386:17	unwanted 59:7 205:13
truth 144:14 307:13	Twenty-seven 365:6	umbrella 304:10	undertaken 32:6	unwarranted 173:4
truthfully 71:5	twice 342:1	unacceptable 15:9 17:5	underway 156:11 160:6	upcoming 359:15
try 4:16 14:16 20:11 72:1 95:20 131:21 152:9 158:18 163:19 166:3 170:16 172:18 184:1 211:7 221:22 222:1 223:3 228:19 267:11 279:21 322:16 333:18 346:17 347:19 355:2	two 33:9 34:7 38:19 47:6,13 67:11 69:21 70:2 72:16 72:19 77:4 85:22 126:7,15 130:13 131:13 132:9 152:18 154:5 170:21 175:14 234:7 241:11,19 247:14 285:8 296:17 297:5 311:6 313:3 323:19 329:5 338:7 342:9,20 344:13 358:9 367:1 375:16 377:1 378:15,18 383:9 384:11,22 388:16	unanimous 89:13 119:13 315:11	underwrites 178:7	update 3:14 31:4 122:21 146:12 148:4 200:18 221:17
trying 6:3 8:12 9:3 18:15 38:13,14 49:7 92:16 96:1 107:13 116:11 131:12 143:8 156:9 164:11 173:14 178:9 181:14,16 193:16 193:21 242:22 243:17 266:9 277:16 292:2 345:15 349:12	type 16:20 46:15 156:10 201:8 218:14 231:2 259:6 261:5,18 262:15 268:6 293:5 390:4	unanswered 144:16	undue 27:3	updated 91:8
tucked 111:3	types 34:20 42:5 205:5 208:3 237:8 237:14 238:9 244:8,12 262:5,6 266:10 287:6 289:16 295:15 307:20	unavailable 327:7	unfair 187:11 188:15	upsets 284:1
TUCKER 2:20	typically 153:3 385:13	unaware 343:9	unfortunate 19:20	upstate 270:16
TUESDAY 1:7	turned 224:14 225:2,5 277:4 334:7,20	unbiased 72:1	unfortunately 59:9 80:9 165:4 172:4 284:9 337:6 343:2	up-front 99:11
tunnel 270:16		uncertainty 55:6	Unger 21:9,10,11 25:13 26:8 27:16 28:14 29:11	urge 192:18 265:5 312:21 327:12 349:21 387:8,13 388:19
tunnels 226:7 229:19		unclear 71:17 77:14 144:15 276:12	uniformity 116:11 242:21	urging 354:8
turn 4:6 65:14 76:7 121:5 123:22 152:8 221:9 223:13 225:11 371:12 375:15		undergo 276:16	unintended 41:19	Urvashi 3:17 146:15 174:18 175:6 193:3,6 194:18
turnaround 161:6		undermining 13:19 15:7 184:7	unintentionally 13:21	USA 256:12
turned 224:14 225:2,5		understand 33:10 35:15 36:3 44:16 45:4 46:5 81:5,17 96:1 98:10 163:22 167:21 177:19 190:7 219:7 233:2 233:15 237:22 249:22 267:10 276:15 280:3 285:7 288:5 289:18,19 290:3,4 290:16 291:12 293:10,12 297:6,9 299:5 349:11 393:9	Union 3:16 146:16 169:20 174:18	usage 200:8 202:7 341:21,21
turning 225:21		understanding 18:1 52:11,18 55:21 101:11 109:21 156:4 190:14 240:21 248:3,6 288:6 291:9 296:19 308:21 374:7 392:21	unique 7:16 60:22 206:4	USDA 9:2 10:12,21 12:19 17:19 18:6 18:14,16 24:22 34:14,15 41:8 52:8 56:11 57:12 63:8,9 64:2 109:12 153:19 162:13 211:3 219:14 240:6 250:15 273:7 384:19
turns 62:13 105:9 165:2		understands	University 13:10	USDA's 59:2 208:15 214:15 324:6 326:21
tweaked 97:3	UL 337:22		University's 147:10	use 11:12 13:21 16:10 19:6 21:3 24:12 41:4 59:16 75:13 76:15 82:18 89:15 90:2,20 108:22 109:6 111:2,6 114:1
			unlimited 230:17	
			unmarketable 105:20	
			unnecessary 284:1	
			unprecedented 31:7	
			unpublished 164:9	
			unsustainable 329:21	
			untenable 27:9	

117:16,21 118:14	393:7	Values 57:3	verifying 132:11	121:9
118:15,19 121:2	useful 52:10 94:17	value-added 185:4	278:6 285:16,22	voluntary 100:9
123:5 124:6	187:18 200:16	variable 113:7	Vermont 64:20	103:5 110:1 360:7
129:14 132:12	201:3 203:14	varietal 216:20	250:13,14,15	vote 68:3 71:3 79:9
140:8 145:14	273:8 298:18	varieties 24:15	251:1 252:16	85:20,20 119:9,13
151:6,7,9 152:1,8	300:15 341:18	26:16 64:3 151:12	268:14 346:16	119:15 142:4
152:11,19,22	342:3 389:6	151:22 163:17	348:16,17,18,19	314:10 318:4
153:1,3,7,16	users 18:10 113:4,8	164:11 180:16	versed 230:7	322:16,17 327:13
154:2,12,21 157:9	115:11	188:6 192:2 203:3	version 45:15	331:2 356:14,15
158:9,18,21	user-friendly	203:5,22 204:4	272:18 388:11	356:20 357:14
159:21 167:10	212:12	207:4 213:7 217:6	393:15	358:18 359:6
169:3 170:2,15	uses 90:4 103:6	217:10 218:9,13	versus 23:7 80:12	366:1,18 369:1,20
172:22 173:14	106:16 187:2	218:15,19 219:2	118:21 126:14	371:10,12,16
176:8 179:10	229:15 268:20	262:5	132:11 156:4	372:11,12,14,22
180:3,7,22 181:15	299:22 316:17	variety 8:6 23:13	161:8 205:3	374:13 376:4
186:22 187:7,10	326:16 360:13	62:16 162:16	216:21 231:2	377:15
188:12,16 191:19	usually 47:20	165:5 203:2	239:20 240:22	voted 136:7 174:10
201:21 202:13,16	107:18	207:15 216:21,22	242:10 259:5	394:1,2
203:17 204:9	utilize 122:7	217:3 218:2 307:8	290:21	votes 3:20,23 355:3
209:6 211:13	370:10	315:14	vertebrate 317:12	355:8 356:17
213:22 215:18	utilized 117:19	various 114:22	Veterans 387:11	359:15 363:5
222:21,22 224:3,5	utilizing 32:13	119:10 171:4,5	viability 94:15	366:17 368:6
224:10,22 225:3,9	142:18 165:9,20	229:10,12 286:5,6	257:12 385:6	372:10,14 375:9
226:7 227:4	U.S 152:13 196:19	309:6 317:3	viable 119:6 151:13	376:20 378:10
228:14 229:7,18	199:7 200:15	vary 271:19 334:20	182:20 370:4	387:6 399:3
232:17 233:12	201:7 232:12	vegetable 121:9	view 259:15 278:17	voting 97:11
245:2 251:11	241:15 243:4,9	202:5,8 204:5	386:19	120:16 174:13
252:20 254:19	315:3,13,16	223:21 250:18	vigorous 99:5	273:2 355:6 359:7
256:12 257:10	316:19,22 322:3	304:22 348:17	Vilsack 30:15	362:9 367:11
262:12 263:19	330:9	vegetables 84:1	51:10	373:1,2,10 374:8
266:15,17 267:22	U.S.A 165:6	201:11 202:1	violate 317:18	398:9
269:1 270:17		208:17	violates 317:13	
280:2,9 281:19	V	vein 119:22	viral 144:3	W
283:14 286:10,13	Valley 16:18 19:2	vendor 212:17	virtually 64:18	W 310:20
286:19 295:4,4,9	21:13 190:16	verbal 389:3	virtues 352:22	wait 28:11,11 70:16
301:5 307:7	223:15	verbally 388:13	visible 252:4	138:17 141:8
317:21 318:4	Valley/CROPP	verge 342:15	vision 196:18	173:1 295:21
325:8 329:20	9:14 12:9	verification 32:1	visit 352:5	waiting 358:6
330:21 331:14	valuable 352:16	272:19	visiting 60:18	Walker 1:22 73:11
333:21 335:5	384:21	verified 275:7,12	visual 275:8	345:12 357:10
336:5,9,17 343:9	value 16:4 61:6	verify 13:4 130:4	voice 58:22 83:5	362:21 366:10
343:13 345:22	127:13 163:7	131:20 138:14	315:10,12	367:20 372:2
347:22 348:8	176:4 182:14	139:13 140:11	voiced 180:1	374:20 376:9
349:11,17,20	185:11,19 189:19	274:13 275:10	volume 14:8 71:19	377:20 381:17
354:10 359:17,17	194:12 206:21	278:3 286:6	108:7 168:2	392:3 396:1
359:22,22 360:22	207:11 316:16	296:16 297:5,6,13	329:16	398:12
361:10,11 392:11	370:11 398:1	301:11 305:22	volumes 31:16	walls 286:22

292:22	161:1 200:6 215:4	181:12 184:5	375:5 381:19	143:7,8 145:16
Walt 310:19	217:12 221:14	193:10 224:19	went 65:10,10	146:1,10 151:1,5
Walter 304:18	229:4 241:4	236:12,14 237:10	88:12 190:2	154:8 156:8 158:8
310:16	291:12 339:14	238:3 243:21	219:15 221:5,5	162:7 168:7 169:5
want 5:4 20:12	340:4 350:7	244:5 269:6,22	322:19,19 332:7	171:1 174:7,17
21:15 26:9 27:3,6	wanting 112:8	278:13 294:3	345:17 399:10	177:4,12,12,17
30:1 33:2 34:7	212:19	340:22 341:1	weren't 81:8	178:8 179:9 183:7
39:14 49:14 51:20	warm 251:4 263:7	343:15,16 350:15	129:18 164:12	183:9 188:3 192:9
54:4 60:17 66:10	305:19	355:2,14 373:22	173:3 228:16	197:19 198:17
71:16 77:21 79:18	warmer 231:15	391:7,9	West 171:8 172:12	199:10 214:5
80:22 81:17 98:1	warming 263:8	ways 20:17 25:16	265:12	221:2 222:19
108:13 112:7	351:6	26:1 101:17,19	western 158:3	223:17,20 225:2
114:6,16,20	warrant 159:20	161:1 173:1	we'll 4:4 6:11,18	226:9 230:11
116:18 121:16,18	warranted 53:6	183:18 193:15	12:4,9 14:17	235:17,18 236:3,3
130:7 132:1	Washington 91:7	265:19 278:6	15:20 21:4 27:21	236:4,4 237:20
135:19 138:19	147:9,15,21 154:6	304:12	39:3 60:6,6 65:6	242:17,22 243:16
143:2,14 144:6,10	163:9 166:2,17	wealth 168:10	65:22 66:5 73:4	250:21 261:19
144:22 145:22	169:18 171:22	weather 152:6	75:18 76:3,4,7	262:11 264:13
149:15 150:5,6	255:11	173:5,13 332:14	82:7 86:17 93:11	268:7 269:4
168:4 169:11	wasn't 80:8 114:13	webinar 165:13,15	94:7 95:2,4 101:5	278:13 286:19
177:22 185:3	120:18 165:1,1	webinars 165:17	102:16 115:22	287:3,9 295:11
186:18 188:18	190:9 231:7	website 67:17 83:2	117:9 122:15	296:16 297:13
190:13,14 192:7	392:18 396:21,22	118:5 123:13	146:15 169:14	305:14 322:11
200:10 202:9	waste 122:5 288:4	169:13 175:8	176:14 200:12	337:8 340:5 343:3
205:20 207:19	291:7	213:14 214:22	221:8 222:13	345:19 348:22
209:17 215:8	watchdog 362:5	weed 251:5 252:1	294:6 305:4	349:9 373:1,2,10
216:10 221:16	watching 230:8	257:6 272:17	318:22 322:17	374:8 379:5
223:8 224:6,10	water 76:21 78:15	386:6	351:7 356:19	392:20 394:15
226:6 234:18	78:16 124:11	weeds 305:20 351:3	358:4 359:7 361:6	we've 27:20 45:14
239:10 244:2	226:10 230:3,9,17	week 230:12	we're 6:9,10 14:16	48:9,11,14 65:19
248:14 264:7	235:10 253:5	334:14,16,18,22	15:14 18:17 20:13	65:21 66:2 87:10
265:19 272:16	257:6 308:15	weekly 352:5	20:15 21:1,4,7	90:12 94:3 96:6
285:1 287:15	339:12 340:1	weeks 130:22	22:18 36:9,9,10	134:1 137:21
290:3,4,7 292:16	342:20 345:20	223:22 228:4	36:10 37:15,17	146:13 149:20
293:17 308:8	351:4 363:10,18	341:6 343:18,19	38:10,13,14,18	152:2 153:12
350:10 356:12	365:12 380:20	361:20	40:18 46:3 53:9	160:7,16 166:5,9
359:4,8,11 361:11	waterways 339:9	weigh 59:14 245:8	54:1 56:5 61:3,13	168:11 170:8
370:22 382:20	341:2 346:3	weighed 222:4	61:14 62:8,12	176:2 179:14,20
384:2,3 388:17	way 6:8 16:2 32:15	weird 6:15	65:12 66:6 86:19	181:8 190:19
390:14 392:4,12	36:2 47:22 52:2	welcome 147:2,22	88:16 89:3,10	192:11 194:1
393:3 396:19	52:15 55:18 56:15	216:12 221:11	92:16 97:16 98:8	198:8 211:10
398:3,3,4	57:15 62:4 75:18	254:12 346:6	98:13 104:4 109:3	212:18 214:4
wanted 4:21 5:18	80:20 86:14 100:3	welfare 180:21	111:13 115:14	223:22 224:2
47:7 56:4 79:20	102:3 122:6 127:7	Wenatchee 147:21	116:3 122:1	227:10 245:6
128:10,17,22	133:12 136:13	153:19	123:20 130:7	266:16 267:11
144:19 148:22	142:18 143:3	Wendy 1:19 302:6	137:2,17,18	269:4 280:9
149:17 160:17	146:3 165:21	367:12 371:9	139:10 142:21	303:14 344:22

348:1,7 359:1 366:17 whatsoever 271:9 wheat 208:17 wheel 349:13 wholesale 351:17 wholly 327:8 wide 23:13 24:14 175:13 307:8 315:14 widely 387:3 widespread 233:7 wild 163:11 Williams 281:2 willing 12:14 43:16 97:9 99:21 234:12 Wilson 314:1 318:22 319:2,3 322:10 win 183:20 window 140:18 332:21 winter 226:15 win-win 28:21 wish 194:19 355:22 357:17 360:4,6 375:11 Wishing 350:16 witnesses 66:5,6 Wolf 94:5,16 284:12 297:20,22 298:4,4 302:14 304:16 woman 175:16 won 347:7 wonder 35:20 145:17 183:12 wonderful 24:22 212:5 wondering 25:11 49:3 115:6 193:13 218:10 237:10 248:20 278:12 390:4,10 word 87:4 100:17 145:11 259:11,14 269:22 281:9	290:17 391:5 wording 345:22 395:8 words 15:14 17:6 17:13 108:18 110:20 252:22 260:5 304:4 332:7 work 5:15,17 6:12 10:15,16 12:5,5 14:13 19:10 20:21 20:22 21:16 22:13 22:22 23:5,10 27:21,22 40:10 55:16 60:4 75:13 78:19 91:4 94:12 95:12,12 106:8 112:12 121:13 135:11,12,14 149:1 154:16 155:19 156:2,13 158:15 159:7 162:22 173:8 191:7 196:14 197:8 210:6 213:19 216:17 223:9 228:1 253:2 253:14 265:10 266:3,8,12,13,13 267:22 269:3 271:6 289:2 298:2 300:19 301:13 305:17 314:6 319:3 328:3 352:14 353:12 355:14 359:19 360:14 378:20 392:4 workable 30:6 worked 86:18 147:11 195:11 224:8 225:13 267:11 worker 342:5 344:18 346:1 workers 227:16 282:22 317:5 335:21 342:19	working 3:14 5:11 10:19 19:9 20:15 20:19 23:19 25:4 27:21 33:22 55:17 56:11 69:5 70:16 88:4,10,21 89:11 91:3,4,6 92:8,8 112:14 146:13 160:10 170:11 172:3 197:9 199:2 208:11 210:13,18 210:19 211:8,9,10 211:10,15,20 213:11,20 214:10 318:9 321:21 352:17 workings 226:22 works 92:12 114:3 176:1 196:10 266:18 world 5:6,20,21,22 15:2 33:12 35:1 44:21 45:18 80:22 103:8 121:17 143:8 144:17 158:13 180:2 234:4,6 255:13 267:4 268:8 313:1 314:21 315:5 319:15 333:13,16 341:19 worldwide 299:14 319:10 320:10 322:3 worms 385:9 worse 186:4 334:3 worsens 59:10 worst 334:15,21 worth 23:21 189:13 209:3 285:11 297:2 347:15 348:12 wouldn't 110:17 134:8 238:12 293:6 332:9 wrap 209:5 214:19 255:2	wrapping 226:5 write 7:7,20 141:11 144:21 279:19 writer 195:12 writing 355:20 361:18 written 3:3,6,22 22:9 44:1,3,5 53:14 55:3 57:22 67:19 214:9 216:5 220:16,16 252:17 279:13,20 284:21 327:2 379:9,14 380:22 381:6 wrong 100:17 109:22 wrote 105:1 WSDA 91:7 305:3 <hr/> Y <hr/> Yea 375:2 year 20:5 51:9 53:16 54:17 58:20 88:6 90:17 97:2 107:18 110:8 116:21 120:20 121:5 140:18 148:9 150:3,7,19 152:14 154:2,6,7 154:22 162:17 163:4 165:12 166:5 167:11,13 169:22 173:16 197:6 199:18 210:12 223:22 224:3 227:8 230:2 247:1 252:4,10 256:13,14 262:19 268:17 275:13 329:18 334:8,11 334:13 335:1 341:9 342:1,9 351:22 353:20 382:6 383:1 years 48:14 52:5 69:6 73:6 86:11 88:6 94:3 104:2	108:4 110:9 112:13 116:21 125:15 129:15 136:2 140:2 141:8 149:21 156:15 157:3 160:19 162:14 182:2 192:11 200:19 202:10,13,18 224:1,2 227:10 253:3 254:16,18 255:3 260:1,11,14 261:14 262:17,18 266:21 273:14 274:11,12 281:3 298:1,6,21 299:13 302:20 311:15 328:6,18 333:5 340:18 345:17 351:19 year-round 351:20 yellow 158:3 387:7 390:17 yeses 357:15 375:9 376:20 378:10 yesterday 252:8,18 266:11,17 388:12 yield 69:17 yields 257:7 York 64:20 162:1 223:16 270:16 349:15 young 175:14 347:4 348:21 <hr/> Z <hr/> Zea 1:21 4:5 23:15 39:19 40:20 42:2 52:15 56:8 60:5 70:22 76:6 77:11 80:4 86:14 88:6 93:14 98:2 101:5 102:16 108:10,12 112:5 115:6 123:21 124:1 144:9 145:1 193:19 228:6
---	---	--	---	---

237:1 239:6	199:14 201:16	1993 346:20 347:7	152:11 174:10	221 3:19
269:19 277:12	202:17 268:8	1994 103:13 104:4	211:19 329:15	23 205:6
290:14 309:19	102 3:11	1996 77:8 208:11	2012 1:8 67:15	24 82:13
356:10 358:3	11 1:11 69:20	347:7	110:11 117:13	25 146:14,16,19
360:5 361:3,5	124:16 141:15,18	1999 175:7	122:21 153:14	200:11 224:1
362:10 381:22	146:10 149:22	<hr/>	154:1 156:14	227:10
382:6 391:2	150:3 384:6 390:2	2	157:7 177:12	25(b) 90:5 93:19
393:13 394:10	110 256:13	<hr/>	364:22	94:6 102:7,10,13
396:5	114 124:15	2 14:5 96:11 112:13	2013 90:16 91:12	250 165:14
Zealand 164:20	117 3:12	119:13,15 125:12	95:4 174:13 382:6	26 7:2,9 68:16,17
Zea's 75:16	12 66:2 150:3	125:14 129:15	2014 174:11	26th 122:22
zero 69:20 124:19	166:12 236:11	136:2 140:17	2015 112:16	27 117:13 150:3
164:15 304:3	357:15	228:3 262:17,17	2016 108:3 112:3	365:2,2,13,21
368:7 375:9	12-week 241:19	273:13 274:11,12	157:7 168:10	28 152:17
376:21 399:3	12:19 221:5	298:1 302:20	333:21	<hr/>
zucchini 231:17	122 3:13	306:6 317:16	2017 69:10 95:7	3
<hr/>	126 93:1 94:19	327:6 346:12	363:11,19 364:1,3	3 14:5 73:5 87:14
\$	13 65:21 112:13	2,000 154:4 330:12	364:4,21 365:2,14	95:8 96:11 108:4
\$30 209:3	132 250:18	2-month 296:22	365:21	116:21 141:8
\$9 208:13	13432 125:11	2-year 129:10	203(c)(1) 317:15	202:10,13,18
<hr/>	14 94:4 346:20	141:5 161:5	205.105 295:3	224:4 228:3 234:1
0	148 3:14	20 122:21 201:14	205.206 140:20	305:8,11 310:7
0.1 17:8	14995 125:12	201:17 202:16	370:18	327:8 328:6
0.5 262:12	15 52:5 113:21	260:11,14 266:21	205.206(c)(6)	334:19 341:6
06 177:7	146:20 166:12	298:21 299:13	273:17	351:1 357:14
<hr/>	255:3 306:6	302:19 351:16,19	205.601 76:14	3(1) 245:21
1	322:12 328:18	20-some 169:19	82:18 89:6 117:15	3,000 15:15 42:7
1 10:3 17:17 96:10	329:1 368:6	200,000 153:6	123:4 124:6	352:4
108:3 125:7 180:5	376:20 399:3	2000 178:15	377:11	3,000-seed 12:11
237:3 244:17,21	150 232:15	2001 152:11 236:15	205.601(b) 123:8	22:16
245:3 262:19	150th 219:13	2002 298:20	205.601(b)(2)	3-year 332:21
299:13 327:4	16 1:8 93:2	2004 67:8	125:4	333:1
1st 112:3	163 124:15,15	2005 117:22 175:11	205.601(e) 83:16	3-4 262:13
1,000 261:15	17 68:17 93:16	177:7 236:12	368:12,18	3.5 377:5,13
1-year 112:17	149:10 152:15	2006 77:8 117:20	205.601(h) 67:2	3:29 322:19
1.4.1 242:15 243:3	254:16 260:1	118:3 119:9	356:4,10	3:44 322:20
246:7,17 247:15	17088 125:12	2007 70:10 338:6	205.601(j) 377:2	3:45 322:13
1:20 221:3	175 3:17	338:19	205.601(j)(3) 76:20	30 206:19 216:10
1:39 221:6	17556 125:15	2008 311:11 320:5	363:8 365:11	281:3 320:10
10 66:2 141:15,21	1770 347:11	2009 66:21 82:14	205.601(m) 69:4	351:16
152:14 162:14	180 241:20	311:14 321:9	321:19	34 152:16
166:11 200:13	196 3:18	340:13	205.601(3) 363:17	354 3:20
204:17 299:11	1970 280:22	2010 69:9,11 73:15	205.602 104:20	365 351:21
303:8 372:14	1975 147:12	149:22 199:14	108:2 330:17	378 3:22
10,000 42:7	1980 220:2	299:12 328:17	205.670 11:21	38 124:15 350:19
10,000-seed 15:10	1982 114:14 350:17	329:15	21 3:4 364:4,21	385 351:18
15:12	1987 256:15	2011 67:13 76:10	22 76:10 365:21	394 3:23
100 105:14 164:16		88:9 110:10		

4	6 18:17 91:10 119:15 130:11 149:22 181:5 226:13 234:1 334:19 6(d)(2) 245:22 6-0 119:13 60 201:11 203:7 255:21 601 90:1 602 341:19 603 89:6 90:1 6400 130:21 139:12 233:11,19,22 285:8,22 296:3,18 296:20 297:6,9 649 307:5 309:14 65 3:6 650 272:9 652 309:15 66 3:8 6:13 67 167:9 6866 128:4 69 202:7	9		
4 3:3 14:14 68:17 96:11 160:19 181:5 223:17 224:2 305:8,11 310:7 313:17 318:11 320:16 321:12 340:18 345:17 4(a) 87:11 4(b) 87:11 4.3 246:13 247:10 4.5 377:4,12 40 204:7,11 206:16 298:6 351:12 400 165:6 42 237:3 421 308:14 43 150:3 201:9 437 202:7 445 308:18 48 201:12 488 309:1	5	7		
5 65:22 68:18 69:6 73:5 104:1 141:21 160:19 163:3 192:11 221:2 372:14 5,000 330:12 5-year 95:6 5:30 399:10 50 309:17 350:15 351:17 50,000 153:5 503 242:10 52 223:22 545 250:16 57 105:13 208:11 592 309:4 595 309:8 5988 125:16 127:18 233:12 285:12 5998 296:18 297:3	6	8		
	7 6:15 8:20 66:21 166:12 254:18 363:8,17 365:10 366:18 7-acre 223:20 70 205:11 73 167:6 205:4 75,000 329:18 76 3:9 79 6:16			
	8 19:5 66:1 150:2 237:4 366:18 399:6 8:00 1:10 8:04 4:2 80 207:4 82 3:9 85 10:5 86 3:10 889/2008 245:22			

C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Meeting of the National
Organic Standards Board

Before: USDA

Date: 10-16-12

Place: Providence, Rhode Island

was duly recorded and accurately transcribed under
my direction; further, that said transcript is a
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UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURE MARKETING SERVICE (AMS)
NATIONAL ORGANIC PROGRAM (NOP)

+ + + + +

MEETING OF THE NATIONAL ORGANIC
STANDARDS BOARD (NOSB)

+ + + + +

WEDNESDAY

OCTOBER 17, 2012

+ + + + +

The National Organic Standards Board
convened at 8:00 a.m. at the Biltmore Hotel,
11 Dorrance Street, Providence, Rhode Island,
Barry Flamm, Chairperson, presiding.

MEMBERS PRESENT:

BARRY FLAMM, Chairperson
HAROLD AUSTIN
CARMELA BECK

COLEHOUR BONDERA
JOSEPH DICKSON
TRACY FAVRE
JAY FELDMAN
JOHN FOSTER
WENDY FULWIDER
NICHOLAS MARAVELL

JEAN RICHARDSON
ZEA SONNABEND
ROBERT STONE
JENNIFER TAYLOR
CALVIN WALKER

STAFF PRESENT:

MILES McEVOY, Deputy Administrator, National
Organic Program

MICHELLE ARSENAULT, Advisory Board Specialist

MELISSA BAILEY, Director, Standards Division,
National Organic Program

LISA BRINES, Standards Division, National
Organic Program

EMILY BROWN-ROSEN, Agricultural Marketing
Specialist

JENNIFER TUCKER, Associate Deputy
Administrator

A G E N D A

Handling Subcommittee4

Panel Presentations/Questions

Dr. Sue Anderson and Dr. Jatinder Bhatia. . . 22

Public Commenters100

Panel Questions238

Policy Development Subcommittee316

1 P-R-O-C-E-E-D-I-N-G-S

2 8:05 a.m.

3 CHAIRMAN FLAMM: Good morning
4 everyone. We're ready to go. The meeting is
5 in order. Board members, please take your
6 seat. This morning we start off with the
7 Handling Subcommittee. John Foster is chair.
8 John, I'll pass the gavel to you to conduct
9 this session.

10 MR. FOSTER: Thank you, Barry.
11 This is a virtual gavel, I assume. The
12 virtual gavel. That's right. You can hang
13 onto that. I'll be inventive. So welcome
14 back everybody. Thank you for coming back.

15 We've got several materials to,
16 all petition materials in one discussion
17 document to go over this morning. I believe
18 our standard protocol will be back in place,
19 with Lisa Brines presenting proposals and
20 summarizing presenting proposals.

21 We will then have, we'll have
22 representatives from the American Academy of

1 Pediatrics and the FDA, to be available to
2 respond to some member questions, which we
3 presented to them ahead of time.

4 We'll have some public comment.
5 We will break to modify proposals, if needed,
6 and then later after lunch, we'll be going
7 into votes. I anticipate we'll need to scoot
8 one or two materials to tomorrow, maybe more.
9 But hopefully, we can get through most of them
10 today. That would be my preference.

11 So I'm following Jay's lead on
12 being efficient and expeditious. We'll try
13 and move fairly quickly with -- so we have
14 one, two, three, seven, eight proposed
15 petition materials, and then one of the
16 discussion documents.

17 I'd like to proceed in order as
18 they're on the agenda, and if there's --
19 unless there's other things to clarify, we'll
20 just move forward on the first item after. I
21 asked members of the Board to take a look at
22 that list of materials, and if you have any

1 disclosures of interest you'd like to make at
2 this time on any of those materials, now would
3 be the time to do it.

4 (No response.)

5 MR. FOSTER: All right. I think
6 we're good. So Lisa, are you ready to roll?
7 Then take it away.

8 MS. BRINES: Good. Thanks, John.
9 First petition of the morning is ascorbyl
10 palmitate. This petition was received on
11 August 29th, 2011, and was submitted by the
12 International Formula Council.

13 The petition requests the
14 inclusion of ascorbyl palmitate to Section
15 205.605(b) of the National List, for use as an
16 antioxidant in infant formula. In support of
17 its review the Handling Subcommittee did
18 request the development of a new technical
19 report, and both the report and the petition
20 were made available on the NOP website in
21 advance of the opening of the public comment
22 period for this meeting.

1 Written public comment was
2 received on this substance, and a
3 representative for the petitioner is signed up
4 for in-person public comment later this
5 morning. Thank you.

6 MR. FOSTER: Thank you, Lisa.
7 Nick, I believe you were headmaster of this
8 material. Would you take it from here?

9 MR. MARAVELL: Thanks. First in
10 the morning? Boy, all right. I'm going to --
11 I don't have any slides for the audience, but
12 what I'd like to do is summarize briefly some
13 of the comments that we have received, and
14 just note that there, we have basically two
15 types of arguments, if you will, being made.

16 One is primarily coming from a
17 consumer perspective, that synthetics in
18 infant formula are not the most desirable
19 additive. On the other side of the comments,
20 and those are coming primarily from industry,
21 is that ascorbyl palmitate is a very useful
22 synthetic in infant formula, because it has

1 some unique characteristics.

2 One of them is that it is fat-
3 soluble, and it can serve as an antioxidant
4 and function as a preservative, to preserve
5 the essential oils that are added to infant
6 formula, and also that it is heat-tolerant,
7 such that during the manufacturing process it
8 maintains its abilities, whereas some other
9 antioxidants may not have that same
10 capability.

11 There was also some discussion
12 with regard to rosemary extract. The
13 petitioner was saying that rosemary extract
14 was an untested, unproven antioxidant and
15 preservative, and that it could have unknown
16 and harmful effects.

17 There were no citations for this,
18 but the committee did attempt to research it,
19 and there was nothing in the TR to
20 substantiate harmful effects in infant
21 formula. So while that claim is out there, it
22 is true that rosemary extract is not a long-

1 term tested addition to infant formula.

2 However, I think we noted that
3 with the case of ARA and DHA, it is -- in our
4 approval process it was permitted to be used
5 with those additives as well.

6 Ascorbyl palmitate is an approved
7 source of Vitamin C, and can be added for that
8 purpose, and I'd just like to make it clear
9 that that's not what we're voting on here.
10 We're voting on here as to whether ascorbyl
11 palmitate is indeed appropriate for its use as
12 an antioxidant and as a preservative.

13 There has been some discussion
14 that there is a distinction between an
15 antioxidant and a preservative. The
16 distinction would follow along the lines of an
17 antioxidant used during the manufacturing
18 process is indeed to establish the stability
19 and functionality of the formulation, whereas
20 a preservative would be sort of added to, and
21 I'm simplifying it here, would be added to
22 sort of extend the shelf life of the product.

1 Now in consulting with the TR, we
2 definitely found statements that there is no
3 use of ascorbyl palmitate in processed food
4 for nutrient value, and that without the use
5 of ascorbyl palmitate, it would definitely --
6 well the use of ascorbyl palmitate was to
7 prevent rancidity, and therefore extend the
8 shelf life of a product.

9 So we may further explore that
10 distinction between antioxidant and
11 preservative. However, the TR is rather clear
12 that it functions as a preservative, and
13 indeed most antioxidants are preservatives.
14 That's the nature of an antioxidant.

15 I'm not sure I need to go any
16 further. I'm going to see if there's anybody
17 else that has any further comments from the
18 committee on ascorbyl palmitate.

19 MR. FOSTER: If you could kind of
20 summarize the subcommittee's votes.

21 MR. MARAVELL: Summarize the vote?

22 MR. FOSTER: Yes.

1 MR. MARAVELL: Of the
2 subcommittee?

3 MR. FOSTER: Of the subcommittee,
4 yes.

5 MR. MARAVELL: The subcommittee,
6 on the motion to list ascorbyl palmitate,
7 voted unanimously. There was one absent, not
8 to list ascorbyl palmitate. So it was a
9 unanimous vote in that regard. Anything else
10 I may have left out, John? Anyone else on the
11 committee think that we should raise
12 additional issues?

13 MS. SONNABEND: Well, this is the
14 point where I'd like to ask questions of our
15 experts. Is that appropriate?

16 Chair?

17 MR. FOSTER: It's fine with me. I
18 wanted to kind of check with the program, if
19 it's preferable to do in one big block, or is
20 it preferable to do one-offs.

21 MS. BRINES: We're happy to go
22 along one by one, as you go through this. We

1 do need to introduce the speakers for the
2 courtesy of the audience, who doesn't know
3 their background as well. So we're prepared
4 to do that if this would be an appropriate
5 time. Thanks.

6 MR. FOSTER: Okay.

7 CHAIRMAN FLAMM: John, we decided
8 the procedures and agreed that the chair could
9 make that determination, if given the -- if
10 the chair knows what, who it is and whether
11 there's any, you know, Board dissent about
12 getting, make sure we get all points of view
13 and not biased to the questioning.

14 So but it's -- you can make that
15 call, but I think the Board ought to know just
16 who we're calling for.

17 MR. FOSTER: So in our
18 conversations we've had in the previous few
19 days, it sounds like beta carotene, we might
20 have some of the same kind of questions. Can
21 we get through beta carotene and then ask our
22 guests to speak on both at the same time?

1 MS. SONNABEND: As long as we go
2 back and discuss the previous one, if we need
3 to.

4 MR. FOSTER: Yes. Unless there's
5 an objection, let's go that way. All right,
6 let's go that way. Thank you, Nick. Was
7 there any other questions on, that we need to
8 get to on ascorbyl palmitate right now from
9 the Board?

10 (No response.)

11 MR. FOSTER: All right. Thank
12 you, Nick. Next, we'll do beta carotene.
13 Tracy, our point on that. Would you take the
14 pointer? I'm sorry, Lisa. I didn't see you.

15 MS. BRINES: Thanks, John. The
16 petition for beta carotene was received on
17 October 11th, 2011 and was submitted by the
18 International Formula Council. The petition
19 requests the inclusion of synthetic beta
20 carotene to Section 205.605(b) of the National
21 List as an ingredient in infant formula.

22 There is one other listing for

1 beta carotene on the National List, which is
2 on 205.606, as an agriculture ingredient.
3 That's the form of beta carotene extracted as
4 an extract color derived from carrots. So
5 it's distinct from this form that's being
6 petitioned.

7 In support of its review, there
8 was two technical reports available for the
9 substance. There's one that was prepared in
10 2011 in response for the petition for beta
11 carotene color, and in support of its review
12 for this petition, the Handling Subcommittee
13 had requested an updated or supplemental
14 technical review, which was developed.

15 Both of those two previous
16 technical reports for beta carotene, as well
17 as the petition, were available to the public
18 on the NOP website in advance of the opening
19 of the public comment period. And again, the
20 petitioner has signed up for in-person public
21 comment later this morning. Thanks.

22 MR. FOSTER: Thank you, Lisa.

1 Tracy.

2 MS. FAVRE: Thanks, Lisa. Thank
3 you, Nick, for sort of laying the same
4 groundwork. We had essentially the same
5 cluster of categories of comments for beta
6 carotene as we had for ascorbyl palmitate.
7 There were pretty passionate comments for
8 diametrically opposed positions for the
9 substance.

10 It is being petitioned as
11 synthetic beta carotene, and we had some
12 questions that we posed to some experts about
13 the requirement for synthetic, specifically in
14 use in infant formula, and hopefully we'll get
15 some more clarification on that this
16 afternoon.

17 The petition specifically talks
18 about synthetic beta carotene as a lipid
19 stabilizer in the formulas, and even though it
20 does have nutritional value as a provitamin,
21 it also is being petitioned for use as a
22 preservative.

1 As a result, after much discussion
2 back and forth and actually some, needing to
3 get some clarity around the fact that if we
4 declined to list it as petitioned, it still is
5 likely to be used as a vitamin source in
6 infant formula.

7 So and I'm sure that's probably
8 not clear. Some of the public commenters
9 specifically were concerned that we were going
10 to refuse the use of beta carotene or
11 specifically Vitamin A in infant formula, and
12 that's not likely to be the case, regardless
13 of where the vote comes on this today.

14 So in summary, we did vote as a
15 subcommittee to list it as synthetic, since it
16 was specifically petitioned for that, and
17 secondly on the listing motion, it was a
18 unanimous vote to decline to list.

19 But we have had some further
20 discussion, based on not only some of the
21 public comments, but also conversations among
22 the subcommittee, and we want to get some

1 clarity during the question and answer session
2 with the FDA and AAP experts that will speak
3 to us today.

4 MR. FOSTER: Thank you, Tracy, and
5 thank you for that good timing. Appreciate
6 that. Are there any other questions from the
7 Board before we ask our guests to come up?

8 All right. With that, Lisa, would
9 you introduce our guests?

10 MS. BRINES: Sure. Thanks, John.
11 Yes, in support of the Board's deliberation
12 this morning, we had invited two technical
13 experts in this subject area to be available
14 for questions from the Board that might come
15 up as a result of the deliberations, and we're
16 lucky to have two of them available here
17 today.

18 Our first invited speaker is Dr.
19 Jatinder Bhatia, who is the current chair of
20 the American Academy of Pediatrics Committee
21 on Nutrition. Dr. Bhatia is a graduate of the
22 Armed Forces Medical College of the University

1 of Pune, India.

2 He completed his pediatric
3 residency, including a year as chief resident,
4 at the Medical College of Georgia in Augusta,
5 followed by a joint fellowship in Neonatology
6 and Pediatric Nutrition at the University of
7 Iowa.

8 From there, he joined the faculty
9 of the University of Texas Medical Branch in
10 Galveston, in the Departments of Pediatrics
11 and Preventative Medicine and Community
12 Health. He also held a joint appointment at
13 the University's graduate school of biomedical
14 sciences.

15 In 1991, Dr. Bhatia returned to
16 the Medical College of Georgia as a professor
17 of Pediatrics. Three years later, he was
18 named Chief of the Division of Neonatology and
19 Program Director in Neonatal, Perinatal
20 Medicine Fellowship, and he is also a
21 professor in the Medical College of Georgia
22 School of Graduate Studies.

1 Dr. Bhatia's areas of research
2 include a wide variety of neonatal issues
3 including neonatal nutrition and total
4 parenteral nutrition. His research has been
5 supported by the National Institutes of
6 Health, industry and foundations. He's the
7 author of more than 100 articles, abstracts
8 and book chapters, and has edited two books
9 and he has made presentations of his work
10 nationally and internationally.

11 He's a member of a number of
12 different societies in terms of pediatric
13 research and nutrition. He's an active
14 reviewer for numerous journals and serves as
15 an associate editor for a number of journals
16 as well. So I thank him for making the trip
17 to meet with us today.

18 Our second invited speaker is Dr.
19 Sue Anderson. Since 1996, Dr. Anderson has
20 served as the team leader for Infant Formula
21 Regulation at the Center of Food Safety and
22 Applied Nutrition at the Food and Drug

1 Administration.

2 She also serves as the technical
3 expert for international issues in pediatric
4 nutrition for Codex Alimentarius committees.
5 Prior to joining FDA in 1996, for 18 years she
6 worked at the Life Sciences Research Office of
7 the Federation of American Societies for
8 Experimental Biology in Bethesda, Maryland.

9 During her tenure with the Life
10 Sciences Research Office, she worked with the
11 Select Committee on GRAS Substances, and the
12 review of health aspects of food ingredients,
13 and she directed studies by expert panels for
14 the issues related to nutrition, food safety
15 and diet health relationships.

16 Dr. Anderson has a Bachelor of
17 Science degree in Food and Nutrition from the
18 University of Illinois, a Master's degree in
19 Food Science from Auburn University, and a
20 doctorate in Human Nutrition from Purdue
21 University. I thank Dr. Anderson for being
22 available for questions today. Thanks.

1 MR. FOSTER: Thank you, Lisa. So
2 let me just remind Board members we, as a
3 group in the Handling Subcommittee, we had
4 generated a number of questions beforehand,
5 and came to pretty good agreement that that
6 was a good encapsulation of a number of the
7 questions that we wanted to ask our guests
8 today.

9 So let's start with those. I'd
10 like to also, out of kind of respect for the
11 petitioners and the audience, as well as
12 keeping track of our own time, let's make sure
13 we're targeting these questions on the
14 petition materials at the moment.

15 This is why we have the guests
16 here, so we want to kind of focus on that as
17 much as we can. Every once in a while, I'll
18 be reminding everyone that we have a break at
19 ten, and we need to get through all of the
20 materials. At least at this time, we need to
21 sort through all of them in a relatively short
22 time.

1 So keep it focused, and I'll try
2 my best to remind us all of that. So with
3 that, could we have our guests, Zea? I think
4 we want to move into questions around ascorbyl
5 palmitate and beta carotene. Doctors, could
6 you come on up to the podium?

7 DR. ANDERSON: Good morning.

8 MS. SONNABEND: Good morning.

9 MR. FOSTER: Zea?

10 MS. SONNABEND: So as we're
11 considering these two compounds, which have a
12 number of similarities and some differences,
13 we'd like it if you could just clarify for the
14 Board the distinction between what is referred
15 to as an antioxidant and a preservative, and
16 then how people that talk about synergistic
17 effects of antioxidant, and if you could just
18 talk about that, how the different ones would
19 be synergistic?

20 DR. ANDERSON: Okay. Well,
21 preservatives can be a broad spectrum of
22 compounds. They can be added. Antioxidants

1 would be a subcategory. Other preservatives
2 are added to retard spoilage in bread, for
3 example. But the antioxidants are a class of
4 compounds that have preservative products by
5 acting as antioxidants.

6 With regard to the synergistic
7 effect of antioxidants, the role of
8 antioxidants in food depends on the
9 characteristic of the food, the characteristic
10 of the antioxidants that are used, and the
11 storage conditions of the foods, the length of
12 time it needs to be preserved, and all of that
13 is a very complicated chemical process.

14 There's a huge literature on the
15 effects of mixtures of antioxidants. Specific
16 antioxidants can have multiple roles in
17 different food matrices, and they can act
18 differently in different food matrices.

19 The mechanisms of action under
20 specific circumstances need to be understood
21 before there can be any discussion of how they
22 interact, and you would have to know the

1 specifics of the specific antioxidant system
2 you're talking about, and the specific matrix.
3 So really, I can't comment any further than
4 that.

5 MR. FOSTER: Other questions from
6 the Board on the materials? Zea?

7 MS. SONNABEND: So are, and if you
8 have a different perspective on that, we would
9 also --

10 DR. BHATIA: No, I don't. Thank
11 you, first of all, for having me represent the
12 AAP. One of the things we have to understand,
13 I'm sure this audience knows very well, that
14 all these additions or subtractions or
15 approvals or otherwise have come from many,
16 many years ago, and back then, the only issue
17 was safety/efficacy of the added compound.

18 Only now have we added
19 functionality and outcome measures. So these
20 two components, for example, have been shown
21 to be safe, but mainly they are added for
22 manufacturing purposes, not to show any

1 efficacy or effect in the neonate.

2 None of that antioxidants have
3 really been studied to say "If I add this
4 mixture, I'm going to have outcome X in the
5 baby." These are all manufacturing issues
6 that started off in the first place.

7 MS. SONNABEND: Okay, thank you.
8 Our next question has to do with it's similar.
9 Both of these two compounds have shown vitamin
10 activity, and can be used as sources of
11 vitamins.

12 We'd like to confirm that these
13 are both recognized sources of vitamins, beta
14 carotene for Vitamin A and ascorbyl palmitate
15 for Vitamin C, and then we received some
16 public comment that the beta carotene quantity
17 that's used routinely for vitamin activity
18 would be sufficient for the antioxidant
19 effect.

20 In other words, it's like 250
21 units would be used for vitamin activity, but
22 only 20, I don't have the exact figures, but

1 only 20 are needed for antioxidant effect, and
2 we would like to hear from you concerning the
3 relative quantities of their use as a vitamin,
4 versus an antioxidant.

5 DR. BHATIA: Again, clinically the
6 use of Vitamin A has been more as a vitamin
7 for other issues like night blindness and the
8 effect of mortality globally if there's a
9 Vitamin A insufficiency.

10 Approximately 85 percent of the
11 global population, as covered by the current
12 standards, have Vitamin A added into infant
13 formulas and foods. It is a minority of the
14 population that has a deficiency.

15 We're still struggling with this,
16 especially with the confounding variable of
17 malaria, which we don't have in the United
18 States. So yes, it's a source of Vitamin A.
19 Yes, what we have currently in the Infant
20 Formula Act is sufficient for the purposes put
21 in.

22 It was not put in there at that

1 time as an antioxidant. It was put in there
2 as a vitamin by itself, because we knew the
3 vitamins are important for development of
4 babies.

5 MS. SONNABEND: But would the
6 amount put in as a vitamin be enough for the
7 antioxidant activity?

8 DR. ANDERSON: Perhaps I can
9 clarify on that. Vitamin C is added to infant
10 formulas as a source of -- ascorbic acid is
11 added as a source of Vitamin C.

12 Ascorbyl palmitate is added as an
13 antioxidant. In order for the ascorbyl
14 palmitate to be used as a source of Vitamin C,
15 the palmitate and the ascorbic acid would have
16 to be cleaved apart.

17 That is less efficient than
18 providing Vitamin C as such, and infant
19 formula manufacturers add ascorbic acid as the
20 source of Vitamin C for the infant, in the
21 infant formula. Now with Vitamin A, infant
22 formula manufacturers add pre-formed Vitamin

1 A as the Vitamin A source in the formula.

2 They do not rely at all on the
3 beta carotene that is added. The beta
4 carotene is added as an antioxidant in the
5 formula, and like I said, they do not rely on
6 the beta carotene as a source of Vitamin A for
7 the infant.

8 MS. SONNABEND: Thank you.

9 MR. FOSTER: Tracy.

10 MS. FAVRE: Okay. Just to clarify
11 that statement, so pre-formed Vitamin A is
12 already added to infant formula, and therefore
13 meets the vitamin requirements for Vitamin A.
14 Beta carotene is specifically used as an
15 antioxidant?

16 DR. ANDERSON: That's correct, for
17 formulations that are made at the current
18 time.

19 MS. FAVRE: Thank you.

20 MR. FOSTER: Nick.

21 MR. MARAVELL: Yes. Just to
22 clarify on ascorbyl palmitate. Vitamin C

1 would normally be added with ascorbic acid
2 because, as you pointed out, it's more
3 efficacious to do so. So the amounts being
4 added to infant formula of ascorbyl palmitate
5 then are not an amount that would be a
6 consideration for a Vitamin C supplement.
7 It's added solely as an antioxidant.

8 DR. ANDERSON: That's correct.

9 MR. MARAVELL: Thank you.

10 MR. FOSTER: Thank you. Last
11 questions on either of the two materials?
12 Zea?

13 MS. SONNABEND: Okay. Well, this
14 is Question 5 on the questions we sent you,
15 which I may not have phrased exactly right.
16 But our understanding is that these
17 antioxidants are used in the dry powdered
18 formula, which is created with a high heat
19 process and it's used to prevent rancidity of
20 the oils in the formula.

21 I was wondering if the rancidity
22 occurs right away when you make it, or if it's

1 a question of shelf life later on, and if it's
2 the latter, how much shelf life would be lost
3 not using one of the antioxidants?

4 DR. ANDERSON: Okay. It's
5 necessary to provide heat during the
6 processing of infant formula, in order to make
7 it microbiologically safe. During the spray-
8 drying process, which I believe your question
9 was referring to, the infant formula is
10 exposed to heat, but it's also exposed to
11 oxygen.

12 So those two in combination can
13 lead to some oxidation of the product, if it's
14 not adequately protected by antioxidants. So
15 there will be some potential for oxidation,
16 not a whole lot, during the processing. There
17 will be also some potential for oxidation
18 during storage of the product. It's not a
19 lot, because it's stored under nitrogen, and
20 there's not a lot of exposure to oxygen.

21 However, because it's a powder,
22 there's a very large amount of surface area,

1 and it can be -- there's a lot of potential
2 for interaction because of that large surface
3 area.

4 With regard to how much occurs at
5 this point and how much occurs at that point,
6 I'm not prepared to answer that, and if
7 there's somebody from industry that has that
8 expertise, they might be able to do so.

9 MR. FOSTER: All right. Tracy.

10 MS. FAVRE: So I guess we're back
11 to the question of whether or not the
12 antioxidant properties of the beta carotene or
13 the ascorbyl palmitate is absolutely necessary
14 in the manufacturing process, to ensure
15 product safety?

16 DR. ANDERSON: The fat sources
17 that are used in infant formula are used to
18 "mimic" the fat profile in human milk, and
19 that means that there are, is a fairly large
20 percentage of polyunsaturated fatty acids.

21 Those are very subject to
22 oxidation, as are -- and in particular the

1 long-chain polyunsaturated fatty acids, the
2 DHA and ARA, are very much subject to
3 oxidation.

4 They definitely need protection
5 during the manufacturing and storage process,
6 and the ascorbyl palmitate, beta carotene
7 tocopherols system has been shown to be
8 protective.

9 MR. FOSTER: I have Jean and then
10 Nick and --

11 MS. TUCKER: Wait. Can we pause
12 for just a moment?

13 MR. FOSTER: Yes.

14 MS. TUCKER: You folks are going
15 to be up here for a little while. So I'd like
16 to invite you to sit down, so you're not
17 standing up all the time, okay.

18 MR. FOSTER: What fun is that?

19 (Laughter.)

20 MS. TUCKER: Okay. So we have
21 two mics here for you, and two chairs.

22 DR. BHATIA: Thank you.

1 MS. TUCKER: Sure.

2 DR. BHATIA: One thing I would
3 like to add unasked about the heating process
4 for making powdered infant formulas, the
5 United States and all the world manufacturers
6 have bacterial counts and colony-forming
7 units, which is lower than the USDA and the
8 world standard.

9 Yet one is to understand, even
10 with the intense heat and drying process that
11 Dr. Anderson just described, infant powder
12 formula is not sterile. That is why we make
13 liquid formula and the cost will go up.

14 That's a different issue
15 altogether. So having recognized that, if we
16 lowered the heat for other reasons, we run the
17 risk of having more bacterial colonization,
18 because bacteria do not get destroyed with
19 that amount of intense heat. It requires much
20 higher than that.

21 MR. FOSTER: Thank you. So Jean
22 and then Nick, and try and wrap it up after

1 that.

2 MS. RICHARDSON: Yes. My question
3 relates to the shelf life of the infant
4 formula. If you did not add either the
5 ascorbyl palmitate or the beta carotene, what
6 difference would it make in the shelf life of
7 the infant formula?

8 DR. ANDERSON: It would definitely
9 be shorter, much shorter. But I don't have
10 quantitative. I can't say X months with and
11 Y months without. But definitely shorter and
12 one thing that you do not want in products for
13 infants is oxidized fat, or any other
14 deleterious substance.

15 MR. FOSTER: Nick.

16 MR. MARAVELL: Yes. This is less
17 of a question, a little bit more of a factual
18 insertion here, that in previous action, our
19 Board has permitted ascorbyl palmitate and
20 beta carotene. I believe both for
21 particularly an ARA/DHA product added to
22 infant formula.

1 So in terms of ensuring the safety
2 of that specific fatty acid, I think we do
3 have an avenue for that particular fatty acid.

4 MR. FOSTER: All right. So I
5 think we'll wrap up questions on these two
6 materials, have the presentations on, it will
7 be lutein is up next.

8 But please, please make yourselves
9 comfortable and I'm sure there will be
10 additional questions, as far as some of the
11 other materials as we move through that. Is
12 that all right with you? You're our guests,
13 so we want to make sure you're comfortable.
14 Thank you.

15 DR. ANDERSON: Sounds good.

16 MR. FOSTER: All right. Having
17 said that, Lisa in the spotlight. The next
18 material would be lutein.

19 MS. BRINES: Thanks, John. The
20 petition for lutein was received on November
21 14th, 2011, and was submitted by Kemin Health,
22 LLC. The petition had requested the inclusion

1 of lutein at Section 205.606 of the National
2 List as an agricultural product, for use as an
3 ingredient in processed foods.

4 In support of its review, the
5 Handling Subcommittee requested the
6 development of a third party technical report.
7 Both that report and the petition are
8 available to the public by posting on the NOP
9 website in advance of the opening of the
10 public comment period.

11 Written public comment was
12 received in support of this petition, and the
13 petitioner is signed up for public comment
14 later this morning. Thanks.

15 MR. FOSTER: Thank you, Lisa.
16 Harold, you're lead on this. Would you take
17 it from here?

18 MR. AUSTIN: Okay. Thanks, John.
19 Lutein, I'll just go through this and
20 abbreviate as much of it as I can. It's a
21 carotenoid related to beta carotene. It's a
22 strong antioxidant. This material has been

1 petitioned to be added for use in infant
2 formula. Let's just state that right off, up
3 front.

4 It is naturally present in many
5 vegetables such as spinach, kale, broccoli,
6 green beans. The petition form of lutein is
7 derived from dried food grade marigolds, non-
8 organically raised. This is the primary
9 source to be used to be petitioned.

10 Lutein comprises the macular
11 pigment of the eye and is found in the lenses.
12 Acts as a blue light filter and serves an
13 important role, according to what we've been
14 petitioned, in eye health. It also is
15 acquired only through one's diet and cannot be
16 synthesized by the body.

17 The primary source for lutein for
18 infants is human breast milk. The level of
19 lutein in human breast milk will vary,
20 depending on the dietary intake of the lutein-
21 rich vegetables by the infant's mother. This
22 will vary in different parts of the world due

1 to cultural dietary eating habits.

2 Cow milk or soy-based infant
3 formulas would need to be fortified with
4 lutein, to equal the amounts normally found in
5 human breast milk. This ingredient is not
6 required by the FDA under 21 C.F.R.
7 104.20(d)(3).

8 The petitioner has actually
9 requested for this material to be listed for
10 two uses. Number one, in organically labeled
11 infant formula, number two, in organic-labeled
12 foods. The Handling Committee decided that,
13 through deliberation, that there was adequate
14 source for the secondary petition request, and
15 have chosen not to vote upon that.

16 We felt that for adults, for use
17 in foods, that they could get that through
18 natural dietary habits. There is enough
19 alternate sources available. So the only
20 thing that we're discussed today would be the
21 addition of lutein to the list for use in
22 infant formula.

1 This would technically fall under
2 the category of accessory nutrients, and
3 because of the actual method of production of
4 lutein is confidential business information,
5 the subcommittee could not verify that lutein
6 was considered, should be considered as a non-
7 synthetic, as requested by the petitioner.

8 In the TR, it was mentioned that
9 they felt that the formulation process would
10 classify this as a synthetic. The Handling
11 Subcommittee was split on the listing of
12 lutein for use in infant formula. The basis
13 of this vote and those voting in favor of
14 showed that the material is currently being
15 used in infant formulas.

16 Secondly, because the importance
17 of the role that it plays in eye health in
18 infants and adults. Those on the Subcommittee
19 that were opposed to the listing felt that it
20 was not mandated as an additive by the FDA for
21 use in infant formula, did not have enough
22 information because of the CVI version of the

1 petition to determine whether it was a non-
2 synthetic or not.

3 It does not appear to be
4 essential, since it is in some brands, not in
5 others, and there appears to be a viable non-
6 synthetic alternative such as whey protein and
7 microalgal sources.

8 The rationale behind the
9 Subcommittee choosing not to include the
10 petitioner's request for the second was as I
11 stated, that we felt that there was adequate
12 alternatives for that listing.

13 Committee vote on that listing
14 classification or the classification motion
15 as a synthetic was 7 yes, 0 no, no absents.
16 The listing motion to add lutein to the
17 National List 205.605(b) for use in infant
18 formula only, lutein using approved organic
19 delivery ingredients, CAS No. 12740-2, that
20 vote was 3 yes, 4 no.

21 If we could go to the next slide,
22 we could summarize public comments. The

1 other, one other thing I would mention here,
2 that the petitioner did mention that there
3 were a couple of other materials like pectin
4 and lycopene non-bleached that were produced
5 in a similar fashion, and that was one of the
6 basis why they felt that that product material
7 should be listed as a non-synthetic.

8 But because of the information
9 being confidential, the Board felt that we had
10 no choice but to vote it as a synthetic. If
11 we could go up one more, I think Michelle, or
12 do we not have that? Okay, never mind. I've
13 got it here. I'll just summarize.

14 Okay. Public comment summary. We
15 had seven comments that were specifically in
16 favor of listing lutein. We had eight
17 comments that were specifically mentioned
18 against the listing of lutein. There were
19 numerous comments against allowing synthetics
20 in general, 7,418 plus numerous additional
21 ones.

22 There were also several comments

1 against additives, synthetic or otherwise,
2 allowed for use in infant formulas, asking
3 that we don't allow the over-fortification of
4 infant formula. A quick summary of those that
5 were in favor of listing on 205.605(b) is
6 there's enough new scientific data to support
7 the need during infancy, not only for eye
8 growth in development but also for neural
9 growth in development as well.

10 It's also within the last few
11 years that nutritional and medical research
12 has demonstrated positive effects of lutein
13 for adult and infant eye and neural health, a
14 similar quote. Lutein is found in human
15 breast milk and its antioxidant properties can
16 help protect infant's eyes from UV damage.

17 Cow's milk and soy-based formulas
18 contain minimal lutein unless it's fortified.
19 Lutein cannot be synthesized by the bodies;
20 therefore, it is strictly from a dietary
21 origin.

22 Any synthetic added to the

1 National List must be required by law, or
2 essential for the handling of organically-
3 produced agricultural products, and
4 commercially unavailable in natural or organic
5 forms.

6 NOSB was also urged to consider
7 the essentiality, and this is kind of more of
8 a general for the different components or
9 materials that we're looking at today. But
10 one of the general comments was the NOSB is
11 urged to consider essentiality of nutrient-
12 based, of the nutrient based on its critical
13 function to infant, toddler or human
14 development.

15 The decision to call a nutrient
16 non-essential, because it's not specifically
17 listed as essential by FDA in the Code of
18 Federal Regulations, ignores valid and
19 published scientific information by respected
20 organizations.

21 A summary of those that are
22 opposed to the listing of lutein, were opposed

1 to the construction of organic infant formula
2 from synthetic materials. Concerns over
3 fortification of infant formulas that may
4 place undue burdens or metabolic and other
5 physiologic functions on the infant.

6 Breast feeding is by far the
7 better approach to overall infant health
8 development, when compared to the alternative
9 choice of using formula. It's not mandatory,
10 according to the FDA infant formula
11 regulations. It's not permitted in the EU,
12 either in conventional nor in organic infant
13 formula.

14 Still unproven to be beneficial to
15 infant health or development. It's not
16 consistent with organic principles. It's not
17 essential because scientific evidence of its
18 essentiality has not yet been proven. That
19 sums it up, John.

20 MR. FOSTER: Thank you for that
21 summary. Any questions on lutein for -- yes,
22 Jean?

1 MS. RICHARDSON: I'm just seeking
2 clarification on two issues. One, and perhaps
3 this one should go to our experts for
4 clarification, as to whether this should be
5 classified as synthetic or non-synthetic, and
6 secondly, is the primary purpose as an
7 antioxidant preservative or for the health
8 benefits on the eye?

9 DR. ANDERSON: The purpose that
10 infant formula manufacturers add lutein to
11 infant formula is as a mixture of
12 antioxidants, purported to protect tissues in
13 infants, and then the second part of your
14 question please?

15 MS. RICHARDSON: Synthetic or non-
16 synthetic?

17 DR. ANDERSON: Oh. That is not a
18 question I can answer.

19 MR. FOSTER: Additional questions?
20 Harold?

21 MR. AUSTIN: I have a question
22 also for our experts. One of the comments in

1 public comment that was made to us that we'd
2 like some clarification on is Question No. 8.
3 A formula manufacturer commented that the CFR
4 107.100, the list of requirements for infant
5 formula, has not been updated since 1985.

6 Is this correct, and if it is, is
7 there any plans to look at any additions to
8 that list in the future?

9 DR. ANDERSON: The requirements in
10 21 C.F.R. 107.100 were indeed promulgated in
11 1985. They have not been updated since that
12 time. Those values, those substances and
13 those values came about as a result of
14 recommendations from the American Academy of
15 Pediatrics to the agency.

16 As far as updating, it has been 30
17 years or maybe even more. The decision to
18 update will rely on agency priorities and on
19 having the available resources to do so.

20 DR. BHATIA: The Committee on
21 Nutrition is concerned about this old
22 document, because some of them are made on

1 presumption, and some of them are made on data
2 that we now have. However, this is not a
3 simple agency matter. This is a Congressional
4 mandate.

5 So for us, we've started the
6 process of asking the question, but it has to
7 bring all the agencies together and then go
8 through Congress before that Act can be
9 changed.

10 MR. FOSTER: Can we go for two
11 more questions here. We've got to keep
12 moving, and for that I see Jay and Tracy, and
13 with the reminder that if we can get through
14 all these materials, we can circle back to
15 some of these other questions. But Jay and
16 Tracy, and then we'll move on to lycopene.

17 MR. FELDMAN: Thank you, John.
18 Thanks again for being here. As you know,
19 this is not a technical board in the sense of
20 evaluating scientific criteria, and therefore
21 the law that we're operating under is very
22 clear, that we should rely on requirements in

1 other laws, in terms of added materials, added
2 nutrients and so forth.

3 So the use of your word
4 "purportedly" in the context of manufactured
5 claims caught my attention. I'm wondering
6 about the process that we should rely on, this
7 body should rely on, in terms of making these
8 determinations, and whether we should not ask,
9 is it unreasonable for a body like this to
10 request a manufacturer to go back to the FDA,
11 or some other body, so that they can get the
12 classification that would meet our
13 requirements standard, or is that an
14 unreasonable request, and you know,
15 impractical request or not practical request?

16 DR. ANDERSON: Perhaps this would
17 be a good time to say a few words about FDA's
18 regulation of infant formulas. FDA regulates
19 infant formulas as foods, and there are two
20 primary offices that are involved in the
21 regulation: The Office of Nutrition, Labeling
22 and Dietary Supplements, which is my office,

1 regulates the infant formula finished product.

2 The Office of Food Additive Safety
3 regulates the ingredients that are used in
4 infant formulas. The two offices work very
5 closely together on this, whenever there's any
6 question or any issue involved with infant
7 formula or new ingredients in infant formulas.

8 Infant formula manufacturers are
9 required to make a pre-market notification to
10 FDA whenever they propose to market a new
11 infant formula or make a change in a
12 formulation or for one of their existing
13 products.

14 Addition of a new ingredient or a
15 modified ingredient would require a pre-market
16 notification, and in our review of an infant
17 formulation notification, we would want to be
18 assured that the, of the scientific basis of
19 safety of the new ingredients for use in
20 infant formula.

21 What FDA has to regulate
22 ingredients on is their safety. Efficacy is

1 a consideration for drugs. It is not a
2 consideration for food ingredients, for the
3 safety of food ingredients. It is a
4 consideration, efficacy is a consideration for
5 claims on products, but not for their safety
6 of use in the products.

7 We consult with the Office of Food
8 Additive Safety regarding any questions about
9 the safety of use of a new ingredient in
10 infant formula, and we always encourage infant
11 formula manufacturers to work with the Office
12 of Food Additive Safety to resolve any
13 questions about the safety for use in infant
14 formula, before they submit a pre-market
15 notification to us.

16 MR. FOSTER: Thank you. Tracy. MS.

17 FAVRE: I'm going to apologize in advance for
18 my question, because I realize it's going to
19 put you on the spot. But Dr. Bhatia, can you
20 tell me if in your opinion the benefits of
21 these added nutrients outweigh the potential
22 concerns about the fact that we're looking at

1 synthetic additives?

2 DR. BHATIA: I cannot, because
3 what has been shown so far, specifically in
4 the nutrient we're talking in question is yes,
5 breast milk has it; formulas don't. What has
6 been shown so far is if added in formula, you
7 have ocular growth. The functional claims that
8 people are claiming still have not been shown
9 in long-term studies.

10 So addition of a new nutrient to
11 make it similar to human milk has been -- I
12 think for 30 years we've been trying to do
13 that. But to prove a long-term effect, you
14 need more studies. There are studies showing
15 so far short-term safe, but not enough to say
16 this has to be put into infant formula at this
17 current time.

18 MS. FAVRE: Thank you.

19 MR. FOSTER: Thanks. All right.
20 Mindful we're halfway through our time and a
21 third of the way through the agenda, I have to
22 hold on to additional questions on lutein, and

1 move on to lycopene. Lisa.

2 MS. BRINES: Thanks, John. The
3 petition for lycopene was received on
4 September 19th, 2011, and was submitted by the
5 International Formula Council. The petition
6 requests the inclusion of lycopene at Section
7 205.605 of the National List, for use as an
8 ingredient in infant formula.

9 Lycopene does not appear elsewhere
10 on the National List, but there was a previous
11 petition in 2007 for lycopene juice, and that
12 was for use as a color. This petition for
13 lycopene is for the synthetic form.

14 In support of the review of the
15 petition, the Subcommittee had requested the
16 development of a technical report, and both
17 that technical report and the petition for
18 lycopene were available to the public in
19 advance of the opening of the public comment
20 period for this meeting, and again the
21 petitioner is available for in-person public
22 comment later this morning. Thanks.

1 MR. FOSTER: Thank you very much,
2 Lisa. Nick, you had the pleasure of dealing
3 with this through the term. Would you take it
4 from here?

5 MR. MARAVELL: Okay. Thank you,
6 John. The petition for lycopene in the
7 synthetic form is primarily -- the argument
8 for it is primarily based on the fact that
9 natural sources of lycopene would come from
10 food substances, for example, tomato, and it
11 may contain proteins which could potentially
12 induce an allergic response.

13 This is sort of extended from the
14 argument that some people are allergic to
15 tomatoes. We could not find any specific
16 substantiation of that direct connection, and
17 the TR, the Technical Review, hypothesized
18 that any response, allergic response to
19 tomatoes is more than likely related to the
20 acidity rather than the make-up of the
21 proteins in lycopene.

22 In checking with the other

1 standards, European, Canadian, Japanese,
2 synthetic lycopene is not permitted in infant
3 formula, and it does not appear that lycopene
4 is a required addition to infant formula. The
5 public comments fell pretty much along the
6 same lines as for ascorbyl palmitate and beta
7 carotene, with the consumer and interest
8 group, public interest group community
9 questioning the need for the addition of
10 synthetics into infant formula.

11 And there were some industry
12 groups that supported the addition of
13 synthetic lycopene because it is a powerful
14 antioxidant, and could have potential
15 benefits.

16 I don't think that we're disputing
17 that; we're simply disputing the fact that it
18 does not need to come from a synthetic source,
19 and therefore the committee voted to declare
20 it a synthetic, it was petitioned as a
21 synthetic, and to not add it to the National
22 List. Both votes were unanimous. There were

1 two absent at that deliberation.

2 MR. FOSTER: Thank you, Nick.

3 Questions from the Board on lycopene? Jay.

4 MR. FELDMAN: I would just like to
5 ask the same question. I hate to be redundant
6 on this, but again, on the question of
7 required by FDA or any other body that we
8 should be aware of, that would deem this
9 material essential or essentially required to
10 be added to infant formula. Can you address
11 that?

12 DR. ANDERSON: Lycopene is not
13 included in the list of 29 required nutrients
14 for infant formulas. The FDA refers to an
15 authoritative scientific body in determining
16 what nutrients are essential for infants, in
17 this case, the Institute of Medicine of the
18 National Academy of Sciences.

19 FDA regards Vitamin A as
20 essential, and would also recognize that beta
21 carotene, as a source pro-vitamin for Vitamin
22 A, could be considered a vitamin. Lutein and

1 lycopene are not pro-Vitamin A sources, and we
2 do not consider them essential.

3 MR. FOSTER: Thank you. One more?
4 All right. Then with no more questions, let's
5 move on to L-carnitine. Lisa.

6 MS. BRINES: Thanks, John. The
7 petition for L-carnitine was received on
8 November 10th, 2011, and was submitted by the
9 International Formula Council. The petition
10 requests the inclusion of L-carnitine at
11 Section 205.605(b) of the National List for
12 uses as an ingredient in infant formula.

13 In support of its review of this
14 petition, this handling Subcommittee did
15 request the development of a third party
16 technical report, and both the report and the
17 petition were available to the public on the
18 NOP website in advance of the opening of the
19 public comment period for this meeting, and
20 again the petitioner will be available later
21 this morning for in-person public comment.
22 Thanks.

1 MR. FOSTER: Thank you, Lisa.
2 Zea, you were the lead on L-carnitine. Thank
3 you.

4 MS. SONNABEND: Thank you. L-
5 carnitine is a compound that's synthesized in
6 the body from the amino acids lysine and
7 methionine. These amino acids are abundant in
8 foods, such as beans avocados and red meat.

9 The synthetic form has been
10 petitioned for use in infant formula because
11 soy-based formulas contain very low levels of
12 carnitine, and infants are less able to
13 synthesize carnitine for themselves. Cow's
14 milk formulas can also be low in carnitine
15 because the milk is diluted in the formula.

16 Unlike some other ingredients, and
17 one we'll talk about in a minute, L-
18 methionine, carnitine is not required under
19 the FDA 21 C.F.R. sections that refer to
20 infant formula that we could find.

21 We have been led to understand
22 that it is required in the EU, and we're not

1 sure why L-methionine would be required and L-
2 carnitine not, which we'll ask our experts
3 after the L-methionine presentation, I would
4 imagine.

5 But in any event, it appeared to
6 us that it would be feasible to make carnitine
7 or extract it from non-synthetic sources,
8 although this is not commercially done at this
9 time. For these reasons, the Handling
10 Subcommittee is not recommending to add
11 synthetic L-carnitine to the National List.

12 MR. FOSTER: Thank you, Zea. Any
13 questions on L-carnitine at the moment? My
14 guess is we'll have a question on both L-
15 carnitine and L-methionine in a few minutes.
16 All right. Let's move on then to L-
17 methionine. Lisa.

18 MS. BRINES: Thanks, John. The
19 petition for L-methionine was received on
20 October 26, 2011, and was submitted by the
21 International Formula Council. The petition
22 requests the inclusion of L-methionine at

1 Section 205.605(b) of the National List for
2 fortification of infant formula, which is
3 based on isolated soy protein.

4 In support of its review, the
5 Handling Subcommittee did request the
6 development of a third party technical report,
7 and that report and the petition were
8 available to the public on the NOP website in
9 advance of the opening of the public comment
10 period. Thanks.

11 MR. FOSTER: Thank you, Lisa.
12 Tracy, you were lead on this. Take it from
13 here.

14 MS. FAVRE: Yes. L-methionine is
15 an essential amino acid that's required for
16 proper human development, and it has been
17 petitioned for the use in soy-based formulas,
18 because the protein content specifically in
19 soy-based formula is not sufficient without
20 the addition of the L-methionine.

21 We had lots and lots of
22 conversations about this on the Subcommittee.

1 Just like most of the formula additions that
2 we've been talking about this morning, there
3 were pretty strong arguments on both sides in
4 the public comments, primarily from the same
5 sorts of groups, whether it was the consumer,
6 general consumers versus the manufacturers.

7 In the discussion about the
8 inclusion of synthetic L-methionine, I
9 personally was troubled, because the
10 manufacturing process can be fairly toxic.
11 But we do have a significant deficiency, in
12 fact essentially after some clarification
13 during some expert discussion during
14 subcommittee meetings, there essentially would
15 be no soy-based formula with the addition of
16 L-methionine, because of the minimum protein
17 requirements specified for infant formula.

18 So as a result, we did vote
19 unanimously, excuse me. There was 6 votes
20 yes, 1 absent for the classification motion
21 for synthetic L-methionine on 205.605(b), and
22 on the listing motion, there was a 6 yes, 1

1 absent vote on the agreement to include L-
2 methionine on 205.605(b).

3 During some subcommittee
4 discussions prior to the meeting here this
5 week, the original motion was for use in
6 infant formula made with isolated soy-based
7 protein, and we've elected to strike the word
8 "isolated" on the soy-based protein because of
9 concerns about the manufacturing process on
10 isolated soy-based protein.

11 Again, we're hoping our two
12 experts here today can provide us some
13 clarification specifically about L-methionine
14 and the protein requirements, as well as
15 whether or not the isolated soy-based protein
16 is an issue. Thank you.

17 MR. FOSTER: Thank you, Tracy. It
18 sounds like we have a couple of questions for,
19 regarding both L-carnitine and L-methionine
20 that were put forward. So I had Zea and then
21 Tracy. If you want to encapsulate your
22 questions. Zea, you want to go first? Yes,

1 for carnitine or methionine.

2 MS. SONNABEND: Well, I think I
3 posed the question, which is why is L-
4 methionine required by FDA and L-carnitine
5 not?

6 DR. ANDERSON: L-methionine is
7 recognized as an essential amino acid,
8 necessary for the growth and development of
9 infants. It is permitted for use in foods and
10 in infant formulas by FDA's food additive
11 regulations.

12 Carnitine, as you said, can be
13 synthesized from the amino acids L-methionine
14 and L-lysine. It is not as -- there's not as
15 much support for its essentiality in infant
16 nutrition as there is for methionine, and
17 given that it can be synthesized by the
18 infant, it has not been included as essential
19 for inclusion in infant formula.

20 DR. BHATIA: The essentiality of
21 L-methionine soy infant formulas was
22 demonstrated many, many years ago. Soy

1 protein is not the same as common protein, and
2 protein has less L-methionine in it. So there
3 would be an L-methionine deficiency created if
4 you feed soy infant formulas without added
5 methionine.

6 In addition, if you look at soy
7 infant formula label, you will notice that the
8 total protein content per deciliter or per 100
9 calories in soy formulas are higher than
10 common formulas, to make up for the relative
11 inefficiency, if you will, of soy protein
12 formula.

13 Having said that, soy protein
14 isolate, I'm not a manufacturer and neither do
15 I have expertise in manufacturing, is the only
16 soy protein formula used in the United States
17 and in Europe. Plain soy protein is not.

18 Carnitine deficiency is relatively
19 rare. In 30 years of doing clinical
20 neonatology and nutrition, I've probably
21 referred four to five babies for carnitine
22 deficiency. So carnitine, as an essential

1 nutrient for the general population of
2 infants, is actually the evidence is quite
3 low.

4 MR. FOSTER: Okay, thank you.
5 Tracy, do you want to recapture your question,
6 or are you good?

7 (Off record comment.)

8 MR. FOSTER: Okay, okay. Mac and
9 then Jay, and then we should wrap it up, or
10 Zea, if you've got a follow-up.

11 MR. STONE: Do either of you all
12 have a sense of what percentage, I guess I'm
13 heading towards lactose intolerance, or what
14 percentage are soy-based versus cow milk based
15 infant formulas?

16 DR. BHATIA: The actual percent of
17 lactose, true lactose intolerance in the
18 general population is an estimate, because
19 self-reported. In all populations, it's
20 between about 10 to 12 percent perceived.

21 In infants, it's less than five
22 percent, and that is true persistent lactose

1 intolerance, which shows up at approximately
2 two years of age. The secondary lactose
3 intolerance that occurs in neonatal after,
4 say, acute diarrhea.

5 So lactose, true lactose
6 deficiency, which is rare, then is one
7 indication for using soy infant formulas
8 because it's made of sucrose and not lactose.
9 However, that was the only choice available
10 10-15 years ago.

11 Now we have other choices that
12 when used with limited lactose compared to
13 completely going to soy. Soy infant formulas
14 are not indicated in pre-term infants in the
15 first place. In the second place, in term
16 infants, currently the opinion is there are
17 only three indications for soy infant
18 formulas.

19 One, there's a metabolic disease,
20 galactosemia, because they cannot tolerate the
21 glucose-galactose and soy infant formula is
22 indicated for that. Two is secondary

1 persistent lactose intolerance, and three is
2 a personal choice, because we have
3 vegetarianism, which make you who may choose
4 to have soy as a primary source, not cow milk.

5 This can become a concern for
6 nutrition because soy, otherwise for healthy
7 term infants is fine; but for subpopulations,
8 it is not fine.

9 DR. ANDERSON: With regard to the
10 amount of soy infant formula that is sold in
11 the United States, the latest figures that I
12 have seen are that about 10 to 12 percent of
13 infant formula sales are for soy infant
14 formulas.

15 DR. BHATIA: I need to add that in
16 Canada, it's less than two percent, England
17 is two percent, and in New Zealand, you have
18 to go to the pharmacist behind the counter to
19 ask for soy, for the same reasons I've
20 outlined, that there's no need to abuse soy
21 infant formulas in infancy.

22 After infancy, it is relatively

1 data poor, and evidence rich that epidemiology
2 studies have not shown harmful effects. But
3 infancy, there are specific issues. Why use
4 soy when you have other formulas available?

5 MR. FOSTER: Thank you. Jay,
6 question, or Zea. Okay. Straight to the
7 question, if we could?

8 MR. FELDMAN: I'm actually working
9 off this sheet of questions or list of
10 questions that were sent earlier, and I'm not
11 sure where there's a good place. This seems
12 to be the best place to sort of raise this,
13 given what you've already said.

14 First, this distinction. I've
15 read your article, Dr. Bhatia, on use of soy
16 protein-based formulas, and just want to get
17 clarification on this distinction that's being
18 made, I believe to the committee and the Board
19 here, that there is a distinction between soy
20 protein isolate and soy concentrate, and that
21 in effect, there is -- there are different
22 issues that we would address in those

1 different contexts.

2 Again, it would be helpful as the
3 Question No. 9 indicates on this list, given
4 that we are putting essentially a
5 certification on a soy product, driving in
6 effect consumers toward that product based on
7 some assumption of its added value with that
8 certification, that organic certification,
9 presumably that will increase sales of that
10 product, or at least shift sales in that
11 direction.

12 I guess I'm looking, given your
13 work on this, looking to you to advise this
14 body on what questions ought to be answered,
15 may have not been answered in the past, and
16 should be answered in the future, regarding
17 the evaluation of the soy isolate and the
18 impact that that has as a derived material,
19 synthetically derived material, and its
20 safety-related and need related to infant
21 health.

22 You've already identified the pre-

1 term infancy impacts there, but again, we're
2 looking at the broader picture, in terms of
3 soy isolate versus soy concentrate, and its
4 essentiality in the market.

5 DR. BHATIA: In my opinion
6 clinically, soy isolate should be the only
7 protein used in infant formulas. There is no
8 question that if you use intact soy, and you
9 chop it up into different pieces of it and
10 feed it to animal models that you have,
11 deleterious effects.

12 In the last 40 years in infant
13 formula and nutrition research, we have not
14 demonstrated any harmful effects of soy
15 isolate as it is produced and fed to infants
16 in the United States and Europe, using a soy
17 protein isolate.

18 The concerns have been the use and
19 abuse of soy for colic. It does not prevent
20 it. Use and abuse of soy for allergy, it is
21 not a formula to prevent allergy. The concern
22 about premature reproductive issues. Those

1 data are extremely weak in the human model,
2 and I have participated in two NIEHS panels
3 and have come to the same conclusion.

4 In human nutrition, soy infant
5 formulas, as fed in the United States, there's
6 minimal concern about the issue on
7 reproductive health. So for those reasons,
8 there's no other issue for soy except for the
9 three indications I've told you.

10 I'm very happy that since we, the
11 Committee on Nutrition, took over and started
12 espousing the lack of benefit of soy in the
13 routine infant, that the soy formula has
14 dropped from 20 percent ten years ago to 12
15 percent that Dr. Anderson just mentioned.

16 So there is no need for routine
17 indication of soy infant formula in term
18 healthy infants, unless it is a personal
19 choice, or a metabolic disease like I outlined
20 before.

21 MR. FOSTER: All right. Let's
22 bring this back to methionine, away from, if

1 we could. Zea.

2 MS. SONNABEND: Okay. We would
3 like to hear the policy of the American
4 Academy of Pediatrics on breast feeding and
5 the use of formula.

6 DR. BHATIA: The Committee on
7 Nutrition, as well as the Section on
8 Breastfeeding both agree that the period of
9 exclusive breast feeding is about six months.
10 The world bodies come across and tell you
11 between four and six months may be the actual
12 window. We don't need to argue. That's about
13 six months.

14 That's a WHO recommendation,
15 ESAPAGAN recommendation and AAP
16 recommendation. So that's exclusive breast
17 feeding. However, the fact of life is
18 exclusive breast feeding up to six months in
19 the United States is not to the point of the
20 Surgeon General's request that we have
21 exclusivity. We are pushing it, but it's not
22 there.

1 Is there evidence to show that if
2 you feed for 4.1 months, it's less advantages
3 than feeding for 4.9 months? No. Is there
4 evidence to show they feed less than four
5 months? Yes. So there is a dose response
6 relationship.

7 So we feel that between four and
8 six months or about six months will the
9 optimal exclusivity for breast feeding.

10 Infant formula is a safe alternative, if you
11 choose not to breast feed or cannot breast
12 feed or should not breast feed, and they have
13 a safety record of their own for the last
14 decades.

15 MR. FOSTER: Thank you. We have
16 some more time to wrap back, circle back
17 around on carnitine and methionine at the end.
18 We can do that, but in the meantime, we'd like
19 to move on to the topic of nucleotides, and I
20 asked Zea to present this, although I did some
21 of the work on this also. Zea. I'm sorry,
22 Lisa, would you --

1 MS. BRINES: Did we skip taurine,
2 John?

3 MR. FOSTER: Oh, okay. It's
4 different in the order I have, but sure,
5 taurine we can do first.

6 MS. BRINES: Okay. We'll do
7 taurine. I've got that in front of me.

8 MR. FOSTER: Alphabetical order?

9 MS. BRINES: Thanks, John. The
10 petition for taurine was received on September
11 14, 2011, and was submitted by the
12 International Formula Council. The petition
13 requests the inclusion of taurine at Section
14 205.605(b) of the National List as an
15 ingredient for use in infant formula.

16 In support of its review, the
17 Handling Subcommittee did request the
18 development of a third party Technical Report,
19 and both the report and the petition were
20 available to the public on the NOP website in
21 advance of the opening of the public comment
22 period for this substance. Thanks.

1 MR. FOSTER: Thank you, and on
2 taurine, Jean, you were lead on this. Would
3 you take it? Thank you.

4 MS. RICHARDSON: So taurine is
5 neither a vitamin nor a mineral. Although
6 it's referred to as an amino acid, it's
7 actually more accurately classified as a B-
8 amino sulfone. It's found in animal protein,
9 such as seafood, beef, chicken, and it's
10 nearly absent in vegetarian foods.

11 While taurine could be produced
12 non-synthetically, it's not commercially
13 available. But it is, in any event, the
14 synthetic form, which has been petitioned for
15 use in infant formula, and its use is to
16 assist in subfat, subpar fat absorption in
17 infants, because insufficient taurine would
18 result in poor fat absorption, and fat
19 absorption is extremely important in infants.

20 There is, however, conflicting
21 scientific opinion regards the necessity of
22 taurine in either human nutrition, and

1 especially for infants. Taurine is not an
2 FDA-required nutrient in baby formula,
3 although it's often added to both conventional
4 soy and milk-based formula.

5 Taurine is not listed on the IFOAM
6 list, nor is it required in European infant
7 formula, and it does not appear on the JAS
8 list in Japan. It doesn't appear to be listed
9 as GRAS. Taurine as petitioned is intended as
10 a dietary supplement, and it does not appear
11 to be essential, and that's certainly a
12 question that the Subcommittee has for our
13 experts, is the essentiality.

14 So the Handling Committee
15 therefore is not recommending the addition of
16 taurine to the National List at this time.
17 The vote on the Subcommittee, which is here,
18 was 4 to 0 not to list it. Three persons were
19 absent.

20 The public comments were the same
21 as those that have been expressed by other
22 Board members for those other products,

1 inasmuch as there was lack of support from
2 consumers, and there was strong support from
3 Infant Formula Council and the related
4 manufacturing organizations.

5 So perhaps we could ask for first
6 clarification on the necessity of taurine.

7 DR. ANDERSON: Scientific evidence
8 doesn't indicate that taurine is essential in
9 the diets of human infants. The National
10 Academy of Sciences, the Institute of
11 Medicine, National Academy of Sciences,
12 doesn't recognize it as an essential nutrient
13 for humans.

14 It is not on the list of required
15 nutrients for infant formula. However, it has
16 been used as an optional ingredient.

17 MR. FOSTER: Thank you.

18 DR. BHATIA: There have been some
19 classical studies done in the late 80's to
20 show that if you don't have taurine, there are
21 effects, short-term effects of the taurine
22 status, if you will, and there are some new

1 development concerns in a subset of infants,
2 especially low birth weight infants.

3 But having said that, I concur
4 with what Dr. Anderson is saying. Strictly
5 speaking, the answer is no. Relatively
6 speaking, the answer is yes.

7 MR. FOSTER: Thank you.

8 DR. ANDERSON: And just one -- can
9 I make one more comment?

10 MR. FOSTER: Please.

11 DR. ANDERSON: We are really
12 concentrating this morning on infant formulas
13 for healthy term infants. We aren't
14 concentrating on the use of formulas for pre-
15 term infants or infants with special medical
16 problems.

17 MR. FOSTER: Thank you for
18 clarifying and reminding us of this.
19 Additional questions on taurine from the
20 floor?

21 (No response.)

22 MR. FOSTER: Thanks. Then let's

1 move on, then, to nucleotides. Lisa.

2 MS. BRINES: Thanks, John. The
3 petition for nucleotides was received on
4 September 14th, 2011, and was submitted by the
5 International Formula Council. The petition
6 requests the inclusion of nucleotides isolated
7 from yeast, RNA, hydrolosate to Section
8 205.605 of the National List.

9 The petition identifies five
10 specific nucleotides for addition to the
11 National List, including the sodium salts. In
12 support of the review of this petition, the
13 Handling Subcommittee requested the
14 development of a third party technical report.

15 That report was developed, and
16 both the petition and technical report were
17 available to the public on the NOP website in
18 advance of the opening of the public comment
19 period for this meeting. Thanks.

20 MR. FOSTER: Thank you, Lisa.
21 Zea, would you take it away?

22 MS. SONNABEND: Nucleotides are

1 compounds that are made in the body from amino
2 acids. The amino acids are abundant in whole
3 foods with protein.

4 Now in our recommendation, the TR
5 was not very clear on the manufacturing
6 process, and it did lead us to think that it
7 as a synthetic form of nucleotides being
8 petitioned.

9 We have since heard a number of
10 public comments that has convinced the
11 committee, at least, that the nucleotides
12 really are non-synthetic. They're derived
13 from yeast and the processing of them is
14 similar to other things that we list on the
15 National List as non-synthetic, and in fact
16 yeast extracts are already on the National
17 List as non-synthetic.

18 Nucleotides are not mandated to be
19 added to infant formulas under the sections
20 regarding infant formulas, and the Handling
21 Committee is recommending to add non-synthetic
22 nucleotides to the National List.

1 But we are going to recommend
2 changing our motions and the classification
3 motion will not change. It's just the voting
4 may be quite different because we'll leave it
5 as synthetic.

6 But if that motion fails, that
7 they're synthetic, then we will be adding it
8 to 205.605(a) instead of 205.605(b). We also
9 want to change the annotation coming from the
10 committee and remove the last sentence, that
11 the nucleotides be allowed for non-infant
12 formula foods that are made with organic
13 ingredients.

14 MR. FOSTER: Thank you, Zea.
15 Questions on nucleotides? Jay.

16 MR. FELDMAN: Yes. I have a
17 question for the committee. In looking at
18 this change, I guess the issue I saw in the TR
19 was around crystallization and that process
20 for extraction.

21 So the question is, is the
22 crystallization process, what is that exactly,

1 and is that considered non-synthetic? Is that
2 what the change is coming from? I mean where
3 is this change in the classification from?

4 MS. SONNABEND: Public comment was
5 submitted by OMRI and by Rich Theuer,
6 regarding how they perceive the method of
7 extracting the nucleotides, and it would be
8 better if you could ask the public commenters
9 that.

10 MR. FOSTER: Okay, thank you.
11 Additional question on nucleotides at this
12 time?

13 (No response.)

14 MR. FOSTER: Well done. Thank you
15 again Zea for last minute changes especially.
16 All right. Last item on the list is the
17 discussion on auxiliary or Other Ingredients.

18 Zea, you were the lead on this as
19 well. Thank you again for working on this.
20 This took a fair amount of conference call
21 time and a lot of work in writing. So thank
22 you again for that.

1 MS. SONNABEND: I'm going to pull
2 out my notes here for a second. Okay. This
3 was a long and complicated document, and we
4 know that you would all love to spend a few
5 hours talking about this today. But we don't
6 really have a few hours to talk about this
7 today, and so the committee will have to take
8 those few hours and more, maybe, after the
9 meeting ends.

10 So I'm just going to give some
11 very broad sweeps on, you know, what types of
12 comments we received and a few of the points
13 that were made, without getting into very much
14 detail.

15 This is a public comment summary
16 from our discussion document on the screen.
17 We received comments from 17 people and
18 organizations on this subject, and here is the
19 list of them in no particular order, except
20 the order they were in when Michelle gave us
21 the compiled document.

22 Now underpinning this whole thing

1 is a lot of things that have to do with the
2 overall classification of materials and what
3 OFPA and the rule actually say, and how you
4 define terms such as ingredients, substances,
5 processing aids and the like.

6 We're not going to get into all of
7 that here, but I do just want to frame that
8 among the organic community represented here,
9 we have two fairly distinct ways of looking at
10 OFPA Interpretation 1, and I have borrowed
11 language from some of the public comments.
12 There were many that mimicked each other, so
13 I've just selected one representative comment
14 from each interpretation, to provide you here.

15 OFPA Interpretation 1: All
16 ingredients of a product labeled organic must
17 either be organic or on the National List for
18 that purpose. There is nothing in OFPA that
19 justifies making the distinction between
20 Ingredients and Other Ingredients.

21 We support a fourth option. No
22 ingredient of any kind can be in food labeled

1 organic unless it is on the National List.
2 The fourth option that they're naming Option
3 D is very similar to Option C, which almost
4 always requires all ingredients to be on the
5 National List.

6 It's the only option that fully
7 complies with the law, and captures the
8 expectation of the consumer that all non-
9 organic ingredients in organic food will be on
10 the National List. Going on to say that the
11 National List headings in the regulations
12 205.605 and 205.606 specify the use of non-
13 agricultural substances and agricultural
14 products, respectively, referred to as
15 ingredients.

16 OFPA Interpretation 2, and I'm
17 sorry the type is a bit small, but it takes a
18 bit to explain it. OFPA sets out rigorous
19 criteria for evaluating substances for
20 inclusion on the National List.

21 However, it is clear that OFPA
22 never intended to require a separate listing

1 of Other Ingredients, incidental additives on
2 the National List. Rather, OFPA clearly
3 states that Other Ingredients should be
4 evaluated as part and parcel of the
5 consideration of substances for inclusion on
6 the list.

7 In establishing the criteria for
8 what should be included on the National List
9 and how items on the National List should be
10 evaluated, OFPA uses the term "substance" to
11 describe these items. It does use terms like
12 single ingredient or even ingredient in
13 Sections 2118 or 2119, and does not state that
14 substances made with more than one ingredient
15 must be evaluated individually.

16 Indeed, Section 2119 LRI-2 makes
17 it clear that it was understood that
18 substances might contain multiple ingredients,
19 where it says, and this is quoting from OFPA,
20 "Work with manufacturers of substances
21 considered for inclusion on the National List
22 to obtain a complete list of ingredients, and

1 determine whether such substances contain
2 inert materials that are synthetically
3 produced."

4 This is not a loophole in the
5 standard that would allow for incidental
6 additives that are incompatible with organic
7 agriculture to be used; rather, it is a
8 mechanism to allow a substance to be
9 thoroughly evaluated through one petition and
10 evaluation process, rather than requiring
11 multiple petitions and reviews for each item
12 on the National List.

13 Okay. The second interpretation
14 is the one that most previous NOSBs and the
15 Department has generally been using, inputting
16 items on the National List, and Option 1 is
17 being insisted on by many members, some
18 members of the organic community.

19 I don't think until you bring in
20 like large teams of lawyers from either side
21 you're going to get a definitive answer to
22 these two different interpretations of what

1 stands in our rule, which is somewhat vague in
2 its terminology to begin with.

3 With all that in mind, we had a
4 fair number of commenters speaking up about
5 the options that we presented. We presented
6 three options, gave long lists of pros and
7 cons of each option, and I was actually a
8 little surprised that very few if any
9 commenters said that they thought Option A was
10 absolutely the best option. Kind of nobody
11 said that.

12 Option A certainly is the easiest
13 and some would argue it's what we have been
14 doing so far, where these issues weren't fully
15 understood by NOSBs in the past. So if
16 something showed up with another ingredient,
17 it was adopted without much scrutiny in some
18 cases, or adopted with considerable scrutiny
19 in other cases, but adopted nonetheless.

20 I would say that the majority of
21 the commenters favored Option B, but almost
22 all of them had some concerns or additions or

1 subtractions from Option B, and then there
2 were almost none that came out for Option C
3 straight out, but some who came out for this
4 Option D, which is really similar to C except
5 once the secondary, the disinfectants and
6 cleaning agents and things to be added.

7 Okay. The concerns of many
8 people. First of all, our proposal for the
9 database being maintained by the NOP. Many
10 people were concerned that to ask for a
11 database in association with an option. This
12 concern is very valid, because the NOP has
13 enough to do, and maybe keeping another
14 database and more stuff would be outside their
15 ability to do.

16 However, one very good suggestion,
17 I thought, was that because the permitted
18 substances list is coming out anyway, which is
19 an affected database, it could be
20 incorporated. The approvals of Other
21 Ingredients could be incorporated into the
22 permitted substances list, where there will

1 already be some level of spreadsheet or
2 columns or some way to codify that when
3 something is added to that list, it could have
4 the Other Ingredients associated with it.

5 Another concern that many people
6 had is the commercial availability clause.
7 People were -- this would be applying the
8 issue of commercial availability to everything
9 on the National List.

10 Commenters came in all over the
11 map about this. This is something that the
12 committee, the Handling Subcommittee will
13 definitely be taking under advisement and
14 considering.

15 One thing that is very clear from
16 even the people who are proponents of Option
17 B, is that probably in the course of Sunset,
18 some of the inconsistencies in the past
19 reviews of things that are already on the
20 National List have to be cleaned up.

21 So we know that while some things
22 like the enzyme review, for instance, had very

1 long lists of all the Other Ingredients that
2 could possibly be in it, and the NOSB looked
3 at that and adopted the recommendation, there
4 are other things from the past.

5 One I can think of is the wax
6 materials, carnauba and wood resin that
7 although it was known there were Other
8 Ingredients, at the time no one knew what they
9 were, and we couldn't get disclosure or
10 cooperation from industry like we can today.

11 So they went on there with nothing
12 mentioned in Other Ingredients, which has
13 really had a strong detrimental effect on
14 keeping these products from being formulated
15 and used in organic food. So we have work to
16 do, and much of that work will happen in
17 Sunset.

18 Okay. I think that OTA correctly
19 pointed out that along with a policy, we have
20 to develop a whole review procedure. We have
21 to look at what we already have clearly, and
22 that's why we put the spreadsheet that we did

1 as an attachment to the recommendation, so you
2 can see where we started to try and compile
3 the past decisions.

4 But we have to look at what we
5 have, and then we have to develop some steps
6 for how we're going to move forward on this
7 under any scenario that we adopt. Those steps
8 might be somewhat similar to the inerts
9 proposal we gave, because after all, and I
10 joked about this in the college, they didn't
11 really get it, you want us to change the term
12 "inerts" and "other ingredients," and then we
13 have these other other ingredients.

14 Although my nickname for several
15 decades has been "Materials Girl," I think I'm
16 going to change it to "Other Ingredients
17 Girl," and we'll see how that flies.

18 But anyway, I want to thank all
19 the commenters for really giving some
20 thoughtful responses to what was really a very
21 complicated and detailed recommendation, and
22 we can assure you that we will be giving it

1 our close attention in the future. Thank you.

2 MR. FOSTER: Thank you, Zea, for
3 that, and thanks again. That was a tremendous
4 amount of work on the part of the
5 Subcommittee, but you shouldered a large
6 portion of that. So thank you very, very much
7 for that.

8 We have, by my clock, we have 16
9 minutes before we're scheduled for a break.
10 But if there's opportunities for discussion on
11 this last item or burning questions around any
12 of the other materials that we've looked at,
13 now would be the time to do that. Mac?

14 MR. STONE: I have two, but I
15 don't mind taking them one at a time. Where
16 are we going to bump into this confidential
17 business information aspect, as we dig into
18 incidental additives? If the definition of
19 incident means it doesn't have a technical or
20 functional effect on the food, then why is it
21 there?

22 MS. SONNABEND: Well, that last

1 one, I can't answer. So you'll have to ask it
2 to Dr. Anderson. As far as the first one yes,
3 we are always bumping into confidential
4 business information. But beyond that, the
5 biggest problem I see with Option C or D is
6 that it's going to ask for petitions for all
7 these so-called Other Ingredients.

8 It's very, very unlikely that
9 there's enough incentive for every single
10 other ingredient to petition individually to
11 have it, you know, have themselves included.
12 And so it's not a question as much of
13 confidentiality as disclosure.

14 We're not even going to find out
15 what those ingredients are, and that is a big,
16 big obstacle for adopting those options.

17 MR. FOSTER: I'll refrain from
18 asking if we need a COI policy on Other
19 Ingredients. I won't do that.

20 MS. SONNABEND: And partially in
21 answer to that question also, it's on our work
22 plan for the Materials Committee to revise the

1 COI policy that we already have or CBI, not
2 COI, Confidential Business Information. It's
3 something that I am committed to work on
4 between now and the next meeting.

5 MS. SONNABEND: Thank you, Zea.
6 Additional questions. Jay.

7 MR. FELDMAN: This is somewhat
8 related, because later, I think as we
9 discussed, the whole concept of soy formula,
10 there's one other element I wanted to bring to
11 the discussion, besides the issue of whether
12 we have adequately reviewed the implications
13 of the synthetic nature of soy isolate.

14 I direct this attention, this
15 question to Dr. Bhatia, about the estrogenic
16 properties of soy, and whether he or you
17 believe that there are issues that the
18 community should be concerned about in that
19 regard?

20 DR. BHATIA: The estrogenic
21 effects have been shown if you chop up soy
22 protein into individual components like

1 dianisidine and genistein, and feed it in
2 higher quantities in animal models.

3 The estrogenic reports have been
4 reported in case reports and from Puerto Rico,
5 where there has been recall after many, many
6 years, to see if the infants were fed soy
7 formula or not.

8 The estrogenic effects are also
9 based on a JAMA article, which recalled a
10 recall of 30 years later about a, and don't
11 quote me on the actual hours, 30 years later
12 about a probable three to four hour increase
13 in menstrual period, and that was indicated in
14 the statistical analysis.

15 And it was that clinically
16 relevant, even the authors said, to take that
17 in advisement. So basically the extensive
18 exhaustive review that has taken place through
19 the NIEHS times two, has really not shown
20 that in human infants that estrogenic as we
21 know it right now, while feeding soy isolate
22 protein formulas manufactured in the United

1 States, has any adverse effects.

2 So there's no, as far as I
3 concerned, there's no safety concerns on
4 estrogen in the human model as we know it.

5 MR. FOSTER: And you're saying
6 that's from real world data or clinical data
7 that you've reviewed?

8 DR. BHATIA: Yes sir.

9 MR. FOSTER: Thank you.
10 Additional question? I have one kind of
11 following that, but I'll wait until the other
12 people have a chance. Okay. So someone help
13 me, correct me if I'm wrong here, if it's soy,
14 is soy protein isolate? Is that considered --
15 have we defined that as synthetic, and if it's
16 not, then doesn't it need to be organic, if
17 it's in an organic product? Help me out here.
18 This is not my area of expertise clearly.

19 DR. ANDERSON: Soy protein isolate
20 has not been approved by the full Board as
21 synthetic or non-synthetic. It was petitioned
22 as a crop input a long time ago, and as a crop

1 input, it as determined to be synthetic by the
2 Crops Committee.

3 But they got bogged down in the
4 classification and materials issues, so it
5 never came to the full Board and they decided
6 to wait for the Classification and Materials
7 document.

8 Soy protein isolate in infant
9 formula or in food, processed food. If it is
10 organic soy, then it has not been hexane-
11 extracted. But there's no like ruling on
12 processed food that a food is synthetic or not
13 synthetic.

14 MR. FOSTER: Okay. That helps me,
15 thank you. Other questions for any of the
16 agenda items. With ten minutes to go, really?
17 With that then, I would thank you, Doctors,
18 for being here. It's been very, very helpful.

19 I also want to really thank --
20 the agenda for the Handling Subcommittee was
21 pretty aggressive this term, and I just, I
22 want to call out the program staff. Was very,

1 very supportive, very, very helpful in working
2 through a lot of complicated issues.

3 I just, I want to say thank you
4 for that. It was -- it was definitely a team
5 effort, and I appreciate that very, very much,
6 all of the staff. So thank you for that. If
7 that, that's all I have. So Barry, if you
8 want to take that virtual gavel back, it's all
9 yours.

10 CHAIRMAN FLAMM: I think we can
11 take a 15 minute break now and be back at,
12 what is it, five minutes after the hour, and
13 then John, you'll continue with the public
14 comments for your --

15 MR. FOSTER: Thank you, yes.

16 (Whereupon, the above-entitled
17 matter went off the record at 9:51 a.m. and
18 resumed at 10:08 a.m.)

19 MR. FOSTER: If we can reassemble
20 here, get started please. I have to get one
21 of these gavels for my office, I think, at
22 work. Thank you for your attention. Thanks

1 again to our guests this morning. We found
2 that we had some little conversations here in
3 the break, and the Board found that very, very
4 helpful. So we're very appreciative to have
5 you here.

6 I understand they will be here and
7 available through the proceedings, at least
8 through lunch. So I want to just mention that
9 for the Board members. All right, I'll stop.

10 All right. We are moving into our
11 public comment period for the Handling agenda.
12 We are six minutes ahead. Lovely to see that.
13 I haven't counted the number, but we have oh,
14 I don't know, 15 or 18, something like that,
15 to work through.

16 I will follow the pattern we have
17 started with, which is let, you know, two or
18 three people in line, let them know they're
19 coming up, and if anyone particularly
20 Michelle, I think you're the one who's advised
21 of last minute changes. If you could let me
22 know if there's any that I need to skip,

1 please let me know.

2 Other than that, the first three I
3 have here are Beverly Rich, Charlotte Valaise
4 and Brook Anderson, in that order. So if you
5 could just make sure to state your name and
6 affiliation prior to your comments, that would
7 be very helpful. Thank you.

8 MS. RICH: Hello. My name is
9 Beverly Rich. I'm a member of the Cornucopia
10 Institute, but I'm testifying today as a
11 concerned consumer. My personal interest in
12 organic foods is as a health-conscious
13 citizen. I rely on the government to certify
14 that foods are organic and trust this means
15 they're natural and safe without any
16 artificial ingredients.

17 As a 38-year vegetarian, consuming
18 primarily organics, I read lists of
19 ingredients. However, I was not aware of
20 hidden ingredients, especially in organics.
21 Thanks to the vigilance of the Cornucopia
22 Institute, I was informed that my trust in

1 organic certification was misplaced.

2 I was deeply disturbed to find
3 that synthetic ingredients, including known
4 toxins, are being added to organic foods under
5 the guise of "Other Ingredients" or as
6 unlisted components of organic product
7 ingredients.

8 Though I am an attorney, I'm not
9 familiar with food safety laws, but in
10 preparing my testimony did some research. I
11 found as expected that federal law prohibits
12 synthetic additives to organics, though with
13 the exception of ingredients accepted by the
14 NOSB for inclusion on a National List.

15 The Organic Foods Production Act
16 of 1990, Section 2111, 7 U.S. Code 6510 is
17 clear in stating that anyone handling
18 agricultural products covered under the law
19 must not add any synthetic ingredient not
20 appearing on the National List during
21 processing or post-harvest handling.

22 I was shocked when I learned that

1 unapproved ingredients such as polysorbate 80,
2 sodium benzoate, polyacrylamide and numerous
3 other synthetics, which I carefully avoid when
4 I am aware of them, are routinely added to
5 organic foods as components of the ingredients
6 on the National List.

7 I was even more appalled to learn
8 that toxic materials, such as hexane and
9 propylene glycol, are routinely used in the
10 processing of ingredients found in organic
11 foods. This is a clear violation of the law,
12 and a betrayal of the trust of American
13 consumers.

14 I am not an expert in food science
15 or food processing, nor do I wish to become
16 one. I want to be able to trust the organic
17 label. The organic foods law assures me that
18 each and every ingredient, no matter how
19 small, has been carefully vetted by the NOSB,
20 satisfies organic handling requirements, and
21 is safe for consumption.

22 Now I've learned that the NOSB and

1 the USDA have ignored this important legal
2 requirement, that up to five percent of the
3 ingredients in organic foods may contain
4 unapproved synthetics, which could include
5 toxins and/or carcinogens and more with no
6 oversight.

7 Organic consumers like myself do
8 not want unapproved synthetics in their
9 organic foods, period. Frankly, I don't want
10 any synthetics, but the current law does not
11 seem to give me that choice. I'm not alone in
12 these sentiments. A survey completed in
13 August 2012 by over 1,400 customers of PCC
14 Natural Markets in Seattle, the largest
15 cooperative grocer in the country, confirms
16 such consumer preferences.

17 PCC concluded from their survey
18 that their customers strongly prefer that
19 anything added to their food be from natural
20 sources, not synthetic, and that many, if not
21 most of them, prefer that nothing at all be
22 added to whole organic foods.

1 For instance, 90 percent of
2 customers would not purchase foods with Omega-
3 3's made with synthetic additives or agents,
4 including hexanes, glucose, syrups, solids and
5 modified starch.

6 The inclusion of synthetic
7 preservatives, sweeteners and other unapproved
8 ingredients in organic foods constitutes a
9 massive industry-wide violation of the organic
10 law. It needs to be corrected.

11 Solution, simple. Follow the law.
12 Respect consumer preferences and reasonable
13 expectations. Non-organic and non-agriculture
14 ingredients and processing aids used during
15 organic handling must appear on the National
16 List.

17 Please, don't force us to return
18 to the days, prior to the adoption of organic
19 standards, where consumers had to grow their
20 own food or buy direct from trusted farmers,
21 to ensure a supply of natural and safe food.
22 Thank you for the opportunity to comment.

1 MR. FOSTER: Nicely timed. Quick,
2 quick. Is there a question from the Board?

3 MS. RICH: My apology. This is my
4 first time testifying.

5 MR. FOSTER: No problem, no
6 worries. Question? All right. Thank you for
7 your time.

8 MS. RICH: Thank you.

9 MR. FOSTER: Next up, we have
10 Charlotte Vallaeys. Again, Brook Anderson on
11 deck.

12 MS. VALLAEYS: Good morning. My
13 name is Charlotte Vallaeys. I'm the Director
14 of Farm and Food Policy at the Cornucopia
15 Institute.

16 I have a Master's degree in
17 Nutrition Science and Policy from Tufts
18 University. I also have a Master's degree
19 from Harvard, where I studied Social and
20 Environmental Ethics from the Harvard Divinity
21 School.

22 I'd like to thank all of you for

1 your hard work, with a special thanks to
2 Barry. Almost five years ago was my first
3 time attending an NOSB meeting. It was also
4 Barry's first meeting. I will miss you very
5 much, Barry, and I know a lot of others in the
6 organic community will as well.

7 I'd like to thank the Handling
8 Subcommittee for your very thorough work on
9 these petitions, and especially for inviting
10 experts in infant nutrition to weigh on these
11 very important questions.

12 We agree with the committee's
13 recommendation to reject taurine, lycopene and
14 lutein. They are produced in ways that are
15 legally incompatible with organic handling,
16 involving neurotoxic synthetic solvents. They
17 are not essential.

18 Experts agree that the scientific
19 evidence does not show the claimed benefits
20 exist. It's important to note also that the
21 European Union does not even allow lutein and
22 lycopene in any infant formula, including

1 conventional. They are prohibited by all
2 other international organic standards.

3 Any claims of safety are based on
4 their GRAS status, generally recognized as
5 safe with the FDA. GRAS status relies
6 entirely on safety testing submitted by the
7 petitioner.

8 No independent or long-term safety
9 tests are required, and we know that post-
10 market surveillance by the formula
11 manufacturers is woefully inadequate.

12 This system has been widely
13 criticized as inadequate to protect public
14 health, including by the Governmental
15 Accountability Office, and we urge the NOSB to
16 uphold our higher organic standards.

17 We'd like to thank the Handling
18 Subcommittee also for your very thorough work
19 on the petitions for beta carotene and
20 ascorbyl palmitate, which were petitioned for
21 use as preservatives, and we support the
22 unanimous decision to reject.

1 We also appreciate the
2 clarification from the two experts that these
3 are in fact preservatives. There is a
4 petition material that presents us with a bit
5 of a dilemma, L-methionine. It appears to be
6 required in soy-based formula only. If it is
7 not added, infants on soy formula would not
8 grow and develop properly.

9 Currently, the only sources that
10 appear commercially available are synthetic.
11 The TR states that L-methionine's production
12 includes material such as acryline and EPA
13 hazardous air pollutants, and hydrogen
14 cyanide, described by the CDC as a systemic
15 chemical asphyxiant and a chemical warfare
16 agent.

17 So it is essential, because soy-
18 based infant formula is such an inherently
19 inadequate unhealthy food for human infants,
20 that it requires the addition of synthetic
21 macronutrients, just to keep the infants
22 alive.

1 But production involves synthetic
2 and polluting substances, and is therefore
3 incompatible with organic handling. So let me
4 ask you a question. At what point is a food
5 no longer a food, but a chemical substitute
6 for food, and do chemical substitutes for food
7 deserve the organic label?

8 In the European market, organic
9 soy-based formula does not exist. Where will
10 we draw the line? When the caregiver of an
11 infant sees the organic label on a soy-based
12 formula, their assumption is great; somebody
13 figured out how to make an organic soy
14 formula, with organic and natural ingredients.

15 Approving any additional
16 synthetics for formula would be a huge blow to
17 consumer trust in the organic label. Thank
18 you.

19 MR. FOSTER: Thank you.
20 Questions. Calvin.

21 MR. WALKER: Thank you, John. My
22 question is what would be your views, as it

1 relates to consumers' belief or support for
2 synthetics in infant formulas?

3 MS. VALLAEYS: I think in public
4 comments, the consumers have voiced their
5 opinion on this very clearly, and thousands
6 have commented that they do not think that
7 synthetics belong in organic products.

8 That includes organic infant
9 formula. I do think that when a mother or a
10 caregiver for an infant who needs formula sees
11 the organic label on a product, on that
12 formula, that they do think it's organic.
13 They don't know that it contains the exact
14 same synthetics that are in the conventional,
15 that it is essentially the same in that
16 regard.

17 I think that that is very
18 misleading, and especially for the synthetic,
19 the two synthetic preservatives. I'd like to
20 point out that the natural label is heavily
21 criticized, of course, in the organic
22 community, because it is self-defined and it's

1 so restrictive.

2 There's yet one of the criteria
3 for the natural label that the industry can
4 agree on is no synthetic preservatives, right.
5 So imagine the consumer confusion when it
6 becomes clear to them that an organic product
7 has synthetic preservatives. It wouldn't even
8 qualify for the industry's own natural label.

9 That is going to be a huge blow to
10 again consumer trust in the organic label,
11 that it contains natural and organic
12 ingredients.

13 MR. FOSTER: Jay.

14 MR. FELDMAN: Thank you, John. Hi
15 Charlotte. Can you walk us through the
16 practical effect of a decision to not allow
17 methionine?

18 What impact would that have on
19 what percentage of people that are now relying
20 on soy formula? What are the alternatives to
21 that, and what impact would we have in the
22 marketplace?

1 MS. VALLAEYS: It's important to
2 consider the expert advice we heard this
3 morning about the need for soy-based infant
4 formula, that it is -- in other countries,
5 rates of use are around two percent is what we
6 heard, that it is in fact not necessary for
7 colic.

8 Right now, it appears, from what I
9 understood, that that's kind of abused, that
10 if your infant has colic, you just immediately
11 grab the soy-based formula, really without
12 that being necessary. So at that point, I
13 think soy-based formula has to shift away from
14 being considered a food, and more of a medical
15 product.

16 Again in New Zealand, you have to
17 go to the pharmacist, is what we heard this
18 morning, because it is considered a medical
19 product more than a food. I think that that
20 is very appropriate.

21 MR. FOSTER: Charlotte, just I
22 want to kind of make sure we're talking about

1 methionine. Jay, I know that your question --

2 MS. VALLAEYS: Right, right. But
3 the question --

4 MR. FOSTER: Just bring it back,
5 that's all. Just bring it back.

6 MS. VALLAEYS: So if --

7 MR. FELDMAN: No, just so John
8 understands, excuse me, the impact. If we're
9 going to have soy on the market, the experts
10 seem to agree that it doesn't perform any
11 function, and it could be detrimental without
12 methionine, without that amino acid. That's
13 a missing piece.

14 So the implication is pretty
15 dramatic, you know, if the Board rejects
16 methionine. I understand that that would
17 undermine the market for soy in the U.S. And
18 correct me if I'm wrong on this, I just want
19 to make sure.

20 Now I'm not saying that the Board
21 shouldn't do that, and I had another question
22 about soy isolate and sort of your opinion on

1 that.

2 But I want, I'd like to be clear
3 about what the impact of that decision is, and
4 whether there are alternatives, and you're
5 describing a discrete part of the market that
6 uses this for medical purposes, that might
7 need it for medical purposes, and that's how
8 you're describing that percentage of the
9 market.

10 MS. VALLAEYS: Right, because if
11 L-methionine is rejected, I do think soy-based
12 formula with the organic label would not be
13 possible. I mean I wouldn't want to see an
14 organic soy formula without L-methionine, that
15 infants are going to not grow and develop
16 properly. Nobody wants to see that.

17 But at the same time, what we also
18 don't want is to mislead consumers into
19 thinking that this is organic, yet it contains
20 this L-methionine that is synthetic, very
21 problematic in how it's produced.

22 So that is the dilemma, and I

1 think that's a decision that needs to be made.
2 But considering what we heard about the actual
3 need for soy-based formula for infants.

4 MR. FOSTER: Thank you. Harold.

5 MR. AUSTIN: Charlotte, thank you.

6 I think listening to your presentation right
7 now just kind of helps to emphasize for all of
8 us the struggles that we have with some of the
9 decisions that we try to make up here, that
10 what is right and what isn't right.

11 In this particular situation, when
12 should a synthetic be allowed, and under what
13 circumstance. So I appreciate your
14 presentation. You're walking through the
15 explanation.

16 But I think it also helps to show
17 the difficulty and the degree of difficulty
18 that these decisions bring with them on all of
19 these materials, and I appreciate your
20 presentation, your clarity on what you just
21 brought forth to us. Thank you.

22 MR. FOSTER: Additional questions?

1 (No response.)

2 MR. FOSTER: All right, thank you.
3 Next up we have Brook Anderson, Eric Lien or
4 Lean on deck. Yes, Brook Anderson, Perrigo
5 Nutritionals.

6 MR. ANDERSON: My name is Brook
7 Anderson. I'm the Director of Product
8 Development at PBM Nutritionals. I've been
9 developing and making infant formula for 29
10 years, all in one location in Vermont. Breast
11 milk is best, but we offer the best
12 alternative available for parents who, for
13 whatever reason, choose not to breast feed.

14 While many ingredients are not
15 mandated by the FDA to be added to infant
16 formula, advances in nutritional sciences and
17 research obligate infant formula manufacturers
18 to identify and add new ingredients to infant
19 formula, in order to provide optimal,
20 wholesome and safe infant nutrition.

21 I'm going to talk about two
22 petition substances. Beta carotene is the

1 first one. Beta carotene, which was discussed
2 earlier, is a source of Vitamin A and also a
3 vitamin-based antioxidant. Beta carotene is
4 a vitamin that should already be allowed in
5 the organic products under CFR 205.605.

6 Beta carotene is added to the PBM
7 infant formulas to mimic the levels of beta
8 carotene commonly found in breast milk. Beta
9 carotene was first added to U.S. infant
10 formula in 1933. It may also serve as an
11 antioxidant.

12 Beta carotene is also a vitamin-
13 based antioxidant that acts to scavenge
14 oxygen, and typically used in a combination
15 with other various substances including
16 tocopherols, ascorbyl palmitate, etcetera. As
17 an antioxidant, beta carotene serves to
18 protect fats, lipids and fat-soluble vitamins.

19 Because of its synergistic effect
20 among vitamin-based antioxidants, beta
21 carotene serves an essential role in the
22 keeping quality of infant formula.

1 The only source of beta carotene
2 allowed for use in the U.S. is synthetic beta
3 carotene. Other potential sources that have
4 been mentioned previously, for example,
5 natural carotene or red palm oil are not
6 currently allowed or used in infant formula,
7 and would require GRAS notification safety
8 before their use.

9 Beta carotene is also listed as an
10 approved source of Vitamin A for direct
11 fortification for infant formula. US FDA,
12 CODEX, GB, China Regulations and allowed by
13 Health Canada.

14 Beta carotene is not toxic at high
15 levels unlike Vitamin A, and is a safe,
16 nutritional nutrient, an essential part of the
17 total Vitamin A content, required for optimal
18 infant nutrition or for meeting the total
19 Vitamin A content of the product.

20 The next petition substance is
21 ascorbyl palmitate. It is also known as AP.
22 It's a vitamin-based antioxidant. Its primary

1 use in infant formula as an antioxidant
2 required for nutrient stability. Its
3 secondary effect is for sensorial
4 preservation, a keeping quality of infant
5 formula.

6 AP is GRAS-approved, is an
7 approved source of Vitamin C, and is an
8 antioxidant that is approved and accepted for
9 use in infant formula by various regulatory
10 agencies, including U.S. FDA, CODEX, the EU
11 Commission and is allowed in Health Canada for
12 use in infant formula.

13 AP is a unique antioxidant, as it
14 is a fat-soluble form of Vitamin C, and is
15 very effective in limiting oxidation reactions
16 in fats. Infant formula contains
17 approximately 28 percent fat, and contains
18 several fatty acids and fat-soluble vitamins
19 that are very susceptible to oxidation.

20 Preventing oxidation is thus
21 critical to the nutritional quality of the
22 product. Ascorbyl palmitate is but one

1 essential substance of the total fat-soluble
2 antioxidant system used in infant formula.

3 AP is used in various combinations
4 with other vitamin substances, tocopherols,
5 beta carotene, etcetera. Due to the
6 synergistic effect that ascorbyl palmitate
7 exhibits on limiting oxidation, the essential
8 role that AP exhibits in various antioxidant
9 systems is well-documented.

10 Rosemary extract, which has been
11 suggested as an alternative to AP, is not
12 currently allowed in infant formula. Rosemary
13 extract also has never been tested, is a
14 completely different chemical structure than
15 AP, and therefore is not an option or isn't
16 considered a viable alternative at this time.

17 Ascorbyl palmitate is thus an
18 essential part of the antioxidant system used
19 in infant formulas. Without AP, our infant
20 formula products would oxidize to the point of
21 not being suitable for consumption within
22 three to six months of manufacture. A shelf

1 life of three to six months is not variable,
2 is not commercially viable. Sorry about that.
3 I went over.

4 MR. FOSTER: Thank you

5 MR. ANDERSON: Last slide. I
6 thank the Board for letting me speak.

7 MR. FOSTER: Thank you. Questions
8 or comments? Jean, Nick, Zea.

9 MS. RICHARDSON: Yes. My question
10 relates to the shelf life and the effect of
11 potential rancidity on the infant formula. So
12 if you don't add the beta carotene and the
13 ascorbyl palmitate, and the food goes rancid,
14 what will be the effect on the infant eating
15 this food, consuming this food?

16 MR. ANDERSON: Fatty oxidation is
17 very complex, but there's a lot of things when
18 fats oxidize. There's a lot of byproducts of
19 fat oxidation that would be considered then,
20 that would not be safe for infants. It's just
21 not a good thing to have, you know, oxidized
22 fats in any type of product, especially infant

1 formula.

2 MS. RICHARDSON: Yes, but what
3 happens to the kid? You give it the formula,
4 did it throw up, get diarrhea?

5 MR. ANDERSON: You could have --
6 I'm not a doctor, but diarrhea is one example
7 that could happen.

8 MS. RICHARDSON: So it has some
9 like food safety aspects to it?

10 MR. ANDERSON: Yes, yes. I think
11 the FDA would be very concerned about oxidized
12 fats, which I think Sue Anderson had mentioned
13 earlier.

14 MR. FOSTER: Nick.

15 MR. MARAVELL: Yes. Just out of
16 curiosity, if you were to take dry infant
17 formula that would have a shortened shelf life
18 of three to six months, and instead of keeping
19 it on the shelf, put it under refrigeration,
20 what would be the impact of the shelf life,
21 and if it were labeled "keep refrigerated
22 until opened" or something like that?

1 MR. ANDERSON: Refrigerated at
2 what, 45 or less?

3 MR. MARAVELL: 45 degree
4 refrigerated temperatures?

5 MR. ANDERSON: Excuse me?

6 MR. MARAVELL: When you talk about
7 temperatures, what temperature are we talking
8 about, 45 degrees or less when you refer to
9 refrigerated temperatures?

10 MR. ANDERSON: Yes, approximately
11 41 degrees, yes. Well, it's never been
12 studied and I think in, you know, for this
13 product sold in the United States, this is not
14 a product where you find in a refrigerated
15 section. It's just I've never heard of infant
16 formula being sold that way. I don't know if
17 it's commercially viable.

18 MR. MARAVELL: Right. But what
19 might be the expected effects?

20 MR. ANDERSON: I wouldn't know.
21 We've never studied it, just because in
22 commercial practice, that's not the way it's

1 sold, distributed. So I don't have an answer
2 for that.

3 MR. FOSTER: Go ahead, Zea and
4 then Calvin.

5 MS. SONNABEND: My question is
6 similar to what I asked Dr. Anderson and Dr.
7 Bhatia. If you put in beta carotene to get,
8 enough to get Vitamin A activity, would that
9 also be enough quantity as an antioxidant, or
10 is it a different quantity that you're adding
11 for one or the other?

12 MR. ANDERSON: Typically, they're
13 different quantities, because antioxidants is
14 a very complex system. Sometimes, if you add
15 more of these substances, that can serve as a
16 pro-oxidant. It's very complex and there's
17 many, you know, there's many combinations, I
18 should say, of these substances added.

19 But the level that you find
20 typically in our product will be in a range of
21 two to four hundred IUs per liter. That level
22 would be similar to that found in human breast

1 milk. It may have some antioxidant effect,
2 but typically antioxidants by definition are
3 added at very low levels.

4 MR. FOSTER: Thank you. Calvin.

5 MR. WALKER: If these two
6 materials are voted down, what would be the
7 impact? What would you do in terms of an
8 alternative?

9 MR. ANDERSON: For ascorbyl
10 palmitate, there isn't any. That's the honest
11 answer. There is none. It's a very, very
12 critical part of protecting this product. So
13 if the committee were to vote ascorbyl
14 palmitate out, we'd have a serious problem
15 with the viability of this product, commercial
16 availability.

17 MR. FOSTER: And last call? All
18 right. Thank you very much.

19 MR. ANDERSON: Thank you.

20 MR. FOSTER: Next we have Eric
21 Lien or Lane. I apologize for not getting one
22 of those right, and then Diane Wilson on deck.

1 DR. LIEN: Good morning. It's a
2 pleasure to be here to address you today. I
3 am currently adjunct professor, Department of
4 Food Science and Human Nutrition at the
5 University of Illinois. Previously, I was
6 Vice President of Nutrition Research at Wyeth
7 Nutrition and have more than 25 years of
8 experience in pediatric nutrition.

9 I'll provide a very brief
10 introduction to infant nutrition, talk about
11 three components of interest, taurine,
12 nucleotides and carnitine, and draw some
13 conclusions.

14 Birth weight of term infants
15 typically doubles in the first three to four
16 months of life. We realize that either breast
17 milk or formula may be the only source of
18 nutrition during this time. So it's important
19 that we find complete feeding systems.

20 What we realize is that human milk
21 is by far the preferred means of providing
22 nutrition to infants. If the mother cannot or

1 chooses not to breast feed, then substitutes
2 of the highest quality must be available.
3 Infant formula is really the only choice and
4 must meet all nutritional needs of the infant.

5 Let me move to components of
6 interest. Taurine functions. Taurine is
7 essential for retinal function. It's a
8 component of the predominant bioacid required
9 for fat absorption in term infants. As you
10 see in the draft here, it's found in
11 exceptionally high concentrations of human
12 milk, and exceptionally low concentrations in
13 both cow's milk and formula.

14 If we look at plasma taurine
15 levels during the first 12 weeks of life in
16 term infants, we see that breast-fed infants
17 have a substantial increase in taurine levels
18 during that time, and unsupplemented formula-
19 fed infants have a substantial decrease, with
20 a highly statistically significant difference
21 at the end of 12 weeks of life.

22 If we look at taurine function in

1 the retina, retina function deteriorates
2 during taurine deficiency, and this is most
3 often seen in either pre-term infants or
4 individuals receiving total parenteral
5 nutrition.

6 Taurine supplementation can
7 reverse these abnormalities, and we can come
8 to the conclusion that taurine does play an
9 essential role in normal visual development.
10 There's also data that indicates that taurine
11 supplementation or taurine plays a role in
12 cognitive, that is mental development, in
13 infants.

14 Let me briefly move to
15 nucleotides. These are simply the monomers of
16 RNA, so RNA being important in all genetic
17 expression. Nucleotides, when added to infant
18 formula, have three roles. They have a GI
19 anti-infective effect, less diarrhea during
20 the first year of life.

21 Immune system is closer to breast-
22 fed infants, improved immunoglobulin

1 production to vaccines, for instance, and the
2 GI maturation effect, which permits nutrient
3 absorption, especially in small poor
4 gestational age term infants. A dietary
5 supply is essential during the first period of
6 rapid growth, such as during infancy.

7 Finally, carnitine is essential
8 for the metabolism of fat. Carnitine couples
9 to fatty acid in the cytosol of the cell.
10 That transports the fatty acids into the
11 mitochondria, where fatty acids then are
12 burned for energy.

13 Carnitine deficiency results in
14 increased urinary excretion of unburned fatty
15 acids, soy formulas and some milk-based
16 formulas require supplementation, and for
17 instance, the EU requires supplementation at
18 one point, two milligrams per hundred kcals of
19 soy formulas. Insufficiency may result in
20 hypoglycemia and failure to thrive.

21 So I just will bring to conclusion
22 human milk and formulas must be complete

1 feeding systems. I've discussed three
2 nutrients, taurine, nucleotides and carnitine.
3 Taurine and carnitine have been added to
4 formulas for more than the last 25 years.

5 So we will not see deficiency
6 syndromes coming from feeding systems. These
7 nutrients support essential bodily functions,
8 and they should be included in infant formula.
9 Thank you for your attention, and I'd be happy
10 to answer questions you may have.

11 MR. FOSTER: Questions? Zea.

12 MS. SONNABEND: Thank you. We
13 heard from our experts earlier that carnitine
14 is not required by the FDA, but L-methionine
15 is. One of the reasons cited was that if you
16 received enough L-methionine, your body could
17 make L-carnitine.

18 I'm wondering if what your
19 perspective is on that subject, and whether an
20 infant can create enough L-carnitine from an
21 L-methionine supplementation.

22 DR. LIEN: This is a matter of

1 maturation. Certainly as adults, who are
2 eating mixed diets, where we see dietary
3 carnitine. But vegetarians and vegans are
4 also capable of synthesizing L-carnitine.

5 Carnitine will increase in
6 production as the infant matures, but it is my
7 opinion in current infant formulas, if
8 carnitine is not present in sufficient
9 amounts, it should be added, to cover any
10 synthetic immaturity of the infant.

11 MR. FOSTER: Jean.

12 MS. RICHARDSON: My question is on
13 taurine. If, you stated that taurine is
14 essential, but it's not required. So can you
15 help us to understand why it's not required if
16 it's essential?

17 DR. LIEN: It's clear in
18 experiments in taurine deficiency that there
19 are problems of fat absorption and also of
20 visual maturation. The FDA approved taurine
21 for use in infant formulas in 1984, and it has
22 been added to all formulas since that time.

1 We will not, under these
2 conditions, see taurine deficiency. Dr.
3 William Heird at the USDA Children Nutritional
4 Research Center in Houston, has indicated it's
5 his opinion that it would be at this point
6 unethical to do further experiments into
7 taurine deficiency, because it may lead to
8 untoward consequences, which I've indicated
9 here.

10 So it will be a very difficult
11 nutrient to remove from formula. We really
12 don't know what kind of situations we may put
13 infants who have true taurine deficiency in,
14 without that added component.

15 MR. FOSTER: Thank you.

16 Additional questions? Colehour.

17 MR. BONDERA: Sorry about that.

18 Thank you. I apologize, and thank you for
19 your testimony, Dr. Lien. I just, I apologize
20 that I may have missed this at the beginning.

21 But according to my sheet, and
22 according to what you're presented, I'd like

1 you to not necessarily repeat your
2 qualifications, but who you're here
3 representing or what brings you here today?

4 I understand and appreciate your,
5 you know, experience and presentation.

6 DR. LIEN: Thank you. I did
7 indicate in my qualifications that I am
8 retired Vice President of Nutrition Research
9 for Wyeth Nutrition, who was a manufacturer of
10 infant formula, and I have been here at the
11 request of the formula manufacturers.

12 MR. BONDERA: Thank you.

13 MR. FOSTER: Additional questions.
14 Harold.

15 MR. AUSTIN: On these three
16 materials, are you aware of any formulas right
17 now, currently on the market, that do not
18 include these three products?

19 DR. LIEN: No, I am not. I should
20 indicate that for carnitine, there are some
21 milk-based formulas that have sufficient
22 endogenous carnitine, which is present in

1 cow's milk. Not to add it, but they would
2 have more than the required amount for soy
3 formula already endogenously provided by
4 bovine milk.

5 MR. AUSTIN: Thank you.

6 MR. FOSTER: Thank you. Last
7 question, Calvin.

8 MR. WALKER: As it relates to
9 infants, does these deficiencies continue
10 after the infancy or breast feeding or milk
11 feeding period, these deficiencies that you
12 mentioned?

13 DR. LIEN: As we move through the
14 weaning process, introduction of what we'd
15 call complementary foods, these foods will
16 start to introduce these components to the
17 infant and young child through other sources.

18 The critical period is the time of
19 exclusive feeding. So that as long as six
20 months, and that's the time when we would be
21 most concerned, as a sole source of nutrition.
22 We as adults have a mixed diet. If we're

1 insufficient in one nutrient from some
2 component of our diet for a few days, it's
3 truly immaterial.

4 This very rapid growth rate may be
5 supported by only one source of nutrition. It
6 must be complete.

7 MR. FOSTER: Thank you. All
8 right. I appreciate your time. Next, we have
9 Diane Wilson with John Ashby on deck.

10 MS. WILSON: Good morning, and
11 thank you for letting me be here today. I'm
12 Diane Wilson. I am Director of Nutrition
13 Services for Nature's One, the manufacturer of
14 organic pediatric medical nutritional
15 products.

16 I would like to remind this Board,
17 as I did at the May Albuquerque meeting, that
18 I'm not talking about infant formula; I am
19 talking about medical nutritional enteral
20 products. These are products that are for
21 medically nutritionally fragile children.

22 Our products are specifically for

1 children, toddler to 13 years of age. These
2 are products that must be usually fed either
3 tube-fed by nose or through the stomach, in
4 order for the child to receive appropriate
5 nutritional care.

6 My comments are that if a nutrient
7 is essential for infant nutrition, then it
8 obviously is going to be essential for a child
9 who requires medical nutritional care. My
10 request is that you amend your proposals to
11 include infant nutrition or infant formula
12 rather, and medical nutritional enteral
13 products.

14 In addition, the proposal for soy
15 isolate should be changed to soy protein. Our
16 products for older children, even though tube-
17 fed, contain soy protein concentrate and not
18 soy isolates. So please consider that
19 recommendation also from me.

20 Next, I want to remind you that at
21 the May meeting, the question arose as to
22 whether we would continue looking for organic

1 alternatives to these essential nutrients that
2 unfortunately are synthetic.

3 My answer was of course we would.
4 I used a different term, which I think got a
5 chuckle out of the group. But we did, and we
6 are. If you remember, choline was one of the
7 topics for the last meeting.

8 Since that time, we have found
9 that our toddler formula with DHA, which I
10 will remind you is not the algal fungal
11 sources of DHA and ARA, but egg phospholipid
12 source, a natural source, we have found that
13 we do not need to add choline bitartrate to
14 our formula with DHA, because the egg
15 phospholipid source provides the natural
16 choline needed to meet the child's nutritional
17 needs.

18 With that, I will close my
19 comments and then be more than welcome to
20 answer any questions. Thank you very much.

21 MR. FOSTER: Thank you. Do we
22 have questions? Jay.

1 MR. FELDMAN: Thank you. Are your
2 products used by prescription only?

3 MS. WILSON: No.

4 MR. FELDMAN: So when you say
5 "medical," who's determining the medical need?

6 MS. WILSON: Well, they're not
7 exclusively used under medical --

8 MR. FELDMAN: I'm sorry. So can
9 you describe that product line that is -- is
10 there any product line that's prescribed?

11 MS. WILSON: I wouldn't say
12 they're prescribed. They're recommended, but
13 obviously for a child that's being tube-fed,
14 there are many alternatives.

15 But most of them are non-organic.
16 I would say just about all of them are non-
17 organic, except for ours. So they would be
18 recommended by the health care professional.

19 MR. FELDMAN: Thank you.

20 MS. WILSON: I believe Dr. Bhatia
21 would agree. Hopefully you and your Committee
22 on Nutrition would agree that for a child in

1 need of a medical nutritional enteral product,
2 these essential synthetic nutrients are
3 extremely important.

4 MR. FOSTER: We'll certainly put
5 that question in the queue for later
6 questioning. Thank you. Do we have more
7 questions for the commenter?

8 (No response.)

9 MR. FOSTER: Okay. Thank you very
10 much.

11 MS. WILSON: Thank you.

12 MR. FOSTER: Next, we have John
13 Ashby, followed by Peggy Miars.

14 MR. ASHBY: John Ashby with
15 California Natural Products. Once upon a
16 morning dreary, while I pondered weak and
17 weary; over many a quaint and curious volume
18 of the CFR, while I nodded, nearly napping,
19 suddenly there came a tapping, as of something
20 gently rapping, rapping at my chamber door.

21 'Tis Other Ingredients tapping,
22 tapping at my chamber door, only this and

1 nothing more. But that is enough, Lenore.
2 How distinctly I remember it was back in bleak
3 October when each separate incidental wrought
4 its ghost upon our door.

5 From my books surcease of sorrow,
6 sorrow for the incidentals. Harmless barely
7 even present, whom the angels named Lenore,
8 called incidentals now and forevermore. In
9 the silken, sad uncertain future of processed
10 organics thrilled me, filled me with fantastic
11 terrors never felt before.

12 So that now, to still the beating
13 of my heart, I stood repeating "processed
14 foods, they are the gateway, in our now
15 organics heyday. Can they really be
16 destroyed? Our enemies won't be annoyed."

17 605 keeps processed growing,
18 unprocessed if we close the door them, growth
19 organics nevermore. Presently, my soul grew
20 stronger, hesitating then no longer. Sir,
21 said I or Madam, truly your forgiveness I
22 implore.

1 But the fact is we've been
2 growing, and so gently you came rapping, and
3 so faintly you came tapping, tapping at my
4 chamber door, that I scarce was sure I heard
5 you, processed organics on the floor; growth
6 organics nevermore.

7 Perfection just cannot be met. We
8 go that way, we lose the bet. That feeds our
9 enemies and we have them. Think otherwise and
10 you will let them beat us. Please make no
11 mistake; the risk is real, this is the stakes.
12 When we were small, we were no threat. Who
13 cares? So what? Big deal, no sweat.

14 But now it may just be our time,
15 and if we really mind the store, then growth
16 organics evermore. And organics never
17 flitting, still is sitting, still is sitting
18 on the milestone of our successes, just beyond
19 our reach and grasp.

20 But we must be both wise and
21 reasoned, careful, balanced, cautioned,
22 seasoned. If we do, then we can have, what it

1 is we most desire, what can be weakened
2 nevermore, growth organics evermore.

3 Now I can't explain incidental
4 ingredients or technical effects in the food
5 if you wish. My bias is really so strongly,
6 does it increase or decrease organic acreage,
7 while keeping within whatever we define as the
8 sphere of maintaining that organic aspect well
9 enough.

10 But also don't let the perfect be
11 the enemy of the way better. You know, let's
12 remember there is a 100 percent category for
13 people who insist upon this. Processed growth
14 is the gateway, and I want to mention, this
15 opens in and it opens out.

16 A positive list of incidentals
17 runs the risk of wiping out huge sections of
18 processed foods, for reasons I'm happy to go
19 into. Okay, here it goes.

20 Option A, I think legally
21 suffices. This is a food. Food has specific
22 way. It deals with the word "ingredients."

1 I agree with Zea. I think we need some
2 lawyers to get in on that.

3 Reviewing these things when we go
4 through it is just a wonderful, is a wonderful
5 idea. This is a good thing. It's the risk of
6 having a positive list that holds the specter
7 open for finding something at parts per
8 trillion in a product, which then causes a
9 recall. You cannot build brands with that
10 kind of risk; you just can't.

11 By the way, the meter is trochaic
12 octameter.

13 MR. FOSTER: Well, let this former
14 Literature major say, thank you for that. It
15 warms my heart, and certainly appropriate in
16 the -- just down the street from the
17 birthplace of Edgar Allen Poe, of course.

18 MR. ASHBY: And in a ghost hotel.

19 MR. FOSTER: Indeed, indeed. Do
20 we have questions for Mr. Ashby? Yes, you
21 will be needing to use iambic pentameter for
22 your questions. Or free form. Free verse is

1 fine. No questions.

2 I would ask for a copy in writing
3 of that little diddy, if you don't mind.

4 MR. ASHBY: Okay. I'll get it to
5 you. Okay, thank you.

6 MR. FOSTER: Thank you very much.
7 Next we have Peggy Miars, followed by
8 Gwendolyn Wyard.

9 MS. MIARS: Thanks, Michelle, for
10 putting me after that.

11 (Laughter.)

12 MS. MIARS: Good morning. My name
13 is Peggy Miars, and I'm Executive Director of
14 OMRI, the Organics Materials Review Institute.
15 My comments today will focus on the Other
16 Ingredients discussion document that was
17 brought by the Handling Subcommittee.

18 OMRI provided written comments on
19 this subject as well, and as a participant in
20 the Materials Working Group, OMRI also
21 provided input to the various options
22 presented by the Subcommittee, including some

1 of the pros and cons that were listed for
2 each.

3 My comments today address two
4 specific points about the importance of
5 adopting a policy, and carefully considering
6 the evidence that's presented to you by
7 various stakeholders with experience on this
8 issue.

9 First, I want to reiterate the
10 importance of adopting a policy to address
11 this issue. However, before doing so, the
12 NOSB should understand the scope of Other
13 Ingredients currently being used and their
14 purpose, as some commenters have suggested, to
15 understand the impact of your recommendation
16 on the organic marketplace.

17 The presence of Other Ingredients
18 and their allowance has been a source of
19 confusion or inconsistency for many years.
20 Although OMRI has been consistent in our
21 approach to this issue, our daily interactions
22 with certifiers discussing Other Ingredients

1 tell us that there is a range of approaches
2 to, and interpretations of this issue.

3 The NOSB has not been consistent
4 in how it has recognized, reviewed and
5 annotated other ingredients. So we're happy
6 to see you address this issue and treat it as
7 seriously as it deserves to be treated.

8 We hope that you will take into
9 account the many opinions and comments, and
10 decide on a reasonable policy that's both
11 practical and that protects the integrity of
12 the organic label.

13 OMRI's policy on Other Ingredients
14 is actually a combination of Option C that's
15 presented in the discussion document, and
16 Option D, as presented in some organization's
17 public comments, including the Cornucopia
18 Institute and Beyond Pesticides.

19 We would like to offer our
20 experience as one of the few organizations
21 that has practiced the alternative Option D.
22 This alternative option proposed by these

1 organizations stipulates in a nutshell that
2 Other Ingredients be organically produced or
3 be on 205.605 or 205.606.

4 OMRI's policy has always been to
5 require that Other Ingredients be organically
6 produced, or be provided for in the
7 annotation, or be on 605 or 606. In rare
8 cases, we've allowed Other Ingredients that
9 have explicitly appeared in the technical
10 review.

11 OMRI lists processing inputs that
12 are generally comprised of 605 or 606
13 materials, such as yeast ingredients,
14 defoamers, food sanitizers such as fluorine
15 and peracetic acid, and formulated ingredients
16 such as fruit coatings.

17 OMRI's list of processing inputs
18 is meager compared to the possible thousands
19 of ingredients in processing aids used in
20 organic foods today, and we attribute this
21 lack of growth in our list to two reasons.

22 One, the policy for allowing Other

1 Ingredients from the NOP and NOSB has been
2 inconsistent and led to varying
3 interpretations, and two, most ingredients and
4 processing aids do not comply with OMRI's
5 strict interpretation and policy.

6 So the NOSB may want to consider
7 OMRI as a real life example of how Option C
8 and Option D may play out if implemented. I
9 want to make it clear, OMRI takes no position
10 on the appropriateness of any specific policy.
11 However, we do urge you to look at the
12 evidence presented, to formulate your final
13 recommendation as soon as possible. Thank
14 you.

15 MR. FOSTER: Thank you for that.
16 Any questions? Zea.

17 MS. SONNABEND: Thank you, Peggy.
18 I'm wondering how comfortable OMRI reviewers
19 feel with going back to look for potential
20 Other Ingredients in the TRs and petitions, as
21 opposed to having a centralized database
22 through the NOP, where those things would

1 exist?

2 MS. MIARS: I'm sorry. I'm not
3 quite sure I understand that question. Can
4 you restate it?

5 MS. SONNABEND: Well, do you find
6 that it's a problem to have to go searching
7 through a lot of TRs and petitions when
8 determining if Other Ingredients were reviewed
9 in the initial review, versus the convenience
10 of having everything in one place, which may
11 or may not be, have the funding to be kept up,
12 for instance, or have other issues?

13 MS. MIARS: Well obviously, it
14 would be much easier just to go to a database
15 or spreadsheet. However, I do know that our
16 reviewers do go back to technical reviews on
17 a regular basis, to do as part of the research
18 for our product reviews.

19 MR. FOSTER: All right. There's
20 some more questions. Jay and Nick. MR.

21 FELDMAN: Thanks, Peggy. This is a question
22 for OMRI. I'm hoping we can get an answer

1 before we have to vote or in further
2 discussion on this issue of soy protein
3 isolate, and these distinctions being made
4 between isolate and concentrate, and how it's
5 derived, how it's formulated. Is that
6 something you can help us with?

7 MS. MIARS: Well, that's not an
8 area that I'm knowledgeable of, so I would
9 defer technical questions to my colleague,
10 Lindsay Fernandez-Salvador.

11 MR. FELDMAN: Okay, thank you.

12 MR. FOSTER: Nick.

13 MR. MARAVELL: Yes. Just out of
14 curiosity, at OMRI, you wouldn't happen to
15 have your own little personal crib sheet or
16 cheat list that would sort of serve the
17 secondary purpose of a database, as you go
18 through and review materials, and review the
19 technical reviews, et cetera.

20 Do you actually sort of keep a
21 tally of what we might be calling Other
22 Ingredients, with annotations as to under what

1 circumstances these surfaces, et cetera?

2 MS. MIARS: Sure. We do keep
3 detailed information like that in our
4 database, because we do see certain materials
5 come up time and time again. So it does make
6 sense for us to maintain those records and
7 refer back to them on a regular basis.

8 MR. FOSTER: Thank you. Last
9 question. No? Thank you, Peggy.

10 MS. MIARS: Thank you.

11 MR. FOSTER: Coming up is
12 Gwendolyn Wyard, to be followed by Britt
13 Lundgren.

14 MS. WYARD: Okay, top of the
15 morning. Mr. Chairman and OP staff and ladies
16 and gentlemen of the gallery. My name is
17 Gwendolyn Wyard. I'm the Regulatory Director
18 of Organic Standards and Food Safety for the
19 Organic Trade Association, representing over
20 6,500 members across 48 states.

21 I also serve on the OMRI Board,
22 and I'm co-chair of the Materials Working

1 Group. First, I want to thank you so much for
2 your dedication, and for the 239-page proposal
3 packet that was prepared for this meeting. I
4 truly appreciate the full time job security
5 your voluntary positions provide me.

6 (Laughter.)

7 MS. WYARD: We did submit comments
8 on ten of the proposals. You have those in
9 writing. My comments today will focus on
10 Other Ingredients, Other.

11 First and foremost, I want to be
12 perfectly clear that OTA supports a careful
13 and thorough review of Other Ingredients. How
14 that review is documented and how allowances
15 and prohibitions are communicated to
16 certifiers and material review organizations,
17 MROs and industry is the crux of our
18 challenge.

19 Historically, the review of Other
20 Ingredients contained within petitioned
21 substances was part of the overall review
22 process. In most instances, the substance and

1 the other ingredients were specifically or
2 generically acknowledged, and the entire
3 substance in its totality was evaluated
4 against OFPA and the National List criteria,
5 and added to the National List.

6 Over the years, the Board has
7 proposed several multi-ingredient or multi-
8 component substances to the National List.
9 Examples include enzymes, vitamins, dairy
10 cultures and natural flavors.

11 These substances are functionally
12 dependent on other ingredients, meaning they
13 cannot be used, they cannot exist, they cannot
14 be used for food application without them. If
15 you purchase Vitamin D, you would never
16 purchase Vitamin D by itself. It would always
17 come with a dispersing agent.

18 The problem is that the review of
19 generic materials at the NOSB level has not
20 been consistently carried out and documented,
21 as Zea pointed out, and accordingly,
22 certifiers, MROs and industries face

1 uncertainties when trying to figure out which
2 other ingredients are allowed in brand name
3 products.

4 The good news and an important bit
5 of perspective is that not all substances on
6 the National List depend on other ingredients.
7 In fact, most do not. Out of the 139 handling
8 materials on the National List, there are
9 about 12 that require other ingredients.

10 But they're a critical 12, and
11 they're commonly used in the organic foods
12 that we love and consume daily, and they've
13 been allowed for over ten years.

14 A large majority of the substances
15 on the National List were reviewed and added
16 as single component substances, and they
17 should remain just that. Any other ingredient
18 would need to be organic or on the National
19 List, because they were not reviewed or
20 considered by NOSB.

21 As for the multi-component
22 substances, we believe we need to take a case-

1 by-case approach, just as they have previously
2 been reviewed, and we have our work cut out
3 for us. OTA's comments present a seven-step
4 procedural plan, spread out over the next
5 three NOSB meetings.

6 I don't have time to discuss each
7 step, but I will say that the first step needs
8 to begin now, and it needs to be an
9 assessment. We need to invite industry to go
10 back and look at their products, and look at
11 what other ingredients are being used.

12 Separate single component
13 substances out from the multi-component
14 substances. Examine the collected information
15 from industry and address each multi-component
16 substance accordingly. For the 12 or so
17 listings that require other ingredients, use
18 annotations to set restrictions and
19 prohibitions when it's appropriate.

20 This is consistent with historical
21 practice, and we believe NOSB has the
22 authority to continue this discretion. Take

1 natural flavors, for example. In '95, the
2 Board considered the fact that carriers and
3 preservatives, which are Other Ingredients,
4 are always added to compounded flavors.

5 They didn't say they all needed to
6 be on the National List. Instead, they said
7 they needed to be non-synthetic, and they
8 annotated the material as such and added that
9 material in its totality to the National List.

10 In conclusion, you cut off my mic?
11 Oh, sorry. Well in conclusion, thank you very
12 much. This is the nuts and bolts of our
13 policy, and we've basically taken elements of
14 Option A, B and C, and pointed out the key
15 factors that we'd like to see worked into our
16 policy. Thank you very much.

17 MR. FOSTER: Thank you.

18 Questions? Mac.

19 MR. STONE: So I'll ask you this
20 incidental additives that don't have a
21 technical or functional effect. How are they
22 there, and again the confidentiality in

1 developing these products, or disclosure of
2 confidentiality?

3 MS. WYARD: Okay. I'll take that
4 in the two parts. So why they're there. In
5 a finished, certified product, the other
6 ingredients are these incidental additives.
7 They are present by way of an ingredient
8 that's been added to that finished product.

9 So the finished product, the
10 consumer's looking at the finished product.
11 They're reading the ingredients statement, and
12 the ingredients statement will read "Vitamin
13 D." Within that Vitamin D, you may have
14 dispersing agents or stabilizers or
15 preservatives.

16 They were added to the Vitamin D
17 during the manufacturing of the Vitamin D.
18 They were not added to the milk, for example,
19 but they're present in the milk by way of
20 being carried in through the Vitamin D.

21 So in the finished product, which
22 would be the milk, they are present at

1 insignificant amounts, and they do not have a
2 technically functional effect on the milk.
3 They had a technically functional effect on
4 the Vitamin D, acting as other stabilizer
5 preservatives, et cetera.

6 Confidentiality for most of the
7 substances on the National List, for 605 and
8 606, really is not that big of an issue.
9 Unlike crop products, where trying to get
10 disclosure of the inerts is very proprietary,
11 the specification sheets that come along with
12 the ingredients that are being used by
13 certified handlers, those specification sheets
14 list the other ingredients that are in that
15 ingredient.

16 So if you are using an enzyme,
17 you're going to get a specification sheet
18 that's going come in with that enzyme, and
19 it's going to list the other ingredients that
20 are there. Certifiers can readily look at
21 them. The manufacturer of the ingredient is
22 required to provide the handler with an

1 ingredient list of those other ingredients.

2 There are some exceptions, and
3 those exceptions would largely be natural
4 flavors, very proprietary. You will actually
5 get the list of the other ingredients in a
6 natural flavor. What you won't get is the
7 proprietary formulation of all of the flavor
8 constituents.

9 But even in natural flavors, you
10 will, you know, they'll disclose the glycerine
11 is being used, for example, as a carrier, or
12 maltodextrin is being used as a carrier.
13 Colors, you would run into also some
14 proprietary information. But again, that
15 would be for the specific color constituents
16 and not so much the other ingredients.

17 MR. FOSTER: Thank you.

18 Additional questions? Nick.

19 MR. MARAVELL: I'm going to change
20 the subject here Gwen, and go a little
21 philosophical. I'm going to quote from your
22 conclusion of your prepared remarks. In

1 effect, you're saying we believe that NOP
2 certified products should be nutritionally
3 equal to their conventional counterparts.

4 For me, the philosophical part of
5 that comes in. Does there need to be a
6 conventional, I mean an organic product sort
7 of standing analogous side by side with every
8 conventional product, and is that sufficient
9 justification for adding things such as
10 synthetic preservatives?

11 So let me go one step further. So
12 how, what's the impact on the industry if your
13 conclusion is not one that is accepted, versus
14 accepting that conclusion? What's the impact,
15 the positives and the negatives, on the
16 organic industry?

17 MS. WYARD: Well I think, you
18 know, OTA has gone on record several times,
19 stating that, you know, we support consumer
20 choice. We support consumer preference, and
21 we envision the day, and I think we're getting
22 there, where organic products are a

1 significant part of our everyday life.

2 So to every extent that it's
3 possible, there's going to be caveat here, and
4 a huge one. But to every extent possible, I
5 would hope that we're all striving to create
6 as many organic products as we possibly can,
7 and that we would create an organic
8 counterpoint to every conventional product out
9 there.

10 Now I know this gets into the
11 organic Twinkie argument, and I'm not going to
12 go there fully. But the caveat is that we
13 have to do this in full compliance with OFPA
14 and the regulations. There is no skirting
15 around that. We would never suggest that we'd
16 do that.

17 If you look at the criteria that
18 are listed out in OFPA for putting materials
19 on the National List, we all know they're
20 rigorous and it's -- here we are going through
21 this process.

22 So I think if you follow the OFPA

1 criteria and the National List criteria and
2 the regulations, then we should have a list of
3 ingredients that are consistent with organic
4 principles, and we should be able to make
5 products that comply with the regulations.

6 I think bringing personal choice
7 in to the matter, in terms of whether you
8 believe infant formula is right or wrong is
9 irrelevant. It's whether or not the product
10 complies with the regulations, and the
11 screening step that takes place prior to that
12 is the, this process that we're all here going
13 through right now.

14 MR. FOSTER: Harold.

15 MR. AUSTIN: I think you partially
16 answered this, Gwen. But on one of your
17 slides, how would you suggest that we conduct
18 assessment of the National List, and what
19 would this ultimately do for us, as we're
20 trying to work through and develop this
21 policy?

22 MS. WYARD: So the first step is

1 to begin this assessment, and I think this
2 assessment should and can happen now, and OTA
3 is absolutely ready and willing to help with
4 that process, in terms of outreach to industry
5 and notification to industry, to go and
6 conduct a very thorough assessment of the non-
7 organic ingredients that they're using in
8 their certified products, and then going back
9 to the manufacturers of those ingredients and
10 finding out exactly what other ingredients are
11 in those approved substances on the National
12 List.

13 I think we need to understand the
14 universe that we're operating in, in the same
15 way that has been conducted for the inerts.
16 For the inerts, you know, you have an idea of
17 these 126 inerts that you're working with,
18 broken into their classes.

19 We have no idea how many other
20 ingredients are in use out there. So I think
21 that's a first step and also, you know, we
22 have the work that's already in the discussion

1 document, the spreadsheet at the end that goes
2 through and it did a review of all of the
3 technical reviews and the petitions.

4 So we have a pretty good idea, and
5 so that's what I base that number 12 on. As
6 far as this list right here, these are the
7 multi-component substances. These rely on
8 other ingredients. We already have a lot of
9 information. They were approved in 2000, well
10 '95, and they've gone through a couple of
11 sunset processes.

12 We have a lot of information, but
13 we don't have a thorough assessment of what is
14 being used out there. But we can at least
15 say, you know, let's focus on this 12, and
16 let's verify that it is just 12 that we're
17 talking about. What have we missed, waxes, et
18 cetera, et cetera.

19 I haven't included the sanitizer,
20 disinfectants and cleaners here. That is
21 another issue, certainly all one in the same
22 topic. But I think that's the first step, is

1 to conduct this assessment, and you know, at
2 that point, if we're only dealing with 12, it
3 kind of helps to find our universe. It makes
4 it a little bit easier.

5 Then you can take it, you know,
6 one by one, because if you're talking about
7 vitamins and minerals, and this would also
8 apply to vitamins and minerals used in
9 certified livestock feed. So in that case,
10 it's not going to be just human foods.

11 If you want to say that every
12 other ingredient needs to be organic or on the
13 National List, and all the vitamins and
14 minerals that are being used in processed food
15 for humans and for livestock, that's going to
16 be a huge train wreck. It's also going to be
17 a regulatory bottleneck, to try to go through
18 a petition process to deal with all of those
19 other ingredients, and that's just in vitamins
20 and minerals.

21 So that's why we're recommending
22 that we use annotations, and I think this

1 assessment and looking, doing a case-by-case
2 review of these 12 substances, can help us
3 define and say well, let's do what we did with
4 natural flavors. We say only non-synthetic
5 other ingredients can be allowed.

6 Or maybe in one instance there's,
7 you know, a few enough other ingredients being
8 used that you can put it in the permitted
9 substance database, or just document in the
10 background. The point is that there are 12
11 different substances, and they really need to
12 be dealt with on a case-by-case basis.

13 So and I think if you look between
14 now and spring of 2014, you can get that work
15 done maybe. This is just a suggestion for a
16 road map. But it's just a way to start
17 thinking about this process.

18 MR. FOSTER: Terrific. Thank you.
19 Jay, this will need to be the last one.

20 MR. FELDMAN: Okay, thanks.

21 MR. FOSTER: We only have ten
22 minutes here.

1 MR. FELDMAN: Okay. Just quickly,
2 then. I'm just trying to decipher how you're
3 looking at the listing, the word "listing" on
4 the National List. So there's that footnote
5 in the discussion document that, you know,
6 recited the findings of the court, you know,
7 on this question of Other Ingredients or
8 processing aids, and basically said that,
9 authorized the use of synthetic substances
10 when ingredients or processing aids for use in
11 handling operations, so long as they appear on
12 the National List.

13 So you're equating this sort of
14 grouping as a listing. Is that how you're
15 interpreting that, compliance with that
16 finding by the court?

17 MS. WYARD: I wouldn't call it a
18 grouping. I would say a substance. A
19 substance can contain multiple ingredients.
20 So if you, you know, OFPA states that a
21 handler must use ingredients that are either
22 organic or on the National List.

1 So dairy cultures, that is an
2 ingredient. So if a handler is using a dairy
3 culture, the handler is using an ingredient
4 that is on the National List. Further on in
5 OFPA, it states that NOSB needs to add
6 substances to the National List.

7 So now we've moved into, you know,
8 we were using ingredients earlier on, and now
9 we're talking about substances. But there's
10 also further on and off where there's -- and
11 I think that Zea put it up in her
12 introduction, where it points out that a
13 substance can be a multi-component substance.
14 It can contain other ingredients.

15 So this is where we get in to
16 these two school of thoughts that Zea
17 presented in her presentation. What does it
18 mean if an ingredient is on the National List?
19 If a substance is on the National List, does
20 that include, in its totality, those other
21 ingredients?

22 The only thing that I can tell is

1 clear is that it's not clear, just as Zea
2 presented, and I won't comment any further
3 there. I think it does definitely get into
4 legal land, and I'm not a lawyer, and that's,
5 I think, where that needs to go.

6 MR. FOSTER: Thank you very much.

7 MS. WYARD: Thank you very much.

8 MR. FOSTER: And just while we're
9 changing here, Britt's coming up, I've already
10 had four requests for John Ashby's - four
11 email requests for John Ashby's, so make it
12 five. Yes, Yes. So you may want to print it
13 in a pamphlet or something.

14 John Ashby will have a signing
15 party in the lobby in the Renaissance Room
16 after the proceedings. So Britt, thank you
17 for your indulgence of our jocularities, and
18 then next up is Elizabeth Johnson.

19 MS. LUNDGREN: Hi. Thank you for
20 this opportunity to comment. My name is Britt
21 Lundgren. I'm the Director of Organic and
22 Sustainable Agriculture at Stonyfield, which

1 is the world's leading organic yogurt company.

2 At Stonyfield, we appreciate that
3 the NOSB has decided to look more closely at
4 the use of other ingredients in substances
5 allowed on the National List.

6 We agree with the Handling
7 Committee's assessment that while the overall
8 ingredient review process is already quite
9 rigorous, improvement and harmonization of
10 this process would be beneficial.

11 We support the establishment of a
12 more clear and consistent process to review
13 other ingredients, because it will promote
14 even greater transparency within the standard,
15 and also provide greater certainty for
16 processors such as ourselves.

17 In general, I think our position
18 on this could be best described as Option B of
19 the Handling Subcommittee's options, with
20 variations. As Zea said earlier, a lot of us
21 have tweaks to that.

22 We believe that this is the best

1 way for NOP to ensure that all other
2 ingredients are evaluated in the process of
3 evaluating substances for inclusion the list,
4 without creating an onerous new set of
5 requirements.

6 We believe that Policy Option C
7 does nothing to advance the actual integrity
8 of organic products, but could create a
9 regulatory bottleneck for the agency, and thus
10 hinder the future growth of organic
11 agriculture.

12 Before NOSB settles on a policy
13 for evaluating other ingredients, like OTA we
14 suggest that the first step is to conduct a
15 more thorough inventory of other ingredients
16 that already in use in allowed substances.

17 In many cases, these other
18 ingredients have already been reviewed as part
19 of approval and sunset processes, while in
20 some cases we may not be aware of the other
21 ingredients that are in use in a substance.

22 By defining and thoroughly

1 investigating the scope of this issue first,
2 NOSB can then design a policy that is more
3 appropriate for the problem in hand. For some
4 substances, it may be most effective to
5 specify the allowance or prohibition of
6 individual other ingredients.

7 In others, it may be more
8 appropriate to allow or prohibit a functional
9 class of other ingredients, or to allow other
10 ingredients based on regulatory reference
11 under another government agency. The point is
12 that a one-size-fits-all policy for evaluating
13 other ingredients may be inadvertently
14 restrictive, or it could result in NOSB having
15 to review many individual other ingredients,
16 when a simple annotation to approve a
17 functional class of ingredients would suffice.

18 For certain proprietary
19 formulations, it may not be possible for NOSB
20 to have full access to a complete list of
21 other ingredients used, and in this case, it
22 should be up to the certifying agency to

1 evaluate these other ingredients.

2 By first reviewing all allowed
3 substances to determine which are likely to
4 have other ingredients, and which of these are
5 likely to be of a proprietary nature, the NOSB
6 can be in a better position to provide
7 appropriate guidance to certifying agencies
8 about how to evaluate these other ingredients,
9 as they have done in the case of natural
10 flavors.

11 Once the review of other
12 ingredients is complete, the NOSB can use what
13 they have learned in this review to develop a
14 policy for evaluating other ingredients. This
15 policy should be designed to foster more
16 transparency within the standard, by requiring
17 the technical evaluation report and any other
18 review done by NOSB, to always note any
19 presence of other ingredients, and establish
20 either specific allowances or restrictions as
21 appropriate.

22 NOSB should also develop guidance

1 for certifying agencies on how to evaluate
2 these other ingredients. That's it. Thank
3 you.

4 MR. FOSTER: Thank you. Do we
5 have questions?

6 (No response.)

7 MR. FOSTER: All right. Thank you
8 very much.

9 MS. LUNDGREN: Thanks.

10 MR. FOSTER: Next up, we have
11 Elizabeth Johnson, followed by Deborah
12 Trinker.

13 MS. JOHNSON: Good morning. I'm
14 Elizabeth Johnson from Tufts University, where
15 I work in the Carotenoids and Health
16 Laboratory, and where I've been working for
17 more than 20 years, looking at the role of
18 carotenoids in human health.

19 There's been a lot of talk about
20 lutein this morning, and I'm here to tell you
21 what it is and where we find it in the body.
22 Lutein is a plant pigment. You find it common

1 in our diet. It's part of the carotenoid
2 family.

3 There are hundreds of carotenoids
4 in nature. We see them this time of the year,
5 the reds, the yellows, the oranges. But of
6 those hundreds, only two get in the eye,
7 lutein and its isomer, zeaxanthin. In the
8 eye, it has a role as an antioxidant in vivo.
9 It's an anti-inflammatory and it's a blue
10 light filter.

11 So that lends a lot of strong
12 biological plausibility that it's important.
13 What really makes a lot of plausibility to its
14 biological importance is that we find a
15 specific binding protein for lutein in the
16 eye, and in biology, when you find a specific
17 binding protein for something, that really
18 lends support for it being important.

19 In the eye, the concentrations of
20 lutein are 500 to 1,000 times more
21 concentrated than anywhere in the body. The
22 only way you get it in there is if you eat it.

1 Now the role for lutein in neural health, a
2 lot of that comes from what we know in adults.

3 We know that lutein preferentially
4 accumulates not only in the eye, but in the
5 brain as well. There's a lot of double-
6 blinded placebo-controlled trials, which are
7 the golden standard when it comes to nutrition
8 research, that show that if you give lutein,
9 you improve cognition, you improve visual
10 function.

11 So we know a lot of the
12 epidemiology, we know the clinical work, we
13 know the intervention trials support a role
14 for lutein in eye health and in cognitive
15 function in the adult.

16 Now a lot of what we know about
17 lutein as an in vivo antioxidant, as an
18 inflammatory, as a structural role, a lot of
19 what we know in the adult, we can really
20 expect that to be true in the infant. Its
21 role as an antioxidant and anti-inflammatory
22 is structural.

1 So in the adult, when we look at
2 lutein status, whether it be in diet, whether
3 in blood, whether it be in brain, we have
4 data. More lutein in the brain, better
5 cognitive function. Those roles of lutein
6 should apply for the infant as well.

7 Now when we look at brain tissue
8 of the adult, the major dietary carotenoid in
9 brain is lutein. It's not beta carotene, it's
10 not lycopene. Despite having increased levels
11 of these other carotenoids, the brain takes
12 that lutein out, just like it does in the
13 retina.

14 For the infant, it's the same
15 story. We've analyzed infant brain that died
16 of natural causes, mostly SIDS, and when we
17 look at the all the carotenoids in their
18 brain, 60 percent is lutein. We analyze these
19 brains in the first year of life, and we know
20 they're not eating lutein in their diet. It's
21 probably taken up in the brain, where we think
22 it's function.

1 There have been studies defined
2 that if you give lutein to infants that are on
3 formula, that otherwise wouldn't have lutein,
4 better antioxidant function. Then that
5 implies there's going to be less formation of
6 something called lipofuscin, which is a long
7 term increased risk of eye health towards
8 later in life.

9 So there's a functional role that
10 we know, of lutein in the eye, that we can
11 really apply to what's going on in the brain
12 as well. So knowing that breast milk contains
13 lutein, that without lutein in early life that
14 you'll see decreased levels of lutein. This
15 really has implication for its role being
16 added to infant formula. So I thank you for
17 your time.

18 MR. FOSTER: Nice timing.

19 Questions from the Board? All right, Zea.

20 MS. SONNABEND: Thank you. Do you
21 know how the lutein is made?

22 MS. JOHNSON: It's a plant

1 pigment, very common to our diet, our green
2 leafys. And when we look at it not being in
3 the diet, the studies we've done in monkeys,
4 if you don't have it there, you see some
5 abnormal morphological differences in the
6 retina that are related to worse functioning.

7 MS. SONNABEND: But do you have
8 any knowledge of whether the lutein that would
9 be fed to the infants is the same exact lutein
10 that's in the plants?

11 MS. JOHNSON: That's where almost
12 all of our lutein comes from, is a plant
13 extract. It's pretty expensive to synthesize,
14 so you really want to go for a plant extract,
15 and I don't know anyone that synthesizes it
16 for commercial reasons.

17 MR. FOSTER: Additional questions?
18 Harold.

19 MR. AUSTIN: Based off of all of
20 the research that you've been doing with it in
21 the University, what do you feel the
22 significant impact to the infants would be if

1 they were lutein-deficient during their growth
2 development?

3 MS. JOHNSON: Well, our best
4 evidence comes from the work that we've done
5 in primates and monkeys, where they actually
6 never, ever were exposed to a carotenoid in
7 their life. When you look at their retinas,
8 it's not normal. It's not normal at all.

9 But when we fed lutein back to
10 those retinas, there's these certain cells in
11 the retina that they kind of traffic the
12 nutrition coming in, the waste products going
13 out, and that profile becomes distorted.

14 When we add lutein back to their
15 diets, you can repair that. To me, that's
16 pretty compelling, to see something like that
17 going on.

18 So it's, you know, it's pretty
19 important, and to find that there's this
20 specific binding protein, which I had
21 mentioned earlier, that to me is pretty strong
22 biological evidence that it's important, when

1 we have evolved to have this protein to zap,
2 to bring it out of the circulation, to put it
3 in the retina exactly where it needs to go.

4 I mean most of us in the room are
5 thinking more about preserving the neural
6 tissue that we have, and one of the major
7 problems we have right now is age-related
8 macular degeneration. I bet everyone in this
9 room can raise their hand, because they know
10 someone who has this.

11 Lutein is in the macula. It's 500
12 times more concentrated there, where it is a
13 blue light filter. The light coming in is
14 blue light. It's a yellow pigment. It grabs
15 that blue light, so it can't go on to those
16 photoreceptor cells and damage them. Light is
17 damaging.

18 The eye is very vulnerable to
19 light damage. It's not like your liver or
20 bones. It's damaging. So we want to protect
21 it with a blue light filter, with an
22 antioxidant, with an anti-inflammatory.

1 MR. FOSTER: Any additional
2 questions?

3 (No response.)

4 MR. FOSTER: Great. Thank you
5 very much. Next up, I'm showing Deborah
6 Trinker, followed by Helen Kor.

7 MS. TRINKER: Good morning. My
8 name is Debbie Trinker. I'm the Vice
9 President of Regulatory Affairs for Kemin
10 Foods, LC.

11 I appreciate this opportunity to
12 appear before the Board, and to provide this
13 statement in support of the addition of lutein
14 USP to the National Organic Standard Board's
15 list for use in organic formula.

16 We're in the manufacture of
17 Floraglo brand of lutein, and we are the
18 petitioner requesting this addition under
19 Section 205.606.

20 My comments this morning will
21 address some of the new scientific and other
22 information that I was disappointed to see was

1 not in the Technical Report, that we think is
2 relevant to your review of this ingredient.

3 Also, when I look at your
4 definition of an accessory nutrient, if it
5 provides an optimal health benefit and there
6 is no viable organic alternative, then this
7 ingredient should be considered and included
8 on the list. Those are the points I'd like to
9 make today.

10 I'd also like to take a little bit
11 of time to discuss some of the issues that
12 came up that are not in my prepared statement,
13 regarding why we listed this ingredient under
14 205.606.

15 We believe that lutein USP is an
16 agriculture product under this section. It's
17 derived from a botanical source, marigold
18 flowers, with minimal processing, and it
19 retains its essential agriculture
20 characteristic.

21 It is a pigment, a xanthan-filled
22 pigment, and in fact under FDA regulations, we

1 are required to label it when it appears in
2 the supplement as lutein, identifying its
3 botanical source and part of the plant, i.e.,
4 the marigold flower.

5 When we prepared the petition, it
6 was our understanding, and we did provide
7 quite detailed information on our
8 manufacturing process, and some of that was
9 labeled as CBI, and it was our understanding
10 that that would be reviewed and would be
11 considered.

12 In the interest of transparency,
13 I can briefly summarize how we process this.
14 There is a solvent used. Hexane is used to
15 extract the xanthan fills from the marigold
16 petals, to create the oleoresin, and this is
17 necessary.

18 The use of synthetic chemicals or
19 solvents under this Board's recommendations
20 would not in and of itself render the
21 substance as synthetic, and I refer to the
22 NOSB recommendation for classification of

1 materials in 2009, and unless there is a
2 chemical alteration of the substance or the
3 synthetic material occurs in the resulting
4 product and is not removed.

5 When we test our crystalline
6 material, we find that the hexane is not
7 detectable. There's a second step in this
8 process, and it's de-estrification step.

9 And if I can go back for a minute,
10 we've also looked at these steps in terms of
11 other substances that you've allowed under
12 this listing, and we find precedent with
13 unbleached lecithin, where hexane is used as
14 a solvent.

15 A second step that is of interest
16 to this discussion and this Board's review is
17 the de-estrification step, and that provides
18 lutein in the free form in which it appears in
19 breast milk.

20 This step uses a processing aid
21 that appears on your list as a substance that
22 may be used in processing, as a processing

1 agent organic handling under 205.605, and the
2 precedent here would be the HMP and LMP
3 pectines, which are proposed to be
4 consolidated under 7 C.F.R. 205.606.

5 Such that our conclusion, to be
6 consistent, is that the de-estrification
7 process, in and of itself, does not render
8 this as a synthetic product.

9 I want to talk briefly about
10 essentiality. I'm a food and drug lawyer.
11 That's been the bulk of my practice, and the
12 listing of ingredients that are allowed in
13 fortification are based on having DVs.

14 That doesn't mean that this
15 ingredient, per Dr. Johnson, is not critical
16 to infant development. Just as one final
17 comment that I'd like to make, because there's
18 been a lot of discussion of EFSA, we define
19 infant formula specifically under our laws,
20 under the Food and Drug Act, and infant
21 formula is supposed to simulate human breast
22 milk, and lutein is in human breast milk at

1 significant levels.

2 So this is consistent with the
3 statutory definition that the Food and Drug
4 Act has, that FDA uses, not what FC uses.

5 Thank you very much.

6 MR. FOSTER: Thank you. Do we
7 have questions? Harold.

8 MR. AUSTIN: Thank you for coming
9 and clearing up some of the complications that
10 we are running into a little bit.

11 MS. TRINKER: Sure.

12 MR. AUSTIN: I know your original
13 petition was for 606. We moved it to 605(b)
14 because of, you know, because part of the
15 information was classified confidential. We
16 then were removing from an agricultural
17 product down to a synthetic material or an
18 ingredient.

19 So that's why we chose to move it
20 there. I do appreciate you coming and
21 clarifying that for us, because that does
22 help. I think most of our Subcommittee would

1 have, at the time we were deliberating on it,
2 which we still are, would have voted in favor
3 of it, if we could have felt comfortable
4 enough to classify it as a non-synthetic.

5 So I think you have helped clear
6 it up a little bit, for at least some of us.
7 So thank you.

8 MS. TRINKER: No, you're welcome,
9 and on the record, in the interest of
10 transparency, we can provide more information
11 on that process. And I apologize. It was my
12 understanding that the discussion and the
13 petition would be subject to review. So
14 that's my fault. I thought that discussion
15 and the petition was sufficient.

16 And there's just one other point
17 too, that I thought the Technical Report did
18 not list any of the new studies done in
19 infants since the EFSA decision in 2008.
20 They're in the petition. They show favorable
21 impacts in infants, in moderating reactive
22 protein that is a mark of anti-inflammation.

1 They're also summarized in my
2 statement, and I'd ask that you all look at
3 these and review them carefully.

4 MR. FOSTER: Thank you. Thank you
5 for your time. John. Oh, I'm sorry. Jay,
6 did you have a question?

7 MR. FELDMAN: Yes, I had one more
8 question. Sorry.

9 MR. FOSTER: I'm sorry I didn't
10 see you, Jay.

11 MR. FELDMAN: When you talk about
12 these ingredients, do you have -- are there
13 published levels in the product that are
14 either assumed or -- I mean since we don't
15 have a standard, I don't believe, how does the
16 industry determine the level of these
17 substances that are added, in this case,
18 lutein?

19 MS. TRINKER: The level of the
20 substance, the amount of lutein in infant
21 formula?

22 MR. FELDMAN: Yes.

1 MS. TRINKER: That's a very good
2 question, and if you look at our petition, we
3 think that there's some safeguards that
4 address your specific point.

5 Lutein, our lutein has gone
6 through the GRAS process, and it cannot be
7 added in infant formula for term infants at
8 levels that exceed 250 micrograms per liter.

9 So by law if we -- and it wouldn't
10 be us; it would be the company, the customer.
11 So if they were to exceed that, legally the
12 ingredient would no longer be GRAS, and the
13 product would be adulterated. So that's a
14 pretty strong deterrent against excess levels.

15 MR. FOSTER: Thank you.

16 MS. TRINKER: Thank you.

17 MR. FOSTER: Next, I'm showing
18 Helen Kor, followed by Troy Aykan.

19 MS. KOR: My name is Helen Kor.
20 I'm a nutritionist with the Hain Celestial
21 Group. My company advocates breast feeding as
22 the first and best choice for infant feeding.

1 However, for mothers who cannot breast feed,
2 my company offers milk based and soy based
3 organic infant formulas, and the precise
4 formulations reflect the combined knowledge
5 of the FDA, international regulatory agencies,
6 professional associations, and the leading
7 experts in the field of infant nutrition and
8 health.

9 I am here to support the petitions
10 for the nutrients used in infant formula. I
11 will focus my comments today on the petitions
12 for methionine, carnitine and taurine. But
13 first, I want to correct some misinformation.

14 It has been stated by some
15 commenters that organic soy-based infant
16 formula contains hexane-extracted soy protein
17 isolate. This is not true, because synthetic
18 solvents may not be used in organic
19 ingredients.

20 Organic soy protein isolate is
21 used in our soy-based infant formula and is
22 certified by an accredited certifier under the

1 NOP.

2 L-methionine is an amino acid that
3 is vital for growth and development of
4 infants. Because soy-based infant formulas do
5 not provide sufficient methionine without
6 fortification, soy-based formulas must be
7 fortified with L-methionine to meet the
8 protein requirements of the FDA. We could not
9 sell or organic soy-based formulas without it.

10 We strongly urge the NOSB to
11 approve the petition to add L-methionine to
12 the National List. L-carnitine is another
13 amino acid that is found in breast milk, and
14 is vital for infant growth and development.

15 An inadequate carnitine intake may
16 result in failure to thrive, low blood sugar
17 and cardiomyopathy. Therefore, carnitine
18 fortification of infant formula is recommended
19 by both the EU and the Life Sciences Research
20 Office, operating under contract with the FDA.

21 Initially, carnitine was only
22 added to soy-based infant formulas, but

1 starting in the 90's, some milk-based infant
2 formulas began to be fortified, to ensure that
3 they meet the minimum recommended level.

4 We strongly urge the Board to
5 approve the petition for L-carnitine to the
6 National List for both soy-based and milk-
7 based infant formulas.

8 Taurine is present in significant
9 amounts in breast milk. Taurine is needed for
10 proper functioning of the retina, for proper
11 digestion and absorption of fats, for heart
12 and motor function and other important
13 physiological functions.

14 Infant formula needs to have added
15 taurine to match the levels in breast milk.
16 This is why taurine has been added to both
17 milk-based and soy-based infant formulas all
18 over the world for decades. We urge the Board
19 to approve the petition for taurine.

20 Some of the people opposing the
21 petitions for infant formula nutrients
22 acknowledge that there are no available

1 substitutes for these nutrients. But their
2 solution, that women should only breast feed,
3 is not feasible, due to physical problems,
4 their jobs and/or upon advice from their
5 health care provider.

6 My son had a slower growth rate
7 than is expected in his first few months of
8 life, and so my pediatrician advised me that
9 my son must be fed infant formula, because
10 breast feeding alone could not provide the
11 calories and nutrients needed for optimum
12 growth and development. This was the best
13 choice for my son.

14 As a nutrition scientist and a
15 mother, every child deserves a formula that
16 delivers adequate nutrients needed for optimal
17 growth and development. I implore this Board
18 to approve all the petitions for nutrients
19 added to organic infant formula. Thank you.

20 MR. FOSTER: Thank you. Do we
21 have any questions for the commenter? Jean,
22 Jay.

1 MS. RICHARDSON: Thank you for
2 your comments. One of the other public
3 comments that we received in the written
4 material before the meeting included a
5 statement that L-carnitine is required in the
6 European Union, for addition to organic
7 formula.

8 Can you tell me if that's correct
9 from your knowledge in the manufacturing
10 process?

11 MS. KOR: I'm not familiar with
12 the EU regulations. I work for a U.S.-based
13 company. But through my understanding and
14 what was written in the petitions, that is
15 indeed the case, that there is a requirement
16 in the EU for carnitine.

17 MR. FOSTER: Thank you. Jay.

18 MR. FELDMAN: Thank you for your
19 statement, and your clarification on the
20 extraction process for the soy isolate. What
21 is the process? Can you explain the process
22 that is currently used?

1 MR. FOSTER: I'm not a food
2 scientist, so I don't know the process for
3 extracting --

4 MR. FELDMAN: Somehow we'll get
5 the answer to that by the end of today, I
6 hope. Thanks.

7 MR. FOSTER: I'm sure it can be.
8 Additional questions?

9 (No response.)

10 MR. FOSTER: All right. Thank you
11 very much. Next up, Troy Aykan, followed by
12 Zareb Herman.

13 MR. AYKAN: Good morning. My name
14 is Troy Aykan. I'm a food scientist and an
15 attorney, specializing in food laws and
16 regulations, and a professor. One of the
17 questions asked by the NOSB is whether a
18 material is essential for organic production.

19 If a material has been shown to be
20 essential for proper growth and development in
21 infants, then it should be considered
22 essential for infant formula. The Infant

1 Formula Act was passed in 1980, and a list of
2 nutrients was codified in 21 C.F.R.

3 Some people erroneously believed
4 that if a nutrient or substance is not listed
5 here, it's not essential for infants. This is
6 not correct. This list is not intended to be
7 only ingredients necessary for infant
8 formulas.

9 There have been many advances in
10 nutrition science since 1980, and other
11 ingredients have been introduced to provide
12 nutrition that infants need.

13 Before a non-listed nutrient can
14 be used in infant formula, it must go through
15 a thorough GRAS notification process with the
16 FDA. After it's granted GRAS status, before
17 the nutrient is used, the component must
18 document the benefits of the nutrient to the
19 satisfaction of the FDA.

20 Every infant formula then is
21 supported by clinical trials, and is
22 thoroughly reviewed by FDA before it can be

1 even sold. It's important to note that many
2 essential nutrients don't even have daily
3 values, such as numerous amino acids, fatty
4 acids and other nutrients.

5 The ingredients in infant formula
6 have nutritional or functional properties that
7 provide for a safe and complete formula. To
8 limit the ingredients to just those nutrients
9 from 1980 will result in an outdated
10 incomplete, unstable nutritionally inferior
11 formula.

12 Consumers expect organic infant
13 formula to be the best formula that they can
14 buy for their babies. To deny the use of
15 these substance will place organic formula at
16 a competitive disadvantage, when compared to
17 non-organic formulas, and more importantly, it
18 will place the health of babies at risk, and
19 could result in the elimination of organic
20 infant formulas altogether.

21 Actions by this Board can have
22 serious consequences. For example, oxidation

1 of essential fatty acids is a major challenge.
2 Oxidized or rancid fats smell terrible and can
3 cause serious diarrhea in infants.

4 If the petition for ascorbyl
5 palmitate is not approved, the shortened shelf
6 life will make infant formula commercially
7 unbuyable. Our products must travel from the
8 production site to our warehouses, then ship
9 to distributor warehouses until orders come
10 in, and then it ships to other warehouses or
11 to the retail stores, which might require
12 shelf lives of up to 15 months.

13 With ascorbyl palmitate, there is
14 a good chance that oxidative destruction of
15 essential fatty acids and vitamins will occur.
16 This may cause the levels of these nutrients
17 to fall below the levels that are required by
18 federal food laws.

19 Such products could be considered
20 adulterated, due to rancid fats, or
21 misbranded, due to insufficient levels of
22 nutrients. Actions which violate the above-

1 mentioned laws and regulations may also be a
2 violation of OFPA, which states in relevant
3 part that "nothing in this chapter shall alter
4 the authority of Secretary of Health and Human
5 Services under the federal food laws."

6 If certain nutrient petitions are
7 denied, this will impact international trade.
8 Without carnitine, we could not sell our
9 formula in the EU. Similarly, without
10 taurine, we could not sell our organic infant
11 formula in Canada, which is a major trading
12 partner.

13 For these reasons, and many more,
14 we urge the Board to approve the petitions for
15 these important nutrients. Thank you. Any
16 questions?

17 MR. FOSTER: Thank you, Mr. Aykan.
18 Questions? Mac?

19 MR. STONE: You had in bold on the
20 previous slide that it could eliminate organic
21 formulas on the market, but it didn't say it
22 "would." What would you have to do to not

1 have it eliminate infant formulas?

2 MR. AYKAN: I don't see the
3 gentleman asking the question. Could you
4 repeat it please? I'm sorry.

5 MR. STONE: On the previous slide,
6 you had a bold statement, said it "could"
7 result in the elimination of organic infant --

8 MR. AYKAN: Yes sir.

9 MR. STONE: It doesn't say it
10 "would" eliminate. So what would you have to
11 do to adjust for this, if the Board were to
12 deny any or all of these?

13 MR. AYKAN: Yes, great questions.
14 There are, with the denial of the petitions,
15 there are two problems, okay. One is
16 oxidation of essential fats. As the previous
17 experts testified, that infant formula
18 contains about 25 to 28 percent fat.

19 Not just VHA. VHA is a very small
20 portion. But a lot of other fats, because
21 linoleic acid is required by law to be there.
22 So to protect these fats from oxidation, we

1 need to have the system of ascorbyl palmitate
2 and tocopherols and beta carotene.

3 If you're asking me what is it
4 that can be done, is that I don't know how
5 science could come up with something, another
6 oxidation system that would be acceptable.
7 But in any case, as you may realize, we're
8 already selling these formulas. They are
9 available.

10 They're available in the U.S. as
11 organic infant formulas. We sell these in
12 Canada. We started selling them in China and
13 Hong Kong. And to think, of course they have
14 different local regulations.

15 That is of no concern here, but it
16 requires some study and I don't know how soon
17 that could be done. Three years, four years.
18 I don't know, but these oxidation systems
19 already exist.

20 The second problem would be the
21 lack of important nutrients, such as taurine,
22 carnitine and methionine, which was, you know,

1 explained in detail by experts.

2 MR. FOSTER: Thank you. Jay. Oh
3 I'm sorry. I thought you -- you have no idea
4 how much I'd love to have you do that. I want
5 to be mindful of time. People are getting
6 hungry. We have a few more speakers. I want
7 to make sure we make sure to get to them.

8 So choose your questions wisely,
9 that's all. I'm happy to go through it. I
10 just want to make sure we're aware of that.
11 Nick's promising me very short. Okay, Nick,
12 Jay and --

13 MR. MARAVELL: The question's
14 short.

15 MR. FOSTER: Nick, Jay and Harold.

16 MR. MARAVELL: No. The answer
17 should be short too. You said you're selling
18 your product abroad now, Canada, China and
19 perhaps other markets. With regard to
20 ascorbyl palmitate, it's our understanding
21 it's not permitted under the Canadian standard
22 for organic infant formula.

1 I'm not familiar with the Chinese
2 situation, and I would -- so I'm asking has
3 that been something that has been brought to
4 your attention with your product, and then the
5 final one is would you anticipate any problems
6 selling your product in Europe? So I'm just
7 trying to get an idea of how that works.

8 MR. AYKAN: Yes. You just
9 switched from Canada to Europe. In Europe,
10 yes, I understand it.

11 MR. MARAVELL: No. It's multiple
12 questions.

13 MR. AYKAN: Yes, I understand it.

14 MR. MARAVELL: I'm a globetrotter,
15 okay.

16 MR. AYKAN: Okay. In Europe
17 obviously, ascorbyl palmitate is approved for
18 use as a proper Vitamin C source, as I looked
19 it up personally myself. As far as the Canada
20 and ascorbyl palmitate, I don't have the
21 answer, but I'll defer to one of my colleagues
22 that may come up after me.

1 As far as these formulas, and let
2 add this too, is that our organic infant
3 formula is made right there in New England, in
4 Vermont, by Vermont dairies, 100 percent, and
5 locally, and we'd like to keep this business
6 here.

7 As far as the Canadian question, I
8 have to check our formula, to see whether
9 there's an ascorbyl palmitate. That's a
10 really good question to know. Yes, yes, I
11 agree with you.

12 MR. FOSTER: Thank you. I have
13 Jay there.

14 MR. FELDMAN: Thank you. With all
15 the expertise -- John, this is actually a
16 question for you, because I don't know how you
17 want to handle this, with all the expertise in
18 the room and the references to GRAS among many
19 of the commenters.

20 I'm wondering if we could have a
21 definition, both by FDA and maybe Mr. Aykan,
22 on what exactly GRAS means. It's been used.

1 We know what it stands for, Generally
2 Recognized as Safe. But this process of FDA
3 granting GRAS status, what exactly does that
4 mean, and does that conform to our standards
5 under OFPA.

6 So if we could use the expertise
7 in the room, I'd appreciate it.

8 MR. FOSTER: My instinct would be
9 going to our guest from the FDA, would be my
10 sense. Does that sound reasonable?

11 MR. FELDMAN: Cool.

12 MR. FOSTER: Okay. Then I had
13 Harold, I believe, had a question.

14 MR. AUSTIN: Just quickly. In
15 regards to taurine, you mentioned that without
16 it, you could not, your formula could not go
17 into Canada? Could you clarify that, or did
18 I mis-hear what you were saying?

19 MR. AYKAN: Yes sir. Taurine is
20 required in Canada, so it must be added to the
21 Canadian formula, and also -- that's my
22 understanding. Yes, just been confirmed. It

1 is required, and I want you to please also
2 understand that if possible, you know, we'd
3 like to use the same formula for our friends
4 in Canada and here, if possible, obviously.

5 But because as you guys know,
6 there's a certain organic equivalency
7 agreements and all that stuff. But yes,
8 taurine is required in Canada, yes.

9 MR. AUSTIN: Thank you.

10 MR. AYKAN: Mandatory.

11 MR. FOSTER: Follow-up, Harold?
12 One more quick one.

13 MR. AUSTIN: Would you happen to
14 know the regulations that are guiding the
15 nutrients required in Canada, how current
16 those are, when those were established, versus
17 1980 for ours, or 1985?

18 MR. AYKAN: My, the answer is that
19 I do not know. My thinking is that they are
20 more recent, but by the day is over, we could
21 give you a report on that as to the date, as
22 information. But I don't have it in front of

1 me.

2 MR. FOSTER: I'm sure that
3 someone's Googling it right now. All right.
4 No more questions? Thank you very much for
5 your time. Next up, thank you, thank you.
6 Next up, I see Zareb Herman, followed by David
7 Cockram.

8 MR. HERMAN: My name is Zareb
9 Herman. I'm a nutritionist with the Hain
10 Celestial Group. I am here to support the
11 petitions for the nutrients used in organic
12 infant formula, because these ingredients are
13 found in breast milk and the science supports
14 their importance for infant growth and
15 development.

16 When the Infant Formula Act was
17 passed in 1980, I was living in Berkeley,
18 California. My graduate advisor was one of
19 the leading experts in maternal and infant
20 nutrition. In the last 30 years, nutritional
21 science has advanced greatly.

22 Infant formula manufacturers have

1 a tremendous responsibility to provide the
2 most current and best possible nutrition for
3 infants during the most crucial stages of
4 their development. When it comes to what is
5 necessary in infant formula, we need to trust
6 the infant formula experts.

7 I prepared a handout for the
8 Board. I don't know if they received it, but
9 I don't have time to go into it. But I would
10 ask you to look at it, because it sort of
11 condenses what would happen if you took each
12 nutrient out of infant formula.

13 And also on the handout, I show
14 this particular slide, and it shows the
15 continuum of views on non-organic ingredients
16 in processed organic foods. On the far right
17 are the people who say heck, add anything you
18 want.

19 On the far left are people who say
20 organic foods should have only organic
21 ingredients, nothing else, no National List.
22 In the middle are people who support a

1 reasonable National List. They support
2 necessary non-organic ingredients in processed
3 organic foods such as infant formula.

4 It is important to remember that
5 over 50 percent of the organic market is
6 processed food. The vast majority of these
7 products require some non-organic ingredients.
8 Without them, these products could not exist.
9 Consumers want organic infant formula.

10 I know this, because organic
11 infant formula is a major portion of the
12 organic foods market, with annual sales of
13 \$500 million. Many organic farmers and many
14 other people make their living because of
15 organic formula.

16 A no vote on these petitions will
17 almost certainly wipe out organic infant
18 formula from the marketplace. The organic
19 regulations provide for the use of synthetic
20 ingredients when necessary. This is why we
21 have Section 605(b) of the National List.

22 We don't live in a perfect world.

1 The reality is that some nutrients are only
2 available in synthetic form. They are
3 identical to the molecules in breast milk.
4 Being synthetic does not make them evil. The
5 rejection of a substance just because it is
6 synthetic is not valid.

7 Some people who oppose these
8 petitions argue that there are substitutes
9 that can be used. However, these substitutes
10 must actually exist, and they must work and be
11 available to be considered viable
12 alternatives.

13 Some people want to keep the
14 National List small. They kind of lean to the
15 left a little. I want to remind that these
16 petitions are not for all organic foods. The
17 petitions are for a small but very important
18 group, with special dietary needs, infants.

19 We all need to stand back from the
20 politics and ask what is really important
21 here. The answer is the health of babies. We
22 should all want what is best for babies, and

1 not sacrifice their health by denying them
2 these nutrients.

3 Lastly, I'm not trying to be funny
4 when I say this, but please, don't throw the
5 baby out with the bath water.

6 MR. FOSTER: Thank you. Questions
7 for Zareb?

8 (No response.)

9 MR. FOSTER: Thank you very much.
10 Next up I see David Cockram, followed by
11 Robert Rankin.

12 DR. COCKRAM: Hi. My name's David
13 Cockram. I'm representing Abbott Nutrition,
14 makers of Similac organic infant formula. I'm
15 a nutrition scientist and a registered
16 dietitian. Have had over 25 years of
17 experience developing infant formulas and
18 adult nutritional products for people with a
19 variety of conditions.

20 Breast feeding is clearly the
21 number one option, the best option for nursing
22 infants in the first year of life, but it

1 isn't always possible or chosen. An infant
2 formula that complies with the Infant Formula
3 Act's requirements for composition, pre-market
4 notification, quality and documented safety is
5 the only appropriate substitute for human
6 milk.

7 The compositional requirements, as
8 you've heard in the Infant Formula Act
9 represents minimum standards for infant
10 formula. However, the Infant Formula Act
11 nutrients have not been updated since the
12 1980's, and I would suggest to you nutrition
13 knowledge has grown, and the Infant Formula
14 Act nutrients no longer fully reflect
15 contemporary nutrition knowledge.

16 Lutein and lycopene are good
17 examples of this. The dietary guidelines for
18 Americans, which have incidentally been
19 updated six times since the Infant Formula Act
20 nutrients were established, encourage us to
21 make half your plate fruits and vegetables,
22 and to eat red, orange and dark green

1 vegetables.

2 The dark colors in these foods are
3 the result of the carotenoid content.

4 Carotenoids are a collective term for, as
5 you've heard, for a number of structurally-
6 related compounds.

7 Some, like lutein and lycopene,
8 are the focus of very intense research
9 efforts, and there's throwing recognition of
10 the role of these substances in human
11 nutrition, especially infant nutrition.

12 I'm going to focus on lutein, but
13 the story is fairly similar for lycopene as
14 well. Diets contain over 50 carotenoids, of
15 which about 20 can be found in the blood. Of
16 these, they are highly concentrated in certain
17 tissues, those being the eye, that bright
18 yellow spot there in the eye, is primarily
19 lutein, and then in the centers of the brain
20 that are associated with learning, memory and
21 vision.

22 Carotenoids are transferred from

1 mom's diet to the infant via breast milk.

2 Early breast milk or colostrum has a very high
3 lutein content, which decreases over time and
4 in breast-fed infants, blood lutein normally
5 rises over the first month of life, something
6 as you see on the right doesn't tap into
7 infant-fed formula without supplemental
8 lutein.

9 Until infants begin consuming
10 complimentary foods, infants only get
11 carotenoids from fortified formulas. Studies
12 now in both term and pre-term infants show
13 that lutein levels approximate those in human
14 milk-fed infants when supplemented formulas
15 are fed, but not when unsupplemented formulas
16 are fed.

17 The brain grows very rapidly, as
18 we've heard, in the first six months of life.
19 This shows relative development of neural
20 pathways in the visual cortex of the brain,
21 and as noted earlier, lutein is highly
22 concentrated in this part of the brain.

1 Evidence from a recent study in
2 premature infants suggests that lutein
3 accumulation early in life may be
4 physiologically important.

5 These are data from premature
6 infants fed a carotenoid-supplemented formula,
7 and showed signs of improved neural retinal
8 health or eye health, based on a sophisticated
9 measure, rod photo-receptor sensitivity, which
10 highlights the role and potential benefit of
11 lutein in infant formula. I'll stop.

12 MR. FOSTER: Thank you. Question
13 for the commenter? The best four minutes of
14 your life, huh?

15 DR. COCKRAM: I'm sorry?

16 MR. FOSTER: Fastest four minutes
17 of your life.

18 DR. COCKRAM: It was a fast four
19 minutes. Can I volunteer the answer to the
20 question of the difference between soy protein
21 isolate and concentrate?

22 MR. FOSTER: Yes.

1 DR. COCKRAM: Since 18 people have
2 asked and nobody's really answered?

3 MR. FOSTER: And you're willing to
4 answer it. Go for it.

5 DR. COCKRAM: Basically, the
6 difference is the concentration of protein.
7 I can't speak to the details of the
8 manufacturing, because I don't know. But soy
9 protein isolate usually has a higher
10 concentration of protein, less fats,
11 carbohydrates, minerals with it.

12 Soy protein concentrate is
13 generally a little bit lower, is lower and
14 it's over a range of protein concentrations.
15 But the tradeoff is with a concentrate, you
16 tend to have more of the other stuff from soy
17 that's still there, the minerals, the
18 electrolytes, etcetera.

19 MR. FOSTER: Thank you. Okay,
20 Jay.

21 MR. FELDMAN: Well, just to follow
22 up. Thank you for asking yourself that

1 question. I guess the question is what is
2 typically used in the industry. I mean
3 somebody is --

4 DR. COCKRAM: In terms of the
5 concentrate versus isolate?

6 MR. FELDMAN: In soy --

7 DR. COCKRAM: I can't speak to
8 that. We don't use that for -- I mean it's
9 isolate in infant formulas for certain.

10 MR. FOSTER: Thank you for your
11 time.

12 MS. SONNABEND: I have a question.

13 MR. FOSTER: Oh, I'm sorry. I'm
14 sorry. David, would you come back? Zea.

15 MS. SONNABEND: Your company
16 manufactures infant formula, not the
17 components of the infant formula; right?

18 DR. COCKRAM: You are correct.

19 MS. SONNABEND: Okay. To your
20 knowledge, are there more than one company
21 that make lutein and lycopene and those types
22 of products?

1 DR. COCKRAM: There are several
2 manufacturers of lutein in particular, as well
3 as lycopene. To my knowledge, there is only
4 form that has been reviewed by FDA for infant
5 formula use, and I guess that kind of gets me
6 to the point I had up on the slide, or that I
7 didn't get to, was other sources certainly
8 have ingredients.

9 Could be developed, but the issue
10 is it just takes a very long time, and it's a
11 fairly painful process to do that. Goes
12 through the, you know, two sequential FDA
13 reviews for ingredient safety, the GRAS part,
14 and then clinical or the appropriateness for
15 infant formula.

16 MR. FOSTER: Thank you. I have a
17 question from Jean.

18 MS. RICHARDSON: We've heard from
19 the commenters that many of these ingredients,
20 if not most of them, are considered by the
21 producers of the formula to be essential for
22 the infant, and yet they're not required by

1 FDA.

2 As you're pointing out on this
3 slide here, that the infant formulas are
4 highly regulated and closely scrutinized. So
5 we have the challenge sitting here, deciding
6 what to do with it. Why are they not required
7 if they're so darned essential? Could you
8 help us with that?

9 DR. COCKRAM: That's a good
10 question, and I guess one that on occasion
11 I've even debated a bit with Dr. Anderson.
12 But you know, frankly, the FDA -- in order for
13 FDA to or actually any regulatory body, and I
14 would submit to you this is probably a good
15 thing, in order for any regulatory agency to
16 change a regulation, it's a fairly cumbersome
17 process and requires a lot of work.

18 Goes through notice and comment
19 rulemaking, gets input from all sides, just
20 like we're getting here today, and you know,
21 it's a major chore for the regulatory agency
22 to go through that.

1 And you know, there are a lot of
2 priorities and under the current regulations,
3 there's really nothing that absolutely forces
4 a manufacturer to limit themselves to -- well
5 obviously there's nothing that forces a
6 manufacturer to limit themselves to only the
7 IFA nutrients.

8 You are obligated to go to FDA and
9 convince them that in fact you will be doing
10 no harm and hopefully some good, and you know,
11 at this point, that system has worked
12 reasonably well with FDA and, you know, Dr.
13 Anderson certainly can comment further on
14 that.

15 But I think we have, you know, I
16 think because of the burden of changing
17 regulations, you know, certainly public health
18 guidelines and recommend, you know, the
19 recommendations for nutrient intake have
20 changed over time. But the regulations,
21 probably as a good thing, haven't.

22 MR. FOSTER: Thank you. Just to

1 follow up on that Jean, my hope is that
2 shortly, the Handling Committee will come back
3 from lunch.

4 We go, according to the agenda, to
5 an immediate Handling Subcommittee break, and
6 so we have -- we will need to get with Dr.
7 Anderson, I believe no later than 1:30, in
8 order to make sure she can leave on her
9 schedule.

10 So my hope is that Handling
11 Subcommittee can get back -- at least Handling
12 Subcommittee can get back by 1:30, so that we
13 have time to take advantage of Dr. Anderson's
14 knowledge with respect to the GRAS question
15 perhaps Jean, as well as the question you just
16 asked, and the rosemary extract.

17 Any -- okay, thank you for your
18 time.

19 DR. COCKRAM: Thank you.

20 MR. FOSTER: Next up, I have
21 Robert Rankin and then the last speaker
22 scheduled is Marsha Walker.

1 MR. RANKIN: Good morning. My
2 name is Robert Rankin. I am the Associate
3 Director of the International Formula Council.
4 The IFC is an association of manufacturers and
5 marketers of formulated nutrition products,
6 including infant formulas, and we appreciate
7 the opportunity to speak today.

8 I would like to thank the NOSB and
9 the NOP for your hard work on these
10 activities. These are a lot of difficult
11 decisions you will need to make. As has been
12 stated today, and we didn't make it any easier
13 with our petitions that we submitted.

14 However, I think it makes an
15 important point, in terms of what has been
16 discussed today, related to what we knew in
17 1980 versus what we know today. So I'll be
18 speaking about that in a second.

19 As stated in our petitions and
20 written comments, the ISC supports the
21 continued use of all nutrients in organic
22 infant formula. They have been reviewed and

1 accepted by the U.S. FDA and regulatory
2 agencies around the world for use in infant
3 formula, and with the exception of ascorbyl
4 palmitate, they're all found in human breast
5 milk.

6 Because there were so many
7 petitions and so many nutrients to discuss, I
8 will not be commenting on each one
9 individually. Instead, I'll be providing some
10 contextual comments, which I hope will help
11 the NOSB in your evaluations.

12 First, the ISC supports the
13 American Academy of Pediatrics'
14 recommendations regarding breast feeding.
15 Human milk is the gold standard for infant
16 nutrition, and provides specific maternal and
17 infant benefits.

18 The ISC also supports positive
19 efforts to support and promote breast feeding.
20 Every mother should breast feed if she can and
21 chooses to do so. The reality is not all
22 mothers can and want to breast feed. There

1 are a variety of reasons for it, be it
2 maternal health, infant health, adoption, lack
3 of workplace support, cultural reasons, a
4 mother's choice and many others.

5 The NOSB was not created, nor are
6 we here to discuss how infants should be fed.
7 What we believe we should be discussing is how
8 to ensure infants who are not breast fed
9 receive the most complete, optimal nutrition
10 possible.

11 As has been said before, U.S.
12 regulations define infants as persons no more
13 than 12 months old. Infants are a very
14 critical population, and require specific
15 nutrients to ensure proper growth and
16 development, and these needs are met through
17 breast milk, infant formula, or a combination
18 of both.

19 U.S. regulations also define
20 infant formula as a food solely for infant
21 use, as a complete or partial substitute for
22 human milk. Infant formula is the most highly

1 regulated food in the world, and is recognized
2 as the only appropriate alternative in meeting
3 the nutritional needs of infants, of mothers
4 who cannot or choose not to breast feed.

5 It is important that infant
6 formula be as nutritionally complete as
7 possible, to ensure proper growth and
8 development.

9 Because infant formula is the sole
10 source of nutrition for many infants,
11 academicians and industry researchers
12 recognize the importance of continuously
13 conducting scientific research, and evaluating
14 results, to ensure and constantly improve the
15 nutritional quality and performance of infant
16 formulas.

17 The primary goal of the infant
18 formula industry is to ensure that infants who
19 are fed infant formula receive a product that
20 is nutritionally close as possible to human
21 breast milk. This requires research and
22 investigation into the composition of human

1 milk, as well as the mechanisms of the
2 benefits associated with breast feeding.

3 When existing data and new
4 research provide a reasonable basis to
5 conclude that a new ingredient is safe and
6 provides a benefit, the manufacturers are
7 required, as has been said, to provide FDA
8 with documentation of that information, to
9 establish its safety and suitability.

10 It can take decades of academic
11 and industry research to result in a
12 nationally or internationally adopted
13 requirement for a particular nutrient. So
14 while it would be nice to be able to do that
15 on an as-needed basis, it's not practical and
16 feasible, as has been discussed.

17 So that brings me to the
18 discussion being had here today, where it's
19 been suggested that infant formulas may only
20 need to include ingredients listed in the
21 Infant Formula Act from 30 years ago.

22 The Infant Formula Act reflects

1 the nutrition science known at that time, and
2 over the past 30 years, significant
3 improvements have been made in learning about
4 infant nutrition and the composition and
5 benefits of breast milk, which has resulted in
6 the products you see today. So I'd like for
7 you to take that into consideration as well.
8 Thank you very much.

9 MR. FOSTER: Thank you. Questions
10 from the Board? Calvin.

11 MR. WALKER: How does the -- if by
12 chance these particular materials are voted
13 down, what kind of impact would that affect
14 your particular business?

15 MR. RANKIN: Well, I'd probably
16 want to refer that to the manufacturers who
17 use the ingredients and manufacture the
18 products. However, I can volunteer a couple
19 of opinions.

20 Obviously, a lot of research and
21 development has gone into the ingredients that
22 are currently used in infant formula. As I

1 said before, they've been reviewed and
2 accepted by the FDA. They've also been
3 accepted by regulatory agencies around the
4 world.

5 So they are safe, they are
6 suitable, and based on the information that is
7 required by manufacturers to submit during the
8 review process, they do show proper growth and
9 development. So those nutrients are
10 researched and proven to be safe and suitable
11 for infants.

12 If any of these ingredients are,
13 especially those which provide a function,
14 such as antioxidant and what have you,
15 manufacturers, if they were no longer allowed
16 to use those ingredients, they would be forced
17 to research and develop alternatives, if those
18 exist.

19 That would require, I think the
20 previous speaker had a table which showed a
21 pretty long time table for what goes into
22 researching, studying alternatives, going

1 through clinical trials, which is required for
2 infant formulas, to show that the ingredients
3 are safe and suitable.

4 The GRAS approval process, which I
5 think it would be great for FDA to discuss a
6 little bit more, because I believe one of the
7 comments I heard from another commenter, in my
8 opinion it kind of -- in my opinion, it
9 downgraded FDA's role in reviewing these
10 ingredients for their safety and suitability.

11 I really believe that the process
12 is robust and it is working, as far as we're
13 concerned, with regards to infant formulas.
14 But then so the manufacturers would need to
15 identify alternatives, determine that they are
16 suitable, determine that they are viable, and
17 then determine if that's something that they
18 want to pursue, in terms of staying in the
19 market.

20 But as I think, as you have heard,
21 there's at least one nutrient for which there
22 is not a suitable alternative. So and I think

1 that affects the antioxidant properties. So
2 that as some have said, could potentially
3 affect the category, although I can't speak to
4 that, because I'm not a manufacturer.

5 MR. FOSTER: Thank you.
6 Additional questions? Nick and then Zea.

7 MR. MARAVELL: Yes. I was
8 wondering if you have a feel for what
9 percentage of infant formula currently sold in
10 the United States is labeled as organic, and
11 if you had a feeling for how much of that is
12 soy-based and milk-based?

13 MR. RANKIN: I actually don't have
14 information on the percentage of organic
15 infant formula. I think the manufacturers
16 might have an idea, because they would produce
17 those.

18 I would like to say, though, that
19 in my opinion and in my history, my wife buys
20 a lot of organic products and my understanding
21 is that those who are interested in organic
22 products are very passionate about having that

1 option.

2 And so I think if you get into a
3 situation where the organic option is not as
4 nutritionally complete, perhaps, as a
5 conventional formula, then they may deselect
6 that product and go with an alternative that
7 is not safe and nutritious and recommended,
8 such as a home-made type of product.

9 And that, I think the FDA would
10 agree and the AAP, is definitely not where we
11 want to go with that. Breast milk and infant
12 formula are the two safe nutritious
13 recommended options, and it's my opinion that
14 that option of an organic product for those
15 consumers, and mothers who want to provide
16 that for their infants, should be preserved.

17 Then as far as soy, again Dr.
18 Bhatia made some comments about the needs for
19 soy formula, and I don't disagree with his
20 comments. But I would like to say that with
21 regards to soy, just like with organic and
22 with everything else the consumers have the

1 opportunity to purchase, we believe that that
2 option should remain available to consumers,
3 because it is an important category for those
4 who want to provide their families with
5 vegetarian options.

6 So we strongly believe that soy
7 formula has its place and it's very important.

8 MR. FOSTER: Thank you. Last
9 question, Zea.

10 MS. SONNABEND: Thank you. In
11 looking at alternatives, particularly to the
12 ascorbyl palmitate and beta carotene, which
13 appear to be preservatives, we're wondering if
14 any of your members or colleagues have looked
15 into the possibility of refrigerated infant
16 formula without preservatives?

17 MR. RANKIN: One of the speakers
18 mentioned that they weren't aware of any
19 research that's been done. You might ask the
20 other manufacturers. But I'm not aware of it
21 myself. Just it's apparently not the way that
22 it has ever been done, and so it's not been

1 considered, and I know if the AAP would have
2 any comments on that either.

3 MS. SONNABEND: A follow-up to
4 that. Would -- you were talking about you
5 need to go GRAS approval if you're adding
6 other ingredients. But if you were just
7 making refrigerated formula without
8 ingredients, would that still need certain FDA
9 or GRAS approvals?

10 MR. RANKIN: As long as it doesn't
11 include an ingredient that has never been used
12 before and never been reviewed. That GRAS
13 review is for any nutrient that's not
14 considered, you know, on the regulatory list,
15 and has not been used before.

16 So it would need to go through
17 that GRAS approval process. So a short
18 answer, if it's a new ingredient, yes, it
19 needs to go through the GRAS process.

20 MS. SONNABEND: Refrigeration
21 isn't an ingredient, so it's just a process or
22 a product?

1 MR. RANKIN: Right. If you're
2 talking about taking out ingredients, I think
3 that would be considered a new formulation.
4 So that would need to go through the FDA
5 approval process again. But as long as there
6 were no new ingredients, it would not need to
7 go through the GRAS review process, just the
8 pre-market notification process.

9 MR. FOSTER: Thank you for
10 clarifying. We have one more speaker,
11 according to my schedule.

12 MR. RANKIN: Thank you.

13 MR. FOSTER: Thank you very much
14 for your time. I had Marsha Walker. Is
15 Marsha in the house? Okay. Marsha's not
16 here. That concludes the public comment that
17 I have on the schedule here.

18 At this point, I need a lot of
19 clarification on the timing of the breaks,
20 because the agenda I have is not clear to me.
21 So I'm going to need help. I want to make
22 sure that we accommodate Dr. Anderson's

1 departure schedule.

2 So I know we need to be back to
3 ask some questions of her by 1:30. But beyond
4 that, help me understand what's in the agenda.
5 When does everyone need to be back, versus
6 when does the Handling Committee need to be
7 back, because there appear to be a difference
8 in the agenda I have.

9 I'm going to hand this over to --
10 yes, go ahead. I'm listening.

11 CHAIRMAN FLAMM: Well, will it
12 meet our guest's time table if we returned on
13 the scheduled time of 1:30, John. We're
14 almost there right now, so it would be just a
15 little over an hour break.

16 MR. FOSTER: Okay, returning at
17 1:30.

18 CHAIRMAN FLAMM: And then you'll
19 have the opportunity to get together with your
20 Subcommittee after we have the chance to ask
21 some more questions. Is that okay?

22 MR. FOSTER: That's fine. So back

1 at 1:30, everyone.

2 CHAIRMAN FLAMM: We'll take a
3 break now for lunch, and be back here at 1:30.

4 (Whereupon, the above-entitled
5 matter went off the record at 12:23 p.m. and
6 resumed at 1:43 p.m.)

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A F T E R N O O N S E S S I O N

1:43 p.m.

1
2
3 MR. FOSTER: All right. Thanks
4 everybody for coming back. I hope you got
5 some provender to keep you going for the rest
6 of the afternoon. We are moving back into the
7 portion of the agenda that's dealing with
8 Handling Subcommittee activities.

9 We had scheduled on the agenda to
10 go directly into additional subcommittee
11 deliberations, which I know the gallery would
12 find fascinating. But instead, we want to
13 accommodate some travel schedules for Dr.
14 Anderson.

15 So with -- Barry, with your okay,
16 I'd rather move straight into the Board
17 members' ability to ask some specific
18 questions of Dr. Anderson. Is that all right
19 with you? Okay. Thank you, Barry. Thank
20 you, Mr. Chairman, I should say.

21 We have a number of questions that
22 came up in the context of earlier dialogue,

1 that we want to reiterate. Jay, I know you
2 have a question about GRAS notifications.
3 Jean, I know rosemary extract is one and oh,
4 it looks like I am buying someone's round
5 tonight. There you go. That's me. That's my
6 fault. That was me. I'll claim it.

7 We had a couple of additional
8 questions that came up in the context of a
9 very unofficial lunch, a fast-paced lunch
10 meeting. So we'd like to move straight into
11 questions of Dr. Anderson and others, if we
12 need to.

13 So with that, Zea I know you had a
14 specific question, and if it's okay with
15 everyone, I'll go Zea, Jay and then Jean, and
16 then take other questions from the Board.

17 MS. SONNABEND: Thank you. Dr.
18 Anderson, my question is following up on what
19 one of the commenters said about going through
20 the FDA process, to get approval for a
21 refrigerated version of an infant formula that
22 did not have preservatives.

1 Could you describe what that would
2 involve? If it didn't have a new added
3 ingredients, but it was just for
4 refrigeration.

5 DR. ANDERSON: That would involve
6 a new processing entirely, and the safety of
7 that processing would have to be evaluated.
8 It would also have to be evaluated for the
9 microbiological quality, the nutrient quality,
10 and they would have to provide an infant
11 formula notification before they go to market,
12 and they would have to show that they were
13 complying with good manufacturing practices,
14 that they were not producing product that
15 could be considered contaminated or
16 adulterated, and that it would support normal
17 growth in infants and be well-tolerated.

18 So they would have to give us an
19 infant formula notification, to give us
20 assurances that the product was being produced
21 in a way that is following good manufacturing
22 practices, and that will meet the needs, the

1 nutritional needs and the safety needs of the
2 infant.

3 One thing we do not approve, these
4 notifications. Congress did not give us
5 approval authority. If an infant formula
6 company comes to us and gives us a
7 notification, they have to do so 90 days
8 before they go to market.

9 But on the 90th day, they are free
10 to go to market, even if we have serious
11 questions about the product. Congress didn't
12 give us approval authority.

13 MS. SONNABEND: Dr. Bhatia, could
14 you address that question?

15 DR. BHATIA: I have a more
16 practical point. Let me, if you take sterile
17 formula, with a long shelf life, what have
18 you. I'm not here representing anybody who
19 manufactures, and open that can or bottle or
20 refrigerate it, you have to throw it away in
21 48 hours.

22 So if you only have non-

1 preservative, refrigerated milk, not only are
2 you reducing shelf life; then you have to
3 prove that the formula, as prepared, is good
4 in the refrigerator, even for that 48 hour
5 period. So it has got a lot of implications
6 and one simple step.

7 MR. FOSTER: Jay.

8 MR. FELDMAN: Thank you. Dr.
9 Anderson, thank you. The earlier question I
10 had was about the standards for FDA, and the
11 actual process that the FDA goes through when
12 a manufacturer lists as GRAS.

13 DR. ANDERSON: Okay. As indicated
14 earlier, GRAS stands for Generally Recognized
15 as Safe, and that's a category of food
16 ingredient. There are two categories of food
17 ingredients. One is food additives, and that
18 has to have food additive status. A compound
19 has to be petitioned to the agency.

20 The agency approves or not
21 approves the petition, and a regulatory
22 decision is made and that has the force of

1 law. For a Generally Recognized as Safe
2 substance, the agency provides a different
3 mechanisms for establishing the Generally
4 Recognized as Safe status, and I should
5 emphasize that the -- it's not the substance
6 that has GRAS status; it's the substance for
7 its intended use that has the GRAS status.

8 So if it's for use in infant
9 formula, that's the use that has to be
10 evaluated in any evaluation of safety.

11 The process that is used for
12 evaluation of Generally Recognized as Safe
13 Ingredients by the Office of Food Additive
14 Safety is a voluntary process, in which infant
15 formula manufacturers, food manufacturers,
16 ingredient manufacturers come to the agency
17 and say that we have self-determined that this
18 substance is GRAS for use in infant formula or
19 whatever, and we base this on either history
20 of use or scientific substantiation,
21 scientific evidence, and in addition, it's
22 recognized in the scientific community by

1 experts qualified by training and experience,
2 that this is indeed a use that is safe for the
3 particular substance.

4 Now with the provision of a GRAS
5 notice, the information all has to be publicly
6 available. The agency cannot consider
7 proprietary or confidential data as primary
8 evidence for the safety of the compound for
9 that particular use, and the agency does not
10 make its own determination of the safety.

11 At the end of the review of that
12 notice, the agency will issue a letter saying
13 either we have no questions of your self-
14 determination, or we do have questions and
15 these are what the questions are.

16 So it is incumbent on the
17 manufacturer to provide the, for the safe use
18 of the ingredients in their products. Neither
19 the infant formula notification process, which
20 is mandatory, nor the GRAS notice process,
21 which is voluntary, are approval processes.

22 And so that in a nutshell is what

1 we, what the process is for new food
2 ingredients for infant formula.

3 MR. FOSTER: Thank you. Follow-
4 up, Jay?

5 MR. FELDMAN: Yes, thanks. I
6 actually had another question after that, but
7 is part of the assessment, it sounds like
8 there's an assessment in there somewhere. In
9 other words, the company or institution is
10 self-certifying, subjecting their information
11 to some review process at FDA by somebody or
12 some panel of people, and then they get a
13 letter of some sort. Is that accurate? Am I
14 summarizing that accurately?

15 DR. ANDERSON: Pretty much so. As
16 you've said, FDA does not make its own
17 independent review of all the data on its own.
18 FDA relies on the information that's provided
19 in the GRAS notice, and other information
20 that's available in the publicly available
21 literature.

22 MR. FELDMAN: Okay.

1 DR. ANDERSON: If there's issues
2 that they have questions about, they
3 communicate those questions to the notifier
4 during the review, and they can provide
5 supplemental information. However, it's not
6 an independent review of the safety of the use
7 of a particular substance.

8 MR. FELDMAN: Okay, and just one
9 other thing on that point. As a part of the
10 information that is submitted to FDA, does any
11 of that information include data or other
12 types of information on the manufacturing
13 processes that are used to produce this?

14 DR. ANDERSON: Oh yes. Yes, it
15 does. It includes information on the
16 composition of the substance, on the
17 manufacturing process, on any toxicological
18 tests that have been done, any clinical tests
19 that have been done, any scientific
20 information that's available on the substance,
21 and I think that pretty much sums it up.

22 MR. FELDMAN: Okay, thank you,

1 thank you. John, I have another question if
2 there's time.

3 MR. FOSTER: Okay, yes. We'll go
4 to Jean and then round back if we have time.
5 Thank you, Jay. Jean.

6 MS. RICHARDSON: Yes, I have two
7 questions. The first question relates to the
8 use of rosemary as a potential antioxidant in
9 infant formula. Do you know if rosemary
10 extract -- some of the technical report
11 information suggested that rosemary extract
12 could be permitted as an antioxidant, and if
13 it is used, does it have any other use that
14 you're aware of?

15 DR. ANDERSON: The only use that
16 I'm aware of for rosemary extract is as a
17 flavoring agent. I'm not aware that it's ever
18 been used in infant formula as an antioxidant.
19 FDA has certainly never evaluated that use for
20 safety.

21 Addition of a new antioxidant
22 system in infant formula would require a pre-

1 market notification for the new infant
2 formula, and in our review of that infant
3 formula notification, we would want to be
4 certain of the scientific basis of the safety
5 for that use of rosemary extract, or any other
6 new antioxidant system in infant formula.

7 Like I said, rosemary extract is
8 generally recognized as safe for use as a
9 flavor, in accordance with good manufacturing
10 practice in FDA's regulations. Whenever we
11 get an infant formula notification that might
12 involve use of a new ingredient, we consult
13 with the Office of Food Additive Safety, which
14 is responsible for the review of GRAS
15 notifications and has the expertise on
16 evaluating food safety, ingredient safety
17 questions.

18 We always encourage infant formula
19 manufacturers to submit a food additive
20 petition or a GRAS notice to the Office of
21 Food Additive Safety, and to work with that
22 office to resolve any safety issues about use

1 of ingredients new to infant formula, before
2 they come to us with an infant formula
3 notification.

4 Just one additional word here, is
5 that the time line for review of a GRAS notice
6 is 180 days. The time line for review of an
7 infant formula notification is 90 days. So if
8 an infant formula manufacturer comes to us
9 with a GRAS notice for, I'm sorry, with an
10 infant formula notification, for which they
11 haven't resolved safety issues of a new
12 ingredient, then that really creates problems
13 getting a review or consulting with the Office
14 of Food Additive Safety on an accelerated time
15 line.

16 MS. RICHARDSON: Thank you. My
17 second question relates to essentiality. As
18 you know, we have to try to determine if
19 anything that's going into the infant formula,
20 is it essential for that formulation, for that
21 product.

22 We know that these items that

1 we're looking at today are not required by the
2 FDA at the present time, but as you heard from
3 the presentations this morning, they are
4 stated, many of them, as being essential for
5 the formula to make a whole food for that
6 infant.

7 So could you help us to understand
8 why if they are indeed essential, why are they
9 not on your -- on the FDA list?

10 DR. ANDERSON: The term "required"
11 is a legal term that's used in our regulations
12 and in the law, to indicate the 29 nutrients
13 that are required in infant formula. The term
14 "essential" is used by the nutrition community
15 to recognize that substances are needed in the
16 diet of humans.

17 The Institute of Medicine of the
18 National Academy of Sciences is an
19 authoritative body that provides information
20 on the essential, on what are essential
21 nutrients. Like I said earlier, it requires
22 a formal rulemaking procedure, which is very

1 long and involved and complicated, to change
2 a regulation.

3 For us to change or update the
4 list of 29 required nutrients and their
5 minimum values would require that formal
6 rulemaking process. However, in another part
7 of the infant formula regulations, there is
8 allowance for addition of other substances in
9 infant formulas.

10 For example, selenium has -- in
11 the time between 1985 and now, selenium was
12 recognized as an essential mineral. It has
13 not been added to the list of 29, and
14 primarily because of agency priorities and the
15 cumbersomeness of rulemaking.

16 However, infant formula
17 manufacturers do add selenium to their
18 products, and they are -- the do so on the
19 basis that the National Academy has found it
20 to be essential in human nutrition. So I hope
21 that answers your question.

22 We don't -- although we have a

1 list of 29 required nutrients, we don't have
2 a list of mandatory ingredients or a
3 restricted list of ingredients that can be
4 added to infant formula.

5 MS. RICHARDSON: Are you aware
6 then if the National Academy has said that any
7 of these ingredients we're looking at today
8 are essential?

9 DR. ANDERSON: No. The-- no.

10 MR. FOSTER: All right. Are there
11 questions from others on the Board? I have
12 one. I think -- I don't think it will be a
13 long one; then we can get back to others.
14 What, in this GRAS notification process, what
15 happens if an operator were to, you know, give
16 you this notification and you've got 180 days
17 to respond to them.

18 What happens if they've provided
19 some information to you that's incorrect or
20 inconsistent with guidelines or standards ore
21 requirements? What can happen them in the
22 context of infant formula, where they've just

1 misreported something?

2 Like if they're trying to pull the
3 wool over your eyes, what happens when you
4 catch them doing that?

5 DR. ANDERSON: If there are safety
6 issues involved, it would be regarded as an
7 adulterated product, and there would be
8 compliance issues with that, and so -- and
9 there could be -- it would be a prohibited act
10 to market that, and there are criminal
11 penalties involved with that.

12 MR. FOSTER: And so what's the
13 consequence to the supplier of that
14 information, if you find something out that
15 they were trying to hide, or if something was
16 bad, something was wrong? So what compliance?
17 What do you mean by compliance action?

18 What happens? Does that mean show
19 up at their house or --

20 DR. ANDERSON: Well, a warning
21 letter could be issued. Product could be
22 seized, an injunction could be issued.

1 MR. FOSTER: That's what I was
2 looking for. Thank you. Questions from
3 others on the Board?

4 DR. BHATIA: It also appears on a
5 FDA warning list.

6 MR. FOSTER: I'm sorry, what
7 appears on a warning list?

8 DR. BHATIA: Not FDA, but when
9 some of these infractions occur, FDA issues a
10 warning that is public domain. So that actual
11 list which is kept forever, saying so and so
12 has manufactured X and Y. So there's an
13 actual warning published to the public domain
14 about any infraction which the FDA is against.

15 MR. FOSTER: The old version of
16 shunning back in the day. Thank you for that.
17 Questions from others on the Board for either
18 of our guests? Then we'll go back to Jay for
19 a last one.

20 MR. FELDMAN: Okay. So this is a
21 question about the levels, the nutrient levels
22 that would be allowed in these products. I

1 assume whether it's organic or not, the levels
2 that would be used would be uniform across
3 conventional and organic products.

4 But if FDA is not setting a level
5 as required or essential, because somebody
6 else does that, where do these levels, these
7 nutrient levels that actually end up in the
8 final product come from? Who makes the
9 determination as to whether the levels are the
10 right levels, or that they, somehow children
11 are being over-exposed or there's a risk
12 factor there that's not being considered
13 fully?

14 DR. BHATIA: Well, it's
15 interesting you ask that question, because
16 right now the NIH has convened a body. NIH,
17 FDA, USDA, AAP, all these different people, to
18 ask that very question. What are the
19 questions from 0 to 24 months which would
20 include the period you're talking about, the
21 infant formula would be the key question.

22 A lot of the requirements at not

1 known. These are best estimates made from
2 epidemiology, are the classic nutrition
3 principles of defining a requirement. So
4 either you find a population that was
5 sufficient, or you find a population that had
6 excess, or you find a population that's
7 deficient, and you guess that it is somewhere
8 between the deficient and the excess.

9 Then a best guess is made. That's
10 one way of looking at nutrients. So we really
11 don't have evidence, informed guidelines for
12 every nutrient that's already there, and
13 that's where the struggle is now, to put
14 together some body of evidence which says this
15 is a human requirement. This has been a
16 slippery slope.

17 DR. ANDERSON: And I can add to
18 that as well. In the GRAS notification, in
19 the GRAS notice process, one of the elements
20 that's required, and I neglected to mention,
21 is that there has to be an exposure estimate,
22 of exposure of -- what the exposure will be,

1 and why that exposure will be safe, and there
2 --

3 In each GRAS notification, there
4 is an upper limit that is specified for the
5 exposure, and that that exposure will be safe.

6 MR. FELDMAN: But again, that is
7 not independently reviewed by FDA, as to
8 whether in fact that level is either effective
9 or potentially problematic?

10 DR. ANDERSON: Yes. FDA does not
11 do its own independent review. However, all
12 of those decisions or all of those no further
13 questions are time-dependent, and if any
14 information becomes available after that
15 letter is issued, FDA would reconsider any
16 updated information.

17 MR. FELDMAN: Thank you.

18 MR. FOSTER: Mac, I saw your hand.

19 MR. STONE: I have one question in
20 reference to rancidity. We heard about the
21 oxidation and rancidity of the oils. If you
22 have -- who determines that shelf life, and if

1 in fact it is a food safety issue? Does the
2 manufacturer determine the date that it should
3 be removed from the shelf, or does anybody
4 verify the preservative value or that length
5 of shelf life?

6 DR. BHATIA: I can't get too
7 technical on this, but I can tell you from my
8 own what the shelf life means. The shelf life
9 specifies that the nutrients on the label, the
10 minimum amounts of nutrients on the label are
11 still present at the end of shelf life.

12 The other issues of being rancid,
13 coloring, all that, that's determined way
14 before the formula is even submitted to the
15 FDA for review. In fact, if you go to any of
16 the manufacturing places, a lot of people from
17 Abbott can confirm what I'm saying, the whole
18 shelves, there are whole shelves of formula
19 that are kept for time to see what happens to
20 formula over time.

21 But that claim is only based on
22 that the formula will have the minimal amounts

1 of nutrients specified in the label. So as a
2 matter of fact, each manufacturer adds much
3 more than the minimal level to assure minimum
4 label is still there one year later.

5 This is especially true for
6 vitamins, which are photo-sensitive and decay
7 over time.

8 MR. FOSTER: All right. I had
9 Nick there, but it seems he's out for a sec.
10 I'll ask for others. Jean, did you get what
11 you need? Okay. All right. I'm assuming Dr.
12 Anderson had to leave; clearly she did.

13 But I'm assuming she had to leave
14 the premises actually, to catch her next
15 appointment. So with that, if there's no more
16 questions, we'll move into a 15 minute break
17 for the Handling Subcommittee, to get our
18 heads together, see what changes, if any, we
19 need to make and then reconvene at -- let's
20 make it 2:25 as a full board. Thanks.

21 Oh, I'm sorry. Thank you Dr.
22 Bhatia. Thank you for being here. Thank you

1 for your -- we found, actually we talked about
2 this at lunch. This was very valuable to have
3 you here, and we'll be recommending to the
4 program that we have more regular interactions
5 like this during our Board meetings.

6 So I thank you for that, for
7 setting an excellent precedent. It was very,
8 very helpful to have you here. So thank you
9 very, very much.

10 DR. BHATIA: Thank you for the
11 kind comments, and appreciate the invitation.

12 MR. FOSTER: Thank you.

13 (Whereupon, the above-entitled
14 matter went off the record at 2:10 p.m. and
15 resumed at 2:36 p.m.)

16 MR. FOSTER: Barry, I'm handing
17 the virtual gavel back to you.

18 CHAIRMAN FLAMM: Thank you, John,
19 and I believe we're ready to proceed. The
20 Handling Committee is ready to vote on all of
21 its proposed -- shh, shh, shh. Can't hear
22 myself think.

1 The Handling Committee is ready to
2 proceed on all their petition materials,
3 except for nucleotides, which is being
4 postponed until tomorrow. I think the voting
5 will proceed in the same order that it was
6 presented this morning, and so I'll entertain
7 a motion on the first material, and that is --

8 MR. FOSTER: The first item is
9 ascorbyl palmitate. Nick, I believe you have
10 the goods on that.

11 MR. MARAVELL: Where am I?

12 MR. FOSTER: Ascorbyl palmitate.

13 MR. MARAVELL: Are we entertaining
14 motions?

15 MR. FOSTER: We are accepting
16 motions about the petition to add ascorbyl
17 palmitate to the National List.

18 CHAIRMAN FLAMM: But we need the
19 motion.

20 MR. MARAVELL: The first motion
21 would be a listing, a classification motion?

22 CHAIRMAN FLAMM: That is correct.

1 MR. MARAVELL: Okay. So I am
2 willing, I am going to make a motion that
3 ascorbyl palmitate is synthetic.

4 CHAIRMAN FLAMM: Do we have a
5 second?

6 MS. FULWIDER: I second that.

7 CHAIRMAN FLAMM: We have a motion
8 that's been seconded to classify ascorbyl
9 palmitate, CAS No. 137-66-6 as synthetic.
10 Discussion?

11 (No response.)

12 CHAIRMAN FLAMM: Hearing none,
13 I'll proceed with the vote. The vote will
14 begin with Jean.

15 MS. RICHARDSON: Yes.

16 MR. WALKER: Yes.

17 MR. BONDERA: Yes.

18 MS. TAYLOR: Yes.

19 MR. MARAVELL: Yes.

20 MR. FELDMAN: Yes.

21 MS. SONNABEND: Yes.

22 MR. STONE: Yes sir.

1 MS. FULWIDER: Yes.

2 MR. AUSTIN: Yes.

3 MS. FAVRE: Yes.

4 MS. BECK: Yes.

5 MR. FOSTER: Yes.

6 MR. DICKSON: Yes.

7 CHAIRMAN FLAMM: And the chair
8 votes yes. We have 15 yes, 0 no's. The
9 motion to classify the material as synthetic
10 passes. I'm going to entertain a motion to
11 list.

12 (Off record comments.)

13 CHAIRMAN FLAMM: So we can
14 entertain a motion on listing the material.

15 MR. MARAVELL: I'd like to make a
16 very brief clarification and then go forward
17 with the motion. In the materials prepared by
18 the Subcommittee on Ascorbyl Palmitate, we did
19 reference the fact that rosemary extract was
20 something that this Board had approved with
21 regard to DHA and ARA, which was for use in
22 infant formula.

1 In a private conversation with Dr.
2 Anderson, I asked how that came about, given
3 that FDA has never reviewed rosemary extract,
4 and she had a very straightforward and simple
5 answer. What we approved was not what Martech
6 had submitted to FDA for their GRAS listing.

7 And so indeed, our statement is
8 correct, but it would lead one to believe that
9 perhaps rosemary extract had also been in some
10 way reviewed or submitted to FDA, and that is
11 not the case. On behalf of the Committee, I
12 apologize if we misled anybody, even though
13 our statement is technically correct.

14 Now I'll proceed with a motion. I
15 make a motion to add ascorbyl palmitate, CAS
16 No. 137-66-6 to the National List, Section
17 205.605(b) for use as a preservative in infant
18 formula.

19 MS. RICHARDSON: I second that
20 motion.

21 CHAIRMAN FLAMM: Who seconded it?

22 MS. FULWIDER: Jean.

1 CHAIRMAN FLAMM: Jean seconded the
2 motion. We have a motion, which has been
3 seconded, to add ascorbyl palmitate, CAS No.
4 137-66-6 to the National List, Section
5 205.605(b) for use as a preservative in infant
6 formula. Discussion? Zea.

7 MS. SONNABEND: Thank you. For
8 the purposes of everyone in the audience, and
9 so that everyone is clear on this point, I
10 would like to ask the NOP to state what would
11 happen if something that has previously been
12 allowed in infant formula comes off the list,
13 because we don't vote for it at this time.
14 Could you just say what people can expect from
15 that?

16 MS. BAILEY: Thanks, Zea. So as
17 people are well aware, the Department
18 published a proposed rule in January of this
19 year, with a proposal to amend the listing for
20 nutrient vitamins and minerals on the National
21 List, and we proposed what new language would
22 be.

1 That new language would not
2 provide for the use of the nutrients that are
3 petitioned before you today. So in September,
4 we published an interim rule to continue the
5 listing as it is currently codified in the
6 regulations, which essentially maintains the
7 status quo.

8 We are taking comments on that
9 interim rule for 90 days until December 26th.
10 In the proposed rule, we explicitly asked for
11 input from commenters on the proposed length
12 of the compliance period, which would have
13 been two years after the issuance of any final
14 rule on the matter.

15 So at this point, the interim rule
16 maintains the status quo. We have not issued
17 a final rule, based on the comments that say
18 what the intention of the agency is as far as
19 a compliance period. But we did ask for those
20 comments and would address any comments about
21 compliance in any final rule that we would do.

22 CHAIRMAN FLAMM: Follow-up?

1 MS. SONNABEND: Well, I have one
2 additional clarification. For these
3 particular first two items that are able to be
4 used as vitamins in the proposed rule that
5 already is out, the vitamin, ascorbyl
6 palmitate is a source of Vitamin C and beta
7 carotene is a source of Vitamin A.

8 If we are not voting for them
9 here, that means they can still be used as the
10 source of Vitamin A or Vitamin C, because what
11 we are doing is voting them off for the
12 petition use as a preservative.

13 MR. FELDMAN: And can you verify
14 that -- I'm sorry.

15 CHAIRMAN FLAMM: Jay.

16 MR. FELDMAN: Could you verify the
17 citation under where that fits? Is that just
18 under the general Vitamins and Minerals?
19 Okay. Okay.

20 CHAIRMAN FLAMM: Nick.

21 MR. MARAVELL: Yes. Just to
22 amplify one point on what Zea said, the

1 ascorbyl palmitate, which is the motion that
2 we're considering right now, was petitioned as
3 an antioxidant, which functions as a
4 preservative, and Dr. Anderson clarified from
5 her point of view that antioxidants were a
6 subcategory of preservatives. But the actual
7 petition was as an antioxidant.

8 CHAIRMAN FLAMM: Any further
9 discussion of the material? There's no
10 further discussion, I believe we can proceed
11 with voting, beginning with Calvin.

12 MR. WALKER: No.

13 MR. BONDERA: No.

14 MS. TAYLOR: No.

15 MR. MARAVELL: No.

16 MR. FELDMAN: No.

17 MS. SONNABEND: No.

18 MR. STONE: No sir.

19 CHAIRMAN FLAMM: Wendy?

20 MS. FULWIDER: Yes.

21 MR. AUSTIN: Yes.

22 MS. FAVRE: No.

1 MS. BECK: Yes.

2 MR. FOSTER: Yes.

3 MR. DICKSON: No.

4 MS. RICHARDSON: No.

5 CHAIRMAN FLAMM: And chair votes
6 no. How many yes's do we have? Four. 4
7 yeses, 11 no's. The petition does not pass.
8 The motion does not pass. We can proceed for
9 the next material. John, you're just going to
10 make a motion for --

11 MR. FOSTER: We'll hear a motion
12 regarding beta carotene from Tracy.

13 MS. FAVRE: I make a motion to
14 classify beta carotene as petitioned as
15 synthetic.

16 MR. BONDERA: I'll second that.

17 CHAIRMAN FLAMM: We have a motion
18 and it's been seconded, to classify beta
19 carotene as synthetic. Discussion? Tracy.

20 MS. FAVRE: I would just like to
21 reiterate that the same conditions exist for
22 beta carotene, synthetic beta carotene as

1 petitioned. It is approved for pro Vitamin A
2 use, and it has been -- should we vote this
3 down, it would still be allowed for vitamin
4 use.

5 CHAIRMAN FLAMM: Any other
6 comments?

7 MR. FELDMAN: I'm just -- sorry
8 guys. I'm a little confused on this, because
9 my understanding is that these are not -- if
10 I heard correctly today, neither the Vitamin
11 A or the Vitamin C in these forms are allowed
12 in infant formula. That's what I heard today.

13 So we would not want to give the
14 organic community the impression that we were
15 allowing something in the form of a vitamin
16 through this listing or any other listing that
17 wasn't approved by FDA. So that's just a
18 clarification. I'm probably misinterpreting.

19 CHAIRMAN FLAMM: I think Tracy had
20 her hand up first.

21 MS. FAVRE: Jay, it's my
22 understanding that it is allowed, but it is

1 not typically chosen for use. Vitamin A
2 isolate was used -- Dr. Anderson remarked that
3 Vitamin A isolate was typically used for
4 Vitamin A in infant formula, rather than beta
5 carotene.

6 CHAIRMAN FLAMM: Nick.

7 MR. MARAVELL: By way of
8 clarification, Jay, that, I would not agree
9 with your statement. What we heard and what
10 was contained in the TR is that ascorbyl
11 palmitate is a source of Vitamin C and is
12 approved as such by FDA for infant formula.

13 However, if you look at practice
14 in the industry, the TR states and Dr.
15 Anderson stated that you would use ascorbic
16 acid, because it -- ascorbyl palmitate, when
17 it enters the body, in order to be Vitamin C,
18 it has to hydrolyze and become, part of it,
19 ascorbic acid.

20 So why not just put the ascorbic
21 acid in, if you're looking for the Vitamin C
22 action. However, it is permitted to be used

1 as a source of Vitamin C.

2 MR. FELDMAN: Thanks for that
3 clarification.

4 CHAIRMAN FLAMM: Further
5 discussion?

6 (No response.)

7 CHAIRMAN FLAMM: If not, we can
8 proceed with the voting on the motion to list
9 the material. Beginning with Colehour.
10 Colehour.

11 MR. BONDERA: I apologize this is
12 a classification motion, not a listing motion;
13 correct?

14 CHAIRMAN FLAMM: Yes, sorry.

15 MR. BONDERA: I vote yes.

16 MS. TAYLOR: Yes.

17 MR. MARAVELL: Yes.

18 MR. FELDMAN: Yes.

19 MS. SONNABEND: Yes.

20 MR. STONE: Yes sir.

21 MS. FULWIDER: Yes.

22 MR. AUSTIN: Yes.

1 MS. FAVRE: Yes.

2 MS. BECK: Yes.

3 MR. FOSTER: Yes.

4 MR. DICKSON: Yes.

5 MS. RICHARDSON: Yes.

6 MR. WALKER: Yes.

7 CHAIRMAN FLAMM: And the chair
8 votes yes. 15 yeses, 0 no's. The motion to
9 classify beta carotene is a synthetic passes.
10 Do we have a motion to list beta carotene?

11 MS. FAVRE: Yes. I'd like to make
12 a motion to add beta carotene as petitioned to
13 205.605(b) for use in infant formula.

14 CHAIRMAN FLAMM: Do we have a
15 second?

16 MR. FOSTER: Second.

17 CHAIRMAN FLAMM: It's been moved
18 and seconded to add beta carotene as
19 petitioned to 205.605(b) for use in infant
20 formula. Discussion.

21 (No response.)

22 CHAIRMAN FLAMM: I guess we

1 already had so much discussion on this, under
2 the synthetic part that I almost forgot. I
3 believe then we can proceed with the voting,
4 beginning with Jennifer.

5 MS. TAYLOR: No.

6 MR. MARAVELL: No.

7 MR. FELDMAN: No.

8 MS. SONNABEND: No.

9 MR. STONE: No sir.

10 MS. FULWIDER: No.

11 MR. AUSTIN: No.

12 MS. FAVRE: No.

13 MS. BECK: No.

14 MR. FOSTER: Yes.

15 MR. DICKSON: No.

16 MS. RICHARDSON: No.

17 MR. WALKER: No.

18 MR. BONDERA: No.

19 CHAIRMAN FLAMM: And the chair
20 votes no. 1 yes and 14 no's. The motion to
21 list beta carotene fails. So what's next,
22 John?

1 MR. FOSTER: We will be having a
2 vote on adding lutein to the National List.
3 Harold.

4 MR. AUSTIN: Okay. I would like
5 to make a slight clarification before we make
6 the motion. After listening to the
7 manufacturers' information and presentation,
8 we went back, the Handling Committee went
9 back, took another look at the TR, because we
10 were on the fringe of deciding whether or not
11 to list this as a synthetic, or to reverse our
12 previous decision.

13 But based off of the information
14 and based off of her presentation, the
15 registrant's presentation, and then going back
16 and revisiting the information, and looking at
17 the process actually is through
18 saponification, estrification and de-
19 estrification, actually as it's determined by
20 our process, does classify that as a chemical
21 change.

22 So our motion will be to list

1 lutein as a synthetic.

2 CHAIRMAN FLAMM: Could you restate
3 the motion, Harold?

4 MR. AUSTIN: The motion would be
5 to list lutein, CAS No. 127-40-2, as
6 petitioned, as a synthetic.

7 CHAIRMAN FLAMM: Do we have a
8 second?

9 MS. FULWIDER: I second that
10 motion.

11 CHAIRMAN FLAMM: We have a motion,
12 which has been seconded, to classify lutein as
13 CAS No. 127-40-2, as petitioned, as a
14 synthetic. Discussion.

15 (No response.)

16 CHAIRMAN FLAMM: Would you want to
17 restate what you said previously before the
18 motion was made, Harold, or does anybody feel
19 it necessary to -- are they clear on it? I
20 guess everybody's clear. I guess we can
21 proceed with the vote then. There's no desire
22 for further discussion, so begin with Nick.

1 MR. MARAVELL: Yes.

2 MR. FELDMAN: Yes.

3 MS. SONNABEND: Yes.

4 MR. STONE: Yes sir.

5 MS. FULWIDER: Yes.

6 MR. AUSTIN: Yes.

7 MS. FAVRE: Yes.

8 MS. BECK: Yes.

9 MR. FOSTER: Yes.

10 MR. DICKSON: Yes.

11 MS. RICHARDSON: Yes.

12 MR. WALKER: Yes.

13 MR. BONDERA: Yes.

14 MS. TAYLOR: Yes.

15 CHAIRMAN FLAMM: And the chair
16 votes yes. 15 yes, 0 no. Entertain a listing
17 motion on the material.

18 MR. AUSTIN: Okay. The Handling
19 Subcommittee would move to add lutein, CAS No.
20 127-40-2, to the National List, 205.605(b),
21 for use in infant formula only, lutein using
22 approved organic delivery ingredients.

1 CHAIRMAN FLAMM: Do we have a
2 second?

3 MS. RICHARDSON: I second the
4 motion.

5 CHAIRMAN FLAMM: Jean seconds the
6 motion, to add lutein, CAS 127-40-2 to the
7 National List of 205.605(b) for use in infant
8 formula only, lutein using approved organic
9 delivery ingredients. Discussion. Jay.

10 MR. FELDMAN: This is a broader
11 discussion. Obviously, you know, we don't want
12 to spend a lot of time on this. But I think
13 I'd start with the premise that organic is
14 held to a higher standard in the marketplace,
15 that the expectation is higher, for better or
16 worse.

17 That's the burden and the
18 challenge that we have, I think, as a
19 community, and this area of accessory
20 nutrients in infant formula is really
21 troubling to me, especially because of the way
22 Dr. Bhatia answered the last question that I

1 asked.

2 And that is the recognition or the
3 understanding that a lot of what we're
4 discussing here is really outside the scope of
5 FDA. I mean FDA is in a situation where
6 they're operating under an old statute. They
7 haven't updated their requirements.

8 Our law talks about requirements,
9 for the most part, and we are then being asked
10 to add materials for which the academic and
11 scientific community have not yet agreed on
12 even what the appropriate levels are of these
13 things including lutein.

14 So I think it's unnecessary to put
15 the organic label in the middle of all of this
16 for soy product at this time, and I view this
17 as protecting the label, so that we can grow
18 acreage, by the way.

19 So I see this as our opportunity
20 to say we are about protecting the label and
21 growing acreage. So I think we have to keep
22 that in mind when we vote on these materials

1 cross the board, at this stage, given where we
2 are, and given the lack of scientific cohesion
3 on the value of these things, and the long-
4 term impacts, etcetera. Thank you.

5 CHAIRMAN FLAMM: Further
6 discussion? Zea.

7 MS. SONNABEND: Thank you, Barry.
8 This one, I would have to say, is the toughest
9 one for me to make a decision on. You know,
10 what we've heard today is how valuable it is
11 to developing infants. But when we look at
12 the extraction process and the manufacturing
13 process, which has finally been disclosed to
14 us, we find that this truly is a plant
15 derivative. It's made from marigolds.

16 The great irony of our little
17 corner of the world here is that the reactions
18 that cause it to come out of the marigolds and
19 become lutein would cause it in our definition
20 of thinking to be synthetic.

21 But if the marigolds were grown
22 organically and treated with other compounds

1 on the National List, it could be certified
2 organic product. So oddly enough, I'm going
3 to go along with Jay here, and wait for the
4 organic marigolds to get grown, and expand the
5 acreage and vote against it.

6 (Laughter.)

7 CHAIRMAN FLAMM: Well, when we get
8 done laughing, I'll call on John.

9 MR. FOSTER: On that note, I
10 believe I did just see a pig fly right by that
11 window.

12 (Laughter.)

13 MR. FOSTER: Right as Zea was
14 saying that.

15 CHAIRMAN FLAMM: Organic pig?

16 MR. FOSTER: Absolutely, of
17 course.

18 CHAIRMAN FLAMM: Is that your
19 comment, John?

20 MR. FOSTER: That's it. That's
21 the best I've got right now.

22 (Laughter.)

1 CHAIRMAN FLAMM: Any other
2 discussion? It doesn't appear we have any
3 more comments. We'll proceed with voting on
4 the motion, beginning with Jay.

5 MR. FELDMAN: No.

6 MS. SONNABEND: No.

7 MR. STONE: No sir.

8 MS. FULWIDER: Yes.

9 MR. AUSTIN: Yes.

10 MS. FAVRE: No.

11 MS. BECK: Yes.

12 MR. FOSTER: Yes.

13 MR. DICKSON: Yes.

14 MS. RICHARDSON: Yes.

15 MR. WALKER: No.

16 MR. BONDERA: No.

17 MS. TAYLOR: No.

18 MR. MARAVELL: No.

19 CHAIRMAN FLAMM: And the chair
20 votes no. I'll have to wait for a tally here.
21 The vote is 6 yes, 9 no's. The motion to list
22 fails. We have next material, John.

1 MR. FOSTER: Yes, we do.

2 CHAIRMAN FLAMM: What is it,
3 lycopene.

4 MR. FOSTER: We do. The next
5 material we'll be voting on is lycopene.
6 Nick, would you go forward?

7 MR. MARAVELL: I make a motion. I
8 move that crystalline lycopene be classified
9 as a synthetic material.

10 MR. BONDERA: I'll second that.

11 CHAIRMAN FLAMM: It's been moved
12 and seconded that lycopene be classified as a
13 synthetic material. Discussion.

14 (No response.)

15 CHAIRMAN FLAMM: Doesn't look like
16 there's need for any further discussion, so we
17 can begin with voting. Zea, you may start the
18 voting.

19 MS. SONNABEND: Yes.

20 MR. STONE: Yes sir.

21 MS. FULWIDER: Yes.

22 MR. AUSTIN: Yes.

1 MS. FAVRE: Yes.

2 MS. BECK: Yes.

3 MR. FOSTER: Yes.

4 MR. DICKSON: Yes.

5 MS. RICHARDSON: Yes.

6 MR. WALKER: Yes.

7 MR. BONDERA: Yes.

8 MS. TAYLOR: Yes.

9 MR. MARAVELL: Yes.

10 MR. FELDMAN: Yes.

11 CHAIRMAN FLAMM: And the chair
12 votes yes. We have 15 yes and 0 no. So the
13 motion to classify as synthetic passes. Do we
14 have a motion for the lycopene to be listed?

15 MR. MARAVELL: Yes. I move that
16 crystalline lycopene, CAS No. 502-65-8, for
17 use in infant formula be added to the National
18 List, Section 205.605(b).

19 CHAIRMAN FLAMM: Do we have a
20 second?

21 MR. AUSTIN: Second that.

22 CHAIRMAN FLAMM: Harold seconds.

1 The motion that crystalline lycopene, CAS No.
2 502-65-8 for use in infant formula be added to
3 the National List, Section 205.605(b).

4 Discussion on the motion?

5 (No response.)

6 CHAIRMAN FLAMM: No discussion on
7 the motion? We can proceed with the voting,
8 then, beginning with Mac.

9 MR. STONE: No sir.

10 MS. FULWIDER: No.

11 MR. AUSTIN: No.

12 MS. FAVRE: No.

13 MS. BECK: No.

14 MR. FOSTER: No.

15 MR. DICKSON: No.

16 MS. RICHARDSON: No.

17 MR. WALKER: No.

18 MR. BONDERA: No.

19 MS. TAYLOR: No.

20 MR. MARAVELL: No.

21 MR. FELDMAN: No.

22 MS. SONNABEND: No.

1 CHAIRMAN FLAMM: And the chair
2 votes no. Do we have any yeses? 0 yes, 15
3 no. The motion fails. Let's see, carnitine.
4 Next John on the list is, I believe is --

5 MR. MARAVELL: Carnitine.

6 CHAIRMAN FLAMM: Carnitine.

7 MR. MARAVELL: Indeed. Zea, would
8 you go forward with the motion?

9 MS. SONNABEND: I'll make the
10 motion that L-carnitine, CAS No. 541-15-1, as
11 petitioned, is synthetic.

12 CHAIRMAN FLAMM: Is it --

13 MS. FAVRE: I second the motion.

14 CHAIRMAN FLAMM: It's been moved
15 and seconded to classify L-carnitine, CAS No.
16 541-15-1 as petitioned, as synthetic.
17 Discussion?

18 (No response.)

19 CHAIRMAN FLAMM: I don't believe
20 there's any desire for further discussions, so
21 we can proceed with the vote, beginning with
22 Wendy.

1 MS. FULWIDER: Yes.

2 MR. AUSTIN: Yes.

3 MS. FAVRE: Yes.

4 MS. BECK: Yes.

5 MR. FOSTER: Yes.

6 MR. DICKSON: Yes.

7 MS. RICHARDSON: Yes.

8 MR. WALKER: Yes.

9 MR. BONDERA: Yes.

10 MS. TAYLOR: Yes.

11 MR. MARAVELL: Yes.

12 MR. FELDMAN: Yes.

13 MS. SONNABEND: Yes.

14 MR. STONE: Yes sir.

15 CHAIRMAN FLAMM: And the chair
16 votes yes. So 15 yes, 0 no. We can proceed
17 with the motion to list the material. Who
18 wants it?

19 MS. SONNABEND: The motion is to
20 add L-carnitine, CAS No. 541-15-1 to the
21 National List, 205.605(b), for use in infant
22 formula only.

1 CHAIRMAN FLAMM: Do we have a
2 second?

3 MR. BONDERA: Second that motion.

4 CHAIRMAN FLAMM: It's been moved
5 and seconded to add L-carnitine, CAS No. 541-
6 15-1 to the National List, 205.605(b), for use
7 in infant formula only. Discussion please?

8 (No response.)

9 CHAIRMAN FLAMM: No discussion.
10 No need for further discussion, so we can
11 begin with the vote, beginning with Harold.

12 MR. AUSTIN: Yes.

13 MS. FAVRE: No.

14 MS. BECK: Yes.

15 MR. FOSTER: Yes.

16 MR. DICKSON: Yes.

17 MS. RICHARDSON: Yes.

18 MR. WALKER: No.

19 MR. BONDERA: No.

20 MS. TAYLOR: No.

21 MR. MARAVELL: No.

22 MR. FELDMAN: No.

1 MS. SONNABEND: No.

2 MR. STONE: No sir.

3 CHAIRMAN FLAMM: And the chair
4 votes no. I'm sorry, I did that again.

5 MS. FULWIDER: Okay, yes.

6 CHAIRMAN FLAMM: And the chair
7 votes no. Let's see, 6 yeses and 9 no's. 6
8 yeses, 9 no's. The motion to list fails.
9 Next material is --

10 MR. FOSTER: L-methionine.

11 CHAIRMAN FLAMM: L-methionine, I
12 believe.

13 MR. FOSTER: We have a motion for
14 you. Tracy, would you be so kind?

15 MS. FULWIDER: Make a motion to
16 list L-methionine on 205.605(b) as synthetic,
17 non-agricultural.

18 CHAIRMAN FLAMM: Do we have a
19 second?

20 MR. FOSTER: I'll second.

21 CHAIRMAN FLAMM: We have a motion
22 that's been seconded, to list L-methionine as

1 synthetic. Is there discussion? Question or
2 --

3 MS. BRINES: Just a clarification
4 from the program. It seemed like it was a
5 combined classification and listing, from the
6 wording of the motion. I just want to be
7 clear. The classification motion is first.
8 Thanks.

9 CHAIRMAN FLAMM: All right. We're
10 just doing the --

11 MR. MARAVELL: I would agree.

12 CHAIRMAN FLAMM: Restate it.

13 MS. FAVRE: If I'd just strike the
14 words "non-agricultural," is that sufficient?
15 Is that what the complaint, the comment is?

16 MR. MARAVELL: No, I think the
17 word "list."

18 MS. FAVRE: Oh, I'm sorry, yes.
19 Make a --

20 MR. MARAVELL: Motion to classify.

21 MS. FAVRE: Yes, got it.

22 CHAIRMAN FLAMM: Oh, I get it.

1 MR. MARAVELL: I think we just
2 used the wrong word.

3 MS. FAVRE: Got it, got it, sorry.
4 I make a motion to classify L-methionine as
5 synthetic. Thank you.

6 CHAIRMAN FLAMM: Thank you. I
7 didn't notice it either.

8 MR. AUSTIN: I'll second that one.

9 CHAIRMAN FLAMM: I think I said it
10 right, but I didn't read it right. Okay.
11 Where are we now?

12 So I'll restate the motion for, to
13 make sure it's clear, that the motion is to
14 classify, I mean yes, to classify L-methionine
15 on 205.605(b) as synthetic, non-agricultural.
16 We don't need the non --

17 MS. FAVRE: The motion is to list
18 L-methionine as synthetic, period.

19 CHAIRMAN FLAMM: As synthetic,
20 period, okay.

21 MS. BRINES: Did you guys say
22 "list" again?

1 (Laughter.)

2 MS. FAVRE: I make a motion that I
3 need a cup of coffee before I make any more
4 motions.

5 MR. AUSTIN: I'll second that.

6 CHAIRMAN FLAMM: And I need a new
7 pair of glasses.

8 MR. MARAVELL: I want one of Zea's
9 apples.

10 MS. FAVRE: I make a motion that
11 L-methionine is synthetic.

12 CHAIRMAN FLAMM: To classify it.

13 MS. FAVRE: The classify it as
14 synthetic. I'm scared to death to say
15 anything else.

16 CHAIRMAN FLAMM: Okay. Is there a
17 second?

18 MR. FOSTER: Yes, second.

19 CHAIRMAN FLAMM: Okay. It's been
20 moved and seconded to classify L-methionine on
21 205.605(b) as synthetic. Discussion, Zea.

22 MS. SONNABEND: I'd like to

1 suggest that L-methionine as petitioned, there
2 are non-synthetic forms of L-methionine. So
3 L-methionine as petitioned is synthetic.

4 MS. FAVRE: I would accept that
5 friendly amendment.

6 MR. BONDERA: Excuse me, Mr.
7 Chair.

8 CHAIRMAN FLAMM: All right.

9 MR. BONDERA: I suggest that you
10 have the motions that are on the table
11 withdrawn before they're added to at this
12 point in time.

13 CHAIRMAN FLAMM: I think that
14 would be --

15 MR. BONDERA: Because we have a
16 number of motions on the table at this moment.

17 CHAIRMAN FLAMM: I think that
18 probably would be wise, just to clear the
19 slate. Could you do that, Tracy, and then
20 we'll start all over again. I'm sorry for the
21 confusion. Withdraw your motion.

22 MS. FAVRE: I withdraw my multiple

1 goofy motions.

2 CHAIRMAN FLAMM: We're getting
3 tired, I think. Okay. Would you like to --
4 will you agree to it being removed and we'll
5 start over?

6 MR. FOSTER: I withdraw all my
7 seconds, except the one for her and coffee.
8 But yes I do, all of them. They're all gone.

9 CHAIRMAN FLAMM: Okay. Let's
10 start over, Tracy.

11 MS. FAVRE: I make a motion to
12 classify L-methionine as petitioned as
13 synthetic.

14 CHAIRMAN FLAMM: And okay. Got
15 it? Is that good, Zea? Okay. Do we have a
16 second?

17 MR. FOSTER: I will second that.

18 CHAIRMAN FLAMM: And John is
19 seconding, and I'll re-read it again for the
20 record. Okay. The motion is to classify L-
21 methionine on 205.605(b) as petitioned, as
22 synthetic, and this has been seconded. Do we

1 have any discussion? Sorry for the mix-ups.

2 (No response.)

3 CHAIRMAN FLAMM: No discussion
4 now? Got it all cleared. So we can begin the
5 voting with you, Tracy.

6 MS. FAVRE: Yes.

7 MS. BECK: Yes.

8 MR. FOSTER: Yes.

9 MR. DICKSON: Yes.

10 MS. RICHARDSON: Yes.

11 MR. WALKER: Yes.

12 MR. BONDERA: Yes.

13 MS. TAYLOR: Yes.

14 MR. MARAVELL: Yes.

15 MR. FELDMAN: Yes.

16 MS. SONNABEND: Yes.

17 MR. STONE: Yes sir.

18 MS. FULWIDER: Yes.

19 MR. AUSTIN: Yes.

20 CHAIRMAN FLAMM: And the chair
21 votes yes. So it's 15 yes, 0 no's, to
22 classify L-methionine as synthetic, as

1 petitioned as synthetic. We can now proceed
2 with the motion to list.

3 MR. FOSTER: The next one up is
4 going to be in the same order we did it
5 before, will be -- sorry, listing motion.
6 Back to Tracy.

7 MS. FAVRE: I make a motion to
8 list L-methionine for inclusion on 205.605(b),
9 for use in infant formula made with soy-based
10 protein. Excuse me. L-methionine, as
11 petitioned, for inclusion in 205.605(b) for
12 use in infant formula made with soy-based
13 protein.

14 MS. FULWIDER: I second that
15 motion.

16 CHAIRMAN FLAMM: Who seconded?
17 Okay. We have a motion that's been seconded,
18 to list L-methionine, as petitioned, for
19 inclusion on 205.605(b), for use only in
20 infant formula made with isolated soy-based
21 protein.

22 MR. FELDMAN: We took isolated

1 out.

2 CHAIRMAN FLAMM: Oh that's, sorry.
3 Just soy-based protein? Yes, okay.
4 Correction. I'll re-read it. Motion to list
5 L-methionine, as petitioned, for inclusion on
6 205.605(b), for use only in infant formula
7 made with soy-based protein. Is that right?
8 Okay. That's a motion. Discussion on this
9 motion? No discussion? Zea.

10 MS. SONNABEND: Thank you.
11 Because this is the one of the group that is
12 truly mandated by the FDA for soy formula,
13 much as I hate to do anything to encourage
14 anyone to use soy formula, I feel like I have
15 to vote for this, because if anyone did use
16 soy formula, I wouldn't want the babies to get
17 an incomplete protein.

18 This one, unlike L-carnitine,
19 cannot be made once they have -- in the
20 digestive system, once they have enough of
21 something else.

22 CHAIRMAN FLAMM: Colehour, please.

1 I'm sorry, were you finished?

2 MR. BONDERA: Yes, you can go
3 ahead, Jay.

4 CHAIRMAN FLAMM: Colehour?

5 MR. BONDERA: Yes, thank you.
6 Just in terms of clear understanding, like you
7 just stated Zea, since FDA requires, since
8 it's not a choice; therefore, the conclusory
9 part of your clause isn't accurate, because
10 there never would be a soy formula sold
11 without it. It just wouldn't be organic.

12 It's not that someone's going to
13 be able to buy one, because it's required. So
14 there couldn't be one without it. So
15 therefore, it's not as if any customers are
16 ever going to purchase one that doesn't have,
17 because it's never going to exist that way.

18 It's just not going to be organic.
19 That's the differentiation. Just the way that
20 it came across to me, the way you said it is
21 that --

22 MS. SONNABEND: Conventional, soy-

1 based formula has to have L-methionine too.
2 You could not buy any without it.

3 MR. BONDERA: Right. That is
4 what you said, and the way you said it is that
5 you didn't want people to be buying it
6 without. Well, they're not going to ever be
7 able to, which is the first part of what you
8 said.

9 MS. SONNABEND: I think you
10 misunderstood it. I don't want people to ever
11 buy soy formula.

12 MR. BONDERA: I understand that
13 too. You said that. That's true. That was
14 the very first part of what you said. But in
15 any case, thank you.

16 CHAIRMAN FLAMM: Jay.

17 MR. FELDMAN: Thank you. So this
18 is a little complicated for me, and I wish we
19 had more time to sort through this. First of
20 all, as far as I can tell from reading the
21 literature, when we're talking about soy-based
22 formula, we're talking about isolated soy-

1 based formula. If someone can help me with
2 that, and tell me that's really not the case,
3 I'd appreciate it.

4 But unless we can distinguish here
5 what we're talking about, I think we do a
6 disservice, again, to the organic community,
7 which is held to a higher standard in the
8 marketplace than the conventional side.

9 So I recognize that -- I take this
10 deletion of the word that was in the original
11 listing motion that came out of the
12 Subcommittee as an indication that there's
13 some awareness that there might be a problem
14 with isolated soy-based protein, both in the
15 way it's extracted and because of its reliance
16 on the addition of other synthetic materials,
17 to deliver product that is considered adequate
18 for the infant.

19 Whatever the reason is, I think we
20 should share that with the full Board, why the
21 term was removed from the original listing
22 motion, and I would like to get some technical

1 support, if the chair thinks that's
2 appropriate, on some of the underlying issues
3 associated with the extraction of isolate soy
4 protein and what that means to an organic
5 product, whether in fact we, as a Board, feel
6 that that base product meets the standard that
7 we are charged with enforcing under the law.

8 So again, sort of a request for
9 assistance here.

10 CHAIRMAN FLAMM: Let me take
11 Tracy's question. I'll get back to you, Jay.
12 Tracy?

13 MS. FAVRE: Actually, it's not a
14 question. Jay, I just wanted to let you know
15 that the motivation behind that was that we
16 had received some information that there are
17 some formulas used for later stage infants
18 that are not isolated soy. They're just
19 concentrated soy protein.

20 Therefore, we didn't want to
21 exclude that from the possibility. Rather, we
22 had specific concerns about the isolated soy

1 protein.

2 CHAIRMAN FLAMM: And Jay, were you
3 making a request in that statement you made?

4 MR. FELDMAN: Yes. Well, you
5 know, I don't want to hold the Board back.
6 But I do believe that if we're talking about
7 concentrated soy protein and isolated soy
8 protein in this motion, we need to understand,
9 you know, the differences.

10 Are they made differently? Are
11 they produced with different extractants? Are
12 there issues around our criteria as it relates
13 to health and safety and so forth. So I don't
14 know if we could get a quick rundown on that
15 from one of our esteemed experts in the
16 audience, or if anybody else feels they need
17 that kind of information to vote on this.

18 You know, at this point, I'd just
19 think, share my thought process with you all.
20 I think that if -- I understand that without
21 methionine, this product couldn't be marketed
22 as organic. That's essentially what -- I was

1 asking the chair, I'm sorry, of the Board.

2 No, no. I was asking the chair, if the chair
3 felt it was appropriate.

4 So do you use what I'm saying? So
5 if that were the case, without that kind of
6 information, I feel that it would be
7 appropriate to not allow, recognizing that it
8 would impact on the market availability of
9 this with the organic label.

10 I understand that it's having that
11 effect, but I think we have a duty to first
12 ensure that the product to which we're adding
13 this to meets the standards of the statute.

14 CHAIRMAN FLAMM: Jay, I do think
15 we had experts here this morning that were,
16 that we more or less cleared, could present us
17 with impartial answers to questions, and I
18 don't know. Bringing others, I don't know if
19 you could get the answer in the time we have,
20 since we had that opportunity for several
21 hours this morning.

22 So I'm reluctant to -- I think

1 unless -- I'll entertain other thoughts, but
2 I don't know we can get what we're asking for.
3 Zea, do you have a comment?

4 MS. SONNABEND: Yes. Jay is
5 asking for someone with organic expertise.
6 Our people this morning had a lot of additive
7 expertise, but couldn't explain necessarily
8 how an organic soy formula would be made,
9 whereas either the formulators in the audience
10 or OMRI would perhaps tell how the soy is
11 extracted, or someone like that, to explain
12 how soy could be extracted for organic
13 soybeans, which may be different than
14 conventional soybeans.

15 CHAIRMAN FLAMM: So is there a
16 person that could briefly give that, that's
17 here?

18 MS. SONNABEND: I would recommend
19 Lindsay, if she's in the audience, or
20 Gwendolyn also could do that.

21 CHAIRMAN FLAMM: Lindsay, would
22 you be willing to come forward and -- that's

1 short notice, I know, and that's -- we'll just
2 --

3 MS. FERNANDEZ-SALVADOR: The other
4 politics that are going on around here. Get
5 out and vote, folks.

6 Okay. So soy protein isolate is
7 -- it is a process extract of soy protein, and
8 from what I understand and the form that OMRI
9 reviewed many, many years ago, the form that
10 we reviewed was being used in a fertilizer,
11 and this conventional soy isolate was
12 extracted using hexane, and then further
13 processed to isolate the protein further and
14 separate it from the carbs and the fats and
15 the fiber, through an acid-based
16 precipitation.

17 However, under organic production,
18 and I'm not privy to confidential business
19 information, so I don't know the exact formula
20 by which you would get an organic soy isolate,
21 but it would likely be either through a water
22 or a certified organic ethanol extraction,

1 with a citric acid and sodium hydroxide acid.

2 But it would likely be either
3 through a water or a certified organic ethanol
4 extraction, with a citric acid and sodium
5 hydroxide acid-based precipitation.

6 CHAIRMAN FLAMM: Does that answer
7 your question?

8 MS. FERNANDEZ-SALVADOR: He says
9 I'm on the right track. Without knowing the
10 exact soy isolate, it's hard to say.

11 MR. FELDMAN: Thank you.

12 (Off record comments.)

13 MS. FERNANDEZ-SALVADOR: I don't
14 work for a certifier. I have never seen an
15 organic certified soy isolate manufacturing
16 process.

17 CHAIRMAN FLAMM: Please. Thank
18 you very much, Lindsay. I appreciate you
19 doing this for us.

20 MR. FELDMAN: I have a follow-up
21 question for the Board, or the Committee,
22 Subcommittee.

1 CHAIRMAN FLAMM: Okay. Any other

2 --

3 MR. FELDMAN: So --

4 CHAIRMAN FLAMM: Thank you

5 Lindsay.

6 MR. FELDMAN: Okay. So that then
7 raises for me the question as to whether we
8 need to annotate the extraction process. If
9 there is an organic way of doing this or one
10 that is viewed as acceptable under organic
11 standards, I know we don't have an extraction
12 policy yet.

13 But there have been a number of
14 votes that have debated the methodology by
15 which we extract, and hopefully will be
16 incorporated into a larger policy at some
17 point.

18 But lacking that policy, it is my
19 preference to try to exclude the volatile
20 synthetics, and it sounds like what Lindsay
21 described did just that. Okay. I take that
22 back, yes. Okay. So we're still dealing with

1 volatile synthetics when we're talking about
2 extraction. Is that the case? Okay.

3 CHAIRMAN FLAMM: Okay. You can --

4 MR. FELDMAN: Any other comment,
5 discussion? Yes, okay. Lindsay, you can --

6 MS. FERNANDEZ-SALVADOR: Yes,
7 sorry. I just wanted to clarify one thing,
8 because Jay said something and it wasn't what
9 I said. Lindsay Fernandez-Salvador for OMRI.
10 It's not with the volatile synthetics; it's
11 with certified organic ethanol would be one
12 way of doing it.

13 That's not synthetic. It's
14 volatile, but it's not synthetic. So that's
15 the difference there.

16 MR. FELDMAN: Thank you.

17 CHAIRMAN FLAMM: Thank you for the
18 clarification. Okay. Any other? Jay.

19 MR. FELDMAN: My question for the
20 record is whether in voting this motion, that
21 are we allowing a broad range of processes in
22 its production of the soy isolate, or are we,

1 because of other limitations, narrowing that
2 extraction process to the one Lindsay
3 described, to the non-synthetic ethanol
4 process?

5 I just want to be -- I just want
6 to clarify that we are indeed, through this
7 listing, narrowing that extraction process.

8 CHAIRMAN FLAMM: Does anybody on
9 the Subcommittee wish to tackle that question?
10 Zea.

11 MS. SONNABEND: The extraction
12 process is being limited to things which are
13 organically produced or on the National List.
14 So organic, non-synthetic ethanol or sodium
15 hydroxide, which is on the National List or,
16 if you figured out how to make it with pectin,
17 it would be allowed, because it's on the
18 National List.

19 Anything, you know, that's the
20 rule. That's the basic thing in the rule, and
21 that is limiting what types of agricultural,
22 organic products can be treated with.

1 MR. FELDMAN: Thank you for that
2 clarification.

3 CHAIRMAN FLAMM: Thank you. At
4 one point, I saw somebody. Lisa, did you have
5 a question or clarification you wanted to
6 make?

7 MS. BRINES: No. Zea provided the
8 clarification we were looking for. Thank you.

9 CHAIRMAN FLAMM: I'm sorry. Oh,
10 okay. Thank you. All right. Any other
11 discussion, questions on that? Okay. I
12 believe we can proceed with the vote. Yes,
13 and we're on the motion, aren't we? It's been
14 so long.

15 Okay. We can proceed with the
16 vote on the listing motion, beginning with
17 Carmela.

18 MS. BECK: Yes.

19 MR. FOSTER: Yes.

20 MR. DICKSON: Yes.

21 MS. RICHARDSON: Yes.

22 MR. WALKER: Yes.

1 MR. BONDERA: No.

2 MS. TAYLOR: No.

3 MR. MARAVELL: Yes.

4 MR. FELDMAN: Yes.

5 MS. SONNABEND: Yes.

6 MR. STONE: Yes, sir.

7 MS. FULWIDER: Yes.

8 MR. AUSTIN: Yes.

9 MS. FAVRE: Yes.

10 CHAIRMAN FLAMM: And the chair
11 votes yes. What's the count? 13 yes, 2 no's.
12 The motion to list passes, and we're due for
13 a break, but I suggest we just continue and
14 finish these materials. Is that all right,
15 John, with you?

16 MR. FOSTER: It's okay with me.

17 CHAIRMAN FLAMM: Okay. I believe
18 the next proposal is taurine.

19 MR. FOSTER: It is indeed taurine,
20 and Jean, would you, do you have a motion?

21 MS. RICHARDSON: Yes. I make the
22 motion to, the classification motion for

1 taurine, CAS 107-35-7, as petitioned, is
2 synthetic.

3 MR. BONDERA: I'll second that
4 motion.

5 CHAIRMAN FLAMM: Okay. We have a
6 motion which has been seconded, to -- let's
7 see. We've got a motion on taurine, CAS No.
8 107-35-7, as petitioned, to classify it as
9 synthetic. I can't quite read that. Right.
10 Discussion?

11 (No response.)

12 CHAIRMAN FLAMM: Doesn't appear to
13 be any discussion, so we're going to vote on
14 the motion to classify taurine as synthetic.
15 I believe we're beginning with John.

16 MR. FOSTER: Yes.

17 MR. DICKSON: Yes.

18 MS. RICHARDSON: Yes.

19 MR. WALKER: Yes.

20 MR. BONDERA: Yes.

21 MS. TAYLOR: Yes.

22 MR. MARAVELL: Yes.

1 MR. FELDMAN: Yes.

2 MS. SONNABEND: Yes.

3 MR. STONE: Yes, sir.

4 MS. FULWIDER: Yes.

5 MR. AUSTIN: Yes.

6 MS. FAVRE: Yes.

7 MS. BECK: Yes.

8 CHAIRMAN FLAMM: And the chair

9 votes yes. I believe we have 15 yes, 0 no.

10 You know, to classify taurine as synthetic.

11 We can proceed with a motion to list taurine.

12 MS. RICHARDSON: I make a motion,

13 a listing motion, to add taurine, CAS 107-35-

14 7, to the National List 205.605(b) for use in

15 infant formula only.

16 CHAIRMAN FLAMM: We have a motion,

17 which has been seconded, to add to taurine,

18 CAS No. 107-35-7 to the National List,

19 205.605(b) for use in infant formula only.

20 Can we have discuss on this motion?

21 MS. FAVRE: I second the motion.

22 CHAIRMAN FLAMM: You second the

1 motion. Thank you, Tracy. It was seconded.

2 Discussion on the motion?

3 (No response.)

4 CHAIRMAN FLAMM: No discussion on
5 the motion. We can proceed, then, with a vote
6 on the motion, beginning with Joe.

7 MR. DICKSON: Yes.

8 MS. RICHARDSON: No.

9 MR. WALKER: No.

10 MR. BONDERA: No.

11 MS. TAYLOR: No.

12 MR. MARAVELL: No.

13 MR. FELDMAN: No.

14 MS. SONNABEND: No.

15 MR. STONE: No, sir.

16 MS. FULWIDER: No.

17 MR. AUSTIN: No.

18 MS. FAVRE: No.

19 MS. BECK: No.

20 MR. FOSTER: No.

21 MR. DICKSON: No.

22 MS. RICHARDSON: No.

1 CHAIRMAN FLAMM: And the chair
2 votes no. We have but 1 yes, 14 no's. The
3 motion to list taurine fails. I believe that
4 completes what you were prepared to vote on
5 today, and so we can take a break and be back
6 here in 15 minutes.

7 (Whereupon, the above-entitled
8 matter went off the record at 3:41 p.m., and
9 resumed at 3:56 p.m.)

10 CHAIRMAN FLAMM: Board members,
11 please return to your seats. We're running
12 behind. The next and last session for today
13 is for the Policy Development Subcommittee to
14 present their proposals, and I will turn the
15 gavel symbolically over to Colehour to
16 proceed.

17 MR. BONDERA: Thank you. Thank
18 you, Mr. Chair. Sorry my microphone is being
19 funny. Very good. If Michelle, you could put
20 up -- no, sorry. It's a little confusing. We
21 have a couple of different PowerPoints in our
22 hands over there.

1 So I'm going to just go through
2 briefly the Policy Development Subcommittee
3 generally and our topics, and then we'll be
4 trading back and forth among three of our
5 members. At that time, the first thing I'll
6 talk about, and whether or not it's up there,
7 it'll be up there in a minute, is really what
8 we do.

9 We're providing guidance,
10 clarification or proposed standards of NOSB
11 operations, policies, and procedures. We're
12 maintaining the content and updates to the
13 NOSB policy and procedure manual and the new
14 member guide, and we're working with other
15 Subcommittees to develop joint proposed
16 recommendations, where policy issues are
17 involved.

18 So it looks like I'm just going to
19 read to you rather than you seeing as well,
20 the other part of that slide, which is the
21 members. The members are myself, Joe Dickson,
22 Jay Feldman, Barry Flamm, Jean Richardson, Mac

1 Stone, Jennifer Taylor, and C. Reuben Walker.

2 So we have, and again I apologize
3 that they're not up on the screen, but we have
4 three proposed recommendations, and we will be
5 hearing about them in that order. Thank you.
6 Sorry, thank you. It's all good.

7 There they are. Conflict of
8 Interest or COI, Public Comment and Public
9 Communications. So you know, this is just the
10 background reality and actually, I presented
11 this, a version of this same slide that's up
12 there right now at our previous meeting.

13 But I think that, you know, I
14 think it's worth reiterating the fact that
15 these topics came up because of a combination
16 of requests from the NOP, from the public and
17 from within the NOSB for reviewing and
18 updating the policy procedure manual.

19 And the updated reality is the
20 fact that the conflict of interest was put
21 forth at both the Savannah, Georgia and
22 Albuquerque, New Mexico meetings, and quite

1 honestly -- quite frankly has been
2 substantially revised, you know, like I just
3 said, not once, but multiple times, and I
4 think that that's worthy of note.

5 The public comment that you're
6 going to see was a discussion document at the
7 Savannah meeting, and then it went to the
8 Albuquerque meeting as well, and the public
9 communications, proposed recommendation is,
10 you know, it has some of that same history,
11 but it's to establish a policy that doesn't
12 exist.

13 So at this point in time, what I'd
14 like to do is, and I will be frank and honest
15 with you. Our most complicated of these
16 three, in various ways for various reasons, is
17 the conflict of interest. But due to the way
18 we had the schedule already, that's going to
19 be the very next one, and that's --

20 What I'm going to do is turn it
21 over to C. Reuben Walker, and he's going to
22 lead us through the conflict of interest. So

1 thank you.

2 MR. WALKER: Thank you, Colehour.
3 I would like to begin by saying that conflict
4 of interest, as I mentioned in New Mexico, has
5 been a problem since the beginning of
6 humankind, and today, it is no different.

7 We hope that as we leave from
8 here, that a decision would be made on
9 conflict of interest up or down, and we can
10 move on to something else. Primarily, the
11 conflict of interest was brought about by I
12 call it the "Organic Nation," several groups
13 making a request for more transparency and
14 things centered around conflict of interest.

15 As Colehour, the chair, had
16 mentioned, we went through probably at least
17 30 iterations of this particular document
18 since last year. We have even went as far as
19 requiring the declaration of interest form.
20 No board member can lobby the Board until two
21 years afterwards.

22 We had a financial, we had all

1 kinds of things in this document, and but what
2 we found in doing this is that, and rightfully
3 so, some board members seem sometimes to be,
4 I call it maybe somewhat unfairly picked on,
5 and this is a very sensitive topic.

6 So we decided to take our time,
7 and make sure we get something that hopefully
8 that we can come to a consensus. I believe
9 the attorney from WDA mentioned that at some
10 point, instead of fighting all the time, at
11 some point a consensus need to be done.

12 My view of a consensus is that
13 each side is still pissed off. But we agree
14 to move it along, just for the good of the
15 whole group. So I guess I'll just go the
16 public comment. This is the public comment
17 that was put out.

18 Table 1 shows that it was 104
19 entities or individuals responding to our
20 document. Some of these were form letters.
21 As you can see, no one supported the document,
22 for various reasons. What the Policy

1 Committee said that we just wanted to get it
2 out, to let the organic community weigh in on
3 it, because it was changed from the New Mexico
4 meeting.

5 Table 2, if you chisel down, if
6 you take away the form comments, we had
7 roughly 25 different commenters, groups or
8 individuals, and again, zero percent was for
9 what was placed out there for various reasons.

10 Another question we wanted to know
11 was in our current policy and procedure
12 manual, and we have seen quite a few former
13 Board members, and when they was on the Board,
14 conflict of interest were mainly led by the
15 Board itself, and that particular writing it
16 still is in our policy document, on pages 9,
17 10 and 11.

18 So essentially with this new
19 document, we have agreed to keep it that way,
20 that the Board maintain that particular
21 wording, that NOSB determine a conflict of
22 interest. But we know that AMS and NOP is the

1 final arbiter of anything that we might do.

2 That's a fact. So that's where we're at.

3 That will take care of that, and
4 what I would like to do next is Michelle will
5 go, will assist me here. This is the document
6 that was put out for public comment. It's
7 eight pages, and this shouldn't take long,
8 because I'm going to go through it pretty
9 fast.

10 Page one, there was no change. So
11 we can go down to, Michelle if you don't mind,
12 to the recommendations. What we wanted to do
13 as a Committee was to show what was placed out
14 for you all to review. Then we wanted to show
15 in yellow -- I had some problem with some of
16 this. Some of it was in green, but anything
17 colored is what we changed.

18 How did we change it? We changed
19 it based upon the public. NARC, Cornucopia,
20 OTA, WDA, and essentially what I did, I made
21 a grid for all the objections. Some of the
22 trade groups said keep the conflict of

1 interest policy as it was.

2 If that be the case, we have that
3 in this document. The NOSB Board make the
4 initial determination, and the NOP will be the
5 final arbiter.

6 So Recommendation 1, everyone
7 agreed to that one, of all the stakeholders.
8 Recommendation No. 2, there was an agreement.
9 Simple. We just wanted to add the word
10 "proposed inclusion" into the language.

11 So Recommendation 3. In
12 Recommendation 3, with respect to Michael
13 Jackson, we moonwalked back on this one. The
14 issue we had here, what the public had was it
15 said that all of us was to represent the
16 interest of the entire organic community.

17 But what stakeholders said, that
18 we was placed on this Board to represent the
19 interest in which we was appointed. So
20 essentially, we put the language back.

21 Organic farmers should represent
22 the interests primarily of organic farmers,

1 retailers, retailers, handlers, handlers. But
2 not to overlook the entire organic community,
3 but we was primarily to represent the
4 interests in which we was appointed, and what
5 we had out there was different.

6 So we just essentially placed back
7 what we had in the policy manual, and that's
8 been there for the last, since 1999. So
9 what's in yellow is what we placed back.

10 Instead of saying "board members," I just said
11 his or her, to try to be more personable. So
12 we essentially changed the language back to
13 what we had.

14 What you see in blue redacted is
15 what we had out there, that stakeholders did
16 not like. So we've just taken that back out,
17 kept the policy.

18 Recommendation 4. That was okay.
19 Recommendation 5, disclosure of financial
20 interests. What we decided to do here was to
21 say that in our policy manual, it says
22 "recognize corporate opportunity."

1 So we wanted to change that to
2 "disclosure of financial opportunity," because
3 when you say "corporate," it seems like, you
4 indicate that you're picking on those who may
5 have a corporate leaning, and that is unfair
6 and that is unjust.

7 So what we tried to do was to say
8 we all could have a possible conflict of
9 interest, and we need to disclose it. So what
10 the Committee decided to do was let's remove
11 the term "recognize corporate opportunity,"
12 because it seemed to be, give the indication
13 you're singling out a particular group.

14 Recommendation No. 6. Let's see
15 here. Essentially, this goes back to the
16 first one. It says "NOSB members shall, with
17 the various backgrounds, are recruited to
18 provide a balance to the Board." While the
19 individual NOSB members represent the segment
20 of the population from which they were
21 selected.

22 They are also to represent the

1 greater good of the population as a whole.
2 You can see what was redacted. Essentially,
3 it said that we all was to represent the
4 entire community, and we were not appointed by
5 the Secretary of Agriculture and AMS and NOP.
6 We was not appointed for that. We was
7 appointed for a particular, to advocate for a
8 particular position.

9 So we essentially put the language
10 back that we have in our policy manual. To
11 me, our policy manual is the NOSB Board's
12 Bible. So we don't want to change the bible
13 too much, that it would take away from its
14 effect.

15 Recommendation No. 7. We have 11,
16 so it won't be long. Number 7, essentially
17 where we had "NOP," we returned that back to
18 "NOSB," the language that we had at the New
19 Mexico meeting and Savannah meeting.

20 So what's in yellow, a conflict of
21 interest. The long and short of this is the
22 definition was quite lengthy. It had

1 entities, it had organizations. In Louisiana,
2 we call it, it was a gumbo. It had some of
3 everything in it.

4 What we decided to do was to deal
5 only with a direct financial gain, as opposed
6 to a direct financial interest and affiliates
7 and all those things. So in essence,
8 Recommendation 8 was we reduced it to a direct
9 financial gain.

10 Also, potential conflict of
11 interest was redacted. No one seemed to have
12 liked that in the public comments, trade
13 associations and the public interest groups.
14 Now bear in mind that this doesn't mean that
15 it will not show up again, because the NOP
16 will begin with ethics, to make sure that this
17 is proper.

18 Immediate family member. This was
19 added. What you all read was it was in the
20 definition of a conflict of interest. So what
21 we decided to do was actually just pull that
22 definition out, as opposed to just keeping it

1 in the definition of a conflict of interest.

2 And also, immediate family members
3 is also in our policy on page 11. So the term
4 in the definition of immediate family member
5 is not new. It's already existing in the
6 document already.

7 Okay, number 9. No one seemed to
8 like this one. I was surprised on this one.
9 They didn't like the direct financial
10 interest. So trying to build a consensus at
11 our level, we decided to put the term back,
12 what we originally had in Savannah and New
13 Mexico, which was "direct financial gain."

14 Stakeholders said that direct
15 financial interest was too broad, why did you
16 cut it off, those sort of things. So we
17 thought at our level, we'd just return it back
18 to what we have in our policy.

19 Number 10. Essentially, we
20 returned back and added. What we returned was
21 that we wanted to show that NOSB is, I would
22 say "will take the lead" in determining if

1 there's a disclosure. The Subcommittee or
2 this Board will make that first determination.

3 But we do know that if the program
4 object, they would be the final arbiter,
5 because that just the way it is. So
6 essentially at the Subcommittee level, when
7 work plans are done and for those of you who
8 are not familiar, at some point after this
9 meeting, we would get together and determine -
10 - I think we already determined that now
11 right, work plans?

12 Work plans are actually decided,
13 and as November, December, January go along,
14 we'll determine if all these things going to
15 stay on each of the subcommittees' work plan.
16 We are asking that fellow Board members and
17 subcommittees disclose early on if they have
18 a conflict of interest.

19 If they do, then happens to be
20 determined at the subcommittee level, and it
21 need to be documented in the minutes. This
22 would be done in conjunction with the program.

1 At the Subcommittee Level 2, that's the next
2 page, and all you're seeing in blue is what we
3 kind of redacted.

4 Yes, this one here. Yes, okay.

5 At the biannual meetings, at the beginning of
6 each subcommittee, we are asked -- the chair
7 is to ask committee members or Board members
8 if they want to disclose any potential
9 conflict of interest, any conflict of
10 interest, as we did somewhat during this
11 meeting.

12 So it need to be disclosed in the
13 public, and not at a level where one do not
14 know. So what is in blue, I apologize for not
15 being able to read it, but the scratch-through
16 is what we put out, that individuals tended to
17 have a problem with. So essentially we kind
18 of returned this back to what we had at a
19 previous Board meeting.

20 Next recommendation, or going
21 further down the next page. I think one of
22 the problems that I would like to note here,

1 we had an issue of three days that the program
2 will decide if there was a conflict.

3 That was an error. That was taken
4 out. We also said that if there is any
5 revote, that would be not retroactive.
6 Several groups did not like how far do we go
7 back.

8 Do we go back to 2002 and revote
9 on an issue, and the Board, the committee
10 decided that the revote would only come into
11 play if necessary, and determined by NOP, once
12 this particular document is finally approved
13 at a level above us.

14 And recommendation No. 11. No one
15 liked this particular recommendation. Whether
16 it was trade association or community-based
17 groups or individuals. So essentially what we
18 have here is that we just returned the
19 language of Recommendation 8 back to where it
20 was in our policy manual.

21 The last slide, oh I see. I
22 didn't have it on the other one. It's not

1 there. But that's it. So essentially we are
2 putting before the Board as a whole and the
3 organic community, because what you've seen
4 out there, you have expressed to us that you
5 didn't like it.

6 So essentially we have went back
7 and made quite a few changes, substantial
8 changes as Mr. Colehour mentioned, and we are
9 hoping that this Board tomorrow will digest
10 it, and maybe we can move something forward.
11 There's no guarantee that it would be accepted
12 all by the program.

13 But if we can get a strong vote up
14 or down, a strong vote would be better for
15 NOSB. If it's voted down, it may not be as
16 good.

17 So that's where we're at, and my
18 collaborator here was Mr. Joe Dickson, and the
19 reason why we like it is because when you get
20 a public interest, you get the retailer, you
21 get the environmentalist, you come up with a
22 pretty good document.

1 So we're hopeful that, tomorrow
2 that we can get this through in some form.
3 Thank you.

4 MR. BONDERA: Very good. Thank
5 you very much, Mr. Walker, and I appreciate
6 the complexity of what you were presenting.
7 So we will keep working on that.

8 The next thing that we're going to
9 do is go ahead and listen to the presentation
10 of the next recommendation that's on the
11 table, which is -- the title of it is public
12 comment, and I am going to present that to
13 you.

14 So hopefully here it comes. So
15 the truth is that this is going to be -- what
16 Calvin just took us through, he has notably
17 and significantly modified from what was put
18 forth to the public and the realistic truth is
19 that this particular one does not have any
20 changes at all.

21 So we're just going to go through
22 it, and I think pretty quickly. This is about

1 the policy for public comments at NOSB
2 meetings, and I think honestly, Calvin went
3 through the process very well, and I
4 appreciate that he thanked Joe for his help on
5 the conflict of interest one, and I'd like to
6 start out by doing the same with Jean, who --
7 Jean Richardson, who really played a
8 significant role in helping me work on this,
9 and get it to where it's at. So thank you,
10 Jean.

11 I have led the efforts on this
12 particular topic, both through the discussion
13 document form and as well as to our last
14 meeting in Albuquerque. The goal of this is
15 to amend Section, I guess it's Section 6 of
16 the policy procedure manual, which is entitled
17 "NOSB Policy for Public Comment at NOSB
18 Meetings." These are the new words that we
19 have put forth.

20 So I'll just go ahead and read
21 them to you. There's ten points. The first
22 one is "All persons wishing to comment at NOSB

1 meetings during public comment periods must
2 sign up in advance, per the instructions in
3 the Federal Register notice for the meeting."

4 Number two is "All presenters are
5 encouraged to submit public comment in writing
6 according to the Federal Register notice.
7 Advance submissions allow NOSB members the
8 opportunity to read comments in advance
9 electronically, and decrease the need for
10 paper copies to be distributed during the
11 meeting."

12 Number three is "Persons will be
13 called upon to speak in the order they sign
14 up. Persons called upon who are absent from
15 the room could potentially miss their
16 opportunity for public comment."

17 Number four. "Time allotment for
18 public comment per person will be four
19 minutes, with the options of reducing to a
20 minimum of three and extending to a maximum of
21 five minutes at the discretion of the NOP,
22 working closely with the NOSB chair, in

1 advance of the meeting."

2 Sorry. Yes, next slide. Sorry, I
3 didn't say that. Sorry, I'm looking at my
4 screen and not up there. I apologize. Too
5 many things going on, and I'm tired like all
6 of us. So I hereby take full responsibility
7 for that error, and I hope you'll all just
8 deal, as I read through them, even if they
9 aren't on the screen.

10 Number four. Time allotment for
11 public comment -- I already read that.

12 Number five. "Persons will give
13 their names and affiliations for the record at
14 the beginning of their public comment.

15 Number six. "Proxy speakers are
16 not permitted."

17 Number seven. "Public comment
18 requests may be scheduled by major topics
19 under consideration, as we have -- my comment
20 on that is as we have eased into doing,
21 starting at the Albuquerque meeting, and now
22 it seems like that is our modus operandi." So

1 that's how people are grouped together.

2 Number eight. "Individuals
3 providing public comment will refrain from any
4 personal attacks and from remarks that
5 otherwise impugn the character of any
6 individual."

7 Finally, number nine. "The NOSB
8 will attempt to accommodate all persons
9 requesting public comment time. However,
10 persons requesting time after the closing date
11 in the meeting notice or during last minute
12 sign-up at the meeting, will be placed on a
13 waiting list, and will be considered at the
14 discretion of the NOP, working closely with
15 the NOSB chair, depending on availability of
16 time."

17 Number ten. "Members of the
18 public are asked to define clearly and
19 succinctly the issues they wish to present
20 before the Board. This will give the NOSB
21 members a comprehensible understanding of
22 speaker concerns."

1 And so I think like I wrote here,
2 we didn't receive that many written comments
3 on this topic, and really, all of them were
4 supportive, even when there was a little bit
5 of reluctance in the comments we received, in
6 terms of I think notably the amount of time
7 involved.

8 I think that the other thing worth
9 noting, in terms of written testimony that
10 we've received, is that the one thing that is
11 sought in that testimony is that there would
12 be no restrictions on questions and discussion
13 by NOSB members.

14 I think the honest truth is that,
15 you know, that's going to have to be worked in
16 as is viable, depending upon what our volume
17 of people is and what our topics are. You
18 know, these little -- they aren't quotes
19 actually. These highlights that I've put on
20 this slide are actually from the Albuquerque
21 meeting, not from comment from this meeting.

22 But I think that they all pretty

1 much still apply, since we haven't really
2 modified the document very much at all in
3 fact, and I think they still are all relevant.
4 Allow more time for public commentary is a
5 general feeling that people who comment and
6 communicate about this want and seek.

7 That's why we have public
8 meetings, and you know, so I want to let that
9 proxy topic totally drop, just because it does
10 have history within the NOSB and I think that
11 noting that people do feel like it's helpful
12 for public interest organizations is relevant.

13 What I just said, I think, is also
14 notable, in terms of the fact that the
15 circumstances go into define how things really
16 are played out, and I think in my opinion, as
17 organics grow and, you know, as a meeting
18 plays out, what is anticipated if it's a
19 heavily attended meeting, where a lot of
20 people are interested in the subject areas,
21 and/or it's held in an area where there's a
22 lot of, I don't know what descriptor to use,

1 but vibrance about the topics at hand, then I
2 think that we may have, you know, an issue in
3 terms of how many people have to speak and how
4 much time.

5 I think that those issues will
6 have to just be dealt with, and we all will
7 need to be flexible, according to the
8 circumstances. So I think that that highlight
9 really still pertains.

10 I also do think it's still worth
11 noting that like I alluded to earlier, the
12 reluctance of the support that the written
13 comments that came in on this, you know, were
14 not exclusively and not solely, but were
15 related to, you know, the five minutes instead
16 of four minutes.

17 Then with the concept of adjusting
18 it downward rather than upward. So I just
19 thought those were worth repeating for you
20 all. The final words I want to just share
21 with you are, you know, the reality is that --

22 Well, I'll be honest with you all,

1 and I don't feel bad about it, but you know,
2 Barry Flamm served as the chair of the Policy
3 Development Subcommittee for four years, and
4 you know, he's not the easiest act to follow.

5 I think that that's, you know, I
6 respect and think that Barry deserves the
7 honor that he has earned. But I think that
8 the truth is that I have tried as hard as
9 possible to work with the National Organic
10 Program, and get their input, and they have
11 worked with us and have chosen to, you know,
12 point out some of the clear facts, that the
13 truth is that the Designated Federal Officer
14 is ultimately responsible for the NOSB meeting
15 schedule.

16 I think that that is the truth.
17 No matter how this plays out or what the
18 process is, you have to fit all the things
19 into the reality. I think that that is
20 critical.

21 We're going to have, after our
22 third presentation, we're going to have live

1 testimony and, you know, the live testimony
2 can also affect both the full NOSB discussion
3 and then the final vote on the proposed
4 recommendations.

5 So I encourage those that are
6 going to provide testimony to recognize that,
7 and I'll just finish up with that. Thank you.
8 Mahalo. At that moment then, what I want to
9 do is ask -- Jennifer is going to present the
10 third subject to us, and her topic is public
11 communication.

12 Like I said before, it's something
13 that doesn't exist per se in the policy
14 procedure manual. So it's a new subject,
15 although she has in Albuquerque already
16 presented it to us. So it's not all fresh and
17 new, but I'll turn it over to Jennifer. Thank
18 you.

19 MS. TAYLOR: Thank you, Colehour.
20 Okay. We will review and now discuss as well
21 the public communications document. Okay.

22 "A primary role of the National

1 Organic Standards Board is to advise and
2 counsel the Secretary, to represent the
3 segments of the population from which they
4 were selected, and to treat the business of
5 the Board as fiduciaries for all members of
6 the organic community and public at large."
7 That's coming from the Policy and Procedures
8 Manual.

9 The Organic Foods and Protection
10 Act states that "The statutory mission of the
11 NOSB is to assist in the development of
12 standards for substances to be used in organic
13 production, and to advise the Secretary on any
14 other aspects of the implementation of this
15 title." Okay, thanks.

16 Okay. Can we go to the next
17 slide, please? Thank you. Again as stated,
18 within the Policy and Procedures Manual, the
19 NOSB mission statement is to provide effective
20 and constructive advice, clarification and
21 guidance to the Secretary of Agriculture
22 concerning the National Organic Program, and

1 the consensus of the organic community.

2 The Federal Advisory Committee Act
3 meeting obligations to the public suggests
4 that any member of the public is permitted to
5 file a written statement with the advisory
6 committee during meetings.

7 In addition, the NOSB infrequently
8 receives public communications outside of the
9 designated public comment period. These
10 communications include verbal and written
11 information.

12 Due to the opportunities that the
13 Board has to hear from the organic community,
14 in the course of fulfilling its mission, it
15 has both an opportunity and responsibility to
16 bring to the Secretary of Agriculture
17 information that it believes may impact on the
18 implementation of the Organic Foods Production
19 Act.

20 This communication may, by
21 necessity, extend to organic standards and
22 practices, as well as related issues that may

1 affect those standards and practices.

2 Therefore, based on the
3 communications and input it receives from the
4 public, the National Organic Standards Board
5 may provide effective and constructive advice,
6 clarification and written information as it
7 deems necessary directly to the Secretary of
8 Agriculture after each of its Board meetings.

9 Additionally, and as a part of its
10 responsibility to communicate with the organic
11 community, pertaining to the implementation of
12 the Organic Food Protection Act, the Board
13 must receive and review information from the
14 NOP and other sources during its
15 deliberations.

16 As a stakeholder board, the input
17 from the organic community is valuable in the
18 deliberations of the Board, and the community
19 decision-making process. The procedures of
20 the Board should facilitate public
21 communication to inform these deliberations,
22 and we'll follow with recommendations.

1 The public, I'm sorry, the Policy
2 and Procedures Manual, Section 6,
3 Miscellaneous Policies, page 26, is amended by
4 adding a new subcategory that states "The NOSB
5 policy on its advisory role in communications
6 with the Secretary of Agriculture. Based on
7 the communications and input it receives from
8 the public, the National Organic Standards
9 Board may provide effective and constructive
10 advice, clarification and written information
11 as it deems necessary directly to the
12 Secretary of Agriculture, after each of its
13 Board meetings.

14 "This information is intended to
15 facilitate public communication with the
16 Secretary on critical issues that may emerge,
17 that it believes are important to the
18 implementation and integrity of the organic
19 standards and practices under the Organic Food
20 Protection Act.

21 The policy and procedures manual
22 Section 6 is amended by adding a new

1 subcategory. NOSB policy for public
2 communication between NOSB meetings. "The
3 NOSB seeks public communication outside of the
4 Board meetings and public comment periods, to
5 inform the Board and program work.

6 "The Policy and Procedures Manual,
7 Section 2, role of the executive director, is
8 amended to include the following language:

9 "Identify, implement, administer and maintain
10 a year-round mechanism by which public
11 feedback can be received, posted and archived
12 for viewing by the NOP, the NOSB and by the
13 public itself."

14 Now this document has been before
15 the public before, and we received several
16 comments from the public, all in support of
17 the document. We received comments also from
18 the program that were in support of the
19 document as well.

20 This is a representative comment
21 from the public. "I support both aspects of
22 the proposed public communications policy.

1 The ability for the NOSB to inform the
2 Secretary of the organic community's views is
3 critical, particularly for views that are
4 contrary to USDA's other policies. It is also
5 important that NOSB members be able to receive
6 input from the organic community during all
7 stages of deliberations."

8 Another method that was used was
9 to state "We fully support the following
10 additions to the policy manual, as proposed by
11 the Policy Development Subcommittee."

12 We also received a question during
13 this period, during this fall meeting period,
14 and the questions were "Will NOSB members have
15 to check or will they receive the comments in
16 their email. Will someone alert them if
17 something is posted?"

18 We thought about that same thing
19 actually, and what we're hopeful of is that
20 the communication that we've established with
21 a program through the docket system, we will
22 receive an alert and we will receive an alert

1 that the information is being deposited there.

2 "Is there an opportunity for the
3 NOSB members to respond? Two-way
4 communication is important." We also realize
5 that two-way communication is important, and
6 we're hopeful that we'll be able to respond as
7 well to those comments that we receive.

8 The Subcommittee vote on this
9 particular document is reported as you see.
10 We had a vote of eight in support of the
11 proposed document. Colehour, I return.

12 MR. BONDERA: Thank you very
13 much. Very good. At this point in time, even
14 though we are running slightly late, I would
15 like to turn to the people that have signed up
16 to provide us with live public testimony, and
17 the first one that I have on the sheet is
18 Marnie Karlin, followed by Andy Pollock.

19 So if you can be ready, I will be
20 corrected if it's inaccurate. But the third
21 one I have is Rosemary Galiani. So in that
22 order, if you will please share with us.

1 Thank you.

2 MS. KARLIN: Thank you. Good
3 afternoon, and thank you for the opportunity
4 to comment today. My name is Marnie Karlin,
5 and I am Associate Director of Legislative and
6 Legal Affairs of the Organic Trade
7 Association.

8 Just by way of background, I came
9 to OTA after nearly four years as counsel to
10 the United States Senate Judiciary Committee,
11 and before that I practiced law in Washington,
12 D.C. for almost eight years.

13 I also bring with me a little food
14 cred, as I hold a degree from the Cordon Bleu
15 Culinary School, and now I'm here, commenting
16 at my first NOSB meeting. Unfortunately, OTA
17 could not support the proposed changes to the
18 COI policy circulated before the meeting.

19 But we thank you very much for the
20 changes that Calvin explained, that address
21 many of our concerns, and leave me with very
22 little to comment on. I'll just outline some

1 of our concerns, just to add a little color,
2 as to perhaps why some of those changes may
3 have been made.

4 NOSB is a FACA board, an advisory
5 board prohibited from creating policy or
6 issuing regulations. Actual decision-making
7 is done by USDA officials, who are subject to
8 strong COI policies.

9 Your purpose is to provide advice
10 from the perspective of interested parties,
11 which only happens when you each represent
12 your constituencies.

13 You are all chosen because of your
14 professional expertise in a particular area,
15 selected to provide particular points of view.
16 The Board as a whole represents the entire
17 organic industry, but for you to function as
18 Congress intended, each member must represent
19 his or her particular constituency.

20 This leads us to what I see as a
21 misunderstanding between a conflict of
22 interest and an interest. Some commenters

1 suggest that any time a Board member has an
2 interest, he must disclose it for analysis of
3 whether a conflict exists.

4 That is belied by the purpose of
5 the Board. Each of you brings a set of
6 interests -- that is exactly why you were
7 appointed -- to bring your relevant interests
8 to bear as you advise the Department. You
9 were each selected to represent your
10 constituency, farmers, handlers, scientists,
11 and you would not be doing your job if you did
12 not represent that interest.

13 Now a conflict of interest is
14 different. It arises when a member's interest
15 conflicts with his official responsibility.
16 When serving on a FACA board such as NOSB,
17 your official responsibility is to have an
18 interest and represent that interest.

19 It is only when your personal
20 interest conflicts with your ability to
21 represent your constituency's interest, that
22 any conflict would arise. It is important

1 that we not show having an interest, but
2 regulate only conflicts.

3 I'd also like to talk for a minute
4 about transparency. Some commenters suggest
5 that transparency requires open discussion of
6 individual Board members' personal interests.
7 Respectfully, this misunderstands the
8 transparency requirement.

9 Transparency is absolutely
10 important, but does not require or even
11 suggest public discussion of Board members'
12 personal interests. FACA's transparency
13 requirements are that Board advice is
14 accessible to the public, and committee
15 meetings are open to the public.

16 As we've seen this week, NOSB
17 meetings, deliberations and votes are public,
18 and public comment is welcome. FACA-required
19 openness already does what a stringent COI
20 policy must do in less open government
21 processes: it shines light on and makes
22 transparent the process, so the decision-maker

1 and the public know what interests were
2 represented.

3 Finally, I'd like to thank you for
4 a couple of changes in specific areas where
5 the original proposal went too far. First, it
6 allowed application of a new COI policy
7 retroactively to votes or deliberations taken
8 before adoption of the new policy.

9 Not only is that a bad idea, but
10 U.S. jurisprudence is clear that retroactively
11 is not favored in the law. Finally, we oppose
12 the terms of "potential or perceived conflict
13 of interest," which are uncertain, vague and
14 overbroad. So we appreciate them being
15 stricken as well. Thank you for your time.

16 MR. BONDERA: Thank you very
17 much. Any questions for Ms. Karlin? Jay.

18 MR. FELDMAN: Thank you for your
19 statement. Do you have any comment on the
20 revisions that -- I know it's --

21 MS. KARLIN: So I just heard them,
22 you know, five minutes ago. At first blush,

1 they look like a much-improved proposal. I
2 would love to have a moment to actually read
3 through them before I make an official, you
4 know, have an official statement on behalf of
5 OTA. But I'd be happy to do that if I could
6 take a read on them.

7 MR. BONDERA: Thank you. Any
8 other comments? Harold.

9 MR. AUSTIN: I know you haven't
10 had a chance to see some of the revisions that
11 they just made. I'd be interested in your
12 feeling on the conflict of interest policy
13 where we're putting the verbiage back in, that
14 that, those decisions would be controlled by
15 the NOSB Board itself, rather than being
16 directed firsthand through the NOP. What are
17 your thoughts there?

18 MS. KARLIN: That tends to concern
19 me a little. I tend to feel that there is an
20 opportunity for NOSB members to have their own
21 interests in whether or not something is
22 determined a conflict of interest.

1 That raises a bit of concern for
2 me, in terms of that being where the decision
3 is made. So I generally prefer seeing an
4 objective, outside body of the NOP making that
5 decision.

6 MR. BONDERA: Any other
7 questions?

8 (No response.)

9 MR. BONDERA: Very good. Thank
10 you very much.

11 MS. KARLIN: Thank you.

12 MR. BONDERA: Do we have Andy
13 Pollock present?

14 (No response.)

15 MR. BONDERA: Okay. Hearing and
16 seeing no response, Rosemary Galiani. Thank
17 you. Please introduce yourself.

18 MS. GALIANI: Hello. You got my
19 name correct. My name is Rosemary Galiani.
20 I am general manager for the Alternative Food
21 Coop.

22 We're located in Wakefield, Rhode

1 Island, which is just about 30 minutes south
2 of here. We've been in business for over 40
3 years, we have 600 members, and I'm here today
4 as the manager, to urge the NOSB Board to keep
5 the organic standards clean.

6 Our members and our shoppers want
7 to know what is in their food. I am also a
8 member of the Cornucopia Institute, and I'm
9 here today as a citizen lobbyist. Cornucopia
10 believes that the conflict of interest
11 proposal is a step in the right direction in
12 the current policy.

13 We are especially concerned with
14 the suggestion that the Board members disclose
15 conflicts to the NOP, but not to the public.
16 Organic stakeholders would like to see greater
17 transparency, not less.

18 Since the NOP has demonstrated it
19 is unlikely to ask a Board member to recuse
20 him or herself, as happened at the last
21 meeting with the carrageenan vote, this could
22 lead to a situation where the NOSB itself has

1 no control over the conflict of interest, and
2 the public might not even know whether
3 potential conflicts were declared.

4 We question where this change in
5 the proposal came from. We support keeping
6 this important responsibility with the Board.
7 We also note that the contracts for technical
8 review are still missing from the proposed
9 conflict of interest policy, despite repeated
10 requests by numerous public interest
11 organizations to add them.

12 Currently, even the identity of
13 technical reviewers is not publicly available,
14 much less the potential conflicts. Technical
15 review essentially happens behind closed
16 doors.

17 We urge you to add a line in the
18 proposal to require technical review
19 contractors and researchers to sign the
20 conflict of interest statement prior to
21 commencing work on the TR.

22 We also question the claims made

1 by some groups and individuals in public
2 comment that the Board is supposed to
3 represent people with different points of view
4 within the organic community, and that a
5 stronger conflict of interest policy is
6 therefore not needed.

7 This system is simply not working
8 as is designed. We have seen too many
9 corporate representatives, all with conflicts,
10 vote on issues while they are serving in seats
11 legally reserved for farmers, consumers and
12 scientists.

13 When the system breaks down, as it
14 has, a conflict of interest policy is needed
15 to provide checks and balances. For example,
16 in recent NOSB history, we have seen an
17 employee of General Mills, a \$16 billion
18 corporation in the scientist's seat, who
19 failed to disclose a conflict when her
20 employer had a license agreement with the
21 petitioner for the very same substance that
22 was being petitioned. That's Martek DHA.

1 We have seen the CEO and employer
2 of an individual in a pharma slot directly
3 contact NOSB members to lobby for a yes vote
4 for carrageenan, while the NOP decided that
5 this pharma Board member had no conflict.

6 If that -- your own boss actively
7 lobbying other Board members -- doesn't
8 constitute a conflict of interest, than what
9 does? The system is clearly broken and needs
10 to be fixed. We would like to see more
11 transparency, not less; more integrity, not
12 less.

13 With regard to your public comment
14 proposal, please allow for unlimited questions
15 and answers. Experts often travel great
16 distances to attend these meetings, and Board
17 members should have the opportunity to
18 publicly engage with public presenters until
19 their questions have been answered. I thank
20 you for your time. I'll answer any questions.

21 MR. BONDERA: Thank you, Ms.
22 Galiani. Any Board member questions?

1 (No response.)

2 MR. BONDERA: Very good. Thank
3 you for your time. I do thank you. This
4 microphone and me are not having the best
5 time, and I apologize. It keeps considering
6 not being on.

7 At this point in time, we have
8 finished with the Policy Development
9 Subcommittee's presentations and testimony,
10 and I would like to call a 15-minute break so
11 that the Policy Development Subcommittee can
12 huddle together and regroup about our voting
13 process, so we can finish up this day.

14 So if that's alright with you, Mr.
15 Chair, I would like to reconvene at five after
16 5:00.

17 CHAIRMAN FLAMM: That is fine.
18 We'll reconvene at five minutes after 5:00.

19 (Whereupon, the above-entitled
20 matter went off the record at 4:49 p.m. and
21 resumed at 5:03 p.m.)

22 CHAIRMAN FLAMM: We've got the

1 chair of the Policy Subcommittee, and I guess
2 we can resume now.

3 MR. BONDERA: Very good.

4 CHAIRMAN FLAMM: Colehour, I
5 understand that the committee has made some
6 decisions on how you wish to proceed for the
7 rest of the afternoon.

8 MR. BONDERA: Yes. Thank you
9 very much, Mr. Chair. At this point in time,
10 based on the discussion within the Policy
11 Development Subcommittee, we have decided that
12 we would like to move forward with our
13 recommendation on public comment and our
14 recommendation on public communications, and
15 postpone our conflict of interest topic until
16 tomorrow so there's more time for discussion
17 about the changes that have happened to the
18 proposed recommendation as it was put forth to
19 the public, since as you saw, there's a fair
20 number of lines crossed off and a fair number
21 of new ones.

22 I want to give the opportunity to

1 entire NOSB members who are not on the Policy
2 Development Subcommittee an opportunity to be
3 prepared with their discussion points and
4 questions when we deal with that, and you
5 have, according to my watch, you know, well
6 over 12 hours to do so. So I'm sure that
7 that's enough time for everybody involved.

8 In any case, so that's our
9 intention, and we have, like I said, two
10 subject areas, and I would like to start out
11 the process, before a motion is made, by
12 asking the NOSB members if there is -- and I
13 do hope we can all, we all already know the
14 answer to this.

15 But nonetheless, just to give the
16 opportunity, in case there is any rationale or
17 logic for any recusals or information-sharing
18 on conflict of interest related to the policy
19 development, this is an opportunity to do so.
20 So I welcome anybody who has something to put
21 forth in that regard.

22 Very good. Hearing and seeing no

1 reaction or action on that, I will move us
2 forward to considering the recommendation, and
3 first the one that I presented on public
4 comment, and so like I said, the
5 recommendation is to amend Section 6 of the
6 PPM, and I don't know if Michelle wants to put
7 it up on the screen, because I didn't prep her
8 put it up on the screen.

9 But know, the actual wording of
10 the actual recommendation, the motion, because
11 otherwise, I have to read through the whole
12 motion again to present it.

13 So it's the same one that's in
14 the, what was publicized too. I don't know
15 whether you have it. Sorry. I apologize for
16 that delay.

17 In any case, I will actually make
18 that motion at this point in time, that we do
19 amend the policy procedure manual as that
20 reads, and would be happy to entertain a
21 second to that motion.

22 MS. RICHARDSON: Second the

1 motion.

2 MR. BONDERA: Thank you very
3 much.

4 CHAIRMAN FLAMM: It's been moved
5 and seconded.

6 MR. BONDERA: Thank you.

7 CHAIRMAN FLAMM: Colehour? It's
8 been moved and seconded. If I understand,
9 your motion is to change the -- to add to the
10 Section 6 of the policy and procedure manual,
11 the following recommendation, and those
12 recommendations are numbered 1 through 10, as
13 shown on the screen.

14 If everybody is satisfied with
15 reading it themselves, rather than have
16 Colehour re-read it. Is there any desire to
17 have Colehour read the full motion?

18 (No response.)

19 CHAIRMAN FLAMM: If not, is there
20 any discussion? Mac.

21 MR. STONE: I haven't asked
22 presenters specifically, but from this vantage

1 point, it seemed like the presenters were more
2 comfortable with a four-minute delivery. I
3 thank Michelle for the little beeping light
4 thing. I think that gave them some time to
5 help their cadence.

6 So obviously I want the public to
7 know too that there's uniform interest for
8 this Board to maximize public comment time
9 because it is deemed extremely valuable. But
10 I think the four minutes was way better than
11 three.

12 CHAIRMAN FLAMM: Any other
13 comments or discussion by the Board? John.

14 MR. FOSTER: Thanks. So on point
15 number one, it says -- basically it says
16 you've got to sign up ahead of time, and then
17 in number nine it says you can do something
18 else. So I'm wondering if there's a way to
19 reconcile that.

20 Number one just says very clearly
21 everyone who wants to speak has to sign up
22 ahead of time. Number nine, I think, it says

1 that, well, actually you can sign up according
2 to certain, if certain criteria are met. I'm
3 wondering if we can change number one to be
4 something other than absolute because clearly
5 we don't want it to be absolute. You know
6 what I mean?

7 MR. BONDERA: So you're
8 specifically referring to the word "must" in
9 that sentence?

10 MR. FOSTER: Yes. Sounds pretty
11 absolute, and maybe it's no big deal. Maybe
12 no one else is worried about it, but I just
13 hate putting something in one part of a new
14 document, and then somewhere else in that same
15 document we're saying we're not going to
16 follow what we just said.

17 Maybe no one else -- I don't know.
18 It doesn't, that's not my preference. Anyway,
19 if no one else is worried about it, I'll pass.
20 But it seems like you could build, you could
21 put all that into one point, and then be not
22 contradicting yourself. That's my first

1 question.

2 Or if there's a reason to do it
3 this way, tell me what that is, please.

4 CHAIRMAN FLAMM: Nick. I'm sorry,
5 John. Have you finished?

6 MR. MARAVELL: I agree with John,
7 and I was about -- he stated what I was about
8 to state. It might make sense just to put it
9 all in one point. I would hate to sit here
10 and wordsmith, but I would leave that to the
11 discretion of the Subcommittee, to get the
12 commas and the tenses and everything else
13 straightened out.

14 But I would say we should
15 encourage, you know, we encourage everyone to
16 sign up in advance, and then go on for point
17 number nine, saying if you don't sign up in
18 advance, then this is what happens.

19 CHAIRMAN FLAMM: Colehour, would
20 you like to respond to --

21 MR. BONDERA: Yes. I think in
22 one second I will, sorry. I'm just looking at

1 the screen, I apologize. Yes. I think that
2 in my opinion, and I thank you for your
3 comment, John. I think if that word "must"
4 were to change to the word "should," and
5 number nine was simply put as a continuing,
6 just take everything that's in number nine, no
7 wordsmithing at all except for that one word
8 I just mentioned.

9 Take number nine and put it
10 directly after number one, as part of number
11 one. So eliminate number nine and put the
12 text of it at the end of number one.

13 The word "should" means that's
14 what you should do, but that we're going to
15 accommodate people if they otherwise fit in,
16 and then not change any of those other words.
17 I don't know if that addresses your question
18 sufficiently or not John, but that would be
19 how I'd handle it.

20 MR. FOSTER: Yes, it does.

21 MR. BONDERA: Okay. Did you have
22 some other points? Sorry.

1 MR. FOSTER: I did. I know this
2 kind of language often uses the word "impugn,"
3 but it's not uncommon to have impugning going
4 on at these proceedings. So by definition, I
5 know we all think it means one thing. It
6 means a little more general than we actually
7 assume it to be.

8 So I'm not suggesting we change
9 it, but those of you who know me know that
10 there's certain words that I like to be very
11 precise about, and impugn has a much more
12 general kind of challenging connotations to it
13 than what we mean, which is don't bad-mouth
14 someone and don't personally attack them.
15 That's what we mean, and I get that.

16 But impugn is more general. I'm
17 not necessarily saying we change it. I just
18 want to call it to everyone's attention that
19 impugn is a very broad -- it's a very broadly
20 applicable challenge or attack. Accusing
21 something, in this case, a person's character
22 as being false.

1 That's a very general statement,
2 and I just want to make sure we know what
3 we're doing when we say that, because we're
4 trying -- I mean this will be a continuously
5 improving document. I'm sure we can always
6 make it better, and I just want to make sure
7 we mean what we say when we say it, that's
8 all.

9 CHAIRMAN FLAMM: Colehour, I think
10 if we're going to do any wordsmithing, we
11 don't have time to do it here. If you wish to
12 do that, I would withdraw your motion and fix
13 it and come back tomorrow, and we can vote on
14 it. We have time tomorrow. John.

15 MR. FOSTER: I want to just make
16 clear, I'm not saying we have to do this in
17 order for me to vote for it or against it or
18 anything. I'm just, I want to get it out
19 there, that this clearly has -- this is a very
20 useful concept to include in our Policy and
21 Procedures Manual.

22 So when we put something in it, I

1 just want to make sure that we're using the
2 words we mean to use. If no one else, or if
3 we don't -- if there's not general consensus
4 that we need to worry about that, then you
5 know, go with the will of the Board.

6 CHAIRMAN FLAMM: I'm just giving
7 Colehour that option, as the maker of the
8 motion.

9 MR. BONDERA: Thank you. I
10 think, Mr. Chair, what I would like to do at
11 this time is, and thank you again, John, for
12 your comments, I would like to see if there's
13 any other comments. So that if I make that
14 decision, then I know -- or if I want to
15 withdraw that, that I know what I'm
16 considering.

17 But I think that it does make
18 sense to me. But I'd appreciate wrapping up
19 any other comments, if there are any more.

20 CHAIRMAN FLAMM: All right. Any
21 other -- yes, I got your point. Any other
22 comments or discussion, and if those were

1 corrected and brought back tomorrow, would
2 that satisfy the Board? Hearing none, I -- we
3 got one.

4 MR. FELDMAN: Yes. I don't have a
5 problem with the word "impugn." I think
6 that's -- we discussed it as a subcommittee,
7 and I think that's what was intended, that
8 there not be any, as you say, broad attack on
9 people.

10 I just think we have other things
11 to do tomorrow, and I also think the issue of
12 aligning number one with number nine is rather
13 simple. We could just say, you know, instead
14 of the word "must," if people feel
15 uncomfortable with that, we could say "must as
16 a general rule," and then add the rest of the
17 sentence in number nine to that paragraph and
18 say "However, if," and then just connect those
19 two thoughts, as you're suggesting, and be
20 done with this, because I think we have other
21 things to do tomorrow, and I think we all
22 basically agree with this.

1 CHAIRMAN FLAMM: Okay. Colehour,
2 I give you the option, Colehour, of either
3 withdrawing it and fixing it and coming back
4 tomorrow, or restating the motion, with the
5 suggested changes.

6 MR. BONDERA: Thank you. I would
7 like to modify my motion that's on the table,
8 to change number one and number nine, as Jay
9 just presented as a suggestion, and I'm sorry
10 I don't know if I should ask --

11 CHAIRMAN FLAMM: Read the changes
12 out.

13 MR. BONDERA: So, can I read
14 this? May I read it? "All persons wishing to
15 comment at NOSB meetings during public comment
16 periods must, comma, as a general rule, comma,
17 sign up in advance per the instructions in the
18 Federal Register notice for the meeting."

19 Number nine could remain or could
20 become a part of number one, which I would
21 suggest. "However," and this would become the
22 last sentence in number one. "However, the

1 NOSB will attempt to accommodate all persons
2 requesting public comment time, comma, delete
3 "however." "Persons requesting time after the
4 closing date in the meeting notice, comma, or
5 during last minute sign-up at the meeting,
6 comma, will be placed on a mailing list and
7 will be considered at the discretion of the
8 NOP, working closely with the NOSB chair,
9 depending on availability." Renumber number
10 ten to number nine, period.

11 CHAIRMAN FLAMM: Do we have those
12 changes, proposed changes recorded? Colehour.

13 MR. BONDERA: Yes, but I don't
14 have them in electronic form.

15 CHAIRMAN FLAMM: I'm taking -- the
16 motion's been withdrawn and a new motion's on
17 the floor. Is there a second?

18 MS. RICHARDSON: Yes, I second the
19 motion.

20 CHAIRMAN FLAMM: Does the Board
21 understand now the changes that were made?
22 Any questions? Discussion?

1 (No response.)

2 CHAIRMAN FLAMM: I call for a vote
3 then. Where are we? The vote begins with
4 Jean.

5 MS. RICHARDSON: Yes.

6 MR. WALKER: Yes.

7 MR. BONDERA: Yes.

8 MS. TAYLOR: Yes.

9 MR. MARAVELL: Yes.

10 MR. FELDMAN: Yes.

11 MS. SONNABEND: Yes.

12 MR. STONE: Yes sir.

13 MS. FULWIDER: Yes.

14 MR. AUSTIN: Yes.

15 MS. FAVRE: Yes.

16 MS. BECK: Yes.

17 MR. FOSTER: Yes.

18 MR. DICKSON: Yes.

19 CHAIRMAN FLAMM: And the Chair
20 votes yes. 15 yes, 0 no. Thank you. Your
21 next proposal, Colehour, and that will finish
22 the afternoon.

1 MR. BONDERA: Yes, very good. I
2 would like to turn it over to the lead on
3 this. Jennifer, if you would present a motion
4 for us, please?

5 MS. TAYLOR: Thank you. Thank
6 you, Colehour and Barry. I would like to
7 motion that the proposal, Public
8 Communications, be accepted. Is that the
9 word? That it be adopted. Thank you.

10 CHAIRMAN FLAMM: We need to either
11 see it or you need to read it, so we know what
12 words.

13 MR. MARAVELL: I think -- let's
14 see if we can get it. Do we have a copy of it
15 for the screen? Yes, that's what we're
16 waiting to see, if we can get a copy of it.

17 MS. TAYLOR: The recommendation is
18 Roman numeral IV. Want me to read it, Barry?

19 CHAIRMAN FLAMM: Well, I think if
20 we could show it on the screen, it would
21 probably be easier for the Board to -- we
22 don't have it.

1 MS. TAYLOR: We also have it in
2 our agenda items.

3 CHAIRMAN FLAMM: Well then go
4 ahead and read what the recommendation is, so
5 we can get it in the record.

6 MS. TAYLOR: Yes sir, thank you.
7 "Recommendation 4. PPM Section 6,
8 Miscellaneous Policy, page 26, is amended by
9 adding a new subcategory in italics. NOSB
10 policy on its advisory role and communication
11 with the Secretary of Agriculture.

12 "Based on the communications and
13 input it receives from the public, the
14 National Organic Standards Board may provide
15 effective and constructive advice,
16 clarification and written information as it
17 deems necessary, directly to the Secretary of
18 Agriculture, after each of its Board meetings.

19 "This information is intended to
20 facilitate public communication with the
21 Secretary on critical issues that may emerge,
22 that it believes are important to the

1 implementation and integrity of the organic
2 standards and practices under the Organic
3 Foods Protection Act, Production Act.

4 PPM Section 6, Miscellaneous
5 Policies, page 27, is amended by adding a new
6 subcategory in italics. "NOSB policy for
7 public communication between NOSB meetings.
8 The NOSB seeks public communication outside of
9 Board meetings and public comment periods to
10 inform Board and program work."

11 PPM Section 2, page 13, Role of
12 the Executive Director, is amended to include
13 the following language, in italics.

14 "Identify, implement, administer and maintain
15 a year-round mechanism by which public
16 feedback can be received, posted and archived
17 for viewing by the NOP, the NOSB and the
18 public itself."

19 CHAIRMAN FLAMM: Thank you. Do we
20 have a second to the motion?

21 MR. FELDMAN: Second.

22 CHAIRMAN FLAMM: It's been

1 seconded to amend the Policy and Procedure
2 Manual to add communication material. Unless
3 any Board member is unclear on what was read,
4 I'll just -- I'll leave it at that. Is there
5 any need for clarification on what we're about
6 to discuss and vote on?

7 (No response.)

8 CHAIRMAN FLAMM: Hearing none,
9 discussion? Any discussion. Thank you. Zea.

10 MS. SONNABEND: Well I've read
11 this a few times in Albuquerque and now, while
12 I don't really support the bottom part of the
13 recommendation, I just don't understand the
14 point of the first part of the recommendation.

15 So I guess I'm going to abstain,
16 because I just -- I'm afraid that it's -- I
17 mean I don't understand what "effective and
18 constructive advice" means. How do you give
19 the Secretary effective advice, by saying that
20 in advance and it's not really public
21 communication you're talking about. It's NOSB
22 communication with the Secretary.

1 What you get from the public, I
2 don't know. So I'm having trouble like really
3 understanding the point of it. So I'm going
4 to abstain.

5 CHAIRMAN FLAMM: Let's see. I
6 think, Nick, you had your hand up first, I
7 believe.

8 MR. MARAVELL: Yes. I think what
9 we're looking at here is the intent. This is
10 establishing sort of the rationale for what
11 we're trying to do. We're trying to provide
12 effective and constructive advice. It's the
13 intent. We can't guarantee it.

14 It's to establish the intent of
15 why we are trying to, in effect, take what we
16 have received from the public and communicate
17 that as part of our responsibility in the
18 statute, to advise the Secretary on any aspect
19 of the National Organic Standards Program. So
20 it's just showing intent. Sort of a
21 rationale.

22 CHAIRMAN FLAMM: John, a comment?

1 MR. FOSTER: I'm a little with Zea
2 on this. I think our mission and mission
3 statement are pretty clearly defined, what
4 this body is about. It says that. I don't
5 perceive that we have a problem delivering
6 information to the Secretary, either directly
7 or through the NOP, and I guess I am puzzled.

8 This feels like a solution in
9 search for a problem to me, and I don't -- I
10 think what we see here is already covered
11 actually more clearly. I don't see the need
12 for it. Then also, I'm with Zea on the
13 effective advice part. That's been a long-
14 time bugaboo for me.

15 But the way this is phrased makes
16 it sound like we are to base our input, our
17 effective and constructive advice,
18 clarification or written information, based on
19 the communication input it receives from the
20 public, and I think we should be basing our
21 advice on not just that.

22 This makes it seem like it should

1 be just that. So that I'm uncomfortable with
2 that. It's very limiting, and I don't think
3 we make our decisions based on one avenue of
4 information.

5 Historically, we certainly
6 haven't, and I think it's pretty clear in our
7 policy and procedures, as well as other
8 guidance we've gotten from the program, and I
9 think the FACA rules are pretty clear.

10 We're getting information from
11 more than there. So I don't like being
12 limited by this, by what this says,
13 irrespective of not knowing what effective
14 advice is, like Zea said.

15 And then -- well, I have something
16 to say on the second part too, but I don't
17 know if you want me to stop there and we can
18 cover that.

19 CHAIRMAN FLAMM: Go ahead. You
20 can finish your comment and then I'll call on
21 Tracy next.

22 MR. FOSTER: Okay. The second

1 part is I don't think we have an executive
2 director anymore. I know there are a lot of
3 references to it in the Policy and Procedures
4 Manual, and I assume the PDC is going to be --
5 or PDS, rather, is going to be working on
6 getting those changed out to current job
7 titles and what-not.

8 But so I recognize here -- I don't
9 know if we want to continue talking about the
10 executive director, where we're making
11 amendments to the Policy and Procedures
12 Manual, or whether we want to change, use
13 language that's more appropriate for current
14 conditions. That's more a question.

15 CHAIRMAN FLAMM: Thanks, John.
16 Tracy.

17 MS. FAVRE: I would like to get
18 some clarity around what is the mechanism by
19 which we communicate with the Secretary of
20 Agriculture, and, as well as receive the
21 public communications. Jennifer, you
22 mentioned something about the public register.

1 But is that the only means by
2 which you intend for NOSB members to receive
3 public comments outside of the specific
4 meeting procedures?

5 CHAIRMAN FLAMM: Nick, you want to
6 respond to that?

7 MR. MARAVELL: Yes, and to John's
8 concerns about the executive director. I
9 think, you know, what we're talking about is
10 house cleaning, and I think that's going to
11 take place at a subsequent time, and really
12 it's not part of this proposal.

13 With regard to the other concern
14 that John had, it's my understanding, and
15 correct me if I'm wrong, is the way you
16 interpret it is correct. We are commenting
17 and this is why I say the intent here is,
18 should be stated.

19 We can communicate with the
20 Secretary for a variety of reasons, you're
21 absolutely correct. But what we're saying
22 here is it's going to be our policy that we

1 intend to provide an avenue specifically for
2 public input, that to the extent we feel it's
3 appropriate, to inform the Secretary of what
4 we have been hearing.

5 Now I'm going into history, and I
6 may not be exactly correct on this. But I
7 know, I was informed that in the early days of
8 the NOSB Board meetings, that it was not at
9 all uncommon for the Board at the end of the
10 meeting to draft a letter to the Secretary.

11 Now I'm not saying I know what was
12 in those letters or anything else, but I
13 understand that's what happened. I don't know
14 if anyone could fill me on this.

15 But the intent back then was
16 because this was a new program in formation,
17 et cetera, was to bring forward public
18 comment, and that was part of the statutory
19 authority, was to advise the Secretary on any
20 matter concerning the implementation of the
21 program. So that's why that was done a long
22 time ago.

1 And Tracy, you had a concern too?

2 I forget what.

3 MS. FAVRE: About public
4 communication with Board members outside of
5 meetings.

6 MR. MARAVELL: Right. So I don't,
7 you know. This is, this would cover
8 communications that we, you know, we've had
9 with the public, whether it's through a
10 working group or through a request for
11 information. It wouldn't have to just be at
12 this type of a meeting.

13 So I don't, I mean I don't think
14 this is a big deal personally, but maybe I'm
15 missing something here, that we're just saying
16 from time to time, we may want to inform the
17 Secretary of things that we have heard from
18 the public concerning the operation of the
19 program, and that's the way I interpret it.

20 CHAIRMAN FLAMM: Miles or Jenny,
21 do you want to make a comment or ask a
22 question?

1 MS. TUCKER: Hi. A couple of
2 comments. This is Jenny Tucker. In terms of
3 the policy on communication with the
4 Secretary, the Secretary delegates authority
5 for the NOSB to the National Organic Program.
6 So we would request that any letter that is
7 sent directly to the Secretary go through our
8 Designated Federal Officer, who is Michelle.

9 As an example, at the last Board
10 meeting, you passed the motion to send the
11 GMO-related letter to the Secretary. That was
12 submitted through the DFO and it was in the
13 Secretary's hands within 24 to 48 hours. So
14 that's an appropriate chain of command to
15 submit information to the Secretary.

16 On the second point related to the
17 public communications capability, a number of
18 questions have come up in terms of, for
19 example, email notification and will Board
20 members be able to respond.

21 The motion here is you're -- would
22 be to state that you want this kind of

1 capability to exist. The program would then
2 come back to you with an implementation plan,
3 in terms of here are the different tools that
4 could be used to accomplish that kind of goal,
5 and that would lead to an implementation and
6 rollout plan that would roll from a
7 recommendation you would make today.

8 But some of those answers have not
9 been answered yet. We have to decide first
10 that you want the capability.

11 CHAIRMAN FLAMM: I think Jay had
12 his hand up next, though. Thank you, Jenny.

13 MR. MARAVELL: Yes. I don't think
14 anybody has a problem with that, Jenny. But
15 I just want to say that we're both a National
16 Organic Standards Board and a federal advisory
17 committee or advisory board.

18 So we're just simply looking for
19 the way to provide our advice. So it would be
20 -- our physical method of doing this is within
21 the constraints of the Department's policy.
22 So I don't see a problem with any of that.

1 CHAIRMAN FLAMM: Jay.

2 MR. FELDMAN: Well, the
3 Subcommittee discussed the issue of how this
4 wording should appear, and felt after
5 discussion that we should just repeat the
6 statutory language, and leave the
7 implementation, as Jenny mentioned, the
8 mechanics of how the thing gets delivered to
9 the program, but that the language in terms of
10 the direct communication, as indicated in the
11 statute, between the Board and the Secretary,
12 be preserved and memorialized in the PPM.

13 To answer John's earlier question,
14 you know, this grew out -- or John's statement
15 that this is a solution in search of a
16 problem: this actually grew out of a problem.
17 As you recall, there was some interest on the
18 part of Board members to communicate with the
19 Secretary after the Seattle meeting.

20 There had been a, what, 50 or
21 some-odd comments on GMO issues, and it felt
22 like, to some Board members, the

1 responsibility of the Board was to make the
2 Secretary aware that the Board had been
3 hearing from the organic community on this
4 issue.

5 So a one-paragraph letter was
6 drafted, and that then turned into a year-long
7 project. But there could be opportunities
8 here to keep the Secretary informed as to what
9 is being heard at the NOSB meetings, to the
10 extent that the Board comes together and feels
11 there is something important to report to the
12 Secretary.

13 So that's the intent here. In
14 some cases, that may be a year-long project,
15 to work something up. But in other cases, it
16 may be a simple note, hey, this is what we
17 heard at the meeting. We wanted to make you
18 aware that this, that we heard x number of
19 comments on this issue. It may affect your
20 thinking one way or another. Sort of a
21 factual communication that again, as Nick said
22 earlier, is intended to be constructive, and

1 is intended to be helpful in terms of the
2 overall program, USDA meshing with what
3 happens here during the NOSB meetings.

4 So that was the intent, and it
5 grew out of a sense that there was a need for
6 this, and I personally believe the need may
7 exist at some point in the future, where the
8 Board feels it's necessary to bring that.

9 I don't see anything particularly
10 at this meeting where this arises, but the
11 authority we know is there, no matter who is
12 managing the program or who's sitting in the
13 Secretary's seat. It's just an ongoing, it
14 reaffirms the ongoing ability of the Board,
15 per the statute, to engage in that type of
16 communication.

17 CHAIRMAN FLAMM: Nick, I'll
18 recognize you in a minute. But I want to give
19 the lead person on this an opportunity to
20 speak, if she wants to. You are the writer.
21 You ushered this through, and I think maybe
22 you should have the opportunity to answer

1 questions.

2 MR. MARAVELL: Yes. I'd like to
3 just state my understanding of this so that
4 we're all clear. We're not talking about
5 providing recommendations to the Secretary
6 here, that would, you know, those go through
7 a different process.

8 This is primarily informational.
9 There may be some advice in it. But we're not
10 providing recommendations under that type of
11 authority.

12 The statute said we're authorized
13 to provide advice. So this is what I would
14 consider to be a lower-level type of
15 communication, rather than saying we recommend
16 this for the National List or something like
17 that.

18 CHAIRMAN FLAMM: Harold.

19 MR. AUSTIN: I guess to me, it
20 would appear that there's already a vehicle
21 and a means and a method in place right now.

22 I think the process in the Board

1 and the communication between the program and
2 the Secretary and the NOSB seems to have been
3 able to function in the past, or we wouldn't
4 probably be to where we are right now.

5 I think this does open up the
6 potential for issues. I don't think it's
7 clearly defined as what the vehicle will be or
8 who will deem it necessary. Is it the entire
9 Board that makes the decision on what
10 communication? It doesn't state that.

11 Is it, you know, are those issues
12 decided by a majority of the Board, or by
13 individuals of the Board. I think if we're
14 going to put something like this into the
15 Policy and Procedures Manual that's going to
16 replace what is in existence today, we need to
17 be a lot more clearer and a lot more specific
18 than what's on there right now.

19 I could not vote for this as it is
20 written right now.

21 CHAIRMAN FLAMM: Colehour, as
22 chair, I want to give you an opportunity to

1 speak before we -- we're past recess time now,
2 so but would you -- you want to address the
3 concerns that some Board members have stated?

4 We have a motion, and we'll need
5 to either -- we need to either vote on it soon
6 or withdraw it, and that's your call.

7 MR. BONDERA: Yes, very good.
8 Thank you. Like when I introduced this, I
9 will just remind the NOSB members that this is
10 nothing new, and this, in this form, has been
11 presented for quite some time.

12 But I appreciate people's
13 responses nonetheless. I think it's relevant
14 to speak about it. I do also, however, want
15 to remind people what the program just told
16 us, which is that they understand that we're
17 seeking ways to achieve these goals, and their
18 understanding is they would work with the NOSB
19 to, like Harold just referred to, lay out the
20 specifics, because that is some of the
21 questions at hand, and I think it --

22 I acknowledge the fact that it

1 does say executive director, and there are
2 other -- there's actually verbiage in the
3 statute that, as John alluded to, is a little
4 bit -- needs updating. But we're not in a
5 role to be playing those kinds of roles very
6 viably or in this context.

7 So that said, I would like to ask
8 you, Jennifer, if you would like for us to --
9 you know, you're the one that made the motion.
10 If you would like to withdraw this motion and
11 we can continue this discussion tomorrow, I
12 think that would be fine, and if you feel
13 otherwise, I'm willing to entertain continuing
14 with it at this moment. But I will ask you
15 that question.

16 MS. TAYLOR: Colehour, I'm hoping
17 that we will be able to go ahead and vote on
18 it. I believe it's been properly seconded,
19 the motion has. Yes. I'd like to continue
20 our vote, to vote on it, please.

21 CHAIRMAN FLAMM: There is a motion
22 that's been seconded on the floor, and we can

1 proceed with a vote, if that's what you would
2 like to do. Any further comments or
3 discussion?

4 If not, we'll proceed with a vote,
5 beginning with Calvin.

6 MR. WALKER: Yes.

7 MR. BONDERA: Yes.

8 MS. TAYLOR: Yes.

9 MR. MARAVELL: Yes.

10 MR. FELDMAN: Yes.

11 MS. SONNABEND: Abstain.

12 MR. STONE: Yes sir.

13 MS. FULWIDER: No.

14 MR. AUSTIN: No.

15 MS. FAVRE: No.

16 MS. BECK: No.

17 MR. FOSTER: No.

18 MR. DICKSON: No.

19 MS. RICHARDSON: Yes.

20 CHAIRMAN FLAMM: And the chair

21 votes yes. Let's see what we have: 8 yes, 6

22 nos and one abstain. We have insufficient

1 votes for the motion to pass, and it fails.
2 That's the end of the session today. We'll
3 recess until eight o'clock tomorrow morning.
4 Have a good evening, everyone.

5 (Whereupon, the above-entitled
6 matter went off the record at 5:47 p.m.)

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AAP 17:2 24:12 71:15 232:10 234:1 255:17	academic 227:10 279:10	306:1,1,4	33:3 34:4 40:16 45:10 54:21 58:10 66:15 79:21 101:19 116:18 121:12 124:14 134:1 137:13 168:5 180:14 192:11 205:2 209:17 251:17 256:17 261:16 264:15 265:3 273:12,18 277:19 278:6 279:10 287:20 288:5 313:13,17 323:9 351:1 358:11,17 365:9 373:16 380:2	addition 9:1 38:21 49:14 51:10 54:4 54:9,12 59:20 60:15 63:6 75:15 78:10 108:20 136:14 182:13,18 195:6 243:21 247:21 251:8 300:16 344:7
Abbott 212:13 258:17	academicians 226:11	acidity 53:20	added 8:5 9:7,20 9:21 22:22 23:2 24:17,18,21 26:12 27:9,11,12 28:3,4 28:12 29:1,4,7 34:21 37:1 42:22 48:1,1 50:21 51:6 55:10 63:4 68:7 75:3 79:19 88:6 89:3 101:4 102:4 103:19,22 108:7 116:15 117:6,9 124:18 125:3 128:17 130:3 131:9,22 132:14 153:5 154:15 156:4,8 157:8,16 157:18 178:16 189:17 190:7 192:22 193:14,16 194:19 206:20 240:2 251:13 252:4 284:17 285:2 293:11 327:19 328:20	additional 11:12 35:10 41:20 45:19 51:22 77:19 81:11 94:6 96:10 109:15 115:22 132:16 133:13 159:18 179:17 182:1 196:8 231:6 238:10 239:7 249:4 267:2
abbreviate 36:20	Academy 4:22 17:20 46:14 55:18 71:4 76:10,11 224:13 250:18 251:19 252:6	acids 31:20 32:1 57:6,7 62:13 79:2 79:2 119:18 129:10,11,15 198:3,4 199:1,15	add 25:3 27:19,22	addresses 369:17 adds 259:2 adequate 38:13 40:11 194:16 300:17 adequately 30:14
abilities 8:8	accelerated 249:14	acid-based 305:15 306:5	adding 80:7 124:10 160:9 234:5 275:2 303:12 346:4,22 378:9 379:5	
ability 88:15 238:17 348:1 352:20 392:14	accept 293:4	act 23:17 26:20 47:8 101:15 186:20 187:4 197:1 208:16 213:8,10,14,19 227:21,22 253:9 341:4 343:10 344:2,19 345:12 346:20 379:3,3		
able 31:8 57:12 102:16 162:4 227:14 267:3 298:13 299:7 330:15 348:5 349:6 388:20 394:3 396:17	acceptable 202:6 307:10	acted 23:17 26:20 47:8 101:15 186:20 187:4 197:1 208:16 213:8,10,14,19 227:21,22 253:9 341:4 343:10 344:2,19 345:12 346:20 379:3,3		
abnormal 179:5	accepted 101:13 119:8 160:13 224:1 229:2,3 332:11 377:8	acting 23:5 158:4		
abnormalities 128:7	accepting 160:14 261:15	action 23:19 34:18 253:17 271:22 364:1		
above-entitled 98:16 237:4 260:13 315:7 361:19 398:5	access 172:20	actions 198:21 199:22		
abroad 203:18	accessible 353:14	active 19:13		
absent 11:7 55:1 60:20 61:1 74:10 75:19 335:14	accessory 39:2 183:4 278:19	actively 360:6		
absents 40:15	accommodate 235:22 238:13 337:8 369:15 375:1	activities 223:10 238:8		
absolute 367:4,5,11	accomplish 389:4	activity 25:10,17 25:21 27:7 124:8		
absolutely 31:13 87:10 163:3 221:3 281:16 353:9 385:21	account 146:9	acts 37:12 117:13		
absorption 74:16 74:18,19 127:9 129:3 131:19 193:11	Accountability 107:15	actual 39:3 64:16 71:11 95:11 115:2 171:7 242:11 254:10,13 268:6 351:6 364:9,10		
abstain 380:15 381:4 397:11,22	accredited 191:22	Act's 213:3		
abstracts 19:7	accumulates 176:4	acute 65:4		
abundant 57:7 79:2	accumulation 216:3	add 25:3 27:19,22		
abuse 66:20 69:19 69:20	accurate 245:13 298:9			
abused 112:9	accurately 74:7 245:14			
	Accusing 370:20			
	achieve 395:17			
	acid 27:10,15,19 29:1 35:2,3 59:15 62:7 74:6 113:12 129:9 147:15 192:2,13 201:21 271:16,19,21			

94:12	393:9,13	157:14	342:15 380:11	232:6 356:20
adjunct 126:3	advise 68:13 343:1	age-related 181:7	alert 348:16,22,22	alternatives 40:12
adjust 201:11	343:13 352:8	aggressive 97:21	algal 137:10	111:20 114:4
adjusting 340:17	381:18 386:19	ago 24:16 62:22	aligning 373:12	137:1 138:14
administer 347:9	advised 99:20	65:10 70:14 96:22	Alimentarius 20:4	211:12 229:17,22
379:14	194:8	106:2 227:21	alive 108:22	230:15 233:11
Administration	advisement 89:13	305:9 354:22	Allen 143:17	altogether 33:15
20:1	95:17	386:22	allergic 53:12,14	198:20
Administrator	advisor 208:18	agree 71:8 106:12	53:18	amend 136:10
2:10,22	advisory 2:12	106:18 111:4	allergy 69:20,21	265:19 334:15
adopt 91:7	344:2,5 346:5	113:10 138:21,22	allotment 335:17	364:5,19 380:1
adopted 87:17,18	351:4 378:10	143:1 170:6	336:10	amended 346:3,22
87:19 90:3 227:12	389:16,17	205:11 232:10	allow 42:3 86:5,8	347:8 378:8 379:5
377:9	advocate 326:7	271:8 290:11	106:21 111:16	379:12
adopting 93:16	advocates 190:21	294:4 320:13	172:8,9 303:7	amendment 293:5
145:5,10	Affairs 182:9 350:6	368:6 373:22	335:7 339:4	amendments
adoption 104:18	affect 228:13 231:3	agreed 12:8 279:11	360:14	384:11
225:2 354:8	342:2 345:1	321:19 323:7	allowance 145:18	American 4:22
adult 42:13 176:15	391:19	agreement 21:5	172:5 251:8	17:20 20:7 46:14
176:19 177:1,8	affiliates 327:6	61:1 323:8 359:20	allowances 152:14	71:3 102:12
212:18	affiliation 100:6	agreements 207:7	173:20	224:13
adulterated 190:13	affiliations 336:13	agricultural 2:18	allowed 42:2 80:11	Americans 213:18
199:20 240:16	afraid 380:16	36:2 43:3 84:13	115:12 117:4	amino 57:6,7 59:15
253:7	afternoon 15:16	84:13 101:18	118:2,6,12 119:11	62:7,13 74:6,8
adults 38:16 39:18	238:6 350:3 362:7	187:16 309:21	120:12 147:8	79:1,2 113:12
131:1 134:22	376:22	agriculture 1:1,1	154:2,13 166:5	192:2,13 198:3
176:2	age 65:2 129:4	14:2 86:7 169:22	170:5 171:16	amount 27:6 29:5
advance 6:21 14:18	136:1	171:11 183:16,19	173:2 185:11	30:22 33:19 66:10
36:9 50:17 52:19	agencies 47:7	326:5 343:21	186:12 229:15	81:20 92:4 134:2
56:18 59:9 73:21	119:10 173:7	344:16 345:8	254:22 265:12	189:20 338:6
78:18 171:7 335:2	174:1 191:5 224:2	346:6,12 378:11	270:3,11,22	amounts 29:3 38:4
335:7,8 336:1	229:3	378:18 384:20	309:17 354:6	131:9 158:1 193:9
368:16,18 374:17	agency 46:15,18	ahead 5:3 99:12	allowing 41:19	258:10,22
380:20	47:3 171:9 172:11	124:3 236:10	147:22 270:15	amplify 267:22
advanced 208:21	172:22 220:15,21	298:3 333:9	308:21	AMS 1:1 321:22
advances 116:16	242:19,20 243:2	334:20 366:16,22	alluded 340:11	326:5
197:9	243:16 244:6,9,12	378:4 383:19	396:3	analogous 160:7
advantage 222:13	251:14 266:18	396:17	Alphabetical 73:8	analysis 95:14
advantages 72:2	agenda 5:18 51:21	aid 185:20	alright 361:14	352:2
adverse 96:1	97:16,20 99:11	aids 83:5 104:14	alter 200:3	analyze 177:18
advice 112:2 194:4	222:4 235:20	147:19 148:4	alteration 185:2	analyzed 177:15
343:20 345:5	236:4,8 238:7,9	167:8,10	alternate 38:19	Anderson 3:15
346:10 351:9	378:2	air 108:13	alternative 40:6	19:19,19 20:16,21
353:13 378:15	agent 108:16	Albuquerque	44:8 72:10 116:12	22:7,20 27:8
380:18,19 381:12	153:17 186:1	135:17 317:22	120:11,16 125:8	28:16 29:8 30:4
382:13,17,21	247:17	318:8 334:14	146:21,22 183:6	31:16 33:11 34:8
383:14 389:19	agents 88:6 104:3	336:21 338:20	226:2 230:22	35:15 45:9,17

46:9 48:16 55:12	303:19 306:6	363:20 389:14	182:11 187:20	26:10 65:1 119:17
62:6 66:9 70:15	360:20 363:14	anymore 384:2	206:7 223:6	123:10
76:7 77:4,8,11	390:13 392:22	anyway 88:18	260:11 300:3	ARA 9:3 32:2
93:2 96:19 100:4	answered 68:14,15	91:18 367:18	306:18 333:5	137:11 263:21
105:10 116:3,4,6	68:16 162:16	AP 118:21 119:6,13	334:4 354:14	ARA/DHA 34:21
116:7 121:5,16	217:2 278:22	120:3,8,11,15,19	372:18 395:12	arbiter 322:1 323:5
122:5,10,12 123:1	360:19 389:9	apart 27:16	appreciative 99:4	329:4
123:5,10,20 124:6	answers 251:21	apologize 50:17	approach 44:7	archived 347:11
124:12 125:9,19	303:17 360:15	125:21 132:18,19	145:21 155:1	379:16
220:11 221:13	389:8	188:11 264:12	approaches 146:1	area 17:13 30:22
222:7 238:14,18	anticipate 5:7	272:11 317:2	appropriate 9:11	31:3 96:18 150:8
239:11,18 240:5	204:5	330:14 336:4	11:15 12:4 112:20	278:19 339:21
242:9,13 245:15	anticipated 339:18	361:5 364:15	136:4 143:15	351:14
246:1,14 247:15	antioxidant 6:16	369:1	155:19 172:3,8	areas 19:1 339:20
250:10 252:9	8:3,14 9:12,15,17	apology 105:3	173:7,21 213:5	354:4 363:10
253:5,20 256:17	10:10,14 22:15,17	appalled 102:7	226:2 279:12	argue 71:12 87:13
257:10 259:12	24:1 25:18 26:1,4	apparently 233:21	301:2 303:3,7	211:8
264:2 268:4 271:2	27:1,7,13 28:4,15	appear 40:3 52:9	384:13 386:3	argument 53:7,14
271:15	29:7 31:12 36:22	54:3 75:7,8,10	388:14	161:11
Anderson's 222:13	42:15 45:7 54:14	104:15 108:10	appropriateness	arguments 7:15
235:22	117:3,11,13,17	167:11 182:12	148:10 219:14	60:3
Andy 349:18	118:22 119:1,8,13	233:13 236:7	approval 9:4	arises 352:14
356:12	120:2,8,18 124:9	282:2 312:12	171:19 230:4	392:10
and/or 103:5 194:4	125:1 175:8	390:4 393:20	234:5,17 235:5	Armed 17:22
339:21	176:17,21 178:4	appeared 58:5	239:20 241:5,12	arose 136:21
angels 140:7	181:22 229:14	147:9	244:21	ARSENAULT
animal 69:10 74:8	231:1 247:8,12,18	appearing 101:20	approvals 24:15	2:12
95:2	247:21 248:6	appears 40:5 108:5	88:20 234:9	article 67:15 95:9
annotate 307:8	268:3,7	112:8 184:1	approve 172:16	articles 19:7
annotated 146:5	antioxidants 8:9	185:18,21 254:4,7	192:11 193:5,19	artificial 100:16
156:8	10:13 22:22 23:3	apples 292:9	194:18 200:14	ascorbic 27:10,15
annotation 80:9	23:5,7,8,10,15,16	applicable 370:20	241:3	27:19 29:1 271:15
147:7 172:16	25:2 29:17 30:3	application 153:14	approved 9:6 40:18	271:19,20
annotations 150:22	30:14 45:12	354:6	96:20 118:10	ascorbyl 6:9,14
155:18 165:22	117:20 124:13	Applied 19:22	119:7,8 131:20	7:21 9:6,10 10:3,5
annoyed 140:16	125:2 268:5	apply 165:8 177:6	163:11 164:9	10:6,18 11:6,8
annual 210:12	anti-infective	178:11 339:1	199:5 204:17	13:8 15:6 22:4
answer 17:1 31:6	128:19	applying 89:7	263:20 264:5	25:14 27:12,13
45:18 77:5,6	anti-inflammation	appointed 323:19	270:1,17 271:12	28:22 29:4 31:13
86:21 93:1,21	188:22	324:4 326:4,6,7	277:22 278:8	32:6 34:5,19 54:6
124:1 125:11	anti-inflammatory	352:7	331:12	107:20 117:16
130:10 137:3,20	175:9 176:21	appointment 18:12	approves 242:20	118:21 119:22
149:22 196:5	181:22	259:15	242:21	120:6,17 121:13
203:16 204:21	anybody 10:16	appreciate 17:5	Approving 109:15	125:9,13 199:4,13
207:18 211:21	241:18 258:3	98:5 108:1 115:13	approximate	202:1 203:20
216:19 217:4	264:12 276:18	115:19 133:4	215:13	204:17,20 205:9
234:18 264:5	302:16 309:8	135:8 152:4 170:2	approximately	224:3 233:12

261:9,12,16 262:3 262:8 263:18 264:15 265:3 267:5 268:1 271:10,16 Ashby 135:9 139:13,14,14 143:18,20 144:4 169:14 Ashby's 169:10,11 asked 5:21 72:20 124:6 196:17 217:2 222:16 264:2 266:10 279:1,9 330:6 337:18 365:21 asking 42:2 47:6 93:18 201:3 202:3 204:2 217:22 303:1,2 304:2,5 329:16 363:12 aspect 92:17 142:8 381:18 aspects 20:12 122:9 343:14 347:21 asphyxiant 108:15 assessment 155:9 162:18 163:1,2,6 164:13 165:1 166:1 170:7 245:7 245:8 assist 74:16 322:5 343:11 assistance 301:9 associate 2:20 19:15 223:2 350:5 associated 89:4 214:20 227:2 301:3 association 88:11 151:19 223:4 331:16 350:7 associations 191:6 327:13 assume 4:11 255:1 370:7 384:4 assumed 189:14	assuming 259:11 259:13 assumption 68:7 109:12 assurances 240:20 assure 91:22 259:3 assured 49:18 assures 102:17 as-needed 227:15 attachment 91:1 attack 370:14,20 373:8 attacks 337:4 attempt 8:18 337:8 375:1 attend 360:16 attended 339:19 attending 106:3 attention 48:5 92:1 94:14 98:22 130:9 204:4 370:18 attorney 101:8 196:15 320:9 attribute 147:20 Auburn 20:19 audience 7:11 12:2 21:11 24:13 265:8 302:16 304:9,19 August 6:11 103:13 Augusta 18:4 AUSTIN 1:15 36:18 45:21 115:5 133:15 134:5 162:15 179:19 187:8,12 206:14 207:9,13 263:2 268:21 272:22 274:11 275:4 276:4 277:6,18 282:9 283:22 284:21 285:11 287:2 288:12 291:8 292:5 295:19 311:8 313:5 314:17 355:9 376:14 393:19 397:14	author 19:7 authoritative 55:15 250:19 authority 155:22 200:4 241:5,12 386:19 388:4 392:11 393:11 authorized 167:9 393:12 authors 95:16 auxiliary 81:17 availability 89:6,8 125:16 303:8 337:15 375:9 available 5:1 6:20 14:8,17 17:13,16 20:22 36:8 38:19 46:19 52:18,21 56:17,20 59:8 65:9 67:4 73:20 74:13 78:17 99:7 108:10 116:12 127:2 193:22 202:9,10 211:2,11 233:2 244:6 245:20,20 246:20 257:14 358:13 avenue 35:3 383:3 386:1 avocados 57:8 avoid 102:3 aware 55:8 100:19 102:4 133:16 171:20 203:10 233:18,20 247:14 247:16,17 252:5 265:17 391:2,18 awareness 300:13 Aykan 190:18 196:11,13,14 200:17 201:2,8,13 204:8,13,16 205:21 206:19 207:10,18 a.m 1:10 4:2 98:17 98:18	<hr/> B <hr/> B 74:7 87:21 88:1 89:17 156:14 170:18 babies 27:4 63:21 198:14,18 211:21 211:22 297:16 baby 25:5 75:2 212:5 Bachelor 20:16 back 4:14,14,18 13:2 16:2 24:16 31:10 47:14 48:10 70:22 72:16,16 98:8,11 113:4,5 140:2 148:19 149:16 151:7 155:10 163:8 180:9,14 185:9 211:19 218:14 222:2,11,12 236:2 236:5,7,22 237:3 238:4,6 247:4 252:13 254:16,18 260:17 275:8,9,15 296:6 301:11 302:5 307:22 315:5 316:4 323:13,20 324:6,9 324:12,16 325:15 326:10,17 328:11 328:17,20 330:18 331:7,8,19 332:6 355:13 371:13 373:1 374:3 386:15 389:2 background 12:3 166:10 317:10 350:8 backgrounds 325:17 bacteria 33:18 bacterial 33:6,17 bad 253:16 341:1 354:9 bad-mouth 370:13 BAILEY 2:14	265:16 balance 325:18 balanced 141:21 balances 359:15 barely 140:6 Barry 1:12,14 4:10 98:7 106:2,5 238:15,19 260:16 280:7 316:22 341:2,6 377:6,18 Barry's 106:4 base 164:5 243:19 301:6 382:16 based 16:20 43:12 43:12 53:8 59:3 64:14 68:6 95:9 107:3 108:18 117:13 172:10 179:19 186:13 191:2,2 193:7 195:12 216:8 229:6 258:21 266:17 275:13,14 299:1 300:1 322:19 345:2 346:6 362:10 378:12 382:18 383:3 basic 309:20 basically 7:14 95:17 156:13 167:8 217:5 366:15 373:22 basing 382:20 basis 39:12 41:6 49:18 149:17 151:7 166:12 227:4,15 248:4 251:19 bath 212:5 beans 37:6 57:8 bear 327:14 352:8 beat 141:10 beating 140:12 BECK 1:15 263:4 269:1 273:2 274:13 277:8
--	---	--	--	---

282:11 284:2	216:10 227:6	26:5 32:22 33:2	181:13,14,15,21	390:22 391:1,2,10
285:13 287:4	benefits 45:8 50:20	46:20 50:19 51:2	324:14 330:2,14	392:8,14 393:22
288:14 295:7	54:15 106:19	62:20 64:16 66:15	blush 354:22	394:9,12,13 395:3
310:18 313:7	197:18 224:17	67:15 69:5 71:6	board 1:5,10 2:12	Board's 17:11
314:19 376:16	227:2 228:5	76:18 94:15,20	4:5 5:21 12:11,15	182:14 184:19
397:16	benzoate 102:2	96:8 124:7 138:20	13:9 17:7,14 21:2	185:16 326:11
beef 74:9	Berkeley 208:17	232:18 241:13,15	22:14 24:6 34:19	bodies 42:19 71:10
beeping 366:3	best 22:2 67:12	254:4,8 255:14	41:9 47:19 55:3	bodily 130:7
began 193:2	87:10 116:11,11	258:6 259:22	67:18 75:22 96:20	body 37:16 48:7,9
beginning 132:20	170:18,22 180:3	260:10 278:22	97:5 99:3,9 105:2	48:11 55:7,15
268:11 272:9	190:22 194:12	Bhatia's 19:1	113:15,20 121:6	57:6 68:14 79:1
274:4 282:4 285:8	198:13 209:2	biannual 330:5	135:16 151:21	130:16 174:21
286:21 288:11	211:22 212:21	bias 142:5	153:6 156:2	175:21 220:13
310:16 312:15	216:13 256:1,9	biased 12:13	178:19 182:12	250:19 255:16
314:6 319:5 330:5	281:21 361:4	bible 326:12,12	193:4,18 194:17	256:14 271:17
336:14 397:5	bet 141:8 181:8	big 11:19 93:15,16	198:21 200:14	356:4 382:4
begins 376:3	beta 12:19,21 13:12	141:13 158:8	201:11 209:8	bogged 97:3
behalf 264:11	13:16,19 14:1,3	367:11 387:14	228:10 238:16	bold 200:19 201:6
355:4	14:10,16 15:5,11	biggest 93:5	239:16 252:11	bolts 156:12
belied 352:4	15:18 16:10 22:5	billion 359:17	254:3,17 259:20	BONDERA 1:16
belief 110:1	25:13,16 28:3,3,6	Biltmore 1:10	260:5 263:20	132:17 133:12
believe 4:17 7:7	28:14 31:12 32:6	binding 175:15,17	280:1 300:20	262:17 268:13
30:8 34:20 67:18	34:5,20 36:21	180:20	301:5 302:5 303:1	269:16 272:11,15
94:17 138:20	54:6 55:20 107:19	bioacid 127:8	306:21 315:10	274:18 277:13
154:22 155:21	116:22 117:1,3,6	biological 175:12	319:20,20 320:3	282:16 283:10
160:1 162:8	117:7,8,12,17,20	175:14 180:22	321:13,13,15,20	284:7 285:18
170:22 171:6	118:1,2,9,14	biology 20:8	323:3,18 324:10	287:9 288:3,19
183:15 189:15	120:5 121:12	175:16	325:18 329:2,16	293:6,9,15 295:12
206:13 222:7	124:7 177:9 202:2	biomedical 18:13	330:7,19 331:9	298:2,5 299:3,12
225:7 230:6,11	233:12 267:6	birth 77:2 126:14	332:2,9 337:20	311:1 312:3,20
233:1,6 260:19	269:12,14,18,22	birthplace 143:17	343:1,5 344:13	314:10 315:17
261:9 264:8	269:22 271:4	bit 34:17 84:17,18	345:4,8,12,16,18	333:4 349:12
268:10 274:3	273:9,10,12,18	108:4 154:4 165:4	345:20 346:9,13	354:16 355:7
281:10 286:4,19	274:21	183:10 187:10	347:4,5 351:4,5	356:6,9,12,15
289:12 302:6	Bethesda 20:8	188:6 217:13	351:16 352:1,5,16	360:21 361:2
310:12 311:17	betrayal 102:12	220:11 230:6	353:6,11,13	362:3,8 365:2,6
312:15 313:9	better 44:7 81:8	338:4 356:1 396:4	355:15 357:4,14	367:7 368:21
315:3 320:8 381:7	142:11 173:6	bitartrate 137:13	357:19 358:6	369:21 372:9
392:6 396:18	177:4 178:4	bleak 140:2	359:2 360:5,7,16	374:6,13 375:13
believed 197:3	278:15 332:14	Bleu 350:14	360:22 366:8,13	376:7 377:1 395:7
believes 344:17	366:10 371:6	blinded 176:6	372:5 373:2	397:7
346:17 357:10	Beverly 100:3,9	blindness 26:7	375:20 377:21	bones 181:20
378:22	beyond 93:4	block 11:19	378:14,18 379:9	book 19:8
belong 110:7	141:18 146:18	blood 177:3 192:16	379:10 380:3	books 19:8 140:5
beneficial 44:14	236:3	214:15 215:4	386:8,9 387:4	borrowed 83:10
170:10	Bhatia 3:15 17:19	blow 109:16 111:9	388:9,19 389:16	boss 360:6
benefit 70:12 183:5	17:21 18:15 24:10	blue 37:12 175:9	389:17 390:11,18	botanical 183:17

184:3	brief 126:9 263:16	burden 221:16	333:16 334:2	15:11,18 16:10
bottle 241:19	briefly 7:12 128:14	278:17	350:20 397:5	22:5 25:14,16
bottleneck 165:17	184:13 186:9	burdens 44:4	Canada 66:16	28:3,4,6,14 31:12
171:9	304:16 316:2	burned 129:12	118:13 119:11	32:6 34:5,20
bottom 380:12	bright 214:17	burning 92:11	200:11 202:12	36:21 54:7 55:21
bovine 134:4	Brines 2:16 4:19	business 39:4 92:17	203:18 204:9,19	107:19 116:22
Boy 7:10	6:8 11:21 13:15	93:4 94:2 205:5	206:17,20 207:4,8	117:1,3,6,8,9,12
brain 176:5 177:3,4	17:10 35:19 52:2	228:14 305:18	207:15	117:17,21 118:1,3
177:7,9,11,15,18	56:6 58:18 73:1,6	343:4 357:2	Canadian 54:1	118:5,9,14 120:5
177:21 178:11	73:9 78:2 290:3	buy 104:20 198:14	203:21 205:7	121:12 124:7
214:19 215:17,20	291:21 310:7	298:13 299:2,11	206:21	177:9 202:2
215:22	bring 47:7 70:22	buying 239:4 299:5	capability 8:10	233:12 267:7
brains 177:19	86:19 94:10 113:4	buys 231:19	388:17 389:1,10	269:12,14,19,22
Branch 18:9	113:5 115:18	byproducts 121:18	capable 131:4	269:22 271:5
brand 154:2	129:21 181:2	by-case 155:1	captures 84:7	273:9,10,12,18
182:17	344:16 350:13		carbohydrates	274:21
brands 40:4 143:9	352:7 386:17	C	217:11	carotenoid 36:21
bread 23:2	392:8	C 9:7 25:15 27:9,11	carbs 305:14	175:1 177:8 180:6
break 5:5 21:18	bringing 162:6	27:14,18,20 28:22	carcinogens 103:5	214:3
92:9 98:11 99:3	303:18	29:6 84:3 88:2,4	cardiomyopathy	carotenoids 174:15
222:5 236:15	brings 133:3	93:5 119:7,14	192:17	174:18 175:3
237:3 259:16	227:17 352:5	146:14 148:7	care 136:5,9 138:18	177:11,17 214:4
311:13 315:5	Britt 151:12 169:16	156:14 171:6	194:5 322:3	214:14,22 215:11
361:10	169:20	204:18 267:6,10	careful 141:21	carotenoid-suppl...
breaks 235:19	Britt's 169:9	270:11 271:11,17	152:12	216:6
359:13	broad 22:21 82:11	271:21 272:1	carefully 102:3,19	carrageenan
breast 37:18,19	308:21 328:15	317:1 318:21	145:5 189:3	357:21 360:4
38:5 42:15 44:6	370:19 373:8	cadence 366:5	caregiver 109:10	carried 153:20
51:5 71:4,9,16,18	broader 69:2	California 139:15	110:10	157:20
72:9,11,11,12	278:10	208:18	cares 141:13	carrier 159:11,12
116:10,13 117:8	broadly 370:19	call 12:15 43:15	Carmela 1:15	carriers 156:2
124:22 126:16	broccoli 37:5	81:20 97:22	310:17	carrots 14:4
127:1 128:21	broken 163:18	125:17 134:15	carnauba 90:6	CAS 40:19 262:9
134:10 178:12	360:9	167:17 281:8	carnitine 57:5,12	264:15 265:3
185:19 186:21,22	Brook 100:4	319:12 320:4	57:13,14,18 58:2	276:5,13 277:19
190:21 191:1	105:10 116:3,4,6	327:2 361:10	58:6,15 62:1,12	278:6 284:16
192:13 193:9,15	brought 115:21	370:18 376:2	63:18,21,22 72:17	285:1 286:10,15
194:2,10 208:13	144:17 204:3	383:20 395:6	126:12 129:7,8,13	287:20 288:5
211:3 212:20	319:11 373:1	called 140:8 178:6	130:2,3,13 131:3	312:1,7 313:13,18
215:1,2 224:4,14	BROWN-ROSEN	335:13,14	131:5,8 133:20,22	case 9:3 16:12
224:19,20,22	2:18	calling 12:16	191:12 192:15,17	55:17 95:4 154:22
225:8,17 226:4,21	bugaboo 382:14	150:21	192:21 195:16	165:9 172:21
227:2 228:5	build 143:9 328:10	calories 63:9	200:8 202:22	173:9 189:17
232:11	367:20	194:11	286:3,5,6	195:15 202:7
Breastfeeding 71:8	bulk 186:11	Calvin 1:22 109:20	carotene 12:19,21	264:11 299:15
breast-fed 127:16	bump 92:16	124:4 125:4 134:7	13:12,16,20 14:1	300:2 303:5 308:2
215:4	bumping 93:3	228:10 268:11	14:3,11,16 15:6	323:2 363:8,16

364:17 370:21	163:8 165:9	276:16 277:15	141:4	chicken 74:9
cases 87:18,19	191:22 281:1	278:1,5 280:5	chance 96:12	chief 18:3,18
147:8 171:17,20	305:22 306:3,15	281:7,15,18 282:1	199:14 228:12	child 134:17 136:4
391:14,15	308:11	282:19 283:2,11	236:20 355:10	136:8 138:13,22
case-by-case 166:1	certifier 191:22	283:15 284:11,19	change 49:11 80:3	194:15
166:12	306:14	284:22 285:6	80:9,18 81:2,3	children 132:3
catch 253:4 259:14	certifiers 145:22	286:1,6,12,14,19	91:11,16 159:19	135:21 136:1,16
categories 15:5	152:16 153:22	287:15 288:1,4,9	220:16 251:1,3	255:10
242:16	158:20	289:3,6,11,18,21	275:21 322:10,18	child's 137:16
category 39:2	certify 100:13	290:9,12,22 291:6	325:1 326:12	China 118:12
142:12 231:3	certifying 172:22	291:9,19 292:6,12	358:4 365:9 367:3	202:12 203:18
233:3 242:15	173:7 174:1	292:16,19 293:8	369:4,16 370:8,17	Chinese 204:1
caught 48:5	cetera 150:19	293:13,17 294:2,9	374:8 384:12	chisel 321:5
cause 199:3,16	151:1 158:5	294:14,18 295:3	changed 47:9	choice 41:10 44:9
280:18,19	164:18,18 386:17	295:20 296:16	136:15 221:20	65:9 66:2 70:19
causes 143:8	CFR 46:3 117:5	297:2,22 298:4	321:3 322:17,18	103:11 127:3
177:16	139:18	299:16 301:10	324:12 384:6	160:20 162:6
cautioned 141:21	chain 388:14	302:2 303:14	changes 81:15	190:22 194:13
caveat 161:3,12	chair 4:7 11:16	304:15,21 306:6	99:21 259:18	225:4 298:8
CBI 94:1 184:9	12:8,10 17:19	306:17 307:1,4	332:7,8 333:20	choices 65:11
CDC 108:14	263:7 269:5 273:7	308:3,17 309:8	350:17,20 351:2	choline 137:6,13,16
Celestial 190:20	274:19 277:15	310:3,9 311:10,17	354:4 362:17	choose 66:3 72:11
208:10	282:19 284:11	312:5,12 313:8,16	374:5,11 375:12	116:13 203:8
cell 129:9	286:1 287:15	313:22 314:4	375:12,21	226:4
cells 180:10 181:16	289:3,6 293:7	315:1,10 361:17	changing 80:2	chooses 127:1
Center 19:21 132:4	295:20 301:1	361:22 362:4	169:9 221:16	224:21
centered 319:14	303:1,2,2 311:10	365:4,7,19 366:12	chapter 200:3	choosing 40:9
centers 214:19	313:8 315:1,18	368:4,19 371:9	chapters 19:8	chop 69:9 94:21
centralized 148:21	319:15 330:6	372:6,20 374:1,11	character 337:5	chore 220:21
CEO 360:1	335:22 337:15	375:11,15,20	370:21	chose 187:19
certain 151:4	341:2 361:15	376:2,19 377:10	characteristic 23:9	chosen 38:15 213:1
172:18 180:10	362:1,9 372:10	377:19 378:3	23:9 183:20	271:1 341:11
200:6 207:6	375:8 376:19	379:19,22 380:8	characteristics 8:1	351:13
214:16 218:9	394:22 397:20	381:5,22 383:19	charged 301:7	chuckle 137:5
234:8 248:4 367:2	Chairman 4:3 12:7	384:15 385:5	Charlotte 100:3	circle 47:14 72:16
367:2 370:10	98:10 151:15	387:20 389:11	105:10,13 111:15	circulated 350:18
certainly 75:11	236:11,18 237:2	390:1 392:17	112:21 115:5	circulation 181:2
87:12 131:1 139:4	238:20 260:18	393:18 394:21	cheat 150:16	circumstance
143:15 164:21	261:18,22 262:4,7	396:21 397:20	check 11:18 205:8	115:13
210:17 219:7	262:12 263:7,13	Chairperson 1:12	348:15	circumstances
221:13,17 247:19	264:21 265:1	1:14	checking 53:22	23:20 151:1
383:5	266:22 267:15,20	chairs 32:21	checks 359:15	339:15 340:8
certainty 170:15	268:8,19 269:5,17	challenge 152:18	chemical 23:13	citation 267:17
certification 68:5,8	270:5,19 271:6	199:1 220:5	108:15,15 109:5,6	citations 8:17
68:8 101:1	272:4,7,14 273:7	278:18 370:20	120:14 185:2	cited 130:15
certified 157:5	273:14,17,22	challenging 370:12	275:20	citizen 100:13
158:13 160:2	274:19 276:2,7,11	chamber 139:20,22	chemicals 184:18	357:9

citric 306:1,4	292:20 294:12,20	337:14 375:8	college 17:22 18:4	comma 374:16,16
claim 8:21 239:6	295:22 312:8,14	closer 128:21	18:16,21 91:10	375:2,4,6
258:21	313:10	closing 337:10	colonization 33:17	command 388:14
claimed 106:19	clause 89:6 298:9	375:4	colony-forming	commas 368:12
claiming 51:8	clean 357:5	cluster 15:5	33:6	commencing
claims 48:5 50:5	cleaned 89:20	coatings 147:16	color 14:4,11 52:12	358:21
51:7 107:3 358:22	cleaners 164:20	Cockram 208:7	159:15 351:1	comment 5:4 6:21
clarification 15:15	cleaning 88:6	212:10,12,13	colored 322:17	7:1,4 14:19,21
45:2,4 46:2 60:12	385:10	216:15,18 217:1,5	coloring 258:13	24:3 25:16 36:10
61:13 67:17 76:6	clear 9:8 10:11	218:4,7,18 219:1	colors 159:13 214:2	36:11,13 41:14
108:2 195:19	16:8 47:22 79:5	220:9 222:19	colostrum 215:2	46:1 52:19,22
235:19 263:16	84:21 85:17 89:15	Code 43:17 101:16	columns 89:2	56:19,21 59:9
267:2 270:18	101:17 102:11	Codex 20:4 118:12	combination 30:12	64:7 73:21 77:9
271:8 272:3 275:5	111:6 114:2	119:10	117:14 146:14	78:18 81:4 82:15
290:3 308:18	131:17 148:9	codified 197:2	225:17 317:15	83:13 99:11
310:2,5,8 316:10	152:12 169:1,1	266:5	combinations	104:22 169:2,20
343:20 345:6	170:12 188:5	codify 89:2	120:3 124:17	186:17 220:18
346:10 378:16	235:20 265:9	coffee 292:3 294:7	combined 191:4	221:13 235:16
380:5 382:18	276:19,20 290:7	cognition 176:9	290:5	281:19 290:15
clarified 268:4	291:13 293:18	cognitive 128:12	come 17:7,14 22:6	304:3 308:4 317:8
clarify 5:19 22:13	298:6 341:12	176:14 177:5	24:15 53:9 54:18	318:5 320:16,16
27:9 28:10,22	354:10 371:16	cohesion 280:2	70:3 71:10 128:7	322:6 333:12
206:17 308:7	383:6,9 393:4	COI 93:18 94:1,2	151:5 153:17	334:17,22 335:1,5
309:6	cleared 295:4	317:8 350:18	158:11,18 199:9	335:16,18 336:11
clarifying 77:18	303:16	351:8 353:19	202:5 204:22	336:14,17,19
187:21 235:10	clearer 394:17	354:6	218:14 222:2	337:3,9 338:21
clarity 16:3 17:1	clearing 187:9	Colehour 1:16	243:16 249:2	339:5 344:9 347:4
115:20 384:18	clearly 85:2 90:21	132:16 272:9,10	255:8 280:18	347:20 350:4,22
class 23:3 172:9,17	96:18 110:5	297:22 298:4	304:22 320:8	353:18 354:19
classes 163:18	212:20 259:12	315:15 319:2,15	331:10 332:21	359:2 360:13
classic 256:2	337:18 360:9	332:8 342:19	371:13 388:18	362:13 364:4
classical 76:19	366:20 367:4	349:11 362:4	389:2	366:8 369:3
classification 40:14	371:19 382:3,11	365:7,16,17	comes 16:13 160:5	374:15,15 375:2
40:14 48:12 60:20	394:7	368:19 371:9	176:2,7 179:12	379:9 381:22
80:2 81:3 83:2	cleaved 27:16	372:7 374:1,2	180:4 209:4 241:6	383:20 386:18
97:4,6 184:22	clinical 63:19 96:6	375:12 376:21	249:8 265:12	387:21
261:21 272:12	176:12 197:21	377:6 394:21	333:14 391:10	commentary 339:4
290:5,7 311:22	219:14 230:1	396:16	comfortable 35:9	commented 46:3
classified 45:5 74:7	246:18	colic 69:19 112:7	35:13 148:18	110:6
187:15 283:8,12	clinically 26:5 69:6	112:10	188:3 366:2	commenter 139:7
classify 39:10	95:15	collaborator	coming 4:14 7:16	194:21 216:13
188:4 262:8 263:9	clock 92:8	332:18	7:20 80:9 81:2	230:7
269:14,18 273:9	close 92:1 137:18	colleague 150:9	88:18 99:19 130:6	commenters 3:17
275:20 276:12	140:18 226:20	colleagues 204:21	151:11 169:9	16:8 81:8 87:4,9
284:13 286:15	closed 358:15	233:14	180:12 181:13	87:21 89:10 91:19
290:20 291:4,14	closely 49:5 170:3	collected 155:14	187:8,20 238:4	145:14 191:15
291:14 292:12,13	220:4 335:22	collective 214:4	343:7 374:3	205:19 219:19

239:19 266:11 321:7 351:22 353:4 commenting 224:8 350:15 385:16 comments 7:13,19 10:17 15:5,7 16:21 40:22 41:15 41:17,19,22 43:10 45:22 54:5 60:4 75:20 79:10 82:12 82:17 83:11 98:14 100:6 110:4 121:8 136:6 137:19 144:15,18 145:3 146:9,17 152:7,9 155:3 182:20 191:11 195:2,3 223:20 224:10 230:7 232:18,20 234:2 260:11 263:12 266:8,17 266:20,20 270:6 282:3 306:12 321:6 327:12 334:1 335:8 338:2 338:5 340:13 347:16,17 348:15 349:7 355:8 366:13 372:12,13 372:19,22 385:3 388:2 390:21 391:19 397:2 commercial 89:6,8 123:22 125:15 179:16 commercially 43:4 58:8 74:12 108:10 121:2 123:17 199:6 Commission 119:11 committed 94:3 committee 8:18 10:18 11:11 17:20 20:11 38:12 40:13 46:20 54:19 67:18	70:11 71:6 75:14 79:11,21 80:10,17 82:7 89:12 93:22 97:2 125:13 138:21 222:2 236:6 260:20 261:1 264:11 275:8 306:21 321:1 322:13 325:10 330:7 331:9 344:2,6 350:10 353:14 362:5 389:17 committees 20:4 committee's 106:12 170:7 common 63:1,10 174:22 179:1 commonly 117:8 154:11 communicate 246:3 339:6 345:10 381:16 384:19 385:19 390:18 communicated 152:15 communication 342:11 344:20 345:21 346:15 347:2,3 348:20 349:4,5 378:10,20 379:7,8 380:2,21 380:22 382:19 387:4 388:3 390:10 391:21 392:16 393:15 394:1,10 communications 317:9 318:9 342:21 344:8,10 345:3 346:5,7 347:22 362:14 377:8 378:12 384:21 387:8 388:17 community 18:11	54:8 83:8 86:18 94:18 106:6 110:22 243:22 250:14 270:14 278:19 279:11 300:6 321:2 323:16 324:2 326:4 332:3 343:6 344:1,13 345:11 345:17,18 348:6 359:4 391:3 community's 348:2 community-based 331:16 company 170:1 190:10,21 191:2 195:13 218:15,20 241:6 245:9 compared 44:8 65:12 147:18 198:16 compelling 180:16 competitive 198:16 compile 91:2 compiled 82:21 complaint 290:15 complementary 134:15 complete 85:22 126:19 129:22 135:6 172:20 173:12 198:7 225:9,21 226:6 232:4 completed 18:2 103:12 completely 65:13 120:14 completes 315:4 complex 121:17 124:14,16 complexity 333:6 compliance 161:13 167:15 253:8,16 253:17 266:12,19 266:21 complicated 23:13	82:3 91:21 98:2 251:1 299:18 318:15 complications 187:9 complies 84:7 162:10 213:2 complimentary 215:10 comply 148:4 162:5 complying 240:13 component 127:8 132:14 135:2 153:8 154:16 155:12 197:17 components 24:20 43:8 94:22 101:6 102:5 126:11 127:5 134:16 218:17 composition 213:3 226:22 228:4 246:16 compositional 213:7 compound 24:17 57:5 242:18 244:8 compounded 156:4 compounds 22:11 22:22 23:4 25:9 79:1 214:6 280:22 comprehensible 337:21 comprised 147:12 comprises 37:10 concentrate 67:20 69:3 136:17 150:4 216:21 217:12,15 218:5 concentrated 175:21 181:12 214:16 215:22 301:19 302:7 concentrating 77:12,14 concentration	217:6,10 concentrations 127:11,12 175:19 217:14 concept 94:9 340:17 371:20 concern 66:5 69:21 70:6 88:12 89:5 202:15 355:18 356:1 385:13 387:1 concerned 16:9 46:21 88:10 94:18 96:3 100:11 122:11 134:21 230:13 357:13 concerning 26:2 343:22 386:20 387:18 concerns 44:2 50:22 61:9 69:18 77:1 87:22 88:7 96:3 301:22 337:22 350:21 351:1 385:8 395:3 conclude 227:5 concluded 103:17 concludes 235:16 conclusion 70:3 128:8 129:21 156:10,11 159:22 160:13,14 186:5 conclusions 126:13 conclusory 298:8 concur 77:3 condenses 209:11 conditions 23:11 132:2 212:19 269:21 384:14 conduct 4:8 162:17 163:6 165:1 171:14 conducted 163:15 conducting 226:13 conference 81:20 confidential 39:4 41:9 92:16 93:3
--	--	---	--	---

94:2 187:15 244:7 305:18 confidentiality 93:13 156:22 157:2 158:6 confirm 25:12 258:17 confirmed 206:22 confirms 103:15 conflict 317:7,20 318:17,22 319:3,9 319:11,14 321:14 321:21 322:22 325:8 326:20 327:10,20 328:1 329:18 330:9,9 331:2 334:5 351:21 352:3,13 352:22 354:12 355:12,22 357:10 358:1,9,20 359:5 359:14,19 360:5,8 362:15 363:18 conflicting 74:20 conflicts 352:15,20 353:2 357:15 358:3,14 359:9 conform 206:4 confounding 26:16 confused 270:8 confusing 315:20 confusion 111:5 145:19 293:21 Congress 47:8 241:4,11 351:18 Congressional 47:3 conjunction 329:22 connect 373:18 connection 53:16 connotations 370:12 cons 87:7 145:1 consensus 320:8,11 320:12 328:10 344:1 372:3 consequence 253:13	consequences 132:8 198:22 consider 43:6,11 56:2 112:2 136:18 148:6 244:6 393:14 considerable 87:18 consideration 29:6 50:1,2,4,4 85:5 228:7 336:19 considered 39:6,6 55:22 81:1 85:21 96:14 112:14,18 120:16 121:19 154:20 156:2 183:7 184:11 196:21 199:19 211:11 219:20 234:1,14 235:3 240:15 255:12 300:17 337:13 375:7 considering 22:11 89:14 115:2 145:5 268:2 361:5 364:2 372:16 consistent 44:16 145:20 146:3 155:20 162:3 170:12 186:6 187:2 consistently 153:20 consolidated 186:4 constantly 226:14 constituencies 351:12 constituency 351:19 352:10 constituency's 352:21 constituents 159:8 159:15 constitute 360:8 constitutes 104:8 constraints 389:21 construction 44:1 constructive	343:20 345:5 346:9 378:15 380:18 381:12 382:17 391:22 consult 50:7 248:12 consulting 10:1 249:13 consume 154:12 consumer 7:17 54:7 60:5 84:8 100:11 103:16 104:12 109:17 111:5,10 160:19 160:20 consumers 60:6 68:6 76:2 102:13 103:7 104:19 110:1,4 114:18 198:12 210:9 232:15,22 233:2 359:11 consumer's 157:10 consuming 100:17 121:15 215:9 consumption 102:21 120:21 contact 360:3 contain 42:18 53:11 57:11 85:18 86:1 103:3 136:17 167:19 168:14 214:14 contained 152:20 271:10 contains 110:13 111:11 114:19 119:16,17 178:12 191:16 201:18 contaminated 240:15 contemporary 213:15 content 59:18 63:8 118:17,19 214:3 215:3 316:12 context 48:4 238:22 239:8	252:22 396:6 contexts 68:1 contextual 224:10 continue 98:13 134:9 136:22 155:22 266:4 311:13 384:9 396:11,19 continued 223:21 continuing 369:5 396:13 continuously 226:12 371:4 continuum 209:15 contract 192:20 contractors 358:19 contracts 358:7 contradicting 367:22 contrary 348:4 control 358:1 controlled 355:14 convened 1:10 255:16 convenience 149:9 conventional 44:12 75:3 107:1 110:14 160:3,6,8 161:8 232:5 255:3 298:22 300:8 304:14 305:11 conversation 264:1 conversations 12:18 16:21 59:22 99:2 convince 221:9 convinced 79:10 Cool 206:11 Coop 356:21 cooperation 90:10 cooperative 103:15 copies 335:10 copy 144:2 377:14 377:16 Cordon 350:14 corner 280:17 Cornucopia 100:9	100:21 105:14 146:17 322:19 357:8,9 corporate 324:22 325:3,5,11 359:9 corporation 359:18 correct 28:16 29:8 46:6 96:13 113:18 191:13 195:8 197:6 218:18 261:22 264:8,13 272:13 356:19 385:15,16,21 386:6 corrected 104:10 349:20 373:1 Correction 297:4 correctly 90:18 270:10 cortex 215:20 cost 33:13 Council 6:12 13:18 52:5 56:9 58:21 73:12 76:3 78:5 223:3 counsel 343:2 350:9 count 311:11 counted 99:13 counter 66:18 counterparts 160:3 counterpoint 161:8 countries 112:4 country 103:15 counts 33:6 couple 41:3 61:18 164:10 228:18 239:7 315:21 354:4 388:1 couples 129:8 course 89:17 110:21 137:3 143:17 202:13 281:17 344:14 court 167:6,16 courtesy 12:2 cover 131:9 383:18
---	---	---	--	---

387:7 covered 26:11 101:18 382:10 cow 38:2 64:14 66:4 cow's 42:17 57:13 127:13 134:1 co-chair 151:22 create 130:20 161:5,7 171:8 184:16 created 29:18 63:3 225:5 creates 249:12 creating 171:4 351:5 cred 350:14 crib 150:15 criminal 253:10 criteria 47:20 84:19 85:7 111:2 153:4 161:17 162:1,1 302:12 367:2 critical 43:12 119:21 125:12 134:18 154:10 186:15 225:14 341:20 346:16 348:3 378:21 criticized 107:13 110:21 crop 96:22,22 158:9 Crops 97:2 cross 280:1 crossed 362:20 crucial 209:3 crux 152:17 crystalline 185:5 283:8 284:16 285:1 crystallization 80:19,22 Culinary 350:15 cultural 38:1 225:3 culture 168:3	cultures 153:10 168:1 cumbersome 220:16 cumbersomeness 251:15 cup 292:3 curiosity 122:16 150:14 curious 139:17 current 17:19 26:11 28:17 51:17 103:10 131:7 207:15 209:2 221:2 321:11 357:12 384:6,13 currently 26:19 39:14 65:16 108:9 118:6 120:12 126:3 133:17 145:13 195:22 228:22 231:9 266:5 358:12 customer 190:10 customers 103:13 103:18 104:2 298:15 cut 155:2 156:10 328:16 CVI 39:22 cyanide 108:14 cytosol 129:9 C.F.R 38:6 46:10 57:19 186:4 197:2 <hr/> D <hr/> D 3:8 84:3 88:4 93:5 146:16,21 148:8 153:15,16 157:13,13,16,17 157:20 158:4 daily 145:21 154:12 198:2 dairies 205:4 dairy 153:9 168:1,2 damage 42:16 181:16,19	damaging 181:17 181:20 dark 213:22 214:2 darned 220:7 data 42:6 47:1 67:1 70:1 96:6,6 128:10 177:4 216:5 227:3 244:7 245:17 246:11 database 88:9,11 88:14,19 148:21 149:14 150:17 151:4 166:9 date 207:21 258:2 337:10 375:4 David 208:6 212:10 212:12 218:14 day 160:21 207:20 241:9 254:16 361:13 days 12:19 104:18 135:2 241:7 249:6 249:7 252:16 266:9 331:1 386:7 de 275:18 deal 141:13 165:18 327:4 336:8 363:4 367:11 387:14 dealing 53:2 165:2 238:7 307:22 deals 142:22 dealt 166:12 340:6 death 292:14 debated 220:11 307:14 Debbie 182:8 Deborah 174:11 182:5 decades 72:14 91:15 193:18 227:10 decay 259:6 December 266:9 329:13 decide 146:10 331:2 389:9 decided 12:7 38:12	97:5 170:3 320:6 324:20 325:10 327:4,21 328:11 329:12 331:10 360:4 362:11 394:12 deciding 220:5 275:10 deciliter 63:8 decipher 167:2 decision 43:15 46:17 107:22 111:16 114:3 115:1 188:19 242:22 275:12 280:9 319:8 356:2 356:5 372:14 394:9 decisions 91:3 115:9,18 223:11 257:12 355:14 362:6 383:3 decision-maker 353:22 decision-making 345:19 351:6 deck 105:11 116:4 125:22 135:9 declaration 319:19 declare 54:19 declared 358:3 decline 16:18 declined 16:4 decrease 127:19 142:6 335:9 decreased 178:14 decreases 215:3 dedication 152:2 deem 55:8 394:8 deemed 366:9 deems 345:7 346:11 378:17 deeply 101:2 defer 150:9 204:21 deficiencies 134:9 134:11 deficiency 26:14	60:11 63:3,18,22 65:6 128:2 129:13 130:5 131:18 132:2,7,13 deficient 256:7,8 define 83:4 142:7 166:3 186:18 225:12,19 337:18 339:15 defined 96:15 178:1 382:3 394:7 defining 171:22 256:3 definitely 10:2,5 32:4 34:8,11 89:13 98:4 169:3 232:10 definition 92:18 125:2 183:4 187:3 205:21 280:19 326:22 327:20,22 328:1,4 370:4 definitive 86:21 defoamers 147:14 degeneration 181:8 degree 20:17,18 105:16,18 115:17 123:3 350:14 degrees 123:8,11 delay 364:16 delegates 388:4 delete 375:2 deleterious 34:14 69:11 deletion 300:10 deliberating 188:1 deliberation 17:11 38:13 55:1 deliberations 17:15 238:11 345:15,18 345:21 348:7 353:17 354:7 deliver 300:17 delivered 390:8 delivering 382:5 delivers 194:16 delivery 40:19
--	--	--	--	---

277:22 278:9 366:2 demonstrated 42:12 62:22 69:14 357:18 denial 201:14 denied 200:7 deny 198:14 201:12 denying 212:1 Department 1:1 86:15 126:3 265:17 352:8 Departments 18:10 Department's 389:21 departure 236:1 depend 154:6 dependent 153:12 depending 37:20 337:15 338:16 375:9 depends 23:8 deposited 349:1 Deputy 2:10,20 derivative 280:15 derived 14:4 37:7 68:18,19 79:12 150:5 183:17 describe 85:11 138:9 240:1 described 33:11 108:14 170:18 307:21 309:3 describing 114:5,8 descriptor 339:22 deselect 232:5 deserve 109:7 deserves 146:7 194:15 341:6 design 172:2 designated 341:13 344:9 388:8 designed 173:15 359:8 desirable 7:18 desire 142:1 276:21 286:20 365:16	despite 177:10 358:9 destroyed 33:18 140:16 destruction 199:14 detail 82:14 203:1 detailed 91:21 151:3 184:7 details 217:7 detectable 185:7 deteriorates 128:1 determination 12:9 244:10,14 255:9 323:4 329:2 determinations 48:8 determine 40:1 86:1 173:3 189:16 230:15,16,17 249:18 258:2 321:21 329:9,14 determined 97:1 258:13 275:19 329:10,20 331:11 355:22 determines 257:22 determining 55:15 138:5 149:8 328:22 deterrent 190:14 detrimental 90:13 113:11 develop 90:20 91:5 108:8 114:15 162:20 173:13,22 229:17 316:15 developed 14:14 78:15 219:9 developing 116:9 157:1 212:17 280:11 development 3:22 6:18 27:3 36:6 42:8,9 43:14 44:8 44:15 52:16 56:15 59:6,16 62:8 73:18 77:1 78:14	116:8 128:9,12 180:2 186:16 192:3,14 194:12 194:17 196:20 208:15 209:4 215:19 225:16 226:8 228:21 229:9 315:13 316:2 341:3 343:11 348:11 361:8,11 362:11 363:2,19 de-estrification 185:8,17 186:6 DFO 388:12 DHA 9:3 32:2 137:9,11,14 263:21 359:22 dialogue 238:22 diametrically 15:8 Diane 125:22 135:9 135:12 dianisidine 95:1 diarrhea 65:4 122:4,6 128:19 199:3 Dickson 1:17 263:6 269:3 273:4 274:15 277:10 282:13 284:4 285:15 287:6 288:16 295:9 310:20 312:17 314:7,21 316:21 332:18 376:18 397:18 diddy 144:3 died 177:15 diet 20:15 37:15 134:22 135:2 175:1 177:2,20 179:1,3 215:1 250:16 dietary 37:20 38:1 38:18 42:20 48:22 75:10 129:4 131:2 177:8 211:18	213:17 dietician 212:16 diets 76:9 131:2 180:15 214:14 difference 34:6 127:20 216:20 217:6 236:7 308:15 differences 22:12 179:5 302:9 different 19:12 22:18 23:17,18 24:8 33:14 37:22 43:8 67:21 68:1 69:9 73:4 80:4 86:22 120:14 124:10,13 137:4 166:11 202:14 243:2 255:17 302:11 304:13 315:21 319:6 321:7 324:5 352:14 359:3 389:3 393:7 differentiation 298:19 differently 23:18 302:10 difficult 132:10 223:10 difficulty 115:17 115:17 dig 92:17 digest 332:9 digestion 193:11 digestive 297:20 dilemma 108:5 114:22 diluted 57:15 direct 53:16 94:14 104:20 118:10 327:5,6,8 328:9 328:13,14 390:10 directed 20:13 355:16 direction 68:11 357:11	directly 238:10 345:7 346:11 360:2 369:10 378:17 382:6 388:7 director 2:14 18:19 105:13 116:7 135:12 144:13 151:17 169:21 223:3 347:7 350:5 379:12 384:2,10 385:8 396:1 disadvantage 198:16 disagree 232:19 disappointed 182:22 disclose 159:10 325:9 329:17 330:8 352:2 357:14 359:19 disclosed 280:13 330:12 disclosure 90:9 93:13 157:1 158:10 324:19 325:2 329:1 disclosures 6:1 discrete 114:5 discretion 155:22 335:21 337:14 368:11 375:7 discuss 13:2 155:6 183:11 224:7 225:6 230:5 313:20 342:20 380:6 discussed 38:20 94:9 117:1 130:1 223:16 227:16 373:6 390:3 discussing 145:22 225:7 279:4 discussion 4:16 5:16 8:11 9:13 16:1,20 23:21 60:7,13 81:17
---	---	--	--	---

82:16 92:10 94:11 144:16 146:15 150:2 163:22 167:5 185:16 186:18 188:12,14 227:18 262:10 265:6 268:9,10 269:19 272:5 273:20 274:1 276:14,22 278:9 278:11 280:6 282:2 283:13,16 285:4,6 286:17 288:7,9,10 290:1 292:21 295:1,3 297:8,9 308:5 310:11 312:10,13 314:2,4 318:6 334:12 338:12 342:2 353:5,11 362:10,16 363:3 365:20 366:13 372:22 375:22 380:9,9 390:5 396:11 397:3 discussions 61:4 286:20 disease 65:19 70:19 disinfectants 88:5 164:20 dispersing 153:17 157:14 disputing 54:16,17 dissent 12:11 disservice 300:6 distances 360:16 distinct 14:5 83:9 distinction 9:14,16 10:10 22:14 67:14 67:17,19 83:19 distinctions 150:3 distinctly 140:2 distinguish 300:4 distorted 180:13 distributed 124:1 335:10 distributor 199:9	disturbed 101:2 Divinity 105:20 Division 2:14,16 18:18 docket 348:21 doctor 122:6 doctorate 20:20 Doctors 22:5 97:17 document 4:17 46:22 82:3,16,21 97:7 144:16 146:15 164:1 166:9 167:5 197:18 318:6 319:17 320:1,20 320:21 321:16,19 322:5 323:3 328:6 331:12 332:22 334:13 339:2 342:21 347:14,17 347:19 349:9,11 367:14,15 371:5 documentation 227:8 documented 152:14 153:20 213:4 329:21 documents 5:16 doing 63:19 87:14 145:11 166:1 179:20 221:9 253:4 267:11 290:10 306:19 307:9 308:12 320:2 334:6 336:20 352:11 371:3 389:20 domain 254:10,13 door 139:20,22 140:4,18 141:4 doors 358:16 Dorrance 1:11 dose 72:5 double 176:5 doubles 126:15 downgraded 230:9 downward 340:18	Dr 3:15,15 17:18 17:21 18:15 19:1 19:18,19 20:16,21 22:7,20 24:10 26:5 27:8 28:16 29:8 30:4 31:16 32:22 33:2,11 34:8 35:15 45:9 45:17 46:9,20 48:16 50:19 51:2 55:12 62:6,20 64:16 66:9,15 67:15 69:5 70:15 71:6 76:7,18 77:4 77:8,11 93:2 94:15,20 96:8,19 124:6,6 126:1 130:22 131:17 132:2,19 133:6,19 134:13 138:20 186:15 212:12 216:15,18 217:1,5 218:4,7,18 219:1 220:9,11 221:12 222:6,13,19 232:17 235:22 238:13,18 239:11 239:17 240:5 241:13,15 242:8 242:13 245:15 246:1,14 247:15 250:10 252:9 253:5,20 254:4,8 255:14 256:17 257:10 258:6 259:11,21 260:10 264:1 268:4 271:2 271:14 278:22 draft 127:10 386:10 drafted 391:6 dramatic 113:15 draw 109:10 126:12 dreary 139:16 dried 37:7 driving 68:5	drop 339:9 dropped 70:14 drug 19:22 186:10 186:20 187:3 drugs 50:1 dry 29:17 122:16 drying 30:8 33:10 due 37:22 120:5 194:3 199:20,21 311:12 318:17 344:12 duty 303:11 DVs 186:13 D.C 350:12 <hr/> E <hr/> E 3:8 238:1,1 earlier 67:10 117:2 122:13 130:13 168:8 170:20 180:21 215:21 238:22 242:9,14 250:21 340:11 390:13 391:22 early 178:13 215:2 216:3 329:17 386:7 earned 341:7 eased 336:20 easier 149:14 165:4 223:12 377:21 easiest 87:12 341:4 eat 175:22 213:22 eating 38:1 121:14 131:2 177:20 Edgar 143:17 edited 19:8 editor 19:15 effect 23:7 25:1,19 26:1,8 51:13 67:21 68:6 90:13 92:20 111:16 117:19 119:3 120:6 121:10,14 125:1 128:19 129:2 156:21 158:2,3 160:1	303:11 326:14 381:15 effective 119:15 172:4 257:8 343:19 345:5 346:9 378:15 380:17,19 381:12 382:13,17 383:13 effects 8:16,20 22:17 23:15 42:12 67:2 69:11,14 76:21,21 94:21 95:8 96:1 123:19 142:4 efficacious 29:3 efficacy 25:1 49:22 50:4 efficient 5:12 27:17 effort 98:5 efforts 214:9 224:19 334:11 EFSA 186:18 188:19 egg 137:11,14 eight 5:14 41:16 322:7 337:2 349:10 350:12 398:3 either 29:11 34:4 44:12 64:11 74:22 83:17 86:20 126:16 128:3 136:2 167:21 173:20 189:14 234:2 243:19 244:13 254:17 256:4 257:8 291:7 304:9 305:21 306:2 374:2 377:10 382:6 395:5,5 elected 61:7 electrolytes 217:18 electronic 375:14 electronically 335:9 element 94:10
--	--	---	---	---

elements 156:13 256:19	entertain 261:6 263:10,14 277:16	76:12 106:17 108:17 117:21	et 150:19 151:1 158:5 164:17,18	76:7 106:19 145:6
eliminate 200:20 201:1,10 369:11	304:1 364:20 396:13	118:16 120:1,7,18 127:7 128:9 129:5	386:17	148:12 180:4,22
elimination 198:19 201:7	entertaining 261:13	129:7 130:7 131:14,16 136:7,8	etcetera 117:16 120:5 217:18	216:1 243:21
Elizabeth 169:18 174:11,14	entire 153:2 323:16 324:2 326:4	137:1 139:2 183:19 196:18,20	280:4	244:8 256:11,14
email 169:11 348:16 388:19	351:16 363:1 394:8	196:22 197:5 198:2 199:1,15	ethanol 305:22 306:3 308:11	evil 211:4
emerge 346:16 378:21	entirely 107:6 240:6	201:16 219:21 220:7 249:20	309:3,14	evolved 181:1
EMILY 2:18	entities 320:19 327:1	250:4,8,14,20,20 251:12,20 252:8	ethics 105:20 327:16	exact 25:22 110:13
emphasize 115:7 243:5	entitled 334:16	255:5	EU 44:11 57:22 119:10 129:17	179:9 305:19
employee 359:17	Environmental 105:20	essentiality 43:7,11 44:18 62:15,20	192:19 195:12,16	306:10
employer 359:20 360:1	environmentalist 332:21	69:4 75:13 186:10 249:17	200:9	exactly 29:15 80:22
encapsulate 61:21	envision 160:21	essentially 15:4 55:9 60:12,14	Europe 63:17 69:16 204:6,9,9	163:10 181:3
encapsulation 21:6	enzyme 89:22 158:16,18	68:4 110:15 266:6 302:22 321:18	204:16	205:22 206:3
encourage 50:10 213:20 248:18	enzymes 153:9	322:20 323:20 324:6,12 325:15	European 54:1 75:6 106:21 109:8	352:6 386:6
297:13 342:5 368:15,15	EPA 108:12	326:2,9,16 328:19 329:6 330:17	195:6	Examine 155:14
encouraged 335:5	epidemiology 67:1 176:12 256:2	331:17 332:1,6 358:15	evaluate 173:1,8 174:1	example 23:3 24:20
endogenous 133:22	equal 38:4 160:3	establish 9:18 173:19 227:9	evaluated 85:4,10 85:15 86:9 153:3	53:10 118:4 122:6
endogenously 134:3	equating 167:13	318:11 381:14	171:2 240:7,8	148:7 156:1
ends 82:9	equivalency 207:6	established 207:16 213:20 348:20	243:10 247:19	157:18 159:11
enemies 140:16 141:9	Eric 116:3 125:20	establishing 85:7 243:3 381:10	evaluating 47:20 84:19 171:3,13	198:22 251:10
enemy 142:11	erroneously 197:3	establishment 170:11	172:12 173:14	359:15 388:9,19
energy 129:12	error 331:3 336:7	esteemed 302:15	226:13 248:16	examples 153:9
enforcing 301:7	ESAPAGAN 71:15	estimate 64:18 256:21	evaluation 68:17 86:10 173:17	213:17
engage 360:18 392:15	especially 26:16 75:1 77:2 81:15	estimates 256:1	243:10,12	exceed 190:8,11
England 66:16 205:3	100:20 106:9 110:18 121:22	estrification 275:18 275:19	evaluations 224:11	excellent 260:7
ensure 31:14 104:21 171:1	129:3 214:11 229:13 259:5	estrogen 96:4	evening 398:4	exception 101:13
193:2 225:8,15 226:7,14,18	278:21 357:13	estrogenic 94:15,20 95:3,8,20	event 58:5 74:13	224:3
303:12	espousing 70:12		evermore 141:16 142:2	exceptionally 127:11,12
ensuring 35:1	essence 327:7		evaluation 68:17 86:10 173:17	exceptions 159:2,3
enteral 135:19 136:12 139:1	essential 8:5 40:4 43:2,17 44:17		243:10,12	excess 190:14
enters 271:17	55:9,16,20 56:2 59:15 62:7,18		evening 398:4	256:6,8
	63:22 75:11 76:8		event 58:5 74:13	exclude 301:21
			evermore 141:16 142:2	307:19
			everybody 4:14 238:4 363:7	exclusive 71:9,16
			365:14	71:18 134:19
			everybody's 276:20	exclusively 138:7
			everyday 161:1	340:14
			everyone's 370:18	exclusivity 71:21
			evidence 44:17 64:2 67:1 72:1,4	72:9
				excretion 129:14
				excuse 60:19 113:8
				123:5 293:6
				296:10
				executive 144:13
				347:7 379:12
				384:1,10 385:8
				396:1

exhaustive 95:18	209:6 244:1	extremely 70:1	219:11 220:16	favor 39:13 41:16
exhibits 120:7,8	302:15 303:15	74:19 139:3 366:9	fall 39:1 199:17	42:5 188:2
exist 106:20 109:9	360:15	eye 37:11,14 39:17	348:13	favorable 188:20
149:1 153:13	explain 84:18	42:7,13 45:8	false 370:22	favored 87:21
202:19 210:8	142:3 195:21	175:6,8,16,19	familiar 101:9	354:11
211:10 229:18	304:7,11	176:4,14 178:7,10	195:11 204:1	FAVRE 1:17 15:2
269:21 298:17	explained 203:1	181:18 214:17,18	329:8	28:10,19 31:10
318:12 342:13	350:20	216:8	families 233:4	50:17 51:18 59:14
389:1 392:7	explanation 115:15	eyes 42:16 253:3	family 175:2	263:3 268:22
existence 394:16	explicitly 147:9		327:18 328:2,4	269:13,20 270:21
existing 49:12	266:10	F	fantastic 140:10	273:1,11 274:12
227:3 328:5	explore 10:9	F 238:1	far 35:10 44:6	277:7 282:10
exists 352:3	exposed 30:10,10	FACA 351:4	46:16 51:3,6,15	284:1 285:12
expand 281:4	180:6	352:16 383:9	87:14 93:2 96:2	286:13 287:3
expect 176:20	exposure 30:20	FACA's 353:12	126:21 164:6	288:13 290:13,18
198:12 265:14	256:21,22,22	FACA-required	204:19 205:1,7	290:21 291:3,17
expectation 84:8	257:1,5,5	353:18	209:16,19 230:12	292:2,10,13 293:4
278:15	expressed 75:21	face 153:22	232:17 266:18	293:22 294:11
expectations	332:4	facilitate 345:20	299:20 319:18	295:6 296:7
104:13	expression 128:17	346:15 378:20	331:6 354:5	301:13 311:9
expected 101:11	extend 9:22 10:7	fact 16:3 50:22	Farm 105:14	313:6,21 314:18
123:19 194:7	344:21	53:8 54:17 60:12	farmers 104:20	376:15 384:17
expeditious 5:12	extended 53:13	71:17 79:15 108:3	210:13 323:21,22	387:3 397:15
expensive 179:13	extending 335:20	112:6 141:1 154:7	352:10 359:11	FC 187:4
experience 126:8	extensive 95:17	156:2 183:22	fascinating 238:12	FDA 5:1 17:2 20:5
133:5 145:7	extent 161:2,4	221:9 257:8 258:1	fashion 41:5	38:6 39:20 43:17
146:20 212:17	386:2 391:10	258:15 259:2	fast 216:18 322:9	44:10 48:10,18
244:1	extract 8:12,13,22	263:19 301:5	Fastest 216:16	49:10,21 55:7,14
Experimental 20:8	14:4 58:7 120:10	317:14,20 322:2	fast-paced 239:9	55:19 57:19 62:4
experiments	120:13 179:13,14	339:3,14 395:22	fat 8:2 31:16,18	107:5 116:15
131:18 132:6	184:15 222:16	factor 255:12	34:13 74:16,18,18	118:11 119:10
expert 20:3,13	239:3 247:10,11	factors 156:15	119:17 121:19	122:11 130:14
60:13 102:14	247:16 248:5,7	facts 341:12	127:9 129:8	131:20 183:22
112:2	263:19 264:3,9	factual 34:17	131:19 201:18	187:4 191:5 192:8
expertise 31:8	305:7 307:15	391:21	fats 117:18 119:16	192:20 197:16,19
63:15 96:18	extractants 302:11	faculty 18:8	121:18,22 122:12	197:22 205:21
205:15,17 206:6	extracted 14:3	failed 359:19	193:11 199:2,20	206:2,9 219:4,12
248:15 304:5,7	97:11 300:15	fails 80:6 274:21	201:16,20,22	220:1,12,13 221:8
351:14	304:11,12 305:12	282:22 286:3	217:10 305:14	221:12 224:1
experts 11:15	extracting 81:7	289:8 315:3 398:1	fatty 31:20 32:1	227:7 229:2 230:5
15:12 17:2,13	196:3	failure 129:20	35:2,3 119:18	232:9 234:8 235:4
45:3,22 58:2	extraction 80:20	192:16	121:16 129:9,10	239:20 242:10,11
61:12 75:13	195:20 280:12	faintly 141:3	129:11,14 198:3	245:11,16,18
106:10,18 108:2	301:3 305:22	fair 81:20 87:4	199:1,15	246:10 247:19
113:9 130:13	306:4 307:8,11	362:19,20	fat-soluble 117:18	250:2,9 254:5,8,9
191:7 201:17	308:2 309:2,7,11	fairly 5:13 31:19	119:14,18 120:1	254:14 255:4,17
203:1 208:19	extracts 79:16	60:10 83:9 214:13	fault 188:14 239:6	257:7,10,15

258:15 264:3,6,10 270:17 271:12 279:5,5 297:12 298:7 FDA's 48:17 62:10 230:9 248:10 FDA-required 75:2 feasible 58:6 194:3 227:16 fed 69:15 70:5 95:6 127:19 128:22 136:2,17 179:9 180:9 194:9 215:15,16 216:6 225:6,8 226:19 federal 43:18 101:11 199:18 200:5 335:3,6 341:13 344:2 374:18 388:8 389:16 Federation 20:7 feed 63:4 69:10 72:2,4,11,12,12 95:1 116:13 127:1 165:9 191:1 194:2 224:20,22 226:4 feedback 347:11 379:16 feeding 44:6 71:4,9 71:17,18 72:3,9 95:21 126:19 130:1,6 134:10,11 134:19 190:21,22 194:10 212:20 224:14,19 227:2 feeds 141:8 feel 72:7 148:19 179:21 231:8 276:18 297:14 301:5 303:6 339:11 341:1 355:19 373:14 386:2 396:12 feeling 231:11 339:5 355:12 feels 302:16 382:8	391:10 392:8 Feldman 1:18 47:17 55:4 67:8 80:16 94:7 111:14 113:7 138:1,4,8 138:19 149:21 150:11 166:20 167:1 189:7,11,22 195:18 196:4 205:14 206:11 217:21 218:6 242:8 245:5,22 246:8,22 254:20 257:6,17 262:20 267:13,16 268:16 270:7 272:2,18 274:7 277:2 278:10 282:5 284:10 285:21 287:12 288:22 295:15 296:22 299:17 302:4 306:11,20 307:3,6 308:4,16,19 310:1 311:4 313:1 314:13 316:22 354:18 373:4 376:10 379:21 390:2 397:10 fell 54:5 fellow 329:16 fellowship 18:5,20 felt 38:16 39:9,19 40:11 41:6,9 140:11 188:3 303:3 390:4,21 Fernandez-Salva... 150:10 305:3 306:8,13 308:6,9 fertilizer 305:10 fiber 305:15 fiduciaries 343:5 field 191:7 fighting 320:10 figure 154:1 figured 109:13 309:16	figures 25:22 66:11 file 344:5 fill 386:14 filled 140:10 fills 184:15 filter 37:12 175:10 181:13,21 final 148:12 186:16 204:5 255:8 266:13,17,21 322:1 323:5 329:4 340:20 342:3 finally 129:7 280:13 331:12 337:7 354:3,11 financial 319:22 324:19 325:2 327:5,6,9 328:9 328:13,15 find 53:15 57:20 93:14 101:2 123:14 124:19 126:19 149:5 165:3 174:21,22 175:14,16 180:19 185:6,12 238:12 253:14 256:4,5,6 280:14 finding 143:7 163:10 167:16 findings 167:6 fine 11:17 66:7,8 144:1 236:22 361:17 396:12 finish 311:14 342:7 361:13 376:21 383:20 finished 49:1 157:5 157:8,9,10,21 298:1 361:8 368:5 first 5:20 6:9 7:9 17:18 24:11 25:6 61:22 65:15 67:14 73:5 76:5 88:8 93:2 100:2 105:4 106:2,4 117:1,9 126:15 127:15	128:20 129:5 145:9 152:1,11 155:7 162:22 163:21 164:22 171:14 172:1 173:2 177:19 190:22 191:13 194:7 212:22 215:5,18 224:12 247:7 261:7,8,20 267:3 270:20 290:7 299:7,14,19 303:11 316:5 325:16 329:2 334:21 349:17 350:16 354:5,22 364:3 367:22 380:14 381:6 389:9 firsthand 355:16 fit 341:18 369:15 fits 267:17 five 63:21 64:21 78:9 98:12 103:2 106:2 169:12 335:21 336:12 340:15 354:22 361:15,18 fix 371:12 fixed 360:10 fixing 374:3 Flamm 1:12,14 4:3 12:7 98:10 236:11 236:18 237:2 260:18 261:18,22 262:4,7,12 263:7 263:13 264:21 265:1 266:22 267:15,20 268:8 268:19 269:5,17 270:5,19 271:6 272:4,7,14 273:7 273:14,17,22 274:19 276:2,7,11 276:16 277:15 278:1,5 280:5 281:7,15,18 282:1	282:19 283:2,11 283:15 284:11,19 284:22 285:6 286:1,6,12,14,19 287:15 288:1,4,9 289:3,6,11,18,21 290:9,12,22 291:6 291:9,19 292:6,12 292:16,19 293:8 293:13,17 294:2,9 294:14,18 295:3 295:20 296:16 297:2,22 298:4 299:16 301:10 302:2 303:14 304:15,21 306:6 306:17 307:1,4 308:3,17 309:8 310:3,9 311:10,17 312:5,12 313:8,16 313:22 314:4 315:1,10 316:22 341:2 361:17,22 362:4 365:4,7,19 366:12 368:4,19 371:9 372:6,20 374:1,11 375:11 375:15,20 376:2 376:19 377:10,19 378:3 379:19,22 380:8 381:5,22 383:19 384:15 385:5 387:20 389:11 390:1 392:17 393:18 394:21 396:21 397:20 flavor 159:6,7 248:9 flavoring 247:17 flavors 153:10 156:1,4 159:4,9 166:4 173:10 flexible 340:7 flies 91:17 flitting 141:17 floor 77:20 141:5
--	---	--	---	--

375:17 396:22	196:1,14,15	334:13 375:14	120:12,20 121:11	271:4,12 273:13
Floraglo 182:17	199:18 200:5	395:10	122:1,3,17 123:16	273:20 277:21
flower 184:4	210:6 225:20	formal 250:22	126:17 127:3,13	278:8,20 284:17
flowers 183:18	226:1 242:15,16	251:5	127:18 128:18	285:2 287:22
fluorine 147:14	242:17,18 243:13	formation 178:5	130:8 132:11	288:7 296:9,12,20
fly 281:10	243:15 245:1	386:16	133:10,11 134:3	297:6,12,14,16
focus 21:16 144:15	248:13,16,19,21	former 143:13	135:18 136:11	298:10 299:1,11
152:9 164:15	249:14 250:5	321:12	137:9,14 162:8	299:22 300:1
191:11 214:8,12	258:1 345:12	forms 43:5 270:11	178:3,16 182:15	304:8 305:19
focused 22:1	346:19 350:13	293:2	186:19,21 189:21	313:15,19
folks 32:14 305:5	356:20 357:7	formula 6:12,16	190:7 191:10,16	formulas 15:19
follow 9:16 99:16	foods 23:11 26:13	7:18,22 8:6,21 9:1	191:21 192:18	26:13 27:10 33:4
104:11 161:22	36:3 38:12,17	13:18,21 15:14	193:14,21 194:9	38:3 39:15 42:2
217:21 222:1	48:19 57:8 62:9	16:6,11 19:20	194:15,19 195:7	42:17 44:3 48:18
245:3 341:4	74:10 79:3 80:12	26:20 27:19,21,22	196:22 197:1,14	48:19 49:4,7 51:5
345:22 367:16	100:12,14 101:4	28:1,5,12 29:4,18	197:20 198:5,7,11	55:14 57:11,14
followed 18:5	101:15 102:5,11	29:20 30:6,9	198:13,13,15	59:17 62:10,21
139:13 144:7	102:17 103:3,9,22	31:17 33:12,13	199:6 200:9,11	63:4,9,10 64:15
151:12 174:11	104:2,8 134:15,15	34:4,7,22 37:2	201:17 203:22	65:7,13,18 66:14
182:6 190:18	140:14 142:18	38:11,22 39:12,21	205:3,8 206:16,21	66:21 67:4,16
196:11 208:6	147:20 154:11	40:18 42:4 44:1,9	207:3 208:12,16	69:7 70:5 77:12
212:10 349:18	165:10 182:10	44:10,13 45:10,11	208:22 209:5,6,12	77:14 79:19,20
following 5:11	209:16,20 210:3	46:3,5 49:1,7,8,11	210:3,9,11,15,18	95:22 110:2 117:7
96:11 239:18	210:12 211:16	49:20 50:10,11,14	212:14 213:2,2,8	120:19 129:15,16
240:21 347:8	214:2 215:10	51:6,16 52:5,8	213:10,10,13,19	129:19,22 130:4
348:9 365:11	343:9 344:18	54:3,4,10 55:10	215:7 216:6,11	131:7,21,22
379:13	379:3	56:9,12 57:10,15	218:16,17 219:5	133:16,21 191:3
follow-up 64:10	footnote 167:4	57:20 58:21 59:2	219:15,21 223:3	192:4,6,9,22
207:11 234:3	force 104:17	59:19 60:1,15,17	223:22 224:3	193:2,7,17 197:8
266:22 306:20	242:22	61:6 62:19 63:7	225:17,20,22	198:17,20 200:21
food 10:3 19:21,22	forced 229:16	63:12,16 65:21	226:6,9,18,19	201:1 202:8,11
20:12,14,17,19	forces 17:22 221:3	66:10,13 69:13,21	227:21,22 228:22	205:1 212:17
23:8,9,17,18 37:7	221:5	70:13,17 71:5	231:9,15 232:5,12	215:11,14,15
49:2 50:2,3,7,12	foremost 152:11	72:10 73:12,15	232:19 233:7,16	218:9 220:3 223:6
53:10 62:10 83:22	forever 254:11	74:15 75:2,4,7	234:7 239:21	226:16 227:19
84:9 90:15 92:20	forevermore 140:8	76:3,15 78:5	240:11,19 241:5	230:2,13 251:9
97:9,9,12,12	forget 387:2	80:12 94:9 95:7	241:17 242:3	301:17
101:9 102:14,15	forgiveness 140:21	97:9 106:22	243:9,15,18	formulate 148:12
103:19 104:20,21	forgot 274:2	107:10 108:6,7,18	244:19 245:2	formulated 90:14
105:14 108:19	form 14:3,5 37:6	109:9,12,14,16	247:9,18,22 248:2	147:15 150:5
109:4,5,6,6	52:13 53:7 57:9	110:9,10,12	248:3,6,11,18	223:5
112:14,19 121:13	74:14 79:7 119:14	111:20 112:4,11	249:1,2,7,8,10,19	formulation 9:19
121:15,15 122:9	143:22 185:18	112:13 114:12,14	250:5,13 251:7,16	39:9 49:12,17
126:4 142:4,21,21	211:2 219:4	115:3 116:9,16,17	252:4,22 255:21	159:7 235:3
147:14 151:18	270:15 305:8,9	116:19 117:10,22	258:14,18,20,22	249:20
153:14 165:14	319:19 320:20	118:6,11 119:1,5	263:22 264:18	formulations 28:17
186:10,20 187:3	321:6 333:2	119:9,12,16 120:2	265:6,12 270:12	172:19 191:4

formulators 304:9	137:21 139:4,9,12	124:22 127:10	287:1 289:5,15	360:22
forth 16:2 48:2	143:13,19 144:6	137:8,12 192:13	295:18 296:14	gallery 151:16
115:21 302:13	148:15 149:19	208:13 214:15	311:7 313:4	238:11
316:4 317:21	150:12 151:8,11	224:4 251:19	314:16 376:13	Galveston 18:10
333:18 334:19	156:17 159:17	260:1 320:2	397:13	gateway 140:14
362:18 363:21	162:14 166:18,21	foundations 19:6	fun 32:18	142:14
fortification 44:3	169:6,8 173:15	four 63:21 71:11	function 8:4 43:13	gavel 4:8,11,12
59:2 118:11	174:4,7,10 178:18	72:4,7 95:12	113:11 127:7,22	98:8 260:17
186:13 192:6,18	179:17 182:1,4	124:21 126:15	128:1 176:10,15	315:15
fortified 38:3 42:18	187:6 189:4,9	169:10,10 202:17	177:5,22 178:4	gavels 98:21
192:7 193:2	190:15,17 194:20	216:13,16,18	193:12 229:13	GB 118:12
215:11	195:17 196:1,7,10	269:6 335:17,18	351:17 394:3	general 41:20 43:8
forward 5:20 61:20	200:17 203:2,15	336:10 340:16	functional 51:7	43:10 60:6 64:1
91:6 263:16 283:6	205:12 206:8,12	341:3 350:9	92:20 156:21	64:18 170:17
286:8 304:22	207:11 208:2	366:10	158:2,3 172:8,17	267:18 339:5
332:10 362:12	212:6,9 216:12,16	fourth 83:21 84:2	178:9 198:6	356:20 359:17
364:2 386:17	216:22 217:3,19	four-minute 366:2	functionality 9:19	370:6,12,16 371:1
foster 1:18 4:7,10	218:10,13 219:16	fragile 135:21	24:19	372:3 373:16
6:5 7:6 10:19,22	221:22 222:20	frame 83:7	functionally 153:11	374:16
11:3,17 12:6,17	228:9 231:5 233:8	frank 318:14	functioning 179:6	generally 86:15
13:4,11 14:22	235:9,13 236:16	frankly 103:9	193:10	107:4 147:12
17:4 21:1 22:9	236:22 238:3	220:12 318:1	functions 10:12	206:1 217:13
24:5 28:9,20	242:7 245:3 247:3	free 143:22,22	44:5 127:6 130:7	242:14 243:1,3,12
29:10 31:9 32:9	252:10 253:12	185:18 241:9	193:13 268:3	248:8 316:3 356:3
32:13,18 33:21	254:1,6,15 257:18	fresh 342:16	funding 149:11	General's 71:20
34:15 35:4,16	259:8 260:12,16	friendly 293:5	fungus 137:10	generated 21:4
36:15 44:20 45:19	261:8,12,15 263:5	friends 207:3	funny 212:3 315:19	generic 153:19
47:10 50:16 51:19	269:2,11 273:3,16	fringe 275:10	further 10:9,16,17	generically 153:2
53:1 55:2 56:3	274:14 275:1	front 37:3 73:7	16:19 24:3 132:6	genetic 128:16
57:1 58:12 59:11	277:9 281:9,13,16	207:22	150:1 160:11	genistein 95:1
61:17 64:4,8 67:5	281:20 282:12	fruit 147:16	168:4,10 169:2	gentleman 201:3
70:21 72:15 73:3	283:1,4 284:3	fruits 213:21	221:13 257:12	gentlemen 151:16
73:8 74:1 76:17	285:14 287:5	fulfilling 344:14	268:8,10 272:4	gently 139:20
77:7,10,17,22	288:15 289:10,13	full 96:20 97:5	276:22 280:5	141:2
78:20 80:14 81:10	289:20 292:18	152:4 161:13	283:16 286:20	Georgia 18:4,16,21
81:14 92:2 93:17	294:6,17 295:8	172:20 259:20	288:10 305:12,13	317:21
96:5,9 97:14	296:3 310:19	300:20 336:6	330:21 397:2	gestational 129:4
98:15,19 105:1,5	311:16,19 312:16	342:2 365:17	future 46:8 68:16	getting 12:12 82:13
105:9 109:19	314:20 366:14	fully 84:6 87:14	92:1 140:9 171:10	125:21 160:21
111:13 112:21	367:10 369:20	161:12 213:14	392:7	203:5 220:20
113:4 115:4,22	370:1 371:15	255:13 348:9	<hr/>	249:13 294:2
116:2 121:4,7	376:17 382:1	FULWIDER 1:19	G	383:10 384:6
122:14 124:3	383:22 397:17	262:6 263:1	G 3:8	ghost 140:4 143:18
125:4,17,20	found 10:2 37:11	264:22 268:20	gain 327:5,9 328:13	GI 128:18 129:2
130:11 131:11	38:4 42:14 74:8	272:21 274:10	galactosemia 65:20	Girl 91:15,17
132:15 133:13	99:1,3 101:11	276:9 277:5 282:8	Galiani 349:21	give 82:10 103:11
134:6 135:7	102:10 117:8	283:21 285:10	356:16,18,19	122:3 176:8 178:2

207:21 240:18,19 241:4,12 252:15 270:13 304:16 325:12 336:12 337:20 362:22 363:15 374:2 380:18 392:18 394:22 given 12:9 62:17 67:13 68:3,12 264:2 280:1,2 gives 241:6 giving 91:19,22 372:6 glasses 292:7 global 26:11 globally 26:8 globetrotter 204:14 glucose 104:4 glucose-galactose 65:21 glycerine 159:10 glycol 102:9 GMO 390:21 GMO-related 388:11 go 4:4,17 10:15 11:21,22 13:1,5,6 33:13 36:19 40:21 41:11 45:3 47:7 47:10 48:10 61:22 66:18 97:16 112:17 124:3 141:8 142:18 143:3 149:6,14,16 150:17 155:9 159:20 160:11 161:12 163:5 165:17 169:5 179:14 181:3,15 185:9 197:14 203:9 206:16 209:9 217:4 220:22 221:8 222:4 232:6,11 234:5,16,19 235:4 235:7 236:10	238:10 239:5,15 240:11 241:8,10 247:3 254:18 258:15 263:16 281:3 283:6 286:8 298:2 316:1 320:15 322:5,8,11 329:13 331:6,8 333:9,21 334:20 339:15 343:16 368:16 372:5 378:3 383:19 388:7 393:6 396:17 goal 226:17 334:14 389:4 goals 395:17 goes 121:13 142:19 164:1 219:11 220:18 229:21 242:11 325:15 going 5:6 7:10 10:16 16:9 25:4 32:14 50:17,18 65:13 80:1 82:1 82:10 83:6 84:10 86:21 91:6,16 92:16 93:6,14 111:9 113:9 114:15 116:21 136:8 148:19 158:17,18,19 159:19,21 161:3 161:11,20 162:12 163:8 165:10,15 165:16 178:5,11 180:12,17 206:9 214:12 229:22 235:21 236:9 238:5 239:19 249:19 262:2 263:10 269:9 275:15 281:2 296:4 298:12,16 298:17,18 299:6 305:4 312:13 316:1,18 318:6,18	318:20,21 322:8 329:14 330:20 333:8,12,15,21 336:5 338:15 341:21,22 342:6,9 367:15 369:14 370:3 371:10 380:15 381:3 384:4,5 385:10,22 386:5 394:14,15 gold 224:15 golden 176:7 good 4:3 6:6,8 17:5 21:5,6 22:7,8 35:15 48:17 64:6 67:11 88:16 105:12 121:21 126:1 135:10 143:5 144:12 154:4 164:4 174:13 182:7 190:1 196:13 199:14 205:10 213:16 220:9,14 221:10,21 223:1 240:13,21 242:3 248:9 294:15 315:19 317:6 320:14 326:1 332:16,22 333:4 349:13 350:2 356:9 361:2 362:3 363:22 377:1 395:7 398:4 goods 261:10 goofy 294:1 Googling 208:3 gotten 383:8 government 100:13 172:11 353:20 Governmental 107:14 grab 112:11 grabs 181:14 grade 37:7 graduate 17:21 18:13,22 208:18	granted 197:16 granting 206:3 GRAS 20:11 75:9 107:4,5 118:7 190:6,12 197:15 197:16 205:18,22 206:3 219:13 222:14 230:4 234:5,9,12,17,19 235:7 239:2 242:12,14 243:6,7 243:18 244:4,20 245:19 248:14,20 249:5,9 252:14 256:18,19 257:3 264:6 grasp 141:19 GRAS-approved 119:6 great 109:12 182:4 201:13 230:5 280:16 360:15 greater 170:14,15 326:1 357:16 greatly 208:21 green 37:6 179:1 213:22 322:16 grew 140:19 390:14 390:16 392:5 grid 322:21 grocer 103:15 groundwork 15:4 group 21:3 54:8,8 137:5 144:20 152:1 190:21 208:10 211:18 297:11 320:15 325:13 387:10 grouped 337:1 grouping 167:14 167:18 groups 54:12 60:5 319:12 321:7 322:22 327:13 331:6,17 359:1 grow 104:19 108:8 114:15 279:17	339:17 growing 140:17 141:2 279:21 grown 213:13 280:21 281:4 grows 215:17 growth 42:8,9 51:7 62:8 129:6 135:4 140:18 141:5,15 142:2,13 147:21 171:10 180:1 192:3,14 194:6,12 194:17 196:20 208:14 225:15 226:7 229:8 240:17 guarantee 332:11 381:13 guess 31:10 58:14 64:12 68:12 80:18 218:1 219:5 220:10 256:7,9 273:22 276:20,20 320:15 334:15 362:1 380:15 382:7 393:19 guest 206:9 guests 12:22 17:7,9 21:7,15 22:3 35:12 99:1 254:18 guest's 236:12 guidance 173:7,22 316:9 343:21 383:8 guide 316:14 guidelines 213:17 221:18 252:20 256:11 guiding 207:14 guise 101:5 gumbo 327:2 guys 207:5 270:8 291:21 Gwen 159:20 162:16 Gwendolyn 144:8 151:12,17 304:20
--	--	---	--	---

H				
habits 38:1,18	253:18 258:19	77:13	helping 334:8	334:2
Hain 190:20 208:9	329:19 351:11	health-conscious	helps 97:14 115:7	Hong 202:13
half 213:21	358:15 368:18	100:12	115:16 165:3	honor 341:7
halfway 51:20	392:3	hear 26:2 71:3	Herman 196:12	hope 146:8 161:5
hand 172:3 181:9	happy 11:21 70:10	260:21 269:11	208:6,8,9	196:6 222:1,10
236:9 257:18	130:9 142:18	344:13	hesitating 140:20	224:10 238:4
270:20 340:1	146:5 203:9 355:5	heard 79:9 112:2,6	hexane 97:10 102:8	251:20 319:7
381:6 389:12	364:20	112:17 115:2	184:14 185:6,13	336:7 363:13
395:21	hard 106:1 223:9	123:15 130:13	305:12	hopeful 333:1
handing 260:16	306:10 341:8	141:4 213:8 214:5	hexanes 104:4	348:19 349:6
handle 205:17	harm 221:10	215:18 219:18	hexane-extracted	hopefully 5:9 15:14
369:19	harmful 8:16,20	230:7,20 250:2	191:16	138:21 221:10
handler 158:22	67:2 69:14	257:20 270:10,12	hey 391:16	307:15 320:7
167:21 168:2,3	Harmless 140:6	271:9 280:10	heyday 140:15	333:14
handlers 158:13	harmonization	354:21 387:17	Hi 111:14 169:19	hoping 61:11
324:1,1 352:10	170:9	391:9,17,18	212:12 388:1	149:22 332:9
handling 3:11 4:7	Harold 1:15 36:16	hearing 262:12	hidden 100:20	396:16
6:17 14:12 21:3	45:20 115:4	317:5 356:15	hide 253:15	hotel 1:10 143:18
36:5 38:12 39:10	133:14 162:14	363:22 373:2	high 29:18 118:14	hour 95:12 98:12
43:2 56:14 58:9	179:18 187:7	380:8 386:4 391:3	127:11 215:2	236:15 242:4
59:5 73:17 75:14	203:15 206:13	heart 140:13	higher 33:20 63:9	hours 82:5,6,8
78:13 79:20 89:12	207:11 275:3	143:15 193:11	95:2 107:16 217:9	95:11 241:21
97:20 99:11	276:3,18 284:22	heat 29:18 30:5,10	278:14,15 300:7	303:21 363:6
101:17,21 102:20	288:11 355:8	33:10,16,19	highest 127:2	388:13
104:15 106:7,15	393:18 395:19	heating 33:3	highlight 340:8	house 235:15
107:17 109:3	Harvard 105:19,20	heat-tolerant 8:6	highlights 216:10	253:19 385:10
144:17 154:7	hate 55:5 297:13	heavily 110:20	338:19	Houston 132:4
167:11 170:6,19	367:13 368:9	339:19	highly 127:20	huddle 361:12
186:1 222:2,5,10	hazardous 108:13	heck 209:17	214:16 215:21	hug 23:14 109:16
222:11 236:6	heading 64:13	Heird 132:3	220:4 225:22	111:9 142:17
238:8 259:17	headings 84:11	held 18:12 278:14	hinder 171:10	161:4 165:16
260:20 261:1	headmaster 7:7	300:7 339:21	historical 155:20	huh 216:14
275:8 277:18	heads 259:18	Helen 182:6 190:18	Historically 152:19	human 20:20 31:18
handout 209:7,13	health 18:12 19:6	190:19	383:5	37:18,19 38:5
hands 315:22	20:12,15 35:21	Hello 100:8 356:18	history 231:19	42:14 43:13 51:11
388:13	37:14 39:17 42:13	help 42:16 96:12,17	243:19 318:10	59:16 70:1,4
hang 4:12	44:7,15 45:7	131:15 150:6	339:10 359:16	74:22 76:9 95:20
happen 90:16	68:21 70:7 107:14	163:3 166:2	386:5	96:4 108:19
122:7 150:14	118:13 119:11	187:22 220:8	HMP 186:2	124:22 126:4,20
163:2 207:13	138:18 174:15,18	224:10 235:21	hold 51:22 302:5	127:11 129:22
209:11 252:21	176:1,14 178:7	236:4 250:7 300:1	350:14	165:10 174:18
265:11	183:5 191:8 194:5	334:4 366:5	holds 143:6	186:21,22 200:4
happened 357:20	198:18 200:4	helped 188:5	home-made 232:8	213:5 214:10
362:17 386:13	211:21 212:1	helpful 68:2 97:18	honest 125:10	215:13 224:4,15
happens 122:3	216:8,8 221:17	98:1 99:4 100:7	318:14 338:14	225:22 226:20,22
252:15,18 253:3	225:2,2 302:13	260:8 339:11	340:22	251:20 256:15
	healthy 66:6 70:18	392:1	honestly 318:1	humankind 319:6

humans 76:13 165:15 250:16	114:3 122:20 125:7 145:15	improved 128:22 216:7	inclusion 6:14 13:19 35:22 52:6	172:6,15 325:19 337:6 353:6 360:2
hundred 124:21 129:18	160:12,14 179:22 200:7 228:13	improvement 170:9	56:10 58:22 60:8 62:19 73:13 78:6	individually 85:15 93:10 224:9
hundreds 175:3,6	303:8 344:17	improvements 228:3	84:20 85:5,21 101:14 104:6	individuals 128:4 320:19 321:8
hungry 203:6	impacts 69:1 188:21 280:4	improving 371:5	171:3 296:8,11,19 297:5 323:10	330:16 331:17 337:2 359:1
hydrogen 108:13	impartial 303:17	impugn 337:5 370:2,11,16,19	incompatible 86:6 106:15 109:3	394:13
hydrolosate 78:7	implement 347:9 379:14	373:5	incomplete 198:10 297:17	induce 53:12
hydrolyze 271:18	implementation 343:14 344:18	impugning 370:3	inconsistent 198:10 297:17	indulgence 169:17
hydroxide 306:1,5 309:15	345:11 346:18	inaccurate 349:20	inconsistencies 89:18	industries 153:22
hypoglycemia 129:20	379:1 386:20 389:2,5 390:7	inadequate 107:11 107:13 108:19	inconsistency 145:19	industry 7:20 19:6 31:7 54:11 90:10
hypothesized 53:17	implemented 148:8	192:15	inconsistent 252:20	111:3 152:17 155:9,15 160:12
I	implication 113:14 178:15	inadvertently 172:13	incorporated 88:20 88:21 307:16	160:16 163:4,5 189:16 218:2
iambic 143:21	implications 94:12 242:5	inasmuch 76:1	incorrect 252:19	226:11,18 227:11 271:14 351:17
idea 143:5 163:16 163:19 164:4	implies 178:5	incentive 93:9	increase 68:9 95:12 127:17 131:5	271:14 351:17
203:3 204:7 231:16 354:9	implore 140:22 194:17	incident 92:19	142:6	industry's 111:8
identical 211:3	importance 39:16 145:4,10 175:14	incidental 85:1 86:5 92:18 140:3	increased 129:14 177:10 178:7	industry-wide 104:9
identified 68:22	208:14 226:12	142:3 156:20 157:6	incumbent 244:16	inefficiency 63:11
identifies 78:9	important 27:3 37:13 74:19 103:1	incidentally 213:18	independent 107:8 245:17 246:6	inert 86:2
identify 116:18 230:15 347:9	106:11,20 112:1 126:18 128:16	incidentals 140:6,8 142:16	257:11	inerts 91:8,12 158:10 163:15,16
379:14	139:3 154:4 175:12,18 180:19	include 19:2 40:9 61:1 103:4 133:18	independently 257:7	163:17
identifying 184:2	180:22 193:12 198:1 200:15	136:11 153:9 168:20 227:20	India 18:1	infancy 42:7 66:21 66:22 67:3 69:1
identity 358:12	202:21 210:4 211:17,20 216:4	234:11 246:11 255:20 344:10	indicate 76:8 133:7 133:20 250:12	129:6 134:10
IFA 221:7	223:15 226:5 233:3,7 346:17	347:8 371:20 379:12	325:4	infant 6:16 7:18,22 8:5,20 9:1 13:21
IFC 223:4	348:5 349:4,5 352:22 353:10	included 55:13 62:18 85:8 93:11	indicated 65:14,22 95:13 132:4,8	15:14 16:6,11 19:20 26:12,19
IFOAM 75:5	358:6 378:22 391:11	183:7 195:4	242:13 390:10	27:9,18,20,21,21 28:7,12 29:4 30:6
ignored 103:1	importantly 198:17	includes 108:12 110:8 246:15	indicates 68:3 128:10	30:9 31:17 33:4 33:11 34:3,7,22
ignores 43:18	impractical 48:15	including 18:3 19:3 78:11 101:3 104:4	indication 65:7 70:17 300:12	37:1 38:2,11,22 39:12,15,21 40:17
Illinois 20:18 126:5	impression 270:14	106:22 107:14 117:15 119:10	325:12	42:2,4,13 43:13 44:1,3,5,7,10,12
imagine 58:4 111:5	improve 176:9,9 226:14	144:22 146:17 223:6 279:13	indications 65:17 70:9	44:15 45:10,11 46:4 48:18,19
immaterial 135:3			individual 94:22	49:1,4,6,7,8,11,16 49:20 50:10,10,13
immaturity 131:10				
immediate 222:5 327:18 328:2,4				
immediately 112:10				
Immune 128:21				
immunoglobulin 128:22				
impact 68:18 111:18,21 113:8				

51:16 52:8 54:2,4 54:10 55:10,14 56:12 57:10,20 59:2 60:17 61:6 62:10,15,18,19,21 63:4,7 64:15 65:7 65:13,17,21 66:10 66:13,13,21 68:20 69:7,12 70:4,13 70:17 72:10 73:15 74:15 75:6 76:3 76:15 77:12 79:19 79:20 97:8 106:10 106:22 108:18 109:11 110:2,8,10 112:3,10 116:9,15 116:17,18,20 117:7,9,22 118:6 118:11,18 119:1,4 119:9,12,16 120:2 120:12,19,19 121:11,14,22 122:16 123:15 126:10 127:3,4 128:17 130:8,20 131:6,7,10,21 133:10 134:17 135:18 136:7,11 136:11 162:8 176:20 177:6,14 177:15 178:16 186:16,19,20 189:20 190:7,22 191:3,7,10,15,21 192:4,14,18,22 193:1,7,14,17,21 194:9,19 196:22 196:22 197:7,14 197:20 198:5,12 198:20 199:6 200:10 201:1,7,17 202:11 203:22 205:2 208:12,14 208:16,19,22 209:5,6,12 210:3 210:9,11,17 212:14,17 213:1,2	213:8,9,10,13,19 214:11 215:1 216:11 218:9,16 218:17 219:4,15 219:22 220:3 223:6,22 224:2,15 224:17 225:2,17 225:20,20,22 226:5,9,15,17,19 227:19,21,22 228:4,22 230:2,13 231:9,15 232:11 233:15 239:21 240:10,19 241:2,5 243:8,14,18 244:19 245:2 247:9,18,22 248:1 248:2,6,11,18 249:1,2,7,8,10,19 250:6,13 251:7,9 251:16 252:4,22 255:21 263:22 264:17 265:5,12 270:12 271:4,12 273:13,19 277:21 278:7,20 284:17 285:2 287:21 288:7 296:9,12,20 297:6 300:18 313:15,19 infants 34:13 37:18 39:18 45:13 55:16 57:12 62:9 64:2 64:21 65:14,16 66:7 69:15 70:18 74:17,19 75:1 76:9 77:1,2,13,15 77:15 95:6,20 108:7,19,21 114:15 115:3 121:20 126:14,22 127:9,16,16,19 128:3,13,22 129:4 132:13 134:9 178:2 179:9,22 188:19,21 190:7 192:4 196:21	197:5,12 199:3 209:3 211:18 212:22 215:4,9,10 215:12,14 216:2,6 225:6,8,12,13 226:3,10,18 229:11 232:16 240:17 280:11 301:17 infant's 37:21 42:16 infant-fed 215:7 inferior 198:10 inflammatory 176:18 inform 345:21 347:5 348:1 379:10 386:3 387:16 information 39:4 39:22 41:8 43:19 92:17 93:4 94:2 151:3 155:14 159:14 164:9,12 182:22 184:7 187:15 188:10 207:22 227:8 229:6 231:14 244:5 245:10,18 245:19 246:5,10 246:11,12,15,20 247:11 250:19 252:19 253:14 257:14,16 275:7 275:13,16 301:16 302:17 303:6 305:19 344:11,17 345:6,13 346:10 346:14 349:1 378:16,19 382:6 382:18 383:4,10 387:11 388:15 informational 393:8 information-shar... 363:17 informed 100:22	256:11 386:7 391:8 infraction 254:14 infractions 254:9 infrequently 344:7 ingredient 13:21 14:2 36:3 38:5 49:14,15 50:9 52:8 56:12 73:15 76:16 83:22 85:12 85:12,14 87:16 93:10 101:19 102:18 154:17 157:7 158:15,21 159:1 165:12 168:2,3,18 170:8 183:2,7,13 186:15 187:18 190:12 219:13 227:5 234:11,18,21 242:16 243:16 248:12,16 249:12 ingredients 20:12 40:19 49:3,7,19 49:22 50:2,3 57:16 80:13 81:17 83:4,16,20,20 84:4,9,15 85:1,3 85:18,22 88:21 89:4 90:1,8,12 91:12,13,16 93:7 93:15,19 100:16 100:19,20 101:3,5 101:7,13 102:1,5 102:10 103:3 104:8,14 109:14 111:12 116:14,18 139:21 142:4,22 144:16 145:13,17 145:22 146:5,13 147:2,5,8,13,15 147:19 148:1,3,20 149:8 150:22 152:10,13,20 153:1,12 154:2,6 154:9 155:11,17 156:3 157:6,11,12	158:12,14,19 159:1,5,16 162:3 163:7,9,10,20 164:8 165:19 166:5,7 167:7,10 167:19,21 168:8 168:14,21 170:4 170:13 171:2,13 171:15,18,21 172:6,9,10,13,15 172:17,21 173:1,4 173:8,12,14,19 174:2 186:12 189:12 191:19 197:7,11 198:5,8 208:12 209:15,21 210:2,7,20 219:8 219:19 227:20 228:17,21 229:12 229:16 230:2,10 234:6,8 235:2,6 240:3 242:17 243:13 244:18 245:2 249:1 252:2 252:3,7 277:22 278:9 inherently 108:18 initial 149:9 323:4 Initially 192:21 injunction 253:22 input 96:22 97:1 144:21 220:19 266:11 341:10 345:3,16 346:7 348:6 378:13 382:16,19 386:2 inputs 147:11,17 inputting 86:15 insertion 34:18 insignificant 158:1 insist 142:13 insisted 86:17 instance 89:22 104:1 129:1,17 149:12 166:6 instances 152:22 instinct 206:8
--	---	--	--	--

Institute 55:17 76:10 100:10,22 105:15 144:14 146:18 250:17 357:8	326:21 327:6,11 327:13,20 328:1 328:10,15 329:18 330:9,10 332:20 334:5 339:12 351:22,22 352:2 352:12,13,14,18 352:18,20,21 353:1 354:13 355:12,22 357:10 358:1,9,10,20 359:5,14 360:8 362:15 363:18 366:7 390:17	395:8 introduction 126:10 134:14 168:12 inventive 4:13 inventory 171:15 investigating 172:1 investigation 226:22 invitation 260:11 invite 32:16 155:9 invited 17:12,18 19:18 inviting 106:9 involve 240:2,5 248:12 involved 48:20 49:6 251:1 253:6 253:11 316:17 338:7 363:7 involves 109:1 involving 106:16 in-person 7:4 14:20 52:21 56:21 Iowa 18:7 irony 280:16 irrelevant 162:9 irrespective 383:13 ISC 223:20 224:12 224:18 Island 1:11 357:1 isolate 63:14 67:20 68:17 69:3,6,15 69:17 94:13 95:21 96:14,19 97:8 113:22 136:15 150:3,4 191:17,20 195:20 216:21 217:9 218:5,9 271:2,3 301:3 305:6,11,13,20 306:10,15 308:22 isolated 59:3 61:6,8 61:10,15 78:6 296:20,22 299:22 300:14 301:18,22 302:7	isolates 136:18 isomer 175:7 issuance 266:13 issue 24:16 33:14 49:6 61:16 70:6,8 80:18 89:8 94:11 145:8,11,21 146:2 146:6 150:2 158:8 164:21 172:1 219:9 244:12 258:1 323:14 331:1,9 340:2 373:11 390:3 391:4,19 issued 253:21,22 257:15 266:16 issues 11:12 19:2 20:3,14 25:5 26:7 45:2 67:3,22 69:22 87:14 94:17 97:4 98:2 149:12 183:11 246:1 248:22 249:11 253:6,8 254:9 258:12 301:2 302:12 316:16 337:19 340:5 344:22 346:16 359:10 378:21 390:21 394:6,11 issuing 351:6 italics 378:9 379:6 379:13 item 5:20 81:16 86:11 92:11 261:8 items 85:9,11 86:16 97:16 249:22 267:3 378:2 iterations 319:17 it'll 316:7 IUs 124:21 IV 377:18 i.e 184:3	January 265:18 329:13 Japan 75:8 Japanese 54:1 JAS 75:7 Jatinder 3:15 17:19 Jay 1:18 47:12,15 55:3 64:9 67:5 80:15 94:6 111:13 113:1 137:22 149:20 166:19 189:5,10 194:22 195:17 203:2,12 203:15 205:13 217:20 239:1,15 242:7 245:4 247:5 254:18 267:15 270:21 271:8 278:9 281:3 282:4 298:3 299:16 301:11,14 302:2 303:14 304:4 308:8,18 316:22 354:17 374:8 389:11 390:1 Jay's 5:11 Jean 1:20 32:9 33:21 44:22 74:2 121:8 131:11 194:21 219:17 222:1,15 239:3,15 247:4,5 259:10 262:14 264:22 265:1 278:5 311:20 316:22 334:6,7,10 376:4 Jennifer 1:22 2:20 274:4 317:1 342:9 342:17 377:3 384:21 396:8 Jenny 387:20 388:2 389:12,14 390:7 job 152:4 352:11 384:6 jobs 194:4 jocularity 169:17
--	---	--	--	---

Joe 314:6 316:21 332:18 334:4	355:18 356:11 kcals 129:18	159:10 160:18,19 161:10,19 163:16	394:11 396:9 knowing 178:12	326:9,18 331:19
John 1:18 4:7,8 6:8 11:10 12:7 13:15	keep 22:1 47:11 108:21 122:21	163:21 164:15 165:1,5 166:7	306:9 383:13 knowledge 179:8	347:8 370:2
17:10 35:19 36:18 44:19 47:17 52:2	150:20 151:2 205:5 211:13	167:5,6,20 168:7 176:2,3,11,12,13	191:4 195:9 213:13,15 218:20	379:13 384:13
53:6 56:6 58:18 73:2,9 78:2 98:13	238:5 279:21 321:19 322:22	176:16,19 177:19 178:10,21 179:15	219:3 222:14 knowledgeable	390:6,9
109:21 111:14 113:7 135:9	333:7 357:4 391:8 keeping 21:12	180:18 181:9 187:12,14 196:2	150:8 known 90:7 101:3	large 30:22 31:2,19
139:12,14 169:10 169:11,14 189:5	88:13 90:14 117:22 119:4	202:4,16,18,22 205:10,16 206:1	118:21 228:1 256:1	86:20 92:5 154:14
205:15 236:13 247:1 260:18	122:18 142:7 327:22 358:5	207:2,5,14,19 209:8 210:10	knows 12:10 24:13 Kong 202:13	343:6
269:9 274:22 281:8,19 282:22	keeps 140:17 361:5 Kemin 35:21 182:9	217:8 219:12 220:12,20 221:1	Kor 182:6 190:18 190:19,19 195:11	largely 159:3
286:4 294:18 311:15 312:15	kept 149:11 254:11 258:19 324:17	221:10,12,15,17 221:18 223:17	<hr/> L <hr/>	larger 307:16
366:13 368:5,6 369:3,18 371:14	key 156:14 255:21 kid 122:3	234:1,14 236:2 238:11 239:1,3,13	L 57:4,17 58:1,14	largest 103:14
372:11 381:22 384:15 385:14	kind 10:19 11:18 12:20 21:10,16	247:9 249:18,22 252:15 278:11	58:16 61:1 62:3	Lastly 212:3
396:3 Johnson 169:18	43:7 83:22 87:10 96:10 112:9,22	280:9 301:14 302:5,9,14,18	294:20 label 63:7 102:17	late 76:19 349:14
174:11,13,14 178:22 179:11	115:7 132:12 143:10 165:3	303:18,18 304:2 305:1,19 307:11	109:7,11,17 110:11,20 111:3,8	latest 66:11
180:3 186:15 John's 385:7	180:11 211:14 219:5 228:13	309:19 313:10 317:9,13 318:2,10	111:10 114:12 146:12 184:1	laughing 281:8
390:13,14 joined 18:8	230:8 260:11 289:14 302:17	321:10,22 329:3 330:14 338:15,18	258:9,10 259:1,4	Laughter 32:19
joining 20:5 joint 18:5,12	303:5 330:3,17 370:2,12 388:22	339:8,17,22 340:2 340:13,15,21	279:15,17,20 303:9	144:11 152:6
316:15 joked 91:10	389:4 kinds 320:1 396:5	341:1,4,5,11 342:1 354:1,20,22	labeled 38:10 83:16	281:6,12,22 292:1
JOSEPH 1:17 journals 19:14,15	knew 27:2 90:8 223:16	355:4,9 357:7 358:2 363:5,13	83:22 122:21 184:9 231:10	law 43:1 47:21 84:7
Judiciary 350:10 juice 52:11	know 12:2,11,15 23:22 47:18 48:14	364:6,9,14 366:7 367:5,17 368:15	110:11,20 111:3,8 146:12 184:1	101:11,18 102:11
jurisprudence 354:10	82:4,11 89:21 93:11 95:21 96:4	369:17 370:1,5,9 370:9 371:2 372:5	258:9,10 259:1,4 279:15,17,20	102:17 103:10
justification 160:9 justifies 83:19	99:14,17,18,22 100:1 106:5 107:9	372:14,15 373:13 374:10 377:11	303:9 label 63:7 102:17	104:10,11 190:9
<hr/> K <hr/>	110:13 113:1,15 121:21 123:12,16	381:2 383:17 384:2,9 385:9	109:7,11,17 110:11,20 111:3,8	201:21 243:1
kale 37:5 Karlin 349:18	123:20 124:17 132:12 133:5	386:7,11,13 387:7 387:8 390:14	111:10 114:12 146:12 184:1	250:12 279:8
350:2,4 354:17,21	142:11 149:15	392:11 393:6	258:9,10 259:1,4 279:15,17,20	301:7 350:11
			303:9 labeled 38:10 83:16	354:11
			83:22 122:21 184:9 231:10	laws 48:1 101:9
			Labeling 48:21 Laboratory 174:16	186:19 196:15
			lack 70:12 76:1 147:21 202:21	199:18 200:1,5
			225:2 280:2 lacking 307:18	lawyer 169:4
			lactose 64:13,17,17 64:22 65:2,5,5,8	186:10
			65:12 66:1 ladies 151:15	lawyers 86:20
			land 169:4 Lane 125:21	143:2
			language 83:11 265:21 266:1	lay 395:19
			323:10,20 324:12	laying 15:3
				LC 182:10
				lead 5:11 30:13
				36:16 57:2 59:12
				74:2 79:6 81:18
				132:7 264:8
				318:22 328:22
				357:22 377:2
				389:5 392:19
				leader 19:20
				leading 170:1
				191:6 208:19
				leads 351:20
				leafys 179:2

lean 116:4 211:14	189:16,19 193:3	Lindsay 150:10	167:22 168:4,6,18	290:5 296:5
leaning 325:5	255:4 257:8 259:3	304:19,21 306:18	168:19 170:5	300:11,21 309:7
learn 102:7	328:11,17 329:6	307:5,20 308:5,9	171:3 172:20	310:16 313:13
learned 101:22	329:20 330:1,13	309:2	182:15 183:8	listings 155:17
102:22 173:13	331:13	line 99:18 109:10	185:21 188:18	lists 87:6 90:1
learning 214:20	levels 57:11 117:7	138:9,10 249:5,6	192:12 193:6	100:18 147:11
228:3	118:15 125:3	249:15 358:17	197:1,6 209:21	242:12
leave 80:4 222:8	127:15,17 177:10	lines 9:16 54:6	210:1,21 211:14	liter 124:21 190:8
259:12,13 319:7	178:14 187:1	362:20	234:14 250:9	literature 23:14
350:21 368:10	189:13 190:8,14	linoleic 201:21	251:4,13 252:1,2	143:14 245:21
380:4 390:6	193:15 199:16,17	lipid 15:18	252:3 254:5,7,11	299:21
lecithin 185:13	199:21 215:13	lipids 117:18	261:17 263:11	little 32:15 34:17
led 57:21 148:2	254:21,21 255:1,6	lipofuscin 178:6	264:16 265:4,12	87:8 99:2 144:3
321:14 334:11	255:7,9,10 279:12	liquid 33:13	265:21 272:8	150:15 159:20
left 11:10 209:19	license 359:20	Lisa 2:16 4:19 6:6	273:10 274:21	165:4 183:10
211:15	Lien 116:3 125:21	7:6 13:14 14:22	275:2,11,22 276:5	187:10 188:6
legal 103:1 169:4	126:1 130:22	15:2 17:8 21:1	277:20 278:7	211:15 217:13
250:11 350:6	131:17 132:19	35:17 36:15 52:1	281:1 282:21	230:6 236:15
legally 106:15	133:6,19 134:13	53:2 56:5 57:1	284:18 285:3	270:8 280:16
142:20 190:11	life 9:22 10:8 20:6	58:17 59:11 72:22	286:4 287:17,21	299:18 315:20
359:11	20:9 30:1,2 34:3,6	78:1,20 310:4	288:6 289:8,16,22	338:4,18 350:13
Legislative 350:5	71:17 121:1,10	list 5:22 6:15 11:6,8	290:17 291:17,22	350:22 351:1
lends 175:11,18	122:17,20 126:16	13:21 14:1 16:4	296:2,8,18 297:4	355:19 366:3
length 23:11 258:4	127:15,21 128:20	16:15,18 36:2	309:13,15,18	370:6 382:1 396:3
266:11	148:7 161:1	38:21 40:17 43:1	311:12 313:11,14	live 210:22 341:22
lengthy 326:22	177:19 178:8,13	46:4,8 52:7,10	313:18 315:3	342:1 349:16
Lenore 140:1,7	180:7 192:19	54:22 55:13 56:11	337:13 375:6	liver 181:19
lenses 37:11	194:8 199:6	58:11 59:1 67:9	393:16	lives 199:12
letter 244:12	212:22 215:5,18	68:3 73:14 75:6,8	listed 38:9 41:7	livestock 165:9,15
245:13 253:21	216:3,14,17	75:16,18 76:14	43:17 75:5,8	living 208:17
257:15 386:10	241:17 242:2	78:8,11 79:14,15	118:9 145:1	210:14
388:6,11 391:5	257:22 258:5,8,8	79:17,22 81:16	161:18 183:13	LLC 35:22
letters 320:20	258:11	82:19 83:17 84:1	197:4 227:20	LMP 186:2
386:12	light 37:12 175:10	84:5,10,11,20	284:14	lobby 169:15
letting 121:6	181:13,13,14,15	85:2,6,8,9,21,22	listen 333:9	319:20 360:3
135:11	181:16,19,21	86:12,16 88:18,22	listening 115:6	lobbying 360:7
let's 13:5,6 21:9,12	353:21 366:3	89:3,9,20 101:14	236:10 275:6	lobbyist 357:9
37:2 56:4 58:16	liked 327:12	101:20 102:6	listing 13:22 16:17	local 202:14
70:21 77:22	331:15	104:16 142:16	39:11,19 40:12,13	locally 205:5
142:11 164:15,16	limit 198:8 221:4,6	143:6 147:17,21	40:16 41:16,18	located 356:22
166:3 259:19	257:4	150:16 153:4,5,8	42:5 43:22 60:22	location 116:10
286:3 289:7 294:9	limitations 309:1	154:6,8,15,19	84:22 167:3,3,14	logic 363:17
312:6 325:10,14	limited 65:12	156:6,9 158:7,14	185:12 186:12	long 8:22 13:1 82:3
377:13 381:5	309:12 383:12	158:19 159:1,5	261:21 263:14	87:6 90:1 96:22
397:21	limiting 119:15	161:19 162:1,2,18	264:6 265:19	134:19 167:11
level 37:18 89:1	120:7 309:21	163:12 164:6	266:5 270:16,16	178:6 219:10
124:19,21 153:19	383:2	165:13 167:4,12	272:12 277:16	229:21 234:10

235:5 241:17	186:18 201:20	189:18,20 190:5,5	108:11	297:12
251:1 252:13	220:17 221:1	213:16 214:7,12		mandatory 44:9
280:3 310:14	223:10 228:20	214:19 215:3,4,8	M	207:10 244:20
322:7 326:16,21	231:20 235:18	215:13,21 216:2	Mac 64:8 92:13	252:2
382:13 386:21	242:5 255:22	216:11 218:21	156:18 200:18	manual 316:13
longer 109:5	258:16 278:12	219:2 275:2 276:1	257:18 285:8	317:18 321:12
140:20 190:12	279:3 304:6	276:5,12 277:19	316:22 365:20	324:7,21 326:10
213:14 229:15	339:19,22 384:2	277:21 278:6,8	macronutrients	326:11 331:20
long-chain 32:1	394:17,17	279:13 280:19	108:21	334:16 342:14
long-term 51:9,13	lots 59:21,21	lutein-deficient	macula 181:11	343:8,18 346:2,21
107:8	Louisiana 327:1	180:1	macular 37:10	347:6 348:10
look 5:21 46:7 63:6	love 82:4 154:12	lycopene 41:4	181:8	364:19 365:10
90:21 91:4 127:14	203:4 355:2	47:16 52:1,3,6,9	Madam 140:21	371:21 380:2
127:22 148:11,19	Lovely 99:12	52:11,13,18 53:6	Mahalo 342:8	384:4,12 394:15
155:10,10 158:20	low 57:11,14 64:3	53:9,21 54:2,3,13	mailing 375:6	manufacture
161:17 166:13	77:2 125:3 127:12	55:3,12 56:1	maintain 151:6	120:22 182:16
170:3 177:1,7,17	192:16	106:13,22 177:10	321:20 347:9	228:17
179:2 180:7 183:3	lower 33:7 217:13	213:16 214:7,13	379:14	manufactured 48:4
189:2 190:2	217:13	218:21 219:3	maintained 88:9	95:22 254:12
209:10 271:13	lowered 33:16	283:3,5,8,12	maintaining 142:8	manufacturer 46:3
275:9 280:11	lower-level 393:14	284:14,16 285:1	316:12	48:10 63:14 133:9
283:15 355:1	LRI-2 85:16	lysine 57:6	maintains 8:8	135:13 158:21
looked 90:2 92:12	lucky 17:16	L-carnitine 56:5,7	266:6,16	221:4,6 231:4
185:10 204:18	lunch 5:6 99:8	56:10 57:2 58:11	major 143:14	242:12 244:17
233:14	222:3 237:3 239:9	58:13 61:19 62:4	177:8 181:6 199:1	249:8 258:2 259:2
looking 43:9 50:22	239:9 260:2	130:17,20 131:4	200:11 210:11	manufacturers
68:12,13 69:2	Lundgren 151:13	192:12 193:5	220:21 336:18	27:19,22 33:5
80:17 83:9 136:22	169:19,21 174:9	195:5 286:10,15	majority 87:20	45:10 49:8 50:11
157:10 166:1	lutein 35:7,18,20	287:20 288:5	154:14 210:6	60:6 85:20 107:11
167:3 174:17	36:1,19 37:6,10	297:18	394:12	116:17 133:11
233:11 250:1	37:17,19,20 38:4	L-lysine 62:14	maker 372:7	163:9 208:22
252:7 254:2	38:21 39:4,5,12	L-methionine 58:1	makers 212:14	219:2 223:4 227:6
256:10 271:21	40:16,18 41:16,18	58:3,15,19,22	make-up 53:20	228:16 229:7,15
275:16 310:8	42:12,14,18,19	59:14,20 60:8,16	making 19:16 33:4	230:14 231:15
336:3 368:22	43:22 44:21 45:10	60:21 61:13,19	48:7 83:19 116:9	233:20 243:15,15
381:9 389:18	51:22 55:22	62:6,13,21 63:2,3	234:7 302:3	243:16 248:19
looks 239:4 316:18	106:14,21 174:20	108:5 114:11,14	319:13 356:4	251:17 275:7
loophole 86:4	174:22 175:7,15	114:20 130:14,16	384:10	manufactures
lose 141:8	175:20 176:1,3,8	130:21 192:2,7,11	malaria 26:17	218:16 241:19
lost 30:2	176:14,17 177:2,4	289:10,11,16,22	maltodextrin	manufacturing 8:7
lot 30:16,19,20	177:5,9,12,18,20	291:4,14,18	159:12	9:17 24:22 25:5
31:1 81:21 83:1	178:2,3,10,13,13	292:11,20 293:1,2	manager 356:20	31:14 32:5 60:10
98:2 106:5 121:17	178:14,21 179:8,9	293:3 294:12	357:4	61:9 63:15 76:4
121:18 149:7	179:12 180:9,14	295:22 296:8,10	managing 392:12	79:5 157:17 184:8
164:8,12 170:20	181:11 182:13,17	296:18 297:5	mandate 47:4	195:9 217:8
174:19 175:11,13	183:15 184:2	299:1	mandated 39:20	240:13,21 246:12
176:2,5,11,16,18	185:18 186:22	L-methionine's	79:18 116:15	246:17 248:9

258:16 280:12 306:15 map 89:11 166:16 MARAVELL 1:19 7:9 10:21 11:1,5 28:21 29:9 34:16 53:5 122:15 123:3 123:6,18 150:13 159:19 203:13,16 204:11,14 231:7 261:11,13,20 262:1,19 263:15 267:21 268:15 271:7 272:17 274:6 277:1 282:18 283:7 284:9,15 285:20 286:5,7 287:11 288:21 290:11,16 290:20 291:1 292:8 295:14 311:3 312:22 314:12 368:6 376:9 377:13 381:8 385:7 387:6 389:13 393:2 397:9 marigold 183:17 184:4,15 marigolds 37:7 280:15,18,21 281:4 mark 188:22 market 49:10 69:4 107:10 109:8 113:9,17 114:5,9 133:17 200:21 210:5,12 230:19 240:11 241:8,10 248:1 253:10 303:8 marketed 302:21 marketers 223:5 Marketing 1:1 2:18 marketplace 111:22 145:16 210:18 278:14	300:8 markets 103:14 203:19 Marnie 349:18 350:4 Marsha 222:22 235:14,15 Marsha's 235:15 Martech 264:5 Martek 359:22 Maryland 20:8 massive 104:9 Master's 20:18 105:16,18 match 193:15 material 7:8 35:18 36:22 38:9 39:14 41:6 55:9 68:18 68:19 108:4,12 152:16 156:8,9 185:3,6 187:17 195:4 196:18,19 261:7 263:9,14 268:9 269:9 272:9 277:17 282:22 283:5,9,13 287:17 289:9 380:2 materials 4:15,16 5:8,15,22 6:2 21:14,20 24:6 29:11 35:6,11 41:3 43:9 44:2 47:14 48:1 83:2 86:2 90:6 91:15 92:12 93:22 97:4 97:6 102:8 115:19 125:6 133:16 144:14,20 147:13 150:18 151:4,22 153:19 154:8 161:18 185:1 228:12 261:2 263:17 279:10,22 300:16 311:14 maternal 208:19 224:16 225:2 matrices 23:17,18	matrix 24:2 matter 47:3 98:17 102:18 130:22 162:7 237:5 259:2 260:14 266:14 315:8 341:17 361:20 386:20 392:11 398:6 maturation 129:2 131:1,20 matures 131:6 maximize 366:8 maximum 335:20 McEVOY 2:10 meager 147:18 mean 81:2 114:13 160:6 168:18 181:4 186:14 189:14 206:4 218:2,8 253:17,18 279:5 291:14 327:14 367:6 370:13,15 371:4,7 372:2 380:17 387:13 meaning 153:12 means 31:19 92:19 100:14 126:21 205:22 258:8 267:9 301:4 369:13 370:5,6 380:18 385:1 393:21 measure 216:9 measures 24:19 meat 57:8 mechanics 390:8 mechanism 86:8 347:10 379:15 384:18 mechanisms 23:19 227:1 243:3 medical 17:22 18:4 18:9,16,21 42:11 77:15 112:14,18 114:6,7 135:14,19 136:9,12 138:5,5	138:7 139:1 medically 135:21 Medicine 18:11,20 55:17 76:11 250:17 meet 19:17 48:12 127:4 137:16 192:7 193:3 236:12 240:22 meeting 1:4 4:4 6:22 52:20 56:19 61:4 78:19 82:9 94:4 106:3,4 118:18 135:17 136:21 137:7 152:3 195:4 226:2 239:10 317:12 318:7,8 321:4 326:19,19 329:9 330:11,19 334:14 335:3,11 336:1,21 337:11,12 338:21 338:21 339:17,19 341:14 344:3 348:13 350:16,18 357:21 374:18 375:4,5 385:4 386:10 387:12 388:10 390:19 391:17 392:10 meetings 60:14 155:5 260:5 317:22 330:5 334:2,18 335:1 339:8 344:6 345:8 346:13 347:2,4 353:15,17 360:16 374:15 378:18 379:7,9 386:8 387:5 391:9 392:3 meets 28:13 301:6 303:13 MELISSA 2:14 member 5:2 19:11 100:9 316:14 319:20 327:18 328:4 344:4	351:18 352:1 357:8,19 360:5,22 380:3 members 1:13 4:5 5:21 21:2 75:22 86:17,18 99:9 151:20 233:14 238:17 315:10 316:5,21,21 320:3 321:13 324:10 325:16,19 328:2 329:16 330:7,7 335:7 337:17,21 338:13 343:5 348:5,14 349:3 353:6,11 355:20 357:3,6,14 360:3 360:7,17 363:1,12 385:2 387:4 388:20 390:18,22 395:3,9 member's 352:14 memorialized 390:12 memory 214:20 menstrual 95:13 mental 128:12 mention 41:1,2 99:8 142:14 256:20 mentioned 39:8 41:17 70:15 90:12 118:4 122:12 134:12 180:21 200:1 206:15 233:18 319:4,16 320:9 332:8 369:8 384:22 390:7 meshing 392:2 met 141:7 225:16 367:2 metabolic 44:4 65:19 70:19 metabolism 129:8 meter 143:11 methionine 57:7,18 58:17 61:2 62:1,4
--	--	---	--	---

62:16 63:5 70:22	178:12 185:19	329:21 335:19,21	32:12 58:13	264:15,20 265:2,2
72:17 111:17	186:22,22 191:2	340:15,16 354:22	293:16 342:8	268:1 269:8,10,11
113:1,12,16	192:13 193:6,9,15	357:1 361:18	355:2 396:14	269:13,17 272:8
191:12 192:5	208:13 211:3	366:10	mom's 215:1	272:12,12 273:8
202:22 294:21	213:6 215:1,2	misbranded 199:21	monkeys 179:3	273:10,12 274:20
302:21	224:5,15 225:17	Miscellaneous	180:5	275:6,22 276:3,4
method 39:3 81:6	225:22 226:21	346:3 378:8 379:4	monomers 128:15	276:10,11,18
348:8 389:20	227:1 228:5	misinformation	month 215:5	277:17 278:4,6
393:21	232:11 242:1	191:13	months 34:10,11	282:4,21 283:7
methodology	milk-based 75:4	misinterpreting	71:9,11,13,18	284:13,14 285:1,4
307:14	129:15 133:21	270:18	72:2,3,5,8,8	285:7 286:3,8,10
Mexico 317:22	193:1,17 231:12	mislead 114:18	120:22 121:1	286:13 287:17,19
319:4 321:3	milk-fed 215:14	misleading 110:18	122:18 126:16	288:3 289:8,13,15
326:19 328:13	milligrams 129:18	misled 264:12	134:20 194:7	289:21 290:6,7,20
Miars 139:13 144:7	million 210:13	misplaced 101:1	199:12 215:18	291:4,12,13,17
144:9,12,13 149:2	Mills 359:17	misreported 253:1	225:13 255:19	292:2,10 293:21
149:13 150:7	mimic 31:18 117:7	missed 132:20	moonwalked	294:11,20 296:2,5
151:2,10	mimicked 83:12	164:17	323:13	296:7,15,17 297:4
mic 156:10	mind 41:12 87:3	missing 113:13	morning 4:3,6,17	297:8,9 300:11,22
Michael 323:12	92:15 141:15	358:8 387:15	6:9 7:5,10 14:21	302:8 308:20
Michelle 2:12	144:3 279:22	mission 343:10,19	17:12 22:7,8	310:13,16 311:12
41:11 82:20 99:20	322:11 327:14	344:14 382:2,2	36:14 52:22 56:21	311:20,22,22
144:9 315:19	mindful 51:20	mistake 141:11	60:2 77:12 99:1	312:4,6,7,14
322:4,11 364:6	203:5	misunderstanding	105:12 112:3,18	313:11,12,13,16
366:3 388:8	mineral 74:5	351:21	126:1 135:10	313:20,21 314:1,2
microalgae 40:7	251:12	misunderstands	139:16 144:12	314:5,6 315:3
microbiological	minerals 165:7,8	353:7	151:15 174:13,20	363:11 364:10,12
240:9	165:14,20 217:11	misunderstood	182:7,20 196:13	364:18,21 365:1,9
microbiologically	217:17 265:20	299:10	223:1 250:3 261:6	365:17 371:12
30:7	267:18	mis-hear 206:18	303:15,21 304:6	372:8 374:4,7
micrograms 190:8	minimal 42:18 70:6	mitochondria	398:3	375:19 377:3,7
microphone 315:18	183:18 258:22	129:11	morphological	379:20 388:10,21
361:4	259:3	mixed 131:2	179:5	395:4 396:9,10,19
mics 32:21	minimum 60:16	134:22	mortality 26:8	396:21 398:1
middle 209:22	193:3 213:9 251:5	mixture 25:4 45:11	mother 37:21	motions 80:2
279:15	258:10 259:3	mixtures 23:15	110:9 126:22	261:14,16 292:4
Miles 2:10 387:20	335:20	mix-ups 295:1	194:15 224:20	293:10,16 294:1
milestone 141:18	minority 26:13	model 70:1 96:4	mothers 191:1	motion's 375:16,16
milk 31:18 37:18	minute 57:17 81:15	models 69:10 95:2	224:22 226:3	motivation 301:15
37:19 38:2,5	98:11 99:21 185:9	moderating 188:21	232:15	motor 193:12
42:15,17 51:5,11	259:16 316:7	modified 49:15	mother's 225:4	move 5:13,20 22:4
57:14,15 64:14	337:11 353:3	104:5 333:17	motion 11:6 16:17	35:11 47:16 52:1
66:4 116:11 117:8	375:5 392:18	339:2	40:14,16 60:20,22	56:5 58:16 72:19
125:1 126:17,20	minutes 58:15 92:9	modify 5:5 374:7	61:5 80:3,6 261:7	78:1 91:6 127:5
127:12,13 129:22	97:16 98:12 99:12	modus 336:22	261:19,20,21	128:14 134:13
134:1,4,10 157:18	166:22 216:13,16	molecules 211:3	262:2,7 263:9,10	187:19 238:16
157:19,22 158:2	216:19 315:6	moment 21:14	263:14,17 264:14	239:10 259:16

277:19 283:8	36:1 40:17 43:1	173:5 175:4	193:9 194:11,16	249:11 265:21
284:15 319:10	52:7,10 54:21	Nature's 135:13	250:15 359:6,14	266:1 292:6
320:14 332:10	55:18 56:11 58:11	nearly 74:10	needing 16:2	316:13 317:22
362:12 364:1	59:1 73:14 75:16	139:18 350:9	143:21	319:4 321:3,18
moved 168:7	76:9,11 78:8,11	necessarily 133:1	needs 23:12 104:10	326:18 328:5,12
187:13 273:17	79:15,16,22 83:17	304:7 370:17	110:10 115:1	334:18 342:14,17
283:11 286:14	84:1,5,10,11,20	necessary 30:5	127:4 137:17	346:4,22 354:6,8
288:4 292:20	85:2,8,9,21 86:12	31:13 62:8 112:6	155:7,8 165:12	362:21 367:13
365:4,8	86:16 89:9,20	112:12 184:17	168:5 169:5 181:3	375:16 378:9
moving 47:12	101:14,20 102:6	197:7 209:5 210:2	193:14 211:18	379:5 386:16
99:10 238:6	104:15 153:4,5,8	210:20 276:19	225:16 226:3	395:10
MROs 152:17	154:6,8,15,18	331:11 345:7	232:18 234:19	news 154:4
153:22	156:6,9 158:7	346:11 378:17	240:22 241:1,1	nice 178:18 227:14
much-improved	161:19 162:1,18	392:8 394:8	360:9 396:4	Nicely 105:1
355:1	163:11 165:13	necessity 74:21	negatives 160:15	NICHOLAS 1:19
multi 153:7	167:4,12,22 168:4	76:6 344:21	neglected 256:20	Nick 7:7 13:6,12
multiple 23:16	168:6,18,19 170:5	need 5:7 10:15 12:1	neither 63:14 74:5	15:3 28:20 32:10
85:18 86:11	182:14 192:12	13:2,7 21:19,20	244:18 270:10	33:22 34:15 53:2
167:19 204:11	193:6 209:21	23:20 32:4 38:3	neonatal 18:19	55:2 121:8 122:14
293:22 318:3	210:1,21 211:14	42:7 51:14 54:9	19:2,3 65:3	149:20 150:12
multi-component	250:18 251:19	54:18 66:15,20	neonate 25:1	159:18 203:11,15
154:21 155:13,15	252:6 261:17	68:20 70:16 71:12	neonatology 18:5	231:6 259:9 261:9
164:7 168:13	264:16 265:4,20	93:18 96:16 99:22	18:18 63:20	267:20 271:6
multi-ingredient	275:2 277:20	112:3 114:7 115:3	neural 42:8,13	276:22 283:6
153:7	278:7 281:1	137:13 138:5	176:1 181:5	368:4 381:6 385:5
	284:17 285:3	139:1 143:1	215:19 216:7	391:21 392:17
N	287:21 288:6	154:18,22 155:9	neurotoxic 106:16	nickname 91:14
N 3:8 238:1,1,1	309:13,15,18	160:5 163:13	never 41:12 84:22	Nick's 203:11
name 100:5,8	313:14,18 341:9	166:11,19 197:12	97:5 120:13	NIEHS 70:2 95:19
105:13 116:6	342:22 343:22	202:1 209:5	123:11,15,21	night 26:7
144:12 151:16	345:4 346:8	211:19 222:6	140:11 141:16	NIH 255:16,16
154:2 169:20	378:14 381:19	223:11 227:20	153:15 161:15	nine 337:7 366:17
182:8 190:19	388:5 389:15	230:14 234:5,8,16	180:6 234:11,12	366:22 368:17
196:13 208:8	393:16	235:4,6,18,21	247:19 264:3	369:5,6,9,11
223:2 350:4	nationally 19:10	236:2,5,6 239:12	298:10,17 306:14	373:12,17 374:8
356:19,19	227:12	259:11,19 261:18	nevermore 140:19	374:19 375:10
named 18:18 140:7	natural 38:18 43:4	283:16 288:10	141:6 142:2	nitrogen 30:19
names 336:13	53:9 100:15	291:16 292:3,6	new 6:18 42:6 49:7	nobody's 217:2
name's 212:12	103:14,19 104:21	302:8,16 307:8	49:10,14,19 50:9	nodded 139:18
naming 84:2	109:14 110:20	320:11 325:9	51:10 66:17 76:22	non 37:7 39:6 40:1
napping 139:18	111:3,8,11 118:5	329:21 330:12	112:16 116:18	40:5 45:15 84:8
NARC 322:19	137:12,15 139:15	335:9 340:7 372:4	171:4 182:21	84:12 138:16
narrowing 309:1,7	153:10 156:1	377:10,11 380:5	188:18 205:3	163:6 241:22
Nation 319:12	159:3,6,9 166:4	382:11 392:5,6	227:3,5 234:18	291:16
National 1:2,4,10	173:9 177:16	394:16 395:4,5	235:3,6 240:2,6	non-agricultural
2:10,15,16 6:15	naturally 37:4	needed 5:5 26:1	245:1 247:21	289:17 290:14
13:20 14:1 19:5	nature 10:14 94:13	137:16 156:5,7	248:1,6,12 249:1	291:15

non-agriculture 104:13	173:12,18,22 184:22 192:10	374:18 375:4	391:18	126:8,10,18,22
non-bleached 41:4	196:17 223:8	notification 49:9	numbered 365:12	128:5 133:8,9
non-essential 43:16	224:11 225:5	49:16,17 50:15	numeral 377:18	134:21 135:5,12
non-infant 80:11	224:11 225:5	118:7 163:5	numerous 19:14	136:7,11 138:22
non-listed 197:13	316:10,13 317:17	197:15 213:4	41:19,20 102:2	176:7 180:12
non-organic	321:21 323:3	235:8 240:11,19	198:3 358:10	191:7 194:14
104:13 138:15	325:16,19 326:11	241:7 244:19	nursing 212:21	197:10,12 208:20
198:17 209:15	326:18 328:21	248:1,3,11 249:3	nutrient 10:4 43:11	209:2 212:13,15
210:2,7	332:15 334:1,17	249:7,10 252:14	43:12,15 51:4,10	213:12,15 214:11
non-synthetic 41:7	334:17,22 335:7	252:16 256:18	64:1 75:2 76:12	214:11 223:5
45:5 58:7 79:12	335:22 337:7,15	257:3 388:19	118:16 119:2	224:16 225:9
79:15,17,21 81:1	337:20 338:13	notifications 239:2	129:2 132:11	226:10 228:1,4
96:21 156:7 166:4	339:10 341:14	241:4 248:15	135:1 136:6 183:4	250:14 251:20
188:4 293:2 309:3	342:2 343:11,19	notifier 246:3	197:4,13,17,18	256:2
309:14	344:7 346:4 347:1	noting 338:9	200:6 209:12	nutritional 15:20
non-synthetically	347:2,3,12 348:1	339:11 340:11	221:19 227:13	42:11 116:16
74:12	348:5,14 349:3	November 35:20	230:21 234:13	118:16 119:21
NOP 1:2 6:20	350:16 351:4	56:8 329:13	240:9 254:21	127:4 132:3
14:18 36:8 56:18	352:16 353:16	no's 263:8 269:7	255:7 256:12	135:14,19 136:5,9
59:8 73:20 78:17	355:15,20 357:4	273:8 274:20	265:20	136:12 137:16
88:9,12 148:1,22	357:22 359:16	282:21 289:7,8	nutrients 39:2 48:2	139:1 198:6
160:1 171:1 192:1	360:3 363:1,12	295:21 311:11	50:21 55:13,16	208:20 212:18
223:9 265:10	374:15 375:1,8	315:2	76:15 130:2,7	226:3,15 241:1
317:16 321:22	378:9 379:6,7,8	nucleotides 72:19	137:1 139:2	nutritionally
323:4 326:5,17	379:17 380:21	78:1,3,6,10,22	191:10 193:21	135:21 160:2
327:15 331:11	385:2 386:8 388:5	79:7,11,18,22	194:1,11,16,18	198:10 226:6,20
335:21 337:14	391:9 392:3 394:2	80:11,15 81:7,11	197:2 198:2,4,8	232:4
345:14 347:12	395:9,18	126:12 128:15,17	199:16,22 200:15	Nutritionals 116:5
355:16 356:4	NOSBs 86:14	130:2 261:3	202:21 207:15	116:8
357:15,18 360:4	87:15	number 19:11,15	208:11 211:1	nutritionist 190:20
375:8 379:17	nose 136:3	21:4,6 22:12	212:2 213:11,14	208:9
382:7	notable 339:14	38:10,11 79:9	213:20 221:7	nutritious 232:7,12
normal 128:9	notably 333:16	87:4 99:13 164:5	223:21 224:7	nuts 156:12
180:8,8 240:16	338:6	212:21 214:5	225:15 229:9	nutshell 147:1
normally 29:1 38:4	note 7:14 106:20	238:21 293:16	250:12,21 251:4	244:22
215:4	173:18 198:1	307:13 326:16	252:1 256:10	
nos 397:22	281:9 318:4	328:7,19 335:4,12	258:9,10 259:1	<hr/> O <hr/>
NOSB 1:5 43:6,10	330:22 358:7	335:17 336:10,12	266:2 278:20	O 238:1,1,1
90:2 101:14	391:16	336:15,17 337:2,7	nutrition 17:21	object 329:4
102:19,22 106:3	noted 9:2 215:21	337:17 362:20,20	18:6 19:3,4,13,22	objection 13:5
107:15 145:12	notes 82:2	366:15,17,20,22	20:4,14,17,20	objections 322:21
146:3 148:1,6	notice 63:7 220:18	367:3 368:17	46:21 48:21 62:16	objective 356:4
153:19 154:20	244:5,12,20	369:5,6,9,10,10	63:20 66:6 69:13	obligate 116:17
155:5,21 168:5	245:19 248:20	369:11,12 373:12	70:4,11 71:7	obligated 221:8
170:3 171:12	249:5,9 256:19	373:12,17 374:8,8	74:22 105:17	obligations 344:3
172:2,14,19 173:5	291:7 305:1 335:3	374:19,20,22	106:10 116:20	obstacle 93:16
	335:6 337:11	375:9,10 388:17	118:18 126:4,6,7	obtain 85:22

obviously 136:8 138:13 149:13 204:17 207:4 221:5 228:20 278:11 366:6	36:18 41:12,14 53:5 64:4,8,8 67:6 71:2 73:3,6 81:10 82:2 86:13 88:7 90:18 96:12 97:14 139:9 142:19 144:4,5 150:11 151:14 157:3 166:20 167:1 201:15 203:11 204:15,16 206:12 217:19 218:19 222:17 235:15 236:16,21 238:15 238:19 239:14 242:13 245:22 246:8,22 247:3 254:20 259:11 262:1 267:19,19 275:4 277:18 289:5 291:10,20 292:16,19 294:3,9 294:14,15,20 296:17 297:3,8 305:6 307:1,6,21 307:22 308:2,3,5 308:18 310:10,11 310:15 311:16,17 312:5 324:18 328:7 330:4 342:20,21 343:15 343:16 356:15 369:21 374:1 383:22	once 21:17 88:5 139:15 173:11 297:19,20 318:3 331:11 onerous 171:4 ones 22:18 41:21 362:21 one's 37:15 one-offs 11:20 one-paragraph 391:5 one-size-fits-all 172:12 ongoing 392:13,14 OP 151:15 open 143:7 241:19 353:5,15,20 394:5 opened 122:22 opening 6:21 14:18 36:9 52:19 56:18 59:9 73:21 78:18 openness 353:19 opens 142:15,15 operandi 336:22 operating 47:21 163:14 192:20 279:6 operation 387:18 operations 167:11 316:11 operator 252:15 opinion 50:20 65:16 69:5 74:21 110:5 113:22 131:7 132:5 230:8 230:8 231:19 232:13 339:16 369:2 opinions 146:9 228:19 opportunities 92:10 344:12 391:7 opportunity 104:22 169:20 182:11 223:7 233:1 236:19 279:19	303:20 324:22 325:2,11 335:8,16 344:15 349:2 350:3 355:20 360:17 362:22 363:2,16,19 392:19,22 394:22 oppose 211:7 354:11 opposed 15:8 39:19 43:22,22 148:21 327:5,22 opposing 193:20 optimal 72:9 116:19 118:17 183:5 194:16 225:9 optimum 194:11 option 83:21 84:2,2 84:3,6 86:16 87:7 87:9,10,12,21 88:1,2,4,11 89:16 93:5 120:15 142:20 146:14,16 146:21,22 148:7,8 156:14 170:18 171:6 212:21,21 232:1,3,14 233:2 372:7 374:2 optional 76:16 options 87:5,6 93:16 144:21 170:19 232:13 233:5 335:19 orange 213:22 oranges 175:5 order 4:5 5:17 27:13 30:6 73:4,8 82:19,20 100:4 116:19 136:4 220:12,15 222:8 261:5 271:17 296:4 317:5 335:13 349:22 371:17 orders 199:9 ore 252:20	organic 1:2,4,10 2:11,15,17 40:18 43:4 44:1,12,16 68:8 80:12 83:8 83:16,17 84:1,9,9 86:6,18 90:15 96:16,17 97:10 100:12,14 101:1,4 101:6,15 102:5,10 102:16,17,20 103:3,7,9,22 104:8,9,15,18 106:6,15 107:2,16 109:3,7,8,11,13 109:14,17 110:7,8 110:11,12,21 111:6,10,11 114:12,14,19 117:5 135:14 136:22 138:17 142:6,8 145:16 146:12 147:20 151:18,19 154:11 154:18 160:6,16 160:22 161:6,7,11 162:3 163:7 165:12 167:22 169:21 170:1 171:8,10 182:14 182:15 183:6 186:1 191:3,15,18 191:20 192:9 194:19 195:6 196:18 198:12,15 198:19 200:10,20 201:7 202:11 203:22 205:2 207:6 208:11 209:16,20,20 210:3,5,9,10,12 210:13,15,17,18 211:16 212:14 223:21 231:10,14 231:20,21 232:3 232:14,21 255:1,3 270:14 277:22 278:8,13 279:15
---	--	---	---	---

281:2,4,15 298:11 298:18 300:6 301:4 302:22 303:9 304:5,8,12 305:17,20,22 306:3,15 307:9,10 308:11 309:14,22 319:12 321:2 323:16,21,22 324:2 332:3 341:9 343:1,6,9,12,22 344:1,13,18,21 345:4,10,12,17 346:8,18,19 348:2 348:6 350:6 351:17 357:5,16 359:4 378:14 379:1,2 381:19 388:5 389:16 391:3 organically 37:8 38:10 43:2 147:2 147:5 280:22 309:13 organics 100:18,20 101:12 140:10,15 140:19 141:5,6,16 141:16 142:2 144:14 339:17 organic-labeled 38:11 organizations 43:20 76:4 82:18 146:20 147:1 152:16 327:1 339:12 358:11 organization's 146:16 origin 42:21 original 61:5 187:12 300:10,21 354:5 originally 328:12 OTA 90:18 152:12 160:18 163:2 171:13 322:20 350:9,16 355:5	OTA's 155:3 ought 12:15 68:14 outcome 24:19 25:4 outdated 198:9 outline 350:22 outlined 66:20 70:19 outreach 163:4 outside 88:14 279:4 344:8 347:3 356:4 379:8 385:3 387:4 outweigh 50:21 overall 44:7 83:2 152:21 170:7 392:2 overbroad 354:14 overlook 324:2 oversight 103:6 over-exposed 255:11 over-fortification 42:3 oxidation 30:13,15 30:17 31:22 32:3 119:15,19,20 120:7 121:16,19 198:22 201:16,22 202:6,18 257:21 oxidative 199:14 oxidize 120:20 121:18 oxidized 34:13 121:21 122:11 199:2 oxygen 30:11,20 117:14 o'clock 398:3	palm 118:5 palmitate 6:10,14 7:21 9:6,11 10:3,5 10:6,18 11:6,8 13:8 15:6 22:5 25:14 27:12,14,15 28:22 29:4 31:13 32:6 34:5,19 54:6 107:20 117:16 118:21 119:22 120:6,17 121:13 125:10,14 199:5 199:13 202:1 203:20 204:17,20 205:9 224:4 233:12 261:9,12 261:17 262:3,9 263:18 264:15 265:3 267:6 268:1 271:11,16 pamphlet 169:13 panel 3:14,19 245:12 panels 20:13 70:2 paper 335:10 paragraph 373:17 parcel 85:4 parenteral 19:4 128:4 parents 116:12 part 45:13 85:4 92:4 114:5 118:16 120:18 125:12 149:17 152:21 160:4 161:1 171:18 175:1 184:3 187:14 200:3 215:22 219:13 245:7 246:9 251:6 271:18 274:2 279:9 298:9 299:7 299:14 316:20 345:9 367:13 369:10 374:20 380:12,14 381:17 382:13 383:16	384:1 385:12 386:18 390:18 partial 225:21 partially 93:20 162:15 participant 144:19 participated 70:2 particular 31:22 35:3 82:19 115:11 209:14 219:2 227:13 228:12,14 244:3,9 246:7 267:3 319:17 321:15,20 325:13 326:7,8 331:12,15 333:19 334:12 349:9 351:14,15 351:19 particularly 34:21 99:19 233:11 348:3 392:9 parties 351:10 partner 200:12 parts 37:22 143:7 157:4 party 36:6 56:15 59:6 73:18 78:14 169:15 pass 4:8 269:7,8 367:19 398:1 passed 197:1 208:17 388:10 passes 263:10 273:9 284:13 311:12 passionate 15:7 231:22 pathways 215:20 pattern 99:16 pause 32:11 PBM 116:8 117:6 PCC 103:13,17 PDC 384:4 PDS 384:5 pectin 41:3 309:16 pectines 186:3 pediatric 18:2,6	19:12 20:3 126:8 135:14 pediatrician 194:8 Pediatricians 71:4 Pediatrics 5:1 17:20 18:10,17 46:15 224:13 Peggy 139:13 144:7 144:13 148:17 149:21 151:9 penalties 253:11 pentameter 143:21 people 22:16 51:8 53:14 82:17 88:8 88:10 89:5,7,16 96:12 99:18 111:19 142:13 193:20 197:3 203:5 209:17,19 209:22 210:14 211:7,13 212:18 217:1 245:12 255:17 258:16 265:14,17 299:5 299:10 304:6 337:1 338:17 339:5,11,20 340:3 349:15 359:3 369:15 373:9,14 395:15 people's 395:12 peracetic 147:15 perceive 81:6 382:5 perceived 64:20 354:12 percent 26:10 64:16,20,22 66:12 66:16,17 70:14,15 103:2 104:1 112:5 119:17 142:12 177:18 201:18 205:4 210:5 321:8 percentage 31:20 64:12,14 111:19 114:8 231:9,14 perfect 142:10 210:22
---	---	---	---	--

Perfection 141:7	351:10	petitions 86:11	385:11 393:21	112:12 120:20
perfectly 152:12	pertaining 345:11	93:6 106:9 107:19	placebo-controlled	129:18 132:5
perform 113:10	pertains 340:9	148:20 149:7	176:6	165:2 166:10
performance	Pesticides 146:18	164:3 191:9,11	placed 321:9	172:11 188:16
226:15	petals 184:16	193:21 194:18	322:13 323:18	190:4 219:6
Perinatal 18:19	petition 4:16 5:15	195:14 200:6,14	324:6,9 337:12	221:11 223:15
period 6:22 14:19	6:9,10,13,19	201:14 208:11	375:6	235:18 241:16
36:10 52:20 56:19	13:16,18 14:10,12	210:16 211:8,16	places 258:16	246:9 265:9
59:10 71:8 73:22	14:17 15:17 21:14	211:17 223:13,19	Plain 63:17	266:15 267:22
78:19 95:13 99:11	35:20,22 36:7,12	224:7	plan 93:22 155:4	268:5 293:12
103:9 129:5	37:6 38:14 40:1	pharma 360:2,5	329:15 389:2,6	302:18 307:17
134:11,18 242:5	52:3,5,11,12,15	pharmacist 66:18	plans 46:7 329:7,11	310:4 318:13
255:20 266:12,19	52:17 53:6 56:7,9	112:17	329:12	320:10,11 329:8
291:18,20 344:9	56:14,17 58:19,21	philosophical	plant 174:22	341:12 349:13
348:13,13 375:10	59:7 73:10,12,19	159:21 160:4	178:22 179:12,14	361:7 362:9
periods 335:1	78:3,5,9,12,16	phospholipid	184:3 280:14	364:18 366:1,14
347:4 374:16	86:9 93:10 108:4	137:11,15	plants 179:10	367:21 368:9,16
379:9	116:22 118:20	photoreceptor	plasma 127:14	372:21 380:14
permits 129:2	165:18 184:5	181:16	plate 213:21	381:3 388:16
permitted 9:4	187:13 188:13,15	photo-receptor	plausibility 175:12	392:7
34:19 44:11 54:2	188:20 190:2	216:9	175:13	pointed 29:2 90:19
62:9 88:17,22	192:11 193:5,19	photo-sensitive	play 128:8 148:8	153:21 156:14
166:8 203:21	199:4 242:21	259:6	331:11	pointer 13:14
247:12 271:22	248:20 261:2,16	phrased 29:15	played 334:7	pointing 220:2
336:16 344:4	267:12 268:7	382:15	339:16	points 12:12 82:12
Perrigo 116:4	269:7	physical 194:3	playing 396:5	145:4 168:12
persistent 64:22	petitioned 14:6	389:20	plays 39:17 128:11	183:8 334:21
66:1	15:10,21 16:4,16	physiologic 44:5	339:18 341:17	351:15 359:3
person 304:16	37:1,9,14 54:20	physiological	please 4:5 35:8,8	363:3 369:22
335:18 392:19	57:10 59:17 74:14	193:13	45:14 77:10 98:20	policies 316:11
personable 324:11	75:9 79:8 96:21	physiologically	100:1 104:17	346:3 348:4 351:8
personal 66:2	107:20 152:20	216:4	136:18 141:10	379:5
70:18 100:11	242:19 266:3	picked 320:4	201:4 207:1 212:4	policy 3:22 71:3
150:15 162:6	268:2 269:14	picking 325:4	288:7 297:22	90:19 93:18 94:1
337:4 352:19	270:1 273:12,19	picture 69:2	306:17 315:11	105:14,17 145:5
353:6,12	276:6,13 286:11	piece 113:13	343:17 349:22	145:10 146:10,13
personally 60:9	286:16 293:1,3	pieces 69:9	356:17 360:14	147:4,22 148:5,10
204:19 370:14	294:12,21 296:1	pig 281:10,15	368:3 377:4	156:13,16 162:21
387:14 392:6	296:11,18 297:5	pigment 37:11	396:20	171:6,12 172:2,12
persons 75:18	312:1,8 359:22	174:22 179:1	pleasure 53:2	173:14,15 307:12
225:12 334:22	petitioner 7:3 8:13	181:14 183:21,22	126:2	307:16,18 315:13
335:12,14 336:12	14:20 36:13 38:8	pissed 320:13	plus 41:20	316:2,13,16
337:8,10 374:14	39:7 41:2 52:21	place 4:18 25:6	podium 22:6	317:18 318:11
375:1,3	56:20 107:7	44:4 65:15,15	Poe 143:17	320:22 321:11,16
person's 370:21	182:18 359:21	67:11,12 95:18	point 11:14 13:13	323:1 324:7,17,21
perspective 7:17	petitioners 21:11	149:10 162:11	31:5,5 71:19	326:10,11 328:3
24:8 130:19 154:5	petitioner's 40:10	198:15,18 233:7	109:4 110:20	328:18 331:20

334:1,16,17 341:2 342:13 343:7,18 346:1,5,21 347:1 347:6,22 348:10 348:11 350:18 351:5 353:20 354:6,8 355:12 357:12 358:9 359:5,14 361:8,11 362:1,10 363:1,18 364:19 365:10 371:20 378:8,10 379:6 380:1 383:7 384:3,11 385:22 388:3 389:21 394:15 politics 211:20 305:4 Pollock 349:18 356:13 pollutants 108:13 polluting 109:2 polyacrylamide 102:2 polysorbate 102:1 polyunsaturated 31:20 32:1 pondered 139:16 poor 67:1 74:18 129:3 population 26:11 26:14 64:1,18 225:14 256:4,5,6 325:20 326:1 343:3 populations 64:19 portion 92:6 201:20 210:11 238:7 posed 15:12 62:3 position 148:9 170:17 173:6 326:8 positions 15:8 152:5 positive 42:12 142:16 143:6	224:18 positives 160:15 possibility 233:15 301:21 possible 114:13 147:18 148:13 161:3,4 172:19 207:2,4 209:2 213:1 225:10 226:7,20 325:8 341:9 possibly 90:2 161:6 post 107:9 posted 347:11 348:17 379:16 posting 36:8 postpone 362:15 postponed 261:4 post-harvest 101:21 potential 30:15,17 31:1 50:21 54:14 118:3 121:11 148:19 216:10 247:8 327:10 330:8 354:12 358:3,14 394:6 potentially 53:11 231:2 257:9 335:15 powder 30:21 33:11 powdered 29:17 33:4 powerful 54:13 PowerPoints 315:21 PPM 364:6 378:7 379:4,11 390:12 practical 48:15 111:16 146:11 227:15 241:16 practice 123:22 155:21 186:11 248:10 271:13 practiced 146:21 350:11	practices 240:13,22 344:22 345:1 346:19 379:2 pre 68:22 77:14 247:22 precedent 185:12 186:2 260:7 precipitation 305:16 306:5 precise 191:3 370:11 predominant 127:8 prefer 103:18,21 356:3 preferable 11:19 11:20 preference 5:10 160:20 307:19 367:18 preferences 103:16 104:12 preferentially 176:3 preferred 126:21 premature 69:22 216:2,5 premise 278:13 premises 259:14 prep 364:7 prepared 12:3 14:9 31:6 152:3 159:22 183:12 184:5 209:7 242:3 263:17 315:4 363:3 preparing 101:10 prescribed 138:10 138:12 prescription 138:2 presence 145:17 173:19 present 1:13 2:8 37:4 72:20 131:8 133:22 140:7 155:3 157:7,19,22 193:8 250:2 258:11 303:16	315:14 333:12 337:19 342:9 356:13 364:12 377:3 presentation 58:3 115:6,14,20 133:5 168:17 275:7,14 275:15 333:9 341:22 presentations 19:9 35:6 250:3 361:9 Presentations/Q... 3:14 presented 5:3 87:5 87:5 132:22 144:22 145:6 146:15,16 148:12 168:17 169:2 261:6 317:10 342:16 364:3 374:9 395:11 presenters 335:4 360:18 365:22 366:1 presenting 4:19,20 333:6 Presently 140:19 presents 108:4 preservation 119:4 preservative 8:4,15 9:12,15,20 10:11 10:12 15:22 22:15 23:4 45:7 242:1 258:4 264:17 265:5 267:12 268:4 preservatives 10:13 22:21 23:1 104:7 107:21 108:3 110:19 111:4,7 156:3 157:15 158:5 160:10 233:13,16 239:22 268:6 preserve 8:4 preserved 23:12 232:16 390:12	preserving 181:5 President 126:6 133:8 182:9 presiding 1:12 presumably 68:9 presumption 47:1 pretty 15:7 21:5 54:5 60:3 97:21 113:14 164:4 179:13 180:16,18 180:21 190:14 229:21 245:15 246:21 322:8 332:22 333:22 338:22 367:10 382:3 383:6,9 prevent 10:7 29:19 69:19,21 Preventative 18:11 Preventing 119:20 previous 12:18 13:2 14:15 34:18 52:10 86:14 200:20 201:5,16 229:20 275:12 317:12 330:19 previously 118:4 126:5 155:1 265:11 276:17 pre-formed 27:22 28:11 pre-market 49:9 49:15 50:14 213:3 235:8 pre-term 65:14 128:3 215:12 primarily 7:16,20 53:7,8 60:4 100:18 214:18 251:14 319:10 323:22 324:3 393:8 primary 37:8,17 45:6 48:20 66:4 118:22 226:17 244:7 342:22 primates 180:5
---	--	--	---	---

principles 44:16 162:4 256:3	385:4 394:15	36:3 97:9,12 140:9,13,17 141:5 142:13,18 165:14 209:16 210:2,6 305:13	249:21 253:7,21 255:8 279:16 281:2 300:17 301:5,6 302:21 303:12	383:8 386:16,21 387:19 388:5 389:1 390:9 392:2 392:12 394:1 395:15
print 169:12	proceed 5:17 260:19 261:2,5 262:13 264:14 268:10 269:8 272:8 274:3 276:21 282:3 285:7 286:21 287:16 296:1 310:12,15 313:11 314:5 315:16 362:6 397:1,4	processes 164:11 171:19 244:21 246:13 308:21 353:21	production 39:3 101:15 108:11 109:1 129:1 131:6 196:18 199:8 305:17 308:22 343:13 344:18 379:3	prohibit 172:8 prohibited 107:1 253:9 351:5 prohibition 172:5 prohibitions 152:15 155:19 prohibits 101:11 project 391:7,14 promising 203:11 promote 170:13 224:19
prior 20:5 61:4 100:6 104:18 162:11 358:20	proceedings 99:7 169:16 370:4	processing 30:6,16 79:13 83:5 101:21 102:10,15 104:14 147:11,17,19 148:4 167:8,10 183:18 185:20,22 185:22 240:6,7	products 23:4 34:12 43:3 49:13 50:5,6 75:22 84:14 90:14 101:18 110:7 117:5 120:20 133:18 135:15,20 135:20,22 136:2 136:13,16 138:2 139:15 154:3 155:10 157:1 158:9 160:2,22 161:6 162:5 163:8 171:8 180:12 199:7,19 210:7,8 212:18 218:22 223:5 228:6,18 231:20,22 244:18 251:18 254:22 255:3 309:22	prohibit 172:8 prohibited 107:1 253:9 351:5 prohibition 172:5 prohibitions 152:15 155:19 prohibits 101:11 project 391:7,14 promising 203:11 promote 170:13 224:19 promulgated 46:10 proper 59:16 193:10,10 196:20 204:18 225:15 226:7 229:8 327:17 properly 108:8 114:16 396:18 properties 31:12 42:15 94:16 198:6 231:1 proponents 89:16 proposal 88:8 91:9 136:14 152:2 265:19 311:18 354:5 355:1 357:11 358:5,18 360:14 376:21 377:7 385:12 proposals 4:19,20 5:5 136:10 152:8 315:14 propose 49:10 proposed 5:14 146:22 153:7 186:3 260:21 265:18,21 266:10 266:11 267:4 316:10,15 317:4 318:9 323:10 342:3 347:22
priorities 46:18 221:2 251:14	process 8:7 9:4,18 23:13 29:19 30:8 31:14 32:5 33:3 33:10 39:9 47:6 48:6 60:10 61:9 79:6 80:19,22 86:10 134:14 152:22 161:21 162:12 163:4 165:18 166:17 170:8,10,12 171:2 184:8,13 185:8 186:7 188:11 190:6 195:10,20 195:21,21 196:2 197:15 206:2 219:11 220:17 229:8 230:4,11 234:17,19,21 235:5,7,8 239:20 242:11 243:11,14 244:19,20 245:1 245:11 246:17 251:6 252:14 256:19 275:17,20 280:12,13 302:19 305:7 306:16 307:8 309:2,4,7 309:12 334:3 341:18 345:19 353:22 361:13 363:11 393:7,22	processors 170:16 produce 231:16 246:13 produced 41:4 43:3 69:15 74:11 86:3 106:14 114:21 147:2,6 240:20 302:11 309:13 producers 219:21 producing 240:14 product 9:22 10:8 30:13,18 31:15 34:21 36:2 41:6 49:1 68:5,6,10 83:16 96:17 101:6 110:11 111:6 112:15,19 116:7 118:19 119:22 121:22 123:13,14 124:20 125:12,15 138:9,10 139:1 143:8 149:18 157:5,8,9,10,21 160:6,8 161:8 162:9 183:16 185:4 186:8 187:17 189:13 190:13 203:18 204:4,6 226:19 232:6,8,14 234:22 240:14,20 241:11	production 39:3 101:15 108:11 109:1 129:1 131:6 196:18 199:8 305:17 308:22 343:13 344:18 379:3 products 23:4 34:12 43:3 49:13 50:5,6 75:22 84:14 90:14 101:18 110:7 117:5 120:20 133:18 135:15,20 135:20,22 136:2 136:13,16 138:2 139:15 154:3 155:10 157:1 158:9 160:2,22 161:6 162:5 163:8 171:8 180:12 199:7,19 210:7,8 212:18 218:22 223:5 228:6,18 231:20,22 244:18 251:18 254:22 255:3 309:22 professional 138:18 191:6 351:14 professor 18:16,21 126:3 196:16 profile 31:18 180:13 program 1:2 2:11 2:15,17 11:18 18:19 97:22 260:4 290:4 329:3,22 331:1 332:12 341:10 343:22 347:5,18 348:21 379:10 381:19	prohibit 172:8 prohibited 107:1 253:9 351:5 prohibition 172:5 prohibitions 152:15 155:19 prohibits 101:11 project 391:7,14 promising 203:11 promote 170:13 224:19 promulgated 46:10 proper 59:16 193:10,10 196:20 204:18 225:15 226:7 229:8 327:17 properly 108:8 114:16 396:18 properties 31:12 42:15 94:16 198:6 231:1 proponents 89:16 proposal 88:8 91:9 136:14 152:2 265:19 311:18 354:5 355:1 357:11 358:5,18 360:14 376:21 377:7 385:12 proposals 4:19,20 5:5 136:10 152:8 315:14 propose 49:10 proposed 5:14 146:22 153:7 186:3 260:21 265:18,21 266:10 266:11 267:4 316:10,15 317:4 318:9 323:10 342:3 347:22
private 264:1	processed 10:3			
privy 305:18				
pro 270:1				
probable 95:12				
probably 16:7 63:20 89:17 177:21 220:14 221:21 228:15 270:18 293:18 319:16 377:21 394:4				
problem 93:5 105:5 125:14 149:6 153:18 172:3 202:20 300:13 319:5 322:15 330:17 373:5 382:5,9 389:14,22 390:16 390:16				
problematic 114:21 257:9				
problems 77:16 131:19 181:7 194:3 201:15 204:5 249:12 330:22				
procedural 155:4				
procedure 90:20 250:22 316:13 317:18 321:11 334:16 342:14 364:19 365:10 380:1				
procedures 12:8 316:11 343:7,18 345:19 346:2,21 347:6 371:21 383:7 384:3,11				

348:10 349:11	126:9 152:5	78:17,18 79:10	153:15,16 233:1	qualify 111:8
350:17 358:8	158:22 170:15	81:4,8 82:15	298:16	quality 117:22
362:18 375:12	173:6 182:12	83:11 98:13 99:11	Purdue 20:20	119:4,21 127:2
proprietary 158:10	184:6 188:10	107:13 110:3	purported 45:12	213:4 226:15
159:4,7,14 172:18	192:5 194:10	146:17 195:2	purportedly 48:4	240:9,9
173:5 244:7	197:11 198:7	221:17 235:16	purpose 9:8 45:6,9	quantitative 34:10
propylene 102:9	209:1 210:19	254:10,13 317:8,8	83:18 145:14	quantities 26:3
pros 87:6 145:1	227:4,7 229:13	317:16 318:5,8	150:17 351:9	95:2 124:13
protect 42:16 45:12	232:15 233:4	320:16,16 322:6	352:4	quantity 25:16
107:13 117:18	240:10 244:17	322:19 323:14	purposes 24:22	124:9,10
181:20 201:22	246:4 266:2	327:12,13 330:13	26:20 114:6,7	question 17:1 25:8
protected 30:14	325:18 342:6	332:20 333:11,18	265:8	29:14 30:1,8
protecting 125:12	343:19 345:5	334:1,17 335:1,5	pursue 230:18	31:11 34:2,17
279:17,20	346:9 349:16	335:16,18 336:11	pushing 71:21	45:14,18,21 46:2
protection 32:4	351:9,15 359:15	336:14,17 337:3,9	put 26:20,22 27:1,6	47:6 49:6 50:18
343:9 345:12	378:14 381:11	337:18 339:4,7,12	50:19 51:16 61:20	51:4 55:5,6 58:14
346:20 379:3	386:1 389:19	342:10,21 343:6	90:22 122:19	62:3 64:5 67:6,7
protective 32:8	393:13	344:3,4,8,9 345:4	124:7 132:12	68:3 69:8 75:12
protects 146:11	provided 134:3	345:20 346:1,8,15	139:4 166:8	80:17,21 81:11
protein 40:6 59:3	144:18,21 147:6	347:1,3,4,10,13	168:11 181:2	93:12,21 94:15
59:18 60:16 61:7	245:18 252:18	347:15,16,21,22	256:13 271:20	96:10 105:2,6
61:8,10,14,15	310:7	349:16 353:11,14	279:14 315:19	109:4,22 113:1,3
63:1,1,2,8,11,13	Providence 1:11	353:15,17,18	317:20 320:17	113:21 121:9
63:16,17 67:20	provider 194:5	354:1 357:15	322:6 323:20	124:5 131:12
69:7,17 74:8 79:3	provides 137:15	358:2,10 359:1	326:9 328:11	134:7 136:21
94:22 95:22 96:14	183:5 185:17	360:13,18 362:13	330:16 333:17	139:5 149:3,21
96:19 97:8 136:15	224:16 227:6	362:14,19 364:3	334:19 338:19	151:9 167:7 189:6
136:17 150:2	243:2 250:19	366:6,8 374:15	362:18 363:20	189:8 190:2 201:3
175:15,17 180:20	providing 27:18	375:2 377:7	364:6,8 367:21	205:7,10,16
181:1 188:22	126:21 224:9	378:13,20 379:7,8	368:8 369:5,9,11	206:13 216:12,20
191:16,20 192:8	316:9 337:3 393:5	379:9,15,18	371:22 394:14	218:1,1,12 219:17
216:20 217:6,9,10	393:10	380:20 381:1,16	putting 68:4	220:10 222:14,15
217:12,14 296:10	provision 244:4	382:20 384:21,22	144:10 161:18	233:9 239:2,14,18
296:13,21 297:3,7	provitamin 15:20	385:3 386:2,17	332:2 355:13	241:14 242:9
297:17 300:14	proxy 336:15 339:9	387:3,9,18 388:17	367:13	245:6 247:1,7
301:4,19 302:1,7	pro-oxidant 124:16	publicized 364:14	puzzled 382:7	249:17 251:21
302:8 305:6,7,13	pro-vitamin 55:21	publicly 244:5	P-R-O-C-E-E-D-...	254:21 255:15,18
proteins 53:11,21	56:1	245:20 358:13	4:1	255:21 257:19
protein-based	public 3:17 5:4	360:18	p.m 237:5,6 238:2	278:22 290:1
67:16	6:21 7:1,4 14:17	published 43:19	260:14,15 315:8,9	301:11,14 306:7
protocol 4:18	14:19,20 16:8,21	189:13 254:13	361:20,21 398:6	306:21 307:7
prove 51:13 242:3	25:16 36:8,10,11	265:18 266:4		308:19 309:9
proven 44:18	36:13 40:22 41:14	Puerto 95:4	Q	310:5 321:10
229:10	46:1 52:18,19,21	pull 82:1 253:2	quaint 139:17	348:12 358:4,22
provender 238:5	54:5,8 56:17,19	327:21	qualifications	368:1 369:17
provide 30:5 61:12	56:21 59:8,9 60:4	Pune 18:1	133:2,7	384:14 387:22
83:14 116:19	73:20,21 75:20	purchase 104:2	qualified 244:1	390:13 396:15

questioning 12:13 54:9 139:6	207:12 302:14	reactive 188:21	reason 116:13 300:19 332:19 368:2	342:6 384:8 392:18
questions 3:19 5:2 11:14 12:20 13:7 15:12 17:6,14 20:22 21:4,7,13 22:4 24:5 29:11 29:14 35:5,10 44:21 45:19 47:11 47:15 50:8,13 51:22 55:3 56:4 58:13 61:18,22 67:9,10 68:14 77:19 80:15 92:11 94:6 97:15 106:11 109:20 115:22 121:7 130:10,11 132:16 133:13 137:20,22 139:7 143:20,22 144:1 148:16 149:20 150:9 156:18 159:18 174:5 178:19 179:17 182:2 187:7 194:21 196:8,17 200:16,18 201:13 203:8 204:12 208:4 212:6 228:9 231:6 236:3,21 238:18,21 239:8 239:11,16 241:11 244:13,14,15 246:2,3 247:7 248:17 252:11 254:2,17 255:19 257:13 259:16 303:17 310:11 338:12 348:14 354:17 356:7 360:14,19,20,22 363:4 375:22 388:18 393:1 395:21	quickly 5:13 167:1 206:14 333:22 quite 64:2 80:4 149:3 170:8 184:7 312:9 317:22 318:1 321:12 326:22 332:7 395:11 quo 266:7,16 quote 42:14 95:11 159:21 quotes 338:18 quoting 85:19	read 67:15 100:18 157:12 291:10 312:9 316:19 327:19 330:15 334:20 335:8 336:8,11 355:2,6 364:11 365:17 374:11,13,14 377:11,18 378:4 380:3,10 readily 158:20 reading 157:11 299:20 365:15 reads 364:20 ready 4:4 6:6 163:3 260:19,20 261:1 349:19 reaffirms 392:14 real 96:6 141:11 148:7 realistic 333:18 reality 211:1 224:21 317:10,19 340:21 341:19 realize 50:18 126:16,20 202:7 349:4 really 24:3 25:3 77:11 79:12 82:6 88:4 90:13 91:11 91:19,20 95:19 97:16,19 112:11 127:3 132:11 140:15 141:15 142:5 158:8 166:11 175:13,17 176:19 178:11,15 179:14 205:10 211:20 217:2 221:3 230:11 249:12 256:10 278:20 279:4 300:2 316:7 334:7 338:3 339:1,15 340:9 380:12,20 381:2 385:11	reasonable 104:12 146:10 206:10 210:1 227:4 reasonably 221:12 reasoned 141:21 reasons 33:16 58:9 66:19 70:7 130:15 142:18 147:21 179:16 200:13 225:1,3 318:16 320:22 321:9 385:20 reassemble 98:19 recall 95:5,10 143:9 390:17 recalled 95:9 recapture 64:5 receive 136:4 225:9 226:19 338:2 345:13 348:5,15 348:22,22 349:7 384:20 385:2 received 6:10 7:2 7:13 13:16 25:15 35:20 36:12 52:3 56:7 58:19 73:10 78:3 82:12,17 130:16 195:3 209:8 301:16 338:5,10 347:11 347:15,17 348:12 379:16 381:16 receives 344:8 345:3 346:7 378:13 382:19 receiving 128:4 recess 395:1 398:3 recited 167:6 recognition 214:9 279:2 recognize 55:20 76:12 226:12 250:15 300:9 324:22 325:11	recognized 25:13 33:15 62:7 107:4 146:4 206:2 226:1 242:14 243:1,4,12 243:22 248:8 251:12 recognizing 303:7 recommend 80:1 221:18 304:18 393:15 recommendation 71:14,15,16 79:4 90:3 91:1,21 106:13 136:19 145:15 148:13 184:22 318:9 323:6,8,11,12 324:18,19 325:14 326:15 327:8 330:20 331:14,15 331:19 333:10 362:13,14,18 364:2,5,10 365:11 377:17 378:4,7 380:13,14 389:7 recommendations 46:14 184:19 221:19 224:14 316:16 317:4 322:12 342:4 345:22 365:12 393:5,10 recommended 138:12,18 192:18 193:3 232:7,13 recommending 58:10 75:15 79:21 165:21 260:3 reconcile 366:19 reconsider 257:15 reconvene 259:19 361:15,18 record 64:7 72:13 98:17 160:18 188:9 237:5
	R			
question's 203:13 queue 139:5 quick 42:4 105:1,2	R 238:1 raise 11:11 67:12 181:9 raised 37:8 raises 307:7 356:1 rancid 121:13 199:2,20 258:12 rancidity 10:7 29:19,21 121:11 257:20,21 range 124:20 146:1 217:14 308:21 Rankin 212:11 222:21 223:1,2 228:15 231:13 233:17 234:10 235:1,12 rapid 129:6 135:4 rapidly 215:17 rapping 139:20,20 141:2 rare 63:19 65:6 147:7 rate 135:4 194:6 rates 112:5 rationale 40:8 363:16 381:10,21 reach 141:19 reaction 364:1 reactions 119:15 280:17			

260:14 263:12	refuse 16:10	220:13,15,21	210:4	representatives
294:20 306:12	regard 8:12 11:9	224:1 229:3	remind 21:2 22:2	4:22 359:9
308:20 315:8	23:6 31:4 66:9	234:14 242:21	135:16 136:20	represented 83:8
336:13 361:20	94:19 110:16	reiterate 145:9	137:10 211:15	354:2
378:5 398:6	203:19 263:21	239:1 269:21	395:9,15	representing 133:3
recorded 375:12	360:13 363:21	reiterating 317:14	reminder 47:13	151:19 212:13
records 151:6	385:13	reject 106:13	reminding 21:18	241:18
recruited 325:17	regarded 253:6	107:22	77:18	represents 213:9
recusals 363:17	regarding 50:8	rejected 114:11	remove 80:10	351:16
recuse 357:19	61:19 68:16 79:20	rejection 211:5	132:11 325:10	reproductive 69:22
red 57:8 118:5	81:6 183:13	rejects 113:15	removed 185:4	70:7
213:22	224:14 269:12	related 20:14 36:21	258:3 294:4	request 6:18 38:14
redacted 324:14	regardless 16:12	53:19 68:20 76:3	300:21	40:10 48:10,14,15
326:2 327:11	regards 55:19	94:8 179:6 214:6	removing 187:16	48:15 56:15 59:5
330:3	74:21 206:15	223:16 340:15	Renaissance	71:20 73:17
reds 175:5	230:13 232:21	344:22 363:18	169:15	133:11 136:10
reduced 327:8	register 335:3,6	388:16	render 184:20	301:8 302:3
reducing 242:2	374:18 384:22	relates 34:3 110:1	186:7	319:13 387:10
335:19	registered 212:15	121:10 134:8	Renumber 375:9	388:6
redundant 55:5	registrant's 275:15	247:7 249:17	repair 180:15	requested 14:13
refer 57:19 123:8	regroup 361:12	302:12	repeat 133:1 201:4	35:22 36:5 38:9
151:7 184:21	regular 149:17	relationship 72:6	390:5	39:7 52:15 78:13
228:16	151:7 260:4	relationships 20:15	repeated 358:9	requesting 182:18
reference 172:10	regulate 49:21	relative 26:3 63:10	repeating 140:13	337:9,10 375:2,3
257:20 263:19	353:2	215:19	340:19	requests 6:13 13:19
references 205:18	regulated 220:4	relatively 21:21	replace 394:16	52:6 56:10 58:22
384:3	226:1	63:18 66:22 77:5	report 6:19,19 36:6	73:13 78:6 169:10
referred 22:14	regulates 48:18	relevant 95:16	36:7 52:16,17	169:11 317:16
63:21 74:6 84:14	49:1,3	183:2 200:2 339:3	56:16,16 59:6,7	336:18 358:10
395:19	regulation 19:21	339:12 352:7	73:18,19 78:14,15	require 49:15
referring 30:9	48:18,21 220:16	395:13	78:16 173:17	84:22 118:7
367:8	251:2	reliance 300:15	183:1 188:17	129:16 147:5
refers 55:14	regulations 43:18	relies 107:5 245:18	207:21 247:10	154:9 155:17
reflect 191:4	44:11 62:11 84:11	reluctance 338:5	391:11	199:11 210:7
213:14	118:12 161:14	reluctancy 340:12	reported 95:4	225:14 229:19
reflects 227:22	162:2,5,10 183:22	reluctant 303:22	349:9	247:22 251:5
refrain 93:17 337:3	195:12 196:16	rely 28:2,5 46:18	reports 14:8,16	353:10 358:18
refrigerate 241:20	200:1 202:14	47:22 48:6,7	95:3,4	required 38:6 43:1
refrigerated	207:14 210:19	100:13 164:7	represent 24:11	49:9 54:4 55:7,9
122:21 123:1,4,9	221:2,17,20	relying 111:19	323:15,18,21	55:13 57:18,22
123:14 233:15	225:12,19 248:10	remain 154:17	324:3 325:19,22	58:1 59:15 62:4
234:7 239:21	250:11 251:7	233:2 374:19	326:3 343:2	75:6 76:14 107:9
242:1	266:6 351:6	remarked 271:2	351:11,18 352:9	108:6 118:17
refrigeration	regulatory 119:9	remarks 159:22	352:12,18,21	119:2 127:8
122:19 234:20	151:17 165:17	337:4	359:3	130:14 131:14,15
240:4	171:9 172:10	remember 137:6	representative 7:3	134:2 158:22
refrigerator 242:4	182:9 191:5	140:2 142:12	83:13 347:20	184:1 195:5

199:17 201:21	resolved 249:11	129:19 172:14	152:14,16,19,21	131:12 195:1
206:20 207:1,8,15	resources 46:19	192:16 198:9,19	153:18 164:2	219:18 247:6
219:22 220:6	respect 21:10	201:7 214:3	166:2 170:8,12	249:16 252:5
227:7 229:7 230:1	104:12 222:14	227:11	172:15 173:11,13	262:15 264:19
250:1,10,13 251:4	323:12 341:6	resulted 228:5	173:18 183:2	269:4 273:5
252:1 255:5	respected 43:19	resulting 185:3	185:16 188:13	274:16 277:11
256:20 298:13	Respectfully 353:7	results 129:13	189:3 229:8	278:3 282:14
requirement 15:13	respectively 84:14	226:14	234:13 235:7	284:5 285:16
103:2 195:15	respond 5:2 252:17	resume 362:2	244:11 245:11,17	287:7 288:17
227:13 256:3,15	349:3,6 368:20	resumed 98:18	246:4,6 248:2,14	295:10 310:21
353:8	385:6 388:20	237:6 260:15	249:5,6,13 257:11	311:21 312:18
requirements	responding 320:19	315:9 361:21	258:15 322:14	313:12 314:8,22
28:13 46:4,9	response 6:4 13:10	retail 199:11	342:20 345:13	316:22 334:7
47:22 48:13 60:17	14:10 53:12,18,18	retailer 332:20	358:8,15,18	364:22 375:18
61:14 102:20	72:5 77:21 81:13	retailers 324:1,1	reviewed 94:12	376:5 397:19
171:5 192:8 213:3	116:1 139:8 174:6	retains 183:19	96:7 146:4 149:8	Rico 95:4
213:7 252:21	182:3 196:9 212:8	retard 23:2	154:15,19 155:2	right 4:12 6:5 7:10
255:22 279:7,8	262:11 272:6	retina 128:1,1	171:18 184:10	13:5,8,11 17:8
353:13	273:21 276:15	177:13 179:6	197:22 219:4	29:15,22 31:9
requires 33:19 84:4	283:14 285:5	180:11 181:3	223:22 229:1	35:4,12,16 37:2
108:20 129:17	286:18 288:8	193:10	234:12 257:7	51:19 56:4 58:16
136:9 202:16	295:2 312:11	retinal 127:7 216:7	264:3,10 305:9,10	70:21 81:16 95:21
220:17 226:21	314:3 356:8,14,16	retinas 180:7,10	reviewer 19:14	99:9,10 105:6
250:21 298:7	361:1 365:18	retired 133:8	reviewers 148:18	111:4 112:8 113:2
353:5	376:1 380:7	retroactive 331:5	149:16 358:13	113:2 114:10
requiring 86:10	responses 91:20	retroactively 354:7	reviewing 143:3	115:6,10,10 116:2
173:16 319:19	395:13	354:10	173:2 230:9	123:18 125:18,22
research 8:18 19:1	responsibility	return 104:17	317:17	133:16 135:8
19:4,13 20:6,10	209:1 336:6	315:11 328:17	reviews 86:11	149:19 162:8,13
42:11 69:13	344:15 345:10	349:11	89:19 149:16,18	164:6 174:7
101:10 116:17	352:15,17 358:6	returned 18:15	150:19 164:3	178:19 181:7
126:6 132:4 133:8	381:17 391:1	236:12 326:17	219:13	196:10 205:3
149:17 176:8	responsible 248:14	328:20,20 330:18	revise 93:22	208:3,3 209:16
179:20 192:19	341:14	331:18	revised 318:2	215:6 218:17
214:8 226:13,21	rest 238:5 362:7	returning 236:16	revisions 354:20	235:1 236:14
227:4,11 228:20	373:16	Reuben 317:1	355:10	238:3,18 252:10
229:17 233:19	restate 149:4 276:2	318:21	revisiting 275:16	255:10,16 259:8
researched 229:10	276:17 290:12	reverse 128:7	revote 331:5,8,10	259:11 268:2
researchers 226:11	291:12	275:11	re-read 294:19	281:10,13,21
358:19	restating 374:4	review 6:17 14:7,11	297:4 365:16	290:9 291:10,10
researching 229:22	restricted 252:3	14:14 20:12 36:4	Rhode 1:11 356:22	293:8 297:7 299:3
reserved 359:11	restrictions 155:18	49:16 52:14 53:17	rich 37:21 67:1	306:9 310:10
residency 18:3	173:20 338:12	56:13 59:4 73:16	81:5 100:3,8,9	311:14 312:9
resident 18:3	restrictive 111:1	78:12 89:22 90:20	105:3,8	317:12 329:11
resin 90:6	172:14	95:18 144:14	Richardson 1:20	357:11 372:20
resolve 50:12	result 16:1 17:15	147:10 149:9	34:2 45:1,15 74:4	387:6 393:21
248:22	46:13 60:18 74:18	150:18,18 152:13	121:9 122:2,8	394:4,18,20

rightfully 320:2	265:18 266:4,9,10	safety-related	school 18:13,22	390:19
rigorous 84:18	266:14,15,17,21	68:20	105:21 168:16	sec 259:9
161:20 170:9	267:4 309:20,20	safety/efficacy	350:15	second 19:18 40:10
rises 215:5	373:16 374:16	24:17	science 20:17,19	45:13 65:15 82:2
risk 33:17 141:11	rulemaking 220:19	sales 66:13 68:9,10	102:14 105:17	86:13 185:7,15
142:17 143:5,10	250:22 251:6,15	210:12	126:4 197:10	202:20 223:18
178:7 198:18	rules 383:9	salts 78:11	202:5 208:13,21	249:17 262:5,6
255:11	ruling 97:11	sanitizer 164:19	228:1	264:19 269:16
RNA 78:7 128:16	run 33:16 159:13	sanitizers 147:14	sciences 18:14 20:6	273:15,16 276:8,9
128:16	rundown 302:14	saponification	20:10 55:18 76:10	278:2,3 283:10
road 166:16	running 187:10	275:18	76:11 116:16	284:20,21 286:13
Robert 1:21 212:11	315:11 349:14	satisfaction 197:19	192:19 250:18	288:2,3 289:19,20
222:21 223:2	runs 142:17	satisfied 365:14	scientific 42:6	291:8 292:5,17,18
robust 230:12		satisfies 102:20	43:19 44:17 47:20	294:16,17 296:14
rod 216:9	S	satisfy 373:2	49:18 55:15 74:21	312:3 313:21,22
role 23:7 37:13	S 238:1,1,1	Savannah 317:21	76:7 106:18	364:21,22 368:22
39:17 117:21	sacrifice 212:1	318:7 326:19	182:21 226:13	375:17,18 379:20
120:8 128:9,11	sad 140:9	328:12	243:20,21,22	379:21 383:16,22
174:17 175:8	safe 24:21 30:7	saw 80:18 257:18	246:19 248:4	388:16
176:1,13,18,21	51:15 72:10	310:4 362:19	279:11 280:2	secondary 38:14
178:9,15 214:10	100:15 102:21	saying 8:13 77:4	scientist 194:14	65:2,22 88:5
216:10 230:9	104:21 107:5	96:5 113:20 160:1	196:2,14 212:15	119:3 150:17
334:8 342:22	116:20 118:15	206:18 244:12	scientists 352:10	seconded 262:8
346:5 347:7	121:20 198:7	254:11 258:17	359:12	264:21 265:1,3
378:10 379:11	206:2 227:5 229:5	281:14 303:4	scientist's 359:18	269:18 273:18
396:5	229:10 230:3	319:3 324:10	scoot 5:7	276:12 283:12
roles 23:16 128:18	232:7,12 242:15	367:15 368:17	scope 145:12 172:1	286:15 288:5
177:5 396:5	243:1,4,12 244:2	370:17 371:16	279:4	289:22 292:20
roll 6:6 389:6	244:17 248:8	380:19 385:21	scratch-through	294:22 296:16,17
rollout 389:6	257:1,5	386:11 387:15	330:15	312:6 313:17
Roman 377:18	safeguards 190:3	393:15	screen 82:16 317:3	314:1 365:5,8
room 169:15 181:4	safety 19:21 20:14	says 85:19 256:14	336:4,9 364:7,8	380:1 396:18,22
181:9 205:18	31:15 35:1 49:2	306:8 324:21	365:13 369:1	seconding 294:19
206:7 335:15	49:19,22 50:3,5,8	325:16 366:15,15	377:15,20	secondly 16:17
rosemary 8:12,13	50:9,12,13 72:13	366:17,20,22	screening 162:11	39:16 45:6
8:22 120:10,12	96:3 101:9 107:3	382:4 383:12	scrutinized 220:4	seconds 278:5
222:16 239:3	107:6,8 118:7	scarce 141:4	scrutiny 87:17,18	284:22 294:7
247:8,9,11,16	122:9 151:18	scared 292:14	se 342:13	Secretary 200:4
248:5,7 263:19	213:4 219:13	scavenge 117:13	seafood 74:9	326:5 343:2,13,21
264:3,9 349:21	227:9 230:10	scenario 91:7	search 382:9	344:16 345:7
356:16,19	240:6 241:1	schedule 222:9	390:15	346:6,12,16 348:2
roughly 321:7	243:10,14 244:8	235:11,17 236:1	searching 149:6	378:11,17,21
round 239:4 247:4	244:10 246:6	318:18 341:15	seasoned 141:22	380:19,22 381:18
routine 70:13,16	247:20 248:4,13	scheduled 92:9	seat 4:6 359:18	382:6 384:19
routinely 25:17	248:16,16,21,22	222:22 236:13	392:13	385:20 386:3,10
102:4,9	249:11,14 253:5	238:9 336:18	seats 315:11 359:10	386:19 387:17
rule 83:3 87:1	258:1 302:13	schedules 238:13	Seattle 103:14	388:4,4,7,11,15

390:11,19 391:2,8 391:12 393:5 394:2 Secretary's 388:13 392:13 section 6:14 13:20 36:1 52:6 56:11 59:1 71:7 73:13 78:7 85:16 101:16 123:15 182:19 183:16 210:21 264:16 265:4 284:18 285:3 334:15,15 346:2 346:22 347:7 364:5 365:10 378:7 379:4,11 sections 57:19 79:19 85:13 142:17 security 152:4 see 10:16 13:14 47:12 91:2,17 93:5 95:6 99:12 114:13,16 127:10 127:16 130:5 131:2 132:2 146:6 151:4 156:15 175:4 178:14 179:4 180:16 182:22 189:10 201:2 205:8 208:6 212:10 215:6 228:6 258:19 259:18 279:19 281:10 286:3 289:7 312:7 318:6 320:21 324:14 325:14 326:2 331:21 349:9 351:20 355:10 357:16 360:10 372:12 377:11,14 377:16 381:5 382:10,11 389:22 392:9 397:21 seeing 316:19	330:2 356:3,16 363:22 seek 339:6 seeking 45:1 395:17 seeks 347:3 379:8 seen 66:12 128:3 306:14 321:12 332:3 353:16 359:8,16 360:1 sees 109:11 110:10 segment 325:19 segments 343:3 seized 253:22 Select 20:11 selected 83:13 325:21 343:4 351:15 352:9 selenium 251:10,11 251:17 self 121:10 244:13 self-certifying 245:10 self-defined 110:22 self-determined 243:17 self-reported 64:19 sell 192:9 200:8,10 202:11 selling 202:8,12 203:17 204:6 Senate 350:10 send 388:10 sense 47:19 64:12 151:6 206:10 368:8 372:18 392:5 sensitive 320:5 sensitivity 216:9 sensorial 119:3 sent 29:14 67:10 388:7 sentence 80:10 367:9 373:17 374:22 sentiments 103:12 separate 84:22	140:3 155:12 305:14 September 52:4 73:10 78:4 266:3 sequential 219:12 serious 125:14 198:22 199:3 241:10 seriously 146:7 serve 8:3 117:10 124:15 150:16 151:21 served 19:20 341:2 serves 19:14 20:2 37:12 117:17,21 SERVICE 1:1 Services 135:13 200:5 serving 352:16 359:10 session 4:9 17:1 315:12 398:2 set 155:18 171:4 352:5 sets 84:18 setting 255:4 260:7 settles 171:12 seven 5:14 41:15 336:17 seven-step 155:3 share 300:20 302:19 340:20 349:22 sheet 67:9 132:21 150:15 158:17 349:17 sheets 158:11,13 shelf 9:22 10:8 30:1 30:2 34:3,6 120:22 122:17,19 122:20 199:5,12 241:17 242:2 257:22 258:3,5,8 258:8,11 shelves 258:18,18 shh 260:21,21,21 shift 68:10 112:13	shines 353:21 ship 199:8 ships 199:10 shocked 101:22 shoppers 357:6 short 21:21 203:11 203:14,17 234:17 305:1 326:21 shortened 122:17 199:5 shorter 34:9,9,11 shortly 222:2 short-term 51:15 76:21 shouldered 92:5 show 24:22 72:1,4 76:20 106:19 115:16 176:8 188:20 209:13 215:12 229:8 230:2 240:12 253:18 322:13,14 327:15 328:21 353:1 377:20 showed 39:14 87:16 216:7 229:20 showing 51:14 182:5 190:17 381:20 shown 24:20 25:9 32:7 51:3,6,8 67:2 94:21 95:19 196:19 365:13 shows 65:1 209:14 215:19 320:18 shunning 254:16 side 7:19 86:20 160:7,7 300:8 320:13 sides 60:3 220:19 SIDS 177:16 sign 335:2,13 358:19 366:16,21 367:1 368:16,17 374:17 signed 7:3 14:20	36:13 349:15 significant 60:11 127:20 161:1 179:22 187:1 193:8 228:2 334:8 significantly 333:17 signing 169:14 signs 216:7 sign-up 337:12 375:5 silken 140:9 Similac 212:14 similar 25:8 41:5 42:14 51:11 79:14 84:3 88:4 91:8 124:6,22 214:13 similarities 22:12 Similarly 200:9 simple 47:3 104:11 172:16 242:6 264:4 323:9 373:13 391:16 simplifying 9:21 simply 54:17 128:15 359:7 369:5 389:18 simulate 186:21 single 85:12 93:9 154:16 155:12 singling 325:13 sir 96:8 140:20 201:8 206:19 262:22 268:18 272:20 274:9 277:4 282:7 283:20 285:9 287:14 289:2 295:17 311:6 313:3 314:15 376:12 378:6 397:12 sit 32:16 368:9 site 199:8 sitting 141:17,17 220:5 392:12 situation 115:11
---	---	--	--	---

204:2 232:3 279:5 357:22	solvent 184:14 185:14	132:17 138:8 149:2 156:11	53:9 56:1 58:7 103:20 108:9	296:20 297:3,7 299:21 300:14
situations 132:12	solvents 106:16 184:19 191:18	189:5,8,9 201:4 203:3 216:15	118:3 134:17 137:11 219:7	so-called 93:7
six 71:9,11,13,18 72:8,8 99:12	somebody 31:7 109:12 218:3	218:13,14 249:9 254:6 259:21	345:14	speak 12:22 17:2 121:6 217:7 218:7
120:22 121:1 122:18 134:19	245:11 255:5 310:4	267:14 270:7 272:14 289:4	south 357:1	223:7 231:3 335:13 340:3
213:19 215:18 336:15	someone's 208:3 239:4 298:12	290:18 291:3 293:20 295:1	soy 59:3 62:21,22 63:4,6,9,11,13,16	366:21 392:20 395:1,14
skip 73:1 99:22	somewhat 87:1 91:8 94:7 320:4	296:5 297:2 298:1 303:1 308:7 310:9	63:17 65:7,13,13 65:17,21 66:4,6	speaker 17:18 19:18 222:21
skirting 161:14	330:10	315:18,20 317:6 336:2,2,3 346:1	66:10,13,19,20 67:4,15,19,20	229:20 235:10 337:22
slate 293:19	some-odd 390:21	364:15 368:4,22 369:22 374:9	68:5,17 69:3,3,6,8 69:14,16,19,20	speakers 12:1 203:6 233:17
slide 40:21 121:5 200:20 201:5	son 194:6,9,13	sort 9:20,22 15:3 21:21 53:13 67:12	70:4,8,12,13,17 75:4 94:9,13,16	336:15
209:14 219:6 220:3 316:20	SONNABEND 1:21 11:13 13:1	113:22 150:16,20 160:6 167:13	94:21 95:6,21 96:13,14,19 97:8	speaking 77:5,6 87:4 223:18
317:11 331:21 336:2 338:20	22:8,10 24:7 25:7 27:5 28:8 29:13	209:10 245:13 299:19 301:8	97:10 108:7,17 109:13 111:20	special 77:15 106:1 211:18
343:17	57:4 62:2 71:2 78:22 81:4 82:1	328:16 381:10,20 391:20	113:9,17,22 114:14 129:15,19	Specialist 2:12,19
slides 7:11 162:17	92:22 93:20 94:5 124:5 130:12	sorts 60:5 sought 338:11	134:2 136:14,15 136:17,18 150:2	specializing 196:15
slight 275:5	148:17 149:5 178:20 179:7	soul 140:19 sound 206:10	191:2,16,20 195:20 216:20	specific 23:15,20 24:1,2 35:2 53:15
slightly 349:14	218:12,15,19 233:10 234:3,20	382:16 sounds 12:19 35:15	217:8,12,16 218:6 232:17,19,21	67:3 78:10 142:21 145:4 148:10
slippery 256:16	239:17 241:13 262:21 265:7	61:18 245:7 307:20 367:10	233:6 279:16 297:12,14,16	159:15 173:20 175:15,16 180:20
slope 256:16	267:1 268:17 272:19 274:8	source 9:7 16:5 26:18 27:10,11,14	298:10,22 299:11 299:22 301:3,18	190:4 224:16 225:14 238:17
slot 360:2	277:3 280:7 282:6 283:19 285:22	27:20 28:1,6 37:9 37:17 38:14 54:18	301:19,22 302:7,7 304:8,10,12 305:6	239:14 301:22 354:4 385:3
slower 194:6	286:9 287:13,19 289:1 292:22	55:21 66:4 117:2 118:1,10 119:7	306:10,15 308:22	394:17
small 84:17 102:19 129:3 141:12	295:16 297:10 298:22 299:9	126:17 134:21 135:5 137:12,12	soybeans 304:13,14	specifically 15:13 15:17 16:9,11,16
201:19 211:14,17	304:4,18 309:11 311:5 313:2	137:15 145:18 183:17 184:3	soy-based 38:2 42:17 57:11 59:17	28:14 41:15,17 43:16 51:3 59:18
smell 199:2	314:14 376:11 380:10 397:11	204:18 226:10 267:6,7,10 271:11	59:19 60:15 61:6 61:8,10,15 64:14	61:13 135:22 153:1 186:19
Social 105:19	soon 148:13 202:16 395:5	272:1 sources 25:10,13	108:6 109:9,11 112:3,11,13	365:22 367:8 386:1
societies 19:12 20:7	sophisticated 216:8	31:16 38:19 40:7	114:11 115:3 191:15,21 192:4,6	specification 158:11,13,17
sodium 78:11 102:2 306:1,4	sorrow 140:5,6		192:9,22 193:6,17 231:12 296:9,12	specifics 24:1 395:20
309:14	sorry 13:14 72:21 84:17 121:2			specified 60:17 257:4 259:1
sold 66:10 123:13 123:16 124:1				
198:1 231:9 298:10				
sole 134:21 226:9				
solely 29:7 225:20 340:14				
solids 104:4				
soluble 8:3				
solution 104:11 194:2 382:8				
390:15				

specifies 258:9	346:8,19 357:5	271:14 343:10	storage 23:11	268:6 346:4 347:1
specify 84:12 172:5	378:14 379:2	346:4 350:10	30:18 32:5	378:9 379:6
specter 143:6	381:19 389:16	stating 101:17	store 141:15	subcommittee 3:11
spectrum 22:21	standing 32:17	160:19	stored 30:19	3:22 4:7 6:17
spend 82:4 278:12	160:7	statistical 95:14	stores 199:11	11:2,3,5 14:12
sphere 142:8	stands 87:1 206:1	statistically 127:20	story 177:15	16:15,22 21:3
spinach 37:5	242:14	status 76:22 107:4	214:13	36:5 39:5,11,18
split 39:11	starch 104:5	107:5 177:2	straight 67:6 88:3	40:9 52:15 56:14
spoilage 23:2	start 4:6 21:9	197:16 206:3	238:16 239:10	58:10 59:5,22
spot 50:19 214:18	134:16 166:16	242:18 243:4,6,7	straightened	60:14 61:3 73:17
spotlight 35:17	278:13 283:17	266:7,16	368:13	75:12,17 78:13
spray 30:7	293:20 294:5,10	statute 279:6	straightforward	89:12 92:5 97:20
spread 155:4	334:6 363:10	303:13 381:18	264:4	106:8 107:18
spreadsheet 89:1	started 25:6 47:5	390:11 392:15	street 1:11 143:16	144:17,22 187:22
90:22 149:15	70:11 91:2 98:20	393:12 396:3	stricken 354:15	222:5,11,12
164:1	99:17 202:12	statutory 187:3	strict 148:5	236:20 238:8,10
spring 166:14	starting 193:1	343:10 386:18	strictly 42:20 77:4	259:17 263:18
stability 9:18 119:2	336:21	390:6	strike 61:7 290:13	277:19 300:12
stabilizer 15:19	state 37:2 85:13	stay 329:15	stringent 353:19	306:22 309:9
158:4	100:5 265:10	staying 230:18	striving 161:5	315:13 316:2
stabilizers 157:14	348:9 368:8	step 155:7,7 160:11	strong 36:22 60:3	329:1,6,20 330:1
staff 2:8 97:22 98:6	388:22 393:3	162:11,22 163:21	76:2 90:13 175:11	330:6 341:3
151:15	394:10	164:22 171:14	180:21 190:14	348:11 349:8
stage 280:1 301:17	stated 40:11 131:13	185:7,8,15,17,20	332:13,14 351:8	361:11 362:1,11
stages 209:3 348:7	191:14 223:12,19	242:6 357:11	stronger 140:20	363:2 368:11
stakeholder 345:16	250:4 271:15	steps 91:5,7 185:10	359:5	373:6 390:3
stakeholders 145:7	298:7 343:17	sterile 33:12	strongly 103:18	subcommittees
323:7,17 324:15	368:7 385:18	241:16	142:5 192:10	316:15 329:15,17
328:14 357:16	395:3	stipulates 147:1	193:4 233:6	subcommittee's
stakes 141:11	statement 28:11	stomach 136:3	structural 176:18	10:20 170:19
stand 211:19	157:11,12 182:13	Stone 1:21 64:11	176:22	361:9
standard 4:18 33:8	183:12 189:2	92:14 156:19	structurally 214:5	subfat 74:16
48:13 86:5 170:14	195:5,19 201:6	200:19 201:5,9	structure 120:14	subject 17:13 31:21
173:16 176:7	264:7,13 271:9	257:19 262:22	struggle 256:13	32:2 82:18 130:19
182:14 189:15	302:3 343:19	268:18 272:20	struggles 115:8	144:19 159:20
203:21 224:15	344:5 354:19	274:9 277:4 282:7	struggling 26:15	188:13 339:20
278:14 300:7	355:4 358:20	283:20 285:9	studied 25:3	342:10,14 351:7
301:6	371:1 382:3	287:14 289:2	105:19 123:12,21	363:10
standards 1:5,10	390:14	295:17 311:6	studies 18:22 20:13	subjecting 245:10
2:14,16 26:12	statements 10:2	313:3 314:15	51:9,14,14 67:2	submissions 335:7
54:1 104:19 107:2	states 1:1 26:18	317:1 365:21	76:19 178:1 179:3	submit 50:14 152:7
107:16 151:18	33:5 63:16 66:11	376:12 397:12	188:18 215:11	220:14 229:7
206:4 213:9	69:16 70:5 71:19	Stonyfield 169:22	study 202:16 216:1	248:19 335:5
242:10 252:20	85:3 96:1 108:11	170:2	studying 229:22	388:15
303:13 307:11	123:13 151:20	stood 140:13	stuff 88:14 207:7	submitted 6:11
316:10 343:1,12	167:20 168:5	stop 99:9 216:11	217:16	13:17 35:21 52:4
344:21 345:1,4	200:2 231:10	383:17	subcategory 23:1	56:8 58:20 73:11

78:4 81:5 107:6 223:13 246:10 258:14 264:6,10 388:12 subpar 74:16 subpopulations 66:7 subsequent 385:11 subset 77:1 substance 7:2 14:9 15:9 34:14 73:22 85:10 86:8 118:20 120:1 152:22 153:3 155:16 166:9 167:18,19 168:13,13,19 171:21 184:21 185:2,21 189:20 197:4 198:15 211:5 243:2,5,6 243:18 244:3 246:7,16,20 359:21 substances 20:11 46:12 53:10 83:4 84:13,19 85:5,14 85:18,20 86:1 88:18,22 109:2 116:22 117:15 120:4 124:15,18 152:21 153:8,11 154:5,14,16,22 155:13,14 158:7 163:11 164:7 166:2,11 167:9 168:6,9 170:4 171:3,16 172:4 173:3 185:11 189:17 214:10 250:15 251:8 343:12 substantial 127:17 127:19 332:7 substantially 318:2 substantiate 8:20 substantiation 53:16 243:20	substitute 109:5 213:5 225:21 substitutes 109:6 127:1 194:1 211:8 211:9 subtractions 24:14 88:1 successes 141:18 succinctly 337:19 sucrose 65:8 suddenly 139:19 Sue 3:15 19:19 122:12 suffice 172:17 suffices 142:21 sufficient 25:18 26:20 59:19 131:8 133:21 160:8 188:15 192:5 256:5 290:14 sufficiently 369:18 sugar 192:16 suggest 161:15 162:17 171:14 213:12 293:1,9 311:13 352:1 353:4,11 374:21 suggested 120:11 145:14 227:19 247:11 374:5 suggesting 370:8 373:19 suggestion 88:16 166:15 357:14 374:9 suggests 216:2 344:3 suitability 227:9 230:10 suitable 120:21 229:6,10 230:3,16 230:22 sulfone 74:8 summarize 7:12 10:20,21 40:22 41:13 184:13 summarized 189:1	summarizing 4:20 245:14 summary 16:14 41:14 42:4 43:21 44:21 82:15 sums 44:19 246:21 sunset 89:17 90:17 164:11 171:19 supplement 29:6 75:10 184:2 supplemental 14:13 215:7 246:5 supplementation 128:6,11 129:16 129:17 130:21 supplemented 215:14 Supplements 48:22 supplier 253:13 supply 104:21 129:5 support 6:16 14:7 14:11 17:11 36:4 36:12 42:6 52:14 56:13 59:4 62:15 73:16 76:1,2 78:12 83:21 107:21 110:1 130:7 160:19,20 170:11 175:18 176:13 182:13 191:9 208:10 209:22 210:1 224:19 225:3 240:16 301:1 340:12 347:16,18 347:21 348:9 349:10 350:17 358:5 380:12 supported 19:5 54:12 135:5 197:21 320:21 supportive 98:1 338:4 supports 152:12 208:13 223:20 224:12,18	supposed 186:21 359:2 surcease 140:5 sure 10:15 12:12 16:7 17:10 21:12 24:13 33:1 35:9 35:13 58:1 67:11 73:4 100:5 112:22 113:19 141:4 149:3 151:2 187:11 196:7 203:7,7,10 208:2 222:8 235:22 291:13 320:7 327:16 363:6 371:2,5,6 372:1 surface 30:22 31:2 surfaces 151:1 Surgeon 71:20 surprised 87:8 328:8 surveillance 107:10 survey 103:12,17 susceptible 119:19 Sustainable 169:22 sweat 141:13 sweeps 82:11 sweeteners 104:7 switched 204:9 symbolically 315:15 syndromes 130:6 synergistic 22:16 22:19 23:6 117:19 120:6 synthesize 57:13 179:13 synthesized 37:16 42:19 57:5 62:13 62:17 synthesizes 179:15 synthesizing 131:4 synthetic 7:22 13:19 15:11,13,18 16:15 39:7,10 40:2,6,15 41:10 42:1,22 44:2 45:5	45:15,16 51:1 52:13 53:7 54:2 54:13,18,20,21 57:9 58:11 60:8 60:21 74:14 79:7 80:5,7 94:13 96:15,21 97:1,12 97:13 101:3,12,19 103:20 104:3,6 106:16 108:10,20 109:1 110:18,19 111:4,7 114:20 115:12 118:2 131:10 137:2 139:2 160:10 167:9 184:18,21 185:3 186:8 187:17 191:17 210:19 211:2,4,6 262:3,9 263:9 269:15,19,22 273:9 274:2 275:11 276:1,6,14 280:20 283:9,13 284:13 286:11,16 289:16 290:1 291:5,15,18,19 292:11,14,21 293:3 294:13,22 295:22 296:1 300:16 308:13,14 312:2,9,14 313:10 synthetically 68:19 86:2 synthetics 7:17 41:19 54:10 102:3 103:4,8,10 109:16 110:2,7,14 307:20 308:1,10 syrops 104:4 system 24:1 32:7 107:12 120:2,18 124:14 128:21 202:1,6 221:11 247:22 248:6 297:20 348:21 359:7,13 360:9
--	--	--	--	--

systemic 108:14	255:20 299:21,22	149:16 150:9,19	356:2 388:2,18	137:20,21 138:1
systems 120:9	300:5 302:6 308:1	156:21 164:3	389:3 390:9 392:1	138:19 139:6,9,11
126:19 130:1,6	380:21 384:9	173:17 183:1	terrible 199:2	143:14 144:5,6
202:18	385:9 393:4	188:17 247:10	Terrific 166:18	148:13,15,17
T	talks 15:17 279:8	258:7 300:22	terrors 140:11	150:11 151:8,9,10
T 238:1	tally 150:21 282:20	358:7,13,14,18	test 185:5	152:1 156:11,16
table 229:20,21	tap 215:6	technically 39:1	tested 9:1 120:13	156:17 159:17
236:12 293:10,16	tapping 139:19,21	158:2,3 264:13	testified 201:17	166:18 169:6,7,16
320:18 321:5	139:22 141:3,3	tell 50:20 71:10	testifying 100:10	169:19 174:2,4,7
333:11 374:7	targeting 21:13	146:1 168:22	105:4	178:16,20 182:4
tackle 309:9	taurine 73:1,5,7,10	174:20 195:8	testimony 101:10	187:5,6,8 188:7
take 4:5 5:21 6:7	73:13 74:2,4,11	258:7 299:20	132:19 338:9,11	189:4,4 190:15,16
7:8 13:13 36:16	74:17,22 75:1,5,9	300:2 304:10	342:1,1,6 349:16	194:19,20 195:1
53:3 59:12 74:3	75:16 76:6,8,20	368:3	361:9	195:17,18 196:10
78:21 82:7 95:16	76:21 77:19	temperature 123:7	testing 107:6	200:15,17 203:2
98:8,11 122:16	106:13 126:11	temperatures	tests 107:9 246:18	205:12,14 207:9
146:8 154:22	127:6,6,14,17,22	123:4,7,9	246:18	208:4,5,5 212:6,9
155:22 157:3	128:2,6,8,10,11	ten 21:19 70:14	Texas 18:9	216:12 217:19,22
165:5 183:10	130:2,3 131:13,13	97:16 152:8	text 369:12	218:10 219:16
222:13 227:10	131:18,20 132:2,7	154:13 166:21	thank 4:10,14 7:5,6	221:22 222:17,19
228:7 237:2	132:13 191:12	334:21 337:17	13:6,11 14:22	223:8 228:8,9
239:16 241:16	193:8,9,15,16,19	375:10	15:2 17:4,5 19:16	231:5 233:8,10
300:9 301:10	200:10 202:21	tend 217:16 355:19	20:21 21:1 24:10	235:9,12,13
307:21 315:5	206:15,19 207:8	tended 330:16	25:7 28:8,19 29:9	238:19,19 239:17
320:6 321:6 322:3	311:18,19 312:1,7	tends 355:18	29:10 32:22 33:21	242:8,9 245:3
322:7 326:13	312:14 313:10,11	tenses 368:12	35:14 36:15 44:20	246:22 247:1,5
328:22 336:6	313:13,17 315:3	tenure 20:9	47:17 50:16 51:18	249:16 254:2,16
355:6 369:6,9	Taylor 1:22 262:18	term 9:1 53:3 65:15	53:1,5 55:2 56:3	257:17 259:21,22
381:15 385:11	268:14 272:16	66:7 69:1 70:17	57:1,2,4 58:12	259:22 260:6,8,10
taken 95:18 156:13	274:5 277:14	77:13,15 85:10	59:11 61:16,17	260:12,18 265:7
177:21 324:16	282:17 284:8	91:11 97:21	64:4 67:5 72:15	280:4,7 291:5,6
331:3 354:7	285:19 287:10	126:14 127:9,16	74:1,3 76:17 77:7	297:10 298:5
takes 84:17 148:9	288:20 295:13	129:4 137:4 178:7	77:17 78:20 80:14	299:15,17 306:11
162:11 177:11	311:2 312:21	190:7 214:4	81:10,14,19,21	306:17 307:4
219:10	314:11 317:1	215:12 250:10,11	91:18 92:1,2,6	308:16,17 310:1,3
talk 22:16,18 57:17	342:19 376:8	250:13 280:4	94:5 96:9 97:15	310:8,10 314:1
82:6 116:21 123:6	377:5,17 378:1,6	300:21 325:11	97:17,19 98:3,6	315:17,17 317:5,6
126:10 174:19	396:16 397:8	328:3,11	98:15,22 100:7	319:1,2 333:3,4
186:9 189:11	team 19:20 98:4	terminology 87:2	104:22 105:6,8,22	334:9 342:7,17,19
316:6 353:3	teams 86:20	terms 19:12 35:1	106:7 107:17	343:17 349:12
talked 260:1	technical 6:18 14:8	48:1,7 69:2 83:4	109:17,19,21	350:1,2,3,19
talking 24:2 51:4	14:14,16 17:12	85:11 125:7 162:7	111:14 115:4,5,21	354:3,15,16,18
60:2 82:5 112:22	20:2 36:6 47:19	163:4 185:10	116:2 121:4,6,7	355:7 356:9,11,16
123:7 135:18,19	52:16,17 53:17	218:4 223:15	125:4,18,19 130:9	360:19,21 361:2,3
164:17 165:6	56:16 59:6 73:18	230:18 298:6	130:12 132:15,18	362:8 365:2,6
168:9 234:4 235:2	78:14,16 92:19	338:6,9 339:14	132:18 133:6,12	366:3 369:2 372:9
	142:4 147:9	340:3 354:12	134:5,6 135:7,11	372:11 374:6

376:20 377:5,5,9	62:2 79:6 86:19	389:11,13 392:21	time 5:3 6:2,3 12:5	380:11
378:6 379:19	90:5,18 91:15	393:22 394:5,6,13	12:22 21:12,20,22	time-dependent
380:9 389:12	94:8 98:10,21	395:13,21 396:12	23:12 27:1 28:18	257:13
395:8	99:20 110:3,6,9	thinking 114:19	32:17 46:12 48:17	timing 17:5 178:18
thanked 334:4	110:12,17 112:13	166:17 181:5	51:17,20 58:9	235:19
thanks 6:8 7:9 12:5	112:19 114:11	207:19 280:20	72:16 75:16 81:12	tired 294:3 336:5
13:15 14:21 15:2	115:1,6,16 122:10	391:20	81:21 90:8 92:13	Tis 139:21
17:10 20:22 35:19	122:12 123:12	thinks 301:1	92:15 96:22 105:4	tissue 177:7 181:6
36:14,18 47:18	137:4 141:9	third 36:6 51:21	105:7 106:3	tissues 45:12
51:19 52:2,22	142:20 143:1	56:15 59:6 73:18	114:17 120:16	214:17
56:6,22 58:18	160:17,21 161:22	78:14 341:22	126:18 127:18	title 333:11 343:15
59:10 73:9,22	162:6,15 163:1,13	342:10 349:20	131:22 134:18,20	titles 384:7
77:22 78:2,19	163:20 164:22	thorough 106:8	135:8 137:8	tocopherols 32:7
92:3 98:22 100:21	165:22 166:13	107:18 152:13	141:14 151:5,5	117:16 120:4
106:1 144:9	168:11 169:3,5	163:6 164:13	152:4 155:6 175:4	202:2
149:21 166:20	170:17 177:21	171:15 197:15	178:17 183:11	today 5:10 16:13
174:9 196:6 238:3	183:1 187:22	thoroughly 86:9	188:1 189:5 203:5	17:3,17 19:17
245:5 259:20	188:5 190:3	171:22 197:22	208:5 209:9 215:3	20:22 21:8 38:20
265:16 272:2	202:13 221:15,16	thought 87:9 88:17	218:11 219:10	43:9 61:12 82:5,7
290:8 343:15	223:14 229:19	188:14,17 203:3	221:20 222:13,18	90:10 100:10
366:14 384:15	230:5,20,22	302:19 328:17	228:1 229:21	126:2 133:3
Theuer 81:5	231:15 232:2,9	340:19 348:18	235:14 236:12,13	135:11 144:15
thing 33:2 34:12	235:2 246:21	thoughtful 91:20	247:2,4 249:5,6	145:3 147:20
38:20 41:1 82:22	252:12,12 260:22	thoughts 168:16	249:14 250:2	152:9 183:9
89:15 121:21	261:4 270:19	304:1 355:17	251:11 258:19,20	191:11 196:5
143:5 168:22	278:12,18 279:14	373:19	259:7 265:13	220:20 223:7,12
220:15 221:21	279:21 290:16	thousands 110:5	278:12 279:16	223:16,17 227:18
241:3 246:9 308:7	291:1,9 293:13,17	147:18	293:12 299:19	228:6 250:1 252:7
309:20 316:5	294:3 299:9 300:5	threat 141:12	303:19 316:5	266:3 270:10,12
333:8 338:8,10	300:19 302:19,20	three 5:14 18:17	318:13 320:6,10	280:10 315:5,12
348:18 366:4	303:11,14,22	65:17 66:1 70:9	335:17 336:10	319:6 350:4 357:3
370:5 390:8	317:13,14 318:4	75:18 87:6 95:12	337:9,10,16 338:6	357:9 389:7
things 5:19 24:12	329:10 330:21	99:18 100:2	339:4 340:4	394:16 398:2
79:14 83:1 88:6	333:22 334:2	120:22 121:1	349:13 352:1	toddler 43:13
89:19,21 90:4	338:1,6,8,14,22	122:18 126:11,15	354:15 360:20	136:1 137:9
121:17 143:3	339:3,10,13,16	128:18 130:1	361:3,5,7 362:9	told 70:9 395:15
148:22 160:9	340:2,5,8,10	133:15,18 155:5	362:16 363:7	tolerate 65:20
279:13 280:3	341:5,6,7,16,19	202:17 316:4	364:18 366:4,8,16	tomato 53:10
309:12 319:14	366:4,10,22	317:4 318:16	366:22 371:11,14	tomatoes 53:15,19
320:1 327:7	368:21 369:1,3	331:1 335:12,20	372:11 375:2,3	tomorrow 5:8
328:16 329:14	370:5 371:9	366:11	382:14 385:11	261:4 332:9 333:1
336:5 339:15	372:10,17 373:5,7	thrilled 140:10	386:22 387:16,16	362:16 371:13,14
341:18 373:10,21	373:10,11,20,21	thrive 129:20	395:1,11	373:1,11,21 374:4
387:17	377:13,19 381:6,8	192:16	timed 105:1	396:11 398:3
think 6:5 9:2 11:11	382:2,10,20 383:2	throw 122:4 212:4	times 95:19 160:18	tonight 239:5
12:15 22:3 35:2,5	383:6,9 384:1	241:20	175:20 181:12	tools 389:3
41:11 51:12 54:16	385:9,10 387:13	throwing 214:9	213:19 318:3	top 151:14

topic 72:19 164:22 320:5 334:12 338:3 339:9 342:10 362:15	transparency 170:14 173:16 184:12 188:10 319:13 353:4,5,8 353:9,12 357:17 360:11	249:18 307:19 324:11	232:8 387:12 392:15 393:10,14	375:21 380:13,17 386:13 395:16
topics 137:7 316:3 317:15 336:18 338:17 340:1	transparent 353:22	trying 51:12 154:1 158:9 162:20 167:2 204:7 212:3 253:2,15 328:10 371:4 381:11,11 381:15	types 7:15 82:11 218:21 246:12 309:21	understanding 29:16 184:6,9 188:12 195:13 203:20 206:22 231:20 270:9,22 279:3 298:6 337:21 381:3 385:14 393:3 395:18
total 19:3 63:8 118:17,18 120:1 128:4	transports 129:10	tube 136:16	typically 117:14 124:12,20 125:2 126:15 218:2 271:1,3	
totality 153:3 156:9 168:20	travel 199:7 238:13 360:15	tube-fed 136:3 138:13	U	
totally 339:9	treat 146:6 343:4	Tucker 2:20 32:11 32:14,20 33:1 388:1,2	ultimately 162:19 341:14	understands 113:8
toughest 280:8	treated 146:7 280:22 309:22	Tufts 105:17 174:14	unanimous 11:9 16:18 54:22 107:22	understood 23:20 85:17 87:15 112:9
toxic 60:10 102:8 118:14	tremendous 92:3 209:1	turned 391:6	unanimously 11:7 60:19	undue 44:4
toxicological 246:17	trials 176:6,13 197:21 230:1	turn 315:14 318:20 342:17 349:15 377:2	unapproved 102:1 103:4,8 104:7	unethical 132:6
toxins 101:4 103:5	tried 325:7 341:8	tweaks 170:21	unavailable 43:4	unfair 325:5
TR 8:19 10:1,11 39:8 53:17 79:4 80:18 108:11 271:10,14 275:9 358:21	trillion 143:8	Twinkie 161:11	unasked 33:3	unfairly 320:4
track 21:12 306:9	Trinker 174:12 182:6,7,8 187:11 188:8 189:19 190:1,16	two 5:8,14 7:14 14:8,15 17:12,16 19:8 22:11 24:20 25:9 29:11 30:12 32:21,21 35:5 38:10,11 45:2 47:10 48:19 49:4 55:1 61:11 65:2 65:22 66:16,17 70:2 83:9 86:22 92:14 95:19 99:17 108:2 110:19 112:5 116:21 124:21 125:5 129:18 145:3 147:21 148:3 157:4 168:16 175:6 201:15 219:12 232:12 242:16 247:6 266:13 267:3 319:20 335:4 363:9 373:19	unapproved 102:1 103:4,8 104:7	unfortunately 137:2 350:16
Tracy 1:17 13:13 15:1 17:4 28:9 31:9 47:12,16 50:16 59:12 61:17 61:21 64:5 269:12 269:19 270:19 289:14 293:19 294:10 295:5 296:6 301:12 314:1 383:21 384:16 387:1	trip 19:16	two-way 349:3,5	unasked 33:3	unhealthy 108:19
Tracy's 301:11	trochaic 143:11	type 84:17 121:22	unavailable 43:4	uniform 255:2 366:7
trade 151:19 200:7 322:22 327:12 331:16 350:6	trouble 381:2		unbleached 185:13	Union 106:21 195:6
tradeoff 217:15	troubled 60:9		unburned 129:14	unique 8:1 119:13
trading 200:11 316:4	troubling 278:21		unbuyable 199:7	United 1:1 26:17 33:5 63:16 66:11 69:16 70:5 71:19 95:22 123:13 231:10 350:10
traffic 180:11	Troy 190:18 196:11,14		uncertain 140:9 354:13	units 25:21 33:7
train 165:16	TRs 148:20 149:7		uncertainties 154:1	universe 163:14 165:3
training 244:1	TRs 148:20 149:7 196:11,14		unclear 380:3	University 17:22 18:6,9 20:18,19 20:21 105:18 126:5 174:14 179:21
transferred 214:22	true 8:22 64:17,22 65:5 132:13 176:20 191:17 259:5 299:13		uncomfortable 373:15 383:1	University's 18:13
	trust 100:14,22 102:12,16 109:17 111:10 209:5		uncommon 370:3 386:9	unjust 325:6
	trusted 104:20		underlying 301:2	unknown 8:15
	truth 333:15,18 338:14 341:8,13 341:16		undermine 113:17 82:22	unlimited 360:14
	truly 135:3 140:21 152:4 280:14 297:12		underpinning 82:22	unlisted 101:6
	try 5:12 22:1 33:22 91:2 115:9 165:17		understand 24:12 33:9 57:21 99:6 113:16 131:15 133:4 145:12,15 149:3 163:13 204:10,13 207:2 236:4 250:7 299:12 302:8,20 303:10 305:8 362:5 365:8	unnecessary 279:14
				unofficial 239:9

unprocessed 140:18	143:21 155:17 163:20 165:22	Vallaey's 105:10,12 105:13 110:3	160:13 207:16 218:5 223:17	270:10,11,15 271:1,3,4,11,17
unproven 8:14 44:14	167:9,10,21 170:4 171:16,21 173:12	112:1 113:2,6 114:10	236:5	271:21 272:1
unreasonable 48:9 48:14	182:15 184:18 198:14 204:18	valuable 260:2 280:10 345:17	vatted 102:19	vitamins 25:11,13
unstable 198:10	206:6 207:3	366:9	VHA 201:19,19	27:3 117:18
unsupplemented 127:18 215:15	210:19 218:8 219:5 223:21	value 10:4 15:20 68:7 258:4 280:3	viability 125:15	119:18 153:9
untested 8:14	224:2 225:21	values 46:12,13 198:3 251:5	viable 40:5 120:16	165:7,8,13,19
untoward 132:8	228:17 229:16	vantage 365:22	121:2 123:17	199:15 259:6
update 46:18 251:3	243:7,8,9,18,20	variable 26:16 121:1	183:6 211:11	265:20 267:4,18
updated 14:13 46:5 46:11 213:11,19	244:2,9,17 246:6 247:8,13,15,19	variations 170:20 225:1 385:20	230:16 338:16	vitamin-based 117:3,20 118:22
257:16 279:7 317:19	248:5,8,12,22 263:21 264:17	variety 19:2 212:19 225:1 385:20	viably 396:6	vivo 175:8 176:17
updates 316:12	265:5 266:2	various 117:15 119:9 120:3,8	vibrance 340:1	voiced 110:4
updating 46:16 317:18 396:4	267:12 270:2,4 271:1,15 273:13	144:21 145:7 318:16,16 320:22	Vice 126:6 133:8 182:8	volatile 307:19 308:1,10,14
uphold 107:16	273:19 277:21	321:9 325:17	view 12:12 268:5 279:16 320:12	volume 139:17 338:16
upper 257:4	278:7 284:17	vary 37:19,22	351:15 359:3	voluntary 152:5 243:14 244:21
upward 340:18	285:2 287:21	varying 148:2	viewed 307:10	volunteer 216:19 228:18
urge 107:15 148:11 192:10 193:4,18	288:6 296:9,12,19 297:6,14,15 303:4	vast 210:6	viewing 347:12 379:17	vote 10:21 11:9 16:13,14,18 38:15
200:14 357:4 358:17	313:14,19 339:22 372:2 384:12	vegans 131:3	379:17	39:13 40:13,20
urged 43:6,11	useful 7:21 371:20	vegetables 37:5,21 213:21 214:1	views 109:22 209:15 348:2,3	41:10 60:18 61:1 75:17 125:13
urinary 129:14	uses 38:10 56:12 85:10 114:6	vegetarian 74:10 100:17 233:5	209:15 348:2,3	150:1 210:16
USDA 33:7 103:1 132:3 255:17	185:20 187:4,4 370:2	vegetarianism 66:3 213:21 214:1	vigilance 100:21	260:20 262:13,13
351:7 392:2	ushered 392:21	vegetarians 131:3	violate 199:22	265:13 270:2
USDA's 348:4	USP 182:14 183:15	vehicle 393:20 394:7	violation 102:11 104:9 200:2	272:15 275:2
use 6:15 9:11 10:3 10:4,6 15:14,21	usually 136:2 217:9	verbiage 355:13 396:2	virtual 4:11,12 98:8 260:17	276:21 279:22
16:10 26:3,6 36:2 37:1 38:16,21	UV 42:16	verify 39:5 164:16 258:4 267:13,16	vision 214:21	281:5 282:21
39:12,21 40:17	U.S. 101:16 113:17 117:9 118:2	Vermont 116:10 205:4,4	visual 128:9 131:20 176:9 215:20	286:21 288:11
42:2 48:3 49:19	119:10 195:12	verse 143:22	vital 192:3,14	297:15 302:17
50:6,9,13 52:7,12	202:10 224:1	version 39:22 239:21 254:15	vitamin 9:7 16:5,11 25:9,14,15,17,21	305:5 310:12,16
57:10 59:17 61:5	225:11,19 354:10	317:11	26:3,6,6,9,12,18	312:13 314:5
62:9 67:3,15 69:8		versus 26:4 60:6 64:14 69:3 149:9	27:2,6,9,11,14,18	315:4 332:13,14
69:18,20 71:5	V		27:20,21,22 28:1	342:3 349:8,10
73:15 74:15,15	vaccines 129:1		28:6,11,13,13,22	357:21 359:10
77:14 84:12 85:11	vague 87:1 354:13		29:6 55:19,21,22	360:3 371:13,17
107:21 112:5	Valaise 100:3		74:5 117:2,4,12	376:2,3 380:6
118:2,8 119:1,9	valid 43:18 88:12 211:6		118:10,15,17,19	394:19 395:5
119:12 131:21			119:7,14 120:4	396:17,20,20
			124:8 153:15,16	397:1,4
			157:12,13,16,17	voted 11:7 54:19 125:6 188:2
			157:20 158:4	228:12 332:15
			204:18 267:5,6,7	
			267:10,10 270:1,3	

votes 5:7 10:20 54:22 60:19 263:8 269:5 273:8 274:20 277:16 282:20 284:12 286:2 287:16 289:4,7 295:21 307:14 311:11 313:9 315:2 353:17 354:7 376:20 397:21 398:1	83:7 91:11,18 97:19,22 98:3,8 99:8 102:16 103:8 103:9 112:22 113:18 114:2,13 114:18 136:20 142:14 145:9 148:6,9 152:1,11 165:11 169:12 179:14 181:20 186:9 191:13 203:4,6,10 205:17 207:1 209:18 210:9 211:13,15 211:22 224:22 228:16 230:18 232:11,15 233:4 235:21 238:12 239:1 248:3 270:13 276:16 278:11 290:6 292:8 297:16 299:5,10 301:20 302:5 309:5,5 326:12 330:8 339:6,8 340:20 342:8 357:6 362:22 366:6 367:5 370:18 371:2,6,15,18 372:1,14 377:18 383:17 384:9,12 385:5 387:16,21 388:22 389:10,15 392:18 394:22 395:2,14	warfare 108:15 warms 143:15 warning 253:20 254:5,7,10,13 Washington 350:11 wasn't 270:17 308:8 waste 180:12 watch 363:5 water 212:5 305:21 306:3 wax 90:5 waxes 164:17 way 13:5,6 51:21 89:2 123:16,22 141:8 142:11,22 143:11 157:7,19 163:15 166:16 171:1 175:22 233:21 240:21 256:10 258:13 264:10 271:7 278:21 279:18 298:17,19,20 299:4 300:15 307:9 308:12 318:17 321:19 329:5 350:8 366:10,18 368:3 382:15 385:15 387:19 389:19 391:20	weight 77:2 126:14 welcome 4:13 137:19 188:8 353:18 363:20 well-documented 120:9 well-tolerated 240:17 Wendy 1:19 268:19 286:22 went 90:11 98:17 121:3 237:5 260:14 275:8,8 315:8 318:7 319:16,18 332:6 334:2 354:5 361:20 398:6 weren't 87:14 233:18 we'll 4:21 5:4,6,7 5:12,19 13:12 15:14 35:5 47:16 57:17 58:2,14 73:6 80:4 91:17 139:4 196:4 237:2 247:3 254:18 259:16 260:3 269:11 282:3 283:5 293:20 294:4 305:1 316:3 329:14 345:22 349:6 361:18 395:4 397:4 398:2	168:9 169:8 182:16 202:7 203:10 220:20 230:12 233:13 236:13 250:1 252:7 260:19 268:2 279:3 290:9 294:2 299:21,22 300:5 302:6 303:12 304:2 307:22 308:1 310:13 311:12 312:13,15 315:11 316:9,11,14 322:2 332:17 333:1,8,21 341:21,22 348:19 349:6 355:13 356:22 367:15,15 369:14 371:3,3,10 372:1 377:15 380:5 381:9,11,11 383:10 384:10 385:9,21 387:15 389:15,18 393:4,4 393:9,12 394:13 395:1,16 396:4
vulnerable 181:18	270:13 276:16 278:11 290:6 292:8 297:16 299:5,10 301:20 302:5 309:5,5 326:12 330:8 339:6,8 340:20 342:8 357:6 362:22 366:6 367:5 370:18 371:2,6,15,18 372:1,14 377:18 383:17 384:9,12 385:5 387:16,21 388:22 389:10,15 392:18 394:22 395:2,14	ways 83:9 106:14 318:16 395:17 WDA 320:9 322:20 weak 70:1 139:16 weakened 142:1 weaning 134:14 weary 139:17 website 6:20 14:18 36:9 56:18 59:8 73:20 78:17 WEDNESDAY 1:7 week 61:5 353:16 weeks 127:15,21 weigh 106:10 321:2	we've 4:15 12:18 37:13 47:5,11 51:12 60:2 61:7 92:12 123:21 141:1 147:8 156:13 168:7 177:15 179:3 180:4 185:10 215:18 219:18 280:10 312:7 324:16 338:10 348:20 353:16 357:2 361:22 383:8 387:8 what-not 384:7 whew 40:6 wholesome 116:20 wide 19:2 widely 107:12 wife 231:19 William 132:3	
W				
wait 32:11 96:11 97:6 281:3 282:20	wanted 11:18 21:7 94:10 301:14 308:7 310:5 321:1 321:10 322:12,14 323:9 325:1 328:21 391:17			
waiting 337:13 377:16	wants 114:16 287:18 364:6 366:21 392:20			
Wakefield 356:22	warehouses 199:8 199:9,10			
walk 111:15				
Walker 1:22 109:21 125:5 134:8 222:22 228:11 235:14 262:16 268:12 273:6 274:17 277:12 282:15 284:6 285:17 287:8 288:18 295:11 310:22 312:19 314:9 317:1 318:21 319:2 333:5 376:6 397:6				
walking 115:14				
want 16:22 21:16 22:4 34:12 35:13 49:17 61:21,22 64:5 67:16 80:9				

104 320:18	1980's 213:12	84:12 147:3	45 123:2,3,8	80's 76:19
104.20(d)(3) 38:7	1984 131:21	182:19 183:14	48 151:20 241:21	85 26:10
107-35 313:13	1985 46:5,11	186:4	242:4 388:13	<hr/>
107-35-7 312:1,8	207:17 251:11	21 38:6 46:10 57:19	<hr/>	9
313:18	1990 101:16	197:2	5	<hr/>
107.100 46:4,10	1991 18:15	2111 101:16	5 29:14 324:19	9 68:3 282:21 289:7
11 1:11 269:7	1996 19:19 20:5	2118 85:13	5:00 361:16,18	289:8 321:16
321:17 326:15	1999 324:8	2119 85:13,16	5:03 361:21	328:7
328:3 331:14	<hr/>	22 3:15	5:47 398:6	9:51 98:17
11th 13:17	2	223 3:19	50 210:5 214:14	90 104:1 241:7
12 64:20 66:12	<hr/>	239-page 152:2	390:20	249:7 266:9
70:14 127:15,21	2 84:16 311:11	24 255:19 388:13	500 175:20 181:11	90th 241:9
154:9,10 155:16	321:5 323:8 330:1	25 126:7 130:4	502-65-8 284:16	90's 193:1
164:5,15,16 165:2	347:7 379:11	201:18 212:16	285:2	95 156:1 164:10
166:2,10 225:13	2:10 260:14	321:7	541 288:5	
363:6	2:25 259:20	250 25:20 190:8	541-15-1 286:10,16	
12:23 237:5	2:36 260:15	26 58:20 346:3	<hr/>	
126 163:17	20 25:22 26:1 70:14	378:8	6	
127-40-2 276:5,13	174:17 214:15	26th 266:9	6 60:19,22 282:21	
277:20 278:6	2000 164:9	27 379:5	289:7,7 325:14	
12740-2 40:19	2002 331:8	28 119:17 201:18	334:15 346:2,22	
13 136:1 311:11	2007 52:11	29 55:13 116:9	364:5 365:10	
379:11	2008 188:19	250:12 251:4,13	378:7 379:4	
137-66-6 262:9	2009 185:1	252:1	397:21	
264:16 265:4	2011 6:11 13:17	29th 6:11	6,500 151:20	
139 154:7	14:10 35:21 52:4	<hr/>	60 177:18	
14 73:11 274:20	56:8 58:20 73:11	3	600 357:3	
315:2	78:4	3 40:20 323:11,12	605 140:17 147:7	
14th 35:21 78:4	2012 1:8 103:13	3's 104:3	147:12 158:7	
15 98:11 99:14	2014 166:14	3:41 315:8	605(b) 187:13	
199:12 259:16	205.605 52:7 78:8	3:56 315:9	210:21	
263:8 273:8	84:12 117:5 147:3	30 46:16 51:12	606 147:7,12 158:8	
277:16 284:12	186:1	63:19 95:10,11	187:13	
286:2 287:16	205.605(a) 80:8	208:20 227:21	6510 101:16	
295:21 313:9	205.605(b) 6:15	228:2 319:17	<hr/>	
315:6 376:20	13:20 40:17 42:5	357:1	7	
15-minute 361:10	56:11 59:1 60:21	316 3:22	7 40:15 101:16	
15-1 288:6	61:2 73:14 80:8	38-year 100:17	186:4 313:14	
16 92:8	264:17 265:5	<hr/>	326:15,16	
17 1:8 82:17	273:13,19 277:20	4	7,418 41:20	
18 20:5 99:14 217:1	278:7 284:18	4 3:11 40:20 75:18	<hr/>	
180 249:6 252:16	285:3 287:21	269:6 324:18	8	
19th 52:4	288:6 289:16	378:7	8 46:2 327:8 331:19	
1933 117:10	291:15 292:21	4.1 72:2	397:21	
1980 197:1,10	294:21 296:8,11	4.9 72:3	8:00 1:10	
198:9 207:17	296:19 297:6	4:49 361:20	8:05 4:2	
208:17 223:17	313:14,19	40 69:12 357:2	80 102:1	
	205.606 14:2 36:1	41 123:11		

C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Meeting of the National
Organic Standards Board

Before: USDA

Date: 10-17-12

Place: Providence, Rhode Island

was duly recorded and accurately transcribed under
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UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURE MARKETING SERVICE (AMS)
NATIONAL ORGANIC PROGRAM (NOP)

+ + + + +

MEETING OF THE NATIONAL ORGANIC
STANDARDS BOARD (NOSB)

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THURSDAY

OCTOBER 18, 2012

+ + + + +

The National Organic Standards
Board convened at 8:00 a.m. at the Biltmore
Hotel, 11 Dorrance Street, Providence, Rhode
Island, Barry Flamm, Chairperson, presiding.

MEMBERS PRESENT

BARRY FLAMM, Chairperson
HAROLD AUSTIN
CARMELA BECK

COLEHOUR BONDERA
JOSEPH DICKSON
TRACY FAVRE
JAY FELDMAN
JOHN FOSTER
WENDY FULWIDER
NICHOLAS MARAVELL

JEAN RICHARDSON
ZEA SONNABEND
MAC STONE
JENNIFER TAYLOR
CALVIN WALKER

STAFF PRESENT

MILES McEVOY, Deputy Administrator, National
Organic Program

MICHELLE ARSENAULT, Advisory Board

Specialist

MELISSA BAILEY, Director, Standards

Division, National Organic Program

LISA BRINES, Standards Division, National

Organic Program

EMILY BROWN-ROSEN, Agricultural Marketing

Specialist

JENNIFER TUCKER, Associate Deputy

Administrator

TABLE OF CONTENTS

Compliance Accreditation &
 Certification Subcommittee (CACS)

Calculating Percentage of 5
 Organic Ingredients

Biodiversity Recommendation 19
 Update

Public Comment

CACS Work Plan. 28

Crop Committee Proposal 53

Handing Subcommittee

Nucleotide Proposal151
 Policy Committed Proposal167
 Election of Officers.170

Work Plans

Certification183

GMO Ad-Hoc Subcommittee185

Handling Committee.188

Livestock Committee190

Materials Committee193
 Policy Committee.194

Adjourn

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22

P-R-O-C-E-E-D-I-N-G-S

8:00 a.m.

CHAIRPERSON FLAMM: Board Members,
please take your seats.

Good morning, everyone. We're on
the home stretch here.

Our first and last Subcommittee
session to present proposals this morning,
CACCS, and Joe Dickson as Chair, will handle
this, and I'll symbolically pass him the
gavel, for now. Joe, would you take over,
please?

MR. DICKSON: Thank you, Barry.
The Compliance Accreditation and Certification
Subcommittee has two discussion documents on
the agenda for this meeting. One on
calculating the percentage of organic
ingredients and another on -- a sort of update
on the Board's biodiversity recommendation and
it's progress, and some feedback from the
organic community.

I'd like to first ask Dr. Jean

1 Richardson to present a summary of the
2 calculating percentage of organic ingredients
3 discussion document, and summarize the public
4 comment that the Committee has received to
5 date. Jean?

6 MS. RICHARDSON: Thank you. I'm
7 going to try to be relatively brief on this
8 very complicated topic. So, bear with me, and
9 then of course, there is time for questions
10 later on.

11 So, the problem, as presented to
12 us, basically is that there may be a lack of
13 uniformity amongst the accrediting certifying
14 agencies, the ACAs, in their procedures for
15 verifying the verification of the calculation
16 of percentage of organic in multi-ingredient
17 products.

18 And so, what happened was that the
19 NOP asked us, the NOSB, if we would develop a
20 discussion on this issue and seek public
21 comment, in order to get a clear understanding
22 of what the situation was, and if we could

1 scroll through that, Michelle, to where the
2 relevant area of the rule is, just so that --
3 not everybody is necessarily familiar with it.
4 Yes, if we could just scroll that up and then
5 just sort of leave that up there, for your
6 reading, while I talk.

7 So, here is the relevant area of
8 the rule, of how to calculate the percentage
9 organic in multi-ingredient products.

10 It's relatively straight forward
11 on the surface of it, take out the water, take
12 your liquids, take your dries, add them up and
13 it should be relatively straight forward to
14 do.

15 But the NOP had found, in doing
16 their audits around the country, that there
17 was a lack of consistency from their
18 perspective.

19 So, we sort -- so, we worked on
20 this ourselves, on the NOSB Subcommittee. We
21 sought information from -- well, I'm an
22 inspector, John is in inspection and Zea and

1 other people on the Board have some
2 experience, obviously, in just doing this
3 themselves, from different perspectives.

4 So, that was helpful, and then we
5 talked to some different major certifying
6 agencies, and got copies of their forms and so
7 on, and then developed a set of questions to
8 send out to the broader community.

9 I should say at this point, that
10 we received an absolutely excellent response
11 from several major certifying agencies. It
12 was in fine detail.

13 They spent a long time, helping us
14 to understand more clearly, the issue from
15 their perspective, and we also got them from
16 Organic Trade Association, excellent detail
17 that we -- was very useful, from a major
18 processing company and from Organic Valley, as
19 well as from individuals from individual
20 people, and they were just really, really
21 useful.

22 So, basically, what I'll try to do

1 is summarize, using some of these documents,
2 just summarize sort of the findings.

3 Generally speaking, if you just
4 put it into one paragraph, in most cases, the
5 ACA, the Accredited Certifier's Association,
6 the Association of all of the accrediting
7 agencies, they really feel, from their
8 perspective and all the work that they've
9 done, that there is training that goes on, and
10 not everybody goes to the trainings, however.

11 But by and large, most of the
12 certifying agencies are doing a relatively
13 consistent job, if not, a very consistent job,
14 obviously amongst the large certifiers, but
15 processing, especially for multi-ingredient
16 processing, has grown so fast, that some
17 inconsistencies may have sort have been built
18 in, as the industry has grown.

19 And so, therefore, they
20 appreciated, apparently very much, the fact
21 that we were putting out this discussion
22 document, and came back with some excellent

1 recommendations to us, as to what to do,
2 including especially, that there should be a
3 large amount of training and information
4 materials placed on the NOP website, that
5 would be easily available to the larger, the
6 smaller ACAs, whoever they are, whenever they
7 feel that they need some information, together
8 with specific examples of what you do in this
9 situation.

10 How do you actually develop a
11 specification sheet? How do you deal with the
12 individual materials that are not properly
13 described on their certificates, and examples
14 of better ways to do this, and then they
15 provide some specific examples, which we will
16 be putting into our recommendation or
17 guidance, as we begin to develop it.

18 So, some of the other -- we posed
19 a series of questions, and I'll just sort of
20 give some of the answers that we got from all
21 of the public comment.

22 Nobody seems to want there to be a

1 standardized form, and by that, you know,
2 there is like a -- you know, we looked at
3 these in our Committee, this was a simple,
4 self-calculating sort of Excel spreadsheet
5 type form that the larger accrediting agencies
6 use, where you just type in the numbers and
7 magically, the organic percentage appears at
8 the other side, which makes for relatively
9 easy verification, when you're an inspector,
10 and it puts the burden where it should be, on
11 the processor and the handler, in terms of
12 keeping track of that information.

13 The complexities come in, of
14 course, when you have sub-ingredients and sub-
15 ingredients, and you go back through the
16 system, trying to track all of those
17 percentages, narrowing it down to less than
18 one percent of some minor ingredients, as
19 you're trying to do the calculation, and
20 that's where we need to have some of these
21 specific examples put onto the website.

22 But there was a general feeling

1 from everybody that we didn't want just one
2 form, that there is enough subtle difference
3 between the way in which the different
4 accrediting agencies do their forms for their
5 calculations, that they should be -- have
6 their own forms, as long as they meet the
7 letter of the law, in terms of the ability to
8 verify the percentage organic.

9 So, in fact, the statement was,
10 "It's not the form itself that's important,
11 it's the method of calculating, is what is
12 really important," and guidance is really
13 needed for that.

14 Same thing with specification
15 sheets, which came up from several of the
16 commenters. If you have sub-ingredients, and
17 you know, you're doing a cookie mix and you've
18 got a bunch of flavors and chocolate chips and
19 all kinds of stuff that are going to go in,
20 each of those need to have specification
21 sheets that would make it much easier, as that
22 product goes through from the processor to the

1 handler/distributor, through the processing
2 system.

3 On salt, we asked them if the only
4 salt that was used in their calculation --
5 excluded from the calculations was sodium
6 chloride, and the answer to that was, yes,
7 sodium chloride is the only salt that is used
8 to be excluded from the calculations, and that
9 needs to be clearly stated on our guidance
10 document and on the NOP website.

11 Let's see, other things, yes,
12 there is -- very often, when a certificate
13 comes out, like for example, there is a
14 producer that has -- they're producing apples
15 and lettuce and a whole range of vegetable
16 crops, sometimes, those certificates say 100
17 percent on it. Other times, they just say
18 'organic', and they may or may not have an
19 addendum that goes with their certificate.

20 It may just be a general
21 certificate that says fruits and vegetables
22 organic, and that is not very helpful, if that

1 product is going to go into a multi-ingredient
2 processing product to be developed, because
3 you don't know whether you're dealing with 100
4 percent, or are you dealing with 95 percent.

5 Are processing aides being used?
6 Has there been any post-harvest handling that
7 would indicate that the product was less than
8 100 percent?

9 So, we need to have clarification
10 on what would be -- what is needed on the
11 certificates, to make sure that that label,
12 that the consumer sees at the end, clearly
13 reflects what the percentage organic was that
14 went into that, because sometimes, these aides
15 that are used or post-harvest treatments or
16 the manner in which the raw ingredients is
17 handled, sometimes those become ingredients
18 and not just processing aides and not just --
19 like the citric acid that goes into the
20 tomatoes.

21 So, we need to have examples,
22 specific examples of when you need to have --

1 what you need to have on those certificates,
2 that will allow for clarity.

3 Let's see, other things. Yes, it
4 was pointed out that most of the ACAs do not
5 include processing aides in their
6 calculations. They will be on the back sheet,
7 or they -- and they may be on the calculation
8 sheet itself, just as an aside, but they're
9 not normally -- they're not used in the
10 calculations, but then some of the ACAs do.

11 So, again, we need information
12 about what -- we need to be sure clearly, that
13 we've expressed request to be sure that the
14 processing aides used, are listed clearly, so
15 that the handler, the processor can clearly
16 demonstrate the extent to which there is a lot
17 of that processing aide, a little bit. Does
18 it -- when does it become an ingredient, in
19 order to again, determine if it should be
20 counted in the organic calculations or not.

21 So, like here is one statement
22 from ACA, "Based on the results of our survey,

1 it appears certifiers could use guidance in
2 determining when a processing aide is
3 considered present in the finished product, at
4 an insignificant level versus present at a
5 significant level, and when a processing aide
6 warrants re-classification as an ingredient,
7 counted in the organic calculations, and
8 listed on the finished product label," and
9 it's those subtle nuances that the small
10 numbers below five-percent and often, below
11 one-percent, that become kind of critical
12 between -- because if you don't do the
13 calculation properly as you obviously know,
14 then your product will drop down from being --
15 from the organic category into the 'made with'
16 category, which is not what a processor
17 necessarily wants.

18 There was general consensus that
19 we didn't need a rule change for the fact that
20 in the present language, the language of the
21 law at Section 205.302A, one, two, three,
22 wherever that is, up there, is that the -- in

1 regards, the finished product versus the use
2 of all ingredients, it was considered that
3 that would just be a very simple minor change
4 to make, and the accrediting agencies felt
5 that simply a recommendation or guidance from
6 the NOSB would help to clarify that, since it
7 is, indeed, that we calculate the ingredients
8 based on all ingredients, and not just the
9 finished product numbers.

10 The salts, we did that. Yes,
11 there was -- another one is that we need to
12 clarify when we're presenting our guidance,
13 our recommendations, whether water that comes
14 in with the processed ingredient is removed
15 from the calculation of the organic content in
16 a finished product.

17 For example, chicken broth. You
18 don't consider all of the chicken broth, only
19 the solids in the chicken broth, and not the
20 water.

21 So, at what point -- if you're
22 adding chicken broth to your multi-ingredient

1 product, you've got to be sure you've taken
2 out the water of the chicken broth that you're
3 adding in, before you make your final
4 calculation.

5 And again, we'll need to have
6 specific examples of these, when we put them
7 on the -- when we put out guidance and when we
8 put them on the website.

9 Let's see, and we could -- and
10 would we please -- another question or
11 statement was, "Could we please provide
12 specific examples that would demonstrate the
13 impact of failing to exclude water and salt on
14 the proper labeling category?"

15 All of these are just very doable
16 and very straight forward things, I think,
17 that the NOSB can certainly work on in this
18 coming semester.

19 Okay, so, sort of in sum, that
20 we've got a lot of encouragement from
21 everybody to move forward with a detailed
22 recommendation, as soon as possible, regarding

1 a need for clear and comprehensive guidance
2 document, and to request that additional
3 webinar style training for ACAs be done by the
4 NOP, on a relatively regular basis, so that as
5 this burgeoning and fast increasing market
6 really, means that there is an increasing
7 level of confidence of the consumer in what
8 that label actually means at the end, that
9 says percentage organic.

10 So, that's, I think basically, all
11 I really need to do on this topic, and take
12 questions from the Board.

13 MR. DICKSON: Thank you, Jean.
14 Are there questions or discussion from the
15 Board?

16 MR. STONE: I'll just add that we
17 intend to engage the certifier's ACA on some
18 of these judgement calls, if you will, that
19 the folks that are using and that help all the
20 time, working with handlers, so, the people
21 that are close to the decision making can
22 advise us in the best way.

1 The people that are close to the
2 decision, help make that decision and engage
3 them very closely, so, we don't kind of sit in
4 a -- we're not going behind the curtain to
5 finalize this recommendation, I guess is what
6 I'm saying.

7 MR. DICKSON: Any other questions
8 from the Board?

9 As far as next steps on that
10 discussion document, our work plan is
11 currently to take the feedback that we
12 received and fashion a recommendation on this
13 topic for the Spring 2013 meeting.

14 Next, we have Barry Flamm
15 presenting the discussion document on
16 biodiversity.

17 Barry?

18 CHAIRPERSON FLAMM: Thank you,
19 Joe. This discussion document is about
20 implementing biodiversity conservation in our
21 organic agricultural systems.

22 The purpose of the document was to

1 review progress in implementing the Board's
2 recommendations on biodiversity conservation,
3 which was made back on May 6, 2009, and
4 approved by the Board, by all, but also, to
5 identify other aspects of implementing
6 biodiversity conservation standards that may
7 require further attention, and by seeking the
8 input of the organic community, and another
9 purpose was to further call attention to the
10 importance of biodiversity in organic
11 production systems.

12 As a way of a little background,
13 which isn't really needed with this group, I
14 think, because I think the value of healthy
15 agriculture and for society at large, depends
16 on protecting biodiversity, and this is
17 reflected in a number of places in the -- in
18 our organic regulations, and in response to
19 this, the NOSB issued guideline statements in
20 2004, 2005 and again, in 2009.

21 And during all this period, there
22 has been tremendous, outstanding work done by

1 the organic community. Much of that is --
2 really, great work has been done by the Wild
3 Farm Alliance, the International Organic
4 Inspector's Association has done a lot of work
5 on training inspectors, and we got help from
6 ATTRA, providing producing guidelines and so
7 forth.

8 My first meeting in May 2008, five
9 years ago, Lynn Coody, representing her --
10 both herself, and the Wild Farm Alliance,
11 called to attention to the Board, the -- a
12 need for some follow up action by the Board,
13 and this ended up with the Board -- the Board
14 agreed with these comments, and established a
15 joint CACC then, and Crops Committee, to look
16 into the problem and issue a statement.

17 There was a draft document
18 produced, that received lots of comments, lots
19 of ideas, and that led to the recommendations
20 and guidance that was produced in the
21 following year, in May 2009.

22 That document sort of divided the

1 issue up into two parts. One dealt -- one
2 part -- the first part dealt with what the
3 Board itself could do, and that dealt with a
4 material review and looking at our checklist
5 and so forth, and see how biodiversity could
6 be better addressed.

7 The other dealt with the organic
8 system plan, which is so key to the whole --
9 our whole system. That's what gives us both
10 a way of implementing organic standards and
11 guidelines, but it allows for the flexibility
12 to fit the situations, and certainly,
13 biodiversity is a case where every --
14 practically every farm is a little bit
15 different. So, you're going to have different
16 solutions.

17 The recommendations there, again,
18 under the plan, the recommendations were
19 divided up for the certified producer, what
20 they could do, what the inspectors could do,
21 what certifiers could do, and what the NOP
22 could do.

1 And in this review, we looked at
2 each segment of this, and asked them some
3 questions that -- of each, not only, we wanted
4 to find out what the progress was, but also,
5 whether there was other things we could do,
6 and then -- and in this process, there were a
7 few questions asked that we were trying to get
8 some response to.

9 Just those -- under the material
10 review, a question that was asked was,
11 originally in the first -- and the Board had
12 added questions about biodiversity
13 conservation, the impact, but this was sort of
14 a negative statement.

15 The question was, what are the
16 positive impacts a particular material might
17 have on biodiversity, and that was a question.

18 One of the issues that was raised
19 as an issue, but without any proposed
20 solutions, really in the 2009, was a high
21 value lands, you know, natural lands, high
22 value conservation lands, that might be

1 converted to organic production, and you know,
2 those lands might -- they can be tempting, for
3 one thing, because you don't have to wait for
4 the transitioning, if they're natural.

5 So, there was some issues there,
6 and we -- the Wild Farm Alliance, besides some
7 39 other groups working with them, had made
8 some recommendations, and we raised the
9 question about their recommendation, what the
10 whole organic community thought of that.

11 Then there is -- I think the other
12 question was about handling operations, and we
13 had heard that some certifiers didn't think
14 that asking -- that handling operations had
15 any impact or needed to pay any attention to
16 biodiversity. So, we asked questions about
17 that.

18 We really got some really good
19 written comments back from -- we got excellent
20 comments back from all these people, the ACA,
21 Beyond Pesticides, Center for Food Safety,
22 Cornucopia, NOC, OCA, Oregon Tilth, Wild Farm

1 Alliance and several individuals, and yes, I
2 found this one a little late, but QAI had
3 comments also, and I hope I didn't miss
4 anybody else.

5 The way it's organized between
6 general and specific topics, it takes a little
7 bit of searching.

8 But these are excellent comments,
9 and I think we'll give these, all of them,
10 further review in the Committee, and then we
11 got some very excellent comments during the
12 meeting, the session, and I'm personally
13 looking forward to Lynn Coody's comments
14 today.

15 So, I think it's sort of
16 appropriate, five years, 10 meetings later,
17 that she starts it off and has, not the final
18 word, but today, because there is no final
19 word on biodiversity. It will be something
20 we're always going to be -- if we're diligent,
21 we'll always be working on it.

22 I think, as I said, this -- the

1 comments are, you know, really very useful.
2 I think the -- everybody, all the comments
3 acknowledges and recognizes the value of
4 biodiversity. I think everyone thought the
5 approach that was taken into those recommended
6 in 2009 were the right approach.

7 I think everybody agreed that, you
8 know, we ought to address the positive impacts
9 of a material on the -- when we review it, on
10 material checklist.

11 I believe the only comment we had
12 that questioned doing that was Oregon Tilth.
13 I think there was agreement on conversion of
14 high value conservation lands, as really, an
15 important issue.

16 There wasn't universal support,
17 but there was strong support for the approach
18 that Wild Farm Alliance made, and those
19 recommendations actually were in a package of
20 other recommendations to the National Organic
21 Program.

22 Not surprising, there was

1 universally strong support for the need for
2 further education and training, and I think
3 there was agreement that handling operations
4 can affect biodiversity, and that is something
5 that cannot be ignored, and finally, I think
6 several commenters pointed out the importance
7 and need for further National Organic Program
8 guidance, in order to achieve better
9 implementation.

10 There has been excellent progress
11 in that area, and much of the recommendations
12 were -- that had been made in 2009, either
13 have been accomplished or are being
14 implemented or on the work plan to be done,
15 soon.

16 So, I think Joe, that is the
17 summary, and I hope we, you know -- I think we
18 need, as a Committee, to study these comments
19 and look at what we got out of that and figure
20 out in the Committee, you know, what further
21 action or how we should proceed. So, that
22 concludes my comments.

1 MR. FOSTER: Thank you so much,
2 Barry, for keeping up the momentum on this
3 important issue.

4 Is there discussion from the
5 program or the Board, on this particular
6 discussion document? Questions?

7 All right, thank you, Barry. Now,
8 we move on to public comment on the CACS work
9 plan.

10 We have Lynn Coody up first,
11 followed by Bonnie Wideman, on deck.

12 MS. COODY: Good morning. My name
13 is Lynn Coody and I'm commenting on behalf of
14 the National Organic Coalition, a national
15 alliance of organizations representing
16 farmers, environmentalists and other organic
17 industry members and consumers who are
18 concerned about the integrity of the national
19 organic standards, and today, I'm commenting
20 on the biodiversity discussion document.

21 NOC concurs with the CAC that both
22 the NOP rule and the principles of organic

1 farming recognize the value of fostering
2 biodiversity in organic production systems.

3 NOC has consistently supported the
4 NOSB's recommendations that have encouraged
5 NOP to implement the existing standards on
6 biodiversity and nature resources
7 conservation. We're pleased that the CAC has
8 developed a discussion document to assess the
9 progress on this topic.

10 On the topic of the NOP
11 instruction on biodiversity.

12 CAC reports on NOSB's earlier
13 discussion for the need of additional guidance
14 on biodiversity and nature resource
15 conservation, because both operators and
16 certifiers and have expressed that more
17 information would be helpful to them, in
18 implementing NOP standards on these topics.

19 NOC thinks that some further
20 explanation from NOP about its expectations,
21 with regard to implementation, will serve to
22 both clarify and standardized certifier's

1 approaches to these topics.

2 NOC favors development of an NOP
3 instruction that would be framed as a
4 requirement for certifiers under Section
5 205.501-A21, which is the provision on other
6 requirements for certifiers. This would make
7 it a mandatory requirement.

8 Applicability to handling
9 operations. NOC notes that the regulation
10 requires that operations of all scopes of
11 certification address biodiversity. So,
12 instruction on the NOP's expectations with
13 regard to assessment of handling operations
14 would be especially helpful.

15 Although handling operations deal
16 mainly with indoor environments, NOC suggests
17 that there are many opportunities for
18 addressing biodiversity in natural resource
19 conservation, such as, here are a few
20 examples.

21 Landscaping methods and materials
22 around processing facilities. Management of

1 nearby lands, to mitigate the loss of natural
2 environments, such as wetlands or other
3 sensitive environments, when building
4 processing facilities.

5 Pest control systems that are
6 sensitive to non-target species. Wastewater
7 treatment systems that protect both water
8 quality and quantity.

9 Air handling systems that shield
10 natural systems from dust and fumes, and
11 plantings that create shelter and food for
12 beneficial insects, bats and birds.

13 Audit checklist. NOC notes that
14 the NOP previously recommended revision of the
15 checklist used to audit certifiers, so that
16 the checklist include questions about NOP's
17 biodiversity standards in every assessment of
18 certifiers.

19 We are pleased to see that the NOP
20 recently posted revised checklists that do
21 implement this recommendation.

22 Now, that NOP has taken that

1 positive step, we endorse a further step,
2 recommended by the NOSB, that is including the
3 topic of biodiversity standards in trainings
4 that NOP provides for the accredited
5 certifiers.

6 Finally, penalty matrices. NOC
7 continues to review new policies of the NOP
8 with an eye to evaluating their sufficiency
9 for supplementing the standards on
10 biodiversity and natural resources. In
11 September 2012, NOP issued an instruction, and
12 NOC reviewed the penalty matrix associated
13 with this instruction for the requirements of
14 implementing biodiversity.

15 We concur with the comments of
16 Wild Farm Alliance, about the importance of
17 specifically mentioning biodiversity and
18 natural resources in the penalty matrix, as
19 NOC thinks that the current mention of soil
20 and water quality is not broad enough to
21 address operators compliance with all elements
22 of Section 205.200.

1 Thank you. Just perfect. The
2 only other thing I'd like to say is, again,
3 thanks so much to Barry, for spearheading this
4 great effort on biodiversity. It was really
5 great to be there, making my presentation and
6 having Barry as his first meeting, really
7 speak up strongly and help out. So, I
8 appreciate it.

9 MR. DICKSON: Thank you, Lynn.
10 Any questions for Lynn? Jay?

11 MR. FELDMAN: Thanks, Lynn, for
12 all your work on this.

13 What should -- what do you think
14 the NOSB should expect, in terms of things
15 moving forward?

16 You know, if you were to lay out a
17 time line for things to happen vis-a-vis
18 training and certification in this area, what
19 should be the expectation of the NOSB, for
20 that time line?

21 MS. COODY: Well, I think that
22 we've come a long way and we have a lot of

1 pieces that the NOP, itself, has actually
2 worked on.

3 So, I would like to see -- I mean,
4 there is a great training coming up in
5 January, and I think there could at least be
6 an initial review of what is in place now, and
7 what -- how certifiers can implement this.

8 Of course, many certifiers are
9 already implementing this, you know, they have
10 taken steps voluntarily to include
11 biodiversity in their OSP forms and things
12 like this.

13 But as far as the penalty matrix
14 and the expectations about the way that
15 certifiers will be assessed in their
16 accreditation audits, I think that would be
17 really great topic for including in the NOP's
18 training in January.

19 So, I don't think it would be that
20 hard, and they are already obviously, doing
21 these assessments. So, just letting
22 certifiers in on what to expect, would be

1 great.

2 So, that is one -- that is -- you
3 know, I'd like to do that. I'll be at the
4 training, and I'd love to see that.

5 MR. DICKSON: John, did you have a
6 comment?

7 MR. FOSTER: Yes, a question,
8 actually. Thank you, Lynn. That was very
9 good.

10 My question, not surprisingly, is
11 on the handling.

12 MS. COODY: Yes.

13 MR. FOSTER: Kind of the
14 expectation. So, do you see that eventually
15 ending up in the form of standards, regulation
16 or is that guidance or -- because that -- the
17 options that you laid out there are all very
18 sensible, you know, thoughtful and likely,
19 doable kind of things.

20 MS. COODY: Yes.

21 MR. FOSTER: Where, in that
22 hierarchy, do you see that falling and what --

1 you know, how do you see that playing out?

2 MS. COODY: Well, I think, John,
3 it could easily be included in this
4 instruction, that I recommend that the NOP use
5 to help certifiers understand exactly what is
6 expected.

7 So, some certifiers have already
8 included, as I said, they already include this
9 in the handling inspections. But others, it's
10 a new area for them.

11 So, I think it would be a good
12 thing, to have a specific area in this
13 instruction, about handling -- the
14 applicability of these standards to handling
15 operations.

16 It would help, not only certifiers
17 know how to implement this, it would give
18 handlers an idea of, you know, what they could
19 actually put in on their -- how they could
20 fill out the portion of the OSP and what is --
21 many handlers are already doing things like
22 this.

1 So, they can kind of get
2 biodiversity credit for some of these
3 activities that are already occurring.

4 MR. DICKSON: Thank you, Lynn.

5 MS. COODY: Okay, thank you.

6 MR. DICKSON: Next is Bonnie
7 Wideman, and on deck is Marty Mesh. Don't
8 leave the room, Marty.

9 MS. WIDEMAN: Good morning. I'm
10 Bonnie Wideman. I'm the director of Midwest
11 Organic Services Association, or MOSA, and we
12 certified 1,500 operations in 20 states. I'm
13 also the steward of the land at Pine Knob
14 Organic Farm, and I raise sheep, beef and have
15 organic wool and lamb skins.

16 I'm retiring at the end of this
17 year, and I'm going to be able to devote
18 myself to my farming, and because I'm
19 retiring, I'm at a point where I can look back
20 and I look forward, and I want to express my
21 concerns, that are joined with the concerns of
22 other farmers, in that we are being

1 overwhelmed with paperwork and the need for
2 documentation.

3 And also, at the same time, I
4 think many farmers would agree with what Vashi
5 said, about the floorboards of organic being
6 taken out, but the ceiling not being raised,
7 and I think the biodiversity is a really,
8 really important area.

9 On my own farm, I have it in a
10 conservation easement, no mining, no
11 development, no conventional farming. I'm
12 going to read to you, a comment by an
13 outstanding conservation farmer that we
14 certified organic, and when I read it, I don't
15 want it to come across as anti-biodiversity,
16 but what I want to stress is that we're not
17 following through on this age of enforcement
18 by increasing the length of the organic system
19 plan.

20 What we need is guidance from the
21 NOP, as to what we are to look for in
22 biodiversity.

1 I would love it, if we didn't
2 certify corn that was planted on land coming
3 out of CSP. You know, but give us the tools to
4 enforce. Empower the certifiers. You could
5 do the same with animal welfare. We don't
6 need to lengthen the OSP. We need to feel
7 empowered.

8 So, here is a statement, and
9 again, this is from a farmer whose family,
10 generations back, were leaders in conservation
11 farming, in the Coulee Region of South Western
12 Wisconsin.

13 "Well, Bonnie, I am," this was in
14 2006. We had included a few questions on our
15 OSP, suggested by the Wild Farm Alliance. I
16 took them out the next year.

17 "Well, Bonnie, I am about done
18 with my MOSA application, and I have to
19 confess, I hate it more every year."

20 "Nowhere in bureaucratic heaven or
21 hell are there more extensive or more complete
22 collections of inane, pointless, redundant,

1 stupid and just plain impossible questions.
2 Like, have you assessed the farm for
3 biodiversity problems and greatest
4 opportunities, then developed goals and a time
5 line for biodiversity conversation, then
6 please describe or explain."

7 "To make the point of how stupid
8 your question is, you give me one quarter-inch
9 of unlined paper for an answer that the EAP
10 would spend \$3.6 million in four years,
11 answering."

12 "The final insult is when you are
13 done with this monstrosity, the organic
14 application, the instructions say, take your
15 47 pages, pull out the staples and make two-
16 sided copies of everything. MOSA needs to
17 review this process. I have spent two days on
18 it, and I am sure, I am going to be told it is
19 incomplete. Compliantly yours, Vince."

20 So, I made it before the buzzer.

21 So, thank you, all. Any questions?

22 MR. DICKSON: Thank you, Bonnie.

1 MR. MARAVELL: Thank you for your
2 comments. I know that many farmers share the
3 sentiment of the quote that you just gave, and
4 they are sincerely trying to meet the goals of
5 biodiversity.

6 So, to the extent that we can come
7 up with the type of flexibility that a farmer
8 is willing to respect, in dealing with a
9 certifier, would be great, because I must --
10 I guess I should -- for full disclosure, it
11 takes me more than two days, to fill out my
12 OSP, and it's getting longer, each year.

13 So, I applaud you on your courage
14 and for the goals that you stand for, and
15 please, help us come to -- give me the time to
16 go out and do the work of biodiversity, get me
17 out of the office.

18 MS. WIDEMAN: Thank you.

19 MR. FOSTER: Bonnie, one more.
20 Bonnie, one more question.

21 MS. RICHARDSON: Bonnie, I want to
22 thank you very much for your comments, and

1 they're really right on point.

2 You know, I've been doing organic
3 inspections for the last -- and this is to the
4 Board, too, for the last 13 years, and when we
5 started doing the inspections 13 years ago, we
6 had like three sheets was the OSP, and our
7 inspection report was maybe two sheets.

8 I mean, it was really, pretty
9 much, check off, and there was a lot of
10 exchange, and just -- I mean, there was
11 probably more discussion than Miles would have
12 liked us to have had, but you know, we -- it
13 worked pretty effectively and it was very sort
14 of educational and empowering to the farmers.

15 But then now, when I go there,
16 their OSP's are usually, I don't know, 25
17 pages long and plus, all the necessary
18 attachments they have to put in, and then my
19 inspection report is usually, I don't know, 25
20 pages long for a vegetable farm. I mean, it
21 is excessive, to put it mildly.

22 And I really agree with you, and I

1 think it's an important thing for us to be
2 looking at on the NOSB Board, as we begin to
3 work to exchange information with the ACAs, to
4 say, you know, all those folks sitting in the
5 accreditation offices, you know, the kind of
6 people that are there, and I mean, I know lots
7 of these nice people, but they're very focused
8 on forms, and they don't necessarily go out on
9 the field and do a lot of the actual
10 inspections, perhaps as much as they ought to.

11 So, to try to reduce the amount of
12 paperwork, and that just doesn't mean turning
13 everything into computer systems, I'm not sure
14 that that is the answer, either, because I
15 think we have to remember, as you're pointing
16 out in your presentation, that these farmers
17 are human beings trying to make a living, and
18 we do have to be empowering and helpful in
19 every -- in many different aspects.

20 So, I think greater exchange
21 between what the accrediting agencies feel
22 that they need, what NOP thinks that they need

1 to do their audits right, remembering that
2 we're dealing with either processors and
3 producers or farmers who are trying to make a
4 living by working with a system, which has
5 become increasingly complex, especially as we
6 begin to add in things related to gap
7 certification, as well, and all the other
8 things that are coming in.

9 So, I really appreciated your
10 comments, and I hope you stay, even though
11 you're going to retire, I hope you'll continue
12 to give us some specific examples and
13 feedback, as we try to come up with some
14 useful guidance that doesn't swamp the
15 processors and producers, anymore.

16 MS. WIDEMAN: Right, I think it
17 needs to be -- farmers have commented that
18 inspectors don't inspect anymore, they just
19 review the paperwork.

20 But biodiversity should be
21 inspected and enforced, and it needs to be
22 done on the farm, not on the paper. Thank

1 you.

2 MR. DICKSON: Wait, don't go
3 anywhere, yet.

4 Zea?

5 MS. SONNABEND: Thank you for the
6 comments, Bonnie, and in general, we at CCOF
7 completely agree with you, and really hope the
8 NOSB, in the future work plans, will get
9 around to working on some issues regarding how
10 much paper is appropriate.

11 However, in my long experience as
12 a farm inspector also, I know that just as
13 biodiversity encompasses a great deal of
14 different types of systems, there are a great
15 deal of different types of farmers, and those
16 questions which are irrelevant to, you know,
17 many, many farmers, will be really significant
18 for some farmer with some type of farming
19 system, somewhere.

20 And so, at some point or another,
21 you know, all of those 25 pages come into
22 play, although not all on the same farm, and

1 that is what we have to struggle with, to make
2 sure we can encompass all the situations we
3 find out there in the farming world.

4 So, we hope you will continue to
5 participate and help with that, as we struggle
6 with that.

7 MS. WIDEMAN: I certainly will.

8 MR. FOSTER: Hey, Bonnie. I think
9 we have one more question, sorry.

10 MS. WIDEMAN: It's getting
11 embarrassing.

12 MR. DICKSON: Barry?

13 CHAIRPERSON FLAMM: I don't want
14 to wear you out, but I just want to -- as sort
15 of lead person on this, thank you for those
16 comments, because we did get those kind of
17 comments back on -- in 2008 and 2009, from
18 farmers, and we're --

19 But I think what you said is a
20 good reminder to keep it down to earth and
21 what we all want is the -- is to be able to
22 help the farmer do a better job in

1 biodiversity conservation, because that will
2 help him, in the long run on his farm.

3 And I thank you very much for
4 reading that and reminding us of the realities
5 and impacts, and we don't want more paperwork.
6 We want better practices, and to help the
7 farmer do it. So, thank you very much.

8 MS. WIDEMAN: You're welcome.

9 MR. DICKSON: All right, I think
10 you can go now. Thanks, Bonnie, and Marty
11 Mesh, with the last word.

12 MR. MESH: I'm Marty Mesh, the
13 executive -- you don't have to be sorry, they
14 all appreciated it, actually.

15 I run a non-profit called Florida
16 Organic Grower's, just a credit, Florida
17 Organic Grower's, our certification program,
18 quality certification services. I think, I
19 didn't prepare written comments, because I
20 didn't even know how long you get with these
21 things, whether it's three or four minutes,
22 and I was too busy.

1 But I think the overarching
2 thought that I had is to thank the Board,
3 obviously, for all the work. It's a
4 tremendous amount, on behalf of everybody. I
5 think, Barry, the other night -- and the
6 biodiversity stuff, we certainly were
7 supportive of, although our certification
8 program, Bonnie articulated it all well, and
9 I didn't know what she was going to say,
10 beforehand.

11 You know, I was scared when Barry
12 no longer has a valid certificate, but wanted
13 to keep his old certificate, you know, during
14 the reception the other day, I that I heard,
15 I came up to him and asked, "I hope that you
16 didn't give up your certification because of
17 the expectation of increased paperwork related
18 to complying with the biodiversity standard,"
19 and so, Bonnie's comments, I just want to echo
20 and reiterate.

21 I've expressed concern that, you
22 know, our certification program again, while

1 it's supported, biodiversity had a real fear
2 of increasing the amount of paperwork in time,
3 and sometimes, it feels to me like, you know,
4 we're our own worst enemy, as far as the goal
5 of growing organic agriculture, and I see it
6 sometimes in materials review, changing the
7 landscape, changing the rules, you know, you
8 encourage.

9 You know, when I buy a product
10 personally, I really look at, you know, what
11 effect does it have on the farm workers,
12 farmers, the environment, and I want to
13 support that product, and that is why, you
14 know, I choose to buy organic products a lot,
15 and so, to have something that is, you know,
16 99.9 percent organic product, I look upstream,
17 and I don't really care that it has some
18 little thing in it, and I wonder sometimes, on
19 the process of it.

20 I also, you know, I am scared
21 somewhat, I heard the talk about inerts
22 ingredients reviews, which I know are

1 important, you know.

2 But you know, the amount of work
3 and materials reviews that I think the staff -
4 - I don't know if you guys even talk about to
5 the National Organic Program staff, or your
6 own materials review committee, about what the
7 inerts review will entail. It seems just a
8 tremendous amount, and so, the whole thing
9 seems to be getting not only paperwork-y, but
10 you know, top heavy in the sense of the
11 program.

12 And you know, when I think back
13 years ago, that was what my farming partner
14 said is, you know, when he didn't support the
15 National Organic Program and I did, he asked
16 me, "You know, tell me one thing that the U.S.
17 Government has done, that has been good for
18 organic farmers like us," and it was deathly
19 quiet in the watermelon field that day,
20 because I couldn't think of it, and I said,
21 "I'll make this one different."

22 But you know, I see farmers

1 fleeing now, from organic because of not so
2 much that they're running away from farming
3 organically or the commitment to environmental
4 stewardship, but from the paperwork and the
5 bureaucracy and stuff like that.

6 But I wanted really, to make sure
7 that I was the last public commenter that
8 Barry ever heard, sitting on the Board, so, I
9 signed up for the last slot, and I just wanted
10 to say thanks, and we have a little parting
11 gift for you, a little DVD from a film that
12 has biodiversity methods in it.

13 MR. DICKSON: Thank you, Marty.
14 That concludes the compliance -- that
15 concludes our part of the meeting. Barry, I
16 return the imaginary gavel to you.

17 CHAIRPERSON FLAMM: I've been
18 asked to make an announcement, that the Board
19 should sign the 10-year anniversary poster.
20 It's in the back there, and so it can be put
21 up.

22 So, everyone, when we have our

1 upcoming break, please, if you haven't signed
2 it, sign the board back there, and Michelle
3 can put it where you're going to put it.

4 Anyway, I think we're scheduled
5 for a break, now. We may be a little ahead of
6 schedule, but we'll take our break, and then
7 we'll come back to address the proposals that
8 were deferred. We have four proposals from, I
9 guess, three committees that will be further
10 discussed and voted on, this morning.

11 So, let's take a 15-minute break
12 and be back here at, let's see, 10 after the
13 hour.

14 (Whereupon, the above-entitled
15 matter went off the record at 8:57 a.m. and
16 resumed at 9:17 a.m.)

17 CHAIRPERSON FLAMM: Board Members,
18 please take your seat.

19 Our business now is to address the
20 deferred proposals, from the last several
21 days.

22 We have four deferred proposals

1 for the final vote, and beginning with the
2 Crop Committee.

3 Crop Committee, do you have a
4 motion on any of your deferred proposals?

5 MR. FELDMAN: Yes, Barry, thank
6 you very much.

7 CHAIRPERSON FLAMM: Do you --

8 MR. FELDMAN: I have the motion on
9 rotenone here.

10 CHAIRPERSON FLAMM: Okay.

11 MR. FELDMAN: Okay, sorry for the
12 delay. Appreciate your indulgence.

13 The classification motion, first.
14 I move that rotenone is a natural substance.
15 Can I get a second on that?

16 MS. SONNABEND: I'll second.

17 CHAIRPERSON FLAMM: It's been
18 moved and seconded to classify rotenone as a
19 natural substance. Discussion? Any
20 discussion by the Board?

21 To clarify the motion, if you'll
22 agree, Jay, it's to add rotenone to the

1 National List 205.602 as a prohibited natural
2 substance. No, that is the next part, sorry,
3 I'm ahead of the game.

4 MR. FELDMAN: You're ahead.

5 CHAIRPERSON FLAMM: Excuse me.

6 MR. FELDMAN: Yes, that's where
7 we're headed.

8 CHAIRPERSON FLAMM: Okay, sorry.

9 Any discussion?

10 Hearing no discussion, I think we
11 can proceed with a vote, beginning with
12 Colehour.

13 MR. BONDERA: Yes.

14 MS. TAYLOR: Yes.

15 MR. MARAVELL: Yes.

16 MR. FELDMAN: Yes.

17 MS. SONNABEND: Yes.

18 MR. STONE: Yes, sir.

19 MS. FULWIDER: Yes.

20 MR. AUSTIN: Yes.

21 MS. FAVRE: Yes.

22 MS. BECK: Yes.

1 MR. FOSTER: Yes.

2 MR. DICKSON: Yes.

3 MS. RICHARDSON: Yes.

4 MR. WALKER: Yes.

5 CHAIRPERSON FLAMM: And the Chair
6 votes yes. So, we have 15 'yes', zero 'no',
7 and the motion to classify rotenone as a
8 natural substance passes.

9 Okay, now, for the listing motion.

10 MR. FELDMAN: I move that we --
11 the motion -- the following motion, to add
12 rotenone to the National List 205.602 as a
13 prohibited natural substance, effective
14 January 1, 2016. Second, please?

15 MS. SONNABEND: I'll second.

16 CHAIRPERSON FLAMM: We have a
17 motion, which has been seconded, to add
18 rotenone to the national list 205.602, as a
19 prohibited natural substance, effective date --
20 - effective January 2016.

21 Discussion on the motion? Hearing
22 none --

1 MS. SONNABEND: I'll discuss.

2 CHAIRPERSON FLAMM: John?

3 MR. FOSTER: I'm surprised I'm the
4 only one, but so far.

5 So, I've kind of gone back and
6 forth on this, and I mentioned some of my
7 concerns, the other day, about the optics of
8 it.

9 But I want to at least, talk a
10 little bit about the process of it, you know,
11 having not been a petitioned move, and how
12 that impacts timelines in people's minds, and
13 that it was something we brought forward, as
14 opposed to a different process that we're more
15 used to, and I really -- I would like to be
16 more comfortable with that process, and where
17 we all feel -- how we're feeling about that.

18 Because I haven't been involved in
19 a lot of those conversations, so, I wouldn't
20 mind hearing how people are feeling about the
21 process of it.

22 CHAIRPERSON FLAMM: Jay or Zea,

1 would you like to address that?

2 MR. FELDMAN: Okay, just to
3 clarify, John, I'm sorry, I was a little
4 distracted.

5 You want to hear about a
6 discussion on the process?

7 MR. FOSTER: Just that this came
8 about --

9 MR. FELDMAN: Okay.

10 MR. FOSTER: -- you know, as a
11 result of an atypical process.

12 MR. FELDMAN: Yes, yes, yes.

13 MR. FOSTER: And you know --

14 MR. FELDMAN: Yes, exactly.

15 MR. FOSTER: And I would like to
16 have more thoughts on that.

17 MR. FELDMAN: Okay.

18 MR. FOSTER: Because I'm a little
19 sketchy about that.

20 MR. FELDMAN: Well, I think this
21 is -- good point.

22 This has been a learning

1 experience. This was a Board initiated
2 action, essentially. A Committee member
3 brought this issue to the Crops Committee.

4 Based on, almost a housekeeping
5 issue, that rotenone had been voluntarily
6 cancelled for use in the U.S., by the
7 registrant, by the manufacturer, and it was
8 being phased out and it was determined that
9 even though there is an existing stocks
10 provision of rotenone, that there was -- it
11 was still legal to use in the U.S., and it was
12 confusing that it was not prohibited on our
13 national list, given that there was no longer
14 any use.

15 Now, because it was initiated
16 through the Committee process, there wasn't a
17 full petition, and as you -- as we all know,
18 the petition process essentially, is public
19 notice. It is posted -- the petitions are
20 posted on the NOP website, and gives the
21 public an opportunity to first of all, be
22 aware, and then bring information forward, et

1 cetera.

2 So, and prepare, really prepare
3 for a potential outcome that might change
4 their practices.

5 So, since we didn't have that
6 process, I think there is a feeling that more
7 time is needed on the back end, as almost a
8 notice to folks, to let them know.

9 But that is why the date certain
10 was added to this provision.

11 Now, you know, there is also the
12 feeling that when you take an action, that
13 requires people to plan, change their
14 practices, their tools or whatever, that
15 giving them a date certain is a very helpful
16 tool.

17 We recognize that dates cannot
18 always be met, and it's hard to predict when
19 something will actually work its way through
20 the regulatory process, but that a three-year
21 time frame sets the right tone and message,
22 that there is concern, as there was within the

1 EPA regulatory process of the harm associated
2 with the use of this thing, and that the
3 organic standard should not counsel the use of
4 this -- of a material with these sorts of
5 hazards.

6 How that gets implemented around
7 the world, domestically and around the world,
8 is hopefully in a uniform way. We're leveling
9 the playing field for everybody that is
10 growing under the organic standard, to ensure
11 that a material that does not meet the
12 criteria of our statute is being following,
13 and we realize at this point in time, that the
14 remaining users are in developing countries,
15 in banana growing regions of the world.

16 But again, our role here is to
17 establish a uniform standard that we believe
18 is in compliance with the organic law, and we
19 hope that folks in Latin America and around
20 the world can find a -- we trust they will
21 find an alternative to address the thrip
22 problem that they're struggling with in

1 production, and Zea, I guess has more to say.

2 MS. SONNABEND: My personal
3 agenda, in coming onto the Board, has a lot to
4 do with being very familiar with the history
5 of this Board and the 20 years that it's been
6 around, for which I've been privy to most of,
7 and there are a lot of loose ends that have
8 occurred over that time.

9 Petitions that were tabled, never
10 to be seen again, and things that got resolved
11 in different ways, at different times, and
12 past arguments that really got resolved by the
13 Board saying, "We'll take a look at this in
14 another five years," and then it never
15 happened, and that is what this is.

16 In 1994, there were people at the
17 equivalent of this table, screaming over this,
18 and the review at the time was not really that
19 complete by today's standards.

20 I quoted the entire review, in our
21 document, the one paragraph, that made it into
22 the transcript.

1 So, it's really worth honoring the
2 sense of the previous Boards, by taking
3 another look at something like this, and also,
4 the fact that we get questions from consumers
5 and constituents all the time, concerning
6 this, and so, that is why it got brought up.

7 But that being said, I agree with
8 Jay, it's very important that the organic
9 community at large has plenty of notice about
10 pending actions, and that is why we feel like
11 we've chosen a sufficiently long time frame,
12 but have a certain date on it, so, rather than
13 just open-ended for however long the rule
14 making takes, because the certain date enables
15 people to get ready and start doing the work
16 on alternatives.

17 CHAIRPERSON FLAMM: Harold?

18 MR. AUSTIN: While I support the
19 motion as it's been presented, I would like to
20 point out, on behalf of that stakeholder
21 group, that we sprung this upon them pretty
22 unexpectedly.

1 The regulatory process, for
2 goodness sakes, we know is slow enough in our
3 own country, let alone if we go into a third-
4 world country.

5 My concern is that the expiration
6 date that we've given will possibly not be
7 sufficient for them, but at the same time, I
8 think it does engage them to the fact that
9 there is a pending drop-dead date out there,
10 and it will then, help them to get involved
11 and start the process moving forward.

12 I would suspect that they will
13 come before us at some point in time, and ask
14 for an extension of time, and I hope when that
15 point in time comes, that does not fall upon
16 deaf ears, and we give it full and due
17 consideration, when they come and they, as a
18 stakeholder, as for our help and
19 consideration, because I think a part of this,
20 the time frame that we've done is also part.

21 Our lack of doing our job as a
22 Board, and not -- and we ignored outside of

1 our country, stakeholders that are certified
2 by the program, that we are still -- that are
3 also engaged and follow the same rules that we
4 all follow.

5 CHAIRPERSON FLAMM: Nick?

6 MR. MARAVELL: Yes, thank you,
7 Barry. I'd like to draw a little bit of a
8 parallel to tetracycline and streptomycin, in
9 this situation.

10 I think it's appropriate to
11 consider an extension of timeline, but not
12 without certain considerations or conditions.

13 One is that for the date certain,
14 this gives them the ammunition or the sense or
15 urgency in their own countries, and number
16 two, if people come back to us without a
17 report of what they've done, the progress that
18 they've made, the actions that they've taken,
19 and to justify an extension, I would hope that
20 any future Board would not look too kindly
21 upon that.

22 Then again, I harken back to

1 streptomycin and tetracycline. We can put
2 date certain's in there. We can make our
3 intentions known, but we're flexible, and but
4 when you come back, you better have something
5 to say.

6 And so, I think that should be in
7 the record, that in deed, we're not trying to
8 be unreasonable here, but we expect
9 responsible action on the other side of this
10 recommendation.

11 CHAIRPERSON FLAMM: Further
12 comments? Mac?

13 MR. STONE: I remember hearing in
14 past meetings, that program is -- has asked
15 for specific dates when they're shorter than
16 the normal five-year, and just make sure that
17 everything is in line, or it doesn't hinder
18 the process by some date.

19 CHAIRPERSON FLAMM: Was that a
20 question you were wanting a response to, or
21 just a comment?

22 MR. STONE: If they didn't raise

1 their hand, then I guess it's okay.

2 CHAIRPERSON FLAMM: Okay, John?

3 MR. FOSTER: So, the time line
4 that you're talking about here, 2016, that
5 we're talking about here, 2016, is -- if part
6 of the intent of that is to allow time for
7 research to be done, to explore the
8 alternatives, and allow for, you know, perhaps
9 another material registration process to
10 unfold, registration process, I can see, but
11 my experience is that three years is not an
12 adequate period of time to generate the kind
13 of data that would convince this body, one way
14 or another.

15 I just don't see how that --
16 unless it's already studies that have been
17 done, to say, now, go, complete something in
18 three years, and bring us back the data, I
19 just -- that feels unreasonable to me.

20 Knowing the standards that this
21 body has, with respect to the data they
22 expect, in order to change a date,

1 empirically, it's pretty clear, we expect some
2 pretty hardcore data, and certainly, the
3 public demands that.

4 So, I'm not sure how genuine in
5 feel about saying, well, you got three years
6 to generate the data, and you got to meet a
7 pretty high bar, so, I'm uncomfortable saying
8 that with a straight face, because I don't
9 feel like -- I don't feel like that is
10 something they can be successful at, and if
11 I'm off-base on that, let me know, but that's
12 been my observation over the last couple of
13 years, anyway, and if I'm wrong, please tell
14 me.

15 CHAIRPERSON FLAMM: Nick?

16 MR. MARAVELL: No, John, you're
17 not wrong. I share your concern, and that's
18 why I drew the parallel to tetracycline and
19 streptomycin.

20 That is why I think we should have
21 it in the record, that we can be flexible, but
22 we need to see some action on the other side.

1 As simple as that.

2 I mean, we're not asking for
3 things that are un-achievable, but they need
4 something on their side, to go back to their
5 country and to their interests, and say, "We
6 got to move."

7 CHAIRPERSON FLAMM: Any further
8 comments? Zea?

9 MS. SONNABEND: I would just ask
10 John if he has a better suggestion of a date?

11 MR. FOSTER: I mean, it's -- at
12 that point, it's kind of splitting hairs, 17,
13 18, 19, I mean, right, I get what Harold --
14 what you were saying, I get about, you know,
15 having a date. I understand the rationale for
16 that. I think that is probably sensible.

17 But four years is -- it's only
18 marginally better than three, and so, I -- I
19 still haven't made up my mind on the vote yet,
20 but I don't want to put things out, that
21 people can't be successful at, knowing that
22 they -- and then if everyone is in agreement,

1 that they can't be successful at that, then --
2 and providing, you know, the data we need,
3 then I don't know, that seems -- that feels
4 very disingenuous, to me, and if there is --
5 I wish I could come up with a better date. I
6 can't, and still be kind of responsible to the
7 -- obviously, the data that shows that health
8 impacts are a problem, and -- but I am very
9 reluctant about this, but I -- so, anyway, no,
10 I don't have a better date, other than one --
11 you know, one more year.

12 CHAIRPERSON FLAMM: Miles, would
13 you like to comment?

14 MR. McEVOY: Yes, you're -- I
15 think you're mixing up a few things, here.

16 The notification to foreign
17 governments and to the community is done
18 through the Federal Register Notice, when we
19 put out a proposed rule to add rotenone to the
20 prohibited list.

21 So, your recommendation here is
22 not an official notification, and there are a

1 lot of people that will not note this. Some
2 will, for sure, but there will be a lot of
3 stakeholders that won't note this, until there
4 is Federal Register Notice and the foreign
5 governments are officially notified through
6 the WTO process, where we have to notify them
7 of these types of changes.

8 So, the other thing you have to
9 keep in mind is that this is -- you're adding
10 -- you're making a recommendation to add
11 something to the prohibited natural list, and
12 so, the expiration date is not as critical.

13 It would give an indication to the
14 program of what your recommendation is for
15 that effective date, but this will be
16 determined by the proposed rule that we would
17 put out and the comments that we would
18 receive.

19 We would try to mirror the intent
20 of the recommendation, but this is not a
21 sunset, where -- or an annotation that you're
22 adding to a recommendation for an expiration

1 date.

2 So, it's a little bit different
3 than that.

4 CHAIRPERSON FLAMM: Thank you,
5 Miles, for that explanation. Zea?

6 MS. SONNABEND: And I just wanted
7 to reflect to John, about my thinking on this
8 and why I think it's quite substantially
9 different than the antibiotic argument.

10 In that case, there are few, if
11 any, alternatives to be looked into. There is
12 one promising one, but there isn't a range,
13 yet the list that I read of possible
14 alternatives for thrips control, which are
15 well studied in this country, offer many
16 opportunities for them to look into a lot of
17 different things down there, that may not have
18 been looked into, yet.

19 And so, I think that there is --
20 it's not just a long road, as it is on a tree
21 crop, with very few alternatives. There is
22 plentiful research to be done in those three

1 years.

2 CHAIRPERSON FLAMM: Harold?

3 MR. AUSTIN: Earlier, in our
4 meetings, I made a comment regarding the
5 alternatives that are available.

6 Just because a product is listed
7 as an available alternative material, does not
8 necessarily mean that it has true efficacy and
9 control on that insect species.

10 Thrip, I think will find that a
11 lot of the materials, a lot of the products
12 that are listed will give minimal control, at
13 best. Spinosad will be, by far, the best
14 approach that they'll have, if they can get
15 that certified in the country.

16 But a lot of the alternatives,
17 based off of use here in our country on other
18 crops, are relatively non-effective.

19 So, I think we have to be
20 cautious, when we're looking at any material
21 for review or for addition to the list, that
22 just because there is natural or organic

1 alternatives available, just because they're
2 classified, and the comments made that they're
3 available, does not necessarily mean that
4 they'd have true efficacy for what they're
5 being called -- they're claimed for.

6 CHAIRPERSON FLAMM: Okay,
7 Jennifer?

8 MS. TAYLOR: Thank you, Barry. I
9 think we also need to remember some of the
10 health concerns and health issues that were
11 brought about, that have to do with not only
12 the environment of the applicator, but
13 probably the environment of other workers,
14 within the distance of the application.

15 CHAIRPERSON FLAMM: Further
16 comments? Further discussion? Harold?

17 MR. AUSTIN: I would agree with
18 Jennifer's comment, that we do need to look at
19 those type of concerns and issues, but I also
20 reflect back onto the information that was
21 provided to us, and I know that it was an
22 isolated snapshot of one company and what they

1 were doing, but what we saw here, during Luis'
2 presentation and the following presentation,
3 showed an extremely solid process, where
4 adequate -- where it looked like they had
5 adequate PPE in place, protected -- personal
6 protective equipment.

7 The application method looked to
8 be a very specific zone was not an air-blast,
9 cover all of the tree canopy, cover all of the
10 rows, like we do in a lot of our crops here in
11 the country.

12 So, it was very controlled,
13 environmental controlled application, so, I
14 was -- and I can't say that this is the only
15 method being used. I don't know what the
16 label is, in the countries in question.

17 But the process that we saw
18 presented to us made me feel a lot more
19 comfortable than if I would have seen an air-
20 blast speed sprayer that was putting material
21 on at 400 gallons and going up into the air
22 and covering the entire canopy.

1 So, I was a little more
2 comfortable with the application and the
3 process that I saw, but that doesn't
4 necessarily mean it's the only application
5 technique that they're using.

6 CHAIRPERSON FLAMM: Further
7 comments? Discussion?

8 I think we've had a very thorough
9 discussion on this material, and I believe
10 we're probably ready for the vote, and I think
11 the begins with -- am I correct? Anybody else
12 have anything else to say? I don't want to
13 shut anybody off.

14 Okay, we can --

15 MR. BONDERA: Can you repeat the
16 motion, please?

17 CHAIRPERSON FLAMM: I'm sorry?

18 MR. BONDERA: Can the people that
19 made the motion, repeat it, please?

20 CHAIRPERSON FLAMM: Okay, I can
21 read. The motion is to add rotenone to the
22 National List 205.602, as a prohibited natural

1 substance, effective January 2016. Do I have
2 the correct date?

3 Okay, is that all clear? That is
4 what we'll be voting on, beginning with
5 Jennifer.

6 MS. TAYLOR: Yes.

7 MR. MARAVELL: Yes.

8 MR. FELDMAN: Yes.

9 MS. SONNABEND: Yes.

10 MR. STONE: Yes, sir.

11 MS. FULWIDER: Yes.

12 MR. AUSTIN: Yes.

13 MS. FAVRE: Yes.

14 MS. BECK: Yes.

15 MR. FOSTER: Yes.

16 MR. DICKSON: Yes.

17 MS. RICHARDSON: Yes.

18 MR. WALKER: Yes.

19 MR. BONDERA: Yes.

20 CHAIRPERSON FLAMM: And the Chair
21 votes yes, 15 'yes', zero 'no'. The motion
22 passes.

1 The Crops Committee, you have
2 another proposal to present to the Board?

3 MR. FELDMAN: Yes, thank you,
4 Barry. The Crops Committee has a proposal on
5 the petition material biodegradable mulch film
6 made with bio-plastic and -- or made from bio-
7 plastics, and Carmela is going to lead us
8 through that. I think there is a PowerPoint.

9 MS. SONNABEND: Thank you, Jay.
10 Well, I was trying to figure out how to
11 prepare for this, last night, and when I
12 started thinking about the overall philosophy
13 behind organic farming, I think it goes much
14 beyond the details of how to review materials
15 and categorize ingredients, to the positive
16 effects that we can have on the land through
17 fuzzy concepts like stewardship or nurturing.

18 We wouldn't all be here if we
19 didn't think that less pesticides and petro-
20 chemicals weren't a good thing, and farms
21 should achieve ecological balance with their
22 environment.

1 There are times when a broader
2 concept can take precedence over the minutiae
3 of our daily work, and by using the
4 precautionary principle on a global level, we
5 can forgive the taking of a risk on something
6 new, that all the data is not quite gathered
7 for.

8 Biodegradable, bio-based mulch is
9 one of those opportunities to make a real
10 difference in reducing pollution in the whole
11 world, without sacrificing our principles.

12 It's an interesting concept here,
13 to me, between -- or dichotomy I guess,
14 between long term thinking of trying to reduce
15 the plastic burden on landfills worldwide,
16 with the lack of fully long term information
17 on these products.

18 Okay, our studies of the materials
19 over the last several months has led us to
20 want to pursue a recommendation at this
21 meeting.

22 That being said, we've tried to

1 write an annotation that is as tight as
2 possible, while still allowing the best of
3 these products to be reviewed and allowed in
4 organic farming.

5 Our recommendation is set up, so
6 the first several criteria -- okay, wait,
7 we're going to skip that for now.

8 The first several criteria refer
9 to those certifiers and MRO's who will figure
10 out which products are allowed.

11 Our last clause is the only one
12 that refers to what a grower has to do, and
13 correspondingly, what their certifier will
14 have to evaluate.

15 It is anticipated that the NOSB
16 and the NOP together, will work on a guidance
17 document that will come out accompanying the
18 final rule, that will outline what the
19 appropriate actions in our annotation are, for
20 the large variety of environmental conditions
21 in soils, that are governed by this
22 regulation.

1 So, Carmela is going to read our
2 recommended motion and annotations, and
3 needless to say, I skipped the slide that our
4 first motion will be determined, these
5 products are synthetic, but we'll go into the
6 listing motion.

7 MS. BECK: All right, so, that's a
8 long one.

9 So, to list on 205.601B2 mulches,
10 biodegradable, bio-based mulch films, to be
11 reviewed and meet the following criteria.

12 A) completely biodegradable, as
13 shown by one, meeting the requirements of ASTM
14 standard D6400 or D6868, specifications or
15 other international standards specifications,
16 with essentially identical criteria, that is
17 to say EN13432, EN14995, ISO17088 and two,
18 showing at least 90 percent bio-degradation --
19 bio-degradation, absolute or relative to
20 micro-crystalline cellulose in less than two
21 years in soil, tested according to ISO17556 or
22 ASTM5988.

1 B) must be bio-based with content
2 determined using the ASTM D6866 method, C)
3 must be produced without organisms or
4 feedstock derived from excluded methods, D)
5 must be produced without engineered nano-
6 materials and E) grower must take appropriate
7 actions to ensure complete degradation.

8 MS. SONNABEND: Thank you. So,
9 here is our analysis of the annotation and
10 some of the accompanying issues.

11 First of all, the title,
12 biodegradable, bio-based mulch film reflects
13 our intention to define bio-based, so that
14 this category would not allow products made
15 from AAC, which come from petroleum,
16 originally.

17 Carmela, you want to read that
18 definition?

19 MS. BECK: All right, bio-based.
20 The ASTM definition of bio-based material is
21 organic material in which carbon is derived
22 from a renewable resource via biological

1 processes.

2 Bio-based materials include all
3 plant and animal mass derived from carbon
4 dioxide, recently fixed via photosynthesis,
5 per definition of a renewable resource.

6 Bio-based materials are certified
7 using the ASTM D6866 method, which certifies
8 the biologically derived content of bio-
9 plastics.

10 MS. SONNABEND: Thank you. We
11 have chosen not to use the word bio-plastic,
12 so, that it makes it easier for the NOP to
13 jump through whatever hurdles they're
14 undoubtedly going to encounter in writing this
15 regulation.

16 The Committee also feels that the
17 process of bio-degradation is equivalent to
18 removal of the substance at the end of each --
19 the growing season, as is stated in the rules.

20 Okay, back to -- now, Clause A, we
21 believe the standards referred to here will
22 cover the range of products in the range of

1 temperatures in environments.

2 We also acknowledge that the ASTM
3 6400 will involve testing for any residues and
4 eco-toxic effects.

5 We welcome the creation of a
6 certification program to these standards, but
7 we cannot endorse such a program ahead of its
8 creation.

9 Clause B, must be bio-based. We
10 feel that with a good definition of bio-based,
11 we are making sure that this testing protocol
12 means something.

13 C), we have decided to be specific
14 about our excluded method language, and we
15 wish to -- I believe we wish to change just
16 slightly, what this says on the screen, but
17 right now it says, "Must be produced without
18 organisms or feedstock derived from excluded
19 methods," and I think we want to at least say
20 and/or, because we don't want either of them.
21 We don't want someone to choose between one or
22 the other, but we definitely intend to keep

1 these out.

2 Our feeling is that in the --
3 let's see, while we have some concerns about
4 consistency between this and the excluded
5 methods in other soil inputs, since this will
6 be a brand new category of materials, we wish
7 to shut the door to GMO's at the outset.

8 The annotation regarding the
9 feedstock is not to be construed as carrying
10 over to other soil applied materials.

11 D), must be produced without
12 engineered nano-materials. In the absence of
13 an overall NOP written statement on this
14 subject, we are putting this clause in, to
15 make sure that we keep these out.

16 If the previous NOSB
17 recommendation on the subject gets formally
18 acknowledged before this rule comes out, then
19 it may be removed, and E), the only clause
20 that applies to growers and the certifiers who
21 monitor them.

22 Growers must take appropriate

1 actions to ensure complete degradation.

2 As mentioned above, we'll be --
3 previously, we'll be issuing a further
4 guidance, we hope, on what actions growers
5 need to take, what certifiers need to do with
6 those actions.

7 We do think that there may be
8 situations where the use of this mulch is not
9 appropriate, because soil can -- or other
10 conditions will not allow it to break down,
11 and we hope to have -- use the next year or
12 more, to explore those situations, look at the
13 ongoing research and come up with some
14 guidance.

15 Okay, I want to just flag a few
16 other concerns that have been brought up, and
17 this is referring back to the TR, in some
18 cases.

19 This is from lines 592 to 597 of
20 the TR.

21 Researchers have argued for more
22 extensive research into the bio-degradation

1 pathways of the various bio-plastics for a
2 more complete understanding of potential
3 impacts, citation given.

4 Complete degradation of the bio-
5 plastics depends on blending polymers to
6 maximize degradability, and depends on the
7 composition of soil micro-organisms.

8 Due to the biodiversity of bio-
9 plastics currently being developed, testing is
10 necessary to determine which polymer mixtures
11 are degraded completely and what effects
12 incomplete degradation will have on the agro-
13 ecosystem.

14 This, as we know, is true. There
15 could always be more testing and more study
16 done on bio-degradation pathways and the
17 potential impacts.

18 We feel that by removing the
19 petroleum source films from this
20 recommendation, that we'll have less to study
21 about residual components and less testing to
22 be done on fewer chemicals.

1 From lines 649 to 654 of the TR,
2 comprehensive studies were not found that
3 describe the environmental impacts of the use
4 of bio-plastic mulches. Most researchers
5 concluded that the mulches would degrade to
6 carbon dioxide, water and soluble bio-mass,
7 citation given.

8 Due to the wide variety of
9 potential chemicals released from incomplete
10 degradation of bio-plastics, this is a data
11 gap.

12 Some reports have shown that bio-
13 plastics containing terephthalic -- well, some
14 stuff, acid, at concentrations over 50 percent
15 do not completely bio-degrade in soil.

16 While of the 14 chemicals named in
17 the TR, six of them are from the AAC source,
18 including this one that I can't pronounce.
19 Therefore, they would be ruled out from
20 materials.

21 Two of them are the pigments.
22 Three of them are the polymers, themselves,

1 and three of them are the plasticizing agents
2 that break down completely.

3 There are slight data gaps here,
4 but we see no red flags by prohibiting the
5 petroleum source product.

6 Okay, conclusion. Very clearly,
7 our work on this subject is not over, by
8 passing this recommendation. We need to keep
9 investigating this until a proposed rule comes
10 out, and if red flags arrive during that time,
11 we can point them out during the proposed
12 rules comment period or before, potentially.

13 We are suggesting putting this on
14 our work plan for grower certifier guidance
15 document and putting the unanswered questions
16 into our research priorities for the coming
17 year, as a high priority topic.

18 We understand that the work plan
19 is not finalized on this subject, until the
20 NOP and the Executive Committee takes a look
21 at it, after the meeting.

22 We hope all of us on both sides of

1 this table will bring a positive message about
2 true sustainability and stewardship motives
3 behind this recommendation, and help inform
4 your constituents about this positive step for
5 the future of our planning. Thank you.

6 CHAIRPERSON FLAMM: Thank you,
7 Zea. That was an incredible statement. Thank
8 you. Jay, where are we?

9 MR. FELDMAN: Well, I think we are
10 at the discussion phase of this. I think we
11 should treat this as a listing motion, and
12 begin the discussion on it.

13 CHAIRPERSON FLAMM: Yes, we have
14 to have a classification motion.

15 MR. FELDMAN: Yes.

16 MS. SONNABEND: Carmela, do you
17 want to make the motion?

18 MS. BECK: So, I'd like to make a
19 classification motion, that biodegradable,
20 bio-based mulch film is synthetic.

21 MR. FELDMAN: Second.

22 CHAIRPERSON FLAMM: We have a

1 motion that has been seconded, that
2 biodegradable, bio-based mulch film is
3 synthetic.

4 Further discussion? Colehour?

5 MR. BONDERA: Yes, thank you. I
6 just want to say, and I think that in Zea's
7 presentation, it was already addressed, but to
8 reiterate the -- what I personally and I think
9 is received as a little confusing, in terms of
10 the -- what is being, in this case, classified
11 not-listed, but it applies to both.

12 And while I fully understand the
13 conceptualization, I do not think it would
14 hurt if it were repeated, that biodegradable,
15 bio-based mulch film, as the listing, is
16 leaving out reference directly, to what is
17 being considered, which is -- which is the
18 point of why it says it is synthetic, which is
19 the bio-plastic part.

20 And so, I just would like to
21 ensure that that is, at minimum, recognized,
22 that we have removed the word bio-plastic in

1 this, and I think as Zea said, you know,
2 changes could happen, through this whole
3 process, but your title is unlikely to get
4 very changed.

5 So, I just wanted to say that.
6 Thank you.

7 CHAIRPERSON FLAMM: Further
8 discussion or comment or response to
9 Colehour's statement?

10 MR. FELDMAN: Thank you. Yes, I
11 agree with that, Colehour, you know, and we
12 did hear from the industry, the bio-plastics
13 industry, which has that exact word in its
14 name, and recognizes the process that produces
15 this material to be a plastic process. We
16 talk about plasticizers, and so forth and so
17 on.

18 So, this is a problem. You know,
19 we all want to be transparent. That is one of
20 our cornerstones, and but you know, this is
21 where it seems like the majority wants to go,
22 the decisive majority wants to go.

1 I'd feel more comfortable if we
2 had bio-plastics in the title, but the
3 critical thing is really how we manage this
4 material, at the end of the day.

5 CHAIRPERSON FLAMM: John?

6 MR. FOSTER: This has been such an
7 interesting dialogue on this material, and
8 I've really appreciated the opportunity to
9 kind of come around and to appreciate
10 different nuances of it.

11 I was very taken by the long
12 annotation, as I mentioned, and it was -- I
13 thought the process actually did exactly what
14 it was supposed to do, which was present a
15 platform for exchange of ideas, and everyone
16 comes to the table with an open mind and argue
17 points and business.

18 I always pick one material, at
19 every meeting, that exemplifies for me, the
20 process by the -- that I think this is
21 supposed to be, and this was the one for me,
22 where I felt like it was very smart,

1 respectful exchange on the material.

2 I definitely came around to
3 different points of view then I started with,
4 and I wanted to point that out, including the
5 kind of the nomenclature, with respect to
6 plastics being out, I thought that dialogue
7 was really very well informed and mature, and
8 I really appreciated that.

9 So, this was exactly what this
10 process -- our process was supposed to be, for
11 me, and I think we came to a very good place
12 that is mindful of all of the considerations,
13 and maybe I would go so far as to say, you
14 know, like Calvin, where everyone is a little
15 pissed off about the outcome. I don't think
16 it's quite there.

17 But I think everyone came to it
18 with an open mind, and I'm -- I was -- I felt
19 actually, very privileged to be part of the
20 discussion. So, I wanted to throw that out
21 there, because this is the best that -- I
22 think this represents our best work. So,

1 thank you for that.

2 CHAIRPERSON FLAMM: Additional
3 comments on the classification motion? We're
4 talking about the classification motion, right
5 now.

6 If there is no additional
7 comments, we can proceed with the vote, with
8 Nick leading off.

9 MR. MARAVELL: Yes.

10 MR. FELDMAN: Yes.

11 MS. SONNABEND: Yes.

12 MR. STONE: Yes, sir.

13 MS. FULWIDER: Yes.

14 MR. AUSTIN: yes.

15 MS. FAVRE: Yes.

16 MS. BECK: Yes.

17 MR. FOSTER: Yes.

18 MR. DICKSON: Yes.

19 MS. RICHARDSON: Yes.

20 MR. WALKER: Yes.

21 MR. BONDERA: Yes.

22 MS. TAYLOR: Yes.

1 CHAIRPERSON FLAMM: And the Chair
2 votes yes, 15 'yes', zero 'no'. The motion to
3 classify the material as synthetic passes.

4 Now, we're ready for the motion to
5 list. Jay, who would you -- Jay?

6 MR. FELDMAN: Yes, sir.

7 CHAIRPERSON FLAMM: How would you
8 like to proceed on the motion to list, and
9 we'll then open.

10 MR. FELDMAN: I was going to
11 suggest that Zea read or cite, what she has
12 already read, the listing, proposed listing
13 motion.

14 MR. FELDMAN: Carmela, do you want
15 to read it?

16 MS. SONNABEND: Okay, the listing
17 motion. To list -- the motion is to list on
18 205.601B2 mulches, iii, biodegradable, bio-
19 based mulch films to be reviewed and meet the
20 following criteria.

21 A), completely biodegradable, as
22 shown by 1) meeting the requirements of ASTM

1 standard 6400 or 6868, specifications or of
2 other international standard specifications,
3 with essentially identical criteria, such as
4 EN13432, EN14995, ISO17088, and 2) show at
5 least 90 percent bio-degradation, absolute or
6 relative to micro-crystalline cellulose and
7 less than two years in soil, tested according
8 to ISO17556 or ASTM5988.

9 B), must be bio-based with content
10 determined using the ASTM6866 method, C), must
11 be produced without organisms and/or feedstock
12 derived from excluded methods, D), must be
13 produced without engineered nano-materials,
14 and E), growers must take appropriate actions
15 to ensure complete degradation, and that is
16 the definition part of the motion.

17 I believe we want to read the
18 definition into the motion, to also add the
19 definition to the rule in the appropriate
20 place, bio-based.

21 The ASTM definition of bio-based
22 material is organic material in which carbon

1 is derived from a renewable resources via
2 biological processes.

3 Bio-based materials include all
4 plant and animal mass derived from carbon
5 dioxide recently fixed via photosynthesis, per
6 definition of renewable resource.

7 MR. FELDMAN: So, that would be
8 205.2.

9 MS. SONNABEND: Okay, 205.2 for
10 the definition.

11 CHAIRPERSON FLAMM: Do we have a
12 second?

13 MR. AUSTIN: Second.

14 CHAIRPERSON FLAMM: It's been
15 moved and seconded, to -- now, I've got
16 switched here.

17 Could we go back to the first
18 screen?

19 MS. SONNABEND: Which first
20 screen?

21 CHAIRPERSON FLAMM: The listing
22 motion. So, I won't reread this, unless you

1 request it.

2 Is the motion, the listing motion
3 clear, and then we'll look at the definition,
4 which will be added. Does anybody object to -
5 - or unclear, I should say, about what we're
6 about to -- we will vote on? No question?
7 Does the program have a -- Miles?

8 MR. McEVOY: Yes, we have a
9 comment. If you want these, what you're
10 calling biodegradable, bio-based mulch films
11 to be allowed to be used in organic
12 production, within the -- a shorter time
13 frame, we would suggest that you remove the
14 Clause D, must be produced without engineered
15 nano-materials.

16 We have a recommendation from the
17 Board on nano-materials, that we're working
18 with. We'll be meeting with OMB and other
19 agencies, to look at the implementation of
20 that particular recommendation.

21 But part of the problem with that
22 recommendation is, there is no Federal

1 definition, consistent definition of nano-
2 materials.

3 So, in order for us to incorporate
4 that particular clause into this rule making
5 action, would significantly slow down and
6 potentially, even stop the ability to get this
7 substance listed. It's just going to make it
8 very, very difficult and slow down the
9 process.

10 So, if you want that to happen, if
11 it's that important, leave it in, but if you
12 really want these substances to be allowed by
13 organic farmers, then I would suggest taking
14 it out and working on nano-materials through
15 other mechanisms.

16 CHAIRPERSON FLAMM: Sort of a two-
17 part thing. The first part is that the Board
18 is clear on the motion that is now before us.
19 If they're clear, I'll -- I'll move the
20 discussion, and Miles has made a comment on
21 the motion, and what he has identified as a
22 problem with the motion.

1 So, first of all, I want to be
2 sure that everybody understands what the
3 motion is before us.

4 So, I think everybody is
5 acknowledging, they are clear on the motion,
6 and so, I'll open it to discussion, and
7 perhaps, the first -- I think I'll just ask
8 either Zea or Jay, to respond or open the
9 discussion with a comment on Miles' comment
10 and the concerns that he expressed.

11 MS. SONNABEND: Okay, Nick, did
12 you want to say something?

13 Let me, okay. We wanted to ask
14 Miles if instead of this clause about nano-
15 materials, if we referred to the NOSB's own
16 recommendation about nano-materials, would
17 that help solve the problem at all, because we
18 have our own recommendation, and if it's
19 internal, maybe that would help.

20 MR. McEVOY: Yes, the problem is
21 putting it into the recommendation, because
22 that is what would have to be in the

1 regulatory text, that we would have to get
2 through all the various legal and clearance
3 processes, and it's a complicated situation,
4 without -- with a lot of agencies involved, in
5 terms of nano-materials, the definition of
6 nano-materials, how they're overseen and
7 regulated by the Federal Government.

8 So, if you had it in your -- the
9 body of your recommendation, that would be
10 different, but having it in the actual
11 annotation, is where it would cause us
12 significant difficulties in getting this
13 approved and through the clearance process.

14 MR. MARAVELL: Miles, I completely
15 understand, and I'm just wondering if there is
16 a way to indicate that it would be produced
17 without nano-materials, when such definition
18 is promulgated, you know, but it would not be
19 effective until such definition is
20 promulgated.

21 I mean, would that give you enough
22 of an out? I think we need to be able to tell

1 the community, fairly definitively. So, does
2 that work?

3 So, that is just a question you
4 may want to think about it, before you get
5 back to us, on that, but we clearly, do not
6 want to hold this up, and if this will hold it
7 up, we can take other action, but if there is
8 a middle ground there, we would be willing to
9 consider that, too.

10 MR. McEVOY: Yes, well, we can
11 consider that, but again, that would slow it
12 down.

13 You've already made it -- you
14 already have a final recommendation on nano-
15 materials. You've made it -- you've proposed
16 a -- or made a recommendation on a definition
17 for nano-materials. So, we have that.

18 So, the problem is, is if you put
19 it in the annotation, we're going to have
20 extreme difficulty. There is just -- the
21 difficulty, it's just going to take a lot of
22 time, where there is a lot of different

1 entities that we'll have to work with, to get
2 that through the process.

3 It's going to take a lot more
4 analysis, a lot more staff time, to do that.

5 Now, nano-materials is not a
6 recommendation that we're ignoring. We are
7 moving forward on that, but it is a final
8 recommendation. There is many NOSB final
9 recommendations that we still have to work on
10 and implement.

11 What we're suggesting is that this
12 is not the place that you -- in order for us
13 to effectively move forward, if you leave it
14 in the annotation, it will make it extremely
15 difficult for us to move forward in any kind
16 of expeditious way.

17 CHAIRPERSON FLAMM: John?

18 MR. FOSTER: So, this is kind of
19 the discussion I was referring to earlier,
20 where this kind of dialogue is just, as some
21 would say, a natural and zesty enterprise.

22 But my -- anything having to do

1 with holding this up, and this came up in our
2 Subcommittee meeting last night, was my
3 biggest concern, other than what I have
4 already said about making preferable materials
5 easier to use than the less preferable
6 materials, is that every month, every day,
7 every year, this doesn't move forward, is that
8 much more un-biodegradable plastic in the
9 environment, and it ends up everywhere, we
10 know.

11 We all know where it ends up, and
12 I don't -- we're so close to giving -- to
13 putting a dent in that, I think it's really,
14 really important that we design this, so that
15 it moves as quickly as possible.

16 That is a big priority for me, and
17 as I said last night in our evening
18 Subcommittee meeting, but so, if that is a
19 hazard, and it's going to postpone this, it
20 sounds like it is, then I want to avoid that
21 hazard.

22 It's predictable, and as my mom

1 would say, therefore, it's preventable. So,
2 I think we should prevent that.

3 CHAIRPERSON FLAMM: Further
4 comments? Jay?

5 MR. FELDMAN: Thanks, Barry and
6 Miles, for your comment.

7 I'm trying to understand the
8 process here, and I, you know, I know that as
9 has been mentioned, we, as a Board, adopted in
10 2010, unanimously, as you know, the definition
11 of engineered nano-materials, and we
12 appreciate the program working -- moving that
13 forward.

14 Then in December of that year,
15 2010, you wrote a memo, that really, I hope,
16 could be used in this instance. It ended with
17 -- you know, you explained the uncertainty and
18 the lack of Federal guidance and so forth on
19 this, and then you ended with something that
20 I really appreciated at the time, the NOP
21 accepts the NOSB recommendations and tends to
22 gather additional information about how nano-

1 materials are regulated and used in the
2 agricultural production process.

3 So, I guess my point here, or
4 question maybe, is if the program accepts the
5 process that the Board went through in
6 defining this thing, and the Board, as you
7 know, worked a long time and heard a lot of
8 public testimony on this issue, is there a way
9 we can incorporate that statement that the
10 Board adopted, as guidance, and then add
11 Nick's language, you know, pending some other
12 action by the Federal Government, or by USDA,
13 so we can expedite this, just so that, you
14 know, we can do this in a way that, as John
15 says, moves this along quickly, but also gives
16 the Board some assurance that there won't be
17 plastics folks jumping all over this thing,
18 with nano, because we know that there are
19 folks out there that would like to do that
20 kind of thing.

21 So, it's just a way of almost
22 setting a moratorium, until the USDA comes up

1 with a definition, that it feels is
2 appropriate.

3 MR. McEVOY: Yes, well, you
4 already have the recommendation -- final
5 recommendation on nano-materials defined,
6 nano-materials and consider nano-materials to
7 be a synthetic substance. We've accepted
8 that.

9 So, that is the way that the
10 program and the, we expect certifiers and
11 companies to accept that, as well, that nano-
12 materials are considered synthetic substances,
13 and therefore, not allowed unless they're
14 added to the national list.

15 So, that is the concept, and that
16 is what some of the power of your final
17 recommendations can do. They set the tone.

18 For us to issue various documents,
19 requires different levels of clearance and
20 approval. So, for us to issue a memo to the
21 Board, that we accept your final
22 recommendation on nano-materials, sends a

1 statement, but it's not a regulatory text. It
2 hasn't gone through public comment and rule
3 making.

4 So, it doesn't have the same level
5 of authority, as a rule on nano-materials or
6 putting nano-materials and prohibiting nano-
7 materials into the USDA organic regulations
8 would have.

9 That is going to take a lot more
10 time and a lot more work, because there is a
11 lot of affected parties there, and a lot of
12 people that probably will have comments on
13 that particular thing.

14 So, my suggestion would be that
15 the -- if you want to have this particular
16 substance be available to organic producers,
17 that you remove that clause, and you include
18 that in the background information that you
19 have around this particular recommendation.

20 But if you leave it in, as part of
21 the annotation, that means that we have to do
22 all the rule making around your particular

1 final recommendation on nano-materials, which
2 is very complex. It's not an easy task for us
3 to do that.

4 We have recommendations from the
5 Board, from 10 years ago, that we still have
6 not implemented. So, and nano-materials is
7 not an easy one.

8 We have accepted. We do recognize
9 that the Board considers nano-materials as
10 synthetic and therefore, they're not allowed
11 in organic production or handling.

12 But to raise it into the rule
13 making process will delay that in very
14 substantial ways.

15 CHAIRPERSON FLAMM: Thank you,
16 Miles. Nick?

17 MR. MARAVELL: Yes, Miles, maybe
18 the easiest way to do this is put it in the
19 positive.

20 Can you explain to the Board, if
21 we drop that clause, let's say we just take
22 'D' out, how the program would proceed and how

1 that would have an impact on the review of
2 this material, and what would be permitted
3 under your understanding of how you would
4 proceed?

5 In other words, tell us how it
6 would play out. What would be the impact, if
7 we dropped that and put it in the -- and put
8 it in the background material, just say how --
9 how would you then review materials? How
10 would you expect materials to be reviewed?
11 How would this have an impact?

12 MR. McEVOY: Well, we would expect
13 these materials would be reviewed by material
14 review organizations, and that they would --
15 once this was added to the national list, that
16 they would then review these materials, based
17 on the annotation.

18 Then if there were particular
19 questions about, let's say, the clause and
20 nano-materials is removed, if there were
21 questions that a manufacturer was using nano-
22 materials, they would go to the final

1 recommendation from the NOSB on nano-materials
2 to say that those are synthetic substances and
3 are not allowed in those substance -- those
4 products that are being approved.

5 So, they could rely on the
6 background information on this particular
7 recommendation, as well as the final
8 recommendation on nano-materials. That would
9 be their guidance.

10 MR. MARAVELL: And at this point,
11 we have no reason to believe that nano-tech
12 materials are included in the substances that
13 are included in the petition. Is that
14 correct?

15 Right, so, we are not approving
16 nano-technology materials. We are approving
17 what is in the petition? Would that be also,
18 a correct statement?

19 MS. SONNABEND: There were --
20 there are no -- none of the products submitted
21 in the petition are made using nano-materials,
22 at this time, and to our knowledge and asking

1 the petitioners, none are planned.

2 So, I don't -- you know, this is
3 not something that we have to keep out,
4 because it's in there on a day-to-day basis.
5 This is a protective clause, and as a
6 protective clause, it is my opinion that we
7 shouldn't bog the whole thing down by keeping
8 this in. We should just put it in the
9 background material, just as we're putting in
10 the clause about, that we interpret the bio-
11 degradation to be equivalent to the removal
12 step.

13 I think if we also put a sentence
14 in the cover, saying that we fully expect that
15 these materials will have to meet the NOSB's
16 recommendation on nano-materials.

17 MR. MARAVELL: But weren't we also
18 going to be making a statement that what we
19 have reviewed in the petition, is what we are
20 approving, and that people can't just use the
21 moniker of a bio-based, bio-film mulch, to put
22 any synthetic that they would desire into that

1 product, is that also correct?

2 Weren't we planning to make that
3 statement? Yes, so, this might work.

4 CHAIRPERSON FLAMM: We have other
5 Board members that would like to ask
6 questions. Jean, please.

7 MS. RICHARDSON: I was looking
8 forward today, to voting on something that is
9 actually going to give something to the
10 organic farming community, because we always
11 seem to be voting 'no' on everything.

12 So, it is important to me, if I
13 want to get back to Vermont and the Northeast
14 alive, that we do vote on this today in a
15 positive way, and so, I would actually
16 encourage a modification of the listing
17 motion, to remove the line 'D', a this time,
18 on the clear understanding, obviously, the
19 issue on engineered nano-materials will be
20 within the body of the general statement that
21 is attached to the listing motion.

22 CHAIRPERSON FLAMM: Tracy?

1 MS. FAVRE: Thanks, Barry. Jean, I
2 would -- actually, I was just getting ready to
3 make a similar comment.

4 I feel as though that if we don't
5 remove it, we are essentially, creating a
6 backdoor veto to the listing of the product
7 itself, and I think as long as we have
8 sufficient intent expressed in the background
9 materials, that will then be used in
10 combination with the nano-technology materials
11 recommendation, that should be sufficient, and
12 I, personally, would like to see this move
13 forward, as well.

14 CHAIRPERSON FLAMM: Zea?

15 MS. SONNABEND: As the maker of
16 the motion, I would like to accept what Jean
17 and Tracy said as a friendly amendment, and
18 remove Clause D of the annotation, to be put
19 in the background materials, appropriately.
20 Does the second agree?

21 CHAIRPERSON FLAMM: Okay, just a
22 technical point, there is -- Robert's Rules of

1 Order doesn't recognize friendly amendments,
2 but if the Board, as a whole --

3 MS. SONNABEND: What is that?

4 CHAIRPERSON FLAMM: I'm just about
5 to tell you. It's a technical point, but let
6 the record show that we follow Robert's Rules
7 of Order.

8 If it's a -- if the Board does not
9 disagree, we can accept this change. So, it's
10 a full Board decision, not an individual
11 decision.

12 Seeing no objection to the change,
13 I believe it's accepted. So, would you
14 briefly restate what the change is, so
15 everybody is clear on what we're voting on?

16 MS. SONNABEND: The motion on the
17 floor then is the entire thing you see on your
18 screen, except for Point D.

19 But be assured that Point D will
20 appear in our narrative that accompanies this.

21 CHAIRPERSON FLAMM: And do we have
22 -- does the -- do we have a second to this

1 motion?

2 MR. AUSTIN: Second.

3 CHAIRPERSON FLAMM: It's been
4 seconded, that the listing motion, plus the
5 definition, which has not changed, minus what
6 is the number now? Minus 'D', is every -- is
7 the Board clear on what we're -- we will vote
8 on?

9 Jay, do you have a -- further -

10 MR. FELDMAN: Yes, thank you. I
11 realize the sense of urgency to move this, and
12 we'll talk about that a little later, when it
13 comes down to another text change that we've
14 discussed.

15 But on nano, specifically, and
16 this particular amendment, or this motion, I
17 hope we can include in the statement, the
18 background material, the actual policy itself,
19 so that the Board is aware of what, at least
20 has been established by the Board previously,
21 as the responsibility for recognizing the
22 unique properties of nano, that distinguish

1 them from all other listings of this
2 substance, sort of in the realm of what Nick
3 is saying.

4 That we understand, we're
5 approving, in effect, non-nano forms of this
6 bio -- I can't say bio-plastic, can I?
7 Biodegradable mulch film, and that they are
8 not allowed, that is the nano-form of this
9 material, should it become available, are not
10 allowed by a listing of the bulk form of the
11 substance, on the national list, and that, in
12 effect, serves as a prohibition of the
13 engineered form, the engineered nano-material
14 form of this listing.

15 So, I hope we can be more -- I am
16 just hopeful and maybe we can get an agreement
17 here, that we will re-list that, so that
18 everyone is clear on -- as to what the policy
19 says, and how it is intended to function.

20 CHAIRPERSON FLAMM: Jay, I want to
21 -- I'm not clear myself, on that. Maybe
22 others aren't.

1 We have a motion on the floor.

2 MR. FELDMAN: Well, the motion
3 included -- well, the motion was to take this
4 out, but as it was described to us, it
5 included the incorporation of the no-nano
6 clause in the recommendation, itself.

7 So, I just to amplify on that --
8 Zea's proposal on that, to suggest that we
9 actually include and cite the policy that was
10 adopted by the Board, previously.

11 CHAIRPERSON FLAMM: So, this is
12 for the background statement, and not changing
13 the motion?

14 MR. FELDMAN: Background, yes.

15 CHAIRPERSON FLAMM: I'm just
16 trying to --

17 MR. FELDMAN: In the background
18 statement.

19 CHAIRPERSON FLAMM: I am just
20 trying to clarify that for the record --

21 MR. FELDMAN: Yes, in the
22 background statement.

1 CHAIRPERSON FLAMM: -- that that
2 is what you're doing.

3 MR. FELDMAN: Yes, yes.

4 CHAIRPERSON FLAMM: Okay, further
5 discussion? Nick?

6 MR. MARAVELL: Yes, Jay, I just
7 think we need to be a little bit flexible.
8 I'm not sure we want to prohibit nano. I
9 think we want to just say, "We have not
10 approved any nano in our review of this
11 petition, if the program needs such
12 flexibility, in the way they proceed."

13 So, you know, do you -- well, let
14 me ask the program. Do you care whether we
15 say, "We would prohibit nano-technology," or
16 simply that it is not in this petition, we did
17 not review it, and we are not approving it?

18 CHAIRPERSON FLAMM: Miles, would
19 you respond to that question, please?

20 MR. McEVOY: What we are saying is
21 that if you leave Clause D into the motion,
22 that that would significantly decrease our

1 likelihood of getting this listed in the near
2 future.

3 CHAIRPERSON FLAMM: Mac?

4 MR. STONE: Shift gears a little
5 bit. So, from the certifier point of view,
6 couple of thoughts.

7 The word 'complete degradation', I
8 have a little concern that if a grower is in
9 a dry climate or an environment where he is
10 having trouble, they try it and it doesn't
11 work the way they hope it does, for various
12 environmental conditions, that they, or the
13 certifier/inspector is not in a position of
14 dinging the farmer, even though they're
15 assuring appropriate actions are be taken, but
16 completeness didn't happen.

17 So, I guess some guidance is
18 necessary around that, which in conversation
19 with the program, that is behind the scenes of
20 this, the guidance behind that.

21 But just to make people aware,
22 that that could be an issue for somebody, and

1 since it's not a plastic, it doesn't fall into
2 the 'must be removed' thing.

3 So, I think that language helps
4 for that side, but 'complete' is a little bit
5 worrisome, I guess, not to -- I am not
6 amending the motion, I'm just acknowledging
7 that.

8 CHAIRPERSON FLAMM: Further
9 questions and discussions on the motion that
10 is before us?

11 If not, we can proceed with the
12 voting.

13 MR. FELDMAN: Well, yes, I have
14 another issue, I'm sorry.

15 MR. MARAVELL: Point of
16 clarification. Are we just voting on the
17 motion to take 'D' out of the proposal, or are
18 we voting on the entire proposal?

19 CHAIRPERSON FLAMM: We already --

20 MR. MARAVELL: Took 'D' out?

21 CHAIRPERSON FLAMM: -- did that.

22 We already did that.

1 MR. MARAVELL: Right, well, then I
2 think there is additional discussion, before
3 we call the vote.

4 CHAIRPERSON FLAMM: Okay, that's
5 what we've been doing, I thought.

6 MR. MARAVELL: Yes, yes, yes.

7 CHAIRPERSON FLAMM: Okay.

8 MR. MARAVELL: I'm just saying, I
9 think there is quite a bit more, yes.

10 CHAIRPERSON FLAMM: Okay, I assume
11 if you -- then you want to make another
12 comment?

13 MR. MARAVELL: I want to give
14 others an opportunity to speak, but I have
15 more points.

16 CHAIRPERSON FLAMM: Okay, I think
17 I tried to give everybody an opportunity, and
18 if you go ahead, Nick, if you've got further
19 discussion.

20 MR. MARAVELL: Yes, well, first of
21 all, I want to associate myself with the --
22 with Mac's comments, as it -- as a farmer,

1 you're going to read this and it says
2 'complete degradation'.

3 Well, I know that in regulatory
4 language, 'complete' may mean something else,
5 but a farmer says, "That means 100 percent,"
6 and I hope that in the guidance, it will be
7 clear, that nothing is 100 percent, and we're
8 not going to scare people from using this
9 product, because they're going to say, "Does
10 that mean I've got to cover it up and bury it,
11 so that nobody can possibly ever see it," and
12 actually, that may -- if they cover it up and
13 bury it too deep, reducing moisture, oxygen
14 and temperature to the product, it may
15 actually retard its degradation.

16 So, I would like to know what
17 other think about this, in terms of what
18 message we're sending, and whether or not the
19 program has any views on, if they anticipate
20 putting out guidance on this particular aspect
21 that Mac raised.

22 CHAIRPERSON FLAMM: Any other

1 questions? Discussion by the Board? Miles, do
2 you want to respond to Nick's question?

3 MR. McEVOY: Okay, so, Nick,
4 you're asking what -- about the grower must
5 take appropriate action to ensure complete
6 degradation, and part of this proposal, I
7 heard was that the Crops Committee would want
8 to work on developing guidance for how that
9 would be implemented, is that correct?

10 MR. MARAVELL: Yes, yes.

11 MR. McEVOY: So, it seems like it
12 could be handled through that process, of
13 working with the Crops Committee, on what the
14 appropriate guidance or instruction to
15 certifiers would be, to meet the intent there,
16 that the growers, which is the active word
17 there, they're the ones that have to take the
18 appropriate actions, yes.

19 CHAIRPERSON FLAMM: Jay, and then
20 Mac.

21 MR. FELDMAN: Okay, thank you.

22 Okay, so, here, I'd like to follow up on your

1 comment, Jean, about sort of weighing the need
2 and the need to go forward with this, in an
3 expeditious manner, and our need, as a Board,
4 to make sure that we are evaluating this thing
5 under our criteria.

6 I understand there are always
7 uncertainties and I think we have to bring --
8 you know, address those uncertainties in ways
9 that -- best ways we can.

10 I, for one, am willing to accept
11 some uncertainties, if there are threshold
12 issues that I think we, as a Board, have
13 adequately addressed, and on the science here,
14 I'm willing to accept some of the
15 uncertainties that we've heard about, that Zea
16 actually referenced, in terms of the
17 unanswered questions that are in the technical
18 review.

19 And I think that is something that
20 we all have to come to, maybe in a different
21 way, but understand what those things are.

22 So, I want to put that context

1 around what I have to say about the last
2 clause in the listing motion.

3 One of the things I've learned,
4 being on the Board for three years now, is
5 that it's very hard to get the horse back in
6 the barn, after the barn door is open. I
7 mean, we all know, we've experienced that
8 probably, literally and figuratively.

9 So, the issue with something like
10 this, where there is a fair amount of
11 uncertainty still, everybody acknowledges
12 that, and there is a need to do more research,
13 there is a need to develop guidance, there is
14 all kinds of needs.

15 My feeling is that we really need
16 to start with the narrow, a narrow -- get this
17 -- get a foot-hold with this material, get it
18 going, but do that in a narrow way, and expand
19 on it.

20 It's easier, much easier to expand
21 on something, in a deliberate way, with better
22 information, than pull something back, once

1 it's out there. We've experienced this over
2 and over and over again.

3 So, with that being the theme, I -
4 - when we started this discussion, the Crop
5 Subcommittee, we started with the presumption
6 that -- and looking at the data from the
7 manufacturer, that we would be able to assume
8 compliance with the degradation, or the
9 removal, equal in degradation, within the time
10 frame that was envisioned by the law.

11 At that time, since the
12 manufacturer petitioned as a bio-plastic, we
13 evaluated as a -- we evaluated it as a plastic
14 and we looked at OFPA, and OFPA says removal,
15 at the end of the growing season, or -- yes,
16 at the end of the growing season.

17 So, or the harvest season. So,
18 that obviously, has changed. We're now
19 talking about this not being a plastic, even
20 though I reiterate again, that the industry
21 itself has called this thing a bio--plastic.

22 I think at the end of the day,

1 legally, we're going to find that this will be
2 called a plastic, whether we rename it or not.

3 You know, if someone chooses to
4 sue on this material down the road, there will
5 be no question, in my view, that this will be
6 deemed a plastic.

7 So, it's within our
8 responsibility, I believe, to try to manage
9 this thing, within the frame work of the law,
10 which -- and get it on the market, because I
11 believe the product we're -- that would --
12 that I believe would at least, one, would
13 qualify would meet this standard, at least in
14 terms of most of its applications at this
15 time, is the -- is our -- does suggest that
16 biodegradation within the growing or harvest
17 season, by the end of the growing or harvest
18 season, with it -- is the one year time frame
19 within the statute.

20 There may be some outliers there.
21 The certifiers can manage those outliers, in
22 the short term. If we find out through more

1 and more experience, that in fact, that cannot
2 be done, they can come back with a petition to
3 expand on that. By then, we'll have more
4 data.

5 But we have gotten a foot-hold
6 with this. We will be forward thinking. We
7 will be reducing plastic substantially, but we
8 wouldn't be trying to get the horse back in
9 the barn, after the door was open.

10 So, that is my -- I just wanted to
11 explain my philosophy, my sort of strategy
12 would be to start narrow, limit the
13 uncertainties to the degree that we can, build
14 on that over time, as we get more data coming
15 in.

16 So, in that respect, I would like
17 to propose, I know this isn't a form of
18 proposal, Barry, but I'd like people to
19 consider putting back in, that language at --
20 let's see, let's just see, on the last 'E'.

21 The original language for 'E' was,
22 "Grower must take appropriate actions to

1 ensure complete degradation at the end of each
2 growing or harvest season."

3 Now, having said that, I'd like to
4 hear, if anybody has a comment in response to
5 that, I'd like to hear it, but I'm also
6 interested in hearing from the program on this
7 element of our proposed listing motion.

8 You know, what are the
9 constraints, given the law, given the nature
10 of this material? What are the constraints,
11 in terms of removal equals degradation, equals
12 one year, et cetera?

13 I hope that is clear. I just want
14 to throw that out. Thank you.

15 CHAIRPERSON FLAMM: Mac? Okay,
16 Jean, you had a follow up question?

17 MS. RICHARDSON: Yes, and I tend
18 to agree with you Jay, actually, it would be
19 good to see some -- the careful use of that
20 'end of the growing season phrase'.

21 But do we need the word 'complete'
22 in the last sentence, under 'E'? I'm not

1 certain about that, either, quite frankly.

2 I mean, but let me tell you from
3 the point of view, if I am the inspector,
4 because I think if we're going to make
5 proposals, that have to be able to be verified
6 in the field, if that grower is utilizing the
7 bio-mulch, this year and next year, in the
8 same field, before they move into, perhaps
9 some different kind of rotation, from a
10 verifying point of view, it's going to be very
11 difficult for me to be sure, when I go into
12 that field, is this mulch a little tiny bit
13 that I might see, left from this year or last
14 year?

15 So, from the -- so, I do think we
16 have to be careful, if we're going to make
17 language, that you've got to say how are we
18 going to have that verified in the field, in
19 that -- at the end of that growing season?

20 Having seen the mulch being used
21 all over New England, I mean, obviously, if
22 the farmer is not going to use it in the same

1 field for two crops in a row, or two growing
2 seasons in a row, then it wouldn't be an
3 issue.

4 But if they -- but you know, we
5 don't dictate their rotation that they have.

6 CHAIRPERSON FLAMM: Yes, I'll call
7 on Tracy next, and then Harold, but I've got
8 to remind the Board, we do have a motion on
9 the floor. So, let's keep the discussion
10 germane to the motion that's on the floor, and
11 we may -- and then if you have a proposal and
12 want to amend the motion, we have a procedure
13 for doing that.

14 But I'm just saying, this is not a
15 complete free-wheeling discussion, because
16 we've done that previously, in Committee, and
17 I think we've got to get some closure on this,
18 and with that, Tracy, would you proceed?

19 MS. FAVRE: I was going to only
20 ask the question, if we have a standard, which
21 it looks like 90 percent biodegradable per ISO
22 17556 or ASTM 5988, is there some description

1 in there, that describes what degradation
2 would be, that would also be applicable for
3 the field verification, rather than using some
4 word that is absolute?

5 I mean, is there some criterion
6 that is used? No, I'm seeing 'no'.

7 CHAIRPERSON FLAMM: So, shaking
8 the head, but that doesn't make it on the
9 record. So, you know, yes, Zea or Jay, would
10 you answer the question Tracy posed?

11 MS. SONNABEND: No, that 90
12 percent is for products being tested in the
13 controlled environment of the standard
14 testing, not for verification in the field,
15 because you would never be able to assess what
16 90 percent was, in the field situation.

17 CHAIRPERSON FLAMM: Harold, I
18 believe you had a question or a comment, I
19 should say.

20 MR. AUSTIN: Yes, I think part of
21 it, too, we mentioned earlier that we have
22 suggested that this be added to our research

1 priority list.

2 So, I think some of the answers
3 could be sought out through how we pose that
4 research priority project.

5 So, some of these may be some
6 uncertainties, but I agree, we do have a
7 motion on the floor. So, I think we've got
8 some guidelines, that the certifiers and
9 reviewers could be following, as it exists,
10 and if we need to modify that, I think based
11 off of research and information that we do not
12 have at this time, we can better adapt the
13 policy, as we move forward, based off of
14 science, not based off of human assumption.

15 CHAIRPERSON FLAMM: Nick, you have
16 a comment?

17 MR. MARAVELL: Barry, I would
18 respectfully request the chair, a little
19 forbearance, here. I have more than one
20 comment, and I'm certainly willing to give
21 others plenty of opportunity to comment.

22 But I think this is an important

1 material decision, in that the complete
2 reasoning and rationale of the Board should be
3 put on the record. It should be placed, so
4 that there can be responses to this, later on.

5 So, I ask a little bit of
6 forbearance on this one material, to perhaps
7 extend the discussion, and I would like to
8 introduce a comment, now, is that okay?

9 CHAIRPERSON FLAMM: That's okay.
10 I was just suggesting, we try to stay at least
11 around the motion, itself.

12 MR. MARAVELL: And I take we --
13 yes, we'll stay within our time constraints.

14 I would like to address a couple
15 of issues, in a little bit of a round-about
16 way, and just say what we're looking at here,
17 and why we're looking at it.

18 In the deliberations to pass the
19 original Organic Foods Production Act of 1990,
20 the statute contains a provision, which
21 clearly states, "If you're going to use
22 plastic mulch, that you remove it at the end

1 of the year."

2 At that time, the only mulches
3 available were made from petro-chemicals, and
4 that was what was in everybody's mind.

5 So, I just want to state that I
6 don't think there is any intention here, of
7 going back on that original intent of the law,
8 but we have substantially different material
9 to deal with now.

10 Now, I want to deal with the end
11 of the growing season, or the complete
12 degradation issue, and I see it coming about
13 for two reasons, and one of them goes back to
14 the original law, where clearly, there was no
15 intent to leave a black plastic mulch made
16 from petroleum products, down on the ground,
17 year after year, but you would remove it at
18 the end of the growing season.

19 So, part of the rationale of the
20 Committee, in terms of degradation, was to
21 show that the removal of a bio-mulch, and I'm
22 going to just abbreviate here and call it a

1 bio-mulch film, the removal of a bio-mulch
2 film can be accomplished through the
3 degradation of that film, and I think that --
4 so, that one, put that out as one criteria
5 that we are trying to achieve, in trying to
6 meet a definition that was intended for black
7 plastic coming from petroleum source.

8 On the other side, and now, I'm
9 speaking as a farmer, there is something
10 called organic matter, and organic matter is
11 managed, and I think what, you know, where Mac
12 and I are having a little bit of an issue here
13 is, I don't consider it mandatory, if plow
14 down my corn stover or my cover crop or
15 whatever additions I'm adding to the soil,
16 that it be 100 percent completely bio-degraded
17 at the end of a year or two years.

18 In fact, I consider it sort of a
19 bonus if I have different carbon fractions of
20 most recent to least recent, adequately mixed
21 in an active, biological soil, in the top
22 layer.

1 And so, I think from an agronomic
2 -- from a farming standpoint, I don't think
3 it's imperative that 100 -- if we were using
4 newspaper, or more appropriately in my case,
5 if we were using straw or stover or other
6 types of materials, that they necessarily be
7 100 percent degradable or 90 percent
8 degradable in a particular period of time.

9 So, having said that, what I would
10 urge the program, is to -- we are trying to
11 fit this into existing law and existing
12 regulation. The regulation contains and
13 additional prescription, not in the statute,
14 with regard to other synthetic mulches.

15 And so, I guess my point here is
16 that if our intent is clear, that we see this
17 as a bio-based mulch, made out of -- now, I'm
18 saying organic matter, but not certified
19 organic matter, but made out of a material
20 that came from recently alive material, if you
21 will, then it might be necessary to review
22 other sections of the regulations, to make

1 sure that we are -- we have -- and maybe
2 modify those, so that this, in deed, does fit
3 within the program's definition of adequate
4 removal of the synthetic.

5 So, I'm desperately trying here to
6 outline the thinking of the Committee, in
7 putting this forward. Are we creating a
8 conflict, or is this something that the
9 program can accommodate, in terms of the
10 removal of a synthetic mulch?

11 CHAIRPERSON FLAMM: John, you had
12 one.

13 MR. McEVOY: It just seems like
14 that was a question for the program, and we
15 don't see a problem with making the necessary
16 changes, based on what we see in front of us.

17 I mean, just one thing that we see
18 here, if we take your recommendation and go
19 through the regulatory process of review, to
20 ensure that it fits into the complete picture
21 of the regulation.

22 So, for instance, up here, you

1 have, "Grower must take appropriate actions."
2 We would change that to 'producer', because we
3 don't define grower in the regulation. We
4 define producer.

5 So, it's things like that, that we
6 do with all of your recommendations, as we go
7 through the proposed rule, as we then put out
8 something that may not be exactly the language
9 that you choose, but it is -- it gets your
10 recommendation.

11 CHAIRPERSON FLAMM: Thank you,
12 Miles. John, you have a comment or a
13 question?

14 MR. FOSTER: So, with respect to
15 my previous comments, and my mellow is getting
16 harshed a little bit here, on the process, can
17 we -- I'd like to call the question on this
18 issue.

19 CHAIRPERSON FLAMM: The question
20 has been called. Is there -- there needs to
21 be a second to the question.

22 MS. RICHARDSON: Second.

1 CHAIRPERSON FLAMM: The question
2 is to call for a vote, to end discussion.

3 I'll just ask for votes or
4 objections to the question. Any objections?

5 MR. MARAVELL: I would object. I
6 think there is legit -- no, but I'm saying, I
7 would object to the motion, if I were asked.
8 There's been not adequate discussion, in my
9 mind, yet.

10 CHAIRPERSON FLAMM: Since there is
11 -- I'll rule that since there is an objection
12 to the question, I'll let the question
13 continue, but I would hope we could end this
14 fairly soon, because I think we're covering
15 some ground, again, that was at least been
16 discussed in Committee.

17 I'll recognize Jay, right now.

18 MR. FELDMAN: I'm just trying to
19 get clarity on Nick's question.

20 Looking at the rule, we're talking
21 about 205.206C, "Weed problems may be
22 controlled through six, plastic or other

1 synthetic mulches, provided that they are
2 removed from the field at the end of the
3 growing season."

4 Miles, I didn't quite understand
5 your response. Maybe I was a little
6 distracted. So, help me out here, I
7 apologize.

8 This is a rule that was adopted by
9 the Board, I mean, it was proposed by the
10 Board, adopted by the program, incorporated
11 into the rule, presumably, and maybe we can
12 get a correction.

13 But in any event, it's a -- in my
14 view, it's a principle of soil management, you
15 know, because when we look at the other
16 elements of 205.206C, we're talking about
17 mulching with fully biodegradable materials,
18 mowing, livestock grazing, hand-weeding and
19 mechanical cultivation, flame, heat or
20 electrical means, or the plastic, provided
21 it's removed. Disease problems may be -- and
22 then 'D', Disease problems.

1 But in any event, plastic or other
2 synthetic mulches is the last on the list.
3 You know, obviously, it's not necessarily a
4 prioritized list, but the presumption here is
5 that this is a principle of soil management,
6 that we don't leave synthetics or put
7 synthetics into the soil, and that if we do
8 use synthetics as mulches, we remove them.

9 This is, again, what I'm talking
10 about here is specific to weed problems, we're
11 talking weed management.

12 So, I mean, I'm not sure how much
13 leeway the program really has, to redefine
14 what we remove or don't remove, in the terms
15 of synthetic mulches.

16 The Committee, the Subcommittee
17 has been working under the presumption that
18 first of all, the material does degrade within
19 the time frame of the law, and of this rule,
20 and that removal or degradation equals
21 removal.

22 To change this underlying

1 principle is what I thought I heard you say,
2 to change this principle that synthetic
3 mulches may remain in the soil, or i.e., not
4 degrade, as ASTM suggests they would degrade
5 and as the manufacturer testified to their
6 degradation, seems to me, over-reaching, if
7 I'm interpreting this correctly, over-reaching
8 the intent of the existing standard, as
9 supported by the NOSB.

10 MR. McEVOY: Okay, it think it
11 seems like your question is, is whether or not
12 205.206C is relevant, and it definitely is
13 relevant to this particular proposal.

14 If this proposal is adopted and is
15 a final recommendation from the Board, then
16 that is our responsibility, is to take that
17 and then add this particular material to the
18 national list, and make sure that it doesn't
19 conflict with other parts of the regulations.

20 So, that particular clause that
21 you're referring to would have to be amended,
22 most likely. I mean, looks like it, in terms

1 of, to be compliant.

2 So, what we do is, we take your
3 final recommendation and make changes to
4 205.206C, so that it is compliant with the
5 final recommendation of this Board, that is
6 recommending that this particular substance is
7 added to the national list.

8 It's a normal part of our process,
9 to do that.

10 MR. FELDMAN: Okay.

11 CHAIRPERSON FLAMM: Okay, can you
12 make one more -- can you wrap up with another
13 question? We have a couple other people who
14 want to talk.

15 MR. MARAVELL: Okay, well, no, but
16 this is direct follow up on this, but I can --

17 CHAIRPERSON FLAMM: Well, if --

18 MR. MARAVELL: It's short.

19 CHAIRPERSON FLAMM: I'll take
20 that, you make yours now, if it's a direct on
21 this.

22 MR. MARAVELL: Yes, in effect, I'm

1 going to restate this another way. We already
2 saw that fully biodegradable mulches are
3 permitted. We didn't specify in that, you
4 know, they can't be, it's only non-synthetic
5 fully biodegradable mulches are permitted, and
6 I think where we're trying to get, in my mind,
7 Jay, is that this really qualifies.

8 This is a material that was never
9 really anticipated in the formation of law or
10 the regulation. So, this -- we're now finding
11 a material that is fully biodegradable.

12 So, I could almost make the
13 argument that it's covered above, as a fully
14 biodegradable mulch, but I do certainly not
15 want to second guess the program on that.

16 So, that is where I'm heading with
17 this, and I think it's important to have this
18 discussion.

19 CHAIRPERSON FLAMM: Mac? Mac
20 doesn't have any further questions. Nick, do
21 you still have a question? Comment?

22 MR. MARAVELL: I have one closing

1 comment. I say, I have one closing comment.

2 CHAIRPERSON FLAMM: You have a
3 closing comment?

4 MR. MARAVELL: Yes, if you --

5 CHAIRPERSON FLAMM: Okay, and then
6 we're going to proceed to -- if nobody has any
7 comment or question, after Nick makes his
8 final comment, we'll proceed to the vote on
9 the motion.

10 MR. MARAVELL: Yes, I would simply
11 like to thank Carmela and Zea, for sticking
12 with us, through all of this. This has gone
13 through many twists and turns, and they have
14 valiantly kept us on track, and steered the
15 course for us.

16 I would also like to thank all the
17 members of the public, who have commented on
18 this, because this is what we need, as a full
19 and open discussion, when we're trying to move
20 forward, and I really feel that we have
21 benefitted greatly from the public comment.

22 MR. FELDMAN: May I have a closing

1 comment, too, just one second?

2 CHAIRPERSON FLAMM: You're going
3 to vote.

4 MR. FELDMAN: I'm going to vote,
5 but I'm going to --

6 CHAIRPERSON FLAMM: Jay, go ahead.

7 MR. FELDMAN: I also want to thank
8 the Subcommittee and all the commenters for
9 participating in this process.

10 I really feel like we're close on
11 this. Unfortunately, I'm not going to be able
12 to support this with these last outstanding
13 questions.

14 But please don't take that as my
15 lack of enthusiasm for getting to a place
16 where this material can be used safely and
17 effectively.

18 Again, I appreciate everybody's
19 work on this.

20 CHAIRPERSON FLAMM: We're ready to
21 begin the vote with -- on the motion, it's
22 been a long time, so, anybody -- is everybody

1 clear on what we're voting on?

2 I'm taking the silence is that
3 everybody is clear on the motion.

4 MR. BONDERA: Barry?

5 CHAIRPERSON FLAMM: Yes?

6 MR. BONDERA: Sorry, I was raising
7 my hand, sorry. I just want to verify that
8 the motion, even though the screen shows it
9 with Item D, "Must be produced without
10 engineered nano-tech materials and," that's
11 not -- that is not the motion being voted
12 upon.

13 CHAIRPERSON FLAMM: That was --

14 MR. BONDERA: That was removed and
15 now there is --

16 CHAIRPERSON FLAMM: That was
17 removed and --

18 MR. BONDERA: There is no -- yes,
19 I just want to --

20 CHAIRPERSON FLAMM: The motion on
21 the floor does not contain 'D'.

22 MR. MARAVELL: Barry, also, when

1 we read the motion, with regard to bio-
2 technology concerns, it was 'and/or', and I
3 don't know if that -- does that -- is that on
4 the screen? Oh, it's on the screen? Okay.

5 CHAIRPERSON FLAMM: Any other
6 questions about the vote, the motion we're
7 voting on.

8 Hearing none, I'll proceed with
9 starting the vote with Jay.

10 MR. FELDMAN: No.

11 MS. SONNABEND: Yes.

12 MR. STONE: Yes, sir.

13 MS. FULWIDER: Yes.

14 MR. AUSTIN: Yes.

15 MS. FAVRE: Yes.

16 MS. BECK: Yes.

17 MR. FOSTER: Yes.

18 MR. DICKSON: Yes.

19 MS. RICHARDSON: Yes.

20 MR. WALKER: Yes.

21 MR. BONDERA: No.

22 MS. TAYLOR: No.

1 MR. MARAVELL: Yes.

2 CHAIRPERSON FLAMM: The Chair
3 votes yes. Three, let's see, 12 'yes', three
4 'no'. The motion passes.

5 That concludes the Crop Session. I
6 think we deserve a little break, 15 minute
7 break, and then we'll move to handling
8 proposal.

9 (Whereupon, the above-entitled
10 matter went off the record at 11:06 a.m. and
11 resumed at 11:31 a.m.)

12 CHAIRPERSON FLAMM: Board Members,
13 please take your seat.

14 Okay, the Board's back in session.
15 Our next business matter is the Handling
16 Subcommittee's proposal that was deferred on
17 nucleotides.

18 John Foster, Chair, would you
19 proceed, please?

20 MR. FOSTER: Yes, we have one
21 remaining item from our agenda yesterday, and
22 that's the subject of nucleotides, it was

1 petitioned item, I believe Lisa Brines, if I
2 speak slowly, has time to -- you already
3 introduced it.

4 Lisa, you've already introduced
5 the material of nucleotides. You need not do
6 it again, excellent.

7 One remaining material. Again,
8 I'll give them on to Zea, who did some heavy
9 lifting on this, and Michelle has already put
10 up the current, what will be the current
11 motion on the screen. So, Zea, if you would.

12 MS. SONNABEND: Thank you, John.
13 As we discussed yesterday, the Committee,
14 based on public comment, has -- is likely to
15 change our vote because we think the
16 nucleotides are non-synthetic.

17 We held this back from voting
18 yesterday, though, primarily to make sure that
19 we were creating a listing motion in the right
20 way, and so, we have added, since yesterday,
21 to the listing motion, instead of just saying,
22 "Motion to list nucleotides for inclusion on

1 the list," we're saying, "Nucleotides as
2 petitioned," to add to the list.

3 The reason for this is, there are
4 several different nucleotides and their salts.
5 They are spelled out in the TR, and we just
6 want to -- and in the petition, and we want to
7 make sure that the correct reference to the
8 correct materials is given.

9 So, with that, I'll go ahead and
10 make the motion to classify nucleotides as
11 petitioned, as synthetic.

12 CHAIRPERSON FLAMM: Do we have a
13 second?

14 MR. BONDERA: I'll second that.

15 CHAIRPERSON FLAMM: Okay,
16 discussion? Jay?

17 MR. FELDMAN: Thank you. So, I've
18 heard some discussion about how this is
19 manufactured, and I wanted, if you could -- I
20 don't know, Zea, you may not be able to do
21 this, but if somebody could enlighten us, as
22 to the manufacturing process and the

1 crystallization process, and how people are
2 thinking about that, and whether or not it's
3 viewed as a synthetic process.

4 If you go to line 258 of the
5 technical review, it says, "Nucleotides are
6 processed and prepared for packaging using
7 filtration crystallization, centrifuging,
8 drying, sizing, milling and blending."

9 So, if you could help me, or just
10 get on the record, at least, what that process
11 is, so that we understand it to be a natural
12 process, as some people have described it.

13 MS. SONNABEND: Well, I would
14 refer you to OMRI's and Rich Theuer's comments
15 on this, and I'm looking for them, but does
16 someone else on the Board have them more
17 accessible, and could explain to Jay?

18 MR. FOSTER: I'm looking for them.
19 I'm trying to get there, too.

20 MS. SONNABEND: Okay, or we could
21 call up an audience member, although Lindsey
22 has left, but there are other audience members

1 who could explain it, if that's acceptable to
2 Barry.

3 CHAIRPERSON FLAMM: What would be
4 the --

5 MS. SONNABEND: Jay is asking for
6 an explanation of how those terms that he just
7 read off in the processing of it, made it non-
8 synthetic, and it was in our written comments,
9 but it's going to take us a bit to find them,
10 but someone from the audience, such as
11 Gwendolyn or -- no, or someone else who maybe
12 has the handling comment.

13 Okay, Emily, thank you.

14 MR. FELDMAN: Thank you.

15 CHAIRPERSON FLAMM: Thank you,
16 Emily. You may proceed.

17 MR. FELDMAN: I can read in the
18 record, what OMRI said, now.

19 Just so the Board is aware of
20 this, they restated that crystallization is
21 used in the manufacturing of nucleotide, in
22 the final mix, classifying such materials that

1 go through this process, as synthetic because
2 the resulting material was created via
3 synthetic systems, to generate large volumes,
4 is not in keeping with the criteria set forth
5 in OMRI' synthetic/non-synthetic decision
6 tree, nor with common understanding of the
7 definition of synthetic.

8 "Using the same reasoning on a
9 number of other materials, such as yeast
10 extract, some amino acids, citric acid, et
11 cetera, these substances would have to be
12 considered synthetic because these substances
13 are generated in large volumes via synthetic
14 systems."

15 We asked the NOSB to reconsider
16 this classification for the sake of
17 consistency.

18 So, that answers OMRI's position.
19 If Lindsey were here, I would just ask a few
20 more questions about what that crystallization
21 process is, but thank you.

22 MS. BROWN-ROSEN: Can you hear me?

1 Well, our concern was just that when we looked
2 back at the petition, that I agree that the,
3 you know, the explanation is basically
4 biological processes of enzymes extracting the
5 yeast, but the actual final product, which I
6 believe the petitioner -- no, I'm not sure if
7 they're -- did they comment or not? I don't
8 know if they did.

9 But anyway, the petition actually
10 asked to include nucleotides, isolated from
11 yeast RNA, hydrolyzate on the national list,
12 and specifically, it says it requested the
13 listing to be nucleotides from yeast, RNA
14 hydrolyzate, identified as the following, and
15 their sodium salt. So, then it listed the
16 five different nucleotides.

17 So, once, you know, these yeast
18 bits are extracted into the adenosine,
19 cytodine, guanosine, uridine, inosine-5, then
20 you know, what they're actually asking to be
21 listed is adenosine diphosphate and sodium
22 salt.

1 So, that process has not been like
2 well elucidated in the TR or in the comments,
3 and we feel like there are similar salts of
4 other possibly natural materials that are on
5 the national list as synthetic, as well. That
6 was the concern there.

7 CHAIRPERSON FLAMM: Yes, I'll call
8 on you.

9 MS. SONNABEND: But Emily, isn't
10 that creation of the salt is the
11 crystallization that Jay is referring to,
12 because it's just precipitating out at a
13 certain saturation point.

14 MS. BROWN-ROSEN: You know, it's
15 not clear. We don't have a clear definition
16 or description of the final processing phase
17 there, I don't think.

18 MS. SONNABEND: What do you
19 suggest we do?

20 MS. BROWN-ROSEN: That's a
21 judgment call, to you. If you think that
22 renders it synthetic or not, it's -- you know,

1 there seems to be that it's a salt formed
2 through -- you know, a basically natural
3 extraction, but then there is a salt form.

4 So, you don't have -- I mean, it's
5 based on your own recommendation on
6 classification.

7 CHAIRPERSON FLAMM: Emily, could
8 you --

9 MS. BROWN-ROSEN: It's up to you.

10 CHAIRPERSON FLAMM: Could you
11 repeat what you said, and speak up? At least,
12 I couldn't hear it, so, we can be sure we get
13 it on the record.

14 MS. BROWN-ROSEN: Just saying that
15 it's -- you know, there is a lot of -- this is
16 sort of a borderline call. You know, it's
17 extracted from a natural product, using a
18 biological process. So, that is all considered
19 non-synthetic, in your position.

20 It's just that the formation of
21 the final salt, there must be an added
22 synthetic phosphate source or sodium source,

1 to get the final salt.

2 So, normally, that is considered a
3 chemical reaction, but it's, you know, not a -
4 - you know, maybe you might not consider that
5 a fundamental change. It's up to you guys.

6 CHAIRPERSON FLAMM: Anymore
7 questions? Discussion on the topic? Zea?

8 MS. SONNABEND: So, I know we
9 decided that saying 'as petitioned' would
10 cover this issue, but now, I'm feeling that if
11 we -- no matter which way we vote, it will be
12 confusing to the likes of OMRI and other
13 professionals, who are trying to look at these
14 materials.

15 And so, now, I feel like maybe we
16 need to change the classification motion to
17 say, "Motion to classify nucleotides
18 (including their salts) as petitioned, as
19 synthetic." So, that's extra clear, that that
20 is what our concern may be. Does that make
21 sense to anyone?

22 CHAIRPERSON FLAMM: John, do you

1 have a comment? No?

2 MS. SONNABEND: I made the motion,
3 so, if the second agrees, I guess I'll amend
4 my motion.

5 CHAIRPERSON FLAMM: Why don't you
6 just withdraw your motion and restate it?

7 MS. SONNABEND: Okay, I'll
8 withdraw my motion and make this new motion.

9 CHAIRPERSON FLAMM: So, would you
10 state your new motion?

11 MS. SONNABEND: Okay,
12 classification motion, "Motion to classify
13 nucleotides (including their salts) as
14 petitioned, as synthetic."

15 CHAIRPERSON FLAMM: Is there a
16 second?

17 MR. BONDERA: I'll second.

18 CHAIRPERSON FLAMM: It's been
19 moved and seconded. In a moment, I'll -- it's
20 moved to classify nucleotides -- what is this?
21 Including their salts, as petitioned, as
22 synthetic, is that correct? Further

1 discussion? Is there further discussion? Do
2 you want to ask a question?

3 MS. SONNABEND: Tracy has her hand
4 up.

5 CHAIRPERSON FLAMM: Tracy?

6 MS. FAVRE: Zea, as you know,
7 we've gone back and forth on this, in the
8 Subcommittee, a couple of times, and I guess
9 I'm a little confused now, in regards to the
10 process, specifically, that has caused us to
11 sort of reverse this decision.

12 CHAIRPERSON FLAMM: Zea, would you
13 like to respond to that question?

14 MS. SONNABEND: I don't consider
15 it reversed, before we vote, but what caused
16 us is, the department flagging it, that it
17 wasn't properly annotated to include the salt
18 forms.

19 CHAIRPERSON FLAMM: Does that
20 answer your question, Tracy?

21 Further questions? If not, we'll
22 proceed with the vote on the classification

1 motion, beginning with Zea.

2 MS. SONNABEND: Abstain.

3 MR. FELDMAN: We can't vote, if we
4 abstain.

5 MS. SONNABEND: You don't have to
6 abstain. I will.

7 CHAIRPERSON FLAMM: Everybody else
8 abstains?

9 MS. SONNABEND: Okay, yes.

10 MR. STONE: I guess yes.

11 MS. FULWIDER: Yes.

12 MR. AUSTIN: Yes.

13 MS. FAVRE: Abstain.

14 MS. BECK: Yes.

15 MR. FOSTER: No.

16 MR. DICKSON: Abstain.

17 MS. RICHARDSON: Abstain.

18 MR. WALKER: Yes.

19 MR. BONDERA: Yes.

20 MS. TAYLOR: Yes.

21 MR. MARAVELL: Yes.

22 MR. FELDMAN: Yes.

1 CHAIRPERSON FLAMM: And the Chair
2 votes yes. We have a record number of
3 abstentions, I think. I'll give you the count
4 on whether it passed, in a moment. I've got
5 to look at this tally, what constitutes --

6 I have to refer to the table, to see
7 that. What is your tally? Okay, give me the
8 count again.

9 MS. FULWIDER: Eleven.

10 CHAIRPERSON FLAMM: Eleven 'yes'.

11 MS. FULWIDER: One 'no'.

12 CHAIRPERSON FLAMM: One 'no', and
13 three abstentions. The motion passes. Sorry
14 for the time element, but I had to double-
15 check the chart that we had the right amount
16 for passing.

17 MS. SONNABEND: Okay, in light of
18 it passing, Barry, the listing motion needs to
19 be changed back to, "Motion to list
20 nucleotides, including their salts, as
21 petitioned, for inclusion on 205.605B, instead
22 of A, allowed for infant formulas labeled

1 'organic' or made with organic specific
2 ingredients or food groups, only in the
3 organic and made with organic categories."

4 CHAIRPERSON FLAMM: Do we have a
5 second?

6 MR. FOSTER: I'll second.

7 CHAIRPERSON FLAMM: It's been
8 moved and seconded. If I can -- I'll make
9 sure I've got all the changes, before
10 restating the motion.

11 MS. SONNABEND: Michelle needs to
12 remove the strike out from B. Okay, I see,
13 there is a new B.

14 So, yes, I believe that is
15 correct.

16 CHAIRPERSON FLAMM: The motion is
17 to list nucleotides, including their salts, as
18 petitioned for inclusion on 205.605B, allowed
19 for infant formulas labeled 'organic' or made
20 with organic specified ingredients or food
21 groups, only in the organic and made with
22 organic categories."

1 Discussion on the motion? No
2 discussion?

3 Okay, we will proceed with the
4 vote, if there is no discussion. Starting the
5 voting with Mac.

6 MR. STONE: Yes, sir.

7 MS. FULWIDER: Yes.

8 MR. AUSTIN: Yes.

9 MS. FAVRE: No.

10 MS. BECK: Yes.

11 MR. FOSTER: Yes.

12 MR. DICKSON: Yes.

13 MS. RICHARDSON: Yes.

14 MR. WALKER: No.

15 MR. BONDERA: No.

16 MS. TAYLOR: No.

17 MR. MARAVELL: No.

18 MR. FELDMAN: No.

19 MS. SONNABEND: No.

20 CHAIRPERSON FLAMM: And the Chair
21 votes 'no'. Seven 'yes', eight 'no', the
22 motion fails.

1 I believe that completes the
2 Handling Subcommittee options and actions.

3 MR. FOSTER: Yes, it does, and
4 again, I'd like to thank the Subcommittee for
5 a lot of hard work, lot of hours on conference
6 calls, and again, the program, for their
7 excellent support.

8 CHAIRPERSON FLAMM: We'll break
9 for lunch now, and return at 1 o'clock. Thank
10 you.

11 (Whereupon, the above-entitled
12 matter went off the record at 11:52 a.m. and
13 resumed at 1:18 p.m.)

14 CHAIRPERSON FLAMM: The meeting
15 will come to order. The next item on the
16 agenda is the -- is for the Policy Committee
17 and to address their deferred proposal on
18 conflict of interest, and I'll turn the gavel
19 and the microphone over to the Chair Colehour
20 Bondera.

21 MR. BONDERA: Thank you very much,
22 Barry. At this moment, I request that in order

1 for us to best be able to address the conflict
2 of interest proposed recommendation that is on
3 the -- that was presented yesterday, that the
4 Policy Development Subcommittee have a short
5 meeting to discuss our options.

6 So, I hereby request 10 minutes to
7 do that, if you can so.

8 CHAIRPERSON FLAMM: The request is
9 granted.

10 (Whereupon, the above-entitled
11 matter went off the record at 1:19 p.m. and
12 resumed at 1:30 p.m.)

13 MR. BONDERA: Board Members,
14 please be seated.

15 Thank you very much. Thank you
16 all, for the time. I apologize for the
17 impacts of things that needed to be further
18 considered.

19 So, at this point in time, because
20 -- the Policy Development Subcommittee just
21 got together, and we're dealing with the
22 topic, which is on the table, which is our

1 conflict of interest proposed recommendation,
2 and because of the fact that the conflict of
3 interest document that was submitted for
4 public input and to be considered has received
5 -- and also, from NOSB members, has received
6 such substantial changes, at this point in
7 time, from where it was, and to properly deal
8 with that fact, and separately and in addition
9 from talking to the program people on this
10 topic, we have decided that the best approach
11 is what I am going to do at this moment, which
12 is to table the motion, table the topic of the
13 conflict of interest and pull it off of our
14 plate, at this point in time.

15 So, that said, I would like to
16 turn the gavel back to you, Barry. Thank you.

17 CHAIRPERSON FLAMM: Thank you,
18 Colehour, and I understand that completes not
19 only the Policy Subcommittee's work and
20 proposals, that we have no other deferred
21 proposal for consideration and voting? Am I
22 correct?

1 I think we've completed -- yes,
2 Zea?

3 MS. SONNABEND: I would just like
4 to say that I think the public communication
5 portion about the open docket should come back
6 up at this meeting, that part of it, because
7 I think we really need an open docket, and
8 we're delaying it for six more months.

9 CHAIRPERSON FLAMM: I understand
10 that has been discussed, but it's going to be
11 -- probably be somewhat reworked and brought
12 up at the next Board meeting.

13 Okay, that completes the work on
14 the proposals, and I think we're -- the next
15 order of business is election of officers.

16 So, I'll turn that over. Wendy,
17 are you going to distribute the ballots?

18 MS. FULWIDER: I have already
19 distributed the ballots. You all have three
20 cards. So, we'll use one for Chair, one for
21 Vice Chair and one for Secretary, and it
22 doesn't matter which one.

1 CHAIRPERSON FLAMM: And just, if I
2 could, a reminder of the procedures.

3 There will be separate votes on
4 the -- the first vote will be for the Chair,
5 and after the vote is taken and tallied and
6 the winner announced, then we'll proceed to
7 the Vice Chair position, just for
8 clarification. That's the order, and I don't
9 have any voting cards.

10 MR. McEVOY: Do you not need to
11 nominate people for these positions, to start
12 with?

13 CHAIRPERSON FLAMM: Yes.

14 MR. McEVOY: Okay.

15 CHAIRPERSON FLAMM: We'll have to
16 have nominations.

17 MR. BONDERA: Excuse me, Wendy.

18 CHAIRPERSON FLAMM: Okay,
19 Colehour?

20 MR. BONDERA: Yes, I unfortunately
21 need to not turn this ballot, which turned
22 into a card from a friend, who came to find

1 me, into a ballot. So, I wonder, can I please
2 request a replacement and leave this on the
3 table? I apologize. Thank you.

4 CHAIRPERSON FLAMM: I thought you
5 were going to make a nomination, Colehour.

6 MR. BONDERA: I apologize, that's
7 why -- so, this is sitting here. I'm not
8 double-balloting. It will still be sitting
9 here, sorry. Thank you.

10 CHAIRPERSON FLAMM: Okay, thank
11 you. So, is there a nomination for the
12 position of Board Chair? Zea?

13 MS. SONNABEND: I'd like to
14 nominate Mac for Board Chair.

15 CHAIRPERSON FLAMM: Mac, you've
16 been nominated for Board Chair. Do you accept
17 the nomination?

18 MR. STONE: Could we take about a
19 10 minute break for me to think about that?

20 CHAIRPERSON FLAMM: Chair refuses.

21 MR. STONE: I'll accept that.

22 CHAIRPERSON FLAMM: Okay, is there

1 further -- further nominations for Board
2 Chair?

3 I think the normal procedure is,
4 ask that question three times. I only got two
5 more.

6 Is there nomination for Board
7 Chair?

8 One more time, is there nomination
9 for Board Chair?

10 Hearing none, we just saved a
11 bunch of paper and cardboard.
12 Congratulations.

13 We can proceed for the nomination
14 for Vice Chair. Nomination for Vice Chair?

15 MS. FULWIDER: There is a
16 question.

17 CHAIRPERSON FLAMM: Question? I'm
18 sorry? This glare, I can't see, right now,
19 the people. Who?

20 MS. FULWIDER: Miles.

21 MR. McEVOY: I think you still
22 need to vote, or at least do an acclamation

1 for --

2 CHAIRPERSON FLAMM: By
3 acclamation, that's what I -- I didn't use the
4 proper word, I'm sorry, couldn't think of it.

5 But yes, it was by acclamation.
6 So, with no other -- with three requests for
7 nomination, if there is no other nomination,
8 you can declare the vote by acclamation.
9 That's what I did, but I might have missed the
10 terminology.

11 MR. BONDERA: That is correct.

12 CHAIRPERSON FLAMM: Yes, I'm
13 having -- I'm getting blinded, looking off
14 that way. As much as I like the sunshine, I
15 couldn't see.

16 Are we all clear then? Mac is the
17 new Chair, and then we -- I'm looking for a
18 nomination for Vice Chair.

19 Nick, I believe you had your hand
20 up?

21 MR. MARAVELL: Yes, I nominate
22 Colehour.

1 CHAIRPERSON FLAMM: Colehour,
2 you've been nominated for Vice Chair. Do you
3 accept the nomination?

4 MR. BONDERA: Yes, I will accept
5 that nomination. Thank you, Nick.

6 CHAIRPERSON FLAMM: Is that 'yes'?

7 MR. BONDERA: Yes, it was.

8 CHAIRPERSON FLAMM: Okay, and I
9 saw that Jennifer had her hand up.

10 MS. TAYLOR: I was going to
11 nominate the same person.

12 CHAIRPERSON FLAMM: All right,
13 Harold?

14 MR. AUSTIN: I nominate John
15 Foster.

16 CHAIRPERSON FLAMM: John Foster
17 has been nominated for Vice Chair. John, do
18 you accept the nomination?

19 MR. FOSTER: I accept.

20 CHAIRPERSON FLAMM: Okay, we have
21 -- at this time, we have Colehour Bondera
22 nominated for Vice Chair and John Foster,

1 nominated for Vice Chair.

2 Any additional nominations? Any
3 additional nominations? Any additional
4 nominations?

5 Okay, not hearing any, I think we
6 can vote.

7 I have counted the votes and it's
8 been verified by the program, by Miles, and
9 John Foster is the next Vice Chair.
10 Congratulations, John.

11 Okay, we have the important
12 position of Secretary to be elected now. Do
13 we have -- is there a nomination for Secretary
14 of the Board? Harold?

15 MR. AUSTIN: I'd like to nominate
16 Wendy.

17 CHAIRPERSON FLAMM: Wendy, you've
18 been nominated to serve as Secretary, for a
19 third term. Do you accept?

20 MS. FULWIDER: I accept.

21 CHAIRPERSON FLAMM: Are there
22 further -- is there additional nominations?

1 Yes, Wendy?

2 MS. FULWIDER: I'm going to
3 nominate Calvin.

4 CHAIRPERSON FLAMM: Calvin has
5 been nominated to serve as Secretary. Calvin,
6 do you accept the nomination?

7 MR. WALKER: Wendy, you are
8 running?

9 MS. FULWIDER: Yes, but I feel
10 that you should run, as well.

11 MR. WALKER: I decline. I
12 respectfully decline.

13 MS. FULWIDER: You're hurting my
14 feelings.

15 CHAIRPERSON FLAMM: Calvin, I
16 understand you do not accept the nomination to
17 be Secretary?

18 MR. WALKER: That's correct, I
19 would not want to run against my Chair of the
20 Livestock Committee.

21 CHAIRPERSON FLAMM: Is there any
22 further nominations for the position of

1 Secretary?

2 Is there any further nominations
3 for the position of Secretary?

4 Yes, would you like to make a
5 nomination for Secretary?

6 MR. MARAVELL: Well, what I'd like
7 to do is just to point out the general policy
8 of the Board, and I think it may be in the
9 policy and procedures manual, that we
10 encourage a turnover, and I think that's what
11 Wendy is indicating here, and I would ask
12 Calvin to reconsider.

13 But I'm just going to indicate
14 that the policy is generally, to encourage,
15 you know, not a lot of consecutive terms.

16 So, Calvin, would you possibly
17 reconsider?

18 CHAIRPERSON FLAMM: I could -- I
19 just reread the procedures of the manual
20 position. Consecutive terms are allowed,
21 however, I would say that more than two terms
22 aren't, by the language, not particular

1 encouraged. But it's not -- no prohibited.

2 I just wanted to clarify that.

3 It's not prohibited.

4 At any case, I want -- okay, I'm
5 asking for one more time, for nominations.

6 Wendy, do you have a nomination?

7 MS. FULWIDER: Under, you know,
8 the situation, you know, if Calvin is not
9 going to run against me, I feel that I should
10 decline.

11 CHAIRPERSON FLAMM: So, we've gone
12 from two nominations now, to no nominations.
13 Most unusual, I would say, at elections, but
14 okay, I'm going to accept that Wendy has
15 declined.

16 So, I'm going to ask for
17 nominations for the office of Secretary.
18 Colehour?

19 MR. BONDERA: Yes, I would like to
20 nominate Calvin to serve in that role.

21 CHAIRPERSON FLAMM: Calvin?

22 MR. WALKER: I accept.

1 CHAIRPERSON FLAMM: Will you
2 accept the nomination?

3 MR. WALKER: Yes, sir.

4 CHAIRPERSON FLAMM: Okay, Calvin
5 has accepted the nomination to be Secretary of
6 the Board. Is there additional nominations?
7 John, do you have a nomination?

8 MR. FOSTER: I feel like there is
9 a full circle thing here, that needs to
10 happen, and I'm going to nominate Wendy, and
11 she can do as she wishes.

12 CHAIRPERSON FLAMM: Wendy, are you
13 going to accept or decline that?

14 MS. FULWIDER: I will accept,
15 providing Calvin does not decline.

16 CHAIRPERSON FLAMM: Most unusual.

17 MR. WALKER: I will not decline.

18 CHAIRPERSON FLAMM: Okay, so, as I
19 understand, we have Calvin has accepted the
20 nomination to serve as Secretary, and Wendy
21 has accepted the nomination to serve as
22 Secretary. Do we have further nominations?

1 Okay, hearing none, I'll ask it,
2 now. Do we have further nominations? Do we
3 have further nominations?

4 Hearing none, we'll proceed with
5 the vote.

6 I've counted the votes for the
7 position of Secretary of the Board, and it's
8 been confirmed by the program, by Miles, and
9 Calvin has been elected Secretary, and
10 congratulations, Calvin.

11 I want to extend my thank you to
12 Wendy, for her great service over two years.
13 That's a tough job, so, thank you very much,
14 Wendy.

15 At this point in time, I'd like to
16 restart a tradition that was on the Board when
17 I joined it, and that is that I pass the gavel
18 to the new Chair.

19 I want to thank the Board for
20 their honoring me with serving as your Chair,
21 and I appreciate all the cooperation and good
22 work you done, and now.

1 MR. STONE: The first order of
2 business is not only thanking Barry, and I'm
3 humbled by the shoes that he has filled, but
4 Barry, you've got a new name tag, and we'll
5 have this one framed and sent to the house for
6 you.

7 CHAIRPERSON FLAMM: I love that,
8 and you can't believe how truthful that is.

9 MR. STONE: Well, it's again,
10 Barry, I know that following your footsteps
11 of, you know, a lot of people were very
12 comfortable with your leadership and steady
13 guidance.

14 So, I do have a strong sense of
15 responsibility, obviously. There is a lot of
16 very strong and passionate and caring people,
17 and we can agree to disagree, but then we
18 agree to go forward, in a unified voice, after
19 some -- we made some very tough votes this
20 past week, but we still have to look forward
21 and at the end of the day, come together and
22 do what we all think is best for the industry,

1 if you will.

2 I think we have work plans, next.

3 I don't know, Michelle, if you have that to
4 put up, or if each Subcommittee Chair has
5 their own, and maybe we'll just go in the same
6 order that they're in on the screen.

7 Looks like starting with
8 certification, Joe, if you want to reference
9 the document.

10 MR. DICKSON: Thank you, Mr.
11 Chairman. The Compliance Accreditation and
12 Certification Subcommittee's work plan for
13 2013 for the Spring meeting has three items on
14 it.

15 The first of which is the
16 extension of the calculating percentage of
17 organic ingredients items, which we presented
18 the discussion document for today. We will
19 take that feedback and work as a Committee, to
20 assemble that into a concrete recommendation
21 for the next meeting.

22 We will also be exploring the

1 issue of the use of sanitizers, as they relate
2 to 100 percent organic products, based on
3 input that we should be receiving from the
4 National Organic Program, in the near future.

5 Finally, we will be rekindling the
6 issue of retail certification. It's an issue
7 that came up back in 2007 and 2008, with the
8 previous Board. There was an earlier
9 discussion document on the sort of question of
10 the retail exemption, the extent to which
11 retailers are able to use it, what happens
12 when a retailer opts to become a certified
13 entity.

14 There are these sort of grey areas
15 of the certification policy around retail
16 stores. So, we will be dusting that
17 discussion document off and fashioning that
18 into a recommendation from the Committee for
19 the Spring meeting, as well.

20 Those are our three work plan
21 items. Thank you.

22 MR. STONE: Thanks, Joe. Are

1 there any questions or discussion for Joe,
2 around that work plan?

3 Okay, scrolling up, does that say
4 GMO? Yes. Zea?

5 MS. SONNABEND: Okay, the GMO ad-
6 hoc Subcommittee will be discussing all of the
7 comments we received about purity and GMOs,
8 and possibly, having a recommendation, or at
9 least a proposal for moving forward at the
10 Spring 2013 meeting.

11 We are going to take up the issue
12 of some of the terms used in plant breeding,
13 to clarify whether they're GMOs or not, things
14 like mutagenesis, cell fusion, micro-
15 encapsulation, and then on the longer term
16 work plan, I think Fall 2013 is optimistic,
17 but we're going to try to get a handle on it,
18 tracing GMOs back in the input and ingredient
19 chain.

20 MR. STONE: Any questions for Zea,
21 over members of that Committee?

22 Okay, crops?

1 MR. FELDMAN: Thank you, Mac. We
2 have a number of petitions that are pending
3 before the Subcommittee, polyoxine D zinc, as
4 a folier spray for fungal disease, vinasse as
5 a soil amendment, tetracycline as a petition,
6 streptomycin, we expect to receive a petition,
7 and then we have a number of aqua-culture
8 petitions, related to plant material and aqua-
9 culture, CO2, chlorine, micro-nutrients,
10 vitamins B1, B12 and H, lignin sulfonate, as
11 a chelating agent.

12 We also have a petition for carbon
13 monoxide, exhaust gas, add to Section 205.601
14 petition, and we will be working on plant
15 breeding issues, related to GMOS, and let's
16 see, inerts, also as a -- we'll have to take
17 a look at, you know, the policy of past and
18 coordinate with the program, on how to move
19 forward on that.

20 Finally, I guess it hasn't been
21 approved yet, but it seems as though we may be
22 working on a set of proposed guidance, or work

1 with the program on guidance, related to the
2 biodegradable mulch, film mulch. Thank you.

3 MR. STONE: Very good, Jay and his
4 Committee. It's quite an aggressive agenda,
5 but I think with the quality of the members,
6 you can work through that. Any questions for
7 Jay?

8 MR. FELDMAN: Excuse me, I guess
9 Zea is saying we have some sunsets, which I
10 wasn't aware of, I must admit.

11 MS. BAILEY: Mac?

12 MR. FELDMAN: Okay, these are --
13 this one is --

14 MS. BAILEY: Mac, sorry. Yes,
15 Jay, we think Miles showed this to you this
16 morning. Those weren't on the Crops
17 Subcommittee list, but we know we're going to
18 have to deal with them next year.

19 So, we had added the three sunset
20 2015 materials onto the Crop Subcommittee work
21 plan, for the Fall.

22 MR. FELDMAN: Okay, so, sulfurous

1 acid, sodium carbonate and not a -- you can
2 pronounce that last one for me, and aqueous
3 potassium silicate. Did I get that? Okay,
4 sorry, Mac, I wasn't aware of that until just
5 now.

6 MR. STONE: All right, any
7 questions or follow up for Jay or that
8 Committee?

9 Okay, next up is Handling, that is
10 Mr. Foster.

11 MR. FOSTER: Thank you. We have a
12 number of petitioned items.

13 First, on this will be gibberellic
14 acid, re-visitation of that, and its current
15 status as determination of whether or not
16 there is substantive new information, as
17 compared to the last one. We haven't made
18 that determination yet. But we'll be looking
19 at that, to see if it needs to go through.

20 We also have petitions for
21 sulfuric acid, barley beta fiber, sugar beet
22 fiber, DBD/MH, and then we're thinking of a

1 proposal, based on this discussion document
2 around auxiliary/other ingredients.

3 Then following something we talked
4 about the last meeting, hopefully getting a
5 jump on Sunset 2015 items, gellan gum,
6 marsala, sherry and tragacanth gum. Those are
7 mostly 606, but the gellan gum will be 605
8 material.

9 So, the farther we can get on
10 those, you know, ahead of the deadline for
11 Sunset, the better. So I'd like to work
12 pretty hard to make sure we cycle through
13 those. That's it.

14 MR. STONE: Any questions for
15 John, not that I knew what all of Jay's were,
16 but what is DBD/MH, whatever it was? What was
17 that one?

18 MR. FOSTER: Really? You're going
19 to ask me that? It's a multi-syllabic word,
20 I do not have in front of me at the moment,
21 and I am not going to guess, right now.

22 MR. STONE: Okay.

1 MR. FOSTER: If you'd like, I'll
2 be happy to tell you perhaps, after the
3 meeting.

4 MR. STONE: No.

5 MR. FOSTER: Actually, Lisa Brines
6 may be able to help. She is good, like that.

7 MR. STONE: Okay.

8 MS. BRINES: For the record, that
9 is dibromo-dimethyl-hydantoin. Thanks.

10 MR. FOSTER: Does that make you
11 feel better?

12 MR. STONE: Yes, like that helps,
13 yes. All right, you better be careful, I'll
14 end up on that Committee, if I'm not careful.

15 Livestock, Ms. Wendy.

16 MS. FULWIDER: Thank you, Mac. We
17 have quite a list of aqua-culture petitions
18 for Spring.

19 We have tocopherol, vitamins,
20 trace minerals, lignin sulfonate and chlorine.

21 We also have a little diversion of
22 chickens. We have a methionine petition

1 coming back, and we also may have a proposal
2 for the omnivore diets, as a follow up to the
3 discussion document.

4 For Fall 2013, we have acidified
5 sodium chlorite and a working group update for
6 the GMOS vaccines, and I would also like to go
7 on record that at some point, I would like to
8 know when we would be able to do the animal
9 welfare guidance, because when we passed the
10 recommendations for animal welfare and animal
11 handling and transport, it was with the
12 understanding that we would have strong
13 outcome based standards to go with that.

14 And so, I would just like to know
15 at some point, you know, when the program
16 would expect we would be able to do that, and
17 we could also take that up on the Executive
18 Committee call. I don't expect an answer
19 today.

20 MR. McEVOY: Yes, we're still
21 working with the animal welfare
22 recommendations that were passed by the Board.

1 So, we still have a lot of work to
2 do, to work on that, and what we requested
3 from the Board was to give us a little bit of
4 time to figure out how we're going to move
5 forward with that, before you developed more
6 recommendations that could potentially
7 complicate our ability to move forward on the
8 original animal welfare recommendation.

9 In addition to that, this is a
10 very lengthy, ambitious list that the
11 Livestock Committee has on their work plan.
12 So, especially for the Spring. I think it's
13 something that we certainly can continue to
14 discuss, how the additional guidance on animal
15 welfare might fit into the work plan for the
16 Livestock Committee in the future.

17 MR. STONE: Okay, any questions,
18 Wendy? Okay, next? I'm sorry, Colehour?

19 MR. BONDERA: And I apologize if I
20 missed it, but I wanted to ask, at the bottom,
21 I think, was a, yes, GMOS vaccines, and my
22 question is, and I don't want to put anybody

1 on the spot, but I'm just going to raise it as
2 a question, which is right now, we're in Fall
3 of 2012.

4 I personally, based on my input
5 and experience with the GMOS vaccine, am a
6 little bit concerned that there wouldn't be a
7 working group update all the way for a whole
8 other year.

9 And so, from a scheduling
10 perspective, I wonder if that could or should
11 say both Spring and Fall?

12 MR. STONE: All right, that's a
13 good point, and we'll talk about it, at the
14 Executive Committee and work with the program,
15 and see how fast that is moving with the
16 working group and certainly, an abbreviated
17 update, if nothing else, I'm sure. So, good
18 catch.

19 Materials, Ms. Jennifer.

20 MS. TAYLOR: Thank you, Mac. Our
21 work plan for the Spring and Fall will include
22 examining update petition, technical review

1 process, define production aides, how to
2 address scientific uncertainty, which is a new
3 item that has been added to our work plan.

4 The confidential business
5 information transparency and its process, and
6 research priorities.

7 MR. STONE: Thank you, Jennifer.

8 MS. TAYLOR: Thank you.

9 MR. STONE: Any questions for
10 Jennifer? Very good. That's one more,
11 Policy, Colehour.

12 MR. BONDERA: Yes, thank you.
13 Yes, the Policy Development Subcommittee will
14 work on reviewing and updating the manual, the
15 policy and procedure manual, doing the same
16 with the new member guide, and ideally, we
17 will have put notable energy into those, and
18 there will be something to consider at the
19 next meeting.

20 A threshold two-stage technical
21 report, which we have talked about before, but
22 it's currently targeted for Spring, as well,

1 and then working with the Materials
2 Subcommittee, as the supporting Subcommittee,
3 but we will lead the material initiation or
4 substance annotation clean up policy and we'll
5 work on the title of that, as necessary.

6 A decisive/indecisive
7 determination of NOSB votes, and finally,
8 convening of technical Advisory Boards, the
9 policy on that.

10 So, those are the things that we
11 have on our sort of, I guess short term agenda
12 and/or like I said, a few of them aren't
13 scheduled, but that is what I have to share.
14 Thank you.

15 MR. STONE: And I guess with the
16 tabling of the conflict of interest, we can
17 add that back in there, as well, I guess.

18 MR. BONDERA: I think that is a
19 good point.

20 MR. STONE: Yes.

21 MR. BONDERA: We may well do that,
22 so, thank you.

1 MR. STONE: All right, well, thank
2 you, all, for that. We all have a lot of work
3 to do.

4 So, just a few sort of remarks.
5 I'll kind of go around and I know the program
6 may have some closing remarks, no particular
7 order, but those of you, the Committee Chairs,
8 get your final recommendations. Michelle sent
9 the new form around, so get those finalized
10 and to her, so that she can complete our work
11 for this week. It's not technically complete
12 until she gets all the paperwork.

13 Rookie mistake, on my part. Those
14 actually go to Barry, for his signature,
15 before they go to the program.

16 So, thank you, and I hope you'll
17 join me next year, when we -- next Spring,
18 keep me on track.

19 So, Lynn, I just wanted to follow
20 up with you, that Barry may not be on the
21 Certification Committee, but we have his phone
22 number, and we will continue with the

1 biodiversity, because we know how to a hold of
2 him, and I'm sure he'll still be interested
3 that we do follow through on it.

4 So, I just want to say some thank
5 yous, but Michelle, do you have any
6 housekeeping or anything that you need for us
7 to know, before we part?

8 MS. ARSENAULT: I don't have
9 housekeeping, but I just wanted to kind of
10 address everyone. I didn't do that at my
11 first meeting, because I was on the job for
12 three weeks, at that time.

13 Most of you guys know I've been --
14 I'm new to the program. I've only been here
15 seven months, but I have a few impressions.
16 This is the most incredible group of people I
17 have ever worked with. I spend an awful lot
18 of time with them on the phone, and I'm
19 incredibly impressed by how respectful and
20 thoughtful and hard working everybody is,
21 staff included.

22 If you guys have received emails

1 from me, you may have noticed weird time
2 stamps, like late at night, weekends. I
3 wouldn't take my work home with me, if I
4 didn't really love my job.

5 But I am probably the least hard
6 working person in the office, because it's
7 definitely a team effort, and everybody works
8 really hard around the office.

9 The Board, they're amazing. I was
10 welcomed with open arms, and they're very
11 gracious and patient with all the mistakes, as
12 I fumble my way through, learning my new
13 position, and I just wanted to say thank you
14 to everyone, which I don't say often enough.
15 So, thank you.

16 MR. STONE: Our thanks to you.
17 Well, now, we have a couple of presentations
18 to make. Is there any comments or anybody
19 want to bring something before the Board, for
20 discussion, before we -- and we also want to
21 get a group picture, as well.

22 So, I see Miles has a plaque

1 there, so, if you'd like to present that.

2 MR. McEVOY: Yes, actually, I'd
3 like to also just say a big thank you to
4 Michelle. She does all the logistics and the
5 background work to support your work, and all
6 of her work supports the NOP, as well, and she
7 has just been so great to work with and just,
8 we couldn't do it without out. Thanks so
9 much, Michelle.

10 Okay, so, I have a bunch of
11 plaques to distribute, and first of all, to
12 Barry Flamm. As I said on my opening remarks
13 on Monday, Barry is an amazing individual, has
14 a lifetime of achievements before he came here
15 to the NOSB.

16 He has contributed so much to the
17 NOSB and the organic community, and we're
18 going to miss you a lot, Barry. We just
19 really appreciate your leadership. Thank you.

20 CHAIRPERSON FLAMM: Miles and
21 staff, and Michelle, as everybody has attested
22 on the Board, that she has been terrific and

1 you out there, it's hard to say you're out
2 there, you're in here, we're all a community
3 and a team, trying to work to further
4 organics, that we all have such a passion for.

5 So, it's been great meeting all of
6 you. Thank you.

7 MR. McEVOY: Thanks, Barry, and
8 then I have plaques for all the new Board
9 Members. You're not so new, now. This is
10 your second meeting, but we failed to give you
11 your plaques and your letters from the
12 Secretary.

13 We actually got a call this
14 Summer, kind of an angry call from the
15 Secretary's office, saying, "Why didn't the
16 Board get their letters, before they started
17 their appointment in May?"

18 So, the Secretary's office takes
19 it really seriously, your appointment, and
20 really honors your contribution to the organic
21 community and American people, by serving on
22 this Board.

1 So, this is just a small token of
2 recognition for your service, through a
3 plaque, and hopefully, you've already received
4 your letter from the Secretary.

5 So, first of all, for Tracy Favre.

6 I guess I could just do this all
7 together. For Andrea Sonnabend, or Zea.

8 For Carmela Beck, thank you so
9 much for your service.

10 For Harold Austin, thank you, and
11 for Jean, for Dr. Jean Richardson.

12 MR. STONE: Good, thank you, I
13 appreciate that. In a word that I hear most
14 often in the Certification Accreditation
15 Committee with John and Joe is awesome. It's
16 awesome to serve on this Board and many of us
17 feel like we -- as much work as it is, we
18 still benefit more than we can contribute,
19 because of the people that are in the room,
20 not just the people at this front table.

21 You know, you all are here for
22 four days and you're on the phone and the

1 email is almost as much we are, around these
2 topics, and we couldn't do our work without
3 what you all provide to us.

4 So, there being no other business
5 to attend to, I guess I'll officially declare
6 the Fall meeting of the NOSB adjourned.

7 (Whereupon, the above-entitled
8 matter concluded at 2:19 p.m.)

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A				
AAC 81:15 87:17	139:9	add 6:12 18:16	106:10 118:10	28:15 32:16 39:15
abbreviate 136:22	accompanies	44:6 53:22 55:11	142:8,10 144:14	allow 14:2 66:6,8
abbreviated 193:16	115:20	55:17 69:19 70:10	advise 18:22	81:14 85:10
ability 11:7 99:6	accompanying	75:21 96:18	Advisory 2:11	allowed 79:3,10
192:7	79:17 81:10	106:10 144:17	195:8	98:11 99:12
able 37:17 46:21	accomplished	153:2 186:13	Ad-Hoc 3:17	107:13 109:10
101:22 127:7	27:13 137:2	195:17	affect 27:4	111:3 117:8,10
131:5 133:15	accreditation 3:2	added 23:12 59:10	age 38:17	164:22 165:18
148:11 153:20	4:14 34:16 43:5	98:4 107:14	agencies 5:14 7:6	178:20
168:1 184:11	183:11 201:14	110:15 133:22	7:11 8:7,12 10:5	allowing 79:2
190:6 191:8,16	accredited 8:5 32:4	145:7 152:20	11:4 16:4 43:21	allows 22:11
above-entitled	accrediting 5:13	159:21 187:19	98:19 101:4	alternative 60:21
52:14 151:9	8:6 10:5 11:4	194:3	agenda 4:16 61:3	72:7
167:11 168:10	16:4 43:21	addendum 12:19	151:21 167:16	alternatives 62:16
202:7	achieve 27:8 77:21	adding 16:22 17:3	187:4 195:11	66:8 71:11,14,21
absence 84:12	137:5	70:9,22 137:15	agent 186:11	72:5,16 73:1
absolute 80:19 96:5	achievements	addition 72:21	agents 88:1	amazing 198:9
133:4	199:14	169:8 192:9	aggressive 187:4	199:13
absolutely 7:10	acid 13:19 87:14	additional 18:2	ago 21:9 42:5 50:13	ambitious 192:10
abstain 163:2,4,6	156:10 188:1,14	29:13 94:2,6	109:5	amend 132:12
163:13,16,17	188:21	105:22 122:2	agree 38:4 42:22	161:3
abstains 163:8	acidified 191:4	138:13 176:2,3,3	45:7 53:22 62:7	amended 144:21
abstentions 164:3	acids 156:10	176:22 180:6	73:17 91:11	amending 121:6
164:13	acknowledge 83:2	192:14	114:20 130:18	amendment 114:17
ACA 8:5 14:22	acknowledged	additions 137:15	134:6 157:2	116:16 186:5
18:17 24:20	84:18	address 26:8 30:11	182:17,18	amendments 115:1
ACAs 5:14 9:6 14:4	acknowledges 26:3	32:21 52:7,19	agreed 21:14 26:7	America 60:19
14:10 18:3 43:3	126:11	57:1 60:21 125:8	agreement 26:13	American 200:21
accept 107:11,21	acknowledging	135:14 167:17	27:3 68:22 117:16	amino 156:10
114:16 115:9	100:5 121:6	168:1 194:2	agrees 161:3	ammunition 64:14
125:10,14 172:16	Act 135:19	197:10	agricultural 2:18	amount 9:3 43:11
172:21 175:3,4,18	action 21:12 27:21	addressed 22:6	19:21 106:2	48:4 49:2 50:2,8
175:19 176:19,20	58:2 59:12 65:9	90:7 125:13	agriculture 1:1,1	126:10 164:15
177:6,16 179:14	67:22 99:5 102:7	addressing 30:18	20:15 49:5	amplify 118:7
179:22 180:2,13	106:12 124:5	adenosine 157:18	agro 86:12	AMS 1:1
180:14	actions 62:10 64:18	157:21	agronomic 138:1	analysis 81:9 103:4
acceptable 155:1	79:19 81:7 85:1,4	adequate 66:12	ahead 52:5 54:3,4	Andrea 201:7
accepted 107:7	85:6 96:14 120:15	74:4,5 139:3	83:7 122:18 148:6	and/or 83:20 96:11
109:8 115:13	124:18 129:22	141:8	153:9 189:10	150:2 195:12
180:5,19,21	140:1 167:2	adequately 125:13	aide 14:17 15:2,5	angry 200:14
accepts 105:21	active 124:16	137:20	aides 13:5,14,18	animal 39:5 82:3
106:4	137:21	Adjourn 3:23	14:5,14 194:1	97:4 191:8,10,10
accessible 154:17	activities 37:3	adjourned 202:6	air 31:9 74:19,21	191:21 192:8,14
acclamation	actual 43:9 101:10	Administrator 2:9	air-blast 74:8	anniversary 51:19
173:22 174:3,5,8	116:18 157:5	2:22	alive 113:14 138:20	annotated 162:17
accommodate	ad 185:5	admit 187:10	alliance 21:3,10	annotation 70:21
	adapt 134:12	adopted 105:9	24:6 25:1 26:18	79:1,19 81:9 84:8

92:12 101:11 102:19 103:14 108:21 110:17 114:18 195:4 annotations 80:2 announced 171:6 announcement 51:18 answer 12:6 40:9 43:14 133:10 162:20 191:18 answering 40:11 answers 9:20 134:2 156:18 antibiotic 71:9 anticipate 123:19 anticipated 79:15 146:9 anti-biodiversity 38:15 anybody 25:4 75:11,13 98:4 130:4 148:22 192:22 198:18 anymore 44:15,18 160:6 anyway 52:4 67:13 69:9 157:9 apologize 142:7 168:16 172:3,6 192:19 apparently 8:20 appear 115:20 appears 10:7 15:1 applaud 41:13 apples 12:14 applicability 30:8 36:14 applicable 133:2 application 39:18 40:14 73:14 74:7 74:13 75:2,4 applications 128:14 applicator 73:12 applied 84:10 applies 84:20 90:11	appointment 200:17,19 appreciate 33:8 53:12 92:9 105:12 148:18 181:21 199:19 201:13 appreciated 8:20 44:9 47:14 92:8 93:8 105:20 approach 26:5,6,17 72:14 169:10 approaches 30:1 appropriate 25:16 45:10 64:10 79:19 81:6 84:22 85:9 96:14,19 107:2 120:15 124:5,14 124:18 129:22 140:1 appropriately 114:19 138:4 approval 107:20 approved 20:4 101:13 111:4 119:10 186:21 approving 111:15 111:16 112:20 117:5 119:17 aqua 186:8 aqua-culture 186:7 190:17 aqueous 188:2 area 6:2,7 27:11 33:18 36:10,12 38:8 areas 184:14 argue 92:16 argued 85:21 argument 71:9 146:13 arguments 61:12 arms 198:10 arrive 88:10 ARSENAULT 2:11 197:8 articulated 48:8 aside 14:8	asked 5:19 12:3 23:2,7,10 24:16 48:15 50:15 51:18 65:14 141:7 156:15 157:10 asking 24:14 68:2 111:22 124:4 155:5 157:20 179:5 aspect 123:20 aspects 20:5 43:19 assemble 183:20 assess 29:8 133:15 assessed 34:15 40:2 assessment 30:13 31:17 assessments 34:21 associate 2:21 122:21 associated 32:12 60:1 Association 7:16 8:5,6 21:4 37:11 assume 122:10 127:7 assumption 134:14 assurance 106:16 assured 115:19 assuring 120:15 ASTM 80:13 81:2 81:20 82:7 83:2 95:22 96:21 132:22 144:4 ASTM5988 80:22 96:8 ASTM6866 96:10 attached 113:21 attachments 42:18 attend 202:5 attention 20:7,9 21:11 24:15 attested 199:21 ATTRA 21:6 atypical 57:11 audience 154:21,22 155:10 audit 31:13,15	audits 6:16 34:16 44:1 Austin 1:15 54:20 62:18 72:3 73:17 76:12 94:14 97:13 116:2 133:20 150:14 163:12 166:8 175:14 176:15 201:10 authority 108:5 auxiliary/other 189:2 available 9:5 72:5,7 73:1,3 108:16 117:9 136:3 avoid 104:20 aware 58:22 116:19 120:21 155:19 187:10 188:4 awesome 201:15,16 awful 197:17 a.m 1:10 4:2 52:15 52:16 151:10,11 167:12 <hr/> B <hr/> B 81:1 83:9 96:9 165:12,13 back 8:22 10:15 14:6 20:3 24:19 24:20 37:19 39:10 46:17 50:12 51:20 52:2,7,12 56:5 59:7 64:16,22 65:4 66:18 68:4 73:20 82:20 85:17 97:17 102:5 113:13 126:5,22 129:2,8,19 136:7 136:13 151:14 152:17 157:2 162:7 164:19 169:16 170:5 184:7 185:18 191:1 195:17 backdoor 114:6 background 20:12	108:18 110:8 111:6 112:9 114:8 114:19 116:18 118:12,14,17,22 199:5 BAILEY 2:14 187:11,14 balance 77:21 ballot 171:21 172:1 ballots 170:17,19 banana 60:15 bar 67:7 barley 188:21 barn 126:6,6 129:9 Barry 1:12,14 4:13 19:14,17 28:2,7 33:3,6 46:12 48:5 48:11 51:8,15 53:5 64:7 73:8 77:4 105:5 114:1 129:18 134:17 149:4,22 155:2 164:18 167:22 169:16 182:2,4,10 196:14,20 199:12 199:13,18 200:7 based 14:22 16:8 58:4 72:17 95:19 110:16 134:10,13 134:14 139:16 152:14 159:5 184:2 189:1 191:13 193:4 basically 5:12 7:22 18:10 157:3 159:2 basis 18:4 112:4 bats 31:12 bear 5:8 Beck 1:15 54:22 76:14 80:7 81:19 89:18 94:16 150:16 163:14 166:10 201:8 beef 37:14 beet 188:21 beginning 53:1 54:11 76:4 163:1
---	--	--	---	---

begins 75:11	20:2,6,10,16 22:5	137:12 140:16	150:21 153:14	burden 10:10
behalf 28:13 48:4	22:13 23:12,17	155:9 192:3 193:6	161:17 163:19	78:15
62:20	24:16 25:19 26:4	bits 157:18	166:15 167:20,21	bureaucracy 51:5
beings 43:17	27:4 28:20 29:2,6	black 136:15 137:6	168:13 171:17,20	bureaucratic 39:20
believe 26:11 60:17	29:11,14 30:11,18	blast 74:20	172:6 174:11	burgeoning 18:5
75:9 82:21 83:15	31:17 32:3,10,14	blending 86:5	175:4,7,21 179:19	bury 123:10,13
96:17 111:11	32:17 33:4 34:11	154:8	192:19 194:12	business 52:19
115:13 128:8,11	37:2 38:7,22 40:3	blinded 174:13	195:18,21	92:17 151:15
128:12 133:18	40:5 41:5,16	board 1:5,10 2:11	Bonnie 28:11 37:6	170:15 182:2
152:1 157:6	44:20 45:13 47:1	4:3 7:1 18:12,15	37:10 39:13,17	194:4 202:4
165:14 167:1	48:6,18 49:1	19:8 20:4 21:11	40:22 41:19,20,21	busy 47:22
174:19 182:8	51:12 86:8 197:1	21:12,13,13 22:3	45:6 46:8 47:10	buy 49:9,14
beneficial 31:12	biological 81:22	23:11 28:5 42:4	48:8	buzzer 40:20
benefit 201:18	97:2 137:21 157:4	43:2 48:2 51:8,18	Bonnie's 48:19	B1 186:10
benefitted 147:21	159:18	52:2,17 53:20	bonus 137:19	B12 186:10
best 18:22 72:13,13	biologically 82:8	58:1 61:3,5,13	borderline 159:16	
79:2 93:21,22	bio-based 78:8	63:22 64:20 77:2	bottom 192:20	C
125:9 168:1	80:10 81:1,12,13	98:17 99:17 105:9	brand 84:6	C 81:2 83:13 96:10
169:10 182:22	81:19,20 82:2,6	106:5,6,10,16	break 52:1,5,6,11	CAC 28:21 29:7,12
beta 188:21	83:9,10 89:20	107:21 109:5,9,20	85:10 88:2 151:6	CACC 21:15
better 9:14 22:6	90:2,15 96:9,20	113:5 115:2,8,10	151:7 167:8	CACS 3:2,8 4:9
27:8 46:22 47:6	96:21 97:3 98:10	116:7,19,20	172:19	28:8
65:4 68:10,18	112:21 138:17	118:10 124:1	breeding 185:12	calculate 6:8 16:7
69:5,10 126:21	bio-degradation	125:3,12 126:4	186:15	calculating 3:4
134:12 189:11	80:19 82:17 85:22	132:8 135:2 142:9	brief 5:7	4:17 5:2 11:11
190:11,13	86:16 96:5	142:10 144:15	briefly 115:14	183:16
beyond 24:21	bio-degrade 87:15	145:5 151:12	Brines 2:16 152:1	calculation 5:15
77:14	bio-degraded	154:16 155:19	190:5,8	10:19 12:4 14:7
big 104:16 199:3	137:16	168:13 170:12	bring 58:22 66:18	15:13 16:15 17:4
biggest 104:3	bio-degration	172:12,14,16	89:1 125:7 198:19	calculations 11:5
Biltmore 1:10	80:18	173:1,6,9 176:14	broad 32:20	12:5,8 14:6,10,20
bio 77:6 82:8 86:4	bio-film 112:21	178:8 180:6 181:7	broader 7:8 78:1	15:7
86:8 87:12 95:18	bio-mass 87:6	181:16,19 184:8	broth 16:17,18,19	call 20:9 122:3
112:10 117:6	bio-mulch 131:7	191:22 192:3	16:22 17:2	132:6 136:22
127:21 150:1	136:21 137:1,1	198:9,19 199:22	brought 56:13 58:3	140:17 141:2
biodegradable 77:5	bio-plastic 77:6	200:8,16,22	62:6 73:11 85:16	154:21 158:7,21
78:8 80:10,12	82:11 87:4 90:19	201:16	170:11	159:16 191:18
81:12 89:19 90:2	90:22 117:6	Boards 62:2 195:8	BROWN-ROSEN	200:13,14
90:14 95:18,21	127:12	Board's 4:19 20:1	2:18 156:22	called 21:11 47:15
98:10 117:7	bio-plastics 86:1	151:14	158:14,20 159:9	73:5 127:21 128:2
132:21 142:17	87:10 91:12 92:2	body 66:13,21	159:14	137:10 140:20
146:2,5,11,14	birds 31:12	101:9 113:20	build 129:13	calling 98:10
187:2	bit 14:17 22:14	bog 112:7	building 31:3	calls 18:18 167:6
biodegradation	25:7 56:10 64:7	Bondera 1:16	built 8:17	Calvin 1:22 93:14
128:16	71:2 119:7 120:5	54:13 75:15,18	bulk 117:10	177:3,4,5,15
biodiversity 3:5	121:4 122:9	76:19 90:5 94:21	bunch 11:18	178:12,16 179:8
4:19 19:16,20	131:12 135:5,15	149:4,6,14,18	173:11 199:10	179:20,21 180:4

180:15,19 181:9 181:10 cancelled 58:6 canopy 74:9,22 carbon 81:21 82:3 87:6 96:22 97:4 137:19 186:12 carbonate 188:1 card 171:22 cardboard 173:11 cards 170:20 171:9 care 49:17 119:14 careful 130:19 131:16 190:13,14 caring 182:16 Carmela 1:15 77:7 80:1 81:17 89:16 95:14 147:11 201:8 carrying 84:9 case 22:13 71:10 90:10 138:4 179:4 cases 8:4 85:18 catch 193:18 categories 165:3,22 categorize 77:15 category 15:15,16 17:14 81:14 84:6 cause 101:11 caused 162:10,15 cautious 72:20 CCOF 45:6 ceiling 38:6 cell 185:14 cellulose 80:20 96:6 Center 24:21 centrifuging 154:7 certain 59:9,15 62:12,14 64:12,13 131:1 158:13 certainly 17:17 22:12 46:7 48:6 67:2 134:20 146:14 192:13 193:16 certain's 65:2	certificate 12:12,19 12:21 48:12,13 certificates 9:13 12:16 13:11 14:1 certification 3:2,16 4:14 30:11 33:18 44:7 47:17,18 48:7,16,22 83:6 183:8,12 184:6,15 196:21 201:14 certified 22:19 37:12 38:14 64:1 72:15 82:6 138:18 184:12 certifier 41:9 79:13 88:14 120:5 certifiers 8:14 15:1 22:21 24:13 29:16 30:4,6 31:15,18 32:5 34:7,8,15,22 36:5,7,16 39:4 79:9 84:20 85:5 107:10 124:15 128:21 134:8 certifier's 8:5 18:17 29:22 certifier/inspector 120:13 certifies 82:7 certify 39:2 certifying 5:13 7:5 7:11 8:12 cetera 59:1 130:12 156:11 chain 185:19 chair 4:9 55:5 76:20 95:1 134:18 151:2,18 164:1 166:20 167:19 170:20,21 171:4,7 172:12,14,16,20 173:2,7,9,14,14 174:17,18 175:2 175:17,22 176:1,9 177:19 181:18,20 183:4 Chairman 183:11	Chairperson 1:12 1:14 4:3 19:18 46:13 51:17 52:17 53:7,10,17 54:5,8 55:5,16 56:2,22 62:17 64:5 65:11 65:19 66:2 67:15 68:7 69:12 71:4 72:2 73:6,15 75:6 75:17,20 76:20 89:6,13,22 91:7 92:5 94:2 95:1,7 97:11,14,21 99:16 103:17 105:3 109:15 113:4,22 114:14,21 115:4 115:21 116:3 117:20 118:11,15 118:19 119:1,4,18 120:3 121:8,19,21 122:4,7,10,16 123:22 124:19 130:15 132:6 133:7,17 134:15 135:9 139:11 140:11,19 141:1 141:10 145:11,17 145:19 146:19 147:2,5 148:2,6 148:20 149:5,13 149:16,20 150:5 151:2,12 153:12 153:15 155:3,15 158:7 159:7,10 160:6,22 161:5,9 161:15,18 162:5 162:12,19 163:7 164:1,10,12 165:4 165:7,16 166:20 167:8,14 168:8 169:17 170:9 171:1,13,15,18 172:4,10,15,20,22 173:17 174:2,12 175:1,6,8,12,16 175:20 176:17,21 177:4,15,21	178:18 179:11,21 180:1,4,12,16,18 182:7 199:20 Chairs 196:7 change 15:19 16:3 59:3,13 66:22 83:15 115:9,12,14 116:13 140:2 143:22 144:2 152:15 160:5,16 changed 91:4 116:5 127:18 164:19 changes 70:7 91:2 139:16 145:3 165:9 169:6 changing 49:6,7 118:12 chart 164:15 check 42:9 164:15 checklist 22:4 26:10 31:13,15,16 checklists 31:20 chelating 186:11 chemical 160:3 chemicals 77:20 86:22 87:9,16 chicken 16:17,18 16:19,22 17:2 chickens 190:22 chips 11:18 chloride 12:6,7 chlorine 186:9 190:20 chlorite 191:5 chocolate 11:18 choose 49:14 83:21 140:9 chooses 128:3 chosen 62:11 82:11 circle 180:9 citation 86:3 87:7 cite 95:11 118:9 citric 13:19 156:10 claimed 73:5 clarification 13:9 121:16 171:8 clarify 16:6,12	29:22 53:21 57:3 118:20 179:2 185:13 clarity 14:2 141:19 classification 53:13 89:14,19 94:3,4 156:16 159:6 160:16 161:12 162:22 classified 73:2 90:10 classify 53:18 55:7 95:3 153:10 160:17 161:12,20 classifying 155:22 clause 79:11 82:20 83:9 84:14,19 98:14 99:4 100:14 108:17 109:21 110:19 112:5,6,10 114:18 118:6 119:21 126:2 144:20 clean 195:4 clear 5:21 18:1 67:1 76:3 98:3 99:18,19 100:5 113:18 115:15 116:7 117:18,21 123:7 130:13 138:16 149:1,3 158:15,15 160:19 174:16 clearance 101:2,13 107:19 clearly 7:14 12:9 13:12 14:12,14,15 88:6 102:5 135:21 136:14 climate 120:9 close 18:21 19:1 104:12 148:10 closely 19:3 closing 146:22 147:1,3,22 196:6 closure 132:17 Coalition 28:14
--	--	--	--	---

<p>Colehour 1:16 54:12 90:4 91:11 167:19 169:18 171:19 172:5 174:22 175:1,21 179:18 192:18 194:11</p> <p>Colehour's 91:9</p> <p>collections 39:22</p> <p>combination 114:10</p> <p>come 10:13 33:22 38:15 41:6,15 44:13 45:21 52:7 63:13,17 64:16 65:4 69:5 79:17 81:15 85:13 92:9 125:20 129:2 167:15 170:5 182:21</p> <p>comes 12:13 16:13 63:15 84:18 88:9 92:16 106:22 116:13</p> <p>comfortable 56:16 74:19 75:2 92:1 182:12</p> <p>coming 17:18 34:4 39:2 44:8 61:3 88:16 129:14 136:12 137:7 191:1</p> <p>comment 3:7 5:4 5:21 9:21 26:11 28:8 35:6 38:12 65:21 69:13 72:4 73:18 88:12 91:8 98:9 99:20 100:9 100:9 105:6 108:2 114:3 122:12 125:1 130:4 133:18 134:16,20 134:21 135:8 140:12 146:21 147:1,1,3,7,8,21 148:1 152:14 155:12 157:7</p>	<p>161:1</p> <p>commented 44:17 147:17</p> <p>commenter 51:7</p> <p>commenters 11:16 27:6 148:8</p> <p>commenting 28:13 28:19</p> <p>comments 21:14,18 24:19,20 25:3,8 25:11,13 26:1,2 27:18,22 32:15 41:2,22 44:10 45:6 46:16,17 47:19 48:19 65:12 68:8 70:17 73:2 73:16 75:7 94:3,7 105:4 108:12 122:22 140:15 154:14 155:8 158:2 185:7 198:18</p> <p>commitment 51:3</p> <p>Committed 3:13</p> <p>committee 3:9,18 3:19,21,22 5:4 10:3 21:15 25:10 27:18,20 50:6 53:2,3 58:2,3,16 77:1,4 82:16 88:20 124:7,13 132:16 136:20 139:6 141:16 143:16 152:13 167:16 177:20 183:19 184:18 185:21 187:4 188:8 190:14 191:18 192:11,16 193:14 196:7,21 201:15</p> <p>committees 52:9</p> <p>common 156:6</p> <p>communication 170:4</p> <p>community 4:21 7:8 20:8 21:1</p>	<p>24:10 62:9 69:17 102:1 113:10 199:17 200:2,21</p> <p>companies 107:11</p> <p>company 7:18 73:22</p> <p>compared 188:17</p> <p>complete 39:21 61:19 66:17 81:7 85:1 86:2,4 96:15 120:7 121:4 123:2 123:4 124:5 130:1 130:21 132:15 135:1 136:11 139:20 196:10,11</p> <p>completed 170:1</p> <p>completely 45:7 80:12 86:11 87:15 88:2 95:21 101:14 137:16</p> <p>completeness 120:16</p> <p>completes 167:1 169:18 170:13</p> <p>complex 44:5 109:2</p> <p>complexities 10:13 4:14 32:21 51:14 60:18 127:8 183:11</p> <p>compliant 145:1,4</p> <p>Compliantly 40:19</p> <p>complicate 192:7</p> <p>complicated 5:8 101:3</p> <p>complying 48:18</p> <p>components 86:21</p> <p>composition 86:7</p> <p>comprehensive 18:1 87:2</p> <p>computer 43:13</p> <p>concentrations 87:14</p> <p>concept 78:2,12 107:15</p> <p>concepts 77:17</p> <p>conceptualization</p>	<p>90:13</p> <p>concern 48:21 59:22 63:5 67:17 104:3 120:8 157:1 158:6 160:20</p> <p>concerned 28:18 193:6</p> <p>concerning 62:5</p> <p>concerns 37:21,21 56:7 73:10,19 84:3 85:16 100:10 150:2</p> <p>concluded 87:5 202:8</p> <p>concludes 27:22 51:14,15 151:5</p> <p>conclusion 88:6</p> <p>concrete 183:20</p> <p>concur 32:15</p> <p>concur 28:21</p> <p>conditions 64:12 79:20 85:10 120:12</p> <p>conference 167:5</p> <p>confess 39:19</p> <p>confidence 18:7</p> <p>confidential 194:4</p> <p>confirmed 181:8</p> <p>conflict 139:8 144:19 167:18 168:1 169:1,2,13 195:16</p> <p>confused 162:9</p> <p>confusing 58:12 90:9 160:12</p> <p>congratulations 173:12 176:10 181:10</p> <p>consecutive 178:15 178:20</p> <p>consensus 15:18</p> <p>conservation 19:20 20:2,6 23:13,22 26:14 29:7,15 30:19 38:10,13 39:10 47:1</p> <p>consider 16:18</p>	<p>64:11 102:9,11 107:6 129:19 137:13,18 160:4 162:14 194:18</p> <p>consideration 63:17,19 169:21</p> <p>considerations 64:12 93:12</p> <p>considered 15:3 16:2 90:17 107:12 156:12 159:18 160:2 168:18 169:4</p> <p>considers 109:9</p> <p>consistency 6:17 84:4 156:17</p> <p>consistent 8:13,13 99:1</p> <p>consistently 29:3</p> <p>constituents 62:5 89:4</p> <p>constitutes 164:5</p> <p>constraints 130:9 130:10 135:13</p> <p>construed 84:9</p> <p>consumer 13:12 18:7</p> <p>consumers 28:17 62:4</p> <p>contain 149:21</p> <p>containing 87:13</p> <p>contains 135:20 138:12</p> <p>content 16:15 81:1 82:8 96:9</p> <p>CONTENTS 3:1</p> <p>context 125:22</p> <p>continue 44:11 46:4 141:13 192:13 196:22</p> <p>continues 32:7</p> <p>contribute 201:18</p> <p>contributed 199:16</p> <p>contribution 200:20</p> <p>control 31:5 71:14 72:9,12</p>
--	---	--	---	--

controlled 74:12,13 133:13 141:22	courage 41:13	D	195:6	delaying 170:8
convened 1:10	course 5:9 10:14 34:8 147:15	D 81:4 84:11 96:12	deck 28:11 37:7	deliberate 126:21
convening 195:8	cover 74:9,9 82:22 112:14 123:10,12	98:14 109:22	declare 174:8 202:5	deliberations 135:18
conventional 38:11	137:14 160:10	113:17 114:18	decline 177:11,12 179:10 180:13,15	demands 67:3
conversation 40:5 120:18	covered 146:13	115:18,19 116:6	180:17	demonstrate 14:16 17:12
conversations 56:19	covering 74:22 141:14	119:21 121:17,20	declined 179:15	dent 104:13
conversion 26:13	CO2 186:9	142:22 149:9,21	decrease 119:22	department 1:1 162:16
converted 24:1	create 31:11	186:3	deed 65:7 139:2	depends 20:15 86:5 86:6
convince 66:13	created 156:2	daily 78:3	deemed 128:6	Deputy 2:9,21
Coody 21:9 28:10 28:12,13 33:21	creating 114:5 139:7 152:19	data 66:13,18,21 67:2,6 69:2,7 78:6	deep 123:13	derived 81:4,21 82:3,8 83:18
35:12,20 36:2 37:5	creation 83:5,8 158:10	87:10 88:3 127:6	deferred 52:8,20 52:22 53:4 151:16	96:12 97:1,4
Coody's 25:13	credit 37:2 47:16	129:4,14	167:17 169:20	describe 40:6 87:3
cookie 11:17	criteria 60:12 79:6 79:8 80:11,16	date 5:5 55:19 59:9 59:15 62:12,14	define 81:13 140:3 140:4 194:1	described 9:13 118:4 154:12
cooperation 181:21	95:20 96:3 125:5	63:6,9 64:13 65:2	defining 107:5	describes 133:1
coordinate 186:18	137:4 156:4	65:18 66:22 68:10	definitely 83:22 93:2 144:12 198:7	description 132:22 158:16
copies 7:6 40:16	criterion 133:5	68:15 69:5,10	definition 81:18,20 82:5 83:10 96:16	deserve 151:6
corn 39:2 137:14	critical 15:11 70:12 92:3	70:12,15 71:1 76:2	96:18,19,21 97:6	design 104:14
cornerstones 91:20	crop 3:9 53:2,3 71:21 127:4	dates 59:17 65:15	97:10 98:3 99:1,1	desire 112:22
Cornucopia 24:22	137:14 151:5	day 48:14 50:19 56:7 92:4 104:6	101:5,17,19	desperately 139:5
correct 75:11 76:2 111:14,18 113:1	187:20	127:22 182:21	102:16 105:10	detail 7:12,16
124:9 153:7,8	crops 12:16 21:15 58:3 72:18 74:10	days 40:17 41:11 52:21 201:22	107:1 116:5 137:6	detailed 17:21
161:22 165:15	77:1,4 124:7,13	day-to-day 112:4	139:3 156:7	details 77:14
169:22 174:11 177:18	132:1 185:22	DBD/MH 188:22 189:16	158:15	determination 188:15,18 195:7
correction 142:12	187:16	deadline 189:10	definitively 102:1	determine 14:19 86:10
correctly 144:7	crystallization 154:1,7 155:20	deaf 63:16	degradability 86:6	determined 58:8 70:16 80:4 81:2
correspondingly 79:13	156:20 158:11	deal 9:11 30:15 45:13,15 136:9,10	degradable 138:7,8	96:10
Coulee 39:11	CSP 39:3	169:7 187:18	degradation 81:7 85:1 86:4,12	determining 15:2
counsel 60:3	cultivation 142:19	dealing 13:3,4 41:8 44:2 168:21	87:10 96:15	develop 5:19 9:10 9:17 126:13
count 164:3,8	culture 186:9	dealt 22:1,2,3,7	112:11 120:7	developed 7:7 13:2 29:8 40:4 86:9
counted 14:20 15:7 176:7 181:6	current 32:19 152:10,10 188:14	deathly 50:18	123:2,15 124:6	192:5
countries 60:14 64:15 74:16	currently 19:11 86:9 194:22	December 105:14	127:8,9 130:1,11	developing 60:14 124:8
country 6:16 63:3,4 64:1 68:5 71:15	curtain 19:4	decided 83:13 160:9 169:10	133:1 136:12,20	development 30:2 38:11 168:4,20
72:15,17 74:11	cycle 189:12	decision 18:21 19:2 19:2 115:10,11	137:3 143:20	194:13
couple 67:12 120:6 135:14 145:13	cytodine 157:19	135:1 156:5	144:6	
162:8 198:17		162:11	degrade 87:5 143:18 144:4,4	
		decisive 91:22	degraded 86:11	
		decisive/indecisive	degree 129:13	
			delay 53:12 109:13	

devote 37:17	discussed 52:10 116:14 141:16 152:13 170:10	183:18 184:9,17 189:1 191:3	easier 11:21 82:12 104:5 126:20,20	empowered 39:7
dialogue 92:7 93:6 103:20	discussing 185:6	documentation 38:2	easiest 109:18	empowering 42:14 43:18
dibromo-dimeth... 190:9	discussion 4:15 5:3 5:20 8:21 18:14 19:10,15,19 28:4 28:6,20 29:8,13 42:11 53:19,20 54:9,10 55:21 57:6 73:16 75:7,9 89:10,12 90:4 91:8 93:20 99:20 100:6,9 103:19 119:5 122:2,19 124:1 127:4 132:9 132:15 135:7 141:2,8 146:18 147:19 153:16,18 160:7 162:1,1 166:1,2,4 183:18 184:9,17 185:1 189:1 191:3 198:20	documents 4:15 8:1 107:18	easy 10:9 109:2,7	enables 62:14
dichotomy 78:13	discussions 121:9	doing 6:15 7:2 8:12 11:17 26:12 34:20 36:21 42:2,5 62:15 63:21 74:1 119:2 122:5 132:13 194:15	echo 48:19	encapsulation 185:15
Dickson 1:17 4:9 4:13 18:13 19:7 33:9 35:5 37:4,6 40:22 45:2 46:12 47:9 51:13 55:2 76:16 94:18 150:18 163:16 166:12 183:10	disease 142:21,22 186:4	domestically 60:7	ecological 77:21	encompass 46:2
dictate 132:5	disingenuous 69:4	door 84:7 126:6 129:9	ecosystem 86:13	encompasses 45:13
diets 191:2	distance 73:14	draft 21:17	eco-toxic 83:4	encounter 82:14
difference 11:2 78:10	distinguish 116:22	draw 64:7	education 27:2	encourage 49:8 113:16 178:10,14
different 7:3,5 11:3 22:15,15 43:19 45:14,15 50:21 56:14 61:11,11 71:2,9,17 92:10 93:3 101:10 102:22 107:19 125:20 131:9 136:8 137:19 153:4 157:16	distracted 57:4 142:6	drew 67:18	educational 42:14	encouraged 29:4 179:1
difficult 99:8 103:15 131:11	distribute 170:17 199:11	dries 6:12	effect 49:11 117:5 117:12 145:22	encouragement 17:20
difficulties 101:12	distributed 170:19	drop 15:14 109:21	effective 55:13,19 55:20 70:15 76:1 101:19	ended 21:13 105:16 105:19
difficulty 102:20 102:21	diversion 190:21	dropped 110:7	effectively 42:13 103:13 148:17	endorse 32:1 83:7
diligent 25:20	divided 21:22 22:19	drop-dead 63:9	effects 77:16 83:4 86:11	ends 61:7 104:9,11
dinging 120:14	Division 2:15,16	dry 120:9	efficacy 72:8 73:4	enemy 49:4
dioxide 82:4 87:6 97:5	doable 17:15 35:19	drying 154:8	effort 33:4 198:7	energy 194:17
diphosphate 157:21	docket 170:5,7	due 63:16 86:8 87:8	eight 166:21	enforce 39:4
direct 145:16,20	document 5:3 8:22 12:10 18:2 19:10 19:15,19,22 21:17 21:22 28:6,20 29:8 61:21 79:17 88:15 169:3 183:9	dust 31:10	either 27:12 43:14 44:2 83:20 100:8 131:1	enforced 44:21
directly 90:16		dusting 184:16	elected 176:12 181:9	enforcement 38:17
director 2:14 37:10		DVD 51:11	election 3:14 170:15	engage 18:17 19:2 63:8
disagree 115:9 182:17		D6400 80:14	elections 179:13	engaged 64:3
disclosure 41:10		D6866 81:2 82:7	electrical 142:20	engineered 81:5 84:12 96:13 98:14 105:11 113:19 117:13,13 149:10
discuss 56:1 168:5 192:14		D6868 80:14	element 130:7 164:14	England 131:21
		E	elements 32:21 142:16	enlighten 153:21
		E 81:6 84:19 96:14 129:20,21 130:22	Eleven 164:9,10	ensure 60:10 81:7 85:1 90:21 96:15 124:5 130:1 139:20
		EAP 40:9	elucidated 158:2	entail 50:7
		earlier 29:12 72:3 103:19 133:21 184:8	email 202:1	enterprise 103:21
		ears 63:16	emails 197:22	enthusiasm 148:15
		earth 46:20	embarrassing 46:11	entire 61:20 74:22 115:17 121:18
		easement 38:10	Emily 2:18 155:13 155:16 158:9 159:7	entities 103:1
			empirically 67:1	entity 184:13
			Empower 39:4	environment 49:12 73:12,13 77:22 104:9 120:9

133:13	148:18	expedite 106:13	169:2,8	162:6 163:13
environmental	exact 91:13	expeditious 103:16	failed 200:10	166:9 201:5
51:3 74:13 79:20	exactly 36:5 57:14	125:3	failing 17:13	fear 49:1
87:3 120:12	92:13 93:9 140:8	experience 7:2	fails 166:22	Federal 69:18 70:4
environmentalists	examining 193:22	45:11 58:1 66:11	fair 126:10	98:22 101:7
28:16	example 12:13	129:1 193:5	fairly 102:1 141:14	105:18 106:12
environments	16:17	experienced 126:7	fall 63:15 121:1	feedback 4:20
30:16 31:2,3 83:1	examples 9:8,13,15	127:1	185:16 187:21	19:11 44:13
envisioned 127:10	10:21 13:21,22	expiration 63:5	191:4 193:2,11,21	183:19
enzymes 157:4	17:6,12 30:20	70:12,22	202:6	feedstock 81:4
EN13432 80:17	44:12	explain 40:6	falling 35:22	83:18 84:9 96:11
96:4	Excel 10:4	109:20 129:11	familiar 6:3 61:4	feel 8:7 9:7 39:6
EN14995 80:17	excellent 7:10,16	154:17 155:1	family 39:9	43:21 56:17 62:10
96:4	8:22 24:19 25:8	explained 105:17	far 19:9 34:13 49:4	67:5,9,9 74:18
EPA 60:1	25:11 27:10 152:6	explanation 29:20	56:4 72:13 93:13	83:10 86:18 92:1
equal 127:9	167:7	71:5 155:6 157:3	farm 21:3,10 22:14	114:4 147:20
equals 130:11,11	excessive 42:21	explore 66:7 85:12	24:6,22 26:18	148:10 158:3
143:20	exchange 42:10	exploring 183:22	32:16 37:14 38:9	160:15 177:9
equipment 74:6	43:3,20 92:15	express 37:20	39:15 40:2 42:20	179:9 180:8
equivalent 61:17	93:1	expressed 14:13	44:22 45:12,22	190:11 201:17
82:17 112:11	exclude 17:13	29:16 48:21	47:2 49:11	feeling 10:22 56:17
especially 8:15 9:2	excluded 12:5,8	100:10 114:8	farmer 38:13 39:9	56:20 59:6,12
30:14 44:5 192:12	81:4 83:14,18	extend 135:7	41:7 45:18 46:22	84:2 126:15
essentially 58:2,18	84:4 96:12	181:11	47:7 120:14	160:10
80:16 96:3 114:5	Excuse 54:5 171:17	extension 63:14	122:22 123:5	feelings 177:14
establish 60:17	187:8	64:11,19 183:16	131:22 137:9	feels 49:3 66:19
established 21:14	executive 47:13	extensive 39:21	farmers 28:16	69:3 82:16 107:1
116:20	88:20 191:17	85:22	37:22 38:4 41:2	FELDMAN 1:18
et 58:22 130:12	193:14	extent 14:16 41:6	42:14 43:16 44:3	33:11 53:5,8,11
156:10	exemplifies 92:19	184:10	44:17 45:15,17	54:4,6,16 55:10
evaluate 79:14	exemption 184:10	extra 160:19	46:18 49:12 50:18	57:2,9,12,14,17
evaluated 127:13	exhaust 186:13	extract 156:10	50:22 99:13	57:20 76:8 77:3
127:13	existing 29:5 58:9	extracted 157:18	farming 29:1 37:18	89:9,15,21 91:10
evaluating 32:8	138:11,11 144:8	159:17	38:11 39:11 45:18	94:10 95:6,10,14
125:4	exists 134:9	extracting 157:4	46:3 50:13 51:2	97:7 105:5 116:10
evening 104:17	expand 126:18,20	extraction 159:3	77:13 79:4 113:10	118:2,14,17,21
event 142:13 143:1	129:3	extreme 102:20	138:2	119:3 121:13
eventually 35:14	expect 33:14 34:22	extremely 74:3	farms 77:20	124:21 141:18
everybody 6:3 8:10	65:8 66:22 67:1	103:14	farther 189:9	145:10 147:22
11:1 17:21 26:2,7	107:10 110:10,12	eye 32:8	fashion 19:12	148:4,7 150:10
48:4 60:9 100:2,4	112:14 186:6		fashioning 184:17	153:17 155:14,17
115:15 122:17	191:16,18	F	fast 8:16 18:5	163:3,22 166:18
126:11 148:22	expectation 33:19	face 67:8	193:15	186:1 187:8,12,22
149:3 163:7	35:14 48:17	facilities 30:22 31:4	favors 30:2	felt 16:4 92:22
197:20 198:7	expectations 29:20	fact 8:20 11:9	Favre 1:17 54:21	93:18
199:21	30:12 34:14	15:19 62:4 63:8	76:13 94:15 114:1	fewer 86:22
everybody's 136:4	expected 36:6	129:1 137:18	132:19 150:15	fiber 188:21,22

field 43:9 50:19 60:9 131:6,8,12 131:18 132:1 133:3,14,16 142:2	143:18 171:4 182:1 183:15 188:13 197:11 199:11 201:5	151:2,12 153:12 153:15 155:3,15 158:7 159:7,10 160:6,22 161:5,9 161:15,18 162:5 162:12,19 163:7 164:1,10,12 165:4 165:7,16 166:20 167:8,14 168:8 169:17 170:9 171:1,13,15,18 172:4,10,15,20,22 173:17 174:2,12 175:1,6,8,12,16 175:20 176:17,21 177:4,15,21 178:18 179:11,21 180:1,4,12,16,18 182:7 199:12,20	165:2,20 Foods 135:19 footsteps 182:10 foot-hold 126:17 129:5 forbearance 134:19 135:6 foreign 69:16 70:4 forgive 78:5 form 10:1,5 11:2 11:10 35:15 117:10,13,14 129:17 159:3 196:9 formally 84:17 formation 146:9 159:20 formed 159:1 forms 7:6 11:4,6 34:11 43:8 117:5 162:18 formulas 164:22 165:19 forth 21:7 22:5 56:6 91:16 105:18 156:4 162:7 forward 6:10,13 17:16,21 25:13 33:15 37:20 56:13 58:22 63:11 103:7 103:13,15 104:7 105:13 113:8 114:13 125:2 129:6 134:13 139:7 147:20 182:18,20 185:9 186:19 192:5,7 Foster 1:18 28:1 35:7,13,21 41:19 46:8 55:1 56:3 57:7,10,13,15,18 66:3 68:11 76:15 92:6 94:17 103:18 140:14 150:17 151:18,20 154:18 163:15 165:6 166:11 167:3	175:15,16,19,22 176:9 180:8 188:10,11 189:18 190:1,5,10 fostering 29:1 found 6:15 25:2 87:2 four 40:10 47:21 52:8,22 68:17 201:22 fractions 137:19 frame 59:21 62:11 63:20 98:13 127:10 128:9,18 143:19 framed 30:3 182:5 frankly 131:1 free-wheeling 132:15 friend 171:22 friendly 114:17 115:1 front 139:16 189:20 201:20 fruits 12:21 full 41:10 58:17 63:16 115:10 147:18 180:9 fully 78:16 90:12 112:14 142:17 146:2,5,11,13 FULWIDER 1:19 54:19 76:11 94:13 150:13 163:11 164:9,11 166:7 170:18 173:15,20 176:20 177:2,9,13 179:7 180:14 190:16 fumble 198:12 fumes 31:10 function 117:19 fundamental 160:5 fungal 186:4 further 20:7,9 25:10 27:2,7,20 29:19 32:1 52:9
fill 36:20 41:11 filled 182:3 film 51:11 77:5 81:12 89:20 90:2 90:15 117:7 137:1 137:2,3 187:2 films 80:10 86:19 95:19 98:10 filtration 154:7 final 17:3 25:17,18 40:12 53:1 79:18 102:14 103:7,8 107:4,16,21 109:1 110:22 111:7 144:15 145:3,5 147:8 155:22 157:5 158:16 159:21 160:1 196:8 finalize 19:5 finalized 88:19 196:9 finally 27:5 32:6 184:5 186:20 195:7 find 23:4 46:3 60:20,21 72:10 128:1,22 155:9 171:22 finding 146:10 findings 8:2 fine 7:12 finished 15:3,8 16:1,9,16 first 4:7,22 21:8 22:2 23:11 28:10 33:6 53:13 58:21 79:6,8 80:4 81:11 97:17,19 99:17 100:1,7 122:20	fit 22:12 138:11 139:2 192:15 fits 139:20 five 21:8 25:16 61:14 157:16 five-percent 15:10 five-year 65:16 fixed 82:4 97:5 flag 85:15 flagging 162:16 flags 88:4,10 flame 142:19 Flamm 1:12,14 4:3 19:14,18 46:13 51:17 52:17 53:7 53:10,17 54:5,8 55:5,16 56:2,22 62:17 64:5 65:11 65:19 66:2 67:15 68:7 69:12 71:4 72:2 73:6,15 75:6 75:17,20 76:20 89:6,13,22 91:7 92:5 94:2 95:1,7 97:11,14,21 99:16 103:17 105:3 109:15 113:4,22 114:14,21 115:4 115:21 116:3 117:20 118:11,15 118:19 119:1,4,18 120:3 121:8,19,21 122:4,7,10,16 123:22 124:19 130:15 132:6 133:7,17 134:15 135:9 139:11 140:11,19 141:1 141:10 145:11,17 145:19 146:19 147:2,5 148:2,6 148:20 149:5,13 149:16,20 150:5	flavors 11:18 fleeing 51:1 flexibility 22:11 41:7 119:12 flexible 65:3 67:21 119:7 floor 115:17 118:1 132:9,10 134:7 149:21 floorboards 38:5 Florida 47:15,16 focused 43:7 folier 186:4 folks 18:19 43:4 59:8 60:19 106:17 106:19 follow 21:12 64:3,4 115:6 124:22 130:16 145:16 188:7 191:2 196:19 197:3 followed 28:11 following 21:21 38:17 55:11 60:12 74:2 80:11 95:20 134:9 157:14 182:10 189:3 food 24:21 31:11		

65:11 68:7 73:15 73:16 75:6 85:3 90:4 91:7 105:3 116:9 119:4 121:8 122:18 146:20 161:22 162:1,21 168:17 173:1,1 176:22 177:22 178:2 180:22 181:2,3 200:3 fusion 185:14 future 45:8 64:20 89:5 120:2 184:4 192:16 fuzzy 77:17	give 9:20 25:9 36:17 39:3 40:8 41:15 44:12 48:16 63:16 70:13 72:12 101:21 113:9 122:13,17 134:20 152:8 164:3,7 192:3 200:10 given 58:13 63:6 86:3 87:7 130:9,9 153:8 gives 22:9 58:20 64:14 106:15 giving 59:15 104:12 glare 173:18 global 78:4 GMO 3:17 185:4,5 GMOs 185:7,13,18 186:15 191:6 192:21 193:5 GMO's 84:7 go 10:15 11:19 13:1 41:16 42:15 43:8 45:2 47:10 63:3 66:17 68:4 80:5 91:21,22 93:13 97:17 110:22 122:18 125:2 131:11 139:18 140:6 148:6 153:9 154:4 156:1 182:18 183:5 188:19 191:6,13 196:5,14,15 goal 49:4 goals 40:4 41:4,14 goes 8:9,10 11:22 12:19 13:19 77:13 136:13 going 5:7 11:19 13:1 19:4 22:15 25:20 37:17 38:12 40:18 44:11 48:9 52:3 74:21 77:7 79:7 80:1 82:14 95:10 99:7 102:19	102:21 103:3 104:19 108:9 112:18 113:9 123:1,8,9 126:18 128:1 131:4,10,16 131:18,22 132:19 135:21 136:7,22 146:1 147:6 148:2 148:4,5,11 155:9 169:11 170:10,17 172:5 175:10 177:2 178:13 179:9,14,16 180:10,13 185:11 185:17 187:17 189:18,21 192:4 193:1 199:18 good 4:5 24:18 28:12 35:9 36:11 37:9 46:20 50:17 57:21 77:20 83:10 93:11 130:19 181:21 187:3 190:6 193:13,17 194:10 195:19 201:12 goodness 63:2 gotten 129:5 governed 79:21 Government 50:17 101:7 106:12 governments 69:17 70:5 gracious 198:11 granted 168:9 grazing 142:18 great 21:2 33:4,5 34:4,17 35:1 41:9 45:13,14 181:12 199:7 200:5 greater 43:20 greatest 40:3 greatly 147:21 grey 184:14 ground 102:8 136:16 141:15 group 20:13 62:21	191:5 193:7,16 197:16 198:21 groups 24:7 165:2 165:21 grower 79:12 81:6 88:14 120:8 124:4 129:22 131:6 140:1,3 growers 84:20,22 85:4 96:14 124:16 Grower's 47:16,17 growing 49:5 60:10 60:15 82:19 127:15,16 128:16 128:17 130:2,20 131:19 132:1 136:11,18 142:3 grown 8:16,18 guanidine 157:19 guess 19:5 41:10 52:9 61:1 66:1 78:13 106:3 120:17 121:5 138:15 146:15 161:3 162:8 163:10 186:20 187:8 189:21 195:11,15,17 201:6 202:5 guidance 9:17 11:12 12:9 15:1 16:5,12 17:7 18:1 21:20 27:8 29:13 35:16 38:20 44:14 79:16 85:4,14 88:14 105:18 106:10 111:9 120:17,20 123:6 123:20 124:8,14 126:13 182:13 186:22 187:1 191:9 192:14 guide 194:16 guideline 20:19 guidelines 21:6 22:11 134:8 gum 189:5,6,7	guys 50:4 160:5 197:13,22 Gwendolyn 155:11
H				
H 186:10 hairs 68:12 hand 66:1 149:7 162:3 174:19 175:9 Handing 3:10 handle 4:9 185:17 handled 13:17 124:12 handler 10:11 14:15 handlers 18:20 36:18,21 handler/distribut... 12:1 handling 3:18 13:6 24:12,14 27:3 30:8,13,15 31:9 35:11 36:9,13,14 109:11 151:7,15 155:12 167:2 188:9 191:11 hand-weeding 142:18 happen 33:17 91:2 99:10 120:16 180:10 happened 5:18 61:15 happens 184:11 happy 190:2 hard 34:20 59:18 126:5 167:5 189:12 197:20 198:5,8 200:1 hardcore 67:2 harken 64:22 harm 60:1 Harold 1:15 62:17 68:13 72:2 73:16 132:7 133:17 175:13 176:14				

201:10 harshed 140:16 harvest 127:17 128:16,17 130:2 hate 39:19 hazard 104:19,21 hazards 60:5 head 133:8 headed 54:7 heading 146:16 health 69:7 73:10 73:10 healthy 20:14 hear 57:5 91:12 130:4,5 156:22 159:12 201:13 heard 24:13 48:14 49:21 51:8 106:7 124:7 125:15 144:1 153:18 hearing 54:10 55:21 56:20 65:13 130:6 150:8 173:10 176:5 181:1,4 heat 142:19 heaven 39:20 heavy 50:10 152:8 held 152:17 hell 39:21 help 16:6 18:19 19:2 21:5 33:7 36:5,16 41:15 46:5,22 47:2,6 63:10,18 89:3 100:17,19 142:6 154:9 190:6 helpful 7:4 12:22 29:17 30:14 43:18 59:15 helping 7:13 helps 121:3 190:12 Hey 46:8 he'll 197:2 hierarchy 35:22 high 23:20,21 26:14 67:7 88:17	hinder 65:17 history 61:4 hoc 185:6 hold 102:6,6 197:1 holding 104:1 home 4:6 198:3 honoring 62:1 181:20 honors 200:20 hope 25:3 27:17 44:10,11 45:7 46:4 48:15 60:19 63:14 64:19 85:4 85:11 88:22 105:15 116:17 117:15 120:11 123:6 130:13 141:13 196:16 hopeful 117:16 hopefully 60:8 189:4 201:3 horse 126:5 129:8 Hotel 1:11 hour 52:13 hours 167:5 house 182:5 housekeeping 58:4 197:6,9 human 43:17 134:14 humbled 182:3 hurdles 82:13 hurt 90:14 hurting 177:13 hydrolyzate 157:11 157:14 <hr/> I <hr/> idea 36:18 ideally 194:16 ideas 21:19 92:15 identical 80:16 96:3 identified 99:21 157:14 identify 20:5 ignored 27:5 63:22	ignoring 103:6 iii 95:18 imaginary 51:16 impact 17:13 23:13 24:15 110:1,6,11 impacts 23:16 26:8 47:5 56:12 69:8 86:3,17 87:3 168:17 imperative 138:3 implement 29:5 31:21 34:7 36:17 103:10 implementation 27:9 29:21 98:19 implemented 27:14 60:6 109:6 124:9 implementing 19:20 20:1,5 22:10 29:18 32:14 34:9 importance 20:10 27:6 32:16 important 11:10,12 26:15 28:3 38:8 43:1 50:1 62:8 99:11 104:14 113:12 134:22 146:17 176:11 impossible 40:1 impressed 197:19 impressions 197:15 inane 39:22 include 14:5 31:16 34:10 36:8 82:2 97:3 108:17 116:17 118:9 157:10 162:17 193:21 included 36:3,8 39:14 111:12,13 118:3,5 197:21 including 9:2 32:2 34:17 87:18 93:4 160:18 161:13,21 164:20 165:17 inclusion 152:22	164:21 165:18 incomplete 40:19 86:12 87:9 inconsistencies 8:17 incorporate 99:3 106:9 incorporated 142:10 incorporation 118:5 increased 48:17 increasing 18:5,6 38:18 49:2 increasingly 44:5 incredible 89:7 197:16 incredibly 197:19 indicate 13:7 101:16 178:13 indicating 178:11 indication 70:13 individual 7:19 9:12 115:10 199:13 individuals 7:19 25:1 indoor 30:16 indulgence 53:12 industry 8:18 28:17 91:12,13 127:20 182:22 inerts 49:21 50:7 186:16 infant 164:22 165:19 inform 89:3 information 6:21 9:3,7 10:12 14:11 29:17 43:3 58:22 73:20 78:16 105:22 108:18 111:6 126:22 134:11 188:16 194:5 informed 93:7 ingredient 14:18	15:6 16:14 185:18 ingredients 3:4 4:18 5:2 10:15,18 13:16,17 16:2,7,8 49:22 77:15 165:2 165:20 183:17 189:2 initial 34:6 initiated 58:1,15 initiation 195:3 inosine-5 157:19 input 20:8 169:4 184:3 185:18 193:4 inputs 84:5 insect 72:9 insects 31:12 insignificant 15:4 inspect 44:18 inspected 44:21 inspection 6:22 42:7,19 inspections 36:9 42:3,5 43:10 inspector 6:22 10:9 45:12 131:3 inspectors 21:5 22:20 44:18 Inspector's 21:4 instance 105:16 139:22 instruction 29:11 30:3,12 32:11,13 36:4,13 124:14 instructions 40:14 insult 40:12 integrity 28:18 intend 18:17 83:22 intended 117:19 137:6 intent 66:6 70:19 114:8 124:15 136:7,15 138:16 144:8 intention 81:13 136:6 intentions 65:3
--	---	--	--	--

interest 167:18 168:2 169:1,3,13 195:16	items 183:13,17 184:21 188:12 189:5	joined 37:21 181:17	68:14 69:2,3,11 73:21 74:15 86:14 91:1,11,18,20 93:14 101:18 104:10,11 105:8,8 105:10,17 106:7 106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	language 15:20,20 83:14 106:11 121:3 123:4 129:19,21 131:17 140:8 178:22
interested 130:6 197:2	i.e 144:3	joint 21:15	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	large 8:11,14 9:3 20:15 62:9 79:20 156:3,13
interesting 78:12 92:7	J	JOSEPH 1:17	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	larger 9:5 10:5
interests 68:5	January 34:5,18 55:14,20 76:1	judgement 18:18	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	late 25:2 198:2
internal 100:19	Jay 1:18 33:10 53:22 56:22 62:8 77:9 89:8 95:5,5 100:8 105:4 116:9 117:20 119:6 124:19 130:18 133:9 141:17 146:7 148:6 150:9 153:16 154:17 155:5 158:11 187:3,7,15 188:7	judgment 158:21	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	Latin 60:19
international 21:3 80:15 96:2	Jay's 189:15	jump 82:13 189:5	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	law 11:7 15:21 60:18 127:10 128:9 130:9 136:7 136:14 138:11 143:19 146:9
interpret 112:10	Jean 1:20 4:22 5:5 18:13 113:6 114:1 114:16 125:1 130:16 201:11,11	jumping 106:17	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	lay 33:16
interpreting 144:7	Jennifer 1:22 2:21 73:7 76:5 175:9 193:19 194:7,10	justify 64:19	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	layer 137:22
introduce 135:8	Jennifer's 73:18	K	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	lead 46:15 77:7 195:3
introduced 152:3,4	job 8:13,13 46:22 63:21 181:13 197:11 198:4	keep 46:20 48:13 70:9 83:22 84:15 88:8 112:3 132:9 196:18	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	leaders 39:10
investigating 88:9	Joe 4:9,11 19:19 27:16 183:8 184:22 185:1 201:15	keeping 10:12 28:2 112:7 156:4	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	leadership 182:12 199:19
involve 83:3	John 1:18 6:22 35:5 36:2 56:2 57:3 66:2 67:16 68:10 71:7 92:5 103:17 106:14 139:11 140:12 151:18 152:12 160:22 175:14,16 175:17,22 176:9 176:10 180:7 189:15 201:15	kept 147:14	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	leading 94:8
involved 56:18 63:10 101:4	join 196:17	key 22:8	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	learned 126:3
irrelevant 45:16		kind 15:11 19:3 35:13,19 37:1 43:5 46:16 56:5 66:12 68:12 69:6 92:9 93:5 103:15 103:18,20 106:20 131:9 196:5 197:9 200:14	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	learning 57:22 198:12
Island 1:12		kindly 64:20	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	leave 6:5 37:8 99:11 103:13 108:20 119:21 136:15 143:6 172:2
ISO 132:21		kinds 11:19 126:14	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	leaving 90:16
isolated 73:22 157:10		knew 189:15	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	led 21:19 78:19
ISO17088 80:17 96:4		Knob 37:13	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	leeway 143:13
ISO17556 80:21 96:8		know 10:1,2 11:17 13:3 15:13 23:21 24:1 26:1,8 27:17 27:20 33:16 34:9 35:3,18 36:1,17 36:18 39:3 41:2 42:2,12,16,19 43:4,5,6 45:12,16 45:21 47:20 48:9 48:11,13,22 49:3 49:7,9,10,14,15 49:20,22 50:1,2,4 50:10,12,14,16,22 56:10 57:10,13 58:17 59:8,11 63:2 66:8 67:11	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	left 131:13 154:22
issue 5:20 7:14 21:16 22:1 23:19 26:15 28:3 58:3,5 106:8 107:18,20 113:19 120:22 121:14 126:9 132:3 136:12 137:12 140:18 160:10 184:1,6,6 185:11		known 65:3	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	legal 58:11 101:2
issued 20:19 32:11		land 37:13 39:2 77:16	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	legally 128:1
issues 23:18 24:5 45:9 73:10,19 81:10 125:12 135:15 186:15		landfills 78:15	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	legit 141:6
issuing 85:3		lands 23:21,21,22 24:2 26:14 31:1	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	length 38:18
item 149:9 151:21 152:1 167:15 194:3		landscape 49:7	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	lengthen 39:6
		Landscaping 30:21	106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	lengthy 192:10
			106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	letter 11:7 201:4
			106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	letters 200:11,16
			106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	letting 34:21
			106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 143:3 146:4 150:3 153:20 157:3,8,17 157:20 158:14,22 159:2,15,16 160:3 160:4,8 162:6 178:15 179:7,8 182:10,11 183:3 186:17 187:17 189:10 191:8,14 191:15 196:5 197:1,7,13 201:21	lettuce 12:15
			106:11,14,18 112:2 119:13 123:3,16 125:8 126:7 128:3 129:17 130:8 132:4 133:9 137:11 142:15 14	

17:9 52:11,12 84:3 109:21 110:19 129:20,20 132:9 151:3 186:15 level 15:4,5 18:7 78:4 108:4 leveling 60:8 levels 107:19 lifetime 199:14 lifting 152:9 light 164:17 lignin 186:10 190:20 liked 42:12 likelihood 120:1 likes 160:12 limit 129:12 Lindsey 154:21 156:19 line 33:17,20 40:5 65:17 66:3 113:17 154:4 lines 85:19 87:1 liquids 6:12 Lisa 2:16 152:1,4 190:5 list 54:1 55:12,18 58:13 69:20 70:11 71:13 72:21 75:22 80:9 95:5,8,17,17 107:14 110:15 117:11 134:1 143:2,4 144:18 145:7 152:22 153:1,2 157:11 158:5 164:19 165:17 187:17 190:17 192:10 listed 14:14 15:8 72:6,12 99:7 120:1 157:15,21 listing 55:9 80:6 89:11 90:15 95:12 95:12,16 97:21 98:2 113:16,21 114:6 116:4	117:10,14 126:2 130:7 152:19,21 157:13 164:18 listings 117:1 literally 126:8 little 14:17 20:12 22:14 25:2,6 49:18 51:10,11 52:5 56:10 57:3 57:18 64:7 71:2 75:1 90:9 93:14 116:12 119:7 120:4,8 121:4 131:12 134:18 135:5,15 137:12 140:16 142:5 151:6 162:9 190:21 192:3 193:6 livestock 3:19 142:18 177:20 190:15 192:11,16 living 43:17 44:4 logistics 199:4 long 7:13 11:6 33:22 42:17,20 45:11 47:2,20 62:11,13 71:20 78:14,16 80:8 92:11 106:7 114:7 148:22 longer 41:12 48:12 58:13 185:15 look 21:15 27:19 37:19,20 38:21 49:10,16 61:13 62:3 64:20 71:16 73:18 85:12 88:20 98:3,19 142:15 160:13 164:5 182:20 186:17 looked 10:2 23:1 71:11,18 74:4,7 127:14 157:1 looking 22:4 25:13 43:2 72:20 113:7 127:6 135:16,17	141:20 154:15,18 174:13,17 188:18 looks 132:21 144:22 183:7 loose 61:7 loss 31:1 lot 14:16 17:20 21:4 33:22 42:9 43:9 49:14 56:19 61:3,7 70:1,2 71:16 72:11,11,16 74:10,18 101:4 102:21,22 103:3,4 106:7 108:9,10,11 108:11 159:15 167:5,5 178:15 182:11,15 192:1 196:2 197:17 199:18 lots 21:18,18 43:6 love 35:4 39:1 182:7 198:4 Luis 74:1 lunch 167:9 Lynn 21:9 25:13 28:10,13 33:9,10 33:11 35:8 37:4 196:19	112:18 139:15 manage 92:3 128:8 128:21 managed 137:11 management 30:22 142:14 143:5,11 mandatory 30:7 137:13 manner 13:16 125:3 manual 178:9,19 194:14,15 manufactured 153:19 manufacturer 58:7 110:21 127:7,12 144:5 manufacturing 153:22 155:21 MARAVELL 1:19 41:1 54:15 64:6 67:16 76:7 94:9 101:14 109:17 111:10 112:17 119:6 121:15,20 122:1,6,8,13,20 124:10 134:17 135:12 141:5 145:15,18,22 146:22 147:4,10 149:22 151:1 163:21 166:17 174:21 178:6 marginally 68:18 market 18:5 128:10 Marketing 1:1 2:18 marsala 189:6 Marty 37:7,8 47:10 47:12 51:13 mass 82:3 97:4 material 22:4 23:9 23:16 26:9,10 60:4,11 66:9 72:7 72:20 74:20 75:9 77:5 81:20,21 91:15 92:4,7,18	93:1 95:3 96:22 96:22 110:2,8,13 112:9 116:18 117:9 126:17 128:4 130:10 135:1,6 136:8 138:19,20 143:18 144:17 146:8,11 148:16 152:5,7 156:2 186:8 189:8 195:3 materials 3:21 9:4 9:12 30:21 49:6 50:3,6 72:11 77:14 78:18 81:6 82:2,6 84:6,10 87:20 97:3 99:2 100:15 102:15 104:4,6 106:1 107:12 108:7 110:9,10,13,16,22 111:12,16 112:15 114:9,10,19 138:6 142:17 149:10 153:8 155:22 156:9 158:4 160:14 187:20 193:19 195:1 matrices 32:6 matrix 32:12,18 34:13 matter 52:15 137:10,10 138:18 138:19 151:10,15 160:11 167:12 168:11 170:22 202:8 mature 93:7 maximize 86:6 McEVOY 2:9 69:14 98:8 100:20 102:10 107:3 110:12 119:20 124:3,11 139:13 144:10 171:10,14 173:21 191:20 199:2 200:7
M				
		Mac 1:21 65:12 120:3 123:21 124:20 130:15 137:11 146:19,19 166:5 172:14,15 174:16 186:1 187:11,14 188:4 190:16 193:20 Mac's 122:22 magically 10:7 major 7:5,11,17 majority 91:21,22 maker 114:15 making 18:21 33:5 62:14 70:10 83:11 99:4 104:4 108:3 108:22 109:13		

mean 34:3 42:8,10 42:20 43:6,12 68:2,11,13 72:8 73:3 75:4 101:21 123:4,10 126:7 131:2,21 133:5 139:17 142:9 143:12 144:22 159:4	85:2 92:12 105:9 133:21 mentioning 32:17 Mesh 37:7 47:11,12 47:12 message 59:21 89:1 123:18 met 59:18 methionine 190:22 method 11:11 74:7 74:15 81:2 82:7 83:14 96:10 methods 30:21 51:12 81:4 83:19 84:5 96:12 Michelle 2:11 6:1 52:2 152:9 165:11 183:3 196:8 197:5 199:4,9,21 micro 185:14 microphone 167:19 micro-crystalline 80:20 96:6 micro-nutrients 186:9 micro-organisms 86:7 middle 102:8 Midwest 37:10 mildly 42:21 Miles 2:9 42:11 69:12 71:5 98:7 99:20 100:9,14 101:14 105:6 109:16,17 119:18 124:1 140:12 142:4 173:20 176:8 181:8 187:15 198:22 199:20 milling 154:8 million 40:10 mind 56:20 68:19 70:9 92:16 93:18 136:4 141:9 146:6 mindful 93:12 minds 56:12	minerals 190:20 minimal 72:12 minimum 90:21 mining 38:10 minor 10:18 16:3 minus 116:5,6 minute 151:6 172:19 minutes 47:21 168:6 minutiae 78:2 mirror 70:19 missed 174:9 192:20 mistake 196:13 mistakes 198:11 mitigate 31:1 mix 11:17 155:22 mixed 137:20 mixing 69:15 mixtures 86:10 modification 113:16 modify 134:10 139:2 moisture 123:13 mom 104:22 moment 161:19 164:4 167:22 169:11 189:20 momentum 28:2 Monday 199:13 moniker 112:21 monitor 84:21 monoxide 186:13 monstrosity 40:13 month 104:6 months 78:19 170:8 197:15 moratorium 106:22 morning 4:5,8 28:12 37:9 52:10 187:16 MOSA 37:11 39:18 40:16 motion 53:4,8,13	53:21 55:7,9,11 55:11,17,21 62:19 75:16,19,21 76:21 80:2,4,6 89:11,14 89:17,19 90:1 94:3,4 95:2,4,8,13 95:17,17 96:16,18 97:22 98:2,2 99:18,21,22 100:3 100:5 113:17,21 114:16 115:16 116:1,4,16 118:1 118:2,3,13 119:21 121:6,9,17 126:2 130:7 132:8,10,12 134:7 135:11 141:7 147:9 148:21 149:3,8,11 149:20 150:1,6 151:4 152:11,19 152:21,22 153:10 160:16,17 161:2,4 161:6,8,8,10,12 161:12 163:1 164:13,18,19 165:10,16 166:1 166:22 169:12 motives 89:2 move 17:21 28:8 53:14 55:10 56:11 68:6 99:19 103:13 103:15 104:7 114:12 116:11 131:8 134:13 147:19 151:7 186:18 192:4,7 moved 53:18 97:15 161:19,20 165:8 moves 104:15 106:15 moving 33:15 63:11 103:7 105:12 185:9 193:15 mowing 142:18 MRO's 79:9 mulch 77:5 78:8	80:10 81:12 85:8 89:20 90:2,15 95:19 98:10 112:21 117:7 131:12,20 135:22 136:15 138:17 139:10 146:14 187:2,2 mulches 80:9 87:4 87:5 95:18 136:2 138:14 142:1 143:2,8,15 144:3 146:2,5 mulching 142:17 multi-ingredient 5:16 6:9 8:15 13:1 16:22 multi-syllabic 189:19 mutagenesis 185:14
<hr/> N <hr/>				
			name 28:12 91:14 182:4 named 87:16 nano 81:5 99:1 100:14 102:14 105:22 106:18 107:11 108:6 110:21 116:15,22 119:8,10 nano-form 117:8 nano-material 117:13 nano-materials 84:12 96:13 98:15 98:17 99:14 100:16 101:5,6,17 102:17 103:5 105:11 107:5,6,6 107:22 108:5,6 109:1,6,9 110:20 111:1,8,21 112:16 113:19 nano-tech 111:11 149:10	

nano-technology 111:16 114:10 119:15 narrative 115:20 narrow 126:16,16 126:18 129:12 narrowing 10:17 national 1:2,4,10 2:9,15,16 26:20 27:7 28:14,14,18 50:5,15 54:1 55:12,18 58:13 75:22 107:14 110:15 117:11 144:18 145:7 157:11 158:5 184:4 natural 23:21 24:4 30:18 31:1,10 32:10,18 53:14,19 54:1 55:8,13,19 70:11 72:22 75:22 103:21 154:11 158:4 159:2,17 nature 29:6,14 130:9 near 120:1 184:4 nearby 31:1 necessarily 6:3 15:17 43:8 72:8 73:3 75:4 138:6 143:3 necessary 42:17 86:10 120:18 138:21 139:15 195:5 need 9:7 10:20 11:20 13:9,21,22 14:1,11,12 15:19 16:11 17:5 18:1 18:11 21:12 27:1 27:7,18 29:13 38:1,20 39:6,6 43:22,22 67:22 68:3 69:2 73:9,18 85:5,5 88:8 101:22 119:7	125:1,2,3 126:12 126:13,15 130:21 134:10 147:18 152:5 160:16 170:7 171:10,21 173:22 197:6 needed 11:13 13:10 20:13 24:15 59:7 168:17 needless 80:3 needs 12:9 40:16 44:17,21 119:11 126:14 140:20 164:18 165:11 180:9 188:19 negative 23:14 never 61:9,14 133:15 146:8 new 32:7 36:10 78:6 84:6 131:21 161:8,10 165:13 174:17 181:18 182:4 188:16 194:2,16 196:9 197:14 198:12 200:8,9 newspaper 138:4 nice 43:7 NICHOLAS 1:19 Nick 64:5 67:15 94:8 100:11 109:16 117:2 119:5 122:18 124:3 134:15 146:20 147:7 174:19 175:5 Nick's 106:11 124:2 141:19 night 48:5 77:11 104:2,17 198:2 NOC 24:22 28:21 29:3,19 30:2,9,16 31:13 32:6,12,19 nomenclature 93:5 nominate 171:11 172:14 174:21 175:11,14 176:15	177:3 179:20 180:10 nominated 172:16 175:2,17,22 176:1 176:18 177:5 nomination 172:5 172:11,17 173:6,8 173:13,14 174:7,7 174:18 175:3,5,18 176:13 177:6,16 178:5 179:6 180:2 180:5,7,20,21 nominations 171:16 173:1 176:2,3,4,22 177:22 178:2 179:5,12,12,17 180:6,22 181:2,3 non 155:7 non-effective 72:18 non-nano 117:5 non-profit 47:15 non-synthetic 146:4 152:16 159:19 non-target 31:6 NOP 1:2 5:19 6:15 9:4 12:10 18:4 22:21 28:22 29:5 29:10,18,20 30:2 31:14,19,22 32:4 32:7,11 34:1 36:4 38:21 43:22 58:20 79:16 82:12 84:13 88:20 105:20 199:6 NOP's 30:12 31:16 34:17 normal 65:16 145:8 173:3 normally 14:9 160:2 Northeast 113:13 NOSB 1:5 5:19 6:20 16:6 17:17 20:19 32:2 33:14 33:19 43:2 45:8	79:15 84:16 103:8 105:21 111:1 144:9 156:15 169:5 195:7 199:15,17 202:6 NOSB's 29:4,12 100:15 112:15 notable 194:17 note 70:1,3 notes 30:9 31:13 notice 58:19 59:8 62:9 69:18 70:4 noticed 198:1 notification 69:16 69:22 notified 70:5 notify 70:6 not-listed 90:11 no-nano 118:5 nuances 15:9 92:10 nucleotide 3:12 155:21 nucleotides 151:17 151:22 152:5,16 152:22 153:1,4,10 154:5 157:10,13 157:16 160:17 161:13,20 164:20 165:17 number 20:17 64:15 116:6 156:9 164:2 186:2,7 188:12 196:22 numbers 10:6 15:10 16:9 nurturing 77:17	143:3 182:15 OCA 24:22 occurred 61:8 occurring 37:3 OCTOBER 1:8 offer 71:15 office 41:17 179:17 198:6,8 200:15,18 officers 3:14 170:15 offices 43:5 official 69:22 officially 70:5 202:5 off-base 67:11 OFPA 127:14,14 Oh 150:4 okay 17:19 37:5 53:10,11 54:8 55:9 57:2,9,17 66:1,2 73:6 75:14 75:20 76:3 78:18 79:6 82:20 85:15 88:6 95:16 97:9 100:11,13 114:21 119:4 122:4,7,10 122:16 124:3,21 124:22 130:15 135:8,9 144:10 145:10,11,15 147:5 150:4 151:14 153:15 154:20 155:13 161:7,11 163:9 164:7,17 165:12 166:3 170:13 171:14,18 172:10 172:22 175:8,20 176:5,11 179:4,14 180:4,18 181:1 185:3,5,22 187:12 187:22 188:3,9 189:22 190:7 192:17,18 199:10 old 48:13 OMB 98:18 omnivore 191:2
--	---	--	--	---

picture 139:20 198:21	playing 36:1 60:9	170:5	present 1:13 2:7 4:8 5:1 15:3,4,20 77:2 92:14 199:1	100:17,20 102:18 139:15
pieces 34:1	please 4:4,12 17:10 17:11 40:6 41:15	pose 134:3	presentation 33:5 43:16 74:2,2 90:7	problems 40:3 141:21 142:21,22 143:10
pigments 87:21	52:1,18 55:14	posed 9:18 133:10	presentations 198:17	procedure 132:12 173:3 194:15
Pine 37:13	67:13 75:16,19	position 120:13 156:18 159:19	presented 5:11 62:19 74:18 168:3 183:17	procedures 5:14 171:2 178:9,19
pissed 93:15	113:6 119:19	171:7 172:12	presiding 1:12	proceed 27:21 54:11 94:7 95:8 109:22 110:4 119:12 121:11 132:18 147:6,8 150:8 151:19 155:16 162:22 166:3 171:6 173:13 181:4
place 34:6 74:5 93:11 96:20 103:12 148:15	148:14 151:13,19 168:14 172:1	176:12 177:22	presumably 142:11	process 23:6 40:17 49:19 56:10,14,16 56:21 57:6,11 58:16,18 59:6,20 60:1 63:1,11 65:18 66:9,10 70:6 74:3,17 75:3 82:17 91:3,14,15 92:13,20 93:10,10 99:9 101:13 103:2 105:8 106:2,5 109:13 124:12 139:19 140:16 145:8 148:9 153:22 154:1,3,10 154:12 156:1,21 158:1 159:18 162:10 194:1,5
placed 9:4 135:3	pleased 29:7 31:19	178:3,20 181:7 198:13	presumption 127:5 143:4,17	processed 16:14 154:6
places 20:17	plentiful 71:22	positions 171:11	pretty 42:8,13 62:21 67:1,2,7 189:12	processes 82:1 97:2 101:3 157:4
plain 40:1	plenty 62:9 134:21	positive 23:16 26:8 32:1 77:15 89:1,4 109:19 113:15	previously 31:14 85:3 116:20 118:10 132:16	processing 7:18 8:15,16 12:1 13:2 13:5,18 14:5,14 14:17 15:2,5 30:22 31:4 155:7 158:16
plan 3:8 19:10 22:8 22:18 27:14 28:9 38:19 59:13 88:14 88:18 183:12 184:20 185:2,16 187:21 192:11,15 193:21 194:3	plow 137:13	possible 17:22 71:13 79:2 104:15	primarily 152:18	processor 10:11
planned 112:1	plus 42:17 116:4	possibly 63:6 123:11 158:4 178:16 185:8	principle 78:4 142:14 143:5 144:1,2	
planning 89:5 113:2	point 7:9 16:21 37:19 40:7 42:1 45:20 57:21 60:13 62:20 63:13,15 68:12 88:11 90:18 93:4 106:3 111:10 114:22 115:5,18 115:19 120:5 121:15 131:3,10 138:15 158:13 168:19 169:6,14 178:7 181:15 191:7,15 193:13 195:19	posted 31:20 58:19 58:20	principles 28:22 78:11	
plans 3:15 45:8 183:2	pointed 14:4 27:6	poster 51:19	priorities 88:16 194:6	
plant 82:3 97:4 185:12 186:8,14	pointing 43:15	postpone 104:19	prioritized 143:4	
planted 39:2	pointless 39:22	post-harvest 13:6 13:15	priority 88:17 104:16 134:1,4	
plantings 31:11	points 92:17 93:3 122:15	potassium 188:3	privileged 93:19	
plaque 198:22 201:3	policies 32:7	potential 59:3 86:2 86:17 87:9	privy 61:6	
plaques 199:11 200:8,11	policy 3:13,22 116:18 117:18 118:9 134:13 167:16 168:4,20 169:19 178:7,9,14 184:15 186:17 194:11,13,15 195:4,9	potentially 88:12 99:6 192:6	probably 42:11 68:16 73:13 75:10 108:12 126:8 170:11 198:5	
plastic 78:15 91:15 104:8 121:1 127:13,19,21 128:2,6 129:7 135:22 136:15 137:7 141:22 142:20 143:1	pollution 78:10	power 107:16	problem 5:11 21:16 60:22 69:8 91:18 98:21 99:22	
plasticizers 91:16	polymer 86:10	PowerPoint 77:8		
plasticizing 88:1	polymers 86:5 87:22	PPE 74:5		
plastics 77:7 82:9 86:5,9 87:13 93:6 106:17	polyoxine 186:3	practically 22:14		
plate 169:14	portion 36:20	practices 47:6 59:4 59:14		
platform 92:15		precautionary 78:4		
play 45:22 110:6		precedence 78:2		
		precipitating 158:12		
		predict 59:18		
		predictable 104:22		
		preferable 104:4,5		
		prepare 47:19 59:2 59:2 77:11		
		prepared 154:6		
		prescription 138:13		

11:22 14:15 15:16 processors 44:2,15 produced 21:18,20 81:3,5 83:17 84:11 96:11,13 98:14 101:16 149:9 producer 12:14 22:19 140:2,4 producers 44:3,15 108:16 produces 91:14 producing 12:14 21:6 product 11:22 13:1 13:2,7 15:3,8,14 16:1,9,16 17:1 49:9,13,16 72:6 88:5 113:1 114:6 123:9,14 128:11 157:5 159:17 production 20:11 24:1 29:2 61:1 98:12 106:2 109:11 135:19 194:1 products 5:17 6:9 49:14 72:11 78:17 79:3,10 80:5 81:14 82:22 111:4 111:20 133:12 136:16 184:2 professionals 160:13 program 1:2 2:10 2:15,17 26:21 27:7 28:5 47:17 48:8,22 50:5,11 50:15 64:2 65:14 70:14 83:6,7 98:7 105:12 106:4 107:10 109:22 119:11,14 120:19 123:19 130:6 138:10 139:9,14 142:10 143:13 146:15 167:6	169:9 176:8 181:8 184:4 186:18 187:1 191:15 193:14 196:5,15 197:14 program's 139:3 progress 4:20 20:1 23:4 27:10 29:9 64:17 prohibit 119:8,15 prohibited 54:1 55:13,19 58:12 69:20 70:11 75:22 179:1,3 prohibiting 88:4 108:6 prohibition 117:12 project 134:4 promising 71:12 promulgated 101:18,20 pronounce 87:18 188:2 proper 17:14 174:4 properly 9:12 15:13 162:17 169:7 properties 116:22 proposal 3:9,12,13 77:2,4 118:8 121:17,18 124:6 129:18 132:11 144:13,14 151:8 151:16 167:17 169:21 185:9 189:1 191:1 proposals 4:8 52:7 52:8,20,22 53:4 131:5 169:20 170:14 propose 129:17 proposed 23:19 69:19 70:16 88:9 88:11 95:12 102:15 130:7 140:7 142:9 168:2 169:1 186:22	protect 31:7 protected 74:5 protecting 20:16 protective 74:6 112:5,6 protocol 83:11 provide 9:15 17:11 202:3 provided 73:21 142:1,20 Providence 1:11 provides 32:4 providing 21:6 69:2 180:15 provision 30:5 58:10 59:10 135:20 public 3:7 5:3,20 9:21 28:8 51:7 58:18,21 67:3 106:8 108:2 147:17,21 152:14 169:4 170:4 pull 40:15 126:22 169:13 purity 185:7 purpose 19:22 20:9 pursue 78:20 put 8:4 10:21 17:6 17:7,8 36:19 42:18,21 51:20 52:3,3 65:1 68:20 69:19 70:17 102:18 109:18 110:7,7 112:8,13 112:21 114:18 125:22 135:3 137:4 140:7 143:6 152:9 183:4 192:22 194:17 puts 10:10 putting 8:21 9:16 74:20 84:14 88:13 88:15 100:21 104:13 108:6 112:9 123:20 129:19 139:7	P-R-O-C-E-E-D... 4:1 p.m 167:13 168:11 168:12 202:8 <hr/> Q <hr/> QAI 25:2 qualifies 146:7 qualify 128:13 quality 31:8 32:20 47:18 187:5 quantity 31:8 quarter-inch 40:8 question 17:10 23:10,15,17 24:9 24:12 35:7,10 40:8 41:20 46:9 65:20 74:16 98:6 102:3 106:4 119:19 124:2 128:5 130:16 132:20 133:10,18 139:14 140:13,17 140:19,21 141:1,4 141:12,12,19 144:11 145:13 146:21 147:7 162:2,13,20 173:4 173:16,17 184:9 192:22 193:2 questioned 26:12 questions 5:9 7:7 9:19 18:12,14 19:7 23:3,7,12 24:16 28:6 31:16 33:10 39:14 40:1 40:21 45:16 62:4 88:15 110:19,21 113:6 121:9 124:1 125:17 146:20 148:13 150:6 156:20 160:7 162:21 185:1,20 187:6 188:7 189:14 192:17 194:9 quickly 104:15	106:15 quiet 50:19 quite 71:8 78:6 93:16 122:9 131:1 142:4 187:4 190:17 quote 41:3 quoted 61:20 <hr/> R <hr/> raise 37:14 65:22 109:12 193:1 raised 23:18 24:8 38:6 123:21 raising 149:6 range 12:15 71:12 82:22,22 rationale 68:15 135:2 136:19 raw 13:16 reaction 160:3 read 38:12,14 71:13 75:21 80:1 81:17 95:11,12,15 96:17 123:1 150:1 155:7,17 reading 6:6 47:4 ready 62:15 75:10 95:4 114:2 148:20 real 49:1 78:9 realities 47:4 realize 60:13 116:11 really 7:20,20 8:7 11:12,12 18:6,11 20:13 21:2 23:20 24:18,18 26:1,14 33:4,6 34:17 38:7 38:8 42:1,8,22 44:9 45:7,17 49:10,17 51:6 56:15 59:2 61:12 61:18 62:1 92:3,8 93:7,8 99:12 104:13,14 105:15 105:20 126:15 143:13 146:7,9
--	--	--	---	--

147:20 148:10 170:7 189:18 198:4,8 199:19 200:19,20 realm 117:2 reason 111:11 153:3 reasoning 135:2 156:8 reasons 136:13 receive 70:18 186:6 received 5:4 7:10 19:12 21:18 90:9 169:4,5 185:7 197:22 201:3 receiving 184:3 reception 48:14 recognition 201:2 recognize 29:1 59:17 109:8 115:1 141:17 recognized 90:21 recognizes 26:3 91:14 recognizing 116:21 recommend 36:4 recommendation 3:5 4:19 9:16 16:5 17:22 19:5 19:12 24:9 31:21 65:10 69:21 70:10 70:14,20,22 78:20 79:5 84:17 86:20 88:8 89:3 98:16 98:20,22 100:16 100:18,21 101:9 102:14,16 103:6,8 107:4,5,22 108:19 109:1 111:1,7,8 112:16 114:11 118:6 139:18 140:10 144:15 145:3,5 159:5 168:2 169:1 183:20 184:18 185:8 192:8 recommendations	9:1 16:13 20:2 21:19 22:17,18 24:8 26:19,20 27:11 29:4 103:9 105:21 107:17 109:4 140:6 191:10,22 192:6 196:8 recommended 26:5 31:14 32:2 80:2 recommending 145:6 reconsider 156:15 178:12,17 record 52:15 65:7 67:21 115:6 118:20 133:9 135:3 151:10 154:10 155:18 159:13 164:2 167:12 168:11 190:8 191:7 red 88:4,10 redefine 143:13 reduce 43:11 78:14 reducing 78:10 123:13 129:7 redundant 39:22 refer 79:8 154:14 164:6 reference 90:16 153:7 183:8 referenced 125:16 referred 82:21 100:15 referring 85:17 103:19 144:21 158:11 refers 79:12 reflect 71:7 73:20 reflected 20:17 reflects 13:13 81:12 refuses 172:20 regard 29:21 30:13 138:14 150:1 regarding 17:22	45:9 72:4 84:8 regards 16:1 162:9 Region 39:11 regions 60:15 Register 69:18 70:4 registrant 58:7 registration 66:9 66:10 regular 18:4 regulated 101:7 106:1 regulation 30:9 35:15 79:22 82:15 138:12,12 139:21 140:3 146:10 regulations 20:18 108:7 138:22 144:19 regulatory 59:20 60:1 63:1 101:1 108:1 123:3 139:19 reiterate 48:20 90:8 127:20 rekindling 184:5 relate 184:1 related 44:6 48:17 186:8,15 187:1 relative 80:19 96:6 relatively 5:7 6:10 6:13 8:12 10:8 18:4 72:18 released 87:9 relevant 6:2,7 144:12,13 reluctant 69:9 rely 111:5 remain 144:3 remaining 60:14 151:21 152:7 remarks 196:4,6 199:12 remember 43:15 65:13 73:9 remembering 44:1 remind 132:8 reminder 46:20	171:2 reminding 47:4 removal 82:18 112:11 127:9,14 130:11 136:21 137:1 139:4,10 143:20,21 remove 98:13 108:17 113:17 114:5,18 135:22 136:17 143:8,14 143:14 165:12 removed 16:14 84:19 90:22 110:20 121:2 142:2,21 149:14 149:17 removing 86:18 rename 128:2 renders 158:22 renewable 81:22 82:5 97:1,6 repeat 75:15,19 159:11 repeated 90:14 replacement 172:2 report 42:7,19 64:17 194:21 reports 29:12 87:12 representing 21:9 28:15 represents 93:22 request 14:13 18:2 98:1 134:18 167:22 168:6,8 172:2 requested 157:12 192:2 requests 174:6 require 20:7 requirement 30:4,7 requirements 30:6 32:13 80:13 95:22 requires 30:10 59:13 107:19 reread 97:22	178:19 research 66:7 71:22 85:13,22 88:16 126:12 133:22 134:4,11 194:6 researchers 85:21 87:4 residual 86:21 residues 83:3 resolved 61:10,12 resource 29:14 30:18 81:22 82:5 97:6 resources 29:6 32:10,18 97:1 respect 41:8 66:21 93:5 129:16 140:14 respectful 93:1 197:19 respectfully 134:18 177:12 respond 100:8 119:19 124:2 162:13 response 7:10 20:18 23:8 65:20 91:8 130:4 142:5 responses 135:4 responsibility 116:21 128:8 144:16 182:15 responsible 65:9 69:6 restart 181:16 restate 115:14 146:1 161:6 restated 155:20 restating 165:10 result 57:11 resulting 156:2 results 14:22 resumed 52:16 151:11 167:13 168:12 retail 184:6,10,15
---	--	--	--	--

retailer 184:12	175:12 188:6	158:3 160:18	seat 52:18 151:13	131:20
retailers 184:11	189:21 190:13	161:13,21 164:20	seated 168:14	sees 13:12
retard 123:15	193:2,12 196:1	165:17	seats 4:4	segment 23:2
retire 44:11	risk 78:5	sanitizers 184:1	second 53:15,16	self-calculating
retiring 37:16,19	RNA 157:11,13	saturation 158:13	55:14,15 89:21	10:4
return 51:16 167:9	road 71:20 128:4	saved 173:10	97:12,13 114:20	semester 17:18
reverse 162:11	Robert's 114:22	saw 74:1,17 75:3	115:22 116:2	send 7:8
reversed 162:15	115:6	146:2 175:9	140:21,22 146:15	sending 123:18
review 20:1 22:4	role 60:16 179:20	saying 19:6 61:13	148:1 153:13,14	sends 107:22
23:1,10 25:10	Rookie 196:13	67:5,7 68:14	161:3,16,17 165:5	sense 50:10 62:2
26:9 32:7 34:6	room 37:8 201:19	112:14 117:3	165:6 200:10	64:14 116:11
40:17 44:19 49:6	rotation 131:9	119:20 122:8	seconded 53:18	160:21 182:14
50:6,7 61:18,20	132:5	132:14 138:18	55:17 90:1 97:15	sensible 35:18
72:21 77:14 110:1	rotenone 53:9,14	141:6 152:21	116:4 161:19	68:16
110:9,14,16	53:18,22 55:7,12	153:1 159:14	165:8	sensitive 31:3,6
119:10,17 125:18	55:18 58:5,10	160:9 187:9	Secretary 170:21	sent 182:5 196:8
138:21 139:19	69:19 75:21	200:15	176:12,13,18	sentence 112:13
154:5 193:22	round-about	says 12:21 18:9	177:5,17 178:1,3	130:22
reviewed 32:12	135:15	83:16,17 90:18	178:5 179:17	sentiment 41:3
79:3 80:11 95:19	row 132:1,2	106:15 117:19	180:5,20,22 181:7	separate 171:3
110:10,13 112:19	rows 74:10	123:1,5 127:14	181:9 200:12	separately 169:8
reviewers 134:9	rule 6:2,8 15:19	154:5 157:12	201:4	September 32:11
reviewing 194:14	28:22 62:13 69:19	scare 123:8	Secretary's 200:15	series 9:19
reviews 49:22 50:3	70:16 79:18 84:18	scared 48:11 49:20	200:18	seriously 200:19
revised 31:20	88:9 96:19 99:4	scenes 120:19	Section 15:21 30:4	serve 29:21 176:18
revision 31:14	108:2,5,22 109:12	schedule 52:6	32:22 186:13	177:5 179:20
reworked 170:11	140:7 141:11,20	scheduled 52:4	sections 138:22	180:20,21 201:16
re-classification	142:8,11 143:19	195:13	see 12:11 14:3 17:9	serves 117:12
15:6	ruled 87:19	scheduling 193:9	22:5 31:19 34:3	service 1:1 181:12
re-list 117:17	rules 49:7 64:3	science 125:13	35:4,14,22 36:1	201:2,9
re-visitation	82:19 88:12	134:14	49:5 50:22 52:12	services 37:11
188:14	114:22 115:6	scientific 194:2	66:10,15 67:22	47:18
Rhode 1:11	run 47:2,15 177:10	scopes 30:10	84:3 88:4 114:12	serving 181:20
Rich 154:14	177:19 179:9	screaming 61:17	115:17 123:11	200:21
Richardson 1:20	running 51:2 177:8	screen 83:16 97:18	129:20,20 130:19	session 4:8 25:12
5:1,6 41:21 55:3		97:20 115:18	131:13 136:12	151:5,14
76:17 94:19 113:7	S	149:8 150:4,4	138:16 139:15,16	set 7:7 79:5 107:17
130:17 140:22	sacrificing 78:11	152:11 183:6	139:17 151:3	156:4 186:22
150:19 163:17	safely 148:16	scroll 6:1,4	164:6 165:12	sets 59:21
166:13 201:11	Safety 24:21	scrolling 185:3	173:18 174:15	setting 106:22
right 26:6 28:7	sake 156:16	searching 25:7	186:16 188:19	seven 166:21
42:1 44:1,16 47:9	sakes 63:2	season 82:19	193:15 198:22	197:15
59:21 68:13 80:7	salt 12:3,4,7 17:13	127:15,16,17	seeing 115:12	shaking 133:7
81:19 83:17 94:4	157:15,22 158:10	128:17,18 130:2	133:6	share 41:2 67:17
111:15 122:1	159:1,3,21 160:1	130:20 131:19	seek 5:20	195:13
141:17 152:19	162:17	136:11,18 142:3	seeking 20:7	sheep 37:14
164:15 173:18	salts 16:10 153:4	seasons 132:2	seen 61:10 74:19	sheet 9:11 14:6,8

sheets 11:15,21 42:6,7	situation 5:22 9:9 64:9 101:3 133:16 179:8	68:9 71:6 76:9 77:9 81:8 82:10 89:16 94:11 95:16 97:9,19 100:11 111:19 114:15 115:3,16 133:11 150:11 152:12 154:13,20 155:5 158:9,18 160:8 161:2,7,11 162:3 162:14 163:2,5,9 164:17 165:11 166:19 170:3 172:13 185:5 201:7	10:21 13:22 17:6 17:12 25:6 36:12 44:12 65:15 74:8 83:13 143:10 165:1	2:14,16 20:6 22:10 28:19 29:5 29:18 31:17 32:3 32:9 35:15 36:14 61:19 66:20 80:15 82:21 83:6 191:13
shelter 31:11	situations 22:12 46:2 85:8,12	111:19 114:15 115:3,16 133:11 150:11 152:12 154:13,20 155:5 158:9,18 160:8 161:2,7,11 162:3 162:14 163:2,5,9 164:17 165:11 166:19 170:3 172:13 185:5 201:7	specifically 32:17 116:15 157:12 162:10	standpoint 138:2
sherry 189:6	six 87:17 141:22 170:8	soon 17:22 27:15 141:14	specification 9:11 11:14,20	staples 40:15
shield 31:9	sizing 154:8	sorry 46:9 47:13 53:11 54:2,8 57:3 75:17 121:14 149:6,7 164:13 172:9 173:18 174:4 187:14 188:4 192:18	specifications 80:14,15 96:1,2	start 62:15 63:11 126:16 129:12 171:11
Shift 120:4	sketchy 57:19	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	specified 165:20	started 42:5 77:12 93:3 127:4,5 200:16
shoes 182:3	skins 37:15	South 39:11	specify 146:3	starting 150:9 166:4 183:7
short 128:22 145:18 168:4 195:11	skip 79:7	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	speed 74:20	starts 25:17
shorter 65:15 98:12	skipped 80:3	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	spelled 153:5	state 136:5 161:10
show 96:4 115:6 136:21	slide 80:3	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	spent 7:13 40:17	stated 12:9 82:19
showed 74:3 187:15	slight 88:3	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	Spinosa 72:13	statement 11:9 14:21 17:11 21:16 23:14 39:8 84:13 89:7 91:9 106:9 108:1 111:18 112:18 113:3,20 116:17 118:12,18 118:22
showing 80:18	slightly 83:16	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	splitting 68:12	statements 20:19
shown 80:13 87:12 95:22	slot 51:9	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	spot 193:1	states 1:1 37:12 135:21
shows 69:7 149:8	slow 63:2 99:5,8 102:11	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	spray 186:4	status 188:15
shut 75:13 84:7	slowly 152:2	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	sprayer 74:20	statute 60:12 128:19 135:20 138:13
side 10:8 65:9 67:22 68:4 121:4 137:8	small 15:9 201:1	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	spreadsheet 10:4	stay 44:10 135:10 135:13
sided 40:16	smaller 9:6	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	Spring 19:13 183:13 184:19 185:10 190:18 192:12 193:11,21 194:22 196:17	steady 182:12
sides 88:22	smart 92:22	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	spring 62:21	steered 147:14
sign 51:19 52:2	snapshot 73:22	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	staff 2:7 50:3,5 103:4 197:21 199:21	step 32:1,1 89:4 112:12
signature 196:14	society 20:15	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	stakeholder 62:20 63:18	steps 19:9 34:10
signed 51:9 52:1	sodium 12:5,7 157:15,21 159:22 188:1 191:5	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	stakeholders 64:1 70:3	steward 37:13
significant 15:5 45:17 101:12	soil 32:19 80:21 84:5,10 85:9 86:7 87:15 96:7 137:15 137:21 142:14 143:5,7 144:3 186:5	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	stamps 198:2	stewardship 51:4 77:17 89:2
significantly 99:5 119:22	soils 79:21	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	stand 41:14	sticking 147:11
silence 149:2	solid 74:3	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	standard 48:18 60:3,10,17 80:14 96:1,2 128:13 132:20 133:13 144:8	stocks 58:9
silicate 188:3	solids 16:19	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	standardized 10:1 29:22	STONE 1:21 18:16
similar 114:3 158:3	soluble 87:6	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4	standards 1:5,10	
simple 10:3 16:3 68:1	solutions 22:16 23:20	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4		
simply 16:5 119:16 147:10	solve 100:17	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4		
sincerely 41:4	somebody 120:22 153:21	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4		
sir 54:18 76:10 94:12 95:6 150:12 166:6 180:3	somewhat 49:21 170:11	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4		
sit 19:3	Sonnabend 1:21 45:5 53:16 54:17 55:15 56:1 61:2	sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4		
sitting 43:4 51:8 172:7,8		sort 4:18 6:5,19 8:2 8:17 9:19 10:4 17:19 21:22 23:13 25:15 42:13 46:14 99:16 117:2 125:1 129:11 137:18 159:16 162:11 184:9,14 195:11 196:4		

54:18 65:13,22 76:10 94:12 120:4 150:12 163:10 166:6 172:18,21 182:1,9 184:22 185:20 187:3 188:6 189:14,22 190:4,7,12 192:17 193:12 194:7,9 195:15,20 196:1 198:16 201:12 stop 99:6 stores 184:16 stover 137:14 138:5 straight 6:10,13 17:16 67:8 strategy 129:11 straw 138:5 Street 1:11 streptomycin 64:8 65:1 67:19 186:6 stress 38:16 stretch 4:6 strike 165:12 strong 26:17 27:1 182:14,16 191:12 strongly 33:7 struggle 46:1,5 struggling 60:22 studied 71:15 studies 66:16 78:18 87:2 study 27:18 86:15 86:20 stuff 11:19 48:6 51:5 87:14 stupid 40:1,7 style 18:3 sub 10:14 Subcommittee 3:2 3:10,17 4:7,15 6:20 104:2,18 127:5 143:16 148:8 162:8 167:2 167:4 168:4,20 183:4 185:6 186:3	187:17,20 194:13 195:2,2 Subcommittee's 151:16 169:19 183:12 subject 84:14,17 88:7,19 151:22 submitted 111:20 169:3 substance 53:14,19 54:2 55:8,13,19 76:1 82:18 99:7 107:7 108:16 111:3 117:2,11 145:6 195:4 substances 99:12 107:12 111:2,12 156:11,12 substantial 109:14 169:6 substantially 71:8 129:7 136:8 substantive 188:16 subtle 11:2 15:9 sub-ingredients 10:14 11:16 successful 67:10 68:21 69:1 sue 128:4 sufficiency 32:8 sufficient 63:7 114:8,11 sufficiently 62:11 sugar 188:21 suggest 95:11 98:13 99:13 118:8 128:15 158:19 suggested 39:15 133:22 suggesting 88:13 103:11 135:10 suggestion 68:10 108:14 suggests 30:16 144:4 sulfonate 186:10 190:20	sulfuric 188:21 sulfurous 187:22 sum 17:19 summarize 5:3 8:1 8:2 summary 5:1 27:17 Summer 200:14 sunset 70:21 187:19 189:5,11 sunsets 187:9 sunshine 174:14 supplementing 32:9 support 26:16,17 27:1 49:13 50:14 62:18 148:12 167:7 199:5 supported 29:3 49:1 144:9 supporting 195:2 supportive 48:7 supports 199:6 supposed 92:14,21 93:10 sure 13:11 14:12,13 17:1 40:18 43:13 46:2 51:6 65:16 67:4 70:2 83:11 84:15 100:2 119:8 125:4 131:11 139:1 143:12 144:18 152:18 153:7 157:6 159:12 165:9 189:12 193:17 197:2 surface 6:11 surprised 56:3 surprising 26:22 surprisingly 35:10 survey 14:22 suspect 63:12 sustainability 89:2 swamp 44:14 switched 97:16 symbolically 4:10 synthetic 80:5	89:20 90:3,18 95:3 107:7,12 109:10 111:2 112:22 138:14 139:4,10 142:1 143:2,15 144:2 153:11 154:3 155:8 156:1,3,7 156:12,13 158:5 158:22 159:22 160:19 161:14,22 synthetics 143:6,7 143:8 synthetic/non-sy... 156:5 system 10:16 12:2 22:8,9 38:18 44:4 45:19 systems 19:21 20:11 29:2 31:5,7 31:9,10 43:13 45:14 156:3,14	198:3 taken 17:1 26:5 31:22 34:10 38:6 64:18 92:11 120:15 171:5 takes 25:6 41:11 62:14 88:20 200:18 talk 6:6 49:21 50:4 56:9 91:16 116:12 145:14 193:13 talked 7:5 189:3 194:21 talking 66:4,5 94:4 127:19 141:20 142:16 143:9,11 169:9 tallied 171:5 tally 164:5,7 targeted 194:22 task 109:2 TAYLOR 1:22 54:14 73:8 76:6 94:22 150:22 163:20 166:16 175:10 193:20 194:8 team 198:7 200:3 technical 114:22 115:5 125:17 154:5 193:22 194:20 195:8 technically 196:11 technique 75:5 technology 150:2 tell 50:16 67:13 101:22 110:5 115:5 131:2 190:2 temperature 123:14 temperatures 83:1 tempting 24:2 tend 130:17 tends 105:21 terephthalic 87:13 term 78:14,16 128:22 176:19
--	--	--	---	---

185:15 195:11	195:22 196:1,16	73:9 75:8,10 77:8	164:13 170:19	token 201:1
terminology	197:4 198:13,15	77:13,19 83:19	173:4 174:6	told 40:18
174:10	199:3,19 200:6	85:7 89:9,10 90:6	183:13 184:20	tomatoes 13:20
terms 10:11 11:7	201:8,10,12	90:8,13 91:1	187:19 197:12	tone 59:21 107:17
33:14 90:9 101:5	thanking 182:2	92:20 93:11,15,17	three-year 59:20	tool 59:16
123:17 125:16	thanks 33:3,11	93:22 100:4,7	threshold 125:11	tools 39:3 59:14
128:14 130:11	47:10 51:10 105:5	101:22 102:4	194:20	top 50:10 137:21
136:20 139:9	114:1 184:22	104:13 105:2	thrip 60:21 72:10	topic 5:8 18:11
143:14 144:22	190:9 198:16	112:13 114:7	thrips 71:14	19:13 29:9,10
155:6 178:15,20	199:8 200:7	119:7,9 121:3	throw 93:20 130:14	32:3 34:17 88:17
178:21 185:12	theme 127:3	122:2,9,16 123:17	THURSDAY 1:7	160:7 168:22
terrific 199:22	Theuer's 154:14	125:7,12,19	tight 79:1	169:10,12
tested 80:21 96:7	they'd 73:4	127:22 131:4,15	Tilth 24:22 26:12	topics 25:6 29:18
133:12	thing 11:14 24:3	132:17 133:20	time 5:9 7:13 18:20	30:1 202:2
testified 144:5	33:2 36:12 43:1	134:2,7,10,22	33:17,20 38:3	tough 181:13
testimony 106:8	49:18 50:8,16	136:6 137:3,11	40:4 41:15 49:2	182:19
testing 83:3,11 86:9	60:2 70:8 77:20	138:1,2 141:6,14	59:7,21 60:13	TR 85:17,20 87:1
86:15,21 133:14	92:3 99:17 106:6	144:10 146:6,17	61:8,18 62:5,11	87:17 153:5 158:2
tetracycline 64:8	106:17,20 108:13	151:6 152:15	63:7,13,14,15,20	trace 190:20
65:1 67:18 186:5	112:7 115:17	158:17,21 164:3	66:3,6,12 88:10	tracing 185:18
text 101:1 108:1	121:2 125:4	170:1,4,7,14	98:12 102:22	track 10:12,16
116:13	127:21 128:9	172:19 173:3,21	103:4 105:20	147:14 196:18
thank 4:13 5:6	139:17 180:9	174:4 176:5 178:8	106:7 108:10	Tracy 1:17 113:22
18:13 19:18 28:1	things 12:11 14:3	178:10 182:22	111:22 113:17	114:17 132:7,18
28:7 33:1,9 35:8	17:16 23:5 33:14	183:2 185:16	127:9,11 128:15	133:10 162:3,5,20
37:4,5 40:21,22	33:17 34:11 35:19	187:5,15 192:12	128:18 129:14	201:5
41:1,18,22 44:22	36:21 44:6,8	192:21 195:18	134:12 135:13	Trade 7:16
45:5 46:15 47:3,7	47:21 61:10 68:3	thinking 71:7	136:2 138:8	tradition 181:16
48:2 51:13 53:5	68:20 69:15 71:17	77:12 78:14 129:6	143:19 148:22	tragacanth 189:6
64:6 71:4 73:8	125:21 126:3	139:6 154:2	152:2 164:14	training 8:9 9:3
77:3,9 81:8 82:10	140:5 168:17	188:22	168:16,19 169:7	18:3 21:5 27:2
89:5,6,7 90:5 91:6	185:13 195:10	thinks 29:19 32:19	169:14 173:8	33:18 34:4,18
91:10 94:1 109:15	think 17:16 18:10	43:22	175:21 179:5	35:4
116:10 124:21	20:14,14 24:11,13	third 63:3 176:19	181:15 192:4	trainings 8:10 32:3
130:14 140:11	25:9,15,22 26:2,4	thorough 75:8	197:12,18 198:1	transcript 61:22
147:11,16 148:7	26:7,13 27:2,5,16	thought 24:10 26:4	timeline 64:11	transitioning 24:4
152:12 153:17	27:17 33:13,21	48:2 92:13 93:6	timelines 56:12	transparency
155:13,14,15	34:5,16,19 36:2	122:5 144:1 172:4	times 12:17 61:11	194:5
156:21 167:4,9,21	36:11 38:4,7 43:1	thoughtful 35:18	78:1 162:8 173:4	transparent 91:19
168:15,15 169:16	43:15,20 44:16	197:20	tiny 131:12	transport 191:11
169:17 172:3,9,10	46:8,19 47:9,18	thoughts 57:16	title 81:11 91:3	treat 89:11
175:5 181:11,13	48:1,5 50:3,12,20	120:6	92:2 195:5	treatment 31:7
181:19 183:10	52:4 54:10 57:20	three 15:21 42:6	tocopherol 190:19	treatments 13:15
184:21 186:1	59:6 63:8,19	47:21 52:9 66:11	today 25:14,18	tree 71:20 74:9
187:2 188:11	64:10 65:6 67:20	66:18 67:5 68:18	28:19 113:8,14	156:6
190:16 193:20	68:16 69:15 71:8	71:22 87:22 88:1	183:18 191:19	tremendous 20:22
194:7,8,12 195:14	71:19 72:10,19	126:4 151:3,3	today's 61:19	48:4 50:8

tried 78:22 122:17	uncertainties 125:7 125:8,11,15 129:13 134:6	urge 138:10	versus 15:4 16:1	150:20 163:18
trouble 120:10	uncertainty 105:17 126:11 194:2	urgency 64:15 116:11	veto 114:6	166:14 177:7,11
true 72:8 73:4 86:14 89:2	unclear 98:5	uridine 157:19	Vice 170:21 171:7 173:14,14 174:18 175:2,17,22 176:1 176:9	177:18 179:22 180:3,17
trust 60:20	uncomfortable 67:7	USDA 106:12,22 108:7	view 93:3 120:5 128:5 131:3,10 142:14	want 9:22 11:1 37:20 38:15,16 41:21 46:13,14,21 47:5,6 48:19 49:12 56:9 57:5 68:20 75:12 78:20 81:17 83:19,20,21 85:15 89:17 90:6 91:19 95:14 96:17 98:9 99:10,12 100:1,12 102:4,6 104:20 108:15 113:13 117:20 119:8,9 122:11,13 122:21 124:2,7 125:22 130:13 132:12 136:5,10 145:14 146:15 148:7 149:7,19 153:6,6 162:2 177:19 179:4 181:11,19 183:8 192:22 197:4 198:19,20
truthful 182:8	underlying 143:22	use 10:6 15:1 16:1 36:4 58:6,11,14 60:2,3 72:17 82:11 85:8,11 87:3 104:5 112:20 130:19 131:22 135:21 143:8 170:20 174:3 184:1,11	viewed 154:3	wanted 23:3 48:12 51:6,9 71:6 91:5 93:4,20 100:13 129:10 153:19 179:2 192:20 196:19 197:9 198:13
try 5:7 7:22 43:11 44:13 70:19 120:10 128:8 135:10 185:17	understand 7:14 36:5 68:15 88:18 90:12 101:15 105:7 117:4 125:6 125:21 142:4 154:11 169:18 170:9 177:16 180:19	useful 7:17,21 26:1 44:14	views 123:19	wanting 65:20
trying 10:16,19 23:7 41:4 43:17 44:3 65:7 77:10 78:14 105:7 118:16,20 129:8 137:5,5 138:10 139:5 141:18 146:6 147:19 154:19 160:13 200:3	understanding 5:21 86:2 110:3 113:18 156:6 191:12	users 60:14	vinasse 186:4	wants 15:17 91:21 91:22
TUCKER 2:21	understands 100:2	usually 42:16,19	Vince 40:19	warrants 15:6
turn 167:18 169:16 170:16 171:21	undoubtedly 82:14	utilizing 131:6	vis-a-vis 33:17	wasn't 26:16 58:16 162:17 187:10 188:4
turned 171:21	unexpectedly 62:22	U.S 50:16 58:6,11	vitamins 186:10 190:19	water 6:11 16:13 16:20 17:2,13 31:7 32:20 87:6
turning 43:12	unfold 66:10		voice 182:18	watermelon 50:19
turnover 178:10	unfortunately 148:11 171:20	V	volumes 156:3,13	
turns 147:13	unified 182:18	vaccine 193:5	voluntarily 34:10 58:5	
twists 147:13	uniform 60:8,17	vaccines 191:6 192:21	vote 53:1 54:11 68:19 75:10 94:7 98:6 113:14 116:7 122:3 141:2 147:8 148:3,4,21 150:6 150:9 152:15 160:11 162:15,22 163:3 166:4 171:4 171:5 173:22 174:8 176:6 181:5	
two 4:15 15:21 22:1 40:15,17 41:11 42:7 64:16 80:17 80:20 87:21 96:7 99:16 132:1,1 136:13 137:17 173:4 178:21 179:12 181:12	uniformity 5:13	valid 48:12	votes 55:6 76:21 95:2 141:3 151:3 164:2 166:21 171:3 176:7 181:6 182:19 195:7	
two-stage 194:20	unique 116:22	Valley 7:18	voted 52:10 149:11	
type 10:5,6 41:7 45:18 73:19	UNITED 1:1	value 20:14 23:21 23:22 26:3,14 29:1	votes 55:6 76:21 95:2 141:3 151:3 164:2 166:21 171:3 176:7 181:6 182:19 195:7	
types 45:14,15 70:7 138:6	universal 26:16	variety 79:20 87:8	voting 76:4 113:8 113:11 115:15 121:12,16,18 149:1 150:7 152:17 166:5 169:21 171:9	
	universally 27:1	various 86:1 101:2 107:18 120:11		
U	unlined 40:9	Vashi 38:4		
unanimously 105:10	unreasonable 65:8 66:19	vegetable 12:15 42:20		
unanswered 88:15 125:17	unusual 179:13 180:16	vegetables 12:21		
	un-achievable 68:3	verification 5:15 10:9 133:3,14		
	un-biodegradable 104:8	verified 131:5,18 176:8		
	upcoming 52:1	verify 11:8 149:7	W	
	update 3:6 4:18 191:5 193:7,17,22	verifying 5:15 131:10	wait 24:3 45:2 79:6	
	updating 194:14	Vermont 113:13	WALKER 1:22 55:4 76:18 94:20	
	upstream 49:16			

way 11:3 18:22 20:12 22:10 25:5 33:22 34:14 59:19 60:8 66:13 101:16 103:16 106:8,14 106:21 107:9 109:18 113:15 119:12 120:11 125:21 126:18,21 135:16 146:1 152:20 160:11 174:14 193:7 198:12	we'll 17:5 25:9,21 52:6,7 61:13 76:4 80:5 85:2,3 86:20 95:9 98:3,18 103:1 116:12 129:3 135:13 147:8 151:7 162:21 167:8 170:20 171:6,15 181:4 182:4 183:5 186:16 188:18 193:13 195:4	Wideman 28:11 37:7,9,10 41:18 44:16 46:7,10 47:8	199:5,5,6,7 200:3 201:17 202:2	50:13 61:5,14 66:11,18 67:5,13 68:17 72:1 80:21 96:7 109:5 126:4 137:17 181:12
ways 9:14 61:11 109:14 125:8,9	we're 4:5 16:12 19:4 25:20,20 29:7 38:16 44:2 46:18 49:4 52:4 54:7 56:14,17 60:8 65:3,7 66:5 68:2 72:20 75:10 79:7 94:3 95:4 98:5,17 102:19 103:6,11 104:12 112:9 115:15 116:7 117:4 123:7 123:18 127:18 128:1,11 131:4,16 135:16,17 141:14 141:20 142:16 143:10 146:6,10 147:6,19 148:10 148:20 149:1 150:6 153:1 168:21 170:8,14 185:17 187:17 188:22 191:20 192:4 193:2 199:17 200:2	Wild 21:2,10 24:6 24:22 26:18 32:16 39:15	worked 6:19 34:2 42:13 106:7 197:17	yeast 156:9 157:5 157:11,13,17
wear 46:14	wishes 180:11	willing 41:8 102:8 125:10,14 134:20	workers 49:11 73:13	yesterday 151:21 152:13,18,20 168:3
webinar 18:3	wishes 180:11	winner 171:6	working 18:20 24:7 25:21 44:4 45:9 98:17 99:14 105:12 124:13 143:17 186:14,22 191:5,21 193:7,16 195:1 197:20 198:6	yous 197:5
website 9:4 10:21 12:10 17:8 58:20	wish 69:5 83:15,15 84:6	Wisconsin 39:12	works 198:7	<hr/> Z <hr/>
weed 141:21 143:10,11	wishes 180:11	wish 69:5 83:15,15 84:6	world 46:3 60:7,7 60:15,20 63:4 78:11	Zea 1:21 6:22 45:4 56:22 61:1 68:8 71:5 89:7 91:1 95:11 100:8 114:14 125:15 133:9 147:11 152:8,11 153:20 160:7 162:6,12 163:1 170:2 172:12 185:4,20 187:9 201:7
week 182:20 196:11	wish 69:5 83:15,15 84:6	withdraw 161:6,8	worldwide 78:15	Zea's 90:6 118:8
weekends 198:2	wish 69:5 83:15,15 84:6	wonder 49:18 172:1 193:10	worrisome 121:5	zero 55:6 76:21 95:2
weeks 197:12	wish 69:5 83:15,15 84:6	wondering 101:15	worst 49:4	zesty 103:21
weighing 125:1	wish 69:5 83:15,15 84:6	wool 37:15	worth 62:1	zinc 186:3
weird 198:1	wish 69:5 83:15,15 84:6	word 25:18,19 47:11 82:11 90:22 91:13 120:7 124:16 130:21 133:4 174:4 189:19 201:13	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	zone 74:8
welcome 47:8 83:5	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	<hr/> \$ <hr/>
welcomed 198:10	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	\$3.6 40:10
welfare 39:5 191:9 191:10,21 192:8 192:15	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	<hr/> 1 <hr/>
Wendy 1:19 170:16 171:17 176:16,17 177:1,7 178:11 179:6,14 180:10 180:12,20 181:12 181:14 190:15 192:18	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	1 55:14 95:22 167:9
went 13:14 52:15 106:5 151:10 167:12 168:11	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	1,500 37:12
weren't 77:20 112:17 113:2 187:16	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	1:18 167:13
Western 39:11	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	1:19 168:11
wetlands 31:2	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	1:30 168:12
	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	10 25:16 52:12 109:5 168:6 172:19
	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	10-year 51:19
	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	100 12:16 13:3,8 123:5,7 137:16 138:3,7 184:2
	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	11 1:11
	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	
	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	
	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	
	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	
	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	
	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	
	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	
	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2,4 27:14 28:8 33:12 41:16 43:3 45:8 48:3 50:2 59:19 62:15 78:3 79:16 88:7,14,18 93:22 102:2 103:1 103:9 108:10 113:3 120:11 124:8 128:9 148:19 167:5 169:19 170:13 181:22 183:2,12 183:19 184:20 185:2,16 186:22 187:6,20 189:11 192:1,2,11,15 193:14,21 194:3 194:14 195:5 196:2,10 198:3	wouldn't 56:19 77:18 129:8 132:2 193:6 198:3	
	wish 69:5 83:15,15 84:6	work 3:8,15 8:8 17:17 19:10 20:22 21:2		

11:06 151:10	205.200 32:22	132:21 133:11,16	
11:31 151:11	205.206C 141:21	138:7	
11:52 167:12	142:16 144:12	95 13:4	
12 151:3	145:4	99.9 49:16	
13 42:4,5	205.302A 15:21		
14 87:16	205.501-A21 30:5		
15 55:6 76:21 95:2	205.601 186:13		
151:6	205.601B2 80:9		
15-minute 52:11	95:18		
151 3:12	205.602 54:1 55:12		
167 3:13	55:18 75:22		
17 68:12	205.605B 164:21		
170 3:14	165:18		
17556 132:22	25 42:16,19 45:21		
18 1:8 68:13	258 154:4		
183 3:16	28 3:8		
185 3:17			
188 3:18	3		
19 3:5 68:13	39 24:7		
190 3:19			
193 3:21	4		
194 3:22	400 74:21		
1990 135:19	47 40:15		
1994 61:16			
2	5		
2 96:4	5 3:4		
2:19 202:8	50 87:14		
20 37:12 61:5	53 3:9		
2004 20:20	592 85:19		
2005 20:20	597 85:19		
2006 39:14	5988 132:22		
2007 184:7			
2008 21:8 46:17	6		
184:7	6 20:3		
2009 20:3,20 21:21	605 189:7		
23:20 26:6 27:12	606 189:7		
46:17	6400 83:3 96:1		
2010 105:10,15	649 87:1		
2012 1:8 32:11	654 87:1		
193:3	6868 96:1		
2013 19:13 183:13			
185:10,16 191:4	8		
2015 187:20 189:5	8:00 1:10 4:2		
2016 55:14,20 66:4	8:57 52:15		
66:5 76:1			
205.2 97:8,9	9		
	9:17 52:16		
	90 80:18 96:5		

C E R T I F I C A T E

This is to certify that the foregoing transcript

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Organic Standards Board

Before: USDA

Date: 10-18-12

Place: Providence, Rhode Island

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