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

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

treat that as a final agenda.

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

Michelle, would you please give the announcements you have?

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

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

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

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

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

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

second year on the board.

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

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

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

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

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

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

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

Committees.

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

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

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

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

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

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

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

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

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

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

in the state of Montana.

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

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

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

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

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

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

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

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

(Applause)

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

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

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

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

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

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

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

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

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

enough. The -- next, please.

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

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

I hope this is clear. If you

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

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

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

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

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

appreciative of Mark coming to this meeting.

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

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

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

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

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

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

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

is needed.

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

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

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

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

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

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

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

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

And then compliance and

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

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

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

the NOSB.

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

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

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

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

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

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

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

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

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

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

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

This has been a very challenging

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

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

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

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

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

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

has lots of services that can benefit organic agriculture.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

unannounced inspections during the future compliance audits for certifiers.

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

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

assessments of those agreements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

So for 2013 the focus areas are

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

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

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

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

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

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

such substance.

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

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

The nutritional quality of the

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

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

tolerances set by FDA.

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

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

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

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

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

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

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

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

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

(Applause)

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

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

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

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

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

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

We had a brief celebration at the

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

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

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

(Video playing)

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

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

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

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

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

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

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

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

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

And to know that we've had 10

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

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

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

In fact, our Strategic Plan at

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

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

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

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

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

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

(End of video)

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

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

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

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

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

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

First of all, Farm Bill results. As the Deputy mentioned, over $100 million in organic research and extension in the last 4 years. Many of those investments of course are still in progress. We're just beginning to see the actual results from that research and extension work come out of the pipeline and be available to producers and handlers. So this is a very, very significant area of work inside USDA and people should be getting involved with their researchers and extension folks in their area to start utilizing those results.

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

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

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

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

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

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

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

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

And I'll just mention very briefly

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

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

So, a very important product to

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

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

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

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

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

directly on organic.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

attention.

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

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

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

MR. LIPSON: Thank you all very much.

(Applause)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRPERSON FLAMM: Thank you,

Mark. Colehour, did you have a quick question?

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

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

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

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

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

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

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

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

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

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

MR. CASTEL: Thank you, Mr. Chairman.

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

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

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

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

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

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

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

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

organic products.

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

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

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

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

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

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

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

Similarly we saw a striking breakdown in process with the publication of the September 12 memo on aquatic plants. Thank you.

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

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

MS. HOODS: Leanna Hoods, National

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

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

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

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

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

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

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

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

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

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

So here's some general specifics.

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

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

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

You can't fix it all, but organic

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

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

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

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

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

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

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

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

synthetics.

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

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

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

So does that answer what you needed, Nick?

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

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

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

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

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

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

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

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

And I wonder if the National

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

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

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

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

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

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

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

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

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

MS. HOODS: Thanks a lot.

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

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

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

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

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

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

We have experience with Romer Labs on qualitative testing which they call AgriStrip for soybeans and meal. We have experience with Envirologics Companies quantitative tests for corn and soybeans, and I can share those results with the committee.

Prior to the meeting we did test

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

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

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

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

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

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

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

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

see allowed.

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

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

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

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

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

CHAIRPERSON FLAMM: Thank you, Bill.

MR. MARAVELL: Can I ask a question?

CHAIRPERSON FLAMM: Can we call Bill back?

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

out of the NOP on that issue?

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

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

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

MR. MARAVELL: Thank you very much.

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

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

(Applause)

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

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

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

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

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

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

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

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

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

For the Crops Subcommittee

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

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

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

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

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

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

MS. ALLAN-FOSTER: Sure, Mac.

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

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

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

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

MS. ALLAN-FOSTER: Thank you.

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

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

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

Dr. Bronner's appreciates this

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

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

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

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

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

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

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

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

So where does that leave us? First, our products that remain in the mass market and spa channels that are labeled outright organic that comply with no standard whatsoever. Secondly, there are products that remain in the natural products marketplace that have prominent organics claims in the brand names but which are certified only to the NSF standard that allows the main cleansing and moisturizing ingredients to be made from non-organic material.

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

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

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

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

MR. SANDLER: All right, thank you.

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

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

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

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

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

Now, compare that with the natural resources conservation part of the regulations. Operators must maintain or improve natural resources and the definition is of natural resources soil, water, wetlands, woodlands and wildlife. Soil, water, wetlands, woodlands and wildlife.

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

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

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

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

So, for instance, an operator

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

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

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

lands into organic grow crops really needs to be addressed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

When I come to a farm and I see

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

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

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

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

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

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

I have to do the whole herd. I

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

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

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

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

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

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

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

CHAIRPERSON FLAMM: Jean has a question for you.

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

would be?

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

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

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

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

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

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

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

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

move them through.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRPERSON FLAMM: Thank you. Jay had a question.

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

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

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

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

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

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

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

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

corroborated, that 2-year time span.

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

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

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

So, what I do want to ask about is

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

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

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

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

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

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

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

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

CHAIRPERSON FLAMM: Thank you very much, Colin.

MR. O'NEIL: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

motivation and commitment.

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

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

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

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

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

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

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

When taxpayers have already funded

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

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

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

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

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

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

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

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

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

researchers are, quote, "not believable."

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

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

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

MS. BEDROSIAN: Thank you.

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

MS. ARSENAULT: It's Bradie Metheny.

CHAIRPERSON FLAMM: Please state

your name and affiliation for the record.

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

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

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

rest.

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

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

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

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

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

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

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

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

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

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

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

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

MR. FOSTER: Yes.

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

MR. FOSTER: Awesome. Thank you.

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

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

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

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

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

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

organic food.

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

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

When these oils were first added

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

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

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

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

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

I am asking first and foremost

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

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

MS. CZERNICKA: Thank you.

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

MS. WALDEN: My name is Jessica

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

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

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

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

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

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

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

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

of that review process or not.

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

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

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

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

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

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

MR. FOSTER: Okay, thanks.

CHAIRPERSON FLAMM: Any other

question for Jessica? Thank you very much, Jessica.

MS. WALDEN: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

to be.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. ENGELBERT: Thanks again.

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

MR. NORMAN: Hello, my name is

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

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

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

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

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

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

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

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

We also assumed that we were not

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

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

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

was no evidence of the mulch in the field.

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

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

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

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

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

MR. NORMAN: Briefly.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRPERSON FLAMM: Carmela has a question for you.

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

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

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

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

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

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

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

CHAIRPERSON FLAMM: Thank you very much, Drew.

MR. NORMAN: Thank you.

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

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

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

certified in 1986.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Organic consumers disagree with

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

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

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

Of course, most parents aren't

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

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

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

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

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

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

CHAIRPERSON FLAMM: Thank you,

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

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

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

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

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

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

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

soy-based formula were not available.

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

MR. FELDMAN: Okay, thank you.

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

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

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

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

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

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

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

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

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

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

MS. BADEN-MAYER: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRPERSON FLAMM: Thank you, Rob.

MR. LAROSE: I want to say thank you.

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

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

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

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

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

MR. AUSTIN: Your comment on the

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

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

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

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

MR. LAROSE: You're welcome.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. FULWIDER: Go ahead, John.

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

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

MS. FULWIDER: Colehour?

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

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

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

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

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

as an ingredient in organic pet food.

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

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

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

MS. FULWIDER: Thank you, Lisa.

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

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

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

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

So briefly, organic pet foods or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

So, given that we do look forward to public comment today. We do look forward to continuing to work with -- listen to public comment and take further input as we deliberate on this through the next semester. Any questions for the board?

MS. FULWIDER: Questions? No

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

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

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

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

The questions basically ask for recommendations for 100 percent organic meat

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

The feedback was sort of a mixed bag but the majority of the respondents responded no. And particularly it was in regards to the perceived degradation of the organic label should meat scraps or byproducts be allowed back into organic. But there were some pretty emphatic comments about the positive benefits of organic meat scraps as well.

The next question, question number 2 was about the herbal methionine and the other sort of alternatives to meat scraps and meat byproducts and how we should encourage this type of research. Obviously that is less controversial and received more overwhelmingly positive support.

Some of the comments were that until synthetic methionine is disallowed there

will be less incentive to further develop more natural methods of L-methionine, and that it's certainly worth exploring all potential alternatives.

There were some concerns raised about the potential scalability of some of these naturals, quote, "natural" methionines and the ability to scale it up for larger-scale production. And certainly, you know, what do we have to do to bring these products to commercial viability within the next 3 years. It was positively received but obviously there's still some question as to how to go about doing it.

One of the suggestions was to conduct detailed studies in the U.S. Pretty consistently we heard please don't eliminate the synthetic methionine until we have a viable alternative for that.

And questions about how to spur more production, manufacturing of natural amino acids. Again, the comment about little

incentive as long as synthetic is allowed, but also recognition that there's been a fair amount of work and conversation about this, not only recently but there was a methionine task force that looked at it as well.

And then if we are to allow organic-approved meat and slaughter byproducts what do we do to ensure that safeguards are in place to -- for public health as well as the perception of it. And there were some issues raised in regards to the rendering facilities and the ability to separate organic versus not organic.

And again, would the organic brand be damaged. Pretty consistently we feel the comments were that they felt the organic brand would be damaged although some people came with the comment that as long as the public was properly educated it would be all right.

There were some comments about a concern on the use of fish meal due to threatened populations and the threat of over-

fishing. And would the rule change be appropriate to help fulfill the essential amino acids requirement, and if yes, state what language would you use. And basically the comments were very ambivalent about this. Again, it was reiterated that even an annotation about this would not really provide an effective solution.

So, in the summary, you know, there's strong broad-based support for developing natural methionine. There's mixed bag but a preponderance on negative response to the introduction of meat byproducts and meat scraps, and an emphasis on comments that we need to enhance and further encourage the development of natural methionine.

Any questions?

MS. FULWIDER: Mac?

MR. STONE: This document kind of focused on meat and poultry products, byproducts. The poultry industry, not just organic but the outdoor poultry people are

looking at insects as a protein source with the high cost of feed grains and availability of feed grains. So I'd just be curious if any commenters are commenting on this. We'd like to hear any interest, if there's any issue with public perception of raising insects. Or if you all discussed that that I missed.

MS. FAVRE: There were comments in regards to the fact that they thought that was a great idea. We didn't see specifically any negative comments about the perception of, you know, feeding grubs or maggots or whatever to poultry.

Calvin coauthored this document with me. Calvin, do you have any comments that you want to add to that?

MR. WALKER: I have none.

MS. FULWIDER: John?

MR. FOSTER: So, the insect thing is really interesting to me. Some of us have had conversations about that. But what came up in conversation yesterday was really

interesting to me and I don't necessarily -- I don't think we have the time to discuss it here but I like -- I think it's appropriate that we recognize some very large macro issues when they come up that maybe we don't get often enough the chance to talk about.

The one that really struck me yesterday was with respect to how use of synthetics might be beneficial to ecosystems in a very indirect, convoluted way.

With respect to, say, fish meal being used as a protein source or a feed source, well, if that does put undue pressure on fish stocks then could that actually be, I think the phrase we were using was a "deep green" approach to actually tipping the scales toward a few synthetics. And I'm not here to make that proposal at the moment but I thought that was a really good, large-scale, higher than 30,000-foot view of the kind of issues that we're probably going to need to contend with more and more often. So I just encourage

people to be thinking about maybe there's some advantage. Not just to synthetics, I don't mean to direct it there, but to other natural sources of other materials, that's great. But I love the idea of looking at preserving fish stocks as a means of -- as a driver if you will of a very sustainable approach to feed stocks for livestock for which is going to be, like that pressure is not going to go anywhere. It's going to get worse, it's going to get higher. People want their protein and there's more people so we're going to need to deal with that at some point.

I really encourage us all to be thinking about those indirect advantages that may not be in our current discourse right now. So that was really helpful for me yesterday and I hope we have ongoing conversations about that.

MS. FULWIDER: Other discussion? Well, moving right along. Last but not least we have a GMO Vaccine Working Group update.

And I will turn this over to Jean.

MS. RICHARDSON: Thank you, Wendy. This is sort of just an update really from the GMO Vaccine Working Group. The names of the people that are on this are up there on this slide. Where you have, it's a joint, this USDA working group.

We've got Melissa Bailey from the NOP and she's sitting across the other side of the table from me, Scott Updike who's not here who has been active on this subject and continues to be, and then we began to work with some people at the -- at APHIS. Patricia Foley has been on our conference calls and a very helpful and active member. And we've got Nick Maravell who is another member of the NOSB board and he'll make some comments after I've done sort of the general introduction here.

And it's important to understand that this is a presentation of the subgroup. It doesn't necessarily represent what our

Livestock Subcommittee was working on earlier but it is in fact a group report.

And just for some background for especially if there's other people in the audience and other committees that don't know where all the pieces on vaccines in organic livestock production are found in our -- in Section 205. There are four different areas of relevance when we're trying to understand what it is that we're trying to resolve, the problem that's before us.

The first place is that in 238(a)(6) it states that the producer must establish and maintain a preventive healthcare practices including administration of vaccines and other biologics. So there's the first place.

And then in second place under the National List of Allowed and Prohibited Substances in terms of vaccines it simply states at 603(a)(4) that biologics, vaccines without any form of annotation.

The third place that vaccines are found in 205 is to deal with emergency pest or disease treatment, and also that includes eradication programs.

The important thing I think for us to be clear about is that under 205.105(e) the use of excluded methods which we commonly call GM or GMO which we should really use the term "excluded methods" this is prohibited in organic production. And as we all know, producers must provide written documentation for seeds to show that they're not -- what their seeds are, non-GMO. And for handlers they have to show that if they have non-organic ingredients they have to have written documentation that they were not produced using excluded methods.

There is an exception, however, for vaccines provided that they are reviewed and recommended for addition to the National List by the NOSB in accordance with 205.600. So, all GMO are prohibited except for vaccines

but it's an important note provided that they're reviewed and recommended by NOSB. And I repeat that because that obviously has not yet taken place.

So because of this inconsistency within the rule in September of 2010 the NOP requested the NOSB to review vaccines made with excluded methods to be in accordance with 205.600. So, we on the Livestock Committee proposed recommendations in a lengthy document ready for the Albuquerque meeting.

But public comment prior to the meeting clearly demonstrated that there were two sort of divergent positions on this. The general public very loudly stated that they wanted no GMO vaccines, but certifiers and producers felt that they needed more detailed information about current vaccine use and production. So therefore this subcommittee was established following the tabling of the subcommittee recommendation.

But the NOSB passed a resolution

requesting more information from the USDA and we then set to work to try to unravel the complexities of this. Initially we're trying to determine which methods used to genetically modify disease-causing agent could be considered excluded and which could be considered allowed. And there are a number of nuances in there which we haven't really sorted out at this point, but we're working on it.

We also wanted to try to determine if in fact we could find a list, could develop a list. There is one presently published by APHIS but would this list actually allow organic producers, certifying agents and veterinarians to determine if a vaccine was made without the use of excluded methods. And we did hear some public comment on that this morning which I found very useful.

We also are trying to determine what are the methods, can we verify the methods by which the vaccines are being

produced. Can we understand the current use of those vaccines. And this is where the public comment comes in in terms of the need for knowledge collection.

We need to know as much as possible from the public those that are using vaccines, whether they look to see if in fact they are made with excluded methods or not. What is the current use, who's using them, are they in combined vaccines, what does it look like, to get as much of that information as possible from Europe, from your perspective. Obviously we're still working with APHIS but they may have a different perspective from producers and certifying agencies.

And, finally we really want to try to understand what would be the required use of vaccines made with excluded methods. Could they be legally used for eradication or for emergency programs and under what circumstances. So obviously this is a very highly complex issue, there's a lack of

clarity in a number of different areas including the definition of excluded methods between NOP and the manufacturers, et cetera. And so it's going to take us some time to come up with a workable solution but we're going to continue working on it.

And I would like to now ask Nick if he would have some additional comments that he wants to make.

MR. MARAVELL: Thank you, Jean. Just for some of you out there in the audience to give you a little bit of background if you haven't been following this issue closely, sort of how we got to where we are in discussing the GMO vaccine issue is that there was a previous board action recommending GMO vaccines. It was reviewed by the USDA general counsel. It was determined that a particular process needed to be carried out in accordance with the statute and the regulations to evaluate it for adding it to the National List. And so we received a request from the

program to go ahead and evaluate this.

And I just want to make it clear, we are not considering a petition here. We do not have a petition before us for a specific vaccine or anything like that.

The Livestock Committee then considered the issue and made a very minor change to current policy which would have affected the organic status of any product, livestock or livestock product that received a GMO vaccine as a result of an emergency treatment program. And that's pretty much all that the Livestock Committee recommended on this.

We did not specifically consider the impact of eradication programs but that's certainly something that I think we plan to explore with the working group.

We also recommended in a resolution to the National Organic Program that there would be potentially three things that would be helpful to us to generate more

information on, "us" being the NOSB.

One was would it be possible to encourage voluntary label claims on the part of manufacturers to state the absence of GMOs in their product and this way it would be more easily accessible to a producer or certifier, et cetera. And our reasoning there fell along the lines of current practices whereby producers are asked to provide documentation about lack of GMO methods or excluded methods used in let's say a seed inoculant or in seed and in other products.

So currently there is some precedent for this type of documentation. It may not be a cure-all and an end-all but certainly something worth exploring.

Then the second thing that we were trying to get more information on is would it be possible to eventually end up at a place whereby there was a realtime list when vaccines went into be registered with USDA through APHIS where it would be easy to

determine is this vaccine indeed made with excluded methods. So that was a second point that we wanted to explore.

And then the third point where we wanted more information is what do we know about the existing vaccines that are registered for use and whether or not these vaccines are made with excluded methods or GMOs, however you'd like to express it. So those were the three things that we were requesting.

We're hoping to continue to work in those areas and come up with some answers to those questions. But as I think Jean may have alluded to, once you get into the GMO issue it gets fairly complex fairly quickly. It's not a monolithic, there isn't one single thing that's a GMO or an excluded method for that matter. So I think we are still exploring the parameters, how big is this question and how much can we come back with, but we are working on it and we hope to come

up with something that can provide guidance to the community in concert with the program.

MS. RICHARDSON: Melissa, would you like to add something?

MS. BAILEY: No, I think that was a great report, Jean. And Nick, appreciate your follow-up comments there. Yes, I think the only thing I would say is that it's been I would say an open, collaborative relationship with Jean and Nick and APHIS to this point and I see that continuing. So thanks for your work with us.

MS. FULWIDER: Okay, thank you. Any discussion? Okay. Seeing none we can break for 15 minutes. We all need to be back at 2:45. And if the Livestock -- Jean?

MS. RICHARDSON: Wendy, perhaps because we're the first subcommittee reporting could you explain when we might be voting on the items, like on nonanoic acid for example?

MS. FULWIDER: Yes, we may be voting on nonanoic acid yet today but that's

why I wanted to have a subcommittee meeting here right during the break. And so we can decide if we're going to vote today or later. So, everybody back here at 2:45.

(Whereupon, the foregoing matter went off the record at 2:27 p.m. and went back on the record at 2:56 p.m.)

MS. FULWIDER: Okay, we're calling the meeting back to order. And we're ahead of schedule a little bit so we are going to be starting public comment a little earlier.

I have an announcement to make before that. At this time in the interest of transparency if any of the board members would like to share any interest related to our Livestock Subcommittee proposals and announce recusal would they please go ahead. So, Barry, is there any?

Okay, hearing none we -- hearing none we will proceed with public comment. Will Fantle is up first. And Christopher, I don't have a name here, from Heritage is on

deck. And if you'd please state your name and affiliation.

MR. FANTLE: My name is Will Fantle. I'm the co-director, co-founder of the Cornucopia Institute. I'm going to talk about some livestock issues. You've got copies, each of you, of our broader testimony. I'm not going to reference that. I've got some additional comments and observations I want to offer.

There are operations engaging in wholesale fraudulent marketing. We've worked with farmers on both sides of the U.S.-Canadian border to gather information about the activities of a Canadian company, Jirah Mills, that has been a major supplier of feed for livestock in this country.

Last year under investigation by the provincial authority in Quebec and knowing that an audit of their company was forthcoming Jirah voluntarily surrendered their organic certification and that prevented the

investigation, further investigation of the company for the activities that they were suspected of engaging in.

The alleged fraudulent grain was being sold to the giant egg operations and grain mills servicing livestock producers in the Northeast and directly to Organic Valley farmers.

Now, here's the rub. One year later they're back in business. They were recently re-certified by Organic Tilth. No one in Canada would touch this hot potato and they're banned from selling their grain in Quebec. But Jirah somehow managed to convince Tilth to certify them. The get out of jail free card was a voluntary surrender of the organic certification.

Miles talked this morning about the accelerated pace of NOP investigation and that's good. We need aggressive and quick enforcement. But we've lost thousands of acres of production of organic feed grain in

the Midwest in the last several years because our domestic farmers are unable to compete with con artists and imports, cheap imports coming in from other countries. In the real world this means less organic acreage in U.S.

Every NOSB meeting I come to I hear so much praise and rightfully so for the efforts of family farmers and others to raise and grow the bounty that so many of us enjoy and treasure. But family farmers in some sectors are being crushed by tight to non-existent margins.

Such is the case right now in dairy. Another suspect operator, Aurora Dairy is a provider of private-label milk for some of the biggest grocers in the country including Walmart, Safeway, Costco, Target. The USDA chose to put Aurora on probation for their 14 willful violations several years ago but they didn't fine them one cent. But somebody else did.

You may have heard news recently

about consumers in 30 states bringing a class action lawsuit charging that the production practices pictured on the pretty cartons sold in these stores of cows grazing contentedly in pastoral conditions really didn't match the reality of the situation. That class action lawsuit was settled a few weeks ago for $7.5 million. It should be an embarrassment to the USDA and the organic community.

The organic production data cited by Mark Lipson also contained some interesting nuggets. For example, just eight organic dairies in Texas have nearly 50 percent more gross sales at the farm gate than the nearly certified 400 farms in Wisconsin. Eight farms in Texas. There are real world consequences of enforcement actions or delays of enforcement actions.

Lastly, I want to mention the Petaluma egg operation in California. You may have heard that they are being sued again for carton picturing of the chickens being outside

and not matching the production practices that are occurring at the operation. That suit has been brought by an animal rights group.

Is this what we're coming to, challenges for flagging practices from other interests?

MS. FULWIDER: Questions for Will? Okay, thank you.

MR. FANTLE: Thanks.

MS. FULWIDER: Christopher. State your name and affiliation, please. And Mohamed Mousa on deck.

MR. PIERCE: Good afternoon, my name is Christopher Pierce, P-I-E-R-C-E with Heritage Poultry Management Services. I'm located in Annville, Pennsylvania. I serve as the president of Heritage Poultry Management Services and we're around 5 hours from here, so 2 a.m. this morning got on the highway and got past Manhattan, lower Connecticut, and got here real easy so it's good to see you folks.

Our company partners with a

variety of egg companies providing technical and hands-on support of egg farming in our mid-Atlantic region's family-sized egg farms. We have a team of certified poultry service technicians, Ph.D. poultry nutritionists and a support team with the emphasis of assisting our farmers group in the detailed hen husbandry care of their flocks in addition to being a tool to assist the farmers in meeting the various organic, hen welfare, food safety requirements for the farm.

We work with many of the family farms producing eggs that are sold here in the cities such as Providence, Boston, Philadelphia, Washington, Baltimore and Manhattan. Of all the farms we work with the families own the farms, personally provide the care and management for the flocks as well as pack the eggs, 7 days a week, 365 days a year meanwhile raising their own families on the farm.

So an important fact to share with

the board is that the average age of our organic farmer is probably around 35. And due to the increased demand of organic eggs there's new opportunities for that next generation family farm.

Our organic farmers are motivated and committed to meeting the consumer's expectations while meeting the increased defined welfare and food safety requirements that our farms follow.

I serve also another position as the chairman of the Pennsylvania Egg Quality Assurance Program which is a program which its standard was used to introduce the FDA Egg Rule which was implemented and followed. The reason that we've had PEQAP is the great importance for successful food safety offers our egg farmers, processors and the end consumers and that's why the FDA used it to turn into their mandatory compliance program. Because all consumers expect and should receive the safest eggs that can be produced

whether they're organic or not.

It was our decision to participate in that voluntary PEQAP program which is the most rigorous egg safety program in the U.S. that besides all the other details includes two unannounced visits by our Department of Agriculture every year. Why do we do that? Because we're committed to producing and providing the highest quality eggs for the marketplace.

In addition, the detailed farm management plan encourages the farms to follow good practices for salmonella risk reduction. Vaccination is an important and valuable tool that even FDA encourages.

In addition, many national grocer retailers also have specific requirements for our flocks, that they must be vaccinated on an FC program at the pullet stage and that's in response to 2010 where half a billion eggs were recalled from two Iowa farms. And that was due to that, that the retailer now cares

more about where are those eggs coming from, what was the vaccination program and they mandate that there must be salmonella vaccination programs.

So I want to encourage the NOSB and the NOP to support standards that provide organic egg farmers with known and effective countermeasures including salmonella vaccination that support future success in those small organic family farms that have committed their lives to organic egg farming. Thanks to the NOSB and to the NOP for allowing me to share this opportunity and happy birthday, NOP.

And if there's any comments on omnivore diets I'd like to throw some comments back to Mac or anything else that I could be helpful today.

MS. FULWIDER: Questions? Mac.

MR. STONE: I want to acknowledge that wasn't a setup so I may not be asking. But what are your growers doing with the high

cost of feed and grains? Are you looking at alternative grains or alternative protein sources?

MR. PIERCE: You know, and we're at historic prices. As I'm sure everybody in this room knows we're at just unthinkable prices. So at this point we're absorbing that price.

And one of the questions you asked one of the commenters earlier, Mr. Robinson from Kramer Feeds, was what is the effect of the methionine. And one of the initial effects that we have the cap on methionine is we're being forced to raise the protein level in our feed so that we can get the birds so that they can obtain higher methionine. And the birds aren't utilizing all that protein so it is kind of passing through the bird into the soil, into the ground, as well as it's raising the cost of our feed then also.

Did you ask about insects, Mac? Did I hear you ask about that? I'd love to

respond to that. So actually, insects are a major challenge for us because the Food and Drug Administration which oversees all the farms that we work with. Any farm of more than 3,000 hens is overseen. They want us to get rid of the vectors. We can't even use insects because they could potentially be a carrier of a salmonella so we have to put in our action plan how to eliminate insects of all types including darkling beetles and any insects on the farm.

If there's any questions on like the omnivore diets. But anyway, I'll just leave it the way it is.

MS. FULWIDER: All right, thank you.

MR. PIERCE: Thank you.

MS. FULWIDER: Mohamed, can you come up, state your name and affiliation. And Brennan Herbruck on deck.

MR. MOUSA: Good afternoon, everybody. Thank you for your hard work, NOSB

members and also NOP program.

My name is Mohamed Mousa. I am vice president for production at Herbruck Poultry Ranch. We're talking about genetics and GMOs. I have a degree in genetics and poultry disease or poultry medicine.

I want to start here with a slide I obtained from CDC. The foodborne diseases in United States is about 19,089 in 2010, 4,247 with hospitalization and 68 fatalities, 68 people dead. Salmonella accounted for 8,256, about 43 percent from that number and hospitalization from salmonella species was 2,290 and 29 fatalities. It's about 42 percent from foodborne disease.

I would like to make sure that I am very clear when I talk about vaccine. There's two types of vaccine. There is viral vaccine against viruses and there is against bacteria.

Last meeting I stood and I said I don't know how they make the vaccine. Well,

today I can tell you how they make it because I went and I visited the vaccine companies. I met with several of the specialists who make that vaccine and I will make my comment here about salmonella.

There is not any salmonella made vaccine in United States is GMO. This statement I clarified it from all the vaccine companies making the vaccine. For Lohmann Animal Health and I took their permission to mention their names, the person whom discovered that vaccine and manufacture it and patent it with USDA, her name is Sandra Kelly. She's a colleague, she's a friend and I had to take her permission also to mention her name.

She found out how to make vaccine by accident. She was tried to suppress the salmonella typhimurium bacteria and she found out that there is a virus available in the environment called the bacteriophage can disable that bacteria. Disable means I want to take you with me here, everyone from us and

all ourselves, we have genetic makeup. All those genetic have genes on them in the chromosomes. They have switches. You can turn them on and off like this light here. She succeeded to find the bacteriophage to turn two genes off, means to disable the cell. And she obtained vaccine by this way.

Other companies which they did not give me permission to mention their names, they're using techniques similar to that or use a different technique which is similar which also through the pH and other treatment they turn also the same two genes off.

So this is not GMO. It happen in any composting pile behind your house or my house. So please, if somebody stand over here I researched that, okay? I researched it. I am a geneticist, I know what I'm talking about. Somebody stand over here and tell you that the salmonella vaccine GMO, don't believe him. Refer him to me.

If you need Dr. Kelly's phone

number, email, I can provide it with you. I have it.

The other issue I want to talk to you about is the viral vaccine. The viral vaccine, there is GMO vaccine in the viral vaccine. How they do it? They slice part of the chromosome from a virus, what they call it. Empty space we call it in genetic, empty space in that chromosome. They take that empty space and get another virus and they put a piece in there. When you vaccinate the chicken the immune system of the birds summarize that and recognize it and develop immunity against it.

Any questions?

MS. FULWIDER: Calvin.

MR. WALKER: Dr. Mousa, I have one question with two parts. Methionine. Could you speak to the impact of the step-down?

MR. MOUSA: Yes, sir.

MR. WALKER: And in the absence, what would be other alternatives in the

absence of synthetic methionine?

MR. MOUSA: Thank you. The birds, if you have 10,000 chickens they will eat approximately 500 pounds of feed in their lives. Two pounds of methionine per ton, that's about 1,000 pounds of methionine. Because we are restricted now to use only maximum of 2 pounds in early of the bird life when they are pullets growing or when they start laying, and when they start laying, by about 30 weeks or so this is the maximum production. They need maximum amount of methionine.

In the front of the bird life we have to watch for the stage of life. And in your comment in many NOSB literature I read there is a stage of life that you watch for the stage of life. Well, in methionine sorry to say you did not. And those birds that's going to suffer a lot in early life but we don't need 2 pound after 45 weeks or 50 weeks of age. We need only less than a pound after

60 weeks.

I would ask the board to consider the average. We don't need more methionine, we just need the average. Right now those 10,000 birds will use only about 75 percent from the allocated protein methionine only. Only 75 percent. We cannot use the other 25 percent because we are restricted and the certifier of course will not accept the average unless there will be a ruling with that.

The alternative. Somebody was talking about fish meal. I want to tell that person who have that idea in their mind don't destroy the organic egg production. As soon as you feed high level of fish meal to get methionine the brown birds is very unique. They take the fish smell and scent and put it in egg. The consumer is going to run away from our organic eggs. Please don't do it. I did that. I did research, that was my research when I was in school. Don't do it.

The other issue is the insects. I think Chris commented on that. The insect meal is a phenomena. Guys over there in China did that and they had a lot of salmonella in the eggs, a lot.

The other issue which is also very critical here, we have to look for the food safety. We have to look for human who's going to use that egg. We cannot contaminate the egg by trying to supply the birds with methionine. Can't do that. Thank you.

Any other questions?

MS. FULWIDER: Jean.

MS. RICHARDSON: Thank you. Earlier today we heard that broilers and turkeys can be given before hatching bunches of vaccine which I found very interesting. What I'd like to know from you is in your experience how common that is.

MR. MOUSA: Yes. In ovo vaccine is common in broiler industry. It's for viral vaccine. You cannot vaccinate bacteria in the

egg. The immune system of that undeveloped embryo is not capable of dealing with the bacteria I will say yet because some research working on that right now to try to see if they can have some bacteria cells treated certain ways and to be in ovo.

For the broiler industry we use all males and females. In layer industry we can't do that. Even if we vaccinate in ovo we have to vaccinate again because the shelf life of broilers is very short, you know, 6-7 weeks, but layers live about 14 months. So we have to build the immune system. In layers we build the immune system. We vaccinate about 9 times and some companies vaccinate 12. And we have a very broad viral and bacteria we vaccinate against and we can't do it all in ovo because the immune system at that time will not recognize it.

MS. FULWIDER: Any other questions? Okay, thank you.

MR. MOUSA: Thank you.

MS. FULWIDER: Brennan Herbruck? Okay, if Brennan's not here I have Ashley Swaffer next on my list.

MS. SWAFFER: Hello, my name is Ashley Swaffer and I'm the operations manager for Arkansas Egg Company. And I'm here today to comment on the Livestock Committee's omnivore diet discussion document.

The committee has asked if they should look to allow 100 percent organic meat byproducts. My response is no.

My first reason is the commercial availability of the product, or lack thereof. For the estimated 8 million laying hens and 7 million replacement layers growing right now you would need approximately 68 million pounds of a product that's not even being certified or produced right now.

And the second reason I'm against the feeding byproducts to poultry is the fact that many producers and marketers have built brands centered on feeding a vegetarian diet.

Consumers are buying eggs that are fed a vegetarian diet right now and they expect that every time they go to the grocery store and buy a carton of eggs. So I really feel that the organic brand would be at risk and be damaged if we fed byproducts to poultry.

And the discussion document has also suggested we look at fish meal as a solution. The problem with fish meal as Mohamed said, it causes a flavor transfer into eggs. And another product of fish meal is that it's not an environmentally sustainable resource. We should not have to use our ocean's resources to feed chickens when we have other options available.

The document also asked if the committee should continue research efforts to find natural alternatives to synthetic methionine and I say yes. We need something we can feed to our hens that meet their nutritional needs in the organic regulations. But there is not a solution right now to

synthetic methionine. And the maximum levels put into place without a solution that is commercially available to producers is unacceptable.

Currently the 2-pound maximum level does not meet the nutritional needs required by chickens which is in direct violation with 205.238(a) which states you have to feed a diet that is nutritionally adequate. Without commercially available natural methionine sources to poultry producers I ask you to please seriously consider the new petition submitted by the methionine task force at the spring 2013 meeting with the revised levels that meet the changing demand in methionine as it relates to age. Thank you.

MS. FULWIDER: Harriet. Dave Carter on deck.

MS. BEHAR: I am Harriet Behar, organic specialist with the Midwest Organic Sustainable Education Service (MOSES) and we

work with a wide range of organic farmers mostly in the upper Midwest doing education and advocacy. MOSES is also a NOC member.

I appreciate the Livestock Committee's discussion document on the omnivore diet aspect of poultry and non-ruminant animals and your wish to find an alternative to synthetic methionine. However, I do not believe that the use of poultry in mammalian slaughter byproducts as a means to provide this nutrient is workable or the right direction to take.

I believe many consumers are attracted to organic livestock products specifically because of the prohibition of slaughter byproducts as feed sources for organic livestock. We have learned that diseases can cross species with devastating results with Mad Cow disease as one example. This alone should rule out the use of slaughter byproducts even if they are organic.

The usual infrastructure for

slaughter byproducts would need to be significantly improved in order to meet organic standards of livestock feed handling. And if there is any fish meal used it must be NOP certified organic.

Hogs and poultry are omnivores and it is their natural behavior to consume meat products. However, in their natural life they would not be consuming meat every day. They are opportunistic in their eating habits but would not necessarily obtain mammalian or poultry food sources on a daily basis.

I do not believe it serves farmers or consumers in the long term to have a rule change to allow this feeding. Instead, we should be putting our resources toward the research and ramping up of non-synthetic methionine options. I am concerned that by allowing this we would become complacent that the synthetic methionine problem has been solved and that our search for non-synthetic plant or invertebrate methionine sources would

no longer be a priority.

Pet food standards should be more clearly defined by the NOP before adding materials to the National List so we have a framework on how best to list them, preferably individually and not as a category, and provide clarity on the manufacturing protocols of these organic pet foods.

I would like to encourage the NOSB to join me in asking the National Organic Program to move forward with the NOSB recommendation on apiculture. This has disappeared from the NOP working list kind of like the honeybees who have succumbed to colony collapse disorder.

Right now there is organic honey being sold in the marketplace with widely differing standards which is confusing to the consumers and damaging to the overall organic label and consumer confidence. My cab driver even talked about it on my way here. Your recommendation to the NOP was a good one and

should be added to the NOP 2013 working list.

I support the committee's position to not approve nonanoic acid for 205.603.

And last of all, as an overall caution, pay attention to what has happened with Chilean nitrate at sunset and how difficult it can be to remove a previously allowed item from use due to the economic ramifications of that removal. Whenever you may think that an item that still has some conserved could be approved now would have thought that the future NOSB could remove it with new information this removal may not be as easy as you think.

I agree with Kevin Engelbert that votes should be done on the last day to allow the NOSB to ruminate on these proposals and public comments over a few days instead of doing them immediately after your discussion.

And I agree with Alexis from the Organic Consumers Association that the current use of GMO vaccines in organic livestock

production is an issue of great concern and the NOP should be working with certifiers to get a listing of all vaccines currently in use so the working group can see what vaccines they should review as a possibility from excluded methods.

And if you want to know more about the Minnesota Supreme Court decision about denying pesticide drift as damage to an organic farm ask me.

MS. FULWIDER: Questions? John.

MR. FOSTER: In thinking about alternate food sources for I think particularly poultry in this case if we came to a world where insects and earthworms became readily available as a food source, a provided food source, not just the ones you might find in the pasture but ones that would be raised for that purpose would those earthworms and insects and other invertebrates need to be certified organic?

MS. BEHAR: Well, that has been --

I remember a few years ago we did talk about that actually with ATTRA. There was a whole group of farmers that were raising red worms and we were trying to figure out if earthworms were livestock and whether they would then have to be fed organic feed to then be considered, they themselves.

MR. FOSTER: Right. What's your opinion about that?

MS. BEHAR: Well, I think that there can be a system produced where the invertebrates are consuming foods that are not toxic. I don't know necessarily they would have to come from organic feedstocks. But I think that we need to be creative and be looking as much as possible at producing livestock feeds that have the least amount of risk to the consumers and to the livestock themselves.

MR. FOSTER: Okay, but should they be certified organic? I mean, I hate to put you on the spot. You're one of the most

knowledgeable people in the room about it.

MS. BEHAR: Well, I would think actually the regulation would mandate that. There would have to be a determination if bugs and earthworms are livestock. But I would imagine if they are being raised, I mean you kind of went through this a little bit with yeast, you remember.

MR. FOSTER: Oh, I know.

MS. BEHAR: Whether, you know, something that's actually being agriculturally produced is then livestock or plant or what is it.

MR. FOSTER: Right, the intended use plays into what production practices might be necessary. Right. Totally there with you.

MS. BEHAR: Yes.

MR. FOSTER: But from your opinion or MOSES, whomever you choose to represent, should they be certified organic. If so, what standard?

MS. BEHAR: Well, we never came to

the answer whether or not earthworms were livestock. That was not really part of a larger community discussion. So I don't have the answer whether earthworms are livestock or not, but I would think that they could be raised organically, yes. So if someone could raise them organically then they should be able to be certified.

MR. FOSTER: Close enough. That's cool. Thanks.

MS. FULWIDER: Mac.

MR. STONE: Well, this came up at lunch the other day and the definition of livestock includes a clause that says other non-plant life. So yes, the insects, earthworms would have to be organically managed.

MS. BEHAR: Okay, let's raise some crickets.

MS. FULWIDER: Miles.

MR. MCEVOY: Yes, in my presentation this morning I only gave you a

tidbit of the things that we're working on. We actually are working on apiculture. We actually have the preamble that's being reviewed by an ARS -- at ARS right now. So it is on the work plan, we're working on it. Whether or not we get a proposed rule out next year or not depends upon lots of different factors but it's on the work plan.

MS. BEHAR: Thank you. I just was disturbed to not see it on the list.

MS. FULWIDER: Thank you. Oh, Jay.

MR. FELDMAN: This may be a little out of sequence but since you're here I might as well try this. I'm trying to sort of get an amplification on your position that trying to revisit something when more information becomes available is a difficult process so that putting something before the board before, you know, it's ripe and fully understood becomes problematic under the supposition that we may in intervening years

acquire information that we could then apply to an adjustment or a revision of that original decision. So you've seen that be problematic over the years.

MS. BEHAR: Well, especially if you say well, we'll put this on the National List now because it looks okay although we have some unanswered questions. And if something comes up in the intervening 5 years then we'll take it off the list. But my caution is it's very difficult to take things off the list. And so unless you're very secure in your decision-making you probably should defer until you get that information.

MR. FELDMAN: And as a follow-up, if we're working on a complex issue like we are in this class of biodegradable film mulch, bioplastic, whatever we call it, and let's say we want to, you know, address some of the complexity with some guidance.

From a certification and inspection standpoint what level of assurance

would this board have that that guidance, assuming -- let's assume hypothetically that it came out perfectly, that that guidance would be instructive and enforceable enough as opposed to putting the specificity into the annotation or in somewhere else somehow in the rule.

MS. BEHAR: I think that for clarity and transparency for the purchasers of the material, for the manufacturers of the material and for the certifiers that needs to be in the regulation. Because in guidance that kind of gets lost, it doesn't have the rule of law and not everyone's going to know to go look to guidance. If a producer is looking to figure out what kind of biofilm they can use they're going to go to the regulation.

They're not going to go back to the minutes of the NOSB, they're not going to go to the NOP program manual, they're going to look at the regulation because that's enough

for them to read.

And the certifiers are also not going to feel like they can enforce anything unless it's in the regulation. Miles has a response.

MS. FULWIDER: Miles.

MR. MCEVOY: Guidance in and of itself is not enforceable. It has to be backed up by the regulations. So you can't make a regulation through guidance. Guidance provides a method to comply with a regulation. And so it basically gives you a path to compliance and if you're not in line with the guidance you have to demonstrate how you're in line with the regulations. But it always comes back to the regulations, that's what's enforceable. If it's not in the regulations then there is limited enforceability.

MS. FULWIDER: Thank you. Dave, state your name and affiliation and we have Sharon Sherman on deck.

MR. CARTER: Thank you. My name's

Dave Carter. From time to time I've been here with the National Bison Association or Crystal Springs Consulting. Today I'm here as a consultant on behalf of the Pet Food Institute.

And I just want to say that I think myself and Kim Dietz are probably the only two former NOSB members that were here in October of 2002 so it's especially a great birthday for the organic program.

I want to talk a little bit about both the materials and the rulemaking for organic pet food. The pet food category, Miles said this morning that it's important to talk about the economic impact of a category. And the organic pet product is between $210 and $240 million. About 30 percent of that is food, the rest is treats and other materials.

And I think that that's pretty amazing given the roller coaster that the folks who make those products have been on for the last 8 years. Two thousand and four, the

Secretary of Agriculture said you cannot certify pet food as organic and then she said well, maybe you can but you've got to certify it under the human food standards.

There was a pet food task force set up that noodled around for awhile, took it to the NOSB. The NOSB filed their report in 2008 and we're kind of moving on since then.

In the meantime, the whole issue of accessory nutrients and vitamins came about in terms of what can and can't be in because we're under the human food standard. So you can see that those folks that are out there trying to do this and build this have been pounding that square peg into that round hole consistently. It's a lot of dedication to build this sector.

In terms of well, let's let the regulations get set before we address the materials we think we need to follow a parallel track. Miles, I'm very pleased this morning that you reviewed the progress that's

being made in developing the pet food standards and what's going on there.

But without having clear, consistent regulations and the knowledge of what you can and can't put in those products it doesn't do any good. You have to remember that with pet food we have one or two chances every day to get it right. Unless that product can be labeled as a complete and balanced diet it has to be labeled as intermittent and supplemental. It can't be listed as a food and that's only right because those pets require that nutrition. So we're very concerned that we have the things that we need to make that.

The NOSB reports in 2008 gave a list of materials that would likely have to be petitioned and that's why after filing the initial petition for taurine then we came in with the petition as a category.

Now, I think that -- I don't think there's any argument about these being

essential or required. Remember, other categories you talk of being accessory incremental. Pets, it's essential and required. I think the debate has been can we get those from natural sources or not.

The Livestock Committee has said well clearly they don't think that taurine for cats falls into that category. Clearly taurine is the critical one. But I think when you look at taurine not only are not dogs and cats all the same, all dogs are not the same, all cats are not the same. And if you look at the literature there's a lot of literature that talks about the inability of large breed dogs like Newfoundlands and the others to synthesize taurine.

Also, remember that the things that were in the TAP report that were cited as an example were conventional companies. The conventional manufacturers have a larger array of ingredients, particularly chicken meal. There is no source of certified organic

chicken meal and so it's much more difficult for those folks to formulate those products.

And the products that are out there in terms of the food that certified organic are a very narrow range, primarily adult dog maintenance. And if every pet out there was an adult dog we needed to maintain that would be fine, but we've got cats, we've got puppies, we've got seniors, et cetera and so on. So thank you very much.

MS. FULWIDER: Questions? Jay.

MR. FELDMAN: Thank you, Dave. I'm trying to understand this citation in the technical review that cites nature's logic. You're probably familiar with that brand. And they cite a full -- well, meeting AAFCO nutrient standards thereby making their products complete and balanced. And so I'm trying to put that in perspective given what you've said. Can you clarify?

MR. CARTER: Without looking at that specific one there are (a) the companies

that have been formulating the complete and balanced products using the materials that have been allowed previously. And then there are the ones that are doing the products but not the full line of completely certified. A lot of the products are in the made-with category right now.

MR. FELDMAN: Okay, so I forgot to say that their claiming these to be natural food ingredients so that -- I imagine that's a slippery slope there.

MR. CARTER: That's a very slippery slope because you can have natural chicken meal but not -- you could have certified organic chicken meal, it's just that we don't have it in the United States. And the difference that that makes is when you're formulating a product with a fresh meat or poultry ingredient you're formulating it with about 80 percent water in there. And so it's very variable, it's very difficult to bring that about.

If you can use the chicken meals which is that dried product you can test that, you can have a very consistent product there. It gives you a lot more flexibility. And the folks that are doing that under the organic have kind of got one hand tied behind their back in terms of that just because of the availability. It's not a price factor, it's just that it's not available.

MR. FELDMAN: If you take a product like this which says that it contains no synthetic ingredients according to the TR, you know, and we, let's say the board is interested in creating an incentive for organics to fill that niche in terms of natural food ingredients. Could it conceivably be produced to create -- to meet these AAFCO standards without synthetic ingredients?

MR. CARTER: Theoretically, perhaps. Right now I don't think anybody's cracked the code. I mean, that's the problem

is we just don't have it, you know. And the folks that are out there are doing it because of this byzantine process -- excuse me, Miles, nothing -- but it's just been this process, you know, since 2004. And then without having the access.

And one of the things that I noticed from the TAP report was, you know, the TAP report for example noted that you could -- that raw food was perhaps a viable alternative although they do have this little provision, concerns with feeding pets raw food include risk of contamination from salmonella, E. coli, and other pathogens, bacteria, dietary imbalances and internal injuries from sharp bones. Some dogs have reportedly died from bacterial poisoning.

I always hate something that says, you know, this is really good for you except you could die from it. So you know, I just, I think what we want to do is make sure that we're getting the best thing out there and

really helping to build this sector.

And I would just say one other thing too, that the folks that have really been out in front of developing the organic pet food have been a lot of the smaller companies that have done this because of their commitment to it through the years. Noticed how I whipped in some of my testimony I didn't get to give there.

MS. FULWIDER: Mac?

MR. STONE: Dave, is there a relationship for the need for methionine in lysine relative to the -- in formulating relative to the grain component versus the meat or poultry component in those feeds?

MR. CARTER: Well, there are, and I think that, you know, some of the things -- I listened with interest to some of the previous discussion of well, fish meal and some other things would be a good source of that. And it gets into those, you know, the same arguments as do we really want to be

going down a path with something that could be environmentally unsustainable in order to meet those.

MS. FULWIDER: Okay, thank you.

MR. CARTER: Just one last thing. When it comes to if you're classifying insects as livestock I want to see the squeeze shoot that you work them in. So, thank you.

MS. FULWIDER: Sharon, please state your name and affiliation, and William Reifenrath on deck.

MS. SHERMAN: I'm Sharon Sherman and I'm with the PetGuard Company. My husband and I co-founded the company in 1979. We're perhaps the first natural foods company to create foods with byproducts, artificial flavors, colors and preservatives back then. We like to be the voice for animals, that's been our passion all these years. And so at that time we actually created these foods.

When we created foods without byproducts we followed the AAFCO standards

realizing that was the only way that they could come to market and the safe way that they needed the vitamins and minerals to be able to -- for maintenance or an all-stage food to make it complete.

We continued on down the road and I would -- I guess people like to believe, you know, they have a marketing company but we're not really a marketing company and that we kind of like listen to what our consumers are saying they need and where there's a need we create a product.

And such came about with the organic issue. People wanted organic foods for their pets. And so at that time when we said, okay, well let's try to see if we can do it. And this was a need for the same reasons that they would eat organic foods, maybe their pets had allergies, maybe that they just understood the benefits of organic food and wanted their pets to have it.

At that time I met Katherine

DiMatteo and she said these are the people that you need to talk to so I met these two gentlemen, Mr. Hutchinson. And then I was turned onto a Mr. Jones. And I wrote a nice letter and just kind of like communicated my passion for being on the pet food task force at the time.

And my passion was, relating back to creating the first foods without byproducts, was I didn't want to have byproducts in my organic pet foods. And I didn't want anybody else to have that as well. I felt like they needed to have the same standards as humans. The only difference is we would be able to supply the pre-mix of vitamins and minerals were necessary to sustain their life because after all this is all they eat. This is what we feed them every single day and there's so much scientific data that relates to the necessity for taurine.

We saw in the nineteen eighties that cats were spontaneously having heart

attacks due to cardiomyopathy, or they were having issues with reproduction. And they could not synthesize the taurine in their system. So you know, those amino acids are important. The cats need the DL-methionine because it acts as an acidifier.

And yes, we use whole meats in our products but through the manufacturing process you can't seem to supply enough to sustain their life in an optimum situation.

So, I guess I'm, you know, I've come here to basically advocate for the animals and of course for our work. I mean, we're 34 years old. We just want to continue our work and do it safely because safety is the answer when you put the product out on a shelf. I think that the AAFCO stage helps the consumer to feel secure in what they're feeding their pet. This is for maintenance and this is for all stages.

I can feed this to my pet and they're going to produce beautiful litters,

they're going to be healthy. And I think anything less would be a tragic situation. We love our animals.

And I do appreciate your work and I appreciate your time and I think it's just very, very important for us to speak for them because they can't speak for themselves.

MS. FULWIDER: Mac?

MR. STONE: Does access to these synthetic amino acids improve your ability to source organic ingredients to build these formulations, these diets?

MS. SHERMAN: Well, yes, absolutely. Because you know, they're required. I mean, you can't get enough taurine and you can't get enough of the methionine.

MR. STONE: But if there's a lack of organic inputs if you will --

MS. SHERMAN: Pardon me?

MR. STONE: If there's a lack of organic chicken meal or organic beef products

available how does this help you to increase the organic content of the feeds?

MS. SHERMAN: Well, we are producing theoretically because we go back -- we are, not theoretically, back to 2004. We just followed the human standards like 95 percent and added the vitamins and minerals required through AAFCO. So the 5 percent are those ingredients. And that's how -- you know, and we have functioned that way, not any health issues or so forth. I mean, we produce all stage foods as well as an important vegan dog food that veterinarians use as an allergy type of product to determine which type of allergy that they have.

MS. FULWIDER: Thank you.

MS. SHERMAN: Thank you.

MS. FULWIDER: William, please state your name and affiliation and we have Ann Petersman on deck.

DR. REIFENRATH: My name is Bill Reifenrath. I am the author of the petition

that's before you for nonanoic acid. I'm the founder of Stratacor whose sole employee stands before you and I'm the inventor of the C8910 mix of fatty acids that we're using as a livestock fly control.

So this is -- the C8910 is a natural fly repellant. It consists of three fatty acids that are normally found on the skin surface of animals and man. This project, the natural fly repellant was initially funded by USDA back in 2005 as a -- because of the lack of alternate and necessary additives for IPM. And I think you have testimony from three universities and South Africa, from veterinary entomologists expressing the same fact.

The 8910 repellant can be applied to ranch cattle for horn fly control. And if you look at this slide you can see the 8910 repellant can reduce the level of horn flies competitive with cypermethrin, piperonyl butoxin. The manufacturer of this concoction

in their own words said the C8910 is the only natural insect repellant to compete with existing organophosphates and pyrethroid repellants, insecticides.

This is data from Kenya where they looked at malaria-carrying mosquitoes to show that with a single application of the 8910 repellant that it will result in mortality of about 90 percent for malaria-carrying mosquitoes. So by treating cattle for flies humans also derive a benefit in killing the malaria-carrying mosquitoes.

Laboratory data from CDC showed that C8910 was effective against Anopheles gabiae, the primary vector of malaria in Africa at levels comparable to other insecticides approved by WHO.

In summary, all the components of 8910 are grass. The only one that can compete with synthetic pyrethroids or OPs. Supporting fly control for livestock producers worldwide. And I think it would enhance organic livestock

production if accepted.

I would like to spend the rest of my time, there was a report and rebuttal. There was a reference to a report by Davies that said that nonanoic acid is toxic to nematodes. But if you read lines 337 and 339 carefully from the independent report it says that the authors did not report whether nonanoic acid may be toxic to beneficial nematode species or earthworms. However, an EC review indicated that nonanoic acid is not toxic to earthworms in short-term toxicity tests.

The independent report further goes on to say that when applied to livestock as an insect repellant that the environmental -- because of its rapid biodegradability and low toxicity that it's not likely to be an expected significant contaminant to the environment.

MS. FULWIDER: Questions? Jean?

MS. RICHARDSON: Thank you. When

you have -- when you apply this sort of smelly oil to the livestock, you know, which is part of what it is. It's a nice, oily kind of smelly thing that repels the insects. How often do you have to do it? When I looked at the technical report it seemed like for house flies the effect lasted maybe less than a day and then for other flies maybe 2 to 3 days.

So do you have to apply this on a regular basis? And if so, can you give us some idea of the actual amounts you would be applying? Say if you're on a healthy beef farm where you maybe have several hundred beef cattle gathering in a hot sweaty day kind of thing.

DR. REIFENRATH: Well first of all, at the doses that we're using say for livestock in the dust form, the use rate for the 8910 dust is the same as the use rate for conventional organophosphate pesticides or permethrin-type pesticides.

A 12 and a half pound charge of a

dust bag will last for 6 weeks on a herd of 30 head of cattle. And that's about the rate of use for the other products.

In terms of the -- you call it a smelly oil. It's -- in the dust form at the doses that we're using the odor is not that perceptible. And in the context of your applying it to a range cattle I don't think that in the context of what it's being applied to that the odor is a big issue.

For horses and other pets or companion animals we can effectively mask the odor through formulation. So I hope that answers your question.

The work that Brad Mullens did at UC Riverside for the oil formulation, a single application would last approximately 2 to 3 days. And I think he indicates that in his report to the posting on your website.

MS. FULWIDER: Jay?

MR. FELDMAN: Thank you. You know, we always have around these types of

materials have a debate over whether it's better, what you've created here, what is being produced and petitioned is better than organophosphate or synthetic pyrethroid or something else that's typically used in conventional systems. And no doubt it is and congratulations on moving a product like this into the market.

But as you can hear from being here at this meeting the standard that is applied to that product is very different than an IPM standard for instance, or reduced toxicity assessment. And so if you -- I suspect you have looked at the technical review on this product. We're looking at issues around impacts on beneficial nematodes, beneficial organisms under this standard which for instance EPA would not be looking at in the context of its pesticide registration program. And so we have to apply that screen and that criterion to this review.

The TRs looked at potential wind

drift impacts on blossoms and weeds and concerns over negative impact as I mentioned on nematodes and earthworms. So when you put that additional screen on materials that are allowed in the organic system it becomes much heavier in terms of allowance in that system.

So what, you know, I know you've studied these management systems and the conclusion of those that have looked at it in the subcommittee really has been that there are alternative management systems that can adequately control for flies or whatever the endpoint is here. Do you disagree with that? Do you feel that what is available now is ineffective or not productive or something to the effect?

DR. REIFENRATH: Well, I would refer to the postings that you've gotten from University of California Riverside, from the University of Nebraska, from the University of Arkansas and from a veterinary company in South Africa that existing IPM for any kind of

livestock production is inadequate. That's their opinion. They're veterinary entomologists. I'm a toxicologist.

In response to your comments about earthworms and nematodes, you know, we have an old saying in toxicology that the dose is the poison. So when you look at the way the 8910 is being applied to an animal it's being sprayed directly on the animal or in the picture that I showed it's being dusted on the back of the animal. So the exposure to the soil is minimal because we're directing it at the animal.

And I don't have the data with me but we've done studies to look at radiolabeled fatty acids that are in these type of formulations and applied to soil that the majority of the fatty acids will evaporate from the surface. So the combination of that as well as we're directing it to the animal rather than we're not tilling it into the soil would minimize the environmental exposure.

And I think your technical report in its summary basically says that, that environmental contamination is not a significant issue here. So that's your report.

MS. FULWIDER: Thank you. Ann, please state your name and affiliation, and we have Susan Czernicka on deck.

MS. PETERSON: Hello. I'm Annie Peterson. I'm from Emery Oleochemicals in Cincinnati. The Emery family began making fatty acids in 1860. They were making them for soap and for candles. So they've been there for a long time.

I'm here to petition to allow nonanoic acid as a synthetic for livestock control and I'm asking that you take a new look. You know, they're saying well, there's not maybe an organic registration or in Canada. Well, what Bill came up with, I mean he's been working on but you know, any semblance of a registration that we would have

to even offer it or present it, it's really only been completed in the last several months. And it's the first step.

So I mean, it's new chemistry and it's something that -- it's my job when I go to -- I'll go to try to make people aware of the chemistry because it's soft chemistry, it's natural fatty acids and it's a low-risk chemistry. And you take it into somebody like a major, or like a big company and they say that it doesn't work. They said that can't work. And then they get a sample of it and they say you know, that really works. And they're surprised because they think how can something natural and basic and low-risk work.

But the Production Act, okay, OFPA permits certain organic -- or certain chemistries that are synthetic. And nonanoic acid that Bill's been using, it's one component of a blend of fatty acids that are used as a tool to control biting flies, ticks and mosquitoes on livestock. And the base for

those, it's sustainable chemistry and it's no residue and it can come from canola, some parts of this can come from coconut, from beef tallow, so it's all naturally sourced. It's not anything that's going to have a petrochemical base.

The -- I think one of the points when we're looking at what's the basis is that the material is safe, it's not harmful to human health and that's supported by the DFDA -- considered grass. Generally regarded as safe since 1965. And it's used in very low concentrations so you don't see issues when you're using it because it's in such a small amount.

And it's not really, you know, it's not a high-toxicity material. And the fatty acids are naturally occurring. And none of the approved essential oils or pyrethrins that are considered organic are part of the normal diet. The pyrethrins are highly toxic to bees and fish and that's the existing

products that are organic.

That's not the case for the fatty acids. They're a significant part of daily diets. Some of the fatty acids in the 8910, they're in dietary lipids. They're also present in a variety of plants and fruits.

This material is registered, the 8910, Bill's product is registered as a biopesticide. And it is IPM-compatible because Integrated Pest Management is an effective, an environmentally sensitive approach that relies on a combination of common sense practices. And that's cultural, biological and can be synthetic means to control all pests while minimizing the public health and environmental risk. This represents good stewardship.

We've got the written recommendations that Bill mentioned. Peter Oberem, the South African Animal Health Association, he's a member of that. And it's a huge boost for organic in South Africa. Ed

Mullens and David Boxler, John Campbell, they have 90 years experience between all four of those people and they have been working with the 8910 since 1999. And they are saying that there really isn't any -- they are not seeing any damage to the environment. They're saying that it's soft chemistry and that it's effective.

And the last thing is cost. But just -- this is a natural material and it's low-risk and it's low-cost. It's less toxic than what's already in some of the materials in the organic program. And I want to ask you to allow this material as a tool.

MS. FULWIDER: Thank you. Any questions? Okay. Being the last commenter of the day thank you and we're going to have a quick break. Please, everyone, be back at 4:15.

(Whereupon, the foregoing matter went off the record at 4:04 p.m. and went back on the record at 4:20 p.m.)

CHAIRPERSON FLAMM: Board members, please take your seat. Board members, we're back in business. And I'll ask the chairperson, Wendy, if the Livestock Committee has any proposals ready for voting.

MS. FULWIDER: Yes, we would like to vote on nonanoic acid.

CHAIRPERSON FLAMM: Do we have a motion on this substance?

MS. FULWIDER: Yes.

MS. RICHARDSON: Do you wish me to read it?

CHAIRPERSON FLAMM: Jean? Jean, are you prepared to make a motion?

MS. RICHARDSON: I am prepared to make the motion. The first motion is classification motion, that nonanoic acid CAS-112050 as petitioned is synthetic.

CHAIRPERSON FLAMM: Do we have a second?

MR. BONDERA: Yes, I second that motion.

CHAIRPERSON FLAMM: We have a motion which has been seconded to classify nonanoic acid as synthetic. I believe we're prepared to vote starting with Jennifer Taylor.

MS. TAYLOR: Isn't there discussion on motions?

CHAIRPERSON FLAMM: We can have discussion on the motion to classify, yes. If you would like to have discussion. Okay. I didn't think there was need for it on the classification, but thank you. So we're prepared to vote on the motion to classify nonanoic acid as synthetic beginning with Jennifer Taylor.

MS. TAYLOR: Yes.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

MS. SONNABEND: Yes.

MR. STONE: Yes, sir.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: Yes.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

MR. BONDERA: Yes.

CHAIRPERSON FLAMM: And the chair votes yes. Do we have a motion to list the material?

MS. RICHARDSON: The listing motion is to add nonanoic acid CAS-112050 to Section 205.603 as an insect repellant insecticide.

CHAIRPERSON FLAMM: Do we have a second?

MR. BONDERA: I'll second that motion.

CHAIRPERSON FLAMM: The motion has been seconded. Discussion on the motion. John?

MR. FOSTER: I have a pretty good

feeling how this will end up going but I feel like I just, I want to say the information about the toxicity relative to beneficial nematodes, or any nematodes for that matter, or earthworms seems still like a maybe to me. And I'm not a huge fan of voting down a material for a maybe, particularly when the use of the material leads me to believe there's minimal contact.

And if a material is so ephemeral as to need to be required many times to be effective it can't be that persistent. And it seems to me based on granted a limited amount of time of me working on cattle ranches just the kind of environment would lead me to believe the material would degrade pretty quickly.

Another argument I've heard is that not a lot of producers are screaming for the material. And that's marginally compelling to me because if it's not listed a lot of organic producers in organic production

environment don't have access to it right now. So a lot of producers wouldn't have the experience, wouldn't have the option of using it. I understand that that's not, you know, that's not a complete -- I understand it's not a perfect rationale but I do know that a lot of materials are useful for a lot of people but not everyone.

And it's hard for me to believe that a whole lot of producers are going to be real vocal about a material that they've never had experience with, hands-on experience with, because most of my experience with producers, both livestock and crop producers is that they really don't believe it until they see it with their own eyes.

So it makes sense to me that there wouldn't be an outcry for this material just on sheer numbers? Most people haven't experienced it. Most organic producers don't have experience with it. So I'm reluctant to say because there's no outcry it's not a good

enough reason to try it.

It does sound to me that there is pretty good evidence that this is a preferable material to other things in current use. That's pretty compelling to me. And I'll leave it there.

CHAIRPERSON FLAMM: Any other discussion? Zea, do you have a point you wanted to make?

MR. FELDMAN: I raised my hand. Just to respond, I mean I think as I said, you know, the fatty acids are used extensively in IPM systems and I understand all that. Again, I feel we have a higher burden to establish need and essentiality which doesn't, you know, I just -- unless someone can show me something I missed here in the comments I just don't see that need established. And -- except from the purveyor of the material which is fine. But I think we have a statutory duty to establish that need before we introduce a synthetic into the organic system.

And that hasn't -- you know, I don't think we've done that. We may be able to do that in the future but we haven't done it to date. So, on that count I would say that we should vote this down and seek out more information on need and also alternatives as well.

And to the issue of establishing hazard, you know, especially under the OFPA standard you know when we talk about an insignificant impact on beneficial organisms in a situation where there is some non-target exposure and there's an admission that there is some. Whether it's deemed significant or not is always going to be the issue of course. But again, when you take that factor into account with the lack of established essentiality or need for a synthetic under OFPA I don't think we have much of a choice at this time. There may be better data that comes along in the future.

CHAIRPERSON FLAMM: Any other

comments? John, do you want to have a follow-up?

MR. FOSTER: The -- in terms of alternatives I think the regulation covers alternatives really well actually in 206. This material or any chemical control wouldn't be in play unless everything else in 206 ahead of it were covered and found to be wanting. So I agree, there are other alternative management practices. The whole context -- we've talked about this at least for 2 and a half years -- is that these materials, pest control materials shouldn't come into play unless those alternatives have been exhausted.

That's why there is this, the only codification of mandated IPM I can find is here, is right there in the regulation, 206(a)(b)(c). It's not till you get down to (e) that you're even allowed to try this stuff. So yes, there are alternatives, but in the context of the whole it's not just a matter of this material, it's that these other

things are found wanting.

So I want to make sure everyone's clear. I'm not saying there's no alternative. There are. Many of them are listed in the regulation and my expectation would be that those are demonstrated to be ineffective, or at least ineffective here and there.

And the here and there is the part where I get a little itchy assuming that people who haven't had the opportunity to try it because it isn't listed are somehow expected to clamor for it. That's just not the nature of producers that I know. Maybe there's -- I'm sure there's other growers and other livestock raisers that do things differently. But my experience is that until they see it used very few are going to start pounding on the table for it to demonstrate that need. I think it's something of a catch-22 there. Not a perfect one, but one I have experience with. So that's all I have to say about that.

CHAIRPERSON FLAMM: Any other board comments? If not we can begin the voting on the petition to add nonanoic acid CAS-112050 to 205.603 as an insect repellant, as an insecticide. And we'll begin voting with Nick.

MR. MARAVELL: No.

MR. FELDMAN: No.

MS. SONNABEND: No.

MR. STONE: No, sir.

MS. FULWIDER: No.

MR. AUSTIN: No.

MS. FAVRE: No.

MS. BECK: No.

MR. FOSTER: Yes.

MR. DICKSON: No.

MS. RICHARDSON: No.

MR. WALKER: No.

MR. BONDERA: No.

CHAIRPERSON FLAMM: And the chair votes no. Oh, I'm sorry.

MS. TAYLOR: No.

CHAIRPERSON FLAMM: I did it again. Sorry. I owe you. Jennifer, you voted no? And the chair votes no.

MS. TAYLOR: Thank you.

CHAIRPERSON FLAMM: The vote is 1 yes, 14 nos, the petition failed. I believe that concludes the business for today and remarkably we've finished a little bit early. Unless, Michelle, you have something to call to my attention we'll be in recess until 8 o'clock tomorrow morning. Have a good evening, everyone.

(Whereupon, the foregoing matter went off the record at 4:34 p.m.)

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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 my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R. Gross

Court Reporter

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

P-R-O-C-E-E-D-I-N-G-S

8:04 a.m.

CHAIRPERSON FLAMM: The meeting will please come to order. This morning we'll begin with a session led by Zea, the Chair of the GMO Ad Hoc Subcommittee. And I'll turn the gavel over to her right now to conduct her session.

MS. SONNABEND: Thank you, Barry, and good morning everyone.

Michelle will put up the posted recommendation. And I heard from some of you in the audience last night that it was very hard to hear in the back of the room so if perhaps the sound people can be conscious of that. And I'll try and speak up to the extent possible.

Okay. As we talked about at the last NOSB meeting in Albuquerque with the mission behind forming this new Ad Hoc GMO Subcommittee we wanted to keep the issues around GMOs of which there are many because

you keep hearing them coming up all the time in front of the board and in front of the public to be able to call attention to the fact that organic does not want to have any GMOs and we consider the effects of the GMO world on our organic industry to be essentially chemical trespass.

And we need to take whatever steps we can to keep them out. And one of the key steps to do this will be to keep talking about it, keep working towards clearer and clearer definitions, places to draw the line and associated issues around GMO presence in our organic community.

So, we started work, and this was at the request of some of the members of AC21 that we started to work on seed purity. We wanted to find out by putting out a discussion document from the organic community what was going on out there in the GMO seed world -- or I shouldn't say GMO seed world -- in the seed world for organic production that may or

may not be contaminated with GMOs. And that includes both organically grown seed and conventionally grown seed that is trying to be kept -- have less GMOs.

I'm not going to read the whole document because those of you interested in it will have read it. But I'm going to summarize the public comment and then along the way have a few thoughts of where we're going to go from here. And then I'm sure we're going to hear some more public comment and we'll take that under advisement as we do our work.

So we received 66 individual comments. Eight-five of them, which I know sounds weird, but it was actually in 7 letters, but one of them represented 79 people, copied the language from Beyond Pesticides which we'll summarize in a moment. Eight people put in comments on GMO subjects not related to seed purity such as labeling, keeping GMO citrus trees out and other things that are important perhaps in the future but

are not the subject of this paper.

And then we got about 26 substantive comments. And then while some of them were duplicative, like we support someone else's comments, but I consider them substantive if the person or group took time to write a distinct letter of their own that raised their own issues.

I'm going to only -- with 26 comments which really were all over the place and we got some really good feedback and some things we hadn't thought of concerns, but I'm not going to be able to summarize every single comment on every single question so I apologize if I leave yours out but I tried to capture all of the unique ideas and suggestions that were present.

Okay. So, in the -- before we get to the actual questions we posed we of course had a number of people write in overarching comments. And Michelle, if you can scroll up just a bit.

Okay, so Blue River Hybrids which is one of the more critical of our proposals said, "Seed purity standard must consider whether organic farmers' choice of seeds would be limited to those of poorer genetics or variety of genetics. It's disappointing that the many positive reasons for using organic seed are not considered."

We of course realize that we didn't put in the many benefits of using organic seed. That was not the focus of the paper and we were trying to keep it short. So we acknowledge the comment.

The ACOA along with the PCO: "The discussion of seed purity standards need to occur at all levels. Certification agency staff, producers, handlers, buyers, marketing, co-ops. Clarification on education on terms in the field is needed." And although that certainly goes with question 7 also but I thought that was important to bring out.

ACOA recommends we take a

leadership role in establishing broadly applicable USDA regulations. That is what we are trying to do, we, the NOSB, and hopefully through us the NOP.

Organic Seed Alliance believes that the next step for the NOSB is to apply more pressure on the Secretary to fulfill his obligation to support the success of organic ag. The NOSB can provide specific recommendations that speak to lack of policies and practices that eradicate GE material and seed. And we need access to good data. We definitely agree.

Organic Valley/CROPP Cooperative feels that the policy memo from the NOP fails to address the issue of adventitious presence. And they believe this testing standard represents -- while it represents a departure from the process standard foundation and carries some risks they think that market expectations and seed industry practice demand and enable such a shift. OTA cites the

benefits to seed growers and farmers of having such a program.

Okay, so question 1, is there a need to establish a seed purity standard or protocol, and please explain. So, the 85 commenters plus Beyond Pesticides say roughly we endorse the development of a seed purity protocol only in combination with a comprehensive plan to prevent GE contamination along with a rigorous enforcement strategy. This enforcement strategy should be spearheaded by the USDA.

I would have to say in general our subcommittee agrees with this. We talked about this quite a bit on our work plan although not -- it won't be immediate work plan but we do have planning to prevent GE contamination as one of the things we will be working on.

OSGATA would like to encourage the USDA to establish seed purity standard and protocols to implement and ensure that organic

and conventional planted seed as well as parental seed lines for breeding and foundation stock seed maintain genetic integrity.

ASTA does not believe there is a need to establish an NOP-required seed purity standard. And they feel it's an additional burden for organic farmers and additional costs would be incurred by organic farmers and then passed onto the consumer.

CCOF is absolutely in support of preventing GMO use in organic production and would consider a seed purity standard but are very concerned about the same thing as ASTA which is additional cost to organic growers. They would rather see a process-based certification that looks to risk analysis and mitigation rather than moving towards product-based certification dependent on testing.

They also point out that the regulations 205.670 requires the certifier to bear the cost of all testing of products and

inputs that we would require as part of certification. And that having the certifiers pay for any testing of seed would become very burdensome very fast. And so we'll have to work on that consideration in our future work.

Blue River would not encourage seed purity standard. It will create more problems than it solves. OGC echoes OSA so we'll get to that. Organic Valley/CROPP recommends seed purity standard of none found in the 3,000-seed sample for seed in the organic production. The seed industry has made it clear that they are technically capable and willing to provide the organic community with a continuous supply of elite genetics that meet such a standard and they can do so at an affordable price.

Oregon Tilth: the genetic purity standard needs to be established by the USDA to meet all seed -- to address all seed organic heritage, convention and GMO. Any farmer purchasing seed deserves assurance it

is pure. OTA believes setting a seed purity standard can be consistent with process-based standard when analytical limits are used to verify that adequate measures are in place to prevent contamination with excluded methods. Seed purity standard if properly established would protect rather than burden organic farmers.

Organic Seed Alliance believes too soon to implement a universal genetic purity standard for reasons described. They're concerned about the impact such a standard would have on organic seed availability which is another risk to organic integrity. They're concerned that adding another risk point such as a standard would discourage further investments in organic breeding and production, thus diminishing choice in seed and undermining progress.

They're also concerned that the potential to unintentionally encourage the use of non-organic seed and therefore further more

the conventional seed industry which can invest in meeting a genetic purity standard where organic seed, it costs more to produce.

Okay, I'm not going to summarize the answers to questions 2 and 3 which were what's known about contamination and testing and what testing methods are appropriate because we didn't quite get the volume of information we were hoping for. While we thank those who did put in something it's kind of all over the map and very difficult to summarize. But the committee will look at it in its future work.

Same with number 4 because that was very specific to each person's business. We're not going to try and just say that for everyone and we'll talk about it within the committee. It's all in the public docket so everyone can read the comments for themselves.

Is there a better suggestion for a seed purity standard? And this was key to us because we were just using one that we had

heard was commonly used in the seed testing world but not the only one. So we received a few responses.

OSGATA's policy on genetic engineering states, "Contamination of organic seed constitutes irreparable harm to the organic seed industry by undermining integrity of organic seed. Any detectable level is unacceptable. International experts in GE detection recommend 10,000-seed sample size for PCR which is one of the testing methods. A 10,000-seed sample takes full advantage of statistical limit of detection. In other words, we're concerned that depending on the lot size in question 3,000 seeds is to small to statistically assess the minimal signal to be determined as meaningful measurement.

And then they go on to suggest a combination test method of qualitative and quantitative PCR and give examples. We'll have to look into the technical aspects and feasibility of that suggestion.

ASTA which is the American Seed Trade Association, by the way, as OSGATA is the Organic Seed Growers Trade Association. If there is for market reasons value in a threshold then the AOSCA standards -- don't ask me what this stands for but Kiki will tell us later because I always forget what AOSCA stands for.

The AOSCA standard for certified seed may be suggested standard to use as guidance. They are a seed certifying agency, AOSCA. In any case regarding testing the scope and appropriateness of testing should be based on the crop. Frequency of testing should consist of new harvest seeds and seed safes for planning. They talk about ISO quality system.

Organic Valley in response to the question, they don't believe there's a better type of seed-testing protocol. This standard appears to strike the right balance between rigor and feasibility. The standard will be

based on non-detectable sample so the discussion therefore revolves around sample size. A standard that would allow for detection of any transgenic material in the sample would be unacceptable to us and that's why we don't like the words "threshold" or "tolerance" and avoid using the statistical equivalent expressions of less than 0.1 percent with 95 percent confidence because such terms and expressions falsely imply some level of presence.

The subcommittee has agreed with us and that's why you don't find the words "threshold" or "tolerance" anywhere in the discussion document. Blue River says if absolutely needed I would suggest a standard of less than 1 percent.

Organic Seed Alliance. The NOSB should apply real pressure on the USDA to establish a system for ongoing testing and monitoring organic and GE. Non-GE community needs a comprehensive data set for

understanding the state of GE contamination.

Testing is necessary but not at the total expense of the organic community. Testing should occur in the context of comprehensive regulatory framework administered by the USDA for GE crops. This would include proven prevention measures in the field, adequate compensation for organic farmers, shared costs for testing and prevention on the part of owners and users of GE products, and routine monitoring of contamination at the seed level.

I would say we agree with that but getting the USDA to do their part outside of the NOSB who is trying to do their part, but the rest of the USDA, not so much as we know.

Question 6. We're not going to summarize that question. We did not get very much response to it.

Training guidance or resources. We did get some responses and I'm not going to read them all out now but we got some good

information from expected groups like the ACA, OTA and Organic Valley about training and who can help with it such as AOSCA and things like that.

Question 8, what approach should an organic seed producer use to safeguard against GMO contamination from adjacent and neighboring farms? And this is something that we will be working on, as I mentioned, in our future work plan about a prevention strategy guidance.

And we got comments similar to some of the above. We need a comprehensive approach that includes not just seed purity but identifies and addresses sources of contamination all along the supply chain. And then Blue River pointing out the problems, that you can do everything right and still get contaminated. We do recognize this and it's very unfortunate.

OSGATA seed growers and seed companies supplying organic seed to the

organic community should follow protocols by which design intercept GE contaminants. And they talk about their prevention strategy that OSGATA will be publishing fairly soon, I believe early next year.

So, I think we have a good starting place. We were hoping for a little bit more specific data on what gets tested and how often and what sample sizes are used and things like that. And clearly one of our first missions is to try and inform ourselves of some of that information. I don't want to say we're going to initiate a survey because that is problematic for the department, but we're going to look into working with maybe the Economic Research Service or some other ways that we can find out more what's happening in the organic community.

We are going to be working towards a recommendation. I'm not sure how fast this work will take place. You will see it on our work plan for the next meeting. But in light

of the fact that we're not really in a consensus mode about this and we could certainly use a lot more stakeholder input we'll see how fast we're getting there. But I'd like to thank all the commenters and that concludes my presentation.

Okay. We're now ready to start the public comment on this but I don't know who's up. Beth Unger.

MS. UNGER: Good morning. I'm Beth Unger with CROPP Cooperative, a farmer-owned cooperative marketing organic products through Organic Valley and Organic Prairie brands.

I want to thank the Ad Hoc Subcommittee for the work they did. I thought this was an excellent start. And we are very much behind you.

We believe that clean seed is the first and most critical component of providing consumers with the purity they expect from certified organic products. In fact, without

first establishing a non-detect standard for the seed used in organic production and gaining the seed industry's cooperation in providing such clean seed it will continue to be very difficult to figure out how to deal with GMO contamination in crops and products further down the supply chain.

Our commitment to clean seed is reflected in our written organic seed policy that contains a phase-in period for our members to begin using tested clean organic seed. To that end we have been and will continue to work with the seed industry to find a path for seed companies to provide farmers with seed that meets the genetic purity standard of none found in a 3,000-seed sample.

We're convinced that such clean tested seed can be technically accomplished by the seed suppliers and will be made available to the organic community if we continue exploring practical options with them and work

together to create an attractive market for them.

Excuse me, I am not a reader for comment, I'm always extemporaneous which didn't work here. All right.

This is not a discussion of process-based versus product-based standards. OFPA requires residue testing. GMO contamination is a residue. Rather, this is an opportunity to work with seed companies to resolve rather straightforward technical and marketing issues in order to provide us with a wide variety of clean foundation seed.

Some seed companies in the comments that you were talking about, Zea, say they can't meet a genetic purity standard. Some don't know if they could and some believe they can.

We believe that working together we can make the standard happen. It is well worth the conversations. The actions that we take as an organic community can facilitate

the process of accessing clean foundation seed.

As we go forward to further discuss and refine the discussion document and ultimately provide a solid proposal to the National Organic Program that is a product of cooperation among the organic community we will protect and build foundation seeds and a supply chain that ensures the future of genetically pure seed.

We believe that establishing a non-detect standard for seed use in organic production and securing cooperation of the seed industry in providing us with a wide selection of varieties that meet the standard will not harm or hinder the development of a robust organic seed supply chain, but will open the door to significant progress and a new round in the growth and development of the organic industry.

This discussion document is a wonderful start. Let's engage the USDA, the

primary seed genetics companies, the companies that grow and sell commercial seed and the organic community to refine the proposal based upon consensus by working with the supply chain in a cooperative manner that will ensure the integrity of the organic seed.

MS. SONNABEND: Thank you, Beth. Are there any questions from the board? I see Carmela.

MS. BECK: Beth, I was just wondering, how do you handle your growers that save their own seeds?

MS. UNGER: I believe -- well first of all, we would definitely support saving seeds. That's a foundation of agriculture. And there are ways to get that tested.

We for instance have established a testing lab in-house where we can help with the testing of seed. I think that that safe seed is something that should be tested on occasion to ensure there's no creeping

contamination. There's ways to do it.

MR. FOSTER: Good morning, Beth. So this question won't be a surprise to the board members. So, the -- do you foresee the seed purity standard increasing, decreasing the burden of testing on growers? No change? How is it going to impact them?

MS. UNGER: Well, I think in a perfect environment, John, you'd want to see the seed companies taking responsibility. And I'm not talking just about organic seed companies. Any seed company supplying seed to the organic community would need to be a part of this. It would be, you know, the best case scenario here is to really increase the foundational varieties for the organic seed suppliers and start growing the organic seed market more and more.

Did I answer your question adequately?

MR. FOSTER: It actually answered a question I didn't ask but thought of. I

don't know how you did that but well done.

But you know, one of my things is I don't want more pressure on -- undue pressure put on growers for things that they may or may not have control over. So as you see these ideas rolling out I just, I want to recognize that, you know, a lot of testing is hard for a lot of growers, and sometimes it's financially untenable.

So, do you see like the burden of testing, do you see that squarely on the manufacturers, or squarely on kind of an MRO, like an OMRI, for example, for seed? Or do you think that could fall to the growers and do you feel like that would be a problem?

MS. UNGER: I feel that the testing goes back to the seed companies, the seed growers. And that's where engaging all of the seed companies in this conversation is critical. We've been doing that, you know, been working on it. We'll continue to work on it and certainly would be happy to work with

the committee in facilitating engagement.

MR. STONE: So Beth if we have a -- anytime we put numbers in regulation it seems to bite us at some point. So how do we have a process-based without strict numbers? I'm kind of along the line of John's question too of it seems like the innocent could get hurt pretty easily. And I'm also concerned that do we have enough clout with the seed industry that they're not going to throw up their hands and kind of say wait, wait, you all are asking too much and I'm just going to get out of that market.

MS. UNGER: Well, you know, in the comment that you received there was really a mixed bag of where the seed companies were at. And so it's really critical, Mac, that this is an engagement of the seed suppliers.

We believe that this is doable. And it's a matter of everybody sitting at the table and figuring out, you know, a win-win position for everybody.

MS. SONNABEND: Any more questions? Thank you, Beth. Oh, sorry. Jennifer.

MS. TAYLOR: I have a question, thank you. What role do you see, or do you see a role for others within the seed system? The growers you're saying and the seed producers as well as the transportation system, other seed cleaners. Are there others within this role?

MS. UNGER: There most likely is and I think the conversation will bear that out.

MS. SONNABEND: Anyone else? Okay, next Dag Falk. Please state into the mike.

MR. FALK: Hello. I am Dag Falk, organic program manager for Nature's Path Foods.

Dear National Organic Standards Board, Nature's Path is North America's largest certified organic breakfast cereal

producer and we want to keep organic standards with a high level of integrity and to match the expectations of the committed organic consumer.

We recognize the standards also have to be workable for producers and production, and a balance needs to be found. Maintaining organic principles is the highest importance and sometimes must override production and market conveniences. Without consumer confidence in the organic label there is no organic market.

Regarding GMOs we are glad that the NOSB sent a letter to Secretary of Agriculture Tom Vilsack and we would like the NOSB to take an even stronger stance.

The organic industry is lagging behind in its approach to protecting itself from GMO contamination. This is likely because GMOs were introduced after the early organic standards were developed and because GMO contamination cannot effectively be dealt

with in the same manner as other prohibited substances because GMOs are linked to living, reproducing organisms.

It is time to update the organic standards to deal with the exposure to GMO contamination risk which is growing at an unprecedented rate.

Organic standards are built around dealing with issues at the core, not applying Band-Aids after the fact. So it makes perfect sense that a key area of focus should be developing a seed base for organic agriculture that is as free as possible from GMO contamination.

Our experience when using high volumes of GMO risk ingredients, corn and soy, that's what we deal with, is that the organic supply chain is contaminated with GMO, sometimes more than conventional ingredients that are expected to be non-GMO. This is a sad reality and our response has been to enroll our products in the Non-GMO Project

verification program which addresses the shortcomings in the organic standards.

Organic as a system has the pitfall of not discovering existing contamination and actually discourages testing from being undertaken by organic farmers and manufacturers. That's the reason to believe that if no one knows there is contamination then no one cares. The problem is someone does care and concerned consumers will begin to demand organic cleanup more than it is today.

Without utilizing the tools of testing for presence of GMO on an ongoing and consistent basis there is no way to improve the situation. Testing must be embraced by the NOP rule as a tool to apply the practice of avoiding GMO contamination for soy, corn, cotton, canola and sugar beet, specifically for seed and finished ingredients. And of course you have to test precursors to some ingredients like oils because they can't be

tested.

I want to make a couple of points on the reason -- in order to make testing meaningful a threshold needs to be established and that's for three reasons. The first reason, provide a safe level for farmers under which they will not encounter the business risk of rejection of their product.

Two, provide a level which consumers can understand and can be achievable, yet necessary because we live in a polluted world and that they can accept.

And third and the most important is to provide a tool to force the conversation about cost and liability for contamination to happen in arenas outside of organic. The industries and farmers that are at the source -- are the source of GE contamination of organic farmers and products must be forced to take responsibility.

We have seen for too long that politely asking for this is not working.

Having a threshold is an essential and key component that must be in place in order to demonstrate the cost -- that cost, harm and hardship has occurred.

There's more detailed answers in my handout that I just passed around. There's two other areas that I want to make brief comments on outside of GE that I guess I don't get to do. Thank you.

MS. SONNABEND: Thank you, Dag. Are there any questions? Well I have one if I don't see any other board members. How do you suggest we as a board who is not the rest of the USDA so we can't really deal with the topics we need the rest of the USDA to deal with, but how do you suggest we collect enough information on the topics that we do need information to proceed? Such as how frequently to test how many seeds in a sample, all of those types of details.

MR. FALK: I think that there is quite a bit of experience out there in the

world internationally and also with the Non-GMO Project and so because that's been ongoing for awhile there's been a lot of experience in dealing with these very complex issues. And so I think that the information is there, we just have to dive into it.

The other thing I think is that if we don't take the first step and actually require ourselves to do some looking, to do some testing, to do some investigation by setting in place some rule we won't start the process of actually gathering information. We need to start gathering it and we cannot gather it unless we say we need to set a threshold, we need to understand that we can't actually get there without taking the first step.

MS. SONNABEND: Thank you. John?

MR. FOSTER: So that made me wonder, I don't follow that. Why is the establishment of a number a necessary precursor to gathering information? I've

never let a number establishment get in the way of information-gathering before. So help me understand that.

MR. FALK: You mean a threshold number?

MR. FOSTER: Right, threshold. Right. Maybe I misheard you.

MR. FALK: Well, if we -- you know, this is what we're doing. We're saying we're going to look for something but we're not really looking.

We have a practice standard today and yet contamination levels in organic are increasing. And I feel like that's because we are not establishing the level because it's not safe to look. Because the number is infinite or, anybody's imagination is where the number is. So everybody is scared to do any testing.

Everybody is scared to know or talk about what their contamination levels might be because there's no safe level.

There's no level which by if I tell you you're going to think I'm okay. So we have to have a level where farmers are safe. Otherwise they're never, ever going to engage with us on this very difficult issue.

MS. SONNABEND: Nick.

MR. MARAVELL: Yes, a follow-up on John's questions. Would a number be identical for all crops? How long would a number stay constant?

MR. FALK: I think that a number should start as high as we can afford to make it as easy as possible as an entry point. Because once we have established a number we're going to start gathering data and then hopefully we'd be able to tighten the number so that we're cleaning up the issue.

So, yes. Does that answer your question?

MR. MARAVELL: Not exactly, but what you said is make the number as high as possible in order to provide entry into this

process. Is that sort of like a "let's take a look" number, or is that a number that would disqualify a product from being in the organic status?

MR. FALK: That's a question I think the whole industry has to struggle with, whether it's a pass/fail number or whether it's an action threshold that means we take certain actions based on it.

You know, preferably -- like we're very concerned about causing hardship for farmers in particular and processors, and that's not the objective here. We're trying to save our own industry. We're not trying to create more hardship. But at the same time we lose our confidence from the consumers if we just let this thing get out of hand.

So we're sort of stuck between these two places and we have to find the best number possible to make it feasible at the same time as we are aiming towards reducing contamination. So we have to be preparing

ourselves to ratchet it down as it becomes feasible. But why set it so low that we can't achieve it? That's the reason why we'll have to look at that, setting that number very carefully.

MS. SONNABEND: Thank you, Dag.

MR. FALK: Thank you.

MS. SONNABEND: The next, Jim Asta.

MR. LANGER: Yes, this is Dave Langer. I'm a research director at Dupont Pioneer Hybrid Seed Company and I'm here today representing the American Seed Trade Association. And I want to thank the board for the opportunity to comment.

On my first slide here I take the opportunity to kind of take you over the flow chart, the basic flow chart of the seed industry. And we have several things. Zea already mentioned the Association of Official Seed Certification Agencies (AOSCA) a process-based approach. We also have ETS here,

Excellence Through Stewardship, by which we identify protocol and procedures throughout our industry.

And the first part there is a module, is the lab research that we conduct. And then we have greenhouse and contained facilities growth chambers. The third module is field trials. That's where we do our plant breeding, our characterization, trait integration work.

And then the fourth module is seed multiplication. This is where associations like the Seed Certification Agency, their process-based protocols are followed in that area to ensure that we produce quality seed that is used then to make commercial seed for sales and distribution. And as this chart shows, and we're doing this all for the farmer customer to provide them seed.

Zea read many of these comments earlier from ASTA. The one on coexistence, the fact that is coexistence between different

bodies is possible. We are an example of that in the seed industry in our seed production. We deal with coexistence issues all the time.

We do take deference to the use of the phrase "GMO contamination." It is misleading for products that have been through a thorough safety assessment. GE things have gone through EPA, USDA, FDA assessment so they are deemed safe.

What testing methods? You know, the standard for seed purity and seed purity labeling is dictated by the Federal Seed Act and compliance with that lies within the Federal Seed Act and that's what the seed industry follows.

There is a range of testing available for testing GE. We, instead of contamination we talk about it as being adventitious presence, defined as unintended low-level presence of GE material.

What testing methods? One thing you have to be aware of is you have to make

sure you're using accredited labs. These tests, the PCR tests that Zea mentioned earlier, they are very sensitive tests. They are prone to err based on that sensitivity.

And there's types of error. There's sampling error. I don't care if it's 3,000 seed or 10,000 seeds, there's going to be sampling error. And it doesn't matter what the seed size is in that regard in some respects. Certainly there is statistics around that.

The other error is the lab error. When the tests are that sensitive there is an inherent level of false positives in the labs.

For purity reasons the summary I would say is, again, the Federal Seed Act is the standard for genetic purity. Adoption of things like the Association of Official Seed Certification protocols is testing positive for adventitious presence does not prevent an organic producer from receiving a label or certification.

For market reasons if a threshold is necessary certified seed standards might be something to consider. Testing for adventitious presence in conventional organic seed needs to be addressed on a crop-by-crop basis. Sample size would be different. Some crops don't have transgenics.

Studies have indicated the stricter the AP/LLP requirements, the higher the cost of seed production. And that's not just the cost of testing, that's also the cost of producing the seed and inventory cost. And those additional costs would be passed onto consumers as well.

I think a final statement to say is the seed industry, we are willing to keep the dialogue open on this issue as we feel it can lead to a reasonable conclusion for all parties involved. Thank you.

MS. SONNABEND: Thank you. Any questions?

MR. FOSTER: I was looking at the

written public comment you sent in. Does that slide showing the process, the nice flow chart, is that part of your written comment?

MR. LANGER: That is not part of the written comment, no.

MR. FOSTER: That would be a helpful diagram for me to look at again and again, so if there's some mechanism to get that to me or the board I certainly would appreciate that.

MR. LANGER: Michelle has it on her computer.

MR. FOSTER: That would be really helpful. It's -- after this many days it's very helpful to have pictures to look at.

MR. LANGER: Right. I understand.

MR. FOSTER: And then the -- oh. The -- I'll ask you kind of the same question I asked Beth. How do you see a seed purity standard affecting the growers? I know it's not your world necessarily but my concern is organic growers. So how do you see that

shaking out relative to the burden of testing on organic crop producers?

MR. LANGER: Well, I think I understand your question from the standpoint that it would be a consideration if we establish a threshold for seed that it would be the next logical step that somebody might consider there needs to be a threshold for the resulting product from the organic growers. So you know, I can't sit here and say if that would occur but that would certainly come to people's minds I would think, yes.

MR. STONE: certifiers are checking the -- we've heard that some of the previous generations may have had some version of excluded method and as the technology changes our definition of, quote, "excluded methods" may not hold up in the modern world. So there's -- I don't know how to ask the question even of how many -- could there be seed development further up the food chain but then it appears as a organic product by the

time it gets to the producer because of these generational development of seeds? Or is it more direct than what we're being told?

MR. LANGER: Well, I'm not sure I understand your question but if --

MR. STONE: I'm not sure I do either.

MR. LANGER: Let me offer a suggested answer then. But with new research techniques there's things, like you can, genetically you can remove a transgenic event from a product. So things like that. So it was, you know, of course in Europe the issue of "derived from" comes up as an issue as well. So, I mean those type of things.

Typically today in the research process for transgenics, it's a parallel process between our base germ plasm breeding and our transgenic efforts, then our back-cross the transgenic into the base breeding.

So there is -- I know there's been some concern about there won't be any germ

plasm but in fact today there is base germ plasm that does not get exposed to transgenics. Now, eventually a lot of it does with the crops that are involved in the transgenic aspects of the market.

MR. MARAVELL: I have two or three questions but I just wanted to make sure I understood something. You said that if you go back in your parentage and you are indeed using a genetically modified strain to get to your current hybrid are you indicating that that would no longer be considered a genetically modified seed? And number two, did you also say that you can go back and reconstruct, in effect take a genetic event out of a seed line?

MR. LANGER: Well, for labeling purposes as in the Federal Seed Act and the guidelines we have from the trait providers usually in the seed aspects, if it's a transgenic it's labeled as a transgenic. That's the way all those around the label of

any seed that's sold.

I'm saying on the removal of the transgene it's technically possible. If there's a transgene inserted, we know where it's inserted in the genome and you can actually take it out actually through breeding process. Because it's just like transgenic has genetically enhanced whatever and in some respects definition we've been doing genetically enhanced forever.

We've been -- humans have been making selection and characterization and picking out inadvertent mutations for thousands of years. So in some respects we've been doing that forever.

MR. MARAVELL: Could you elaborate a little bit about the additional costs? Many people are looking at this as a testing burden. I guess I should in the interest of full disclosure say that I am a seed producer, organically certified seed producer, corn, soybean seeds among other seeds.

There are many other costs which actually far exceed the testing cost of establishing seed purity. And I was wondering if you could just give your read on those, just give some definition or some description of all the things that a seed producer may have to go through in trying to ensure purity and absence of GMO that would not involve just a testing cost.

MR. LANGER: Right, right, and that's the point is I think the testing would actually be the small cost. In the seed production you'd have to take -- maybe you want to take extra steps to ensure that you would reduce the probability of having adventitious presence. Maybe that is increased isolation distance which would have a cost associated with it. Maybe it's a separate line in your conditioning operation to keep the non-GE or the organic separate from the other. That would have a cost to it. Physical separation and stands to make sure

that things are kept physically separated would have a cost to it.

And I think one of the largest costs actually would be inventory costs. Because if you do the testing and monitoring and you find out some lots do not meet whatever the requirement is then all of a sudden you may have just doubled your cost of production on something for that customer. So I think the inventory cost is actually the largest cost but there is a lot of best practices that have a cost associated with them as well.

MS. SONNABEND: Thank you very much.

MR. LANGER: All right, thank you.

MS. SONNABEND: Our next person is Kristina Hubbard from Organic Seed Alliance.

MS. HUBBARD: Good morning. My name is Kristina Hubbard and I'm the director of advocacy and communications for Organic Seed Alliance. OSA is also a member of the

National Organic Coalition and my comments reflect their position as well.

We are so grateful that the NOSB is taking seriously the threat of GMOs to the integrity of the organic label through the Ad Hoc Subcommittee, through the thoughtful discussion document.

And we also applaud the NOSB's decision earlier this year to send a letter to Secretary Vilsack outlining our organic community's longstanding concerns about, again, the threat of genetically engineered products to the integrity of organic. We believe this is a really important first step since I think we can all agree that the onus cannot and should not remain solely on the shoulders of organic.

While we do have some questions and concerns about some of the proposals I don't want any of my comments to be construed as supporting a do-nothing policy. We fully support the GMO Subcommittee's efforts on this

issue and look forward to supporting your ongoing efforts in any way we can.

Genetically engineered seed has been planted in our fields and sold in the marketplace for more than 15 years, yet we lack a profound amount of knowledge on the state of genetic purity of our seed. And the USDA to date has not afforded the agricultural community a transparent testing and monitoring system that would provide useful data for better understanding the state of contamination in our breeding lines and seed sold as organic.

We hope the NOSB will explore the best way to collect this data, as Zea mentioned perhaps through the ERS, or other means. We believe this data is especially important to understanding the feasibility of a genetic purity standard. And ideally this data would be made available publicly to stakeholders and be accompanied by testing protocols, proven prevention measures and

ongoing monitoring to ensure the access to seed that meets an appropriate genetic purity standard should one be implemented.

On the topic of a genetic purity standard we believe the standard may be warranted in at-risk seed, especially corn, but we do caution against implementing it too soon before some serious questions are examined and explored. We're concerned that what may seem like an easy solution could lead to consequences that we have identified as potential consequences, identified in some questions that we developed and provided in written comments.

We have been talking to a number of stakeholders over the last year actually about the adequacy and again any potential consequences of a genetic purity standard. We are most concerned that the standard should not overly burden organic farmers or discourage the overall growth of the organic industry.

We're concerned about the standard's effect on the commercial availability of organic seed which is also an organic seed integrity issue. We don't want to discourage farmers who are producing organic seed or private firms investing in organic seed production and breeding, or simply lose organic farmers who decide that the cost of certifications are simply too great.

Testing is absolutely necessary. Farmers need access to information about the genetic purity of the seed they're planting to organic systems, but this cannot happen at the total expense of organic farmers and certifiers.

Earlier this year we completed a survey with companies who supply organic seed. The purpose was to start to identify some of the risks that these companies are facing in supplying organic seed and what the state of contamination is in the seed that they're

producing and selling.

I encourage and hope that you read through some of our findings in the written comments. Not only do these findings show more evidence of the problem, they do show some uncertainty among companies about a genetic purity standard, at least putting one in place at this time.

As you've heard today, some companies say that they can meet the standard consistently while others have serious concerns that without safety nets to cover ongoing incidences of GE contamination the financial burden and risk to organic seed companies will become too great.

Thank you for your work on this issue and again we look forward to working with you in any way we can to support your efforts to move this conversation forward.

MS. SONNABEND: Thank you, Kiki. We will take a few questions but understanding that there will be more opportunity to ask

questions of Kiki later when she gives a presentation.

MR. FELDMAN: Thank you. I guess I wanted to put this thing in perspective. And we're talking about seed purity. Can we back up a step and talk about the thinking that you all have done on prevention in the area of -- I mean as Zea mentioned, there was real interest on the part of the subcommittee in terms of identifying preventive strategies and working with USDA and enforcement against what she described as trespass.

How do we go down that road? What can the NOSB do to sort of elevate that issue or advance it in a better way?

MS. HUBBARD: Well, first of all I think we just need to acknowledge that already organic farmers and other stakeholders in the organic community are doing testing at times and taking measures to prevent contamination. In fact, it's mandated through the organic system's plans.

I passed around an article that I recently had published in the peer-reviewed journal Agriculture and Human Values. There are further recommendations in that that point to the inadequacy of the current biotech -- the current regulatory framework for biotech crops as well as the role that the NOP plays in protecting the genetic integrity of organic food.

I know it is not an appealing recommendation but I believe applying further pressure on the USDA to fulfill their obligation to the success of organic means that they have to more fully confront in a meaningful way the issue of contamination prevention. Currently there is no requirement on the part of growers and owners of biotechnology products to prevent contamination in the field.

That said, again I think the NOSB should continue to explore some of the questions that we raised in our written

comments and to engage diverse stakeholders. Seed companies being the primary stakeholders that should be at the table, both those who believe that they are successfully preventing contamination as well as those who are doing their best and despite honest efforts not having a ton of success meeting the standard as proposed in the discussion document.

There is -- all the companies that I spoke with for the survey, the fuel crop companies, do conduct testing and they have internal thresholds. And a lot of times they are diverting seed that exceeds their internal thresholds to the non-organic seed marketplace, taking that financial hit. As we know there is no compensation mechanism in place to cover any of these costs and testing alone for some of these small to mid-sized scale companies ranges anywhere from forty to seventy thousand dollars a year.

I will too say that there is an opportunity for the NOSB to voice on behalf of

the organic community concern with some of the recommendations coming out of the USDA's Advisory Committee for Biotechnology. The AC21 committee has been charged with exploring an appropriate compensation mechanism in instances of economic harm resulting from the unwanted presence of genetically engineered material.

Unfortunately their recommendation worsens the status quo by saying organic farmers should purchase crop insurance to self-insure against potential harm. I believe it's a really important for this board to weigh in on that discussion as well.

MS. SONNABEND: Okay. Thank you, Kiki. I'd like to use our remaining few minutes to ask if the board, especially those who are not on the committee to already discuss this have any discussion points they would like to bring up on the discussion document.

Thoughts for our committee,

subcommittee, to move forward. Anyone? No. Then that concludes the presentation of the GMO Subcommittee and we look forward to our future work.

DR. GRANATSTEIN: Thank you, Zea. We'll take a break now and we'll return at --

MS. SONNABEND: Michelle is asking to hold a minute. Do we have another commenter? Sorry.

MR. KITTREDGE: Hi, I signed up outside on the table and I guess nobody got that.

MS. SONNABEND: Okay.

MR. KITTREDGE: My name is Jack Kittredge. I'm with the Northeast Organic Farming Association, Massachusetts chapter.

I want to first thank you for visiting in New England. It's very nice that you have come and I'd like to -- I know some of our farmers and representatives of NOFA will be here to speak with you.

We represent a somewhat unique

region in that our farming is at a very far different scale for most of us. We represent farmers' markets, farm stands, CSAs. We're not talking about the major kinds of crop production acreages but rather small high-value crops.

But we are very much concerned about this issue of genetic modification. We think that already in some areas farmers have dropped corn, for instance, as a product because of the issue of contamination. There is already some corn and soy production in our region that we're concerned about.

We're much more concerned about the developing line of crops that are going to be directly modified we believe that are in the pipeline now and that will be increasingly of concern to our farmers who are producing these high-value crops. As these genetically modified crops become available and contamination takes place, and we do believe it's contamination because we do not believe

there's effective regulation of health and safety at the federal level. So it is contamination or pollution in our minds.

The primary way that the current level of genetic modification is affecting us is through animal feed. We find increasingly there is a local agricultural movement that is strongly supported by our consumers and we're glad to see that. But a number of those producers say we would love to be organic but we cannot afford to buy organic feed and therefore we're going to have to buy local feed. And it turns out that of course much of that feed is GMO. And so for us this is becoming a life or death issue at that level even before the new variety issue becomes more apparent.

In terms of solutions we think that obviously testing by farmers is not a realistic thing, especially in our region where farmers are very small. They're going to drop those crops long before they're going

to be able to afford testing. I agree with Kiki that insurance is not realistic. I would love to see the NOSB speak out against that insurance plan and against the whole idea of coexistence with GMOs which we believe is not realistic.

Some of the things that would be helpful that the USDA could do, maybe some random testing by the USDA of different kinds of crops and samples so that we could get a sense of where we are in terms of the level of threat. Identify contamination sources. Set up some protocols to deal with that. Develop compensation schemes that are in fact realistic and enable small farmers to deal with these problems. One of our members once suggested if GMOs are like pesticide contamination why shouldn't we license GMO farmers and they should be trained so that they can plant things properly instead of contaminating their neighbors. Interesting direction.

But probably the most important realistic thing that USDA can do is help in developing non-GMO seed varieties, and we would like to see as much energy put in that direction as possible because ultimately we are going to have to have seeds that are developed and bred for organic farming purposes. So, thank you very much.

MS. SONNABEND: Thank you. Are there any questions from the board?

MR. FOSTER: No surprise here. Amongst your grower community is there awareness or concern or discussion over the cost that establishment of thresholds might have for them? Is that part of the dialogue? And if so, what's the -- can you capture that?

MR. KITTREDGE: Yes. Very little in Massachusetts. We have virtually no farming of this nature. A little bit more, some of our other states, Vermont, New York have more serious grain crop farming operations. But in Massachusetts there has

been none really.

MS. SONNABEND: Okay, thank you. Now we conclude the presentation of the GMO Subcommittee.

DR. GRANATSTEIN: Thank you. That concludes the GMO presentation. We'll take a break and return at 9:20 and begin the Crop Subcommittee discussions.

(Whereupon, the foregoing matter went off the record at 9:08 a.m. and went back on the record at 9:31 a.m.)

CHAIRPERSON FLAMM: We're now back in order. The next session will be Crops Subcommittee and I'll turn the gavel over to the subcommittee chair Jay Feldman.

MR. FELDMAN: Thank you, Barry. Just to lay out the process for everybody we have a number of materials we need to get through. And we've allocated -- and this is for the board specifically just so you know. We've allocated 13 minutes for every material that we'll be discussing, 5 for presentation

and 8 for discussion except for bioplastic. We've left 10 for the presentation and 12 for discussion.

Now, remember we have a lot of witnesses today so we'll have more time to discuss with the witnesses. But just, we're going to be moving at a pretty quick clip here. And I apologize in advance if I have to interrupt you so that we can move this thing along. Because when -- we don't want to stand between these folks and lunch. That's always a problem for us.

Okay, so the first material, Carmela is going to lead us on ferric phosphate. I'm sorry, I need to recognize Lisa first to explain the petition and the background on this. Thank you.

MS. BRINES: Thank you, Jay. Yes, the first petition on the agenda for the Crops Subcommittee today is ferric phosphate. This petition was received on July 7, 2009 and was submitted by Steptoe & Johnson.

The petition requests the removal of ferric phosphate from Section 205.601(h) of the National List. It's currently permitted as a slug or snail bait.

There's three pieces of technical information that's available for this petition substance. There was an original technical advisory panel report prepared in July 2004 in response to the original petition to list this material.

And there have been two additional technical reports since that date. There was one prepared in 2011 and then a supplemental technical report that was prepared and available in 2012. Both the petition and the three technical reports were available and posted on the NOP website in advance of the opening of the public comment period.

There was written comment received in response to this proposal and the petitioner is signed up for in-person public comment as well. Thanks.

MR. FELDMAN: Thank you. Carmela.

MS. BECK: Okay, so the Crops Subcommittee recommends to vote down the petition to remove ferric phosphate from the National List. The generic active ingredient, ferric phosphate, needs to be considered separately from any other ingredient, either active or inert.

The supplemental TR addressed four questions that are posted on the screen. And I'm not going to go through the questions or the answers as most of you have probably already read those. So I'll jump straight to the public comment.

The total in favor of maintaining the listing of ferric phosphate were 26. Of those 26, 17 were farmers, 4 were consumers and 5 were organizations.

Those in favor of keeping ferric phosphate on the National List cited the following reasons. One, research has shown that ferric phosphate by itself does have an

effect on snails and should not be prohibited because EDTA is questionable.

Second, EDTA is an allowed list for inert per 205.601(m). Three, the Inerts Working Group will determine inerts policy within the next 5 years. Four, currently there is no process in place to add or remove allowed inerts.

Five, in 2010 the NOSB re-listed the EPA list for inerts until 2017. Six, in 2010 the NOSB re-listed ferric phosphate on the National List.

Seven, essentiality. Eight, that there is a real lack of effective practical alternatives. And the last reason cited was that there's a large potential for detrimental economic yield and ecological consequences if the product is removed.

The total in favor of de-listing ferric phosphate was 11. There were zero farmers, nine consumers and two organizations.

Those in favor of de-listing

ferric phosphate cited the following. One, lack of essentiality. Two, incompatibility with organic agriculture. Three, availability of cultural practices and alternative control measures. Four, the TR documented a negative impact on earthworms and soil organisms.

The ARS report and supplemental TR responses supported the petition's reasons for removal. They state that the argument is that due to the 2007 sodium hydroxyl EDTA petition, due to the fact that that was denied by the NOSB the same argument should be carried forward and that the NOP should now prohibit EDTA in all organic formulations.

The commenters feel that the NOSB can't wait on the Inerts Working Group for forthcoming recommendations. In line with the Crops Subcommittee minority opinion ferric phosphate is not effective alone. It must be combined with a synergist such as EDTA to function.

I'm going to go ahead and let Zea

continue the conversation.

MS. SONNABEND: The majority of the Crops Subcommittee did vote in favor of maintaining the listing of ferric phosphate. And truthfully for me as well as a number of the others in the majority the key reason has to do with proper materials review, procedures and protocol. It is not the right thing to remove an item from the list because something else that might be used with that item is a problem. The correct thing would be to put an annotation on that so that it could not be formulated with the other thing if it's shown to be a problem.

The key question here then boiled down to -- and there was a lot of -- if I want to say red herrings and unclear information because both sides tried to impress us with volume in their comments I would say. And it was hard to drill down through everything to get to what the key issues were. That's one of the things that took so long. And also to

try and get some unbiased information.

So the key thing here is whether ferric phosphate belongs on the list by itself because it does have an effect against snails and slugs. And there were three studies that did show that by itself it had some activity.

One of those studies was very hard to find because it had been redacted when it was first sent in as the comments. And the whole study was redacted even though only one clause of it actually was the confidential information. So we did finally get that study after the docket closed and it will be posted into the docket after the meeting I believe.

And that study as well as the other two showed clearly that the ferric phosphate by itself had some activity against snails, more activity than either EDTA by itself or nothing, the two controls. But there's more activity when the ferric phosphate is combined with EDTA, but that doesn't mean that without EDTA it doesn't have

some activity.

So, because we are going to be reviewing EDTA in our proposal on inerts that we'll be talking about in a few minutes, and that review can happen within the next 3 to 5 years the majority of the committee felt that ferric phosphate should be kept on the list. Thank you.

MR. FELDMAN: Board discussion. Any questions? Calvin.

MR. WALKER: The TR. My question is how was the additional information not in the TR. Because there seemed to be a lot of information that came afterwards.

MS. SONNABEND: In 2010 when public comments were accepted on this quite a bit of the attachments were redacted as confidential business information. Typically the TR contractor does not have access to the redacted information nor do we. And therefore when we asked for a supplemental TR and we asked them to review all the new information

that was submitted they could only review the information that was accessible to them, and that's how it got missed. And similarly the ARS who we asked for a further objective opinion, they had access to otherwise of the three studies, but not the third one.

Clarification from Lisa, I believe.

MS. BRINES: Yes. For the supplemental technical report, the most recent one, the contractor did have access to the confidential business information from the original petition as well as I believe the second petition that came in to remove it. Thank you.

MR. FELDMAN: Other questions? I'd like to just make a quick comment on this because I sort of led the charge on the flip side of this. And just to point out that we did do a supplemental TR on this question of the active properties of EDTA.

And this is where there is

disagreement. Obviously the manufacturer of this product claimed that the ingredient that is at issue here was an inert, or is an inert ingredient. And this board has previously denied this product as an active ingredient. It was applied as an active ingredient. And the TR, this is sodium hydroxyl. And the TR supplemental indicated that yes, in fact these were the same materials.

So really what this comes down to is that there is a difference of opinion as to whether this actual product formulation can work, can have efficacy, without the use of this particular ingredient as -- because of its active properties.

Having said all that, Zea's correct. We will be evaluating this material one way or another. We'll either make a choice on it today or we will do it through the inerts process. So I think that's an important point to keep in mind as you think about this and ask questions of the

commenters. Just, that's a clarification and hopefully you feel it's accurate. Okay.

So now we'll move on. Unless there are any other questions on that we'll move onto the next material on the list which is oxidized lignite. Zea will be managing this and we'll turn first to Lisa on the petition.

MS. BRINES: Thanks, Jay. This petition was received on June 22, 2011 and was submitted by SHAC Environmental Products Incorporated.

The petition requests the addition of oxidized lignite to Section 205.601 of the National List for use as a soil amendment. There is one related listing currently on the National List regarding this particular product because it is a humic acid derivative. There is a current allowance at Section 205.601(j)(3) for humic acids, naturally occurring deposits, water and alkali extracts only.

In its review the Crops Subcommittee did request the development of a new technical report in response to the petition. There are also two previous technical reports available that were prepared, previously prepared in response to the existing listings for humic acid, most recently from 2006 and one from 1996 for the original review of humic acid derivatives. Thank you.

MR. FELDMAN: Thank you. Zea?

MS. SONNABEND: Thank you. This one was somewhat confusing to us as a committee at first because it was unclear how to exactly list the product. Although commonly called oxidized lignite by the manufacturer and others there is a truly non-synthetic oxidized lignite that can occur in nature in the process of humates being oxidized by natural processes.

And we didn't want to create a listing that would somehow interfere with, be

confused with a non-synthetic listing for something that does appear to be synthetic. So the product in question was created basically by taking the natural humates and treating them with hydrogen peroxide. Hydrogen peroxide is on the National List by itself and does serve the function of an oxidizing agent, and creates a more readily available humic acid derivative.

And so it was decided that instead of putting oxidized lignite on the list we would call it another humic acid derivative and propose the language that adding to what is already in the rules which is humic acids naturally occurring deposits, water and alkali extracts only, and adding to that water, alkali and hydrogen peroxide extracts only. And this would be the clearest listing for everyone to be able to work with.

That being said we looked at our OFPA and we looked at the rule and while this material may in fact be preferable to the

alkali extracted humic acids because it doesn't -- the hydrogen peroxide leaves only behind hydrogen and oxygen, but while the alkali extracts leave behind excess synthetic phosphorus or potassium. It was felt that there was no real category in the exemptions in OFPA to put synthetic fertilizers onto the list, and therefore the committee -- Michelle, can you scroll down to the committee vote? Because I can't remember what it was. But we did not decide to put a committee recommendation forward to add this to the National List. Three yes and five no, thank you.

The public comment consisted of comments from the manufacturer and then a few people who I didn't think were growers saying that they didn't want more synthetics in agriculture. And I didn't see any comments from growers saying that they wanted or needed this material except one from OGC that said they thought this was a preferable material to

the extract. But while they represent some growers who are their clients they are actually a handler.

MR. FELDMAN: Thank you, Zea. Questions? John.

MR. FOSTER: So my question is around the ability to list synthetic fertilizers. And to what degree -- I wasn't part of the discussion on this, unfortunately. To what degree was the discussion focused on whether this extract could be categorized as a fertilizer versus a fertility input or a soil amendment? How was that discussion handled or was it?

MS. SONNABEND: Well, we did discuss that in general but there's no category for soil amendment or fertility input either. And you know, my personal opinion, and I'm stepping aside from the committee here, but this appears to be way more benign in general than other alkali derivatives. So in a perfect agronomic world I would want this

but I just don't see from an interpreter of the OFPA and the federal rule how this could be added.

MR. FOSTER: So, is alkali extracted humic acid? So help me understand that rationale.

MS. SONNABEND: That also is no category for it but we weren't on the board when that was put on.

MR. FOSTER: Okay, well -- okay. But someone was on the board when that passed.

(Laughter)

MR. FOSTER: So.

MS. SONNABEND: I was in the audience. I remember it.

MR. FOSTER: So, I mean, I understand you don't want to throw good money after bad, for example, but if -- I'm going to go back to one of my old saws is if we have the opportunity to list a preferable material it's hard for me to say no to that when we have the opportunity. I mean, it sounds to me

from your comment as well as others this is clearly a preferable material to the alkali extracted. Alkali extracted is on there. It's really hard for me to say no to something that's better.

MR. FELDMAN: Other questions? Thank you. And we'll get a chance to ask questions about this as we proceed here.

The next material is propylene glycol monolaurate. We refer to it as PGML. So Lisa, if you could cue that up. Thank you.

MS. BRINES: Thanks, Jay. The petition for PGML was received on April 24, 2009, and was submitted by the Technology Services Group Incorporated.

The petition requests the addition of propylene glycol monolaurate to Section 205.601 of the National List for use as a miticide and acaricide.

In support of the review of this material the Crops Subcommittee did request the development of a technical report. The

report was developed and both the report and the petition were posted on the NOP website in advance of the opening of the public comment period. Thanks.

MR. FELDMAN: Your voice was trailing off at the end there so I know it's a lot to --

MS. BRINES: I'll get closer to the mike. Thanks.

MR. FELDMAN: Thank you, Colehour, for leading us on this.

MR. BONDERA: Very good, thank you. I hesitate since -- is it going to be up on the screen, Michelle? Yes.

So, propylene glycol monolaurate (PGML), petition to add it to 205.601(e) is the topic. And PGML is petitioned as an acaricide which is a pesticide that kills members of the acari group, ticks and mites.

The petition states that the PGML is, quote, "a broad-spectrum antimicrobial agent to control fungi and bacteria that cause

decay of post-harvest fruit and vegetables."

So we did go through the process and Crops Subcommittee members were to some degree divided. And those that were in support of PGML I summarized their thoughts into these three.

While there are other organic options they are very sporadic in their control. The impact of crop quality and the potential environmental impact when using the alternative materials can be somewhat of a concern as well. And then third is we can give organic farmers another tool that is better than those they currently rely upon if we can properly look at the risk-benefits.

The majority of the Crops Subcommittee opposed the petition and said that it is not needed as it can be substituted with alternatives, including cultural practices as well as biological controls; that the other options do not have the impacts on human and environmental health; that the

environmental impacts leave more damage overall than the benefit; and that as a synthetic product and tool designed for non-organic agriculture this material is not consistent with either organic or sustainable production systems because it is a broad spectrum and affects beneficial predators as well as the target mites.

So, commenters are opposed to listing of PGML, saying things such as PGML kills natural predators that control the mite pests, that it reduces biodiversity on organic farms, that its manufacture is fossil fuel-dependent, that it is not essential and may actually exacerbate problems, and that it's incompatible with organic production because it's not in any allowed category of synthetic input and is a broad-spectrum pesticide.

And in summary our classification vote and our listing motion vote were such as you see there. Like I said, we were divided. It was two people in favor and six opposed on

listing it. And that's all I had. Thank you.

MR. FELDMAN: Board discussion. That gives me more time for inerts. Thank you. Okay.

I will cue this one up since it's not a petitioned material. Oh, thank you. Thank you, Michelle.

Let me run through this PowerPoint. We are -- obviously we as a community have addressed this issue for many years, the policy and procedure proposal for inert or so-called "other" ingredients in pesticide formulations on the National List.

So, by way of background, and Zea will be helping me with this, or feel free to chime in at any point since she was so instrumental. We'll get to the committee and who all worked on this. But as background we're dealing with inert ingredients and as all of you know I hope we have a definition for this. And it goes back to the EPA definition as well. So the definition on the

screen here is both the definition for inert and active and how they are distinguished.

What is clear to us all as a community is that the word "ingredient" in found in both of this and that's what is driving this process on the one hand.

The statute, the Organic Foods Production Act, has identified inerts of toxicological concern as a focus for us here. And so typically what we've looked at in the past are the lists 4(a) and 4(b) eventually, a category of inerts that were allowed as a group by -- under the National List in addition to list 3 inerts that were allowed in certain pheromone dispensers.

The other element that's driving this process besides a concern about inerts generally -- or ingredients generally is the fact that EPA decided that it was no longer going to maintain a list of inerts. So that left the NOSB with somewhat of a problem in terms of what it would do if it couldn't

reference an EPA list that was kept up to date.

So as a result of all this we formed the working group with NOP and EPA and NOSB. And that group met for a couple of years. Zea joined the group last year when she joined the NOSB. And we brought a discussion document as you recall to this body back in the fall of 2011.

The Inerts Working Group developed this proposal which as a matter of process went to the Crops Committee which then brought the proposal or the discussion document to the board. And we summarized the results of that discussion document at our spring meeting.

So this is what we're proposing today, basically a road map for beginning this process of inerts review. The concern of course was that this was an overwhelming task and there were a lot of materials. So part of the role of the Inerts Working Group was to figure out what the scope of this project was

and whether it was feasible, in what time frame and so forth.

So, we -- our goal here as we're proposing it today is to put together a road map that would address the requirement for review under 205.601 which is crops and 603 which is livestock as these materials move through the process and as they affect the allowance of materials on the National List.

So this is what we're proposing in terms of both the working group and the Crops Committee. This is coming to you with unanimous support from the Crops Committee. New regulatory language, a series of steps to use in preparing for inerts reviews, screening guidelines that the technical reviews will address, a tentative list of groupings that will allow us to address multiple materials in groups because of common mechanisms of effect and so forth. And then a rough time line of how we would review and complete that process.

The new regulatory language would

fit, as I said, into 601 and 603 and establish a review for substances permitted for use in minimal risk products. This is a category that EPA uses under its Federal Insecticide, Fungicide and Rodenticide Act Section 25(b) and then a reserve list of approved or other ingredients. So that simply replaces what's in our language currently which is in the document that you got, the committee document.

MS. SONNABEND: The procedure includes several steps for review, grouping the chemicals into clusters -- and we've given you some examples of where we are at now but we aren't done with the groupings. Full group listing including chemicals to be presented in spring 2013. Anticipated that four to six of the clusters will be evaluated each year with TRs and committee review of the TRs. Manufacturers will have time to identify ingredients in use that are not on the list to request review. And after completion of this process new, other or inert ingredients must

be petitioned.

MR. FELDMAN: Okay, so the proposed procedure includes the NOSB working -- continuing to work with the Inerts Working Group to finalize the proposal. The NOSB will rely on the working group to consult with OMRI and WSDA, the Washington State Department of Agriculture for updated inert lists.

The NOSB will request that NOP investigate and adopt within 6 months of the announcement of this proposal which would be the spring of 2013 the appropriate mechanism for notifying manufacturers. And the NOSB would request under this proposal that NOP commission one TR per group except where noted and coordinate review with the board.

And the NOSB again would request that the NOP determine an appropriate format and commission a special inerts TR for each group. And here's, you know, this is delineated in the documents you have. I'm not going to read all this but these are the steps

that we would go through.

And based on the results of the TR the NOSB Crops Committee would accept these groups to move forward to the NOSB agenda or single out one element or one formulation, one or another formulation or material that was needed for individual review.

The NOSB working with the working group will prioritize and order the reviews considering based on a priority system that looks at the most problematic first and then works through those that are used most often in organic production, et cetera.

And then this would be part of our priority system, having a screening process where we're trying to elevate to the head of the class those materials that go through the screen of highly toxic or ECOTOX or, you know, indicative of some problem that we would consider a concern when it comes to hazard or adverse health effects.

These are the proposed clusters.

Right now we have, for about 126 inerts we created 16 clusters. As noted by OMRI one of those is a non-synthetic cluster. Why is that on there? Well, it was one of the inert materials that showed up so we figured we'd put it on the list. We probably don't have to review those. If they're non-synthetic materials we don't have jurisdiction over those unless they end up being ones that would be natural that we would think we would need to prohibit as we'll be discussing later like with rotenone. But these are the categories, alkali alcohol, alkali alkoxylates, I'm not going to read them all. I'll let Zea read them all. But -- I can't read them all.

The public comment, 17 supporting. We had one that was asking for clarification, asking whether we really needed to look at 25(b) at all. There was this massive influx of organic consumer association sign-ons to a petition which was nice to see at least in terms of public involvement.

Those supporting the proposal say the review of inert ingredients is overdue. We've heard that for a couple of years. I mentioned OMRI pointed out the 14 non-synthetics. Wolf and DiMatteo stated again as I said earlier that the 25(b) review is not necessary and we'll be hearing from them later.

There's some commenters who expressed concern, and this is coming from, you know, everybody has concern about the time line, will it work. That's why this is a procedure. During this procedure one of the elements as I mentioned earlier is to assess the viability of meeting the time frame.

And then Wolf DiMatteo said it would be helpful -- this is a useful comment -- to include in this recommendation the list of 126 individual inerts so that pesticide formulators would be notified in advance of the decision of the NOSB, so they know it's coming.

And then once we go through this procedure if it's adopted by the board we'll finalize a procedure by the spring meeting in 2013 to review all these things. We'll see if it still looks like we can meet this schedule by the 5-year sunset period that we have to align with which is 2017 for the sunsetting of the inert ingredients in the list 3 of pheromones and pheromones in dispensers.

So that's our plan, that's our proposal. I neglected to thank the NOP, Emily and Lisa for their work on this. And the work of the EPA staff, Chris Pfeiffer and Kerri Leifer. Everybody put an extraordinary effort into this. A lot of information had to be evaluated and we all appreciate it very much.

Any questions? Yes.

MS. RICHARDSON: I'm not on Crops Committee so it's sort of mind-blowing the range of things that you're going to try to do on this topic.

And so what I'm sort of interested

in trying to understand is really probably just to get the perspective of NOP staff on the feasibility of being able to deal with such a large number of inerts in such a relatively short time line.

MR. MCEVOY: Yes, we've looked at this. We are concerned about the resources that we would need to commit to make this happen and the time frame. But we do need to look at these inerts. They're in the list 1, 2, 3, 4, the EPA list of inerts is being maintained. It just seems like the best proposal in terms of moving forward. And so we support getting on with this project and let's see how it goes.

The technical reports are probably going to be a lot more complicated than ones that have been done in the past on single substances. So this is very technically complex but we support moving forward. Let's give it a go and the part that is really important that's part of the proposal is that

there's a reassessment how it's going I think, what is it, a year into the process to see whether or not the process needs to be tweaked or the time frame needs to be modified to get through all these substances.

MS. SONNABEND: Thank you. Partly in response to Jane I think that while the NOP has concerns, they have indicated that they will be willing to do it. The truly scary part of it is that you and I as board members are going to have to be looking at and voting for a lot of things that are like oxy-, loxy-, epoxy-, -ethoxylate that we can't even pronounce. And if we don't put them on it has grave impact.

We're going to have to do this without knowing which products they're in probably with a few exceptions, and the outcome will have grave impacts on the industry. And so that's the part that for me is the hardest thing to grapple with but we are going to have to come to terms with that.

MS. RICHARDSON: So I want to follow up that then, Zea. It's that I know they're all inerts and therefore they just, they do nothing, they just sit there, right? So, I would like to be sure that when we get this scientific technical report coming in that we really do ask them to address synergy and synergistic impacts. Even though we're not looking at individual products we do need to understand the interactions and know, I mean, a huge amount of detail really to make a logical decision.

MR. FELDMAN: One thing we're going to have to grapple with along those lines is the limited information that is often available on a lot of these materials. And that's just a fact of life. Synergy is one category of very limited information. So I appreciate that comment.

MR. FOSTER: So, didn't we just hear that we probably will be -- well, maybe not me but the board will be looking at these

materials outside of the context of each formulation? So then the synergy question becomes pretty much impossible. If you don't know the context you won't know the synergy. So I know that's a vigorous head-nodding from you, Jay.

MR. FELDMAN: It's true.

MR. FOSTER: And it is of concern but if that's the realistic context or lack of context that we have then that better be an up-front kind of agreement or common expectation we should have on that. Otherwise it's not going to be a functional deliberation.

MS. SONNABEND: Yes, that is true, John. One of the things that I've been grappling with is I would really like to give some incentive for those companies who do choose to disclose what their product is that has those inerts. And some companies are willing to.

And for the ones who disclose it

would be nice to give them some incentive like getting their thing reviewed faster, or some other way to say okay, if you disclose we can review it better because we know what all the inerts are.

But that is one detail that while I put in many drafts of our proposal we couldn't really figure out what to say about it. But we will have a call for voluntary disclosure I'm sure in the process of doing this.

MR. FELDMAN: Thank you. Other questions? Okay. Oh, I'm sorry. Go ahead.

MR. MARAVELL: Sort of to follow up on Jean and John's comments here. You don't see a subsequent time period? That's the wrong word. You don't see a subsequent process of review where these questions of the synergies will eventually come to light?

MR. FELDMAN: This is a systemic problem that we have in terms of the proprietary nature of this data. That is why

it falls into this inerts category as you know because manufacturers have been protected, their proprietary interests have been protected.

Hopefully as Zea says we'll get to a point in time where the organic community believes and the manufacturers associated with it that full transparency of product ingredients on a formulation basis does not hurt their proprietary interests and that it's in the interest of public understanding and the transparency of organic that we will have full disclosure. At that point we can do this, John.

And I think in many cases, you know, we have done this. OMRI has done it under a protection clause. There are ways to get around this. There may be some creative ways down the road where the board can envision having the ability to review these things with some protection for the manufacturer if they feel there are

proprietary interests.

But to answer your question, Nick, there is no way around that. The law provides in the registration process for disclosure now -- for non-disclosure.

Now, having said that full disclosure is required on 25(b) products. And if you take the position that most manufacturers involved with organic are moving toward the 25(b) category they must disclose all ingredients on the product label. So, that's the silver lining in all of this and if we drive products toward the 25(b) list we will have full disclosure.

MR. FELDMAN: Thank you all. We'll move on to rotenone. And Zea is going to cue this up because there was no petition involved in this process.

MS. SONNABEND: We certifiers and others in the industry have kept getting questioned about rotenone since it's been in the news a lot lately as more and more studies

come out that show a link between rotenone and Parkinson's disease.

I feel our posted document goes into the regulatory history, how the EPA short of recalling it has accepted a voluntary cancellation of the uses in the United States. Because much as we would like to be aware of the whole world, but mostly we have to be focused in United States policy we decided it was time to take this up again. Also, the OFPA calls for a special review of botanicals before creation of the National List.

This review was done in 1994. I was there for it and helped prepare for the review. At that time a lot less was known about rotenone than is now and there was no clear link to health effects.

In the course -- while the transcript of the meeting doesn't say this, but in the course of researching this paper we found a statement from the board at that time requesting from the program that the

botanicals have a special review every 5 years.

Well, a little time has passed since 1994 and we're only getting around to re-review of one of them at this time. In the re-review we have presented some of the more recent literature. And it's important to note that this literature shows a very strong link between rotenone and Parkinson's disease for the applicators and the people who are in contact with this material. It does not show any residual so there's no danger at all of a consumer eating something that was sprayed with rotenone and being exposed to the hazards that lead to Parkinson's disease.

However, we couldn't in good conscience leave something as allowed that had such a clear health effect. And so the committee is proposing adding it to the prohibited natural list in Section 205.602.

The public comment, we received relatively little public comment. Three

people wrote specific comments against it, against rotenone. I think we can infer from all the comments that said no synthetics in organics that they might extend that to natural products that were shown to be hazardous and we didn't count those but there are quite a few of them as you know.

And then we heard from banana growers who it turns out we hadn't realized this but it is commonly used in bananas in many countries in Latin and South America. We got four comments in from banana growers, one of them representing 57 growers in Ecuador, 100 growers in Ecuador, thousands of growers throughout Latin America and one family from Peru.

All of these expressed the issues that there's no other control for thrips that cause a staining on the fruits that make them unmarketable, and that their main control at the moment is alternating rotenone product which is made in the countries in which it is

used with pyrethrin products. And they stated that they do this to avoid building resistance to either one of the products.

So, in response to this concern we started looking into what alternatives there might be at least in this country, recognizing that these alternatives might not be available or might not work or be researched in the other countries.

But we found that as far as this country goes controls for thrips include Entrust which is spinosad, Ryania, another botanical which has recently been -- the formula changed hands and the new company intends to expand the label so it may be labeled for more uses than it is now. Organocide, SucraShield and then some thrips are susceptible to oils. Numerous parasitoids attack thrips and some generalist predators like minute pirate bugs, six-spotted thrip and lacewing.

Also, we heard from an expert that

there has never been reported resistance to pyrethrin as they contain six different compounds at least that are toxic to insects and thrips and therefore have six modes of action to the insects and so they have not been able to mutate for it.

So, we realize a couple of things. We realize that all of these things we mentioned may not be available in the countries where the bananas are grown, but this is a fairly long list and so some of these things could start being researched and start trying to determine what the alternatives are.

And we also realize that unlike a regular petitioned item we kind of sprang this on people fairly quickly. When something is petitioned there's usually at least a year in which you're aware that the petition is in progress and in TR and like that.

And so the Crops Committee is going to consider amending our motion so that

it would say to add rotenone to the National List 205.602 as a prohibited natural substance to take effect on January 1, 2016. This will give 3 years for the potential research and development of alternatives. The Crops Committee did not feel that we could not prohibit it based on the very large volume of research showing it has a link to health problems. Thank you.

MR. FELDMAN: Thank you, Zea. Board questions?

MR. MARAVELL: Zea or Jay or the program may want to respond to this. Given our normal process of making a recommendation to the NOP and having a rule finally implemented what's the likelihood that a final rule would be issued before the proposed phase-out date anyway? In other words, is the phase-out date fairly consistent with what might occur in the natural rulemaking process?

MR. MCEVOY: Well, the phase-out date is for use within the United States and

rotenone is not as far as we know being used on organic production in the United States. So we're talking about banning it for organic production where it's used in foreign countries. So, the phase-out date and the ban on the use of rotenone in organic production is not directly related.

MR. FELDMAN: Okay, that's helpful because my question is if this board adopts allowable materials, you know, in this case a prohibition on a natural, doesn't that affect all USDA certified, all labeled products whether it's domestic or international?

MR. MCEVOY: Yes, that's right. It would affect all products that are produced under the standard. Whether they're produced domestically or in a foreign country they have to meet the same requirement.

MR. FELDMAN: Okay.

MR. MCEVOY: Yes.

MR. MARAVELL: My understanding, and I could be wrong here, is that with the

voluntary cancellation that any existing stock of rotenone sort of still in the stream of commerce, still on the shelf is still permitted to be used or am I incorrect?

MS. SONNABEND: We received information from the EPA fairly recently that the existing stock had been used up as of August of this year. This has been going on for several years now. And one of the citations showed a 2011 survey that showed some still on the market but as of 2012 it is now all gone.

MR. FELDMAN: But if a certifier shows up, Nick, or an inspector and somehow somebody -- you know, EPA doesn't know what's in everybody's barn, right? Somehow somebody has this stuff it wouldn't be illegal unless it was prohibited. It would not be illegal. The existing -- there's no stop-use date in other words.

MR. MARAVELL: Right. So, I'm just thinking of farmers. So there is going

to be a specific date. Let's just say -- I don't use rotenone personally, but let's just say I was a farmer and I had rotenone tucked in the back of my barn. There would be a date though after which I would not be allowed to use it if it were still in my possession. Am I reading that correctly?

MR. MCEVOY: If we put it on the National List as a prohibited natural then it would not be allowed as of the date that it became a prohibited natural substance.

MR. MARAVELL: And by specifying that date now we're giving people notice.

MR. MCEVOY: Right, but it still has to go through the proposed and final rulemaking process. So it would not become final until there was a final rule that put it on the National List as a prohibited natural.

MR. MARAVELL: And I guess my question is are we doing it right here, Miles? Do we have an appropriate date given how the regulatory process sort of lumbers through the

bureaucracy if I can be so blunt?

MR. MCEVOY: Yes. We think we could get it completed by January 1st of 2016.

MR. MARAVELL: Thank you.

MR. FELDMAN: Zea.

MS. SONNABEND: Just to supplement that. Oh, Melissa, do you want to go first?

MS. BAILEY: Just wanting to jump in here. So, just for clarification. So if the board makes a final recommendation here at this meeting we have that recommendation. Say we begin our rulemaking work which as you know takes awhile. January `13, so we plan 2 years for proposed to final rule. I'm just working out the time line here. So we have a final rule in place by January 2015. That would give a 1-year notification to those foreign operators who might be using this for basically coming into compliance with that effective date if that makes sense.

MS. SONNABEND: This is what I was just about to say also. We chose that date

because it's comfortable enough for the NOP to go through rulemaking and yet unlike not putting a date in there it gives a time certain right now for the users to start getting ready to expire. Because if we just put when it's done with rulemaking that takes variable amounts of time and is not as clear to the end users as if we put a certain date in it.

MR. FELDMAN: Other questions? John.

MR. FOSTER: So I think that the -- I think the health information is pretty compelling actually and probably is going to sway me on this. As you all know I'm not a big fan of taking tools out of the organic grower's toolbox. I think this might be a reasonable time to do that.

But just for -- to make sure it's on the table as part of the discussion. I'm not sure I like the optics of 15 North Americans telling what South Americans can and

can't use in production right now.

And since it is not through anyone's fault, it just works out history is such that it's used there. It's pretty important it sounds like for some things there. I just don't want to let the conversation go on without recognizing that this is one of the outcomes when organic becomes a global thing.

And back in the day when regulations, certainly the precursors to the regulation and precursors to OFPA were in discussion this really wasn't part of the thought process in like 1982 for example. So this is one of the outcomes of having a lot of success. And I don't want to let that moment pass without recognizing that with that success comes some much more hard decisions to be made. This is one of them I think.

And I didn't want to let that moment pass. I think it's important to note particularly with respect to various

anniversaries coming up right now that these are bigger questions, they have more global implications and we should recognize that. That's all.

MR. FELDMAN: Jennifer?

MS. TAYLOR: I'm wondering, Zea and Jay, if in your review of the literature were you able to determine if the letters that were coming from representative countries in South America, if they were aware of the health risk to the users.

MR. FELDMAN: You know, they saw the same public documents that we see here so we're assuming they were aware of the literature which was cited in the document that we put in the Federal Register, or published. But I didn't see any comment on the health effects.

MS. SONNABEND: Well, yes. All of the commenters said we have not seen any health effects from it. But that, I believe we'll have at least one commenter on this and

maybe it's a good question to ask them.

MR. FELDMAN: Nick was just saying we're talking about a chronic, long-term effect.

John is raising really important points I think that really serve as the basis for a larger discussion especially as we all recognize we live in a global economy. And of course we know that the program is constantly dealing with international agreements and trying to create uniformity across those agreements.

We, you know, I hope we have an opportunity to explore the issues you've raised in more depth when we have more time. But bioplastics is awaiting, so. Any other discussion? Yes.

MR. STONE: I just want to make sure kind of along that line of importance that John raised that we sort of arbitrarily picked 3 years because it's a year after rulemaking. But if the industry is having

trouble with alternatives that they have time to adapt and it doesn't arbitrarily pull the rug a little quicker than they can adapt.

MR. FELDMAN: Are you suggesting another time frame? We can ask the representatives. Yes, great. Thank you. Any other questions? Okay.

Sulfuric acid is up next. John is managing this and we'll hear from Lisa first on the petition. Thank you.

MS. BRINES: Thanks, Jay. This petition for sulfuric acid was received on March 27, 2012 and was submitted by BioStar Systems, LLC. The petition requests the addition of sulfuric acid to Section 205.601 of the National List for use as a pH adjuster for anaerobically digested poultry manure.

In support of its review the Crops Subcommittee utilized a technical report that was developed in 2006 in response to another petition for sulfuric acid for crop use that was submitted in 2005. So there was no new

technical report that was developed in response to this petition.

Both the petition and the 2006 technical report were posted on the NOP website in advance of the opening of the public comment period for this meeting. Thanks.

MR. FELDMAN: Thank you, Lisa. John?

MR. FOSTER: Thank you. So, I'll move as quickly as I can on this. The discussion focused around the petitioners asking that this is kind of the only hurdle that's left to be cleared in order to use it. OMRI and others have limited the use of this material in the context of poultry manure stabilization.

This is, as most of you know there's an allowance for use with fish-based products. So there's some parity questions here, why would it be good for one versus -- and not for another. That was part of the

discussion.

There's also -- the claim was that other acids, while other acids can be used the claim was that that was insufficient to get the pH to where it needed to be to create a marketable, a commercially viable shelf-stable product.

And let's see. Crops Subcommittee agreed with the 2006 vote as Melissa described because of various adverse environmental and health impacts, lack of essentiality and incompatibility with organic principles. The vote was unanimous, 6-0, 2 absent, that it was synthetic and that the listing motion was not adopted by a vote of 6 against and 2 absent.

My count was five public comments were submitted on this. I should say five specific comments that were about sulfuric acid in this petition specifically. There were other general comments that could be interpreted to apply, as in keep synthetics out of organic, kind of that vein.

But five specifics. Four were from individuals, one was from an environmental organization. And the claims were along the lines I mentioned earlier, essentiality, compatibility and concern about environmental consequences.

I have some comments outside of that encapsulation that I throw in whenever it's appropriate.

MR. FELDMAN: Thank you, John. So John, I'll call on you for starting the discussion.

MR. FOSTER: Thank you. So this is very interesting to me. I'm a big fan of parity. I'm okay with this material in this context. I'll be voting for it for a number of reasons, but among them are ones that didn't come up in the discussion that I wasn't able to participate in some of those, but that my experience particularly over the last year with respect to farm inputs is that my -- on commercial scale organic production there's

starting to be a constriction of what organic producers used to be able to use irrespective of what conventional ag was using.

And that in my experience started to turn pretty dramatically about a year ago. And that was when I noticed that the supply of compost that was compliant and able to be used in organic ag started being used in very large volumes by conventional vegetable and row crop producers, particularly in southern California and Arizona.

And some of the growers that we work with were starting to report significant problems in getting enough compost. And like, that's a great problem to have, right? But still it's not -- I don't want to make it sound like it's the end of the world because it's not, but I do want to be mindful that as organic grows, as conventional production systems evolve, adopt more what we would call organic practices there's going to be a point where organic producers are competing for the

same inputs as conventional. We're not used to thing about that and I think we should get ready for that.

This is one of the areas where I think there's, for now there's a waste product, poultry manure. If there's a way to utilize that more fully, keep it out of places it shouldn't be, I think that has environmental benefits. If this is a processing aid that helps that happen on the whole I think that's a positive thing.

Yes, I'll leave it there. Thanks.

MR. FELDMAN: Thank you. Any other questions or comments? Okay, thank you. We'll move onto the next item which is the proposed biodegradable mulch film from bioplastics petition. And Lisa will cue us up. Thank you.

MS. BRINES: Thanks, Jay. This petition was received originally on January 20, 2012 and there was an update to the petition that was submitted on March 26th.

The petition was submitted by the Biodegradable Products Institute and it requests the addition of biodegradable mulch film made from bioplastics to Section 205.601 of the National List for use as a biodegradable mulch. Related listings for mulch on the National List appear at 205.601(b).

In support of its review the Crops Subcommittee requested the development of a technical report for this material. Both the technical report and the revised petition were posted on the NOP website and available to the public in advance of the opening of the public comment period.

And a representative of the petitioner is signed up for in-person public comment for later this afternoon. Thanks.

MR. FELDMAN: Thank you, Lisa. And we're very grateful to Carmela for shepherding through this process with Zea. So I'll turn it over to you, Carmela. Thanks.

MS. BECK: All right. So Zea and I are going to be tag-teaming on this presentation the entire time. So, all right.

All right. So biodegradable mulch film made from bioplastics is petitioned to Section 205.601 of the National List for use in organic crop production. This is an alternative to petroleum-based plastic mulches that do not biodegrade. And the byproducts of completely biodegraded bioplastics are carbon dioxide, water and soil biomass.

Here's the public -- so, here's the summary of the public comment. The total in favor of adding biodegradable mulch film is 163. Of that 163, 38 were farmers, 114 were consumers and 11 were organizations. The total number of those opposed to listing biodegradable mulch film were four. They were zero farmers, one consumer and three organizations. There were also three organizations that were requesting clarification, annotation changes or further

research.

I'm going to go ahead and read this whole annotation so bear with me. So, the list on 205.601(b)(2). Okay. Biodegradable bio-based bioplastic mulch meeting the following criteria: completely biodegradable as shown by, 1) meeting the requirements of ASTM Standard D6400 or D6868 specifications or of other international standard specifications with essentially identical criteria, that is to say, EN 13432, EN 14995, ISO 17088; and 2) showing at least 90 percent biodegradation absolute or relative to microcrystalline cellulose in less than 2 years in soil, tested according to ISO 17556 or ASTM 5988; (b) bio-based certified using the ASTM D6866 method; (c) must be produced without excluded methods; (d) must be produced without engineered nanomaterials; and (e) grower must take the appropriate actions to ensure complete degradation at the end of each growing or harvest season. So that's our

current Crops Subcommittee recommended annotation.

So the next seven slides are actually just going to be each of the seven sections within the annotation. We listed the public comments there and I'll just comment on one or two of them. You all can read the rest.

So with regards to the name, BPI has requested the following name change to biodegradable mulch film. Section A thought it was important to point out OMRI's comments where they state that meeting the requirements of ASTM versus bio-based certified using ASTM mean two different things.

OMRI interpreted A(1) to mean that the product must meet the requirements of the specific standard but not necessarily be independently certified to those standards. If it is the NOSB intent to require a certification to each cited method the language should read "certified to ASTM

standard."

Let's see. They also stated that they felt that the ASTM reference in A(2) is more applicable in comparison to the ASTM standard references in this section. Other commenters, several commenters suggested that there were way too many standards cited in our annotation.

So in A(2) BPI made a clarification and said that the terms "biodegradation" and "mineralization" are different. As you can see it says the 90 percent threshold value required by the petition and ASTM test methods refer to mineralization. So a complete biodegradation is inferred when a mineralization level of 90 percent is reached.

OMRI points out that 5988 is a testing method rather than a standard to which certification can be obtained. PCO stated that there again are too many standards referenced in the annotation.

In Section B CFS points out that the ASTM standards are based on laboratory testing protocols and they're not field tested. OMRI points out that ASTM 6866 is a testing method and it's not a certification.

Section C. CCOF provided the suggested change to this annotation. They said that "must be produced without organisms derived from excluded methods." Other commenters wanted to -- stated that the feedstock and microbial fermentation processes should both be free from GE products.

The OTA said that in general there's a prohibition on excluded methods and they express concern over this general prohibition in a specific annotation and they wanted to know what the opinion of the program was with regards to this inclusion.

D, both OMRI and OTA expressed concern over the lack of a legal definition of "engineered nanomaterials." And the OTA again wanted to know what the opinion of the NOP was

with regards to including this in the annotation.

Section E. Both BPI and CCOF offered alternatives or additions to this portion. BPI suggested that we put in there "as recommended by the manufacturer." CCOF included methods by which the biodegradation would occur.

CROPP asked what exactly were the grower practices that would achieve the 2-year biodegradability annotation. Organically Grown asked for a definition of "complete degradation." So did PCO, and PCO also specified that we shouldn't be able to use the 2 years consecutively in the same field.

MS. SONNABEND: Okay. Just -- yes. These were additional concerns that were raised by points that weren't exactly part of our annotation. They have to do with short- and long-term impact of pigments on the ecosystem metal catalyst building up in the soil, other additives and processing aids.

And then how will growers and certifiers know when the mulch is completely degraded? And then the comments, insufficient studies to verify biodegradability and effect on the environment.

So before we get into how -- where we're going with this I want to go back through some of the slides to talk about how we are digesting the information that has come in and what our thinking is on this.

So starting back with slide 6. The questioning of why there are so many standards referred to and in particular two standards for ASTM. We have received information about those standards that the first of the ASTM standards is a high-temperature standard in which conditions similar to composting are being applied.

The first test provides an initial rejection point much earlier in the time line of review of the material. The ASTM 6400 which is the first one talks about a few weeks

of composting activity, but it also confirms the absence of ecotoxic effect being via plant growth and seedling germination tests in soils treated with the mulch.

The second test, the ASTM D6868, measures biodegradation under lower temperature conditions. The film would have to meet both specifications of higher and lower temp degradation to be considered appropriate.

Now, we recognized at the outset of public comment that we were trying to do two things with our annotation. One is to make an annotation so that reviewers can review products that they would be suitable to biodegrade enough, and the reviewers being MROs and certifiers who do materials review.

And then the second part is what a grower would have to do and a certifier would have to do to comply -- to verify what the grower was doing. So we are going to try and separate those out in a revised annotation

because going forward we don't want a grower to think that they have to meet a 90 percent breakdown compared to microcrystalline cellulose, you know, that part. And if we can go to the next slide.

This is designed for MROs who are reviewing products, not for growers to have to comply with. And so we will talk about this going forward in the two different facets, what an MRO/certifier reviewing the products versus what a grower and certifier verifying the product use has to do.

Okay. So -- okay. BPI explains the 90 percent which we got questions of in their comments, that there's a certain amount of mineralization and the distinction between mineralization and degradation is -- comes into play.

There are also questions raised about the need for certification for a standard, these ASTM standards, which are only standards but don't have a certification

behind them. I think we will hear more about this in the public comment coming up and so we will defer talking about that exact point at the moment.

The next slide. We realize that we made incorrect terminology here and that the ASTM D6866 is a testing protocol, not a certification.

BPI suggests bio-based content will be determined and disclosed using the ASTM method, but then we have to of course have a way, either a certification or an endpoint so that the MRO can determine what amount of bio-based content is sufficient or desirable in a product. Next slide.

Okay. So, our thinking on excluded methods is this. We realize that excluded methods is in the rule and is supposed to apply to everything in the rule. However, the excluded methods in the rule refers to field application of inputs and then things in processed foods.

We've heard the reasoning already from people that these mulches are not going to be -- they maybe have genetically engineered organisms used to make the mulch, but those organisms are not released into the field. They're in a building that they're manufacturing it in and therefore the excluded method wouldn't apply to this and genetically engineered bacteria could be used to produce this mulch.

We reject that contention and we believe that we should do everything possible to keep sources of GMOs out of our stream at any point. And therefore we feel like although it may seem redundant to some we need to put it should not be used with organisms -- it should not be made from genetically engineered bacteria or organisms.

The feedstock issue is more complicated because right now there's nothing in the rule or in most certifiers' interpretation of it that would prevent you

from going into your neighbor's GMO cornfield, cutting down some corn stalks and bringing them into your farm and mulching with them. There's no prohibition specifically on GMO content of any soil inputs per se. And so it's very -- there is a lack of a comprehensive policy on this.

People have -- and when I say "people" I mean certifiers and MROs primarily have developed their own policies and they differ somewhat. It's clearly on the work plan for the GMO Ad Hoc Subcommittee to work on making these policies more consistent and to work on a structure and a protocol for evaluating GMO inputs.

Therefore our inclination is to not make a statement in this annotation about the feedstock with the acknowledge that we don't like GMOs and we want to keep them out of our chain, but we'd rather have a comprehensive policy that addresses all the GMOs and all the inputs if possible at some

point in the future, and possibly within the 2 years that it takes for this rule to be -- which it's likely to take for this rule to come out.

We are still -- we don't have a -- none of these points I am discussing have been voted by our subcommittee yet but I'm just telling you what our discussion points are and I'm sure you can help address them in comments.

As far as the nanomaterials, we were -- we totally agree that nanomaterials do not belong in organics in any way. And the question becomes whether we need to say this again or whether it's sufficient in the annotation -- to not have it in the annotation but to be clear from the existing NOSB recommendation with NOP affirmation of it that they would be out anyway.

We did hear quite a bit of comments, especially from the people in the field who have to deal with enforcing the

annotation that shorter is better for our annotation. And so we are -- we're thinking that we maybe do not need this clause to go forward.

And then lastly, the grower must take appropriate actions. We acknowledge the comment that it's too confusing to put growing season or harvest season language in that but we feel very strongly that this is the main clause that affects growers and that those appropriate actions are still being determined through research on the material.

The appropriate actions would be things like proper soil incorporation, enough moisture, enough sunlight and like that. But if we make the annotation a lot longer by including it we're not going to cover everything and we're not going to give clear guideline for certifiers of how to assess that those appropriate actions are being followed.

So we've discussed with the Department about this and they concur that

while the rulemaking process is going on if we just leave it at appropriate actions we can then develop a guidance that the NOSB will recommend for and the NOP will cooperate with on exactly what those appropriate actions are, what conditions the mulch may or may not be appropriate from because we think there may be some environmental conditions, soil conditions and the like that these mulches have not been shown to break down properly and the research is still ongoing.

But it would enable us to put all that in guidance along with what a certifier would do to verify that the mulch was completely broken down or that the appropriate actions were being taken. That's it. Oh wait, no, one more slide. Sorry.

The additional concerns slide to the chart because we don't want to leave without addressing the additional concerns. Okay, the short- and long-term impact of additives. The only additives that are being

clearly added in the TR and especially pigments or titanium dioxide in carbon black.

Titanium dioxide is non-synthetic and would be allowed anyway, and carbon black is pure carbon. And although it's synthetic it's in effect already allowed as the main component of the ink in newspaper mulch. Any other pigments would have to be petitioned in the future because this is what is in the TR that we're dealing with right now.

As far as the other components an important part of meeting the ASTM 6400 standard above is to verify that any substances break down completely along with the other ingredients, and those additives will be tested in the course of complying with a standard, either by the MRO or the manufacturer of the materials.

I should add that very recently we were given research out of Europe which they've done considerably more research than we have where they've tested for ecotoxicity

of all the possible chemicals after several years of using the material and no ecotoxic residues were found of anything.

Okay, the processing aids are the same comment as above. The one manufacturer of PLA bioplastic stated that the TR was inaccurate in what solvents they used and they do not use any solvents to produce PLA.

How do we know if the mulch is degraded will be covered in the guidance. And insufficient studies to verify biodegradability. Well, there can always be more studies, we know that. We know that it's a relatively new product in the scheme of things and we are to some extent taking a risk.

We feel that we have roughly a 2-year window because the NOP has to -- in the rulemaking process has to address the clauses in I think it's 205.206 about removing mulch and so it will probably take a little longer than your average thing.

If any problems emerge during that period we will reserve the right to take it up again and reconsider, but we feel that getting the process started because not only will there be at least the 2-year rulemaking process but then the people who are already using it will have used a prohibited material and may have to wait 3 years to get certification back. And so we feel that we'd like to get started with this now and that we can write a good annotation that will satisfy most of the concerns of the whole organic community. Thank you.

MR. FELDMAN: Thank you. We are now at 11 o'clock. We started this session 10 minutes late so I defer to the chair as to how we should proceed. Our next segment of this session starts at 11 o'clock. So if we could steal a little more time, ask if there are any questions that would be my preference and then move on from there. Okay, just 5 or 10 minutes. Any questions from the board on

this?

Just so you all know, our thinking right now as a committee is that we would hold this over till Thursday to have a vote. So don't feel too much pressure but feel some pressure. Go ahead, John.

MR. FOSTER: Thank you. So, no surprise to anyone on the board. So I've kind of evolved my position a little bit on the ASTM. We had a pretty good discussion in previous sessions on that so I've evolved around a little. I can get my head around the ASTM thing now better.

So, but I think more precautionary just that every annotation makes a material that much harder to employ. And while in general I think that can be a fine thing if it serves to get in the way of utilizing a better material which I think this, you know, bioplastics, biofilms, I'm not quite sure where we're going to settle on the name but this stuff seems like it's better than the

current stuff.

And I really don't want to see annotations get in the way or provide any degree of disincentive to a grower particularly to make something better. It's not perfect, we do -- I hate to break it to everyone, but we're not living in a perfect world. We're just trying to make it a little better, at least that's my approach. I think this is an opportunity to do that.

I'd like to provide as many incentives as possible to make it incrementally better. I think that's about all we can hope for and I want to throw it out there. I know you're used to hearing it from me so I'll just stop there. That's my main point.

MR. FELDMAN: Any other comments? Mac.

MR. STONE: In conversation it was discussed is this a plastic or does it fit the definition of plastic? Are we going to hear

from commenters, or is this a starch film? And does that have sort of a trickle-down and not go viral in the rulemaking process by semantics?

MR. FELDMAN: So that's a question we want to pose to folks in the comment period. Any other comments? Colehour.

MR. BONDERA: Thank you and thank you, Zea and Carmela, for the presentation.

I want to just let people know that I actually, if you look at the record I actually abstained from the listing motion on this in the Crops Subcommittee because the truth is that from my perspective at that point in time there were lots of unclear and unanswered questions. And I think like John suggested it's not a perfect world but for me when I don't know then I get concerned.

I wanted to just say that as an introduction because I did while this presentation was happening write down some questions and I want to ask at least one of

them back to you, Zea, to sort of go on a little bit more about. Maybe we can ask some people when they're testifying this same question.

But it's a little bit confusing to me from listening to people. If this product is tilled in in the field then doesn't that make it a field application? And it's not removable? And so I just -- that line between whether or not it's a field application and this issue related to the word plastic and how it fits into regulation is confusing to me.

But if the recommended or the actual use includes tilling the product in then that becomes a field application. And so if we're going to refer to field application then I wonder if you can clarify or address that a little bit. Thank you.

MS. SONNABEND: Yes, it is tilled in and it is a field application.

MR. FELDMAN: Other questions that you want to raise now? Okay. Then with that,

Mr. Chairman, I guess we're moving onto the next session which is still under the Crops Committee so should we just segue way to that right now? Okay.

Thank you all for moving through this so quickly. We really appreciate it. Really good job helping us move this along. And with that we close this, the review of proposals and petitions and so forth.

And now we're moving into the 11 o'clock session where we will do three things. We will update the board from the Tree Fruit Working Group with David Granatstein. We've allocated 25 minutes to that including Q&A. And then we'll hear from Urvashi Rangan with Consumers Union, 25 minutes including Q&A, again on issues related to tetracycline and streptomycin. And then end with Kiki Hubbard from the Organic Seed Alliance, 25 minutes with Q&A. So we have a full hour and 15 minutes until lunch. And why don't we call Dr. Granatstein up to the podium for his

presentation and begin this session.

I'd like to welcome you. Thank you for coming. I'm going to do a little bit of an introduction so folks have background. I know many folks in the room already know you and appreciate your long career and contribution to organic production.

David Granatstein is sustainable agriculture specialist with Washington State University's Center for Sustaining Agriculture and Natural Resources. He has worked with organic farming since 1975 in many different capacities and provides significant support for the organic tree fruit sector in Washington State.

He serves on the state organic advisory board and on the board of directors of Oregon Tilth and is chair of the International Society for Horticultural Science Organic Fruit Tree Group. David is based in Wenatchee, Washington.

Welcome, Dr. Granatstein. Thank

you so much for coming.

DR. GRANATSTEIN: Thank you, Jay, and thank you to the entire board for asking for this update.

So I'm going to start out just with a little bit of context for those on the board that aren't familiar with the history of our group. This group came about after the Seattle meeting a year and a half ago where the issue of antibiotics and fire blight was discussed.

And the general call was put out can we form a group to kind of find out where we are in terms of progress on this issue, on alternatives, on the needs of the industry, et cetera.

So we put a group together with our purpose being broader than just looking at the single issue of antibiotics and fire blight, anticipating there are going to be issues for tree fruit into the future. And we wanted a group of folks ready to address those

and work with the NOSB in terms of providing the best possible information.

So our goal is to create the healthiest, most sustainable organic tree fruit system. That's really what our group is attempting to do. To do this by communicating science-based information and grower experience to you, the NOSB, and help inform deliberations that go on here.

Our group has about 17 people from a range of different backgrounds and different parts of the country. We are an industry group representing more the growing and handling side, not a group that includes all stakeholders. So that's one thing I want to make clear.

So to start out I just wanted to show where we are in terms of organic tree fruit. It is still growing. These data are some that we've been tracking now for a number of years. And you can see the growth from 2010 to `11 we had 6 percent increase in sales

of organic apples at this point in the growing season, 8 percent for pears. In this next year, 11 to 12, 27 percent increase and 43 percent for pears. So dramatic increase in the growth of sales which says consumers want these products and they want them even more than they did a year ago. So that is an indication of consumer demand.

We also can see here in the graph, the blue line represents the price for organic gala apples. The red line is conventional gala apples. And therefore the market has provided a consistent premium price for organic growers over the long haul.

Fire blight is kind of the disease of concern here. That's why people are using antibiotics when they do. It's a very complicated disease. I'm not going to go into it. We did talk about this a year ago when I did my previous presentation, but probably the main point is that fire blight control depends on prevention, not cure. And so everything

we're talking about is how to prevent infection. Once trees are infected the only cure is the chainsaw essentially, cutting out limbs or cutting down trees and burning the material. So that's what we're talking about here. Antibiotic use is not a curative like it is when we use it for medical reasons. It's a very different situation.

Growers use a range of management practices for fire blight. This is a list of many of them. We start with genetic tolerance but this is limited in terms of what varieties of apples and pears are commercially viable. So we have partly a discussion around scale. Small growers have a much larger range of materials to choose from. They can develop relationships with their consumers who will accept the certain characteristics of those fruit that may or may not store very well, may not ship well, may not hold up in a retail environment. But for larger growers those are key considerations as to which varieties they

can use.

We've talked about the Geneva root stocks and I'll mention those in a minute. There is good progress happening there. But bottom line, when it comes down to a risk of infection as determined by the weather conditions, driven by the computer models that growers use, growers will turn to a material to intervene and try to prevent infection.

And to give some perspective on current use, from 2001 to 2011 the percent of bearing acres treated by antibiotics in the U.S. for apples, for tetracycline it was 9.7 percent, about 10 percent in a given year were treated, for streptomycin about 17 percent. When we look at pears it's about 34 percent for tetracycline and 28 percent for strep.

So right away you see those two crops have different intensity of use factors. Pears tend to be more susceptible and are treated on average more often.

We can also look at plant use of

antibiotics relative to, for example, use in animal agriculture. And the EPA has determined that a typical pharmaceutical use of tetracycline, when we take it to control an infection in our body, that exposure is 50,000 to 200,000 times greater than the maximum theoretical dietary exposure from use of antibiotics in plant agriculture. Just to put things in some perspective.

So really the crux of our discussion is around what are the alternatives, how are we progressing. We've heard about Blossom Protect. That's a new material that was registered in early 2012 so it was the first chance for growers to actually use it on a commercial scale.

This is a product interestingly enough that was originally isolated in Wenatchee where I live by a USDA researcher, picked up by some Germans, used for another purpose first and then applied as a potential control for fire blight. And it is looking

very promising. But again, 2012, the first year for growers to use it and there was limited amount of material available, about enough for 2,000 acres.

Two thousand and twelve was a severe fire blight year in Washington State, very, very severe. And it was a very odd year in that the bloom period when we're treating for this disease was extremely compressed. So while the grower reports of efficacy are generally positive there were issues around timing, how to integrate the use of that material with the other activity going on then which is thinning of the blossoms to control the crop load. So this is one area where we clearly need some more work such that the growers have good guidance on how to integrate this new product into an overall management program.

The material is only registered for use on bloom so it will not be allowable during other times of the year such as the

summer if there's a hailstorm. And certainly in the Midwest and the Eastern states often this is a bigger issue for fire blight infection than bloom time. In the Pacific Northwest our primary concern is during the bloom. So different regions are going to experience different possibilities with this particular material.

There's some new materials being developed, some copper materials that are more active than current materials, probably will allow lower rates of actual copper to be used which is good because there are long-term concerns about buildup in the soil. These aren't registered yet and it's not clear if they will be submitted for OMRI or other material review approval. But they are in the pipeline and they are showing good efficacy.

And then finally there's work going on with integrated control. So rather than just replacing an antibiotic with one material that's expected to substitute for it

how do we start to mix and match the different options that are out there? Some work better on a certain part of the flower, the stigma versus the nectarie. Getting an understanding of that, the sequencing of these materials, integrating with thinning programs. Many of the thinning materials are toxic to these biological control agents so we're still in the process of trying to put all that together. But that is the type of research that is underway.

So here's a quick example of some of the work that's been going on. These are 2012 results similar to results from the past several years showing on the top bar streptomycin typically is our standard against which we measure the efficacy of other controls. In the green bars we see -- the green bars are the Blossom Protect. So not quite as good as the streptomycin but right up there in terms of very good efficacy. Some of the new copper materials are next in the blue

bar. So the data have been pretty consistent showing that these are performing well over different years.

These results come from Ken Johnson and the OREI-funded project. This project was started, the first field season in 2012, and will run through 2016. And of course this is just a really great addition to our ability to transition from the use of antibiotics. So again, they're testing different materials and a lot of testing of different combinations of materials to see how they hold up over time.

In this case, again, streptomycin down here is sort of the standard and we see the lime sulfur plus fish oil. That's a standard thinning program that also has activity against the fire blight bacteria followed by the Blossom Protect is doing as well as the streptomycin. So this has been a result that's been pretty consistent as shown here by Ken Johnson.

These are data from three different growing seasons now in Corvallis, Oregon, western Oregon. And the yellow bar with the star represents that treatment of the organic thinning sprays followed by the Blossom Protect and they are doing as well as those treatments with antibiotics.

So again we're starting to see some consistency in the efficacy of use here. But these are all inoculated trials, these are all researcher trials. These aren't yet the large-scale field trials where growers are using these out in the real world, and that's one of the gaps I think that we still face.

Another example of work from the OREI project. This comes from California, northern California where they're looking at the use of coppers pre-bloom to try to knock down the inoculum level of fire blight in the orchards. And in this case they were just comparing the use of oil which is a standard delayed dormant treatment for a number of

insects and some diseases to the copper plus the oil. So the gap between them is the reduction in fire blight by the addition of copper. So, again, very promising developments there.

And this is being accompanied with some new work called LAMP. LAMP is a detection technology using molecular methods to actually be able to go out, sample blossoms from the orchard and see how much fire blight exists and when does it exist, when does it start building up.

Because it may be that the fire blight model says you are in a high-infection period. At this point in time a grower would respond by treating with an antibiotic, with a biological, whatever material they were using. But it could be that there's not enough organisms in the orchard to even warrant that. And we have yet to have a good diagnostic test that a grower can use in that kind of realtime fashion. This LAMP

technology is being developed, is coming along and I think will be a very, very important complement to a non-antibiotic and a more precise fire blight management program in general. So that is also part of the OREI project that's underway.

We've talked a lot in the past about genetic resistance and how this should really be our first line of defense and some of the struggles of working with this.

So, I just completed a survey, I did a phone survey of a number of the major fruit tree-producing nurseries to find out where they are at. And the first question was around the Geneva root stocks. That's something we've talked about before. Those are moving along but if I wanted to order trees today on Geneva root stock it would be 4 to 5 years until I could get those trees. That's how far the backlog is, that's how slow the reproduction of that clonal material is. They are optimistic that it's going to improve

but it's still quite a ways out if I wanted to start today.

And we would compare that to my ordering trees on the M.9 root stock which is highly susceptible to fire blight, 2-year turnaround, no problem. So there's still a bit of a gap between what growers can get through the standard channels versus the Geneva root stocks. But they are looking very promising as far as their fire blight resistance.

And in fact, it does appear from some current research, some very recent research that the Geneva root stock helps the scion that's grafted on top of it to resist the spread of infection a bit more than had been anticipated. So it doesn't slow the infection or reduce the infectability, but if a tree does get infected it appears that there's some nutrient interactions with the root stock that make the infection less damaging. And that's brand new information

from Gennaro Fazio in Geneva, New York.

Resistant cultivars. All the nurseries I talked to, no one could say ah, there's a fire blight-resistant apple coming down the line that's got real promise. Not one could tell me that. Same for pears. So we're still in that dilemma of things being driven by the commercialization characteristics and the breeding specifically for fire blight still is lagging behind.

One example of some promise though is a pear that's being tested at Hood River, Oregon. This is a selection done by USDA that's been tested there now for 10 years that still has not been released, so it's not a named variety yet. It probably will be within the next year. And at that point they plan to plant about a six-tenths of an acre demonstration in Hood River at Oregon State University to begin the whole process of grower evaluation. They need enough fruit for the growers to see how it will work, for the

packing houses to test how it's going to handle and store, and for consumers to get used to it. And that's at least another 5-year process. So that gives you a feeling for the time frame of actually getting these materials out there once they're proven to have some value for resistance.

There's a new project in Washington and with ARS specifically taking traits from another apple species, malus sieversii. This is a wild relative of apple but it's the strain or it's the species that has the more desirable fruit characteristics. Many of the past efforts for fire blight breeding used different malus species for which the fruit quality never transferred across to varieties that were going to be acceptable to consumers.

So they're going to try to bring those genes into the crop reference set that they've developed and using marker-assisted breeding start to understand where they're

getting the fire blight resistance. And it looks like there's at least five different locations of fire blight resistance. It's not a single gene or single cluster kind of relationship. So fairly complicated but that's a very promising project that's just starting.

And then there's been some new field screening, unpublished data so far by Gennaro Fazio and colleagues looking at some of our modern varieties and trying to see where we are. Again, these weren't bred for fire blight resistance but the question is do they have any. And here's our Geneva root stock G.41, zero infection compared to M.9 right below it, up to 100 percent infection. So clearly the Geneva series are progress.

Then here's another example of a scion. This is a Sonya apple out of New Zealand. I called the North American nursery that's producing this. They had no idea it had any fire blight resistance. So again, it

wasn't bred for that, it really wasn't actively screened for it, but it turns out that it actually may have some very good resistance. Unfortunately this is a patented club variety and it's currently restricted to 400 acres of planting in the U.S.A. So it's not a panacea, not -- most people will not be able to grow this. So those are some of the dilemmas around utilizing genetic resistance.

Extension activities, there have been a number of things done over this past year. Probably the most exciting was an e-organic webinar done nationally by Ken Johnson on antibiotic control. And some 250 people attended that webinar.

But what they're finding with these e-organic webinars, because they post them online many more people come after the fact. So I don't know, it's probably up to thousands of people have been utilizing this information. So a very, very powerful way to get the information out there.

I've continued with my surveys of organic tree fruit growers in Washington to try to get a sense of what they think they'll do as the rule change comes into effect. So now this is the third year we've asked them these questions.

How will the loss of antibiotics for fire blight control impact your operation? And what we've seen is a shift where we had more people in the little to no effect, that's the most lefthand bar. That used to be 10, 12, 15 percent. Now it's down to 7 percent so people's concern level is rising. And nearly 90 percent are saying it's going to impact my production or maybe even force me to exit organic apple or pear production. So that's from Washington State growers.

A colleague on our committee surveyed some of his folks in the Northeast, small organic growers. They had the opposite. They said in general it probably won't change what we do very much. So it's going to be a

different reaction depending on the part of the country you're in and the size of your operation.

We also asked them if you tried a non-antibiotic control regime and interestingly enough 73 percent had tried it. That surprised me. We then asked them if it was successful. Thirty-three percent said yes, 67 percent said no. But this was prior to people being able to use the Blossom Protect product that came out this year. So it will be interesting to see if after this year that answer might change.

And then we asked them flat out do you support extending the phase-out date and 93 percent said yes.

So as far as next steps, the feeling that our group has is to develop a rational plan for phase-out. Our group totally supports phase-out. Our growers understand that phase-out is the future, let's get ready for it. But they feel they do need

more time to minimize disruption to the growers, to the actual volume of production and to the market and the consumers who as you saw really want these products. So we believe consideration of an extended expiration date does make a lot of sense.

In the meantime we're going to have the continued testing. Let's let the OREI project come to completion, that will be 2016. It should produce a wealth of information. We've got to transfer that research experience then to good extension materials and good education with growers.

The number one barrier right now is confidence-building. Fire blight is a very, very high-risk proposition and people are not going to bet the farm on it without knowing with a high level of certainty that these alternatives will deliver under the different conditions in different locations that they're facing.

We will have new products like the

copper is coming down the pike to help. More testing of the integration is going to help people figure out how to use these.

Some of the more novel research is beyond the scope of the time frame we're looking at but we believe that will help as well into the future. And again, right now you can't go and find a published extension bulletin on science-based non-antibiotic fire blight control and we need to get to that point. That's what growers want to find for their confidence-building. So we have more information on the website that's listed there and we'll plan to put more information online as we get it.

Probably one of the biggest things to consider as I close here is that the reason we in Washington have had so many people, about 20-some percent of our growers in the European Union program which does not allow antibiotics is because if they hit a situation where it's an extreme year and they are not

comfortable with their control program they can use antibiotics, leave the EU program, but remain certified organic. And so the irony is that the availability of the antibiotic control is probably the reason we have such a high number of people not using antibiotics. So, the risk factor is really huge in terms of the growers and we've got to make sure that we address that.

So at this point I'll close just by saying we are working on some documents looking at the published science on antibiotic residues in tree fruit systems and the risk of antibiotic resistance transferring to human pathogens from use in tree fruit as well. With that I'll close and try to answer any questions that I can.

MR. FELDMAN: Thank you very much. Questions from the board? Go ahead, Nick.

MR. MARAVELL: Yes, thank you for an excellent presentation. I have two questions and you don't have to answer both if

we're short on time.

One question is is there sufficient research taking place in the various -- in your opinion is there sufficient research taking place in the various regions of the country so that we will be able to give that level of confidence to growers Northeast, Midwest, West.

And my second question so you can judge your timing on the response is in your research with the LAMP system where you're taking measurements in specific site locations for the presence of the fire blight is your research built such that that will have a feedback loop to your current predictive models? Is it possible that you might actually be modifying your predictive models based on that data?

DR. GRANATSTEIN: First question, the answer is no. Most of the research right now, the OREI project is focused on Oregon, Washington and California. That's what it was

funded for. Some folks in Michigan did put in a proposal to OREI to carry on some very similar working the Midwest. That proposal was not funded. So unfortunately that eastern part of the country does not have the same level of activity.

I'm not sure how many people are testing these materials. I know folks at Michigan State were testing them on their own. I'm not sure how they were being funded but they don't have a nice well thought through and integrated project like we do in the West. So that is definitely a gap that's out there.

As far as the LAMP currently the models are not based on, quote, "scouting" because there hasn't been a technique. So they would have to figure out how they'd build that in there and I assume they would try to do that. But to date that has not been part of the package.

One thing that's been noticed on the use of the models, the models were

designed in many ways for growers to wait until the last minute to act such that they weren't using these materials in an unwarranted situation based on essentially weather conditions.

But because the non-antibiotic control regimes require more time for everything to begin to work it's probably going to be necessary to back off and act earlier than growers now do, and therefore more risk of acting when there was no need to act based on the ultimate play-out of the weather. So that's one of the challenges of trying to figure out how to use the model with these new tools and that was something people found this year.

The real advantage to the LAMP will be to say the model may predict risk but my level of organisms in the orchard is so low that I just don't need to treat and that would be a huge breakthrough.

MR. FELDMAN: Thank you so much.

We will call you back up if that's okay at the end of the session if we have time for more questions. Thank you very much.

DR. GRANATSTEIN: Thank you for having me.

MR. FELDMAN: And just to make sure everybody on the board knows why we're doing this specifically on the streptomycin, tetracycline. The board back in Seattle which was spring of 2011 voted to adopt an expiration date of October 2014 which means this issue will be on the agenda in the spring of 2013. So we as a board will be voting. That's why Dr. Granatstein had that expiration date, request for an expiration date extension up there on the slide.

So now we're honored to have Urvashi Rangan from Consumers Union. I'll give a little bit of an introduction of Dr. Rangan who has a Ph.D. in environmental health sciences from Johns Hopkins.

She heads up the Consumer Safety

and Sustainability Group for Consumer Reports, is responsible for managing risk analysis, policy assessments, label evaluations and consumer advice for tests, reports. You all know what Consume Reports does.

Urvashi joined the organization in 1999 and developed the rating system database and website. You're familiar with ecolabels.org for evaluating environmental and food labels.

In 2005 she managed the launch of GreenerChoices.org which covers green aspects over a wide range of products and services. She testifies before Congress, has two young children and is generally recognized to be a super woman. So thanks for joining us.

DR. RANGAN: Thanks, Jay, that's really nice. Thanks, everybody. It's good to be here, I haven't been here in a little while. So with that introduction, thanks. I haven't met a lot of the new members on the board but it's a pleasure to be here.

I am a scientist that works for Consumer Reports. We've been educating consumers about what organic is and what it isn't and what it should be and what the value is for consumers for quite a long time.

And so I'm here today to talk a little bit about the consumer perspective with regard to antibiotic use on apples and pears. And really I think kind of what roots what consumers don't know at this point.

And I think Dave gave an excellent presentation and I've had an opportunity to hear his talk before on the alternatives. It's a real problem. We'll definitely give you that, it's a real problem. But I think when it comes to consumers and organic they don't know that antibiotics are being used on apples and pears. We have not had that public discussion.

And so while it may appear that there is a growing demand for this organic commodity and even other organic commodities

that don't quite meet the standard the demand is a little bit hollow in that consumers actually don't know.

And I'm going to mea culpa, we're part of the problem. We haven't talked about this issue in the public and when we learned about it in 2005 or `06 we were hoping for sunset within that period of time and then things just got re-listed. And so we as a consumer group are part of this problem, that we haven't had a public dialogue about it. And now we're standing here in 2012 and we're still having this same discussion.

So I'm going to get into the ins and outs of why this is a problem. And I think we all need to sort of take stock of the fact that we're going to have to prepare to have a public dialogue about this so that consumers can truly understand what it is the problem is. And I think we all need to think about solutions in the short and long term.

So the first thing I want to get

into is the law itself. And the OFPA specifically states that organic is about the reduction of external and off-farm inputs, and elimination of synthetic pesticides and fertilizers and other materials such as hormones and antibiotics. And that's just the law so that's what underwrites all these things. We go back to that often when we're trying to talk to consumers about what organic means, what it should mean, what the basis is, what the principles are.

And just oddly, I was sort of Googling around to prepare for this presentation and I came across our own comments from May 2000 before the rule had been implemented. And we actually noted this very problem. And this was before anything was put on the National List. But we had concerns about the fact that there was an explicit prohibition of antibiotics for livestock production and yet that didn't apply to crop production. And we found that to be

inconsistent and could potentially mislead consumers if antibiotics were to ever be approved for crop production. And so they were.

In terms of the science there's a lot of science behind it. I think -- I'm sorry, this is terrible, it's a little bit too small but let me just read this to you. I think we're in a race to the bottom with antibiotic use in the apple and pear industry. And it's a race to the bottom it seems like not just for organic apples and pears but for the whole industry.

And we've essentially created a super blight. We have blight that is now resistant to a lot of these antibiotics. And it's not unlike a super bug on the farm. It's a growing problem, it's an industry-wide problem. It seems like a problem. I think we've been adequately convinced of that.

Plans to approve other antibiotics like gentamicin have been blocked due to

public health concerns and the CDC has voiced that explicitly. The World Health Organization has actually declared the use of streptomycins and tetracyclines to be both critically important, that's Tier 1 classification of those, and that high-frequency of any use of these antimicrobials regardless of indication can result in pressure for resistance.

Plasmids from gram negative bacteria of which the blight is can transfer resistance. It may be slightly lower in this particular application but the notion that it can transfer resistance is definitely there and rooted in science. And we know that recently introduced varieties over the last decade are more prone to blight.

And so while antibiotic resistance is a major issue there is the minor issue of antibiotic residues. We tend not to focus on that when we talk about animal welfare and antibiotic use in that because it's a more

minor concern.

However, there is a study and I've cited it here that shows streptomycin residues found on some apple and pear samples that were treated 4 to 6 months after application in the fruit itself. And I think that's just yet another problem. It isn't the only problem but it is yet another one. So, we've got scientific issues that consumers can get their heads around.

We have a whole campaign, by the way, called "Meat on Drugs" which is all about antibiotics and the meat production industry trying to get the conventional industry to move toward prudent use of antibiotics and trying to move the market toward getting rid of antibiotics in that production system. It isn't unlike this particular system, it's just that consumers really don't know a whole lot about it.

I think where consumer demand is when it comes to organics is in the integrity

of it. And I hear a lot of discussion over the years about consumer demand, the drive to grow the market, the drive to meet that demand. But when you compromise integrity to meet demand you do something very damaging in the short term and the long term. You do something damaging not only to the particular commodity where standards are being lowered but you do something to the overall integrity of the organic industry and people will extrapolate.

And if the Stanford study isn't proof of that I don't know what is. People extrapolate lack of benefit, lack of value when they feel cheated, when they feel like the threads are sort of coming loose even though maybe from the whole system that's not the problem.

So the importance of organic remaining a credible, commercially viable model of how sustainable ag practices can succeed in a market is really important. It's

important to us too, that's why we spend time educating people about this.

The primary goal for the NOP as a program, for you as a board is to hold the standards strong and strengthen it over time, not to grow a market for sub-par organic products. And that applies to whether we're approving synthetics ad nauseam, or whether we're talking about aquiculture that doesn't meet the standard. We run into this issue over and over and over again.

And so I always wonder is organic going to be a floor or a ceiling. And I have this existential discussion with lots of people. Maybe it's not going to be a ceiling because there's other labels out there that are exceeding organic in lots of different ways and they're going to compete with organic. And in the end the better ones will win out.

And there are other labels like the sustainable label which is going to come

and try and compete directly with this program. So the more the standards start to get chipped away in organic the more equivocal you sort of make it with programs that really aren't going to go all the way to the gold standard. And that is going to be the beginning of really I think the undermining of what organic means to consumers in terms of it being a gold standard.

If it's going to remain a floor at least we need to keep it nailed in. We can't start taking out the boards and having it not have a floor. So the floor that is there needs to exist, it needs to be solid, it needs to be maintained. We'd argue you need to increase the standards over time, but at the very least the floor has to be maintained.

The allowance of antibiotics is just not in line with what organic means for most foods and consumers don't expect it. And the industry is marketing itself as no antibiotics. You just have to take a trip

through the store aisle and start reading boxes of Nature's Path cereal or whatever else you want to pick up. This industry is marketing itself as providing value-added by not using those materials.

So this isn't just a consumer issue. It's not just about consumers don't get it. This is an industry that has staked itself on these principles and yet they're sort of being chipped away. So the honesty and the added value that organic conveys is constantly under scrutiny.

I get calls all the time from reporters and I'm going to get into some of those questions as to how it compares in the marketplace, how is it doing compared to other labels out there. And as the market grows for this industry the scrutiny will also grow. And when the value is compromised so is consumer trust. And that's a very simple equation. It doesn't just apply to organics, it applies across the board.

And as I mentioned before there are other labels on the market that are offering better choices in certain cases and in some cases worse, right? Natural is still constantly confused with organic. And yet chipping away at these standards starts to move it toward natural. And so people who buy natural and even pay more for natural are not going to be enticed to go to organic because it won't be that much of a difference in their minds.

And so this is the long-term ramifications of chipping away at standards slowly where it's confusing as to what the principles are. It isn't always the case that something is prohibited. And so it starts to get dumbed down. And natural is a dumb label. And we don't want to see organic dumbed down to natural.

So, fair competition. You have a whole sector of this industry that's not allowed to use antibiotics and that's really

hard for them. The livestock and dairy industry conventionally uses tons of antibiotics. And as I mentioned it's the subject of a massive marketplace campaign we have going on.

You have a sector that is going over and beyond to not use antibiotics and makes lots of claims about that too in their marketing materials. And yet why should a sector now in organics be able to use it? It is unfair in terms of the competition even within organics itself.

I guess the one advantage of the controversy in all of this is that we finally have some research and development going on and that's a really good thing because it seems like this industry is in a bit of dire straits when it comes to useful tools to fight the diseases that they have going on. And that's a really good thing.

We know Europe organic doesn't -- you can't send those fruits to Europe if

they've been treated with antibiotics. So there's some feasibility here. And as Dave was sort of explaining it's slow but we're starting to get there. And it certainly seems like we can do it at times, we can do it with certain varieties and it is feasible for some of this market to move ahead that is truly organic.

You also have regions where resistance to these drugs is completely persistent so they're at a disadvantage, aren't they, from being able to use this tool to fight those diseases. So even within the organic apple and pear industry sector there is sort of unfair competition going on with the allowed use of these antibiotics. So that kind of covers the fair competition question.

One thing I want to get into here is what we have to field from the media all the time. And here are just some -- here we go again, sorry about this. I'm going to read them.

So, here are some questions we get in the media. What was the purpose of creating an organic law and federal program? Why did we do it? Why did we go to all the trouble? Our answer is generally to impart consistency into what organic meant for consumers and farmers and to minimize confusion in the marketplace. That's why we did it. So why are we creating all these inconsistencies as we move forward? But that is what this is, this is an example of that.

Another question we get, organic food, is it worth it? What does it mean? Often the title -- and it's often the title of a lot of articles. And then we end up with this crazy answer of most organic foods meet certain standards and principles but there are exceptions. And organic foods with the most value are produced without synthetic materials or antibiotics but others aren't. Or the standards that apply to most food don't apply to other foods. Or some animals go outside

but some may not. Or there's inconsistency in the meaning which is why we went to the trouble of creating the federal program in the first place. So we end up with completely convoluted answers for the media to talk about what organic was meant to be, what it is now.

You can start to understand why consumers are going what? What do you mean? I thought that wasn't allowed? Now you're saying it is allowed. I don't get it. And when consumers start to feel cheated, that's when the bottom starts to fall out.

I just, I want to go quickly here into consumer understanding. And I just want to talk very quickly here. This is Organic Valley. Organic means no antibiotics, that's their marketing materials on here. So anyway, suffice to say there's a lot of ads going on.

In terms of moving forward we've got to prepare for the public conversation about this. We have to have a public conversation about this. People don't know

about it. We don't think apples and pears that are treated with antibiotics should be called organic.

And I'm sorry, it's -- that is not something that is easy for us to come here and say. I think we feel like there is a lot of hard work going on in this industry and we have a lot of sympathy for this industry. It seems to be in trouble in terms of the tools it has. It still shouldn't be called organic.

Alternative labels, maybe transitional and conversion should be considered. And truly organic apples and pears that are produced without antibiotics should be able to honestly differentiate themselves in the marketplace. They can't do that right now.

And I think the industry has got to stop pledging the use of antibiotics. We can't have any more exemptions to this. We don't think it should be re-listed. And we think there needs to be a public education

campaign. And we have a role to play in that too in terms of which varieties don't -- are more resistant to fire blight than others. And we think this increased transparency in the marketplace are going to help consumers and farmers get on the right track.

Consumers want to know you're going to hold the integrity of this label high. So if you say we're just not going to have as many apples and pears on the market for the next 5 years because we've got to get our act together so that we can meet the high standard that you've come to expect then that's what we have to do. Because your job in holding that standard high is more important than creating a short-term market for sub-par organic goods now.

And so we really urge you to move in that direction. Let's have an honest dialogue with the public and let's find solutions so that we can eventually have an organic apple and pear industry and do it

right where it truly means what consumers expect from other organic food. Thank you.

MR. FELDMAN: Thank you, Urvashi. A minute for questions.

MS. SONNABEND: Thank you, Urvashi, that was a good presentation. I think all of us on any stakeholder side of this issue agree that part of the reason we got stuck here is because there was no real way to spur more research into the very badly needed alternatives to the antibiotic substances.

And so I'm wondering if you have any suggestions for us on how we can encourage and inspire more research and ways that consumers could help out the growers in trying to put on pressure for more research to be done on this.

DR. RANGAN: Well Zea, I think that's a great question. And I think again in trying to have a transparent public dialogue about it we have to talk about the fact that

we've been stuck in this corner of this box, and that research and development hasn't really taken place. And we need to do that.

And I think hopefully with consumer demand for that and pressure to push back so that we do even increase the amount of R&D that's going on, I think we need to do that. Should they be called organic in the meantime? I think that's where we disagree.

And I think something to demonstrate that there is movement in this direction, that there is clearly some value to be had in the production practices that are going on compared to conventional, we need something different to call them. And is it in conversion? Is it transition? I don't know, but it's not organic.

MR. FELDMAN: Thank you, Urvashi. I wish we had more time for this. We will see if we have more time for questions at the end of this session.

DR. RANGAN: Okay, thanks.

MR. FELDMAN: Thanks again. Kiki. Is Kiki in the house? Yes.

I'd like to introduce our next speaker. And the presentation from Kiki will be on organic seeds. She is a director of advocacy, Kiki Hubbard, the director of advocacy and communications for the Organic Seed Alliance, a national organization that advances the ethical development and stewardship of seed.

She's worked for a decade as an organizer, researcher and writer on projects involving agricultural biotechnology and antitrust issues in the seed industry.

She was awarded a Doris Duke Conservation Fellowship to examine the implications of genetically engineering alfalfa and has taught at the University of Montana.

She's a resident of Montana and serves on the board of directors for the Montana Department of Agriculture's Organic

Commodity Advisory Council and Alternative Energy Resources Organization. Thanks so much for making the trip and coming here. Thanks.

MS. HUBBARD: Thanks, Jay, and thank you to the board members and NOP staff for inviting me. This is actually my first NOSB meeting and I feel really honored to be participating as a presenter.

Organic Seed Alliance as Jay said works to advance the ethical development and stewardship of seed. We believe that seed is a part of our common cultural heritage and demands careful management. And so to that end we work closely with organic farmers and other seed professionals to support the ongoing growth of organic seed systems through research, education and advocacy programs.

Our vision is for us to have here in the U.S. and organic food system built on the foundation of seed that is well adapted to organic conditions and provides diverse options for farmers when it comes to their

regional and market needs.

Today I'm going to talk a bit about an ongoing project of OSA called "The State of Organic Seed." Each of you board members receive a copy of the State of Organic Seed Report I believe last year. I'm going to talk a bit about the findings today and talk about some of our work since publishing this report through diverse working groups to move forward some of the recommendations that were identified in this project.

So "The State of Organic Seed" is an ongoing project as I mentioned to monitor opportunities and challenges in building the organic seed sector. There's a real need for this because as you know despite impressive growth in the organic food industry the organic seed sector has simply not kept up with this demand. And we're facing limited availability of appropriate organic seed for a number of reasons, one of which is the lack of clarity when it comes to how to enforce the

organic seed requirement as I'll talk about a bit later.

But there are other reasons as well, including consolidation in the seed industry where companies who were providing organic seed or looking to invest in organic seed were either merging or bought out by companies with no interest in organic. We've seen a decrease in public funding of plant breeding as well as fewer investments both publicly and privately in organic plant breeding in general among other reasons.

The lack of organic seed we believe is a barrier to the organic food industry. And I think we can all agree that organic food integrity starts with organic seed integrity, whether we're talking about the problem of GMOs or simply the commercial availability of organic seed.

So we set out to look at the challenges in organic seed systems, published the report that you all have a copy of and

then as I mentioned before facilitate some working groups to move some of the solutions forward.

And the assessment tools we used to conduct this analysis included a producer survey. We sent out a survey to certified organic crop growers across the U.S. which I'll talk about in a minute. We looked at organic seed funding both in the public and private sector to see where we're at in terms of investments in improving crops for organic systems.

We hosted an organic seed symposium in 2010 with more than 100 organic stakeholders to look at the preliminary data we had collected and talk about next steps and recommendations which we then published last year in our State of Organic Seed Report.

So, the farmer survey that we conducted, the goal of that was to assess organic farmers' current attitudes and perceptions toward organic seed and to look at

what some of the challenges were or barriers to accessing or using organic seed.

At the time and still today there's a lot of anecdotal evidence as to why more organic seed isn't used in certified operations, but we wanted to go to growers directly and ask very specific questions ranging from usage to challenges to needs and potential in organic plant breeding.

I want to mention that a total of 25 agencies, organizations and businesses helped us distribute this survey. And we'll comfortable saying that it represents about 10 percent of certified organic crop growers in the U.S. And so while we believe it's a very useful discussion tool we do acknowledge that it's not an exact measurement. We do plan to continue this project and update the survey and report every few years or so.

So I can only provide a snapshot of the data today. I encourage board members as well as those in the audience to go to

SeedAlliance.org and access our State of Organic Seed Report. You will find pages and pages of useful data representing the survey we conducted with farmers.

One of our goals was to capture demographics that reflect the diversity of certified organic producers in the U.S. when it came to crop type, geography and scale or size of acreage. You'll see here that 43 percent of the producers who responded to our survey were -- grew some vegetables, 60 percent grew some fuel crops and 48 percent grew some forage crops.

Overall about 20 percent of farmers who responded to the survey indicate that they are using 100 percent organic seeds. So this should not be read as only 20 percent of farmers are using some organic seed. Twenty percent indicate that they are sourcing all organic seed for their operations. Seven percent indicated they use no organic seed. And then you'll see there some numbers

regarding total acreage of vegetables, fuel crops and forage that are planted to certified organic seed again based on our data set that I described earlier.

Vegetable crops clearly lag behind according to our data when it comes to availability and usage with only 69 out of 437 vegetable producers using all organic seed.

Some encouraging data that I want to share today is that over the last 3 years we asked organic farmers if they have increased the percentage of organic seed that they use over the last 3 years and many of them as you can see here, the majority of them indicated that yes, they have increased their use and sourcing of organic seed. About 20 percent have been using 100 percent certified organic seed for at least 3 years.

Another encouraging point is that we asked if their certifiers have been encouraging them to take extra measures to source organic seed, "extra measures" meaning

going beyond three seed catalogs or sources of organic seed or conducting variety trials on their farm to see which organic varieties might be optimal in their systems and replace untreated conventional varieties that they're relying on.

And here we see that more than 60 percent responded yes, that their certifiers were indeed encouraging them to take extra measures to source organic seed. Not surprisingly, lo and behold, when farmers were encouraged to take extra measures to source organic seed they responded by planting more organic seed which I think is very useful in terms of recommendations to the NOP to support certifiers' role in supporting again the increased use of organic seed.

When it came to challenges in sourcing or using organic seed we see that more than half of the farmers responding to our survey indicated that the availability of certain varieties was a significant factor.

Seventy-nine percent indicated that it was a moderate or significant factor.

The lack of availability of certain varieties was more of an issue with vegetable growers according to our data than fuel crop and forage growers. And then more than 40 percent indicated that price was a factor. And we know that price is not allowed to be a factor when choosing not to use organic seed, and yet we see that again more than 40 percent indicated that this was a challenge for them.

We were surprised that distrust of organic seed quality was not more of an issue among our responses. Here we see that with the question when we asked if there was some distrust of organic seed quality that only 10 percent indicated it was a moderate factor and even fewer indicated that it was a moderate or significant factor, more than a moderate factor.

So, furthermore we asked farmers

if they had more, less, or about the same degree of quality issues in organic seed versus conventional and treated seed. And we found that 73 percent of respondents had about the same experience with both types of seed and 23 percent had more problems with organic seed.

We asked some questions about genetic integrity issues which is especially appropriate for today's conversation. More than 70 percent of farmers responding to the survey agreed that seed companies should be testing for the unwanted presence of genetically engineered material. This should come as no surprise I'm sure.

And the majority of farmers responding also indicated that they don't believe the current regulatory framework in place -- governing genetically engineered crops I want to specify -- do not believe that this current framework is strong enough to protect organic integrity.

For those of you not familiar with the coordinated framework for biotechnology there has never been a new law created to address the unique concerns of genetically engineered organisms and instead our government relies on a patchwork of existing laws, some of which predate the technology, to govern the oversight and regulation of genetically engineered crops. And I think this response again reiterates that there's a lot of concern in our farm field and in our farming communities especially among organic farmers that we need better oversight and regulations to protect the integrity of organic.

More than 40 percent indicated that their farms are at risk from seed contamination or GE contamination of their seed while 30 percent were neutral.

We asked questions about farmers' perspectives on the value of organic seed in breeding. We were pleased to see that the

majority of those responding agreed that organic seed is important to maintaining the integrity of organic food production and that more than 80 percent agreed that varieties bred for organic systems are important to the overall success of organic agriculture.

And then more than half of the farmers responding said they had some interest in engaging in organic seed production commercially, especially if there was economic value and conducting on-farm crop improvement projects.

Organic Seed Alliance sees a ton of potential for participatory plant breeding projects and on-farm variety trial networks in order to strengthen and increase availability of organic seed. It's a major program goal of ours and our research and education if you want to learn more about that.

But at the end of the day we just believe that farmers are central to expanding crop diversity and expanding innovation in

seed in our farm fields.

We also asked farmers just as a quick side note which crop types they thought were in most need of attention when it came to improvements for organic systems. I have not shared this data today but that is in the report as well.

We looked at, as I mentioned earlier, some of the investments in research to support the growth of organic seed systems. Since 1996 there have been 57 projects working directly on organic seed projects. More than $9 million have been invested in these projects. The largest contributors have been USDA's OREI grant program as well as SARE grants. And the crops that have received the most attention include wheat and vegetables. And regionally the Midwest has received the majority -- not the majority, but more funds than other regions.

I think it's pretty safe to say that this is a modest investment in organic

plant breeding and seed system development given that the organic food sector is now worth more than $30 billion.

So, some conclusions. Just to wrap up some of what I've already said, organic seed use is improving. We have seen improvements with farmers attempting to source more organic seed and pressure from certifiers to do so. But we do believe that there needs to be increased attention and resources given to organic seed system development. And there does seem to be a clear link as I indicated earlier between certifiers encouraging farmers to take extra measures to source organic seed and farmers responding and sourcing more organic seed.

Farmers clearly want organic seed protected from genetically engineered traits. There's a need to improve information-sharing which I'll talk about in a second in the areas of organic seed availability.

And as some of the data indicated

farmers see organic plant breeding and organic plant breeding important to organic farmers and their success to the broader organic industry. And there's a need as I mentioned to create opportunities for organic farmers to work with professionals in on-farm trials and on-farm crop improvement projects.

So, one of the most important outcomes from this project has been that there's a general agreement among stakeholders that we need collaborative and comprehensive solutions. So last year Organic Seed Alliance initiated and facilitated four working groups in the areas of organic plant breeding, seed industry concentration, information-sharing and seed integrity.

I'm not going to talk about all these working groups, I doubt I have time, but the Organic Plant Breeding Working Group is comprised of about a dozen public plant breeders who are actually in the process of creating a research agenda for organic plant

breeding which is pretty exciting. They have also been involved in communicating to the USDA the need to bolster support for classical plant breeding that results in public cultivars that meet the regional needs of farmers including organic farmers.

I'm going to try to touch on the Information Working Group activities and the Seed Integrity Working Group activities. One of the working groups that we've been working closely with has had the objective of improving organic producers' ability to meet the NOP requirement to use organic seed.

I'm pleased to say that this working group has successfully helped launch a new organic seed database as of this month. It is called Organic Seed Finder. We have met monthly, at times more frequently, since March of 2011 to develop and implement a new organic seed database working with OMRI to learn about their experience and develop a model that is sustainable and again meets the needs of all

organic industry members.

This is a snapshot of Organic Seed Finder. It is hosted by AOSCA, the official -- the Association of Official Seed Certifying Agencies. AOSCA has wonderful in-house seed expertise. Organic Seed Alliance and our partners has provided the necessary support on behalf of the organic community to ensure that this database is successful since AOSCA before did not have any real ties with the organic community.

The database is user-friendly. AOSCA is encouraging feedback from all stakeholders. It is free and open to farmers and certifiers and others looking to source organic seed. And it is funded through seed vendor fees as well as sponsorships.

We've had some great response from the organic food industry in wanting to sponsor this database through small and large contributions simply to showcase their support of the organic seed industry and recognize

that food starts with seed and we need good organic seed in order to have good organic food.

I included this red arrow up there because one neat feature of this database is that there's an opportunity for farmers to document and share which varieties they're looking for in an organic farm but can't find. So this creates a feedback loop to the organic seed industry, to organic plant breeders through our working group and others so that we can identify what the needs are among farmers around the country.

This is the website for finding Organic Seed Finder. If you have questions you can contact AOSCA at this email address.

And then quickly, I've already shared a bit this morning in my seed purity comments some work from the Seed Integrity Working Group. And this is a group that looked at some opportunities in protecting the genetic integrity of seed use in organic

systems.

We first sent a letter to the NOSB and NOP asking them to make the GMO issue more of a priority and thankfully as we've learned today they have and we're very grateful for that. We have also had discussions about a seed purity standard some of which is reflected in the questions I included in my written comments.

And then this working group informed the survey that I mentioned earlier today where we discussed some of the risk points for the organic seed industry at the time to inform comments that I provided to the AC21 committee. Again, that's the USDA's Advisory Committee on Biotechnology. And we are tentatively planning a meeting to further this discussion in February.

I think I'm just going to wrap it up here. These were a few more findings from the survey. You can find the survey findings at our website, again, SeedAlliance.org.

But we did ask these seed companies that we talked to many more questions beyond can you meet a genetic purity standard. We wanted to get a sense of were they experiencing financial harm, were they facing barriers to eradicating genetically engineered material.

The last thing I want to mention is that the issue of concentration in the seed industry is very tightly linked to the issue of protecting seed integrity in that our plant genetic resources are often in many cases such as hybrid breeding lines, hybrid corn breeding lines concentrated in the hands of a few.

And seed companies who are looking to provide for the organic industry often have a hard time licensing untreated germ plasm to use for organic seed production. At times these licensing agreements even come with restrictions on testing for genetically engineered material. Again, these are players who are looking to provide seed to the organic

community that meets our standards including not having excluded methods in the end product.

And these were our recommendations that I've already provided in written form regarding the draft guidance document on the commercial availability of organic seed. I've already mentioned some of them. I guess I should stop because I don't have more time unless you want me to take 30 seconds.

MR. FELDMAN: Thank you so much.

MS. HUBBARD: You're welcome.

MR. FELDMAN: Really comprehensive and helpful. Thank you. Are there any questions from board members? John.

MR. FOSTER: Thanks, Kiki. As you know we all appreciate that work you're continuing to do there.

My question is kind of focused on the difference between varietal, limitations on variety versus performance characteristics. And in that survey was the term "variety" used

to mean also performance characteristics? Or was the interpretation on the people who were filling it out more that when you said variety you meant marathon broccoli, for example?

And as you know, there are many different varieties that may have the same performance characteristics. So my question is more about do you think the survey was filled out with that broader kind of idea about other varieties that might also fit the bill, or did most people read it as in I wanted marathon broccoli and I couldn't find marathon broccoli so that's where I stopped.

MS. HUBBARD: John, I prefer it was -- I believe it was the former. I actually was not with Organic Seed Alliance when the survey was first put together. The State of Organic Seed Report does detail the methodology including how the questions were put together. In fact, copies of the questions are in the report. So I'm sorry I can't give you an answer for certain but I

believe it's the first thing you mentioned, just the variety and not performance traits.

MR. FELDMAN: One last quick question.

MR. MARAVELL: You were talking about going forward on farm trials, cooperation with plant breeders for classical plant breeding. And then you mentioned something called public varieties. I was wondering if you could expand a little bit and whether or not there was anything in your survey about how farmers, what sort of varieties they are looking for in terms of public and sometimes called public domain type varieties.

Could you say -- would that be something that organic farmers should continue to desire? Or is that a pipe dream that we will have varieties in the future in the public domain?

MS. HUBBARD: That's a great question, Nick, and it's something we talk a

lot about. Right now when it comes to demand for public varieties I really can only rely on anecdotal evidence through my conversations with farmers who lament the fact that they no longer have as much access to seed held in the public domain. This is especially true in soybeans as I understand it with past research that I've done.

I hope it's not a pipe dream. I think the public sector has an important role to play. It's an important form of competition in the seed industry to have public seed available. It's the 150th anniversary of USDA and when they started one-third of their budget went to germ plasm collection and distribution.

I mean, it's a principle of the Department of Ag and our land grant university system. So we really hope to see funds going toward projects that -- breeding projects that result in cultivars that are held in the public domain.

It's a complicated issue that includes different laws like the 1980 Bayh-Dole Act that allows public research to be patented. It's complicated.

MR. FELDMAN: Thank you. We depend on Nick to raise complicated issues for us. So with that thank you so much.

MS. HUBBARD: Thank you.

MR. FELDMAN: We really appreciate it. We'd like to ask all the presenters today, why don't we give them a round of applause, everybody.

(Applause)

MR. FELDMAN: We'd like to ask if all the presenters could share with us their written documents or written, printed documents of the presentations if that's possible. Could we find that out somehow, Michele, or do you know? Okay. Thank you.

Well, I hand the gavel back to the chairman of the board. Thank you very much.

CHAIRPERSON FLAMM: Thank you very

much. Those were excellent presentations. We're about 5 minutes past our break time so let's get back together at 1:20.

(Whereupon, the foregoing matter went off the record at 12:19 p.m. and went back on the record at 1:39 p.m.)

CHAIRPERSON FLAMM: The meeting is back in order and we'll continue with the Crops Committee and public comment. I'll turn it back over to Jay Feldman.

MR. FELDMAN: Thank you. Welcome back from lunch. I know everybody is energized by their nutritious meals.

So I wanted to, Barry, take just a minute to correct the record on some of our reporting on the public comments. I just want to update the record for the record on the Crops Subcommittee there were some comments that may not have been fully captured in our biodegradable bioplastic mulch film discussion.

What we try to do in that as you

know, what we try to do when we present this information is give you, give the community, give the board a summary of who said what and how many people weighed in on what side of the issue, et cetera.

And I guess what happened is Cornucopia got left off so we need to make sure the record reflects that they suggested that we as a board did not have sufficient information and need separate petitions on the individual synthetic plastic film ingredients. So they're suggesting that they be individually reviewed. And I guess we'll hear more about this from Pam when she speaks during this session.

Similarly we neglected to include during the GMO discussion a comment of Cornucopia on their really strong belief that when we're looking at this question of GMO that we include an equal look at both organic growers' use -- or an especially important focus on organic growers' use of conventional

seed and the GMO implications associated with that.

Again, we try to be as thorough as we can with this process and sometimes we miss the mark a little bit. And those that -- many of you are out there are scrutinizing us closer than others, that's all I can say. So we want to make sure that the record reflects all the hard work that you all put into this process and all the resources that you expend to get to this meeting and prepare for it.

So with that, Barry, I will now turn to the public comment period.

MR. ARNOLD: My name is Paul Arnold. I'm with Pleasant Valley Farm out of Argyle, New York. It's about an hour northeast of Albany. We're about 4 hours away from here. I took the trip down to make some comments.

We're a 7-acre diverse fruit and vegetable farm that sells to farmers markets 52 weeks a year. We've made our living at

farming for 25 years. It's our sole source of income. We've been using BioTelo for 4 years and we use about four rolls per year which equals about 3 miles of that. We previously did not use any black plastic.

Before that we just did not want to get into the labor of removing it and the disposal of it. I had worked on farms before that and been acquainted with it.

Some of our want to use this product is the fact that it does break down quickly. And this helps a lot with the fact that once crops are done we are more inclined to get it turned under right away and put cover crops down immediately which helps us instead of in the summer it's harder to think about taking labor to pick up plastic and then get a cover crop down. So it's helped us a lot in that way.

For us it's an excellent product that's doing exactly what they say it's going to do. Whether we use it for products like

onions in the spring and peas, and then get turned under in July when we're done, the product is gone. Or we use it for products like Brussels sprouts that are going to be there the whole season and will get turned under in the fall, late fall, when they get harvested. That product is always there, it's always good for us.

We also use it for strawberries, planting them in the fall and then harvesting in the spring. And then we turn under the strawberry crop. The plastic is then gone. So it's worked well for us.

It breaks down easily. There is no residual left that we have seen at any time. We do have some pictures. I think you see the one up here now, it's onions. And then there will be another picture that will come up that is actually not that one but it's another one. That's it right there. That's after turning the onions down in August. So that first picture of onions was in April, the

second -- or May, and then that second picture then was in August. So you see it breaks down completely.

It rototills easily with no wrapping. It disappears completely whenever it's put in. I also want to say that we also use it in our high tunnels which is you might say on a dry farm situation in the sense of because we're using drip irrigation that it -- there is no real water in there to break this plastic down.

What we do with it, because it's in there for 6 months because we do summer crops with tomatoes and cucumbers, then we also do winter crops with Swiss chard and kale, that we remove it at the end of the season and it gets composted out in our fields along with all the other sheet composting that we do on our farm. Again, there's just nothing left. It takes a very short time for it to break down and it's just not there.

So all our workings with it so far

is positive. It lays down easily. It breaks down easily. It's actually allowed us to do a lot more adding of organic matter because between the plastic we use straw and that allows us to add organic matter.

We rotate it around our fields and that helps us too. So it's not in one field every year, it's moved around, and that's how we add organic matter to our farm because we've been doing this for 25 years. That's our system so far.

MR. FELDMAN: Thank you. Questions from the board? Mac.

MR. STONE: Does it hold up well enough during the season as far as running transplanters over it, having workers stepping on it when they're harvesting or hand-weeding in the holes? Does it hold up well enough for production purposes?

MR. ARNOLD: It holds up more than well enough. We really don't have anything negative to say about it. The only thing you

learn to work with it is the fact that after -- if you lay it down you need to be transplanting into it within the first 2 or 3 weeks or it starts to get brittle and fall apart.

MR. FELDMAN: Zea.

MS. SONNABEND: When you first decided to start using it what level of investigation did you do, or did you even think about the concerns of whether it left chemical residues behind from the components that made it?

MR. ARNOLD: We looked into the fact that it was already established for use in Europe. And if they had already done the background in it we weren't really chemists enough to know all that background. But as long as it was good for them then we decided we were going to try a small amount.

Our farm is known for doing lots of trials of a lot of different products and keeping up with universities. So this was a

small amount, put it down, one roll, find out what it does and then from there we started using it more when we found it did do what we wanted it to.

I guess the concern was still the fact that someone had approved it in Europe and so we were okay to use it here.

MR. FELDMAN: Other questions? This is your chance. Harold.

MR. AUSTIN: In your various trials you were talking about your irrigation, drip irrigation in the various trials. Do you have any other form of irrigation besides drip?

MR. ARNOLD: Our farm uses overhead irrigation on all of our acreage outside that we grow crops on is overhead irrigation. Where we use drip irrigation is in the high tunnels and things like blueberries in any permanent crop.

MR. AUSTIN: Okay. Along with your -- the irrigation then what's your normal

amount of annual rainfall? And then how much -- in the course of your crop year how many acre feet or inches of irrigation water are you applying?

MR. ARNOLD: We are -- I'm not going to be able to tell you how many inches we normally get. I'm not versed on that. What I'm watching for as a farmer is what is, you know, is there enough water going down for the transplants and the crops.

So we're looking at an inch to an inch and a half a week depending on how hot and dry it is during the summer. In May you're not using as much as you are in July when it's hotter and the plants are bigger and need more. So we have a full irrigation system with unlimited water and so we irrigate as much as the crops need to bring them to their potential. So it's often.

MR. FELDMAN: Other questions? Jennifer.

MS. TAYLOR: Can you tell me if

you have discovered a financial benefit in using this type of mulch versus your previous one that you had? Or what are your benefits, please?

MR. ARNOLD: What are our benefits? Well, we were not doing any black plastic before this so it wasn't a strict one-for-one going from one to the other.

We were doing a lot of mulch, just strictly mulch, putting it down instead of using the black plastic. And what we found was that a lot of crops that liked heat were being held back because this made things too cool for them. So the black plastic made it a little warmer for a lot of the heat crops that you're using as an all-summer crop like cucumbers and zucchini and tomatoes benefitted from earlier pickings on that, a longer season.

The only other thing that was a real benefit was of course at the end of the season there was no residuals that we had to

break up and we could get our cover crops down faster which is what was really important to us.

MR. FELDMAN: Other questions? Thank you, Mr. Arnold. We appreciate it. Steve Mojo?

MR. MOJO: That's correct. Good afternoon. My name is Steve Mojo. I'm the executive director of the Biodegradable Products Institute. I represent the major manufacturers of biodegradable films in the U.S. and Canada.

The BPI or Biodegradable Products Institute is a professional trade association with over 150 key individuals and groups from government, industry and academia. And we promote the use and recovery of biodegradable materials. My comments today are on behalf of the petition that we submitted and we greatly appreciate the support of the Crops Committee and agree with the overall decision that this material will benefit the organic community.

Rather than comment on the annotations which I understand may be modified I'd like to spend my time to talk about responses to the public comments that were submitted in the Federal Register.

First, I appreciate the overall widespread support from the farming community and at the same time I realize that some participants have legitimate concerns. And I'd like to deal with three fundamental issues, one being why we recommended both 6400 and the use of 5988 at the soil test.

ASTM D6400 provides an initial rejection point much earlier in the developmental time line so that we understand if a material has the ability to reach the 90 percent threshold under accelerated aerobic conditions frequently called composted. Importantly, 6400 provides an ecotoxicity test at the end of it so that we know that those materials aren't going to harm plant growth.

Then if a material meets ASTM 6400

in anywhere from 3 to 6 months then it can go onto the longer term development, the longer term soil test to confirm how long it's going to take to go away under real world conditions or laboratory conditions that simulate the real world. So hopefully that clears up why we have two test methods.

Some commenters suggested the materials not only meet these requirements but they also be certified so that the ACAs and MROs can easily determine compliance with the standards. The BPI is willing to establish such a certification program with NSF, an internationally known third party accreditation agency if that's something you would like us to do to make it easier to identify these materials.

Third, I want to take the opportunity to clarify the confusion that seems to exist, or the difference that seems to exist between the terms "biodegradable" and "mineralization." While they're often used

interchangeably, fundamentally they are technically different.

Biodegradation is the process whereby living organisms break down foods, assimilate them and convert them into energy to sustain their lives. The process is fundamentally the same for you and I and the soil microbes, they're just eating different foods. The end products of biodegradation are biomass, water and carbon dioxide.

Conversion to the carbon dioxide is the final step of the process. It's mineralization. We know that when things are converted to carbon dioxide they're removed from the soils and they're put into the atmosphere as an inert material.

The test approach that we're proposing and the standards that we're using consider CO2 evolution as the final measure of biodegradation. So we know that these materials have been broken down by the microbes, assimilated, used as a food source

and then respirated out into the atmosphere. It's the same thing that happens for you and I now that we're eating lunch. We're breaking down our foods, we're breathing, we're moving and sooner or later that's going to be expelled as CO2. So by reaching 90 percent it can be said materials reach complete biodegradation.

I have one other thought that I'd like to stress, is that in our submission we originally brought in 12 published studies dating all the way back to about 2005. Additionally, we have referenced more recently European studies that go back all the way to 2001. So these materials and these chemicals have been looked for over a decade and they have demonstrated their safety in the environment.

So with that I'd like to thank the NOSB for the time and if there are any questions I'll be happy to answer them.

MR. FELDMAN: Thank you very much.

Questions? Zea.

MS. SONNABEND: Thank you. I have about 42 questions but I'll start with 1.

MR. MOJO: I've got 8 hours. I'm ready.

MS. SONNABEND: In our technical report it was explained that there are I believe four different types of materials that fall under this potential category. And what I'm wondering is if by the way we referred to it in the name of saying bio-based bioplastic or by the standards for bio-based content and degradation that we adopted are we excluding -- are we including all four of those types of products in that annotation or are we ruling out the one that started with petroleum originally or any of the other ones?

MR. MOJO: In the petition we referenced four materials, you're right. The standards that we're recognizing will allow all four materials because all of those materials meet the specs. And understand

those materials aren't necessarily used in isolation with one another, but they can be blended together in such a way to give the properties that the farmers need so that these materials can last on the fields as long as they need. Does that address your question?

MS. SONNABEND: Okay. Yes. And then how about the clause about GMO organisms. Does that affect all four of those types of materials or only certain ones?

MR. MOJO: They would only affect potentially certain ones. They wouldn't affect the petroleum ones, for example, because GMO has not been highlighted as part of that.

MS. SONNABEND: Okay, thank you.

MR. MOJO: And there are materials that can be made without GMO I believe, so.

MR. FELDMAN: Other questions? John.

MR. FOSTER: So there are materials that can be made without GMOs? What

does that do to the price point to the grower?

MR. MOJO: I don't honestly know the pricing but I would -- a gentleman from BioTelo is going to speak so you can certainly talk to him about that.

And Zea, I'll be happy to answer any and all of your questions at some -- whenever you'd like.

MS. SONNABEND: And will you be around the whole time if we want to call you back?

MR. MOJO: I'm going to be -- I'll be back here Thursday morning if that's all right. I'll be here all day today and then back Thursday morning.

MR. FELDMAN: Follow-up or is that? Okay. Other questions? Mac.

MR. STONE: I'm back to my semantic question of plastic. When does something become a plastic versus some other something that looks like plastic?

MR. MOJO: A plastic is a

technical definition that talks about products that are formed with heat. So the molding of a material makes it a plastic. So cellulose was the very first plastic naturally based. So plastic has -- in fact the very first plastics as the USDA will tell you were based on products like soybeans and used in your Model A Fords. So it's -- really the process of making something does not make it a plastic. It doesn't necessarily have to be petroleum-based. Does that help?

I mean, it looks and -- I mean these materials will look and feel like plastic but they have different components and all of those components can be consumed by the microbes in the soil.

MR. FELDMAN: Other questions? Okay, I have a few questions. Thanks again for being here. I have several questions. One goes to the international standard, what Canada is doing and what your understanding is about what is allowed in Canada versus what

would be allowed under the annotation that has been proposed, at least passed by the Crops Committee.

And then I wanted to get a little sense -- some sense from you as to the different plasticizers, the PLA, what's the other one, the PHA and the requirements for one or other. You talk about a blending and to what extent are we limited in restricting the plasticizers given the necessity to blend. So let's start with those two if you could. That would be great.

MR. MOJO: Okay. In terms of what's being done -- the European standards and the U.S. standards as well as those used in Canada revolve around four fundamental criteria when it speaks to composting. One is that the material disintegrates rapidly, within a 12-week time frame. Two is it fully biodegrades within 180 days and that's conversion to CO2, the 90 percent number. Three is there's no ecotoxic effects from that

process. And fourth, that there's regulated metals levels for cadmium, chromium, and all those other things that are dictated by either the Code of Federal Register or the Canadian authorities or the European adolescents.

So those four fundamental criteria are the same throughout Europe and North America. There are some minor differences on the metals levels based on what's regulated according to the 503 sludge regs versus what's done in Europe. Hopefully that addresses your questions there.

MR. FELDMAN: To follow up on the international, you're familiar with their reg up there 1.4.1 which lays out the specific restrictions on colorants and ingredients such as GMO, et cetera. We're just -- because we were told by one of the earlier presenters that we were, in adopting this listing, this annotation, we were bringing ourselves into uniformity essentially with Canada.

We're trying to answer that

question, if that in fact is the case given what you know about what's going on through that 1.4.1 and what would be happening here in the U.S. under this standard the Crops Committee has proposed.

MR. MOJO: Well, these materials are allowed in Canada and Europe today. And in fact the crops that are grown in Europe and Canada today can be imported into the U.S. as organic today. So they compete with the very same people --

MR. FELDMAN: So that's all the four materials you're talking about.

MR. MOJO: Yes.

MR. FELDMAN: Because we haven't been able to confirm that. That's why we're trying to nail that down.

MR. MOJO: Well, to the best of my knowledge absolutely. And I mean, these materials are a class of material much in the same way as newspaper is a class of material. I mean, newspapers differ depending on where

you get them off the roll which I think gets us back to why we want -- recommend changing this from bioplastic biodegradable mulch films to a biodegradable mulch film. Because these materials perform much the same way as newspaper does or craft paper does when it's applied to the fields. So we see that as the logical nomenclature for these types of materials.

MR. FELDMAN: Okay. Thank you. And on the plasticizer issue, the different types of plasticizer.

MR. MOJO: I mean, all of the materials that are used in the -- all of the additives that are used in these materials if they're not minerals such as TiO2, all of these materials, no more than 1 percent can go in there and not be proven to be biodegradable. So any of the additives that are in there are biodegradable if they're used in more than 1 percent.

And there's no more than five of

those additives allowed. And most people don't use them. And in fact, some of the materials that are used at less than 1 percent may be fully biodegradable also.

MR. FELDMAN: Miles.

MR. MCEVOY: Yes, we've asked the European Commission and the Canadian Organic Office to weigh in on the biodegradable mulch. And from the European Commission they're going to send us a more formal reply but what they said was that from what they can see it appears that biodegradable mulch has not been allowed to date. And they're asking their colleagues for a more complete assessment.

The questions that they have looked at is the composition and origin of all components of the mulch that are not mechanically removed which would, they believe, have to meet the requirements in their annex on fertilizer, soil conditioners and nutrients that's in Article 3(1) and 6(d)(2) of Regulation 889/2008 as amended. So

that would be that the components of the biodegradable mulch would not be allowed to be genetically modified. So they're going to provide more information on that.

For the Canadian Organic Office it's a much more lengthy response. They reference the 1.4.1 standard that you referred to. And then they have a question and answer on their Standards Interpretation Committee.

I can forward this onto you, Jay. Can you clarify the requirements for removal of plastic mulch films. The annotation for plastic mulches in Table 4.3 of the Prevented Substances List is clearly intended to prohibit the incorporation into the soil for any material other than fully biodegradable films compliant with Section 1.4.1. Where there is any risk of contamination plastic mulch must be removed from the soil.

The distinction between annual and perennial crops is made on the premise that following an annual crop tillage will occur in

preparation for the next year, but this distinction is not essential to fulfilling the intent of the standard which is to avoid contamination of the soil. In situations where the mulch will not be incorporated into the soil then it may be left on.

Are bioplastic mulches made from corn accepted as fully biodegradable films as the term is used in the annotation for mulches Table 4.3 of the Prevented Substances List? The answer: a bioplastic mulch could be accepted as fully biodegradable provided that, one, the mulch is not made using GMO plant material, and two, there are no substances prohibited under 1.4.1 present.

So that's a lot of detail there and I can forward this onto the board for your review.

MR. FELDMAN: Thank you.

MR. MOJO: Thank you, Miles. But I do know there are materials that satisfy that requirement and the gentleman from

BioTelo will come forward and talk about that.

MR. FELDMAN: Is that your understanding, Miles, that there are approved materials in Canada?

MR. MCEVOY: Yes, it's our understanding that there are approved materials in Canada that are currently being used.

MR. FELDMAN: Thank you. Other questions? Comments? John.

MR. FOSTER: So this is more a question of clarification. Hey Marty, it's more of a clarification from the program. Maybe Miles. I just want to clarify something you said about as long as. I think I heard you say something, as long as the material is not from bio?

MR. MCEVOY: Right.

MR. FOSTER: Right? So I'm wondering about consistency on that from other inputs that are applied to the soil that may be derived from I thinking corn gluten meal

for example. What's the thinking? If I heard you incorrectly, tell me, but what's the thinking about as long as the material is not derived from genetically engineered material?

MR. MCEVOY: Right, that's the specific reference for what they term bioplastic mulches under the Canadian standard.

MR. FOSTER: Under the Canadian standard. Okay.

MR. MCEVOY: Right.

MR. FOSTER: Got it.

MR. MCEVOY: So we did not ask them the question on GM material in general but for bioplastic mulches they have a specific answer for that.

MR. FOSTER: Okay. Then Jay, a quick follow-up to that. Does anyone on the board have knowledge of what Canada's position is on, say, corn gluten meal with respect to genetically engineered components? That would be -- that would help me understand, kind of

guide me a little better if we can get that. Thanks.

MR. FELDMAN: Others? Thank you so much. And we look forward to seeing you on Thursday.

MR. MOJO: Absolutely, and if need be I'll come back tomorrow.

MR. FELDMAN: Okay, thank you. Dave Rogers, thank you. And let me say that Eric Menard is up next.

MR. ROGERS: Thank you. I'm Dave Rogers. I'm policy advisor with the Northeast Organic Farming Association of Vermont. And my comments are on behalf of NOFA Vermont and Vermont Organic Farmers which is our USDA accredited certifier representing 545 certified processors and growers or farmers, including 132 certified vegetable growers.

We really appreciate the opportunity to comment on this petition and we're strongly in favor of approval of these products and our farmers are as well.

In Vermont as in the rest of the country black plastic mulch is an important production tool for a lot of growers. As you well know they help warm up the cool soils in spring and suppress weed growth, conserve moisture. And these are all benefits to crop production and marketing and really farmers' bottom line as well.

And we regularly hear from certified growers who question or oppose the current rule that only allows them to use petroleum-based polyethylene films or mulches that have to be removed and disposed of. It's costly, it's labor-inefficient and it's environmentally irresponsible. Our farmers really feel badly about having to do that. Dumpsters and dumpsters full being hauled off to the landfills.

Non-certified growers I've spoken with report and the literature confirms that the performance of these mulch films are comparable to polyethylene mulches in terms of

plant growth and production, weed suppression and such. These growers have found that with light tilling they degrade fully with no visible traces in less than a year and often much less depending on soil and moisture conditions.

One grower with whom I had a conversation yesterday talked about one product he used persisted well into the second year but it was gone by the end of that season. And that was fine with him, it didn't interfere with his farming practices.

So for these reasons the approval of these biodegradable mulch films in organic production is a big deal for many growers in Vermont. And again, many of them submitted written comments to that effect. And indeed, like the Normans yesterday from One Straw Farm we hear from farmers who choose not to become certified organic because they can't use these products.

So finally a couple of words,

thoughts about degradation that sort of stem from my own personal work over a number of years as a microbiologist. These are simple polymers really that have been shown to break down fully to carbon dioxide and water and microbial biomass. And I haven't seen any evidence and there's no reason to think really that the degradation occurring in fields is any less complete. The microbes really jump on this stuff. And there are dozens of species of bacteria and fungi that have been identified in the technical information that's been submitted whose growth is stimulated as they get to work on these products.

As I see it there's really no biochemical reason for them to stop metabolizing this stuff until it's fully mineralized or degraded. And of course there are soil and climatic factors that affect the rate.

For these reasons we don't see any reason to think that there are stable

intermediate breakdown products or residues that will be produced that could be of consequence and concern. And we think that this recommendation should move forward. There's no reason to table it. We think the information we have is sufficient to justify approval. Thank you.

MR. FELDMAN: Thank you. Any questions? Thank you very much, David.

MR. ROGERS: Okay, thank you.

MR. FELDMAN: And Eric Menard with Matt Cotton on deck. Welcome.

MR. MENARD: Good afternoon, everyone. My name is Eric Menard. I'm from Canada. I'm a business development manager at Dubois Agrinovation for 17 years. I'm selling BioTelo mulch film everywhere in the United States and Canada for the past 7 years.

And everyone who use the BioTelo, they never come back on plastic mulch again. They go forward with the biodegradable mulch.

So I'm here today to explain you

much more about the BioTelo, the product. The BioTelo has been first introduced in a wrap about 15 years ago. It is made of Mater-Bi. It's a non-GMO cornstarch. And the film degrades with the microbial activity in the soil. It's very important. The sunlight doesn't have any effect on the film, it's the microbial activity in the ground.

And many study has been done on BioTelo by many universities as Penn State, Cornell, Tennessee, Washington State to McGill in Canada and many other universities all over the world.

So the BioTelo has the same properties as the plastic mulch but the big advantage is that it doesn't have to be removed from the ground. So when it breaks down it decomposes without leaving any toxicity or residue over time. BioTelo reduces the amount of CO2 per hectare of mulching by over 60 percent compared to traditional plastic film. So BioTelo is a

great ecological and responsible alternative to plastic mulch.

So here you can see the processing of the degradation over the time for one season. So you see the summer onions, you see the film starting to get small holes in it. After the tillage you have very small residue left in the ground. And in some case in the fall you don't see anything. In early spring it's practically all gone.

This is conventional plastic mulch. The use of plastic mulch in the USA exceeds 110 millions of pounds every year, and it's a repeat every year. And that data comes from 1987 so probably today it's more than that.

And the plastic have been disposed of routinely by burning, burial or dumping in landfills. So that's what it looks like and that's what I don't like to see. And I'm here today to be -- to solve that big problem here.

And why using biodegradable? It's

avoiding the soil contamination. And it's certified in European region. Also, it's no disposal issues. It's saving time and labor a lot. Its ability to handle with current commercial equipment and systems with only minor adjustment. Weed suppression, water retention, crop quality and yields comparative to those currently provided by standard polyethylene mulch film in the market.

The use of raw material from renewable source rather than fossil fuels. Economic viability. And it's a clean and innovative technology to protect our environment for now and for future generation.

So, I'm here today not for business, for myself and for my son and for the next generation. It's time to do something to move and go forward with this technology that exists today. And that's a good alternative.

MR. FELDMAN: Thank you.

MR. MENARD: Any question?

MR. FELDMAN: Any questions? That's what I was going to say. John?

MR. FOSTER: So my earlier question was about cost but maybe it's an irrelevant question if all -- are all biodegradable plastics from non-GMO sources?

MR. MENARD: I'm not aware about too much the other kind of biodegradable but I can tell you about the BioTelo. It's non-GMO sourced. It can be done with GMO source. It will do the same material basically.

MR. FOSTER: But your company doesn't do --

MR. MENARD: No, this is manufactured in Italy.

MR. FOSTER: Okay.

MR. MENARD: It's not manufactured yet in North America.

MR. FOSTER: Got it. Thank you.

MR. MENARD: It will be and if it has to be the raw material will come from Italy.

MR. FELDMAN: Go ahead.

MS. SONNABEND: Thank you. Do you have a preference of how you think the material should be referred to? I mean, biodegradable mulch film versus bio-based bioplastic and those type of things we mentioned earlier?

MR. MENARD: Yes, I think because this product, it's used and it's very important -- I think for myself it's compostable. It's the word, the terminology, I think it's important in that case to be very -- I think compostable, biodegradable. But the word "compostable" means much more I think, my point of view, of for it goes in the ground, it's organic matter, and it's composting inside the ground. And if it's compost it means it's ecologic.

MS. SONNABEND: Well, so you would rather not have it be called bioplastic?

MR. MENARD: Well, I don't like the plastic. You know, I'm a guy who has been

selling plastic mulch for 17 years so you're talking to a plastic guy who are still selling plastic mulch. But I'm convert today to the compostable mulch or biodegradable mulch film. I'm not using any plastic words anymore for that. So I'm convert and that's I think.

And it's not only myself who say that. I talk to Dr. Michael Orzolek from Penn State and he say to me, and he's a plastic guy like me but much older, and he say to me, he say the future 20 years from now is going to be biodegradable and compostable mulch film. It won't have any more plastic mulch film in the industry from now, I mean in 20 years. So I think compostable biodegradable mulch film should be more than bioplastic.

MR. FELDMAN: Jennifer.

MS. TAYLOR: Thank you. Could you please give us some information about the optimal soil environment that would enhance the breakdown?

MR. MENARD: Okay, that's a good

question. The breakdown is first of all in the product we have different thickness. We have different thickness so the thickness makes the degradation faster or longer depending also the type of soil you have. So more your soil have organic matter it's going to degrade faster. So if it's sandy soil it degrades over time but it's going to be longer. But there's -- that's answer your question? So the clay soil, clay will degrade faster than sandy. But sandy soil will eventually degrade.

And the good thing of it is over the years I never -- I sold over for right now it's over 1,000 acres in the United States and I didn't have any complaints about this product. So the degradation, what we say, it's what you get. So if your type of soil, it's clay soil, we're going to suggest you a thicker mulch so it's going to degrade after the season perfectly.

So that's interesting. As a

product we don't have any complaint. Because if I had complaint I won't be here today to -- talking to you about this product.

MS. TAYLOR: And also -- the different types of varieties, or no, the different types of plants that you're planting would determine the thickness of the mulch itself.

MR. MENARD: Yes. Yes, exactly. So the crops also, if it's short-term crops we're going to go with thinner film. Like for cucumbers we can use a 0.5 mil thickness so it will last like 3-4 months under sandy loam condition. So we have different -- with the type of crops.

But obviously like strawberries for 2 years that product, it doesn't last 2 years. The maximum we have right now, it's about 1 year, one season. So we don't have any product for a long term yet.

MR. FELDMAN: Go ahead, Harold.

MR. AUSTIN: You mentioned that

sunlight really doesn't have an effect on the breakdown of the material but its true breakdown and degradation is by microbial activity.

MR. MENARD: Yes. The sunlight effect doesn't have any impact. Basically it's the warm of the soil, it does. So that's make the warming the soil, but the sunlight doesn't have an impact like the photodegradable or the oxodegradable film. It's more with the microbial activities in the ground. So you have -- that's why you have to tilling the soil, the film after the season and it will degrade faster. But the sunlight doesn't have any impact directly.

MR. FELDMAN: Any other questions? Before you go could you just tell us the products that are used and approved in Canada. Your product is in use in Canada?

MR. MENARD: Yes, it's used in Canada by the organic growers. They're using it since the beginning.

MR. FELDMAN: Do you know of other products besides your own that are used under the organic standard in Canada?

MR. MENARD: There's another one who is approved also.

MR. FELDMAN: Okay.

MR. MENARD: You want I give you the name?

MR. FELDMAN: Sure.

MR. MENARD: It's Bio Neuve. It's my competitors. It's made in France and my product right now it's made in Italy. But we're looking to make the product here in North America, in Montreal in the near future.

MR. FELDMAN: Okay. Merci and … bient“t.

MR. MENARD: Merci beaucoup. Thank you.

MR. FELDMAN: I have Matt up, Matt Cotton, and Kyla Smith on deck.

MR. COTTON: Mr. Chair, members of the board, thank you very much. My name is

Matt Cotton. I'm a technical consultant to BPI on this issue.

I'm going to be brief. I'm really filling in for one of our scientists who couldn't be here from Italy. I do urge you to positively consider the biodegradable mulch petition. Although I'm not a grower I'm extremely familiar with these materials and biodegradable and compostable materials through the work I do with composters and those that buy compost.

On the West Coast our biggest market for compost is agriculture, particularly, not exclusively, but certainly organic agriculture is part of that. I certainly appreciate there are lots of questions and concerns and it's a confusing and somewhat a magical product in a lot of ways. You want it to perform exactly like a plastic mulch and then somehow clap your hands and have it degrade.

Although I've heard a lot of

testimony today I really don't hear a lot of complaints from growers that it's not performing although I know it doesn't work in every situation. It was interesting to me that we had only support from growers and no opposition from growers to the petition.

And it's a needed tool for growers. Is it going to work in every situation? No. I'm trying to anticipate Jennifer's question about the types of soil and there was some discussion yesterday about where this is going to work and not going to work. If it's not going to work for a grower, maybe it's in Arizona, maybe it's too dry, too hot. They're probably not going to use it. But clearly what we've heard, testimony yesterday and today from growers that use it is it works fine. There are some real benefits to it.

And ironically I think if this were 20 years ago and these materials had been available I think they would have been

approved whereas polyethylene mulch which really is a strange contradiction looking at it from my outsider perspective to the organic world, a bit of a contradiction that that's allowable compared to these.

In certain places obviously the growers and the certifiers will figure out the best management practices. Obviously this will be part of a crop plan reviewed by the certifiers. I understand there's some questions there. We've worked to try to address those. I believe it's quite clear there's adequate and sufficient data to determine that there are no negative soil impacts of these materials.

More study is -- what is needed and ironically if we approve, if you see fit to approve these materials there will be study because that's how it goes. We don't have a lot of history of using these materials because they're not allowed. And the professors I work with like to use materials

that people are actually using so their research has benefits. Field experience will continue to inform best practice.

And getting to the question, the linguistic question to some extent, I believe biodegradation should be seen as a type of removal. I think we're living in a fantasy world if we think that 100 percent of all the polyethylene mulch that's used in fields is removed. Biodegradation is a much more efficient of removing, truly removing these materials from that environment.

Ask any farmer, ask the folks from NOFA Vermont, anyone who's used these materials in the soil how well that material is removed, how completely polyethylene mulch gets removed from the soil after a year of being on a crop in the sun. I think you'll find that there's -- hard to find a place that uses that mulch that doesn't have little shards of plastic throughout the soil and that could be studied.

Fundamentally the use and certification to ASTM standards is something that we work with in the composting industry. We're already comfortable with it. We've used the ASTM standards and we think that's a good way to go.

With that I'd be happy to answer any questions.

MR. FELDMAN: Thank you. Questions? Mac.

MR. STONE: How fast is conventional growers adopting this technology?

MR. COTTON: I'm sorry?

MR. STONE: How fast are conventional growers adopting this technology?

MR. COTTON: That's a great question for Eric. I don't know.

MR. FELDMAN: Other questions? Okay, Zea.

MS. SONNABEND: My question which sort of just occurred to me now I might not be able to word in the right way. But in reading

the European studies, the one from Italy particularly they tested biodegradable row covers as well as mulch films. And the row cover is biodegradable but it will last long enough in a season, but then of course as a row cover you would remove it and theoretically compost it. Are there issues there or would it be okay to compost it because you're assured by the same ASTM standards that a row cover would also degrade in composting.

MR. COTTON: That's a great question. To be fair I don't have the experience to answer that question. I believe the gentleman who testified earlier from upstate New York does some row tunnel growing and composts that material on the farm for use on the farm. So actually I would guess these materials would compost quite readily. Eric had some samples. I hope he passed them around.

It's a relatively thin material.

And you may have heard there is some controversy of some of the compostable stuff, maybe you've seen it in the cafes around here, as you get to bigger and bigger thicknesses. But almost every composter will say the bags work just fine. So thin sheets of this stuff allow a lot of surface area for microbes to attack that. So I have not heard of any issues with that whatsoever. It composts great.

MR. FELDMAN: Questions? Are you able to tell us what the time to degradation, complete degradation is?

MR. COTTON: No. That's a question -- we can certainly -- I can absolutely get you that answer.

MR. FELDMAN: Okay.

MR. COTTON: I think that will vary to some extent clearly by the thickness and to some extent material by material. But I'm sure we can provide that, be happy to.

MR. FELDMAN: Okay, thank you.

Thanks a lot.

MR. COTTON: Thank you.

MR. FELDMAN: Kyla Smith. And we have Jim Munger on deck.

MS. SMITH: Okay, good afternoon. My name is Kyla Smith. I am the certification program director for Pennsylvania Certified Organic. PCO is an NOP-accredited non-profit certifying agent that certifies about 650 operations in the mid-Atlantic region. I'd like to comment on the recommendation to add biodegradable mulch film made from bioplastics to the National List.

PCO does not have a position for or against this specific material. We realize the desire for farmers to want more options for weed control. However, the current version of the recommendation prevents challenges for certifier verification.

It is difficult to enforce parts of the regulations, including annotations that leave room for interpretation among producers

and certifiers. We recognize that there will be changes to the annotation prior to voting.

PCO asks that you consider the following requests for clarification to provide clear measurability by certifiers, to ensure compliance of farmers' organic system plans with the USDA organic regulations. We hope these comments prove useful in your deliberations.

The current recommendation defines biodegradable mulch film as showing at least 90 percent biodegradation absolute or relative to microcrystalline cellulose in less than 2 years and simultaneously requires the grower ensures complete degradation at the end of each growing or harvest season. That is consistent with Section 205.206(c)(6) which requires that plastic or other synthetic mulches be removed from the field at the end of the growing or harvest season.

We appreciate the clarification regarding the intent of portions of the

annotation were specifically included for MROs and certifiers to evaluate these materials as opposed to the portions that were specifically included for producers.

The question still remains that since this is a synthetic material it must be removed from the field at the end of the growing or harvest season, and we are seeking further clarification on how we are to enforce that when typically growing or harvest seasons are less than 2 years and this material could take up to 2 years to biodegrade. Guidance for certifiers to verify that growers have taken measures to ensure complete degradation annually is crucial for consistency throughout the organic industry.

Instead of removal from the field the subcommittee's recommendation requires that synthetic bioplastic degrades by the end of the growing or harvest season. If the subcommittee's recommendation infers that degradation equals removal this needs to be

more clearly stated.

We encourage the board to ask the program to develop guidance that will provide further clarification to certifiers and producers regarding the following. What does complete degradation mean and how is complete degradation expected to be verified? By visual confirmation or testing by the certifier, inspector or producer? If the expectation is that the inspectors will verify complete degradation of the product this may not be able to be verified until the following year as many inspections occur prior to the end of the growing season.

We also support the idea of the development of a certification program to the ASTM standards. This will assist MROs and certifiers that may not have the expertise to make these determinations without additional time and resources.

Lastly, the technical evaluation report highlights several sub-ingredients like

titanium dioxide and carbon black that are used in the production of biodegradable mulch film. In future production there could be other pigments that are used and these could potentially be synthetic.

We appreciate the clarification that was provided during the subcommittee's presentation that stated if other synthetics are present in future formulations these must be specifically petitioned for inclusion on the National List.

PCO is unclear if there are synthetic forms of titanium dioxide that are used in biodegradable mulch materials. We understand that titanium dioxide is a mined mineral. However, it may undergo synthetic processes. As a certifier that does material review it is critical that the addition of any synthetic materials to the National List is restricted in the same and consistent manner as similar materials already listed on the National List.

PCO needs to know if it is our responsibility to confirm if a sub-ingredient such as titanium dioxide is mined. Restrictions such as this are typically annotated. PCO supports putting tools in the farmer's toolbox. However, we must do so in a consistent and clear manner. We think it's imperative that the board must address these concerns. And thank you for your time and effort.

MR. FELDMAN: Thank you. Questions? Zea.

MS. SONNABEND: Thank you for that input. If you heard us this morning, I'm sure you did, the direction that we are going is trying to have separate sets of the annotation that are oriented for growers and certifiers, and oriented for MROs.

If we put the onus of assuring complete degradation onto the MRO side of the equation so to speak so that before the product is approved we have to know that in

the right conditions they sufficiently break down. Then all the certifier's role would be is to verify that the appropriate actions as spelled out in the guidance had been taken to assure that it is breaking down in the field. And then one of the ways of verifying that would be to look at the field and see if it hadn't really been broken down and then to see what appropriate actions.

We feel this is somewhat more consistent with a process standard approach to the whole thing. I'm wondering do you feel okay with that if that's the way that we're going.

MS. SMITH: We totally support a process-based standard. I think clarification -- inspectors may view "complete" differently and so if they are onsite evaluating a field I may, I don't know, see little bits or a few bits here and there and may evaluate that differently than a different inspector. So I think that further clarification in that

regard may be helpful.

MS. SONNABEND: Okay. They would not have to evaluating complete. They would have to be evaluating appropriate and then just reporting on what they saw in the field.

MS. SMITH: Yes, that would be helpful.

MS. SONNABEND: Okay.

MS. SMITH: We would -- we would be down with that.

MR. FELDMAN: Other questions? I had a question about your comment in your written testimony about essentiality which I found interesting. Could you tell us where you think this decision or what factors you think should be brought to the question of essentiality of this material in organic systems?

MS. SMITH: I didn't write the written comment. Our policy director did and she's not here so I'll try to address that from conversations with her.

We, most of our producers that obviously use the black plastic and we understand that there's a concern that it does end up in landfills. We do have extensive lists of recycling centers that we have found that take the plastic. I don't know what happens to it after they take it. And so we haven't had a big outcry from our producers to use this product. We've had a few requests. So in regards to whether or not our producers find it essential I'm not sure. I don't know if that really answers your question very well.

MR. FELDMAN: Thank you. Thank you very much.

MS. SMITH: Thanks.

MR. FELDMAN: Jim Munger, is he? Thank you. And Lindsay Fernandez-Salvador is up next.

MR. MUNGER: Hello, I'm Jim Munger. Being here reminds me of coming here in 1970. I had just celebrated the first

Earth Day at the University of the Pacific and came to Roger Williams University and taught environmental chemistry for 30 years. I'm now a farmer and growing things primarily by hydroponics.

I'm a member of the Cornucopia Institute and here as a citizen lobbyist. I know that "lobbyist" can sometimes be sort of a dirty word but I guess it's a necessity to make sure that we get all sides of the positions.

I'll talk today about four materials, ferric phosphate, oxidized lignite, propylene glycol and rotenone. I have grown chrysanthemums and rotenone is actually made from chrysanthemums.

Ferric sulfate, we support the proposal to remove ferric sulfate from the list of synthetic substances allowed for use in organic crop production. Ferric sulfate -- phosphate currently is allowed to be used to kill slugs.

All commercial products that contain ferric sulfate also include EDTA. Ferric phosphate was initially allowed because EDTA was considered an inert ingredient. The recent reviews suggest that EDTA is not inert and is required to ensure efficiency of the product.

This indicates that EDTA must be evaluated as an active ingredient. Previous NOCSB reviews of ferric phosphate with EDTA have shown that EDTA may be harmful to the environment, EDTA may persist in the environment and that EDTA has potential for mammalian toxicity. Products containing ferric phosphate with EDTA should be prohibited.

Oxidized lignite. Cornucopia recommends that you reject the proposal to allow hydrogen peroxide-extracted humic acid derivatives, also called oxidized lignite. These humic acids are a product of coal-mining which is harmful to the workers and the

environment. The TER stated that these coal derivatives may be toxic. The manufacturing process is not known because it was removed from the petition.

Most important, synthetic humic acids are not essential. The same humic acids can be added to the soil through natural methods such as mulches, compost or cover crops.

Propylene glycol monolaurate (PGML). Cornucopia recommends that you reject the proposal to add propylene glycol monolaurate to the National List. PGML was petitioned for use as a miticide although it has broad-spectrum activity against mites, fungi and bacteria.

The broad-spectrum activity can reduce biodiversity. Organic farmers have found that maintaining a diverse, balanced ecosystem approach to guideline will prevent or minimize mite damage on their crops. A broad-spectrum miticide is not only

unnecessary but actually upsets the balance of the ecosystem.

And I make a comment on rotenone, and basically we are suggesting that rotenone be prohibited as a natural substitute. I heard the bell so I --

MR. FELDMAN: Yes.

MR. MUNGER: -- it up.

MR. FELDMAN: Unfortunately. Thank you very much. Any questions? Thank you, sir. Lindsay, you're up. And on deck is, excuse me, Bill Wolf is on deck. Thank you.

MS. FERNANDEZ-SALVADOR: Good afternoon, I'm Lindsay Fernandez-Salvador from OMRI. I'd like to focus the majority of my comments today on the biodegradable mulch films.

We sincerely appreciate the subcommittee's serious consideration of our comments, our written comments. Much of our concerns were addressed in the subcommittee's

presentation of these materials. Thus I want to spend some time here indicating to the NOSB what we agree with to this point and what continues to need further clarification and consideration.

For the definition of biodegradability we understand that the ASTM 6400 is a standard that serves two purposes, both a practical one for the mulch manufacturer to be able to test on a shorter time frame whether it's worth it to pursue certification to the ASTM 5988 and as a test for ecotoxicity of the components as they degrade in a composting condition.

We did question the need for verifying both standards for our purposes but accept this explanation going forward. The one thing I would suggest, however, is to make sure that the subcommittee and the NOSB in its entirety fully understands this argument and evaluates if indeed the certification to ASTM 6400 is needed for verifying the intent of the

NOSB's requirements for the allowance of these films.

We are happy to see the clarification that you intend to require third party certification to the various standards. Although OMRI could verify the various standards independently it would not make me happy to have to do so.

In regards to the clarification for excluded methods and the use of them in the source and manufacture of such substances we appreciate the clarification that it is the intent to prohibit the use of excluded methods in the organisms or microbes that may carry out the manufacture of these biodegradable plastics.

This clarification offered in the presentation concurs with OMRI's policy on the use of GMOs in input products. We're up to date with advances in this technology and it does include GMO microbes that produce biodegradable plastics in their cell walls so

it will potentially become a reason for denying OMRI listing in the future.

A few clarifications. We're concerned about the additives in the mulch films. My previous research indicates that patents for mulch films include other types of additives such as colorants like red colorants, resins to prevent breakdown, fungicides, et cetera. So, we're concerned about whether or not the intent is to limit it to both carbon black and titanium dioxide, or that we would allow any other additives that might come in future petitions or future products.

And finally we want the subcommittee to clarify that by indicating that the mulches should be bio-based that those biodegradable plastics created by microbes are included or excluded from this definition. The subcommittee's recommendation indicates that bio-based is organic material in which carbon is derived from a renewable

resource via biological processes. So does this definition for you include bioplastics made by microbes fermenting on methane gas generated from food waste or plant-based media? We'd like to understand more about your understanding of bio-based.

We know this is a complicated issue. The petition was very thorough but my experience indicates the technology for bioplastics is moving fast and becoming more innovative. OMRI's goal is to ask the question as to whether the NOSB has all the information about what's coming in this technology.

We are concerned that there will be a pressure on OMRI to prove any and all of these materials because there is such a huge demand for them. Thank you.

MR. FELDMAN: Thank you. Questions? John.

MR. FOSTER: If I had all the information about all the products that might

be coming down the pipeline I'd be in a totally different line of work. So given that we will not have that information, we just, we won't, ever, what's the best you see we can do with the information we are likely to be able to have? Because we won't have it all, we never will. So what's the best we can do with what we have? In that regard. You know, preparing and gathering information, what do you --

MS. FERNANDEZ-SALVADOR: Totally.

MR. FOSTER: -- yes.

MS. FERNANDEZ-SALVADOR: Well, I would look at the current technologies right now. The petition outlines several different types of biodegradable plastics that are out there. So I would first go to that and I would make sure that you all understand what those technologies are and understand what you're approving.

I would go back to the source. Do you care about that it's made from cornstarch?

Do you care that it's made by a microbe on fermentation? These are the things that we want to understand from you.

We also want to understand whether or not the additives that are declared in the petition are the only additives that you are going to allow or want to allow. Because going forward we know that manufacturers will put more things because it enhances their product. So we just need to know based on the information that you have today what you're limiting it to and what you're not limiting it to.

MR. FELDMAN: Thank you. Zea?

MS. SONNABEND: Thank you, Lindsay. I'd like you to help me understand your comment about the "bio-based" word. Was it sort of -- was it similar to my question from the BPI gentleman about whether bio-based would include products that had originally stemmed from petroleum versus plant materials, or is it a different point than that?

MS. FERNANDEZ-SALVADOR: No. My main concern here is that there's biodegradable plastics that are derived with feedstocks from plant materials and then there's also biodegradable plastics that are derived by microbes through fermentation of methane gas from food waste facilities and/or plant media.

And so my understanding is that the test that the petitioner proposed for this would test that it was in fact bio-based. But I wanted to understand whether or not you guys understood what bio-based was and if your intent was just that the feedstocks need to be bio-based or if it can also be created by a microbe via fermentation.

MS. SONNABEND: I don't recall seeing the methane gas origin in our petition or TR.

MS. FERNANDEZ-SALVADOR: Right. And so this is where I introduce other technology that's out there. I attended a

presentation by a company that was developing this as we speak so that's where I was trying to seek clarification.

MR. FELDMAN: Questions? Has OMRI been asked to approve this material up to this point?

MS. FERNANDEZ-SALVADOR: No.

MR. FELDMAN: Okay. Okay, thank you, Lindsay. Another question.

MR. FOSTER: To what extent do you feel it's necessary to address the GMO issue on this material relative to the greater context of GMO policies kind of already in place? And I'd also be interested, if NOP has a thought on that I would be interested in that too. But I want to hear what you have to say.

MS. FERNANDEZ-SALVADOR: Sure. Well, that same presentation that I attended where the microbes were in fact creating the biodegradable plastics in their guts, in their cell walls, the presenter indicated that there

were GMO microbes being developed that could produce them faster with different properties.

And according to our current OMRI policy we would not allow biodegradable plastics from that type of genetically modified microbe, the same as we wouldn't allow citric acid derived from genetically modified aspergillus. So I think what has been presented by the subcommittee and what I understand as the changes would then come in concurrence with OMRI's current policy.

So we would -- we do understand that genetically -- cornstarch from, for example, genetically modified corn would be an allowed feedstock and that would also be in concurrence with our current policy.

MR. FELDMAN: Do you want some clarification from the program?

MR. FOSTER: If they're interested. I would be interested in hearing the relative need to review or to consider the GMO issue with respect to this material given

that there's a larger context of excluded methods. That's what I was interested in. Do we need to do it now would be one way of asking that question.

MR. FELDMAN: Should we postpone that till later? Because we'll be back at this.

MS. BAILEY: Was there a question in there? I thought that was more of a statement.

MR. FELDMAN: He's looking -- he's desperately looking for advice.

MR. FOSTER: Well, I'm -- what I'm interested in is what is the perceived need to deal with GMO issue with regard to this specific material given that there is a larger, more what I would consider broader scope approach to GMOs that's evolving and I think getting more refined. But what is the need to do it within the context of this material deliberation.

MR. MCEVOY: Okay, so the question

is should you deal with it now or later. We would like a consistent approach to how you look at 205.105, the excluded methods, what's the use of excluded methods. When is it a use of excluded methods and when it is not.

And in the past the NOP in the questions and answers said that GM crop residue, GM soybean meal as a fertility input was not a use of an excluded method. We don't have those questions and answers up anymore but we're looking for the board to take a look at this through the GMO Ad Hoc Committee and provide us with a recommendation.

So a consistent approach to looking at those types of substances and how they're used or not used in organic agriculture is what we would like to see, a consistent approach. And you have a substance in front of you that you're taking a look at. So you have to make a determination of whether it makes sense to wait and do it as a group or to look at it on a case-by-case basis.

MR. FELDMAN: Thank you. Other questions? Lindsay, one quick question on ASTM 6400 and the ecotoxicity testing. How does that align with the board's responsibility to evaluate long-term or short- and long-term effects on ecotoxicity, on ecosystems.

MS. FERNANDEZ-SALVADOR: OMRI's responsibility?

MR. FELDMAN: Well, the board, as you would see the board in doing its review before listing something.

MS. FERNANDEZ-SALVADOR: Oh. Well, in relation to my comment there what I was really getting at was that because OMRI is going to have to verify this. So we're going to have to get two different certificates for 6400 and 5998.

My initial understanding was that 6400 was really a test for the manufacturer to make sure that they're going to get through the 2-month period of time in a composting

facility and that would indicate to them whether or not it was worth it to pursue the 5998.

And for OMRI I would prefer not to have to verify two standards if I can only verify one. But I understand now that 6400 tests both the threshold on timing and also ecotoxicity. So if you feel that is beneficial and you understand that 6400 in fact does something for the NOSB in their review of it and the effectiveness and its effect on the environment then we accept that argument and we're happy to verify that as well.

MR. FELDMAN: Are you familiar enough with the ECOTOX review?

MS. FERNANDEZ-SALVADOR: That's the first time I'd heard of it.

MR. FELDMAN: Okay, thank you. Thank you very much. Bill Wolf is up and on deck is Pam Coleman.

MR. WOLF: Hi. I haven't been in

front of the board in 2 years and you guys have been doing some great work. I appreciate the opportunity to be here.

I'm Bill Wolf with Wolf DiMatteo & Associates. I'm an organic advocate, a farmer, a gardener for 40 years and been involved in organic inputs as well.

Regarding mulch film our initial client was Joan and Drew Norman of One Straw Farm as actually as a pro bono support for their efforts, later joined by the Biodegradable Products Institute. And I'm making that statement for transparency purposes.

However, as I became involved in looking at this material I actually was a little skeptical and became more and more convinced that it was a useful tool for organic farmers.

In 2002 at the first NOSB meeting 20 years ago I presented the OFPANA guidelines for organic production as one of the tools for

this board to consider in establishing standards and materials review processes.

At that time we were all talking about how the standards need to be easy to understand and encourage conversion of more acreage. Organic practices should encourage an increase in earthworms, improve food quality, biodiversity in the environment and help farmers, eaters and the planet.

I thought at that time that organic acreage would be over 10 percent by 2010 and we even discussed those kinds of goals 20 years ago. But today it's only 1 percent worldwide. We have to ask ourselves why and what we can do about it.

Today a number of organic farmers are leaving organic, especially the smaller farmers. It has become very complicated and very prescriptive and not very friendly for the smaller farmers. There is a risk that organic may have peaked in some markets and in some uses.

Contentious debate rather than consensus-building is now the norm internally. Decisions about what materials should be allowed have always been controversial.

On your screen there's a slide that talks about the roots of organic regulations, showing that really we began with the soil. A lot of the principles behind the decisions about organic regulations I jokingly and perhaps not so jokingly say, you know, think like an earthworm when you're making some of these decisions.

Decisions about materials not only have been controversial but we have to look at the broader picture. It is useful and needed? Is it better than currently available tools? Is it okay with the earthworms and the beneficials? Let's apply common sense and work together for continuous improvement.

Organic was an agricultural standard built from a philosophy rooted in good soil management, not based solely on what

the consumer expected who are often influenced by simplified messages from organizations and businesses.

On your screen right now are slides from One Straw Farm's use of biodegradable mulch. And I think we did a good job, one of the things I'd like you to consider is that I think we did an excellent job establishing these overarching principles in a system of having an organic system plan and the expectation that inspections verify that farmers are protecting the soil. Let's let that system work rather than being overly restrictive.

Here's biodegradable mulch broken down within the same season on One Straw. And here's some of the language about the OSP and farm practices that really manage the process. Remember that growers have to oversee the soil and improve the soil, and that's the case. So please consider biodegradable mulch and approve it. There's a number of bullet points

there on the screen that you've heard about. I'm running out of time here so thank you for your time and your efforts.

MR. FELDMAN: Thank you. Appreciate it. Any questions from the board? Yes, Wendy.

MS. FULWIDER: You made a lot of points about farmers leaving organic and that's certainly been part of the trend, especially with grain farmers. Could you give us some tips on how to make things a little easier to keep farmers in organic and to attract more farmers?

MR. WOLF: Well, the areas where I especially see people departing who have been certified are smaller farmers who are doing a good portion of their farming and marketing in local and direct CSAs, farmers markets. I've probably been to 20 farmers markets in the last 2 years where most of the farmers are no longer organic, many of whom I knew and used to be and have just said, you know, the

constant doubt of what I'm doing on my farm and all the paperwork has become somewhat overwhelming. And I've met a number of farmers who are also using biodegradable film and saying I got out, I liked it, I'm not using it -- I mean, I'm not going organic.

I think there's -- actually there's probably 10 things that we as a community need to look at doing to encourage more acreage. And part of it's education, part of it's research and the research priorities that you are all talking about setting is really important. I think that at the extension level we've seen shift but not as much shift as we need.

But I also think that looking at the regulations in terms of being excessively prescriptive is a piece of it. When you mentioned dairy farmers, I know dairy farmers who have looked at -- the pasture rule has actually had a negative influence on some of the smaller farms because they were used to

the concept of pasture but they didn't keep track of how many grains of grass.

So we get into zero tolerance situations, in other words, we have an incident where there's one bad apple and then we lay down a rule. And I'm not criticizing the pasture rule, I think it was progressive to address those issues of potential CAFOs. But when we deal with a single incident by an umbrella that affects and comes down on everyone it negatively affects the community in many ways. So that's a very good discussion item long-term.

MR. FELDMAN: Thank you. Any other questions? Thank you, Bill.

MR. WOLF: Thank you.

MR. FELDMAN: Pam Coleman is up and Walter Talarek is on deck.

MS. COLEMAN: Good afternoon. My name is Pamela Coleman. I'm a farm policy analyst for the Cornucopia Institute. I'm a scientist with a master's degree in vegetable

crops, a Ph.D. in plant pathology. I'm also a former inspector and reviewer notably for WSDA.

We'll have a slight change of topic because I'd like to congratulate the Crops Subcommittee for developing such a clear and comprehensive proposal for the review of inerts ingredients from EPA Lists 3 and 4.

Cornucopia supports this proposal and we believe that the NOSB should expedite the review of these List 3 and List 4 inerts. We'd like to see the review of inerts be given even higher priority than the review of new materials and we're hoping the NOP can support the project.

And now back to bioplastic. We also appreciate the work that you've done on bioplastic mulches. The promise of this biodegradable plastic to warm soil and control weeds makes it tempting to approve these materials soon. The challenge though is to verify that they truly are biodegradable and

that they don't leave harmful residues in the soil.

Cornucopia is requesting that this petition be tabled until the bioplastics can be thoroughly evaluated. The TER was dated August 2, the proposal completed August 15. Yes, the NOSB is a great group but given the challenging technical nature of the review materials we'd like to see that more time is available for all of us to fully evaluate these materials, and especially the breakdown products.

You'll notice that I'm calling them bioplastics, not biodegradable, and that's because the petition itself calls them bioplastics. We at Cornucopia are not convinced that they're biodegradable to the degree that is consistent with organic principles, that is to maintain or improve the quality of the soil.

The TER also raises concern about the biodegradability in seven different

places. I don't have time to read them all but certainly you can ask me more about them in the question and answer period.

I would like to read one, though, line 649 from the TER. "Comprehensive studies were not found that described the environmental impacts of the use of bioplastic mulch. Due to the wide variety of potential chemicals released from incomplete degradation of bioplastics this is a data gap."

The Crops Subcommittee agreed it might be difficult to separate claims from truth concerning biodegradability. In short, it's clear that synthetic chemicals are used in the manufacture of bioplastics. Therefore, there's a possibility for residues of synthetic chemicals in the soil even after the mulch appears to have degraded.

We'd like to see each of these types being reviewed individually and we think that might shed more light on the products of degradation and perhaps clarify things.

Please table this petition and I thank you for your attention.

MR. FELDMAN: Any questions from the board? Pamela, I'll quickly ask you, you identified data gaps that were identified in the TR. What area -- can you just briefly tell us where those are?

MS. COLEMAN: Okay. Do you want me to just read the lines or read the quotes?

MR. FELDMAN: Well, if you could read the -- yes, read the quotes quickly if you can.

MS. COLEMAN: I'll talk fast and abbreviate. Line 421, "Erucamide binds strongly to soils and sediments in water and is likely to bioconcentrate in aquatic organisms."

Line 445, "Studies were not found that specifically assessed ecotoxicity of bioplastics following degradation in the soil and a better understanding of bioplastic degradation is needed."

Line 488, "AAC" -- that's the aliphatic aromatic copolymer -- "may leave residues of synthetic chemicals."

Line 592, "Researchers have argued for more extensive research into the biodegradation pathways of the various bioplastics."

Line 595, "Due to the diversity of bioplastics currently being developed testing is necessary to determine which polymer mixtures are degraded completely and what effects incomplete degradation may have on the agro ecosystem."

Line 649 I've already read. Line 652, "Reports have shown that bioplastics containing terephthalic acid at concentrations over 50 percent do not completely biodegrade in soil."

I will say I noticed that Zea mentioned some studies from Europe. I did not see a scientific citation on that and I would -- I believe that's another reason why we

should table this until she can give us the citation and allow the scientific community to review that additional information.

MR. FELDMAN: Thank you. Any other questions? Thank you very much.

MS. SONNABEND: We did only get those European studies about 3 or 4 days before the meeting. They will be posted to the docket I believe after the meeting is over because they were part of the testimony that was put in today by BPI. And one of the studies has a lot of other citations to further research that we have not had a chance to dig up and look at.

MR. FELDMAN: Thank you. Thank you, Pam. Walter Talarek and David Moore is up next.

MR. TALAREK: Good afternoon. My name is Walt Talarek and I'm here representing the W. Neudorff company of Emmerthal, Germany. Neudorff is a very small family-owned and operated producer and registrant of pesticide

products most of which are considered by EPA to be low-risk pesticides. And many of these registrations that it owns are for products that are approved for NOP and OMRI claims and logos.

Two of these products that are approved for NOP and OMRI claims are Sluggo and the slug -- I'm sorry, the Bug-N-Sluggo products. Both of these products contain ferric phosphate as an active ingredient.

Back in 2008 Steptoe & Johnson initially submitted its petition to de-list ferric phosphate from the National List. That petition was subsequently modified in 2009. And since that time over the last few years Neudorff has both testified at a couple of these meetings and submitted on numerous occasions to the docket its scientific information and objections to the Steptoe petition.

Just recently the Crops Subcommittee came out with a recommendation to

reject the Steptoe petition. I'm here today to say that Neudorff the Crops Committee's recommendation. The rationale provided therefore we fully support.

And further, we would like to thank the board, the full board, for going back per our request and requesting a supplemental technical report on this petition. And we might note that that petition included most of the scientific information that we submitted but not all of it. And I'll make a couple of comments here as I go on as to what information was not considered.

Number one primarily was the initial set of comments that was included in the Neudorff opinion. And that opinion was submitted several times to the docket and that was not considered. Okay.

Well, in deciding on the Crops Committee's recommendation we would urge the board to consider in addition the decisions by

other regulatory authorities around the world as to what is the active ingredient in Neudorff's two slug baits.

EPA as well as other organizations such as the EU, IFOAM, Codex Alimentarius Commission, all of them have decided that there is only one active ingredient and it is ferric phosphate. The European Commission also specifically decided that EDTA was not active and the products do not contain ferric EDTA. So, that information was submitted to the docket also on several occasions.

I might like to note that Neudorff slug baits are mixtures. It's not a product that's chemically reacted during production. There's four ingredients all of which are -- well, the inert's on List 4 and the active is on the National List right now.

MR. FELDMAN: Thank you. Any questions? Thank you very much.

MR. TALAREK: Thank you.

MR. FELDMAN: David Moore is up

and Cam Wilson on deck.

MR. MOORE: Good afternoon and thank you for this opportunity to address the board. My name's David Moore. I'm a California licensed agricultural pest control advisor and qualified applicator, and I work for Neudorff.

I'm here to encourage each member of this board to affirm the Crops Subcommittee recommendation and vote to reject the petition to de-list ferric phosphate from the National List.

Ferric phosphate is the sole active ingredient in our product Sluggo, the only effective molluscicide currently available to organic growers. Assertions that ferric phosphate is not an effective active molluscicide and the implication that our registration is somehow flawed by the presence of an allowed inert fly in the face of regulatory findings the world over and have no basis in science.

The finding that ferric phosphate is an active molluscicide is shared by the U.S. EPA, IFOAM, ECOCERT, the EU regulatory body and other regulatory organizations the world round. Neither the supplemental technical report nor the subcommittee recommendation makes any attempt to state a definitive conclusion on this issue because there is no definitive conclusion.

The voice of the organic grower has been unanimous in support of ferric phosphate and this voice includes growers that are large and small all around the U.S. growing a wide variety of crops. In some cases these growers are producing a preponderance of the entire U.S. organic production of that crop.

These growers have spoken directly to the negative impact that removing ferric phosphate will have on production and availability of certified organic citrus, celery, leafy greens, strawberries and other

soft fruits. These are all agronomically challenging high-value crops.

I ask you today to please keep in mind the three E's of sustainability. One of these E's is economics and specialty crops grown organically have been a key factor in the economic sustainability of many small farms. The loss of economically sustainable certified production threatens the survival of these farms and will result in fewer acres in certified organic production.

Many of these growers will choose not to attempt to compete in the conventional market and these acres may then be lost entirely to agriculture because of the far higher land value when developed for other uses.

The removal of the listing for ferric phosphate will place the U.S. organic standards outside the international norm on this material and can have only disruptive effects and will place U.S. growers at a

disadvantage.

The so-called alternatives cited in the various technical reports do not reflect agricultural reality. There are no field workers in strawberry fields or citrus groves hand-picking snails and slugs at night when the pest is active. A grower cannot exclude a pest from their field if that pest is already present and persistent in the soil fostered by the important practices of cover cropping, fallowing and conservation tillage.

The introduction of vertebrate predators such as poultry violates every basic food safety best practice and the soil fertility and crop nutrient standard 203(c)(1) and (2).

The report suggests chemical killing solutions that may violate FIFRA if they're not registered pesticides and more importantly, many of the cited materials are not allowed for this use in certified organic agriculture.

Lastly, data reflecting large-scale industrial dumping of EDTA in the past is not germane to the agricultural product in use at hand for your vote today.

Again, I'd like to encourage every member of this board to affirm the Crops Subcommittee recommendation and reject this petition. The review process developed by the Inerts Working Group and adopted unanimously by the board will address the many allowed synthetic List 4 inert ingredients with due process and proper scrutiny. Thank you very much.

MR. FELDMAN: Perfect timing, thank you.

MR. MOORE: I tried.

MR. FELDMAN: Any questions from the board? Thank you very much.

MR. MOORE: Thank you.

MR. FELDMAN: Okay, Moore and then we will pick up with the next speaker which is -- I'm sorry, Cam Wilson. We'll pick up with

Liane Jenkins after the break. So, thank you.

MR. WILSON: Good afternoon, board members. My name is Cam Wilson. I work for the company Neudorff and I'm here to also talk about ferric phosphate. We support the Crops Committee decision to reject the Steptoe petition to de-list and to keep ferric phosphate on the National List.

A very important point here is all regulatory bodies worldwide agree on one common fact, that ferric phosphate is the only active ingredient in the Neudorff bait. Here we know it as Sluggo. EDTA is not an active ingredient nor has it ever been identified as an active ingredient anywhere in the world.

A similar petition to the Steptoe petition was filed in Europe by a competitor who manufactures metaldehyde baits. Based on this review of this similar document the European authorities concluded the following. And I'd like to quote something from their report.

Ferric phosphate is regarded as the active substance. Annex I listing is therefore justified. The coal formulants EDTA or EDDS have no molluscicidal impact.

In 2008 the EPA reviewed the Sluggo registration, also confirmed that the active ingredient is solely ferric phosphate. It is not EDTA and it is not iron EDTA.

Neudorff has registered ferric phosphate baits in over 30 countries worldwide and the authorities responsible in every one of these countries have determined that ferric phosphate is the only active. None of these countries have determined that the chelate is active. EDTA has no molluscicidal activity and EDTA is a List 4 inert which is compliant with the current organic regulations.

It's important to point out that iron phosphate and EDTA do not react in the bait and do not form other substances. Globally, organic certifiers recognize, such as IFOAM, ECOCERT Canada, and OMRI allow

ferric phosphate and the Neudorff bait as certified for organic production.

Recently it was suggested that ferric phosphate slug and snail baits had adverse effects on earthworms. Neudorff carried out its own extensive studies that determined that the ferric phosphate baits did not harm earthworms. They contracted a third party, Lures Report 2009, that confirmed the same thing, that the ferric phosphate baits do not harm earthworms. This study was done at rates at 4 times the label rate just to challenge the study.

In conclusion, we support the rationale of the Crops Committee that ferric phosphate must be considered independently. And other ingredients and inert ingredients in the ferric phosphate bait are currently allowed under Section 205.601(m). The inert ingredients will be addressed separately by the Inerts Working Group.

We kindly ask that the NOSB keep

ferric phosphate on the National List and remain harmonized with previous decisions and organic certifications worldwide. U.S. organic farmers need iron phosphate baits to stay competitive with other countries. Thank you and I'll leave myself for questions.

MR. FELDMAN: Thank you very much. Any questions from the board? Thank you very much.

MR. WILSON: Thank you.

MR. FELDMAN: So we're going to take a break, folks, 15 minutes. Regroup here at 3:45 on the nose and we will pick up with the five remaining public commenters in the Crops Subcommittee category. And then the board will try to vote on the issues that we figure we can vote on. So we'll let you know.

(Whereupon, the foregoing matter went off the record at 3:29 p.m. and went back on the record at 3:44 p.m.)

MR. FELDMAN: Okay, the meeting is called to order. Thank you all. So, Liane,

go ahead. Thank you.

MS. JENKINS: Hello and thank you for this opportunity to present to the board. My name is Liane Jenkins, senior regulatory and compliance specialist at Lonza. Lonza is a technical manufacturer of metaldehyde which is used in formulating a non-organic molluscicide. Metaldehyde competes with Neudorff's ferric phosphate slug and snail killer. Lonza believes in fair competition between these products based on performance.

Neudorff markets its ferric phosphate products as organic. However, it misleads organic producers and consumers as ferric phosphate should not be considered organic for three basic reasons.

One, ferric phosphate is not an effective molluscicide without adding non-organic EDTA to the formulation. Two, NOSB previously denied organic listing for EDTA and this decision should apply to ferric phosphate products. And three, EDTA does not qualify

for organic status under the National Organics Program. I'll briefly elaborate on each of these points.

First, ferric phosphate by itself is not an effective molluscicide. The supplemental technical review and USDA's Agriculture Research Service assessment concluded that ferric phosphate by itself has limited effect on snails and slugs. Ferric phosphate must be combined with a chelating agent to be used in controlling these pests.

EDTA is what makes the product truly efficacious. EDTA acts as a synergist and only the combination of ferric phosphate and EDTA will there be a toxic effect on these snails and slugs.

Neudorff's own patent documents the need for EDTA in their ferric phosphate slug control formulations. The patent shows that ferric phosphate by itself has little to no effect on the pest until combined with EDTA. NOSB should conclude the combination of

ferric phosphate and EDTA is a complete active system and this active system is not on the National Organics List.

Secondly, NOSB previously assessed sodium ferric hydroxyl EDTA and rejected the petition due to EDTA's behavior in the environment. This assessment stated that EDTA use results in harmful movement of metals in soil and river sediments. EDTA degrades slowly in the environment and EDTA poses a risk to human health.

The recent supplemental technical review determined that EDTA used in ferric phosphate molluscicides poses the same risk as the EDTA in previously assessed sodium ferric hydroxyl. Since NOP already assessed the risk of EDTA and deemed it incompatible with organic production then this existing decision should be implemented for ferric phosphate products containing EDTA.

Lastly, ferric phosphate as a molluscicide contains the ingredient EDTA

which has already been determined to be incompatible with organic production. That means that current ferric phosphate products are not truly organic. It misleads organic producers and consumers of organically grown food when ferric phosphate EDTA products are offered as organic.

The organic consumer understands that organically produced foods are not treated with synthetic pesticides, the ingredients do not cause harm to the environment or to themselves or their families. This is not the case when ferric phosphate is used as a molluscicide due to the EDTA in the formulation.

Ferric phosphate uses EDTA which is known to have an adverse effect on the environment and humans. Based on this, ferric phosphate products are not a true organic material. NOSB should recommend it to de-list from the National Organics List and USDA's National Organic Program should promptly take

the formal step to complete the de-listing.

Our written comments to NOSB submitted last month stated the legal standard for a material to be considered organic: 1) it must not be harmful to human health or the environment; 2) it must be necessary to production because of the unavailability of a wholly natural substitute; and 3) it must be consistent with organic farming and handling.

As I've discussed, ferric phosphate fails to meet the standard and hence should not be considered organic. We urge the board to vote to de-list ferric phosphate from the National Organics List. Thank you very much for your time and attention.

MR. FELDMAN: Thank you. Any board questions? Thank you very much. Luis -- can you pronounce your last name for me?

MR. MONEGE: You did it great.

MR. FELDMAN: Monege?

MR. MONEGE: Yes.

MR. FELDMAN: Okay, perfect.

Okay, and Marco Castor is on deck.

MR. MONEGE: Good afternoon. My name is Luis Monege. I work with organic banana growers in Peru including Colombia. And I'm here today to speak on their behalf.

During the last 3 years the organic banana industry in South America has faced a new threat, the red rust, a small insect that reproduces very fast and affects the quality of the fruit, making it non-exportable.

The insect damages the fruit when the flowers are still closed. The control of this pest is very difficult and most of the available control alternative has proven to be ineffective.

In 2010 on Esperanza Farm in Ecuador, a 15 years old organic banana farm was attacked for the first time by the red rust thrips. The researchers tried all known and reported alternatives such as cultural practices, spraying repellants and approved

insecticides applications. Over 15 different substances and treatments were tested.

Cultural practices and repellants showed to have low or no effect at all over the pest. Only two substances presented acceptable control, pyrethrins and lonchocarpus roots extract also called rotenone. Both substances are needed in an integrated pest management program in order to avoid resistance issues and to control outbreaks that range from slight to severe. In case of a severe outbreak only rotenone has proven effective.

Red rust affected Nueva Esperanza Farm so seriously during 2010 and 2011 that exportable fruit volume was lower on one-sixth of its production, from half a million boxes per year to only 75,000 boxes. This illustrates the severe production decreases that can occur without the use of rotenone, making organic banana production unsustainable and leading to the closing of hundreds of

farming operations.

Nueva Esperanza Farm is not an isolated case. Thousands of small, medium and large organic banana growers in Peru, Ecuador and Colombia are facing similar situations.

The problem is becoming bigger and it has the potential to seriously affect the supply of organic bananas from those countries which represent the 95 percent of the U.S. market supply. Signatures of organic banana growers organization representing more than 2,000 organic growers on more than 5,000 hectares of organic certified land from Peru, Ecuador and Colombia were submitted to the NOSB stating their opposition to the Crops Subcommittee proposal to add rotenone to 205.602 as prohibited natural substance.

This is a clear and loud message, an SOS message from the organic growers in Latin America asking this board to keep the use of this natural plant extract as allowed in organic as it currently is. The future of

these organic growers and their families may depend on your vote.

On the other hand, the organic banana industry in South America is committed on finding new and better alternatives for integrated pest management but it requires time to develop answers to the new challenges.

At the present time rotenone is critical in organic banana production in South America for red rust control. There are no other alternatives available and the potential damage of this pest is catastrophic. Please on behalf of all those growers and those families do not prohibit the use of rotenone in organic agriculture. Thank you.

MR. FELDMAN: Thank you. Any questions? Nick.

MR. MARAVELL: Yes. The damage from the red rust thrip, does that lead to damage -- is that cosmetic or does that lead to spoilage of the fruit itself?

MR. MONEGE: It's cosmetic. It's

just the skin. If you look at the picture it's just the discoloration on the skin of the fruit. But it's -- there is no internal damage of the fruit. But it is rejected by the market.

MR. MARAVELL: Oh, of course. So in other words if it went into storage and was shipped, et cetera, the fruit would still be intact but the customer wouldn't buy it.

MR. MONEGE: Correct.

MR. MARAVELL: Thank you.

MR. FELDMAN: Thank you. Mac.

MR. STONE: Luis, is there a relationship to weather patterns or other factors that create the thrips thrive in certain microclimates rather than others? And kind of related to that, you heard this morning that this group is pretty hard on the apple growers, the poultry growers are being -- the methionine issue and so you don't take this personally, but the 3-year sort of window that was discussed earlier to find an

alternative, how scary is this 3-year alternative to you?

MR. MONEGE: The most appropriate answer I can give you right now is I don't know. Three years from now sounds like a whole bunch of time to develop alternatives but the things in Latin America move a lot slower than here.

We have been investigating into the literature about alternatives and we know that the spinosad is something that has some control in other crops in other regions of the world over thrips similar to the thrips that cause the red rust. But we don't know what is going to happen in a banana plantation in the tropical part of the world.

And the first thing that we have to do is try to convince the manufacturer of the molecule to go to Latin America to each individual country to get the registration so we can use it. So, is 2016 a good period of time? I don't know. But I will say that if

it is a period of time for you in the States to get through the whole paperwork and all the bureaucracy it could be even worse in Latin America.

MR. FELDMAN: Any other questions? John.

MR. FOSTER: Typically how many applications in a given year would you apply to the crop?

MR. MONEGE: Well, it depends because it's not all year round, right? I mean we have our seasons. It depends on the rainfall during the year. But it could be every other week in a short period of time and alternate with pyrethrins. But worst case scenario will be every other week.

MR. FOSTER: Quick clarification on that. Every other week for how long? For 3 months or 6 months? I know it's going to vary from time to time, just typically.

MR. MONEGE: I would say worst case scenario would be every other week during

the whole year.

MR. FOSTER: Okay. Thanks.

MR. FELDMAN: Thank you, Luis. Luis, what about spinosad? Is it registered for use in any of those countries or have you looked at it all --

MR. MONEGE: It's not.

MR. FELDMAN: -- for this particular species of thrip?

MR. MONEGE: No, it's not registered. We are very close to the manufacturer of the Entrust which is the most popular formulation of a spinosad. But they are reluctant to go through Peru, Ecuador and Colombia and get the registration. The process of get registered in those countries is really difficult.

MR. FELDMAN: Thank you. Jennifer. One other question.

MS. TAYLOR: Thank you. What kind of health issues have the workers reported in regard to using this product?

MR. MONEGE: Well, thank you, Jennifer. This is a natural plant extract, right? This substance is coming from pre-Hispanic times. Since then, since the Native Americans use it for different purposes.

We have no registered events related with human health. I mean, there is no negative -- how you call it -- events I will say regarding the use of rotenone. We have no records in Latin America that something like that happened.

MS. TAYLOR: But with the knowledge now that, you know, it's a possibility that it does happen in other places --

MR. MONEGE: Well, yes.

MS. TAYLOR: -- how will you use that knowledge with?

MR. MONEGE: Rudy Amador, my colleague, is going to refer to that topic specifically. I will prefer that he, as he is the expert in that area he will answer that

question. Gracias.

MR. FELDMAN: Gracias. Marco and Jack Manix on deck.

MR. AMADOR: Good afternoon. My name is Rudy Amador. I'm replacing Marco who unfortunately could not be here today.

I'm director of environmental affairs for Dole in Latin America. We're based in San Jose, Costa Rica. And we appreciate the opportunity to come and speak with you today. I will be speaking in favor of maintaining rotenone on the NOP list for some additional reasons as those given by Luis.

I don't have a lot of time to go through risk management theory but if you take a look at this picture we can all agree that it is dangerous to jump off a building. You can have a problem with the cement down below. If you don't manage the exposure side of the risk management equation which is hopefully you will put on a bungee cord which is UL-

tested or an air mattress down below. But basically the point is, and it applies not only to rotenone but anything, any pesticide or actually any farm input is that you need to manage the exposure side of the equation.

Out of the EPA's RED from 2007 I extracted basically the two dangers of rotenone. The first one being acute toxicity for human health, especially inhalation, and the second one being infested environment being very highly toxic to marine organisms. Again, we can manage that risk by decreasing exposure.

This is to answer a little bit of the questions that Luis got, this is the personal protective equipment that's actually on the rotenone label down in Peru. Also the same engineering controls accepted by the RED that the EPA put out in 2007 in order to reduce that risk to acceptable levels. That's regarding the health risk mitigation.

And on the environmental side

similarly there's good air culture practices that are applied. In the case of rotenone it's a liquid. It's applied only to the pseudostem. This is the banana plant. There is -- solids are not applied.

Also, it's applied in areas that, since it's organic bananas, in very low rainfall areas and therefore very difficult for the product to get to waterways and produce an environmental effect. In addition to that obviously we do not allow or permit applications directly to water or drainage canals or anything similar to that.

I wanted to present very quickly a label. This is a label, the registered product in Peru. Four things to point out here. In addition to the local registration that is required for any product and which takes time to achieve for any alternative that is found in that time will need to transpire into the countries where we operate in. The label specifically says, again, those risk

mitigation measures, not contaminating water, using the appropriate personal protective equipment.

In addition, I wanted to point out that there's other crops. We're here representing organic bananas but there are other crops that apparently are using this. This label mentions asparagus, cotton and citrus.

The other very important point to discuss here is the issue on international regulatory scenario with rotenone. As early as 2009 the Codex delegation was not supporting the deletion of rotenone from the Codex Practices on Organic Agriculture. And on the most latest Codex list rotenone is listed.

What they did there after 4 years of discussion was that they were concerned about effect on aquatic organisms. So they added a restriction which is the substance should not be used in such a way as to prevent

-- or should be used in a way to prevent flowing into waterways.

Similarly in the EU it is registered and on the organic list. I'll end up here, but very important for you to know just 3 weeks ago here in the United States the EPA decided not to revoke the tolerance exemptions that it had proposed to do so earlier in the year citing the need for imported produce of this substance.

My time is over. I appreciate your questions if you have any.

MR. FELDMAN: Thank you. Questions? John.

MR. FOSTER: So, the -- as probably everyone knows I kind of have mixed emotions about this particular material. How effective or how useful would it be to imagine a world where rotenone was on 602 with some limiting annotations that would minimize its per-year usage or crop usage? You're here representing bananas so if it were only used

on bananas, I don't know, twice a year and only in rotation with other materials would that be useful or not effective?

MR. AMADOR: I think we favor any limitation that will minimize worker exposure or exposure to the environment regarding good agricultural practices. I do not think it's a good agricultural practice to limit applications to two times a year. That could produce outbreaks that would have to be controlled with other means that may not be as effective as rotenone.

And in some cases as the graph that Luis mentioned we basically had to -- were on the verge of closing the farm until we found this alternative. So we do not favor restricting frequency. We do favor good agricultural practices and establishing mechanisms in which to protect workers and water which are the two main issues.

MR. FELDMAN: Yes, Mac.

MR. STONE: Is rotenone used on

any other tropical fruits?

MR. AMADOR: We are unfortunately not very aware of that. We're basically involved in the pineapple and banana business out of Latin America. And I put that label there on purpose because we found that one that was listing those other four crops, asparagus, cotton and there's one other there. But we were unaware of the use.

We do know, as Luis mentioned in the organic banana industry this could be basically a catastrophe if growers are not allowed to use it as we have not been able to find an alternative. And we continue to look for alternatives, by the way. There's not a better way to look for alternatives than if you have your farm infested with this and you make a decision in a few weeks' time. And we were basically weeks away from closing our farm. We were able to determine that rotenone was effective and began applying it and teaching our growers on how to do so

appropriately.

MR. AUSTIN: In one of your slides it showed the bunches, it showed the guy with the PPE equipment and stuff and it looks like your guys have been well trained. Go back one now. That one.

Okay, so the method of application is not to the entire plant specific but it's to a very specific, it's to the fruit itself, correct? Or am I misinterpreting what's taking place there?

MR. AMADOR: Yes, it could be in two different places. We call it the pseudostem which is the trunk of the banana plant. That is a place where this pest is harbored. And also if you see infestation around the fruit you need to do that too. So in this case what the worker is doing is he's lifting the plastic that's protecting the fruit to make an application within the developing banana stem.

Luis mentioned this but we've

tried oils. One of the things that you see with this is that the other products do not get into contact effectively with the insect and has left only rotenone as the alternative. But yes, the picture basically is showing complete personal protective equipment which is recommended by the product label and also recommended as an engineering control by EPA.

MR. FELDMAN: Other questions? Thank you very much. I'm sorry, Calvin. Go ahead.

MR. WALKER: Could you share with us your last statement about conditional approval?

MR. AMADOR: Yes, I was trying to make a reference to what happened in the Codex process. You know, they went through 4 years of discussions and finally they decided well, we're going to put in a restriction referred to water. And you know, just the thought that you could have an approval for renewable with a conditional use wording to improve good

agricultural practices, including worker protection requirements and protecting waterways.

MR. FELDMAN: Other questions? Thank you. Thank you very much.

MR. AMADOR: You're welcome, thank you.

MR. FELDMAN: So Jack Manix and Skip Paul is up on deck. Thank you.

MR. MANIX: Thank you. I'd like to thank you for allowing me the opportunity to get my 2 cents in on biodegradable mulch, specifically BioTelo. My name is Jack Manix and I'm a certified organic grower. I've traveled from downtown East Dummerston, Vermont to Providence on a beautiful sunny day to try to help persuade you to approve this product which I think is essential for organic growers.

In 1993 14 towns in our county tried to site a landfill and dump on our farm and a KOA campground next to us and take some

of the land by eminent domain. While I'm talking to you I'm going to pass around this highly offensive picture. I'm glad to see there's no young adults on the board. It's a dumpster full of black plastic.

And on our farm we eventually fought that battle from 1993 to 1996 and won the battle. And they gave up the siting of the landfill. So the results of that is that I hate trash. And on our farm which is a family farm, been in my family since 1770 we do everything possible to reduce, reuse and recycle.

Right now I produce about three dumpsters' worth of black plastic. I have one sitting on our property right now that's due to be picked up tomorrow morning. It's embarrassing and I think as an organic grower where we try to do what's right for the Earth it makes it difficult to have that as part of our operation.

But we need to use mulch plastics.

We've used black plastic because, well, the global climate extremes have been a large reason. This past summer the extreme heat has kept, you know, we need that to retain soil moisture. When it's raining we need it to drain the moisture off the crops so that the roots don't get too soggy. So we've tried using hay and straw mulches and we do use a lot of those also but they're costly, they're difficult to apply mechanically and in the long run small growers and large growers alike find the costs involved with mulches worth the effort in producing a product that you can sell competitively, organically to families and neighbors.

I'm a member of NOFA Vermont board of directors, the Vermont Vegetable and Berry Growers Association, Vermont Association of Professional Horticulturalists, the Vermont State Farm Bureau. And I come in contact with a lot of young growers. And one of the previous speakers mentioned that we're losing

organic growers and yes, we are losing some organic growers. I feel a large part of that is because we don't market organics nearly well enough. The only time I see organics is in magazines that are directed toward organic people. I don't see it on Fox News and I don't see it in a lot of periodicals that we should be approaching for our market.

But one of the reasons we're also losing organic growers is because they don't understand the logic of not being able to use these BioTelo mulches. We keep trying to reinvent the wheel. They're being used in Europe and Canada for a long time. I know a lot of growers in New York State and Massachusetts that don't become certified because they need to use these organic mulches.

On our farm it's really essential for reducing the label and the use of fossil fuels. So I urge you to consider the approval of these organic mulches for organic farmers.

Thank you.

MR. FELDMAN: Thank you. Any questions? Thanks for coming down on a beautiful day.

MR. MANIX: Thank you.

MR. FELDMAN: Skip Paul, please.

MR. PAUL: I wanted to thank the board for allowing a few farmers to get away from picking up plastic mulch and come down here and talk to you about what we really want to do is harrow in BioTelo mulch.

My name is Skip Paul and I'm from -- actually a Rhode Island farmer. I'm from Little Compton, Rhode Island which is just as the crow flies about 50 miles down that way. Wishing Stone Farm has been growing organically since 1982. We were one of the first organic farms certified in Rhode Island. Right now our acreage is over 38 acres representing seven small diversified farms near our home farm.

To manage these farms

successfully, and some of them are over 3 miles away, we have come to rely on plastic mulch to control weeds, to retain moisture and manage water efficiency in our crops, and three, to give and add heat to -- as in soil-warming for early crops and even late-season crops. Quite often we'll put broccoli late, or hail Mary broccoli we call it on plastic mulch just because it actually gives us the heat to drive it into December.

At this stage in our evolution we are covering I'm ashamed to say over 40 percent of our crop lands with plastic mulch of some form or another. My family's sole income comes from farming so our marketing is 30 percent farmers markets, 20 percent wholesale and 50 percent CSA which represents over 385 families some of which have been with us for over 20 years.

We are year-round growers which means we grow and cultivate crops over 365 days a year. We are constantly in

communication with our patrons and develop deep relationships with not only our CSA members which we have contact with longer but with over 3,000 farmers market patrons which visit us weekly at our farmers market in Providence.

We are continually in communication with our patrons about issues facing us as farmers, how to do a better job, but also issues facing us as fellow human beings on this planet. Since the arrival of BioTelo on the ag stage more and more conversations have spontaneously developed around what it is and how does it work.

An earlier farmer that came up, Paul and Sandy Arnold, have been valuable pioneers in working and evaluating the BioTelo's effectiveness and biological safety of this product, not to mention reams of papers and articles that have been penned in Europe and Canada and elsewhere extolling its biological virtues.

These conversations are going on with our CSA members and farmers market customers too. As they are getting better and better informed about the safety and effectiveness of BioTelo they are asking the same question as we farmers are. What is the biological rationale of putting tons of oil-based completely synthetic plastic into our nation's landfills when we could be using BioTelo?

I feel BioTelo will save us energy because it's less tractors work going over, taking up plastic and doing other things. It will keep the fields adjacent to us cleaner and more sanitary. It will help us get cover crops more quickly and more efficiently, capturing nutrients left over from other crops and helping keep disease pressure down by more quickly being able to destroy diseased crops. This was particularly important this year with late blight on tomatoes and other things.

Pulling black plastic up, you have

to remove the plants by hand first. You can't -- no machine will take that up and so there's a lot more labor in pulling up black plastic mulch.

This issue has come to the forefront at our farm and has now gained such an importance that our members who are informed about this subject are urging us to drop certification on CSA plastic mulch acreage so we can use BioTelo and be more biologically responsible.

MR. FELDMAN: Thank you very much. Any questions from the board? Well -- oh, I'm sorry. Go ahead.

MR. FOSTER: How have you found its -- you know what, never mind. It's not going to be a relevant question for you.

MR. FELDMAN: Okay. Thank you so much for participating in this process.

MR. PAUL: Thank you.

MR. FELDMAN: And we thank everybody that participated in the comment

process today, public comment process.

We will now try to segue way in the next half hour or so to some of the votes. The Crops Committee came together briefly to get a sense of whether people felt comfortable voting on some of these materials. And we decided, or I didn't hear any objections to moving ahead with at least some of these votes and see how far we get.

It may be after we heard the rotenone discussion we should discuss that more? It's up to you all. But we could start at the top of the list, ferric phosphate, and work our way down if that's okay. Any objections to doing that? Okay. Okay, thank you.

CHAIRPERSON FLAMM: So you're prepared to move forward on ferric phosphate. Is there a motion? And I need something in writing so I can make sure that the motion is in order. Okay, thank you. I've got it.

You wish to proceed with making a

motion?

MS. BECK: All right, so I'd like to make the motion to remove ferric phosphate from Section 205.601(h).

CHAIRPERSON FLAMM: Is there a second to the motion?

MR. BONDERA: I'll second that.

CHAIRPERSON FLAMM: The motion has been seconded to remove ferric phosphate from Section 205.601(h). Discussion? Zea?

MS. SONNABEND: Thank you, Barry. I just want to make a very brief clarification. I hope everyone realizes this, but a vote yes will remove it from the list and a vote no will leave it on the list. It's a little backwards for some of our other votes.

CHAIRPERSON FLAMM: Any other discussion, comments? If not we'll proceed with a vote starting with Jay.

MR. FELDMAN: Yes.

MS. SONNABEND: No.

MR. STONE: No, sir.

CHAIRPERSON FLAMM: No.

MS. FAVRE: No.

MR. AUSTIN: No.

MS. BECK: No.

MS. RICHARDSON: No.

MR. FOSTER: No.

MR. DICKSON: No.

MS. FULWIDER: No.

MR. WALKER: No.

MR. BONDERA: Yes.

MS. TAYLOR: Yes.

MR. MARAVELL: No.

CHAIRPERSON FLAMM: The vote is 3 yeses, 12 nos. The motion fails to pass.

Does the Crops Committee have another proposal that they wish to move on?

MR. FELDMAN: Proposal to the petition on oxidized lignite which you'll state I guess, is that right?

MS. SONNABEND: So the oxidized lignite recommendation is the same as in the

posted document, no changes. And once again -- - well --

CHAIRPERSON FLAMM: Zea, please just state the motion and we'll get discussion afterward.

MS. SONNABEND: Yes, I'm waiting for Michelle to put it up. Okay. To add -- okay.

This has two motions, a classification motion and a listing motion. The classification motion is that humic acids that are hydrogen peroxide-extracted are synthetic.

MR. FOSTER: I'll second that.

CHAIRPERSON FLAMM: Okay, the motion has been made and seconded to classify hydrogen peroxide-extracted as synthetic. We need to take a vote on this. I'll ask if there is any discussion. Any discussion on classification of this material?

We never did the beginning of your committee. You were supposed to do the -- so

we've got a policeman in the court. So we apologize for not doing that earlier but I think for simplicity I'll just do it now and ask if anybody has anything that they want to reveal or discuss or ask an opinion on in terms of their ability to vote on this and any other materials we'll be voting on. And I want to make this retrospective if there was anything regarding ferric phosphate. I apologize. Jay.

MR. FELDMAN: I just want to share with the board what I shared with the program. I'll just read what I sent the program. I do not believe that I have any conflicts of interest regarding upcoming votes of the NOSB. However, the organization that employs me may have members who use or may use petitioned materials under consideration by the NOSB. Similarly, the organization I work for may receive contributions to support the organizations national forum from companies that use or may use materials before the NOSB.

CHAIRPERSON FLAMM: Okay. Jay has disclosed that interest. Is there any comment by anyone on that? Including if the program feels that they wish to speak up. If not we can move on to Zea.

MS. SONNABEND: I wish to make a voluntary disclosure of my interest also. I do not believe I have any conflicts with any of the items on the agenda and have asked the Department for that ruling and they have said I do not need to recuse myself.

However, I am a farmer who certainly uses things with inert ingredients in it and work for an organization that is a certifier that may certify anything that gets approved for the National List as well as being affiliated with three other non-profit entities who may or may not submit comments on anything at any particular time.

I get no financial gain directly from any of those activities except hopefully farming sometime. But not from direct use of

the products on the list.

CHAIRPERSON FLAMM: Board members, you've heard the disclosure by Zea. Any thoughts? Any comments by anybody including the program? And Zea has already indicated that she's run that by the program. We'll move on. John?

MR. FOSTER: So I too, a number of the contract growers -- this will be true for handlers too -- may use some of these materials. I don't -- may want to use them. I'm sure some will. But I don't have any direct financial gain from any of the companies involved.

I'm sure they're somewhere in our supply -- in Earthbound's supply chain but -- or going to be, but that's the limit of it. And that's what I declared in writing to the program, I don't know, whenever it was, a couple of weeks ago.

CHAIRPERSON FLAMM: Thank you for that, John. Any comments on John's disclosure

of his activities which was previously disclosed? I don't believe any comment from the program. Any other? If not we can -- I think we can proceed and thank you, Tracy, for being our watchdog. Thank you.

I believe -- I'd ask whether or not there was any discussion on the classification of this material. Hearing none I believe we can begin with the voting I think starting with Zea.

MS. SONNABEND: Yes, oxidized lignite is synthetic.

MR. STONE: Yes, sir.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: Yes.

MS. BECK: Yes.

MR. DICKSON: Yes.

MR. FOSTER: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

MR. BONDERA: Yes.

MS. TAYLOR: Yes.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

CHAIRPERSON FLAMM: And the chair votes yes. Now we can entertain a motion on the listing of the material.

MS. SONNABEND: The motion is to change the listing in 7 C.F.R. 205.601(j)(3) to humic acids, naturally occurring deposits, water, alkali and hydrogen peroxide extracts only to expire in 2017.

CHAIRPERSON FLAMM: All right. Do we have a second to that motion?

MR. FELDMAN: Second.

CHAIRPERSON FLAMM: We have a second to the motion to change the listing in 7 C.F.R. 205.601(3) to humic acids, naturally occurring deposits, water, alkali and hydrogen peroxide extracts only to expire in 2017. Discussion on the motion?

MS. BAILEY: Excuse me -- thanks. So just a clarification. So the annotation

that you have there says to expire in 2017. We would advocate that you put the actual date for sunset in 2017 there so that it says October, I believe it's October 21, 2017.

MS. SONNABEND: Oh, I accept that amendment as the motion-maker. Does the second accept it?

MR. FELDMAN: Yes, he does.

CHAIRPERSON FLAMM: We have a proposed amendment to the motion. Could you -- is it acceptable to the person making the motion and the second?

MS. SONNABEND: Yes.

MR. FELDMAN: Yes.

CHAIRPERSON FLAMM: Okay. Could you please -- as the originator of the original motion would you state the -- restate the amended motion? Oh, okay.

MS. BROWN-ROSEN: Sorry. Yes, the previous sunset date in the proposed rule was October 21, 2017 but when we issued the final rule for sunset 2012 the sunset date for the

current listing for humic acids was moved up to June 27, 2017. So June 27 would be the date that we would recommend to include. Sorry for the confusion.

MS. SONNABEND: June what?

MS. BROWN-ROSEN: Twenty-seven.

CHAIRPERSON FLAMM: Okay. Just so we get the right date.

MS. SONNABEND: So, the full motion is to change the listing in 7 C.F.R. 205.601(j)(3) to humic acids, naturally occurring deposits, water, alkali and hydrogen peroxide extracts only to expire on June 27, 2017.

CHAIRPERSON FLAMM: And that change of date is accepted by the person seconding the motion?

MR. FELDMAN: Yes.

CHAIRPERSON FLAMM: Okay. So the motion was amended to change the date to June 22 -- 27, 2017. Discussion on the motion? Any discussion on the motion? If not we can

proceed with the vote beginning with Mac.

MR. STONE: Yes, sir.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: Yes.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: No.

MR. BONDERA: No.

MS. TAYLOR: No.

MR. MARAVELL: No.

MR. FELDMAN: No.

MS. SONNABEND: No.

CHAIRPERSON FLAMM: And the chair votes no. So we've got to do a tally here. The vote was 8 yes, 7 no. The motion failed. Jay, do you have another?

MR. FELDMAN: The next proposal is the petition on PGML.

MR. BONDERA: So I would like to

suggest that we entertain two motions on PGML. And the first one is classification and I would like to myself make that motion that PGML is synthetic.

MR. FELDMAN: Second.

CHAIRPERSON FLAMM: I don't have the material here. The motion has been made and seconded to classify PGML as a synthetic. Is there discussion on the motion? Hearing no need for further discussion we can begin the voting on the classification of PGML beginning with Wendy.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: Yes.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

MR. BONDERA: Yes.

MS. TAYLOR: Yes.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

MS. SONNABEND: Yes.

MR. STONE: Yes, sir.

CHAIRPERSON FLAMM: And the chair votes yes. I believe the count is 15 yes, zero no. The motion passes. Do we have a motion on the listing of this material? The PGML.

MR. BONDERA: Yes, thank you. I would like to make that motion to add PGML to the National List 205.601(e) as an acaricide.

CHAIRPERSON FLAMM: Do we have a second to the motion?

MR. FOSTER: I'll second.

CHAIRPERSON FLAMM: Who seconded? Okay, John. It's been moved and seconded to add PGML to the National List 205.601(e) as an acaricide. Discussion? Any discussion on the motion? Harold.

MR. AUSTIN: Yes, I think I would like to just mention that, you know, this is

a material as we look to vote on it. A lot of the materials that we look at deal with essentiality and we have to discern whether or not the other materials that are listed as alternative materials are in fact truly what they're claimed to be. Are they actually alternative, are they effective alternative materials. Do they have the proper efficacy? Do they have the proper control? Are they as environmentally friendly as what we think they are?

I look at this material, I look at the alternatives that have been listed and I have some of the same concerns with those materials as some of the board members have with this particular material, whether to list it or not list it as far as their impact on the environment, their impact on the predacious insects.

I'm going to vote in favor of this but because I think the organic growers need a material that is effective at a time when

it's needed. A lot of the products that are out there right now are not immediately effective if a grower finds himself into a mite situation, a flare-up, there's not viable materials out there, especially in tree fruit and stuff that will really bail them out of a hot spot if they really, truly get into a difficult time. So being able to take and put a material, another tool out there that our organic growers could utilize, I think there's value to that.

CHAIRPERSON FLAMM: Further comments, discussion on this material? PGML. John?

MR. FOSTER: I would add to that -- - I agree with Harold -- add to that that I continue to have faith in the expectation that 205.206 and that kind of mandatory IPM system would necessitate a pretty good look at an appropriate record that other practices, other alternatives have been ineffective. And I want to keep driving that point home because

I don't think it hits the discussion table often enough. So I continue to have faith in that process and the rest of the regulation and how it's implemented. And I think in that context this is an appropriate material.

CHAIRPERSON FLAMM: Further discussion? Mac?

MR. STONE: Just as a tally-taker helping Wendy to make sure, remind everybody that there's no rush to convey your vote so that we can accurately tally. So when it comes your turn there's no rush to vote.

CHAIRPERSON FLAMM: Any further discussion on this proposed -- this petition material to be listed? All right, I believe we can then proceed with a vote starting with Harold.

MR. AUSTIN: Yes.

MS. FAVRE: No.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: No.

MR. WALKER: No.

MR. BONDERA: No.

MS. TAYLOR: No.

MR. MARAVELL: No.

MR. FELDMAN: No.

MS. SONNABEND: No.

MR. STONE: No, sir.

CHAIRPERSON FLAMM: And the chair votes no. Oh, I did it. You're next, Jennifer. Okay, I retract my vote.

MS. FULWIDER: I vote yes.

CHAIRPERSON FLAMM: The chair votes no. The vote is 5 yes, 10 nos. The motion fails. Does the Crops Committee have another proposal for consideration?

MR. FELDMAN: The review of inert ingredients.

MS. SONNABEND: On this one it's a little different than a petitioned item or anything because what -- the reason that we need a vote is to move forward with the whole

procedure. And so when we're voting for this we're not voting for exactly what's in each group of inerts or exactly what regulatory language is going to be or be locked into the details, but just to set in motion the things we need to set in motion in order for the procedure to move forward.

And so therefore the motion is the whole procedure but in terms of making it feasible for the voting sheet we're going to just say the motion to adopt the proposed Policy and Procedure Proposal on other inert ingredients in pesticide formulations on the National List.

MR. FELDMAN: I'll second.

CHAIRPERSON FLAMM: There's -- the motion has been made and seconded to adopt the proposed Policy and Procedures Proposal on other inert ingredients in pesticide formulation on the National List which is I think we should reference the document or the date some way.

MS. SONNABEND: Well, that's the title of the document that I read into the motion.

CHAIRPERSON FLAMM: Okay, this has been read into the record and it was posted on -- properly posted. Is there any question by the board about understanding what the motion is and what we're voting on? If there's any doubt please speak up, otherwise I'll proceed with the discussion.

Any discussion on this document? Procedural document. Any discussion? Hearing none I believe we should proceed with a vote. I think, Tracy, you are first off.

MS. FAVRE: Yes.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

MR. BONDERA: Yes.

MS. TAYLOR: Yes.

MR. MARAVELL: Yes.

MR. FELDMAN: Yea.

MS. SONNABEND: Yes.

MR. STONE: Yes, sir.

CHAIRPERSON FLAMM: Wendy?

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

CHAIRPERSON FLAMM: And the chair votes yes. Fifteen yeses, zero nos, the motion passes. Does the Crops Committee have any other proposals they wish to be considered at this time?

MR. FELDMAN: I'd like to skip to sulfuric acid and do that one. So John, I turn that over to you.

MR. FOSTER: We have two motions regarding sulfuric acid. The first one will be a classification motion. The motion would be to consider sulfuric acid as synthetic. I would move that.

MR. BONDERA: I'll second that.

CHAIRPERSON FLAMM: It's been

moved and seconded to classify -- read what you said -- sulfuric acid as synthetic. Discussion on the motion? Hearing none we can proceed with a vote beginning with Carmela.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

MR. BONDERA: Yes.

MS. TAYLOR: Yes.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

MS. SONNABEND: Yes.

MR. STONE: Yes, sir.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: Yes.

CHAIRPERSON FLAMM: And the chair votes yes. I believe we have 15 yeses and zero nos. We can proceed with a motion on the listing of this material.

MR. FOSTER: The second of two motions, that would be to list on 205.601(j) sulfuric acid for stabilization of digested poultry manure to a pH under 4.5 but not below 3.5. I would so move.

CHAIRPERSON FLAMM: Do we have a second to that motion?

MR. AUSTIN: Second it.

CHAIRPERSON FLAMM: We have a motion which has been seconded to list on 205.601 sulfuric acid for stabilization of digested poultry manure to a pH under 4.5 but not below 3.5. Discussion on the motion? Hearing no desire for discussion we can proceed with a vote and I believe, John, you're the one to start it off.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: No.

MR. WALKER: No.

MR. BONDERA: No.

MS. TAYLOR: No.

MR. MARAVELL: No.

MR. FELDMAN: No.

MS. SONNABEND: No.

MR. STONE: No, sir.

MS. FULWIDER: No.

MR. AUSTIN: Yes.

MS. FAVRE: No.

MS. BECK: No.

CHAIRPERSON FLAMM: And the chair votes no. Three yeses, twelve nos. The motion failed.

MR. FELDMAN: Mr. Chair, unless there are any objections from the subcommittee I'd like to propose postponing the additional two material petitions until -- or motions and petitions until Thursday.

CHAIRPERSON FLAMM: No objection? The remaining two proposals will be dealt with on Thursday. I believe that concludes the Crops Subcommittee work and we can move directly to Materials Committee.

Jennifer, if you would like to

take over. The gavel is passed to you for now. Symbolically, that's okay. Or you could have it for real.

MS. TAYLOR: Audience, please sit down. Please sit down. We're ready now. Thank you. Thank you for your patience.

I thought it would be good to start with some of the public comments, the written comments that we have received.

MS. ARSENAULT: Could you move your mike closer?

MS. TAYLOR: I thought it would be good to start with some of the public comments, our written comments that we received in the general docket that are often foundational to the purposes of many of us here as well as the proposal that we will introduce.

I support having in place the strongest possible standards for organic foods products to protect consumers, to help protect the resources of our planet and to keep us all

safe. Having choices is as important to consumers as keeping our food supply safe and it is information, that is transparency, that helps -- can we move to the first slide please, Michelle? Thank you.

I support having in place the strongest possible standards for organic foods, products to protect consumers, to help protect the resources of our planet, and to keep us all safe. Having choices is as important to consumers as keeping our food supply safe and it is information, that is transparency, that helps assure both.

Please consider chemical additives and processes that harm people, animals and the environment as the enemy and preserve the organic methods of farming, production and living as safeguards of our society by preventing these substances and methods from infiltrating our atmosphere, water, soil and food.

Another written comment. Please

keep the purity of the organic label and do not allow the proposed or any other synthetic substances under the organic label. Please keep synthetics and chemicals out of organic food and products for the good of all.

Another written comment from the general docket. Paying a premium for an honest product is okay with me, but if the organic seal has been compromised in my eyes I see no point in preferably selecting those products.

Another comment. Please keep organics safe.

The members of the National Organic Standards Board Materials Subcommittee include Jay Feldman who is also chair of the Crops Committee, Calvin Walker who is also co-chair of the Policy Development Subcommittee, Wendy Fulwider, co-chair -- I'm sorry, chair of the Livestock Subcommittee, John Foster who chairs the Handling Committee -- I'm saying committee and I mean subcommittee, okay? Zea

Sonnabend who is co-chair of this committee, the Materials Committee, as well as the chair of the GMO Ad Hoc Subcommittee and myself.

The document that you have before you represents the board's research priorities for the year 2013. And Zea and Calvin as leaders of -- key people and leaders in the development of the document will discuss the comments that we received and also the impact, the potential impact that we see that this document will have on the organic research agenda.

MS. SONNABEND: Should we go ahead and do it without slides? Because I believe Calvin and I each have a copy of it and we could just read through it. It's only six slides. It could be short.

Okay, our slides are to summarize the public comment that we received on the research priorities. I want to make clear that in our research priorities framework we stated that the priorities would be collected

over the past year and presented each fall at each fall NOSB meeting.

So you will not see anything in our posted document of research questions that arise during this meeting such as biodegradable mulch. Those will be in our next cycle of research priorities. But what is on this research priorities collection is the ones from the last two NOSB meetings roughly, priorities that have been collected over that time.

The criteria for research topics are -- there we go. So the second slide. Well, it's on there, it's not on there. Okay, the criteria for deciding what research topics to include, and I've shortened these. Everyone can read them in our posted document, but topics that are persistent and chronic, challenging, controversial, nebulous, lacking in primary research and relevant to assessing the need for alternative cultural, biological and mechanical controls to materials on the

National List.

Okay, Calvin, do you want to talk about the public comment? You want me to keep going? Are you sure? All right.

This is the public comments that we received. We received 11 commenters and this is in the regulations.gov docket. All of them supported the research document. None of them were opposed. Some of them had concerns and suggestions. Then in addition after the docket comment period closed we received two more directly which we will talk about at the end.

Okay, so these are the main points that were brought up in the comments. Research needs for organic farmers and processors continue to be significant. Feedback to researchers, research institutions and particularly the USDA, NIFA and the ARS on needs of organic sector is incredibly valuable.

Two, methionine should be listed

as a priority research topic. However, we do not support the inclusion of animal byproducts as an acceptable alternative. We request this focus area be removed.

Three, methionine research should focus on the viability of potential alternatives and explore plant materials, products of microbial fermentation, marine species, insects, worms and other invertebrates.

Four, organic farmers are innovators and solutions developed on farms do not always fit in the typical research framework. And research on whole farm management methods progresses from farms to research institutions and back to farms these systems questions need to be integrated into research proposals.

Five, the NOSB needs to carefully consider evidence available in the independent scientific literature.

Six, proposed areas of research

must be challenging and based on controversial NOSB decisions is okay. However, research needs that is persistent, lacking in primary research and difficult to identify needs to be a priority. For example, improved organic weed control methods. We encourage concerned citizens to include their own comments on areas where they think organic production needs further research.

Seven, research projects that focus on the integration of farm systems are extremely important because much research on farm systems has tended to focus on isolated aspects of farming practice. This methodology limits the scope of the research question so the results can be more easily analyzed and understood. However, organic farming is system-based and the methods used to study it must follow suit if they are to open our view to the interactions between different parts of the system that make up a farm.

We request a change to the

following language which we suspect will be used in the future. Controversial, i.e., topics on which there are widely differing perspectives in the independent scientific community or for which there has been very close NOSB votes, the addition being in the yellow there.

Nine, we urge the board to remove carrageenan from the list of research topics for the simple reason that researchers funded by the NIH and Veterans Administration already provide answers to these questions.

Ten, we urge the board to add the following language to the research priorities proposal. When researchers answer the NOSB's call to perform primary research on topics that are listed as priorities the NOSB will consider this research in its decision-making process. NOSB members in their deliberations will also take into consideration the funding source of research that is presented, especially when research is funded by entities

with a financial stake in the outcome of the research.

Eleven, organic farmers are faced with serious, on-the-ground problems that must be addressed by research. If the board is committed to encouraging research funding it needs to make a systematic attempt to poll farmers on the ground about what they consider to be research priorities.

Now, Michelle, I guess I gave you the version that's one slide short of what I made yesterday which means it's lost in the drop box thing. So I'll just verbally state the last slide but we don't have a slide for it.

We received two additional comments after the docket closed and I want to read them into the record. One of them was from the FMC Company. We urge the board to remove carrageenan from the list of research topics for the simple reason that researchers have already provided the answers to all the

questions and found carrageenan to be perfectly safe.

The next one that was verbal comments from our colleague Mark Lipson on our conference call was that the research topics would be more useful to funders of organic research if we provided direct links for each topic to which of the criteria they addressed so that funders who have set criteria can say here is a direct link from this criteria to this topic.

And then additionally that we prioritize the topics within -- we ask each committee to prioritize the topics and then we put the whole list of committee priorities together as one. But he suggested we prioritize within the committee's top priorities.

So those are the main public comment that we received. Thank you.

MS. TAYLOR: Are there any comments or any discussion? Nick?

MR. MARAVELL: Yes, on comment number 11 about hearing from farmers on the ground as to their research priorities. I was wondering if that type of information is available through OFRF. I was, well, thinking that perhaps the committee may have looked into that. Or perhaps anyone in the audience or anyone else? I mean, OFRF in the past has asked about research priorities. I was just wondering if that was part of -- no? Okay. End of question.

MS. SONNABEND: I think it is appropriate to ask the board if based on any of this public comment we want to make any changes to our posted document, such as the suggestion to remove methionine research on meat byproducts or such as to add that yellow clause into our criteria. Well, yes, we received comment on both sides of carrageenan.

MS. TAYLOR: John, go ahead.

MR. FOSTER: I have a question. What do you think about the research that

someone says is already done around carrageenan? Zea, what do you think about that?

MS. SONNABEND: I think the fact that we heard exactly almost to the word the same thing from both sides, that all the research questions were answered one way and all the research questions were answered the other way indicates it should stay on the list of research topics because not everyone agrees on the answers.

MR. FOSTER: Or rather everyone agrees on the advice but in a totally opposite direction, right? Okay.

I do have one more, actually. All the conversations we had -- you know what? I'm going to stop myself again. I'm good. I'm getting better at that. I think it's a function of getting older, actually. It's the only good thing I can find. So I'm going to hold off on that. Thank you.

MS. TAYLOR: Okay, so we will

introduce the motion. Okay. Yes, I'm sorry, Colehour.

MR. WALKER: Thank you and thank you for your work. I guess I want to for the sake of this being in the record just comment about my own personal perspective. I haven't been directly involved in this.

And I guess since this is a new conceptualization which I actually think is a very good idea and a much-needed idea for us to be making use of. I don't at all mean to come across negatively but I want to ask if it's discovered as was referred to and as is being raised after the NOSB has made a decision about a topic, it's identified that perhaps we don't have the research in place, and realistically and honestly that means it wasn't in place to have made a decision, then it's a little bit confusing that therefore we're going to decide that we need research which from my understanding of a precautionary principle we should have had in place before

we made a decision.

So I don't think it's a catch-22 commentary but I do want to raise that and ask -- I mean, it relates back to some of these topics that are on this current list. But I think from a perspective of coming up with a system that is functional for making use of this idea of annually doing this I would like to understand how we can address that or incorporate that. And I'd like whatever the subcommittee has internally discussed about that shared. Thank you.

MS. TAYLOR: Go ahead, Zea.

MS. SONNABEND: Okay. Michelle found the lost slide version and there's one semi-housekeeping change to our posted document that I would like to bring up.

When the Materials Committee originally passed the document we had an additional bullet point for carrageenan that was suggested within our handling committee by Jean although she missed the call when we

voted on it. But we would like to -- because this was already voted as a research topic we would like to add it to our final document, and that is what are the ecological impacts of seaweed cultivation and harvest in species used for carrageenan.

MS. TAYLOR: Okay, thank you. So do we have a motion to adopt the proposal on the NOSB research priorities with the recommended change? Yes, Zea.

MS. SONNABEND: I'll move to adopt the recommended research priorities. Oh, sorry.

CHAIRPERSON FLAMM: Jennifer, we also failed. We're supposed to by each subcommittee to do our recusal thing and we didn't do it.

MS. TAYLOR: Okay, you're right.

CHAIRPERSON FLAMM: I'll let you conduct that before we move to the motion.

MS. TAYLOR: Are there any conflicts of interest here? Okay, none being

reported let us proceed.

CHAIRPERSON FLAMM: Okay. Thank you, Jennifer. The Materials Committee has a proposal by the consideration of the full board. Is there a motion that the Materials Committee would like us to entertain?

MS. SONNABEND: Well, I'll make the motion but it's the wording in the posted proposal that I don't have in front of me.

CHAIRPERSON FLAMM: And are you going to -- the motion, will that include the amendment that you just gave?

MS. SONNABEND: Yes.

CHAIRPERSON FLAMM: Okay.

MS. SONNABEND: The motion is to adopt the proposal on NOSB research priorities with the amendment to add a bullet point to carrageenan saying what are the ecological impacts of seaweed cultivation and harvest in species used for carrageenan.

CHAIRPERSON FLAMM: Is there a second to the motion?

MR. WALKER: Second.

CHAIRPERSON FLAMM: The motion has been seconded. The motion is accept the proposal on NOSB research priorities that's been -- as amended as read by Zea, if that's satisfactory. I don't have the exact language in front of me but is everybody clear on what the motion is? Any questions about what the motion is?

Okay, the motion has been made and seconded. Discussion on the motion? John.

MR. FOSTER: Just, I'm fine with the language of this but when it comes up kind of with an eye towards traditional sustainability criteria I would just ask that the conversation at some point drift around to also the economic impact of seaweed cultivation and harvest in those areas. It seems appropriate to me not -- I don't want to change the language, I'm fine with that, but that was something that wasn't particularly well discussed. Actually it wasn't discussed

at all as far as I can recall in our discussions.

And when we were talking about adding this component to the research priorities I think it's reasonable to in our discussion have the conversation, what is the economic impact of these activities, particularly because they're not generally well covered in our checklists either going forward. I just think it's fair, that's all.

What does it do for the community economically. It may not be critical for this particular topic but it can be for other materials in front of the board.

CHAIRPERSON FLAMM: Sounds like something that you're suggesting for future research?

MR. FOSTER: No, just on this particular issue there's ecological impacts to the cultivation and harvest. I think we need further exploration on that. But I would hope that the conversation would also include a

discussion of the economic value of that activity to those as well when we talk about it. I don't want to add it, I don't want to go through that process, but I want to be mindful that there's many sides to every activity and economics is one of them.

CHAIRPERSON FLAMM: Any other comments, discussion? Hearing none we can proceed with the voting beginning with Joe.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

MR. BONDERA: Yes.

MS. TAYLOR: Yes.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

MS. SONNABEND: Yes.

MR. STONE: Yes, sir.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: Yes.

MS. BECK: Yes.

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.)

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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 true and accurate record of the proceedings.

Neal R. Gross

Court Reporter

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

P-R-O-C-E-E-D-I-N-G-S

8:05 a.m.

CHAIRMAN FLAMM: Good morning everyone. We're ready to go. The meeting is in order. Board members, please take your seat. This morning we start off with the Handling Subcommittee. John Foster is chair. John, I'll pass the gavel to you to conduct this session.

MR. FOSTER: Thank you, Barry. This is a virtual gavel, I assume. The virtual gavel. That's right. You can hang onto that. I'll be inventive. So welcome back everybody. Thank you for coming back.

We've got several materials to, all petition materials in one discussion document to go over this morning. I believe our standard protocol will be back in place, with Lisa Brines presenting proposals and summarizing presenting proposals.

We will then have, we'll have representatives from the American Academy of

Pediatrics and the FDA, to be available to respond to some member questions, which we presented to them ahead of time.

We'll have some public comment. We will break to modify proposals, if needed, and then later after lunch, we'll be going into votes. I anticipate we'll need to scoot one or two materials to tomorrow, maybe more. But hopefully, we can get through most of them today. That would be my preference.

So I'm following Jay's lead on being efficient and expeditious. We'll try and move fairly quickly with -- so we have one, two, three, seven, eight proposed petition materials, and then one of the discussion documents.

I'd like to proceed in order as they're on the agenda, and if there's -- unless there's other things to clarify, we'll just move forward on the first item after. I asked members of the Board to take a look at that list of materials, and if you have any

disclosures of interest you'd like to make at this time on any of those materials, now would be the time to do it.

(No response.)

MR. FOSTER: All right. I think we're good. So Lisa, are you ready to roll? Then take it away.

MS. BRINES: Good. Thanks, John. First petition of the morning is ascorbyl palmitate. This petition was received on August 29th, 2011, and was submitted by the International Formula Council.

The petition requests the inclusion of ascorbyl palmitate to Section 205.605(b) of the National List, for use as an antioxidant in infant formula. In support of its review the Handling Subcommittee did request the development of a new technical report, and both the report and the petition were made available on the NOP website in advance of the opening of the public comment period for this meeting.

Written public comment was received on this substance, and a representative for the petitioner is signed up for in-person public comment later this morning. Thank you.

MR. FOSTER: Thank you, Lisa. Nick, I believe you were headmaster of this material. Would you take it from here?

MR. MARAVELL: Thanks. First in the morning? Boy, all right. I'm going to -- I don't have any slides for the audience, but what I'd like to do is summarize briefly some of the comments that we have received, and just note that there, we have basically two types of arguments, if you will, being made.

One is primarily coming from a consumer perspective, that synthetics in infant formula are not the most desirable additive. On the other side of the comments, and those are coming primarily from industry, is that ascorbyl palmitate is a very useful synthetic in infant formula, because it has

some unique characteristics.

One of them is that it is fat-soluble, and it can serve as an antioxidant and function as a preservative, to preserve the essential oils that are added to infant formula, and also that it is heat-tolerant, such that during the manufacturing process it maintains its abilities, whereas some other antioxidants may not have that same capability.

There was also some discussion with regard to rosemary extract. The petitioner was saying that rosemary extract was an untested, unproven antioxidant and preservative, and that it could have unknown and harmful effects.

There were no citations for this, but the committee did attempt to research it, and there was nothing in the TR to substantiate harmful effects in infant formula. So while that claim is out there, it is true that rosemary extract is not a long-

term tested addition to infant formula.

However, I think we noted that with the case of ARA and DHA, it is -- in our approval process it was permitted to be used with those additives as well.

Ascorbyl palmitate is an approved source of Vitamin C, and can be added for that purpose, and I'd just like to make it clear that that's not what we're voting on here. We're voting on here as to whether ascorbyl palmitate is indeed appropriate for its use as an antioxidant and as a preservative.

There has been some discussion that there is a distinction between an antioxidant and a preservative. The distinction would follow along the lines of an antioxidant used during the manufacturing process is indeed to establish the stability and functionality of the formulation, whereas a preservative would be sort of added to, and I'm simplifying it here, would be added to sort of extend the shelf life of the product.

Now in consulting with the TR, we definitely found statements that there is no use of ascorbyl palmitate in processed food for nutrient value, and that without the use of ascorbyl palmitate, it would definitely -- well the use of ascorbyl palmitate was to prevent rancidity, and therefore extend the shelf life of a product.

So we may further explore that distinction between antioxidant and preservative. However, the TR is rather clear that it functions as a preservative, and indeed most antioxidants are preservatives. That's the nature of an antioxidant.

I'm not sure I need to go any further. I'm going to see if there's anybody else that has any further comments from the committee on ascorbyl palmitate.

MR. FOSTER: If you could kind of summarize the subcommittee's votes.

MR. MARAVELL: Summarize the vote?

MR. FOSTER: Yes.

MR. MARAVELL: Of the subcommittee?

MR. FOSTER: Of the subcommittee, yes.

MR. MARAVELL: The subcommittee, on the motion to list ascorbyl palmitate, voted unanimously. There was one absent, not to list ascorbyl palmitate. So it was a unanimous vote in that regard. Anything else I may have left out, John? Anyone else on the committee think that we should raise additional issues?

MS. SONNABEND: Well, this is the point where I'd like to ask questions of our experts. Is that appropriate?

Chair?

MR. FOSTER: It's fine with me. I wanted to kind of check with the program, if it's preferable to do in one big block, or is it preferable to do one-offs.

MS. BRINES: We're happy to go along one by one, as you go through this. We

do need to introduce the speakers for the courtesy of the audience, who doesn't know their background as well. So we're prepared to do that if this would be an appropriate time. Thanks.

MR. FOSTER: Okay.

CHAIRMAN FLAMM: John, we decided the procedures and agreed that the chair could make that determination, if given the -- if the chair knows what, who it is and whether there's any, you know, Board dissent about getting, make sure we get all points of view and not biased to the questioning.

So but it's -- you can make that call, but I think the Board ought to know just who we're calling for.

MR. FOSTER: So in our conversations we've had in the previous few days, it sounds like beta carotene, we might have some of the same kind of questions. Can we get through beta carotene and then ask our guests to speak on both at the same time?

MS. SONNABEND: As long as we go back and discuss the previous one, if we need to.

MR. FOSTER: Yes. Unless there's an objection, let's go that way. All right, let's go that way. Thank you, Nick. Was there any other questions on, that we need to get to on ascorbyl palmitate right now from the Board?

(No response.)

MR. FOSTER: All right. Thank you, Nick. Next, we'll do beta carotene. Tracy, our point on that. Would you take the pointer? I'm sorry, Lisa. I didn't see you.

MS. BRINES: Thanks, John. The petition for beta carotene was received on October 11th, 2011 and was submitted by the International Formula Council. The petition requests the inclusion of synthetic beta carotene to Section 205.605(b) of the National List as an ingredient in infant formula.

There is one other listing for

beta carotene on the National List, which is on 205.606, as an agriculture ingredient. That's the form of beta carotene extracted as an extract color derived from carrots. So it's distinct from this form that's being petitioned.

In support of its review, there was two technical reports available for the substance. There's one that was prepared in 2011 in response for the petition for beta carotene color, and in support of its review for this petition, the Handling Subcommittee had requested an updated or supplemental technical review, which was developed.

Both of those two previous technical reports for beta carotene, as well as the petition, were available to the public on the NOP website in advance of the opening of the public comment period. And again, the petitioner has signed up for in-person public comment later this morning. Thanks.

MR. FOSTER: Thank you, Lisa.

Tracy.

MS. FAVRE: Thanks, Lisa. Thank you, Nick, for sort of laying the same groundwork. We had essentially the same cluster of categories of comments for beta carotene as we had for ascorbyl palmitate. There were pretty passionate comments for diametrically opposed positions for the substance.

It is being petitioned as synthetic beta carotene, and we had some questions that we posed to some experts about the requirement for synthetic, specifically in use in infant formula, and hopefully we'll get some more clarification on that this afternoon.

The petition specifically talks about synthetic beta carotene as a lipid stabilizer in the formulas, and even though it does have nutritional value as a provitamin, it also is being petitioned for use as a preservative.

As a result, after much discussion back and forth and actually some, needing to get some clarity around the fact that if we declined to list it as petitioned, it still is likely to be used as a vitamin source in infant formula.

So and I'm sure that's probably not clear. Some of the public commenters specifically were concerned that we were going to refuse the use of beta carotene or specifically Vitamin A in infant formula, and that's not likely to be the case, regardless of where the vote comes on this today.

So in summary, we did vote as a subcommittee to list it as synthetic, since it was specifically petitioned for that, and secondly on the listing motion, it was a unanimous vote to decline to list.

But we have had some further discussion, based on not only some of the public comments, but also conversations among the subcommittee, and we want to get some

clarity during the question and answer session with the FDA and AAP experts that will speak to us today.

MR. FOSTER: Thank you, Tracy, and thank you for that good timing. Appreciate that. Are there any other questions from the Board before we ask our guests to come up?

All right. With that, Lisa, would you introduce our guests?

MS. BRINES: Sure. Thanks, John. Yes, in support of the Board's deliberation this morning, we had invited two technical experts in this subject area to be available for questions from the Board that might come up as a result of the deliberations, and we're lucky to have two of them available here today.

Our first invited speaker is Dr. Jatinder Bhatia, who is the current chair of the American Academy of Pediatrics Committee on Nutrition. Dr. Bhatia is a graduate of the Armed Forces Medical College of the University

of Pune, India.

He completed his pediatric residency, including a year as chief resident, at the Medical College of Georgia in Augusta, followed by a joint fellowship in Neonatology and Pediatric Nutrition at the University of Iowa.

From there, he joined the faculty of the University of Texas Medical Branch in Galveston, in the Departments of Pediatrics and Preventative Medicine and Community Health. He also held a joint appointment at the University's graduate school of biomedical sciences.

In 1991, Dr. Bhatia returned to the Medical College of Georgia as a professor of Pediatrics. Three years later, he was named Chief of the Division of Neonatology and Program Director in Neonatal, Perinatal Medicine Fellowship, and he is also a professor in the Medical College of Georgia School of Graduate Studies.

Dr. Bhatia's areas of research include a wide variety of neonatal issues including neonatal nutrition and total parenteral nutrition. His research has been supported by the National Institutes of Health, industry and foundations. He's the author of more than 100 articles, abstracts and book chapters, and has edited two books and he has made presentations of his work nationally and internationally.

He's a member of a number of different societies in terms of pediatric research and nutrition. He's an active reviewer for numerous journals and serves as an associate editor for a number of journals as well. So I thank him for making the trip to meet with us today.

Our second invited speaker is Dr. Sue Anderson. Since 1996, Dr. Anderson has served as the team leader for Infant Formula Regulation at the Center of Food Safety and Applied Nutrition at the Food and Drug

Administration.

She also serves as the technical expert for international issues in pediatric nutrition for Codex Alimentarius committees. Prior to joining FDA in 1996, for 18 years she worked at the Life Sciences Research Office of the Federation of American Societies for Experimental Biology in Bethesda, Maryland.

During her tenure with the Life Sciences Research Office, she worked with the Select Committee on GRAS Substances, and the review of health aspects of food ingredients, and she directed studies by expert panels for the issues related to nutrition, food safety and diet health relationships.

Dr. Anderson has a Bachelor of Science degree in Food and Nutrition from the University of Illinois, a Master's degree in Food Science from Auburn University, and a doctorate in Human Nutrition from Purdue University. I thank Dr. Anderson for being available for questions today. Thanks.

MR. FOSTER: Thank you, Lisa. So let me just remind Board members we, as a group in the Handling Subcommittee, we had generated a number of questions beforehand, and came to pretty good agreement that that was a good encapsulation of a number of the questions that we wanted to ask our guests today.

So let's start with those. I'd like to also, out of kind of respect for the petitioners and the audience, as well as keeping track of our own time, let's make sure we're targeting these questions on the petition materials at the moment.

This is why we have the guests here, so we want to kind of focus on that as much as we can. Every once in a while, I'll be reminding everyone that we have a break at ten, and we need to get through all of the materials. At least at this time, we need to sort through all of them in a relatively short time.

So keep it focused, and I'll try my best to remind us all of that. So with that, could we have our guests, Zea? I think we want to move into questions around ascorbyl palmitate and beta carotene. Doctors, could you come on up to the podium?

DR. ANDERSON: Good morning.

MS. SONNABEND: Good morning.

MR. FOSTER: Zea?

MS. SONNABEND: So as we're considering these two compounds, which have a number of similarities and some differences, we'd like it if you could just clarify for the Board the distinction between what is referred to as an antioxidant and a preservative, and then how people that talk about synergistic effects of antioxidant, and if you could just talk about that, how the different ones would be synergistic?

DR. ANDERSON: Okay. Well, preservatives can be a broad spectrum of compounds. They can be added. Antioxidants

would be a subcategory. Other preservatives are added to retard spoilage in bread, for example. But the antioxidants are a class of compounds that have preservative products by acting as antioxidants.

With regard to the synergistic effect of antioxidants, the role of antioxidants in food depends on the characteristic of the food, the characteristic of the antioxidants that are used, and the storage conditions of the foods, the length of time it needs to be preserved, and all of that is a very complicated chemical process.

There's a huge literature on the effects of mixtures of antioxidants. Specific antioxidants can have multiple roles in different food matrices, and they can act differently in different food matrices.

The mechanisms of action under specific circumstances need to be understood before there can be any discussion of how they interact, and you would have to know the

specifics of the specific antioxidant system you're talking about, and the specific matrix. So really, I can't comment any further than that.

MR. FOSTER: Other questions from the Board on the materials? Zea?

MS. SONNABEND: So are, and if you have a different perspective on that, we would also --

DR. BHATIA: No, I don't. Thank you, first of all, for having me represent the AAP. One of the things we have to understand, I'm sure this audience knows very well, that all these additions or subtractions or approvals or otherwise have come from many, many years ago, and back then, the only issue was safety/efficacy of the added compound.

Only now have we added functionality and outcome measures. So these two components, for example, have been shown to be safe, but mainly they are added for manufacturing purposes, not to show any

efficacy or effect in the neonate.

None of that antioxidants have really been studied to say "If I add this mixture, I'm going to have outcome X in the baby." These are all manufacturing issues that started off in the first place.

MS. SONNABEND: Okay, thank you. Our next question has to do with it's similar. Both of these two compounds have shown vitamin activity, and can be used as sources of vitamins.

We'd like to confirm that these are both recognized sources of vitamins, beta carotene for Vitamin A and ascorbyl palmitate for Vitamin C, and then we received some public comment that the beta carotene quantity that's used routinely for vitamin activity would be sufficient for the antioxidant effect.

In other words, it's like 250 units would be used for vitamin activity, but only 20, I don't have the exact figures, but

only 20 are needed for antioxidant effect, and we would like to hear from you concerning the relative quantities of their use as a vitamin, versus an antioxidant.

DR. BHATIA: Again, clinically the use of Vitamin A has been more as a vitamin for other issues like night blindness and the effect of mortality globally if there's a Vitamin A insufficiency.

Approximately 85 percent of the global population, as covered by the current standards, have Vitamin A added into infant formulas and foods. It is a minority of the population that has a deficiency.

We're still struggling with this, especially with the confounding variable of malaria, which we don't have in the United States. So yes, it's a source of Vitamin A. Yes, what we have currently in the Infant Formula Act is sufficient for the purposes put in.

It was not put in there at that

time as an antioxidant. It was put in there as a vitamin by itself, because we knew the vitamins are important for development of babies.

MS. SONNABEND: But would the amount put in as a vitamin be enough for the antioxidant activity?

DR. ANDERSON: Perhaps I can clarify on that. Vitamin C is added to infant formulas as a source of -- ascorbic acid is added as a source of Vitamin C.

Ascorbyl palmitate is added as an antioxidant. In order for the ascorbyl palmitate to be used as a source of Vitamin C, the palmitate and the ascorbic acid would have to be cleaved apart.

That is less efficient than providing Vitamin C as such, and infant formula manufacturers add ascorbic acid as the source of Vitamin C for the infant, in the infant formula. Now with Vitamin A, infant formula manufacturers add pre-formed Vitamin

A as the Vitamin A source in the formula.

They do not rely at all on the beta carotene that is added. The beta carotene is added as an antioxidant in the formula, and like I said, they do not rely on the beta carotene as a source of Vitamin A for the infant.

MS. SONNABEND: Thank you.

MR. FOSTER: Tracy.

MS. FAVRE: Okay. Just to clarify that statement, so pre-formed Vitamin A is already added to infant formula, and therefore meets the vitamin requirements for Vitamin A. Beta carotene is specifically used as an antioxidant?

DR. ANDERSON: That's correct, for formulations that are made at the current time.

MS. FAVRE: Thank you.

MR. FOSTER: Nick.

MR. MARAVELL: Yes. Just to clarify on ascorbyl palmitate. Vitamin C

would normally be added with ascorbic acid because, as you pointed out, it's more efficacious to do so. So the amounts being added to infant formula of ascorbyl palmitate then are not an amount that would be a consideration for a Vitamin C supplement. It's added solely as an antioxidant.

DR. ANDERSON: That's correct.

MR. MARAVELL: Thank you.

MR. FOSTER: Thank you. Last questions on either of the two materials? Zea?

MS. SONNABEND: Okay. Well, this is Question 5 on the questions we sent you, which I may not have phrased exactly right. But our understanding is that these antioxidants are used in the dry powdered formula, which is created with a high heat process and it's used to prevent rancidity of the oils in the formula.

I was wondering if the rancidity occurs right away when you make it, or if it's

a question of shelf life later on, and if it's the latter, how much shelf life would be lost not using one of the antioxidants?

DR. ANDERSON: Okay. It's necessary to provide heat during the processing of infant formula, in order to make it microbiologically safe. During the spray-drying process, which I believe your question was referring to, the infant formula is exposed to heat, but it's also exposed to oxygen.

So those two in combination can lead to some oxidation of the product, if it's not adequately protected by antioxidants. So there will be some potential for oxidation, not a whole lot, during the processing. There will be also some potential for oxidation during storage of the product. It's not a lot, because it's stored under nitrogen, and there's not a lot of exposure to oxygen.

However, because it's a powder, there's a very large amount of surface area,

and it can be -- there's a lot of potential for interaction because of that large surface area.

With regard to how much occurs at this point and how much occurs at that point, I'm not prepared to answer that, and if there's somebody from industry that has that expertise, they might be able to do so.

MR. FOSTER: All right. Tracy.

MS. FAVRE: So I guess we're back to the question of whether or not the antioxidant properties of the beta carotene or the ascorbyl palmitate is absolutely necessary in the manufacturing process, to ensure product safety?

DR. ANDERSON: The fat sources that are used in infant formula are used to "mimic" the fat profile in human milk, and that means that there are, is a fairly large percentage of polyunsaturated fatty acids.

Those are very subject to oxidation, as are -- and in particular the

long-chain polyunsaturated fatty acids, the DHA and ARA, are very much subject to oxidation.

They definitely need protection during the manufacturing and storage process, and the ascorbyl palmitate, beta carotene tocopherols system has been shown to be protective.

MR. FOSTER: I have Jean and then Nick and --

MS. TUCKER: Wait. Can we pause for just a moment?

MR. FOSTER: Yes.

MS. TUCKER: You folks are going to be up here for a little while. So I'd like to invite you to sit down, so you're not standing up all the time, okay.

MR. FOSTER: What fun is that?

(Laughter.)

MS. TUCKER: Okay. So we have two mics here for you, and two chairs.

DR. BHATIA: Thank you.

MS. TUCKER: Sure.

DR. BHATIA: One thing I would like to add unasked about the heating process for making powdered infant formulas, the United States and all the world manufacturers have bacterial counts and colony-forming units, which is lower than the USDA and the world standard.

Yet one is to understand, even with the intense heat and drying process that Dr. Anderson just described, infant powder formula is not sterile. That is why we make liquid formula and the cost will go up.

That's a different issue altogether. So having recognized that, if we lowered the heat for other reasons, we run the risk of having more bacterial colonization, because bacteria do not get destroyed with that amount of intense heat. It requires much higher than that.

MR. FOSTER: Thank you. So Jean and then Nick, and try and wrap it up after

that.

MS. RICHARDSON: Yes. My question relates to the shelf life of the infant formula. If you did not add either the ascorbyl palmitate or the beta carotene, what difference would it make in the shelf life of the infant formula?

DR. ANDERSON: It would definitely be shorter, much shorter. But I don't have quantitative. I can't say X months with and Y months without. But definitely shorter and one thing that you do not want in products for infants is oxidized fat, or any other deleterious substance.

MR. FOSTER: Nick.

MR. MARAVELL: Yes. This is less of a question, a little bit more of a factual insertion here, that in previous action, our Board has permitted ascorbyl palmitate and beta carotene. I believe both for particularly an ARA/DHA product added to infant formula.

So in terms of ensuring the safety of that specific fatty acid, I think we do have an avenue for that particular fatty acid.

MR. FOSTER: All right. So I think we'll wrap up questions on these two materials, have the presentations on, it will be lutein is up next.

But please, please make yourselves comfortable and I'm sure there will be additional questions, as far as some of the other materials as we move through that. Is that all right with you? You're our guests, so we want to make sure you're comfortable. Thank you.

DR. ANDERSON: Sounds good.

MR. FOSTER: All right. Having said that, Lisa in the spotlight. The next material would be lutein.

MS. BRINES: Thanks, John. The petition for lutein was received on November 14th, 2011, and was submitted by Kemin Health, LLC. The petition had requested the inclusion

of lutein at Section 205.606 of the National List as an agricultural product, for use as an ingredient in processed foods.

In support of its review, the Handling Subcommittee requested the development of a third party technical report. Both that report and the petition are available to the public by posting on the NOP website in advance of the opening of the public comment period.

Written public comment was received in support of this petition, and the petitioner is signed up for public comment later this morning. Thanks.

MR. FOSTER: Thank you, Lisa. Harold, you're lead on this. Would you take it from here?

MR. AUSTIN: Okay. Thanks, John. Lutein, I'll just go through this and abbreviate as much of it as I can. It's a carotenoid related to beta carotene. It's a strong antioxidant. This material has been

petitioned to be added for use in infant formula. Let's just state that right off, up front.

It is naturally present in many vegetables such as spinach, kale, broccoli, green beans. The petition form of lutein is derived from dried food grade marigolds, non-organically raised. This is the primary source to be used to be petitioned.

Lutein comprises the macular pigment of the eye and is found in the lenses. Acts as a blue light filter and serves an important role, according to what we've been petitioned, in eye health. It also is acquired only through one's diet and cannot be synthesized by the body.

The primary source for lutein for infants is human breast milk. The level of lutein in human breast milk will vary, depending on the dietary intake of the lutein-rich vegetables by the infant's mother. This will vary in different parts of the world due

to cultural dietary eating habits.

Cow milk or soy-based infant formulas would need to be fortified with lutein, to equal the amounts normally found in human breast milk. This ingredient is not required by the FDA under 21 C.F.R. 104.20(d)(3).

The petitioner has actually requested for this material to be listed for two uses. Number one, in organically labeled infant formula, number two, in organic-labeled foods. The Handling Committee decided that, through deliberation, that there was adequate source for the secondary petition request, and have chosen not to vote upon that.

We felt that for adults, for use in foods, that they could get that through natural dietary habits. There is enough alternate sources available. So the only thing that we're discussed today would be the addition of lutein to the list for use in infant formula.

This would technically fall under the category of accessory nutrients, and because of the actual method of production of lutein is confidential business information, the subcommittee could not verify that lutein was considered, should be considered as a non-synthetic, as requested by the petitioner.

In the TR, it was mentioned that they felt that the formulation process would classify this as a synthetic. The Handling Subcommittee was split on the listing of lutein for use in infant formula. The basis of this vote and those voting in favor of showed that the material is currently being used in infant formulas.

Secondly, because the importance of the role that it plays in eye health in infants and adults. Those on the Subcommittee that were opposed to the listing felt that it was not mandated as an additive by the FDA for use in infant formula, did not have enough information because of the CVI version of the

petition to determine whether it was a non-synthetic or not.

It does not appear to be essential, since it is in some brands, not in others, and there appears to be a viable non-synthetic alternative such as whey protein and microayalgae sources.

The rationale behind the Subcommittee choosing not to include the petitioner's request for the second was as I stated, that we felt that there was adequate alternatives for that listing.

Committee vote on that listing classification or the classification motion as a synthetic was 7 yes, 0 no, no absents. The listing motion to add lutein to the National List 205.605(b) for use in infant formula only, lutein using approved organic delivery ingredients, CAS No. 12740-2, that vote was 3 yes, 4 no.

If we could go to the next slide, we could summarize public comments. The

other, one other thing I would mention here, that the petitioner did mention that there were a couple of other materials like pectin and lycopene non-bleached that were produced in a similar fashion, and that was one of the basis why they felt that that product material should be listed as a non-synthetic.

But because of the information being confidential, the Board felt that we had no choice but to vote it as a synthetic. If we could go up one more, I think Michelle, or do we not have that? Okay, never mind. I've got it here. I'll just summarize.

Okay. Public comment summary. We had seven comments that were specifically in favor of listing lutein. We had eight comments that were specifically mentioned against the listing of lutein. There were numerous comments against allowing synthetics in general, 7,418 plus numerous additional ones.

There were also several comments

against additives, synthetic or otherwise, allowed for use in infant formulas, asking that we don't allow the over-fortification of infant formula. A quick summary of those that were in favor of listing on 205.605(b) is there's enough new scientific data to support the need during infancy, not only for eye growth in development but also for neural growth in development as well.

It's also within the last few years that nutritional and medical research has demonstrated positive effects of lutein for adult and infant eye and neural health, a similar quote. Lutein is found in human breast milk and its antioxidant properties can help protect infant's eyes from UV damage.

Cow's milk and soy-based formulas contain minimal lutein unless it's fortified. Lutein cannot be synthesized by the bodies; therefore, it is strictly from a dietary origin.

Any synthetic added to the

National List must be required by law, or essential for the handling of organically-produced agricultural products, and commercially unavailable in natural or organic forms.

NOSB was also urged to consider the essentiality, and this is kind of more of a general for the different components or materials that we're looking at today. But one of the general comments was the NOSB is urged to consider essentiality of nutrient-based, of the nutrient based on its critical function to infant, toddler or human development.

The decision to call a nutrient non-essential, because it's not specifically listed as essential by FDA in the Code of Federal Regulations, ignores valid and published scientific information by respected organizations.

A summary of those that are opposed to the listing of lutein, were opposed

to the construction of organic infant formula from synthetic materials. Concerns over fortification of infant formulas that may place undue burdens or metabolic and other physiologic functions on the infant.

Breast feeding is by far the better approach to overall infant health development, when compared to the alternative choice of using formula. It's not mandatory, according to the FDA infant formula regulations. It's not permitted in the EU, either in conventional nor in organic infant formula.

Still unproven to be beneficial to infant health or development. It's not consistent with organic principles. It's not essential because scientific evidence of its essentiality has not yet been proven. That sums it up, John.

MR. FOSTER: Thank you for that summary. Any questions on lutein for -- yes, Jean?

MS. RICHARDSON: I'm just seeking clarification on two issues. One, and perhaps this one should go to our experts for clarification, as to whether this should be classified as synthetic or non-synthetic, and secondly, is the primary purpose as an antioxidant preservative or for the health benefits on the eye?

DR. ANDERSON: The purpose that infant formula manufacturers add lutein to infant formula is as a mixture of antioxidants, purported to protect tissues in infants, and then the second part of your question please?

MS. RICHARDSON: Synthetic or non-synthetic?

DR. ANDERSON: Oh. That is not a question I can answer.

MR. FOSTER: Additional questions? Harold?

MR. AUSTIN: I have a question also for our experts. One of the comments in

public comment that was made to us that we'd like some clarification on is Question No. 8. A formula manufacturer commented that the CFR 107.100, the list of requirements for infant formula, has not been updated since 1985.

Is this correct, and if it is, is there any plans to look at any additions to that list in the future?

DR. ANDERSON: The requirements in 21 C.F.R. 107.100 were indeed promulgated in 1985. They have not been updated since that time. Those values, those substances and those values came about as a result of recommendations from the American Academy of Pediatrics to the agency.

As far as updating, it has been 30 years or maybe even more. The decision to update will rely on agency priorities and on having the available resources to do so.

DR. BHATIA: The Committee on Nutrition is concerned about this old document, because some of them are made on

presumption, and some of them are made on data that we now have. However, this is not a simple agency matter. This is a Congressional mandate.

So for us, we've started the process of asking the question, but it has to bring all the agencies together and then go through Congress before that Act can be changed.

MR. FOSTER: Can we go for two more questions here. We've got to keep moving, and for that I see Jay and Tracy, and with the reminder that if we can get through all these materials, we can circle back to some of these other questions. But Jay and Tracy, and then we'll move on to lycopene.

MR. FELDMAN: Thank you, John. Thanks again for being here. As you know, this is not a technical board in the sense of evaluating scientific criteria, and therefore the law that we're operating under is very clear, that we should rely on requirements in

other laws, in terms of added materials, added nutrients and so forth.

So the use of your word "purportedly" in the context of manufactured claims caught my attention. I'm wondering about the process that we should rely on, this body should rely on, in terms of making these determinations, and whether we should not ask, is it unreasonable for a body like this to request a manufacturer to go back to the FDA, or some other body, so that they can get the classification that would meet our requirements standard, or is that an unreasonable request, and you know, impractical request or not practical request?

DR. ANDERSON: Perhaps this would be a good time to say a few words about FDA's regulation of infant formulas. FDA regulates infant formulas as foods, and there are two primary offices that are involved in the regulation: The Office of Nutrition, Labeling and Dietary Supplements, which is my office,

regulates the infant formula finished product.

The Office of Food Additive Safety regulates the ingredients that are used in infant formulas. The two offices work very closely together on this, whenever there's any question or any issue involved with infant formula or new ingredients in infant formulas.

Infant formula manufacturers are required to make a pre-market notification to FDA whenever they propose to market a new infant formula or make a change in a formulation or for one of their existing products.

Addition of a new ingredient or a modified ingredient would require a pre-market notification, and in our review of an infant formulation notification, we would want to be assured that the, of the scientific basis of safety of the new ingredients for use in infant formula.

What FDA has to regulate ingredients on is their safety. Efficacy is

a consideration for drugs. It is not a consideration for food ingredients, for the safety of food ingredients. It is a consideration, efficacy is a consideration for claims on products, but not for their safety of use in the products.

We consult with the Office of Food Additive Safety regarding any questions about the safety of use of a new ingredient in infant formula, and we always encourage infant formula manufacturers to work with the Office of Food Additive Safety to resolve any questions about the safety for use in infant formula, before they submit a pre-market notification to us.

MR. FOSTER: Thank you. Tracy. MS. FAVRE: I'm going to apologize in advance for my question, because I realize it's going to put you on the spot. But Dr. Bhatia, can you tell me if in your opinion the benefits of these added nutrients outweigh the potential concerns about the fact that we're looking at

synthetic additives?

DR. BHATIA: I cannot, because what has been shown so far, specifically in the nutrient we're talking in question is yes, breast milk has it; formulas don't. What has been shown so far is if added in formula, you have ocular growth. The functional claims that people are claiming still have not been shown in long-term studies.

So addition of a new nutrient to make it similar to human milk has been -- I think for 30 years we've been trying to do that. But to prove a long-term effect, you need more studies. There are studies showing so far short-term safe, but not enough to say this has to be put into infant formula at this current time.

MS. FAVRE: Thank you.

MR. FOSTER: Thanks. All right. Mindful we're halfway through our time and a third of the way through the agenda, I have to hold on to additional questions on lutein, and

move on to lycopene. Lisa.

MS. BRINES: Thanks, John. The petition for lycopene was received on September 19th, 2011, and was submitted by the International Formula Council. The petition requests the inclusion of lycopene at Section 205.605 of the National List, for use as an ingredient in infant formula.

Lycopene does not appear elsewhere on the National List, but there was a previous petition in 2007 for lycopene juice, and that was for use as a color. This petition for lycopene is for the synthetic form.

In support of the review of the petition, the Subcommittee had requested the development of a technical report, and both that technical report and the petition for lycopene were available to the public in advance of the opening of the public comment period for this meeting, and again the petitioner is available for in-person public comment later this morning. Thanks.

MR. FOSTER: Thank you very much, Lisa. Nick, you had the pleasure of dealing with this through the term. Would you take it from here?

MR. MARAVELL: Okay. Thank you, John. The petition for lycopene in the synthetic form is primarily -- the argument for it is primarily based on the fact that natural sources of lycopene would come from food substances, for example, tomato, and it may contain proteins which could potentially induce an allergic response.

This is sort of extended from the argument that some people are allergic to tomatoes. We could not find any specific substantiation of that direct connection, and the TR, the Technical Review, hypothesized that any response, allergic response to tomatoes is more than likely related to the acidity rather than the make-up of the proteins in lycopene.

In checking with the other

standards, European, Canadian, Japanese, synthetic lycopene is not permitted in infant formula, and it does not appear that lycopene is a required addition to infant formula. The public comments fell pretty much along the same lines as for ascorbyl palmitate and beta carotene, with the consumer and interest group, public interest group community questioning the need for the addition of synthetics into infant formula.

And there were some industry groups that supported the addition of synthetic lycopene because it is a powerful antioxidant, and could have potential benefits.

I don't think that we're disputing that; we're simply disputing the fact that it does not need to come from a synthetic source, and therefore the committee voted to declare it a synthetic, it was petitioned as a synthetic, and to not add it to the National List. Both votes were unanimous. There were

two absent at that deliberation.

MR. FOSTER: Thank you, Nick. Questions from the Board on lycopene? Jay.

MR. FELDMAN: I would just like to ask the same question. I hate to be redundant on this, but again, on the question of required by FDA or any other body that we should be aware of, that would deem this material essential or essentially required to be added to infant formula. Can you address that?

DR. ANDERSON: Lycopene is not included in the list of 29 required nutrients for infant formulas. The FDA refers to an authoritative scientific body in determining what nutrients are essential for infants, in this case, the Institute of Medicine of the National Academy of Sciences.

FDA regards Vitamin A as essential, and would also recognize that beta carotene, as a source pro-vitamin for Vitamin A, could be considered a vitamin. Lutein and

lycopene are not pro-Vitamin A sources, and we do not consider them essential.

MR. FOSTER: Thank you. One more? All right. Then with no more questions, let's move on to L-carnitine. Lisa.

MS. BRINES: Thanks, John. The petition for L-carnitine was received on November 10th, 2011, and was submitted by the International Formula Council. The petition requests the inclusion of L-carnitine at Section 205.605(b) of the National List for uses as an ingredient in infant formula.

In support of its review of this petition, this handling Subcommittee did request the development of a third party technical report, and both the report and the petition were available to the public on the NOP website in advance of the opening of the public comment period for this meeting, and again the petitioner will be available later this morning for in-person public comment. Thanks.

MR. FOSTER: Thank you, Lisa. Zea, you were the lead on L-carnitine. Thank you.

MS. SONNABEND: Thank you. L-carnitine is a compound that's synthesized in the body from the amino acids lysine and methionine. These amino acids are abundant in foods, such as beans avocados and red meat.

The synthetic form has been petitioned for use in infant formula because soy-based formulas contain very low levels of carnitine, and infants are less able to synthesize carnitine for themselves. Cow's milk formulas can also be low in carnitine because the milk is diluted in the formula.

Unlike some other ingredients, and one we'll talk about in a minute, L-methionine, carnitine is not required under the FDA 21 C.F.R. sections that refer to infant formula that we could find.

We have been led to understand that it is required in the EU, and we're not

sure why L-methionine would be required and L-carnitine not, which we'll ask our experts after the L-methionine presentation, I would imagine.

But in any event, it appeared to us that it would be feasible to make carnitine or extract it from non-synthetic sources, although this is not commercially done at this time. For these reasons, the Handling Subcommittee is not recommending to add synthetic L-carnitine to the National List.

MR. FOSTER: Thank you, Zea. Any questions on L-carnitine at the moment? My guess is we'll have a question on both L-carnitine and L-methionine in a few minutes. All right. Let's move on then to L-methionine. Lisa.

MS. BRINES: Thanks, John. The petition for L-methionine was received on October 26, 2011, and was submitted by the International Formula Council. The petition requests the inclusion of L-methionine at

Section 205.605(b) of the National List for fortification of infant formula, which is based on isolated soy protein.

In support of its review, the Handling Subcommittee did request the development of a third party technical report, and that report and the petition were available to the public on the NOP website in advance of the opening of the public comment period. Thanks.

MR. FOSTER: Thank you, Lisa. Tracy, you were lead on this. Take it from here.

MS. FAVRE: Yes. L-methionine is an essential amino acid that's required for proper human development, and it has been petitioned for the use in soy-based formulas, because the protein content specifically in soy-based formula is not sufficient without the addition of the L-methionine.

We had lots and lots of conversations about this on the Subcommittee.

Just like most of the formula additions that we've been talking about this morning, there were pretty strong arguments on both sides in the public comments, primarily from the same sorts of groups, whether it was the consumer, general consumers versus the manufacturers.

In the discussion about the inclusion of synthetic L-methionine, I personally was troubled, because the manufacturing process can be fairly toxic. But we do have a significant deficiency, in fact essentially after some clarification during some expert discussion during subcommittee meetings, there essentially would be no soy-based formula with the addition of L-methionine, because of the minimum protein requirements specified for infant formula.

So as a result, we did vote unanimously, excuse me. There was 6 votes yes, 1 absent for the classification motion for synthetic L-methionine on 205.605(b), and on the listing motion, there was a 6 yes, 1

absent vote on the agreement to include L-methionine on 205.605(b).

During some subcommittee discussions prior to the meeting here this week, the original motion was for use in infant formula made with isolated soy-based protein, and we've elected to strike the word "isolated" on the soy-based protein because of concerns about the manufacturing process on isolated soy-based protein.

Again, we're hoping our two experts here today can provide us some clarification specifically about L-methionine and the protein requirements, as well as whether or not the isolated soy-based protein is an issue. Thank you.

MR. FOSTER: Thank you, Tracy. It sounds like we have a couple of questions for, regarding both L-carnitine and L-methionine that were put forward. So I had Zea and then Tracy. If you want to encapsulate your questions. Zea, you want to go first? Yes,

for carnitine or methionine.

MS. SONNABEND: Well, I think I posed the question, which is why is L-methionine required by FDA and L-carnitine not?

DR. ANDERSON: L-methionine is recognized as an essential amino acid, necessary for the growth and development of infants. It is permitted for use in foods and in infant formulas by FDA's food additive regulations.

Carnitine, as you said, can be synthesized from the amino acids L-methionine and L-lysine. It is not as -- there's not as much support for its essentiality in infant nutrition as there is for methionine, and given that it can be synthesized by the infant, it has not been included as essential for inclusion in infant formula.

DR. BHATIA: The essentiality of L-methionine soy infant formulas was demonstrated many, many years ago. Soy

protein is not the same as common protein, and protein has less L-methionine in it. So there would be an L-methionine deficiency created if you feed soy infant formulas without added methionine.

In addition, if you look at soy infant formula label, you will notice that the total protein content per deciliter or per 100 calories in soy formulas are higher than common formulas, to make up for the relative inefficiency, if you will, of soy protein formula.

Having said that, soy protein isolate, I'm not a manufacturer and neither do I have expertise in manufacturing, is the only soy protein formula used in the United States and in Europe. Plain soy protein is not.

Carnitine deficiency is relatively rare. In 30 years of doing clinical neonatology and nutrition, I've probably referred four to five babies for carnitine deficiency. So carnitine, as an essential

nutrient for the general population of infants, is actually the evidence is quite low.

MR. FOSTER: Okay, thank you. Tracy, do you want to recapture your question, or are you good?

(Off record comment.)

MR. FOSTER: Okay, okay. Mac and then Jay, and then we should wrap it up, or Zea, if you've got a follow-up.

MR. STONE: Do either of you all have a sense of what percentage, I guess I'm heading towards lactose intolerance, or what percentage are soy-based versus cow milk based infant formulas?

DR. BHATIA: The actual percent of lactose, true lactose intolerance in the general population is an estimate, because self-reported. In all populations, it's between about 10 to 12 percent perceived.

In infants, it's less than five percent, and that is true persistent lactose

intolerance, which shows up at approximately two years of age. The secondary lactose intolerance that occurs in neonatal after, say, acute diarrhea.

So lactose, true lactose deficiency, which is rare, then is one indication for using soy infant formulas because it's made of sucrose and not lactose. However, that was the only choice available 10-15 years ago.

Now we have other choices that when used with limited lactose compared to completely going to soy. Soy infant formulas are not indicated in pre-term infants in the first place. In the second place, in term infants, currently the opinion is there are only three indications for soy infant formulas.

One, there's a metabolic disease, galactosemia, because they cannot tolerate the glucose-galactose and soy infant formula is indicated for that. Two is secondary

persistent lactose intolerance, and three is a personal choice, because we have vegetarianism, which make you who may choose to have soy as a primary source, not cow milk.

This can become a concern for nutrition because soy, otherwise for healthy term infants is fine; but for subpopulations, it is not fine.

DR. ANDERSON: With regard to the amount of soy infant formula that is sold in the United States, the latest figures that I have seen are that about 10 to 12 percent of infant formula sales are for soy infant formulas.

DR. BHATIA: I need to add that in Canada, it's less than two percent, England is two percent, and in New Zealand, you have to go to the pharmacist behind the counter to ask for soy, for the same reasons I've outlined, that there's no need to abuse soy infant formulas in infancy.

After infancy, it is relatively

data poor, and evidence rich that epidemiology studies have not shown harmful effects. But infancy, there are specific issues. Why use soy when you have other formulas available?

MR. FOSTER: Thank you. Jay, question, or Zea. Okay. Straight to the question, if we could?

MR. FELDMAN: I'm actually working off this sheet of questions or list of questions that were sent earlier, and I'm not sure where there's a good place. This seems to be the best place to sort of raise this, given what you've already said.

First, this distinction. I've read your article, Dr. Bhatia, on use of soy protein-based formulas, and just want to get clarification on this distinction that's being made, I believe to the committee and the Board here, that there is a distinction between soy protein isolate and soy concentrate, and that in effect, there is -- there are different issues that we would address in those

different contexts.

Again, it would be helpful as the Question No. 9 indicates on this list, given that we are putting essentially a certification on a soy product, driving in effect consumers toward that product based on some assumption of its added value with that certification, that organic certification, presumably that will increase sales of that product, or at least shift sales in that direction.

I guess I'm looking, given your work on this, looking to you to advise this body on what questions ought to be answered, may have not been answered in the past, and should be answered in the future, regarding the evaluation of the soy isolate and the impact that that has as a derived material, synthetically derived material, and its safety-related and need related to infant health.

You've already identified the pre-

term infancy impacts there, but again, we're looking at the broader picture, in terms of soy isolate versus soy concentrate, and its essentiality in the market.

DR. BHATIA: In my opinion clinically, soy isolate should be the only protein used in infant formulas. There is no question that if you use intact soy, and you chop it up into different pieces of it and feed it to animal models that you have, deleterious effects.

In the last 40 years in infant formula and nutrition research, we have not demonstrated any harmful effects of soy isolate as it is produced and fed to infants in the United States and Europe, using a soy protein isolate.

The concerns have been the use and abuse of soy for colic. It does not prevent it. Use and abuse of soy for allergy, it is not a formula to prevent allergy. The concern about premature reproductive issues. Those

data are extremely weak in the human model, and I have participated in two NIEHS panels and have come to the same conclusion.

In human nutrition, soy infant formulas, as fed in the United States, there's minimal concern about the issue on reproductive health. So for those reasons, there's no other issue for soy except for the three indications I've told you.

I'm very happy that since we, the Committee on Nutrition, took over and started espousing the lack of benefit of soy in the routine infant, that the soy formula has dropped from 20 percent ten years ago to 12 percent that Dr. Anderson just mentioned.

So there is no need for routine indication of soy infant formula in term healthy infants, unless it is a personal choice, or a metabolic disease like I outlined before.

MR. FOSTER: All right. Let's bring this back to methionine, away from, if

we could. Zea.

MS. SONNABEND: Okay. We would like to hear the policy of the American Academy of Pediatricians on breast feeding and the use of formula.

DR. BHATIA: The Committee on Nutrition, as well as the Section on Breastfeeding both agree that the period of exclusive breast feeding is about six months. The world bodies come across and tell you between four and six months may be the actual window. We don't need to argue. That's about six months.

That's a WHO recommendation, ESAPAGAN recommendation and AAP recommendation. So that's exclusive breast feeding. However, the fact of life is exclusive breast feeding up to six months in the United States is not to the point of the Surgeon General's request that we have exclusivity. We are pushing it, but it's not there.

Is there evidence to show that if you feed for 4.1 months, it's less advantages than feeding for 4.9 months? No. Is there evidence to show they feed less than four months? Yes. So there is a dose response relationship.

So we feel that between four and six months or about six months will the optimal exclusivity for breast feeding. Infant formula is a safe alternative, if you choose not to breast feed or cannot breast feed or should not breast feed, and they have a safety record of their own for the last decades.

MR. FOSTER: Thank you. We have some more time to wrap back, circle back around on carnitine and methionine at the end. We can do that, but in the meantime, we'd like to move on to the topic of nucleotides, and I asked Zea to present this, although I did some of the work on this also. Zea. I'm sorry, Lisa, would you --

MS. BRINES: Did we skip taurine, John?

MR. FOSTER: Oh, okay. It's different in the order I have, but sure, taurine we can do first.

MS. BRINES: Okay. We'll do taurine. I've got that in front of me.

MR. FOSTER: Alphabetical order?

MS. BRINES: Thanks, John. The petition for taurine was received on September 14, 2011, and was submitted by the International Formula Council. The petition requests the inclusion of taurine at Section 205.605(b) of the National List as an ingredient for use in infant formula.

In support of its review, the Handling Subcommittee did request the development of a third party Technical Report, and both the report and the petition were available to the public on the NOP website in advance of the opening of the public comment period for this substance. Thanks.

MR. FOSTER: Thank you, and on taurine, Jean, you were lead on this. Would you take it? Thank you.

MS. RICHARDSON: So taurine is neither a vitamin nor a mineral. Although it's referred to as an amino acid, it's actually more accurately classified as a B-amino sulfone. It's found in animal protein, such as seafood, beef, chicken, and it's nearly absent in vegetarian foods.

While taurine could be produced non-synthetically, it's not commercially available. But it is, in any event, the synthetic form, which has been petitioned for use in infant formula, and its use is to assist in subfat, subpar fat absorption in infants, because insufficient taurine would result in poor fat absorption, and fat absorption is extremely important in infants.

There is, however, conflicting scientific opinion regards the necessity of taurine in either human nutrition, and

especially for infants. Taurine is not an FDA-required nutrient in baby formula, although it's often added to both conventional soy and milk-based formula.

Taurine is not listed on the IFOAM list, nor is it required in European infant formula, and it does not appear on the JAS list in Japan. It doesn't appear to be listed as GRAS. Taurine as petitioned is intended as a dietary supplement, and it does not appear to be essential, and that's certainly a question that the Subcommittee has for our experts, is the essentiality.

So the Handling Committee therefore is not recommending the addition of taurine to the National List at this time. The vote on the Subcommittee, which is here, was 4 to 0 not to list it. Three persons were absent.

The public comments were the same as those that have been expressed by other Board members for those other products,

inasmuch as there was lack of support from consumers, and there was strong support from Infant Formula Council and the related manufacturing organizations.

So perhaps we could ask for first clarification on the necessity of taurine.

DR. ANDERSON: Scientific evidence doesn't indicate that taurine is essential in the diets of human infants. The National Academy of Sciences, the Institute of Medicine, National Academy of Sciences, doesn't recognize it as an essential nutrient for humans.

It is not on the list of required nutrients for infant formula. However, it has been used as an optional ingredient.

MR. FOSTER: Thank you.

DR. BHATIA: There have been some classical studies done in the late 80's to show that if you don't have taurine, there are effects, short-term effects of the taurine status, if you will, and there are some new

development concerns in a subset of infants, especially low birth weight infants.

But having said that, I concur with what Dr. Anderson is saying. Strictly speaking, the answer is no. Relatively speaking, the answer is yes.

MR. FOSTER: Thank you.

DR. ANDERSON: And just one -- can I make one more comment?

MR. FOSTER: Please.

DR. ANDERSON: We are really concentrating this morning on infant formulas for healthy term infants. We aren't concentrating on the use of formulas for pre-term infants or infants with special medical problems.

MR. FOSTER: Thank you for clarifying and reminding us of this. Additional questions on taurine from the floor?

(No response.)

MR. FOSTER: Thanks. Then let's

move on, then, to nucleotides. Lisa.

MS. BRINES: Thanks, John. The petition for nucleotides was received on September 14th, 2011, and was submitted by the International Formula Council. The petition requests the inclusion of nucleotides isolated from yeast, RNA, hydrolosate to Section 205.605 of the National List.

The petition identifies five specific nucleotides for addition to the National List, including the sodium salts. In support of the review of this petition, the Handling Subcommittee requested the development of a third party technical report.

That report was developed, and both the petition and technical report were available to the public on the NOP website in advance of the opening of the public comment period for this meeting. Thanks.

MR. FOSTER: Thank you, Lisa. Zea, would you take it away?

MS. SONNABEND: Nucleotides are

compounds that are made in the body from amino acids. The amino acids are abundant in whole foods with protein.

Now in our recommendation, the TR was not very clear on the manufacturing process, and it did lead us to think that it as a synthetic form of nucleotides being petitioned.

We have since heard a number of public comments that has convinced the committee, at least, that the nucleotides really are non-synthetic. They're derived from yeast and the processing of them is similar to other things that we list on the National List as non-synthetic, and in fact yeast extracts are already on the National List as non-synthetic.

Nucleotides are not mandated to be added to infant formulas under the sections regarding infant formulas, and the Handling Committee is recommending to add non-synthetic nucleotides to the National List.

But we are going to recommend changing our motions and the classification motion will not change. It's just the voting may be quite different because we'll leave it as synthetic.

But if that motion fails, that they're synthetic, then we will be adding it to 205.605(a) instead of 205.605(b). We also want to change the annotation coming from the committee and remove the last sentence, that the nucleotides be allowed for non-infant formula foods that are made with organic ingredients.

MR. FOSTER: Thank you, Zea. Questions on nucleotides? Jay.

MR. FELDMAN: Yes. I have a question for the committee. In looking at this change, I guess the issue I saw in the TR was around crystallization and that process for extraction.

So the question is, is the crystallization process, what is that exactly,

and is that considered non-synthetic? Is that what the change is coming from? I mean where is this change in the classification from?

MS. SONNABEND: Public comment was submitted by OMRI and by Rich Theuer, regarding how they perceive the method of extracting the nucleotides, and it would be better if you could ask the public commenters that.

MR. FOSTER: Okay, thank you. Additional question on nucleotides at this time?

(No response.)

MR. FOSTER: Well done. Thank you again Zea for last minute changes especially. All right. Last item on the list is the discussion on auxiliary or Other Ingredients.

Zea, you were the lead on this as well. Thank you again for working on this. This took a fair amount of conference call time and a lot of work in writing. So thank you again for that.

MS. SONNABEND: I'm going to pull out my notes here for a second. Okay. This was a long and complicated document, and we know that you would all love to spend a few hours talking about this today. But we don't really have a few hours to talk about this today, and so the committee will have to take those few hours and more, maybe, after the meeting ends.

So I'm just going to give some very broad sweeps on, you know, what types of comments we received and a few of the points that were made, without getting into very much detail.

This is a public comment summary from our discussion document on the screen. We received comments from 17 people and organizations on this subject, and here is the list of them in no particular order, except the order they were in when Michelle gave us the compiled document.

Now underpinning this whole thing

is a lot of things that have to do with the overall classification of materials and what OFPA and the rule actually say, and how you define terms such as ingredients, substances, processing aids and the like.

We're not going to get into all of that here, but I do just want to frame that among the organic community represented here, we have two fairly distinct ways of looking at OFPA Interpretation 1, and I have borrowed language from some of the public comments. There were many that mimicked each other, so I've just selected one representative comment from each interpretation, to provide you here.

OFPA Interpretation 1: All ingredients of a product labeled organic must either be organic or on the National List for that purpose. There is nothing in OFPA that justifies making the distinction between Ingredients and Other Ingredients.

We support a fourth option. No ingredient of any kind can be in food labeled

organic unless it is on the National List. The fourth option that they're naming Option D is very similar to Option C, which almost always requires all ingredients to be on the National List.

It's the only option that fully complies with the law, and captures the expectation of the consumer that all non-organic ingredients in organic food will be on the National List. Going on to say that the National List headings in the regulations 205.605 and 205.606 specify the use of non-agricultural substances and agricultural products, respectively, referred to as ingredients.

OFPA Interpretation 2, and I'm sorry the type is a bit small, but it takes a bit to explain it. OFPA sets out rigorous criteria for evaluating substances for inclusion on the National List.

However, it is clear that OFPA never intended to require a separate listing

of Other Ingredients, incidental additives on the National List. Rather, OFPA clearly states that Other Ingredients should be evaluated as part and parcel of the consideration of substances for inclusion on the list.

In establishing the criteria for what should be included on the National List and how items on the National List should be evaluated, OFPA uses the term "substance" to describe these items. It does use terms like single ingredient or even ingredient in Sections 2118 or 2119, and does not state that substances made with more than one ingredient must be evaluated individually.

Indeed, Section 2119 LRI-2 makes it clear that it was understood that substances might contain multiple ingredients, where it says, and this is quoting from OFPA, "Work with manufacturers of substances considered for inclusion on the National List to obtain a complete list of ingredients, and

determine whether such substances contain inert materials that are synthetically produced."

This is not a loophole in the standard that would allow for incidental additives that are incompatible with organic agriculture to be used; rather, it is a mechanism to allow a substance to be thoroughly evaluated through one petition and evaluation process, rather than requiring multiple petitions and reviews for each item on the National List.

Okay. The second interpretation is the one that most previous NOSBs and the Department has generally been using, inputting items on the National List, and Option 1 is being insisted on by many members, some members of the organic community.

I don't think until you bring in like large teams of lawyers from either side you're going to get a definitive answer to these two different interpretations of what

stands in our rule, which is somewhat vague in its terminology to begin with.

With all that in mind, we had a fair number of commenters speaking up about the options that we presented. We presented three options, gave long lists of pros and cons of each option, and I was actually a little surprised that very few if any commenters said that they thought Option A was absolutely the best option. Kind of nobody said that.

Option A certainly is the easiest and some would argue it's what we have been doing so far, where these issues weren't fully understood by NOSBs in the past. So if something showed up with another ingredient, it was adopted without much scrutiny in some cases, or adopted with considerable scrutiny in other cases, but adopted nonetheless.

I would say that the majority of the commenters favored Option B, but almost all of them had some concerns or additions or

subtractions from Option B, and then there were almost none that came out for Option C straight out, but some who came out for this Option D, which is really similar to C except once the secondary, the disinfectants and cleaning agents and things to be added.

Okay. The concerns of many people. First of all, our proposal for the database being maintained by the NOP. Many people were concerned that to ask for a database in association with an option. This concern is very valid, because the NOP has enough to do, and maybe keeping another database and more stuff would be outside their ability to do.

However, one very good suggestion, I thought, was that because the permitted substances list is coming out anyway, which is an affected database, it could be incorporated. The approvals of Other Ingredients could be incorporated into the permitted substances list, where there will

already be some level of spreadsheet or columns or some way to codify that when something is added to that list, it could have the Other Ingredients associated with it.

Another concern that many people had is the commercial availability clause. People were -- this would be applying the issue of commercial availability to everything on the National List.

Commenters came in all over the map about this. This is something that the committee, the Handling Subcommittee will definitely be taking under advisement and considering.

One thing that is very clear from even the people who are proponents of Option B, is that probably in the course of Sunset, some of the inconsistencies in the past reviews of things that are already on the National List have to be cleaned up.

So we know that while some things like the enzyme review, for instance, had very

long lists of all the Other Ingredients that could possibly be in it, and the NOSB looked at that and adopted the recommendation, there are other things from the past.

One I can think of is the wax materials, carnauba and wood resin that although it was known there were Other Ingredients, at the time no one knew what they were, and we couldn't get disclosure or cooperation from industry like we can today.

So they went on there with nothing mentioned in Other Ingredients, which has really had a strong detrimental effect on keeping these products from being formulated and used in organic food. So we have work to do, and much of that work will happen in Sunset.

Okay. I think that OTA correctly pointed out that along with a policy, we have to develop a whole review procedure. We have to look at what we already have clearly, and that's why we put the spreadsheet that we did

as an attachment to the recommendation, so you can see where we started to try and compile the past decisions.

But we have to look at what we have, and then we have to develop some steps for how we're going to move forward on this under any scenario that we adopt. Those steps might be somewhat similar to the inerts proposal we gave, because after all, and I joked about this in the college, they didn't really get it, you want us to change the term "inerts" and "other ingredients," and then we have these other other ingredients.

Although my nickname for several decades has been "Materials Girl," I think I'm going to change it to "Other Ingredients Girl," and we'll see how that flies.

But anyway, I want to thank all the commenters for really giving some thoughtful responses to what was really a very complicated and detailed recommendation, and we can assure you that we will be giving it

our close attention in the future. Thank you.

MR. FOSTER: Thank you, Zea, for that, and thanks again. That was a tremendous amount of work on the part of the Subcommittee, but you shouldered a large portion of that. So thank you very, very much for that.

We have, by my clock, we have 16 minutes before we're scheduled for a break. But if there's opportunities for discussion on this last item or burning questions around any of the other materials that we've looked at, now would be the time to do that. Mac?

MR. STONE: I have two, but I don't mind taking them one at a time. Where are we going to bump into this confidential business information aspect, as we dig into incidental additives? If the definition of incident means it doesn't have a technical or functional effect on the food, then why is it there?

MS. SONNABEND: Well, that last

one, I can't answer. So you'll have to ask it to Dr. Anderson. As far as the first one yes, we are always bumping into confidential business information. But beyond that, the biggest problem I see with Option C or D is that it's going to ask for petitions for all these so-called Other Ingredients.

It's very, very unlikely that there's enough incentive for every single other ingredient to petition individually to have it, you know, have themselves included. And so it's not a question as much of confidentiality as disclosure.

We're not even going to find out what those ingredients are, and that is a big, big obstacle for adopting those options.

MR. FOSTER: I'll refrain from asking if we need a COI policy on Other Ingredients. I won't do that.

MS. SONNABEND: And partially in answer to that question also, it's on our work plan for the Materials Committee to revise the

COI policy that we already have or CBI, not COI, Confidential Business Information. It's something that I am committed to work on between now and the next meeting.

MS. SONNABEND: Thank you, Zea. Additional questions. Jay.

MR. FELDMAN: This is somewhat related, because later, I think as we discussed, the whole concept of soy formula, there's one other element I wanted to bring to the discussion, besides the issue of whether we have adequately reviewed the implications of the synthetic nature of soy isolate.

I direct this attention, this question to Dr. Bhatia, about the estrogenic properties of soy, and whether he or you believe that there are issues that the community should be concerned about in that regard?

DR. BHATIA: The estrogenic effects have been shown if you chop up soy protein into individual components like

dianisidine and genistein, and feed it in higher quantities in animal models.

The estrogenic reports have been reported in case reports and from Puerto Rico, where there has been recall after many, many years, to see if the infants were fed soy formula or not.

The estrogenic effects are also based on a JAMA article, which recalled a recall of 30 years later about a, and don't quote me on the actual hours, 30 years later about a probable three to four hour increase in menstrual period, and that was indicated in the statistical analysis.

And it was that clinically relevant, even the authors said, to take that in advisement. So basically the extensive exhaustive review that has taken place through the NIEHS times two, has really not shown that in human infants that estrogenic as we know it right now, while feeding soy isolate protein formulas manufactured in the United

States, has any adverse effects.

So there's no, as far as I concerned, there's no safety concerns on estrogen in the human model as we know it.

MR. FOSTER: And you're saying that's from real world data or clinical data that you've reviewed?

DR. BHATIA: Yes sir.

MR. FOSTER: Thank you. Additional question? I have one kind of following that, but I'll wait until the other people have a chance. Okay. So someone help me, correct me if I'm wrong here, if it's soy, is soy protein isolate? Is that considered -- have we defined that as synthetic, and if it's not, then doesn't it need to be organic, if it's in an organic product? Help me out here. This is not my area of expertise clearly.

DR. ANDERSON: Soy protein isolate has not been approved by the full Board as synthetic or non-synthetic. It was petitioned as a crop input a long time ago, and as a crop

input, it as determined to be synthetic by the Crops Committee.

But they got bogged down in the classification and materials issues, so it never came to the full Board and they decided to wait for the Classification and Materials document.

Soy protein isolate in infant formula or in food, processed food. If it is organic soy, then it has not been hexane-extracted. But there's no like ruling on processed food that a food is synthetic or not synthetic.

MR. FOSTER: Okay. That helps me, thank you. Other questions for any of the agenda items. With ten minutes to go, really? With that then, I would thank you, Doctors, for being here. It's been very, very helpful.

I also want to really thank -- the agenda for the Handling Subcommittee was pretty aggressive this term, and I just, I want to call out the program staff. Was very,

very supportive, very, very helpful in working through a lot of complicated issues.

I just, I want to say thank you for that. It was -- it was definitely a team effort, and I appreciate that very, very much, all of the staff. So thank you for that. If that, that's all I have. So Barry, if you want to take that virtual gavel back, it's all yours.

CHAIRMAN FLAMM: I think we can take a 15 minute break now and be back at, what is it, five minutes after the hour, and then John, you'll continue with the public comments for your --

MR. FOSTER: Thank you, yes.

(Whereupon, the above-entitled matter went off the record at 9:51 a.m. and resumed at 10:08 a.m.)

MR. FOSTER: If we can reassemble here, get started please. I have to get one of these gavels for my office, I think, at work. Thank you for your attention. Thanks

again to our guests this morning. We found that we had some little conversations here in the break, and the Board found that very, very helpful. So we're very appreciative to have you here.

I understand they will be here and available through the proceedings, at least through lunch. So I want to just mention that for the Board members. All right, I'll stop.

All right. We are moving into our public comment period for the Handling agenda. We are six minutes ahead. Lovely to see that. I haven't counted the number, but we have oh, I don't know, 15 or 18, something like that, to work through.

I will follow the pattern we have started with, which is let, you know, two or three people in line, let them know they're coming up, and if anyone particularly Michelle, I think you're the one who's advised of last minute changes. If you could let me know if there's any that I need to skip,

please let me know.

Other than that, the first three I have here are Beverly Rich, Charlotte Valaise and Brook Anderson, in that order. So if you could just make sure to state your name and affiliation prior to your comments, that would be very helpful. Thank you.

MS. RICH: Hello. My name is Beverly Rich. I'm a member of the Cornucopia Institute, but I'm testifying today as a concerned consumer. My personal interest in organic foods is as a health-conscious citizen. I rely on the government to certify that foods are organic and trust this means they're natural and safe without any artificial ingredients.

As a 38-year vegetarian, consuming primarily organics, I read lists of ingredients. However, I was not aware of hidden ingredients, especially in organics. Thanks to the vigilance of the Cornucopia Institute, I was informed that my trust in

organic certification was misplaced.

I was deeply disturbed to find that synthetic ingredients, including known toxins, are being added to organic foods under the guise of "Other Ingredients" or as unlisted components of organic product ingredients.

Though I am an attorney, I'm not familiar with food safety laws, but in preparing my testimony did some research. I found as expected that federal law prohibits synthetic additives to organics, though with the exception of ingredients accepted by the NOSB for inclusion on a National List.

The Organic Foods Production Act of 1990, Section 2111, 7 U.S. Code 6510 is clear in stating that anyone handling agricultural products covered under the law must not add any synthetic ingredient not appearing on the National List during processing or post-harvest handling.

I was shocked when I learned that

unapproved ingredients such as polysorbate 80, sodium benzoate, polyacrylamide and numerous other synthetics, which I carefully avoid when I am aware of them, are routinely added to organic foods as components of the ingredients on the National List.

I was even more appalled to learn that toxic materials, such as hexane and propylene glycol, are routinely used in the processing of ingredients found in organic foods. This is a clear violation of the law, and a betrayal of the trust of American consumers.

I am not an expert in food science or food processing, nor do I wish to become one. I want to be able to trust the organic label. The organic foods law assures me that each and every ingredient, no matter how small, has been carefully vetted by the NOSB, satisfies organic handling requirements, and is safe for consumption.

Now I've learned that the NOSB and

the USDA have ignored this important legal requirement, that up to five percent of the ingredients in organic foods may contain unapproved synthetics, which could include toxins and/or carcinogens and more with no oversight.

Organic consumers like myself do not want unapproved synthetics in their organic foods, period. Frankly, I don't want any synthetics, but the current law does not seem to give me that choice. I'm not alone in these sentiments. A survey completed in August 2012 by over 1,400 customers of PCC Natural Markets in Seattle, the largest cooperative grocer in the country, confirms such consumer preferences.

PCC concluded from their survey that their customers strongly prefer that anything added to their food be from natural sources, not synthetic, and that many, if not most of them, prefer that nothing at all be added to whole organic foods.

For instance, 90 percent of customers would not purchase foods with Omega-3's made with synthetic additives or agents, including hexanes, glucose, syrups, solids and modified starch.

The inclusion of synthetic preservatives, sweeteners and other unapproved ingredients in organic foods constitutes a massive industry-wide violation of the organic law. It needs to be corrected.

Solution, simple. Follow the law. Respect consumer preferences and reasonable expectations. Non-organic and non-agriculture ingredients and processing aids used during organic handling must appear on the National List.

Please, don't force us to return to the days, prior to the adoption of organic standards, where consumers had to grow their own food or buy direct from trusted farmers, to ensure a supply of natural and safe food. Thank you for the opportunity to comment.

MR. FOSTER: Nicely timed. Quick, quick. Is there a question from the Board?

MS. RICH: My apology. This is my first time testifying.

MR. FOSTER: No problem, no worries. Question? All right. Thank you for your time.

MS. RICH: Thank you.

MR. FOSTER: Next up, we have Charlotte Vallaeys. Again, Brook Anderson on deck.

MS. VALLAEYS: Good morning. My name is Charlotte Vallaeys. I'm the Director of Farm and Food Policy at the Cornucopia Institute.

I have a Master's degree in Nutrition Science and Policy from Tufts University. I also have a Master's degree from Harvard, where I studied Social and Environmental Ethics from the Harvard Divinity School.

I'd like to thank all of you for

your hard work, with a special thanks to Barry. Almost five years ago was my first time attending an NOSB meeting. It was also Barry's first meeting. I will miss you very much, Barry, and I know a lot of others in the organic community will as well.

I'd like to thank the Handling Subcommittee for your very thorough work on these petitions, and especially for inviting experts in infant nutrition to weigh on these very important questions.

We agree with the committee's recommendation to reject taurine, lycopene and lutein. They are produced in ways that are legally incompatible with organic handling, involving neurotoxic synthetic solvents. They are not essential.

Experts agree that the scientific evidence does not show the claimed benefits exist. It's important to note also that the European Union does not even allow lutein and lycopene in any infant formula, including

conventional. They are prohibited by all other international organic standards.

Any claims of safety are based on their GRAS status, generally recognized as safe with the FDA. GRAS status relies entirely on safety testing submitted by the petitioner.

No independent or long-term safety tests are required, and we know that post-market surveillance by the formula manufacturers is woefully inadequate.

This system has been widely criticized as inadequate to protect public health, including by the Governmental Accountability Office, and we urge the NOSB to uphold our higher organic standards.

We'd like to thank the Handling Subcommittee also for your very thorough work on the petitions for beta carotene and ascorbyl palmitate, which were petitioned for use as preservatives, and we support the unanimous decision to reject.

We also appreciate the clarification from the two experts that these are in fact preservatives. There is a petition material that presents us with a bit of a dilemma, L-methionine. It appears to be required in soy-based formula only. If it is not added, infants on soy formula would not grow and develop properly.

Currently, the only sources that appear commercially available are synthetic. The TR states that L-methionine's production includes material such as acryline and EPA hazardous air pollutants, and hydrogen cyanide, described by the CDC as a systemic chemical asphyxiant and a chemical warfare agent.

So it is essential, because soy-based infant formula is such an inherently inadequate unhealthy food for human infants, that it requires the addition of synthetic macronutrients, just to keep the infants alive.

But production involves synthetic and polluting substances, and is therefore incompatible with organic handling. So let me ask you a question. At what point is a food no longer a food, but a chemical substitute for food, and do chemical substitutes for food deserve the organic label?

In the European market, organic soy-based formula does not exist. Where will we draw the line? When the caregiver of an infant sees the organic label on a soy-based formula, their assumption is great; somebody figured out how to make an organic soy formula, with organic and natural ingredients.

Approving any additional synthetics for formula would be a huge blow to consumer trust in the organic label. Thank you.

MR. FOSTER: Thank you. Questions. Calvin.

MR. WALKER: Thank you, John. My question is what would be your views, as it

relates to consumers' belief or support for synthetics in infant formulas?

MS. VALLAEYS: I think in public comments, the consumers have voiced their opinion on this very clearly, and thousands have commented that they do not think that synthetics belong in organic products.

That includes organic infant formula. I do think that when a mother or a caregiver for an infant who needs formula sees the organic label on a product, on that formula, that they do think it's organic. They don't know that it contains the exact same synthetics that are in the conventional, that it is essentially the same in that regard.

I think that that is very misleading, and especially for the synthetic, the two synthetic preservatives. I'd like to point out that the natural label is heavily criticized, of course, in the organic community, because it is self-defined and it's

so restrictive.

There's yet one of the criteria for the natural label that the industry can agree on is no synthetic preservatives, right. So imagine the consumer confusion when it becomes clear to them that an organic product has synthetic preservatives. It wouldn't even qualify for the industry's own natural label.

That is going to be a huge blow to again consumer trust in the organic label, that it contains natural and organic ingredients.

MR. FOSTER: Jay.

MR. FELDMAN: Thank you, John. Hi Charlotte. Can you walk us through the practical effect of a decision to not allow methionine?

What impact would that have on what percentage of people that are now relying on soy formula? What are the alternatives to that, and what impact would we have in the marketplace?

MS. VALLAEYS: It's important to consider the expert advice we heard this morning about the need for soy-based infant formula, that it is -- in other countries, rates of use are around two percent is what we heard, that it is in fact not necessary for colic.

Right now, it appears, from what I understood, that that's kind of abused, that if your infant has colic, you just immediately grab the soy-based formula, really without that being necessary. So at that point, I think soy-based formula has to shift away from being considered a food, and more of a medical product.

Again in New Zealand, you have to go to the pharmacist, is what we heard this morning, because it is considered a medical product more than a food. I think that that is very appropriate.

MR. FOSTER: Charlotte, just I want to kind of make sure we're talking about

methionine. Jay, I know that your question --

MS. VALLAEYS: Right, right. But the question --

MR. FOSTER: Just bring it back, that's all. Just bring it back.

MS. VALLAEYS: So if --

MR. FELDMAN: No, just so John understands, excuse me, the impact. If we're going to have soy on the market, the experts seem to agree that it doesn't perform any function, and it could be detrimental without methionine, without that amino acid. That's a missing piece.

So the implication is pretty dramatic, you know, if the Board rejects methionine. I understand that that would undermine the market for soy in the U.S. And correct me if I'm wrong on this, I just want to make sure.

Now I'm not saying that the Board shouldn't do that, and I had another question about soy isolate and sort of your opinion on

that.

But I want, I'd like to be clear about what the impact of that decision is, and whether there are alternatives, and you're describing a discrete part of the market that uses this for medical purposes, that might need it for medical purposes, and that's how you're describing that percentage of the market.

MS. VALLAEYS: Right, because if L-methionine is rejected, I do think soy-based formula with the organic label would not be possible. I mean I wouldn't want to see an organic soy formula without L-methionine, that infants are going to not grow and develop properly. Nobody wants to see that.

But at the same time, what we also don't want is to mislead consumers into thinking that this is organic, yet it contains this L-methionine that is synthetic, very problematic in how it's produced.

So that is the dilemma, and I

think that's a decision that needs to be made. But considering what we heard about the actual need for soy-based formula for infants.

MR. FOSTER: Thank you. Harold.

MR. AUSTIN: Charlotte, thank you. I think listening to your presentation right now just kind of helps to emphasize for all of us the struggles that we have with some of the decisions that we try to make up here, that what is right and what isn't right.

In this particular situation, when should a synthetic be allowed, and under what circumstance. So I appreciate your presentation. You're walking through the explanation.

But I think it also helps to show the difficulty and the degree of difficulty that these decisions bring with them on all of these materials, and I appreciate your presentation, your clarity on what you just brought forth to us. Thank you.

MR. FOSTER: Additional questions?

(No response.)

MR. FOSTER: All right, thank you. Next up we have Brook Anderson, Eric Lien or Lean on deck. Yes, Brook Anderson, Perrigo Nutritionals.

MR. ANDERSON: My name is Brook Anderson. I'm the Director of Product Development at PBM Nutritionals. I've been developing and making infant formula for 29 years, all in one location in Vermont. Breast milk is best, but we offer the best alternative available for parents who, for whatever reason, choose not to breast feed.

While many ingredients are not mandated by the FDA to be added to infant formula, advances in nutritional sciences and research obligate infant formula manufacturers to identify and add new ingredients to infant formula, in order to provide optimal, wholesome and safe infant nutrition.

I'm going to talk about two petition substances. Beta carotene is the

first one. Beta carotene, which was discussed earlier, is a source of Vitamin A and also a vitamin-based antioxidant. Beta carotene is a vitamin that should already be allowed in the organic products under CFR 205.605.

Beta carotene is added to the PBM infant formulas to mimic the levels of beta carotene commonly found in breast milk. Beta carotene was first added to U.S. infant formula in 1933. It may also serve as an antioxidant.

Beta carotene is also a vitamin-based antioxidant that acts to scavenge oxygen, and typically used in a combination with other various substances including tocopherols, ascorbyl palmitate, etcetera. As an antioxidant, beta carotene serves to protect fats, lipids and fat-soluble vitamins.

Because of its synergistic effect among vitamin-based antioxidants, beta carotene serves an essential role in the keeping quality of infant formula.

The only source of beta carotene allowed for use in the U.S. is synthetic beta carotene. Other potential sources that have been mentioned previously, for example, natural carotene or red palm oil are not currently allowed or used in infant formula, and would require GRAS notification safety before their use.

Beta carotene is also listed as an approved source of Vitamin A for direct fortification for infant formula. US FDA, CODEX, GB, China Regulations and allowed by Health Canada.

Beta carotene is not toxic at high levels unlike Vitamin A, and is a safe, nutritional nutrient, an essential part of the total Vitamin A content, required for optimal infant nutrition or for meeting the total Vitamin A content of the product.

The next petition substance is ascorbyl palmitate. It is also known as AP. It's a vitamin-based antioxidant. Its primary

use in infant formula as an antioxidant required for nutrient stability. Its secondary effect is for sensorial preservation, a keeping quality of infant formula.

AP is GRAS-approved, is an approved source of Vitamin C, and is an antioxidant that is approved and accepted for use in infant formula by various regulatory agencies, including U.S. FDA, CODEX, the EU Commission and is allowed in Health Canada for use in infant formula.

AP is a unique antioxidant, as it is a fat-soluble form of Vitamin C, and is very effective in limiting oxidation reactions in fats. Infant formula contains approximately 28 percent fat, and contains several fatty acids and fat-soluble vitamins that are very susceptible to oxidation.

Preventing oxidation is thus critical to the nutritional quality of the product. Ascorbyl palmitate is but one

essential substance of the total fat-soluble antioxidant system used in infant formula.

AP is used in various combinations with other vitamin substances, tocopherols, beta carotene, etcetera. Due to the synergistic effect that ascorbyl palmitate exhibits on limiting oxidation, the essential role that AP exhibits in various antioxidant systems is well-documented.

Rosemary extract, which has been suggested as an alternative to AP, is not currently allowed in infant formula. Rosemary extract also has never been tested, is a completely different chemical structure than AP, and therefore is not an option or isn't considered a viable alternative at this time.

Ascorbyl palmitate is thus an essential part of the antioxidant system used in infant formulas. Without AP, our infant formula products would oxidize to the point of not being suitable for consumption within three to six months of manufacture. A shelf

life of three to six months is not variable, is not commercially viable. Sorry about that. I went over.

MR. FOSTER: Thank you

MR. ANDERSON: Last slide. I thank the Board for letting me speak.

MR. FOSTER: Thank you. Questions or comments? Jean, Nick, Zea.

MS. RICHARDSON: Yes. My question relates to the self life and the effect of potential rancidity on the infant formula. So if you don't add the beta carotene and the ascorbyl palmitate, and the food goes rancid, what will be the effect on the infant eating this food, consuming this food?

MR. ANDERSON: Fatty oxidation is very complex, but there's a lot of things when fats oxidize. There's a lot of byproducts of fat oxidation that would be considered then, that would not be safe for infants. It's just not a good thing to have, you know, oxidized fats in any type of product, especially infant

formula.

MS. RICHARDSON: Yes, but what happens to the kid? You give it the formula, did it throw up, get diarrhea?

MR. ANDERSON: You could have -- I'm not a doctor, but diarrhea is one example that could happen.

MS. RICHARDSON: So it has some like food safety aspects to it?

MR. ANDERSON: Yes, yes. I think the FDA would be very concerned about oxidized fats, which I think Sue Anderson had mentioned earlier.

MR. FOSTER: Nick.

MR. MARAVELL: Yes. Just out of curiosity, if you were to take dry infant formula that would have a shortened shelf life of three to six months, and instead of keeping it on the shelf, put it under refrigeration, what would be the impact of the shelf life, and if it were labeled "keep refrigerated until opened" or something like that?

MR. ANDERSON: Refrigerated at what, 45 or less?

MR. MARAVELL: 45 degree refrigerated temperatures?

MR. ANDERSON: Excuse me?

MR. MARAVELL: When you talk about temperatures, what temperature are we talking about, 45 degrees or less when you refer to refrigerated temperatures?

MR. ANDERSON: Yes, approximately 41 degrees, yes. Well, it's never been studied and I think in, you know, for this product sold in the United States, this is not a product where you find in a refrigerated section. It's just I've never heard of infant formula being sold that way. I don't know if it's commercially viable.

MR. MARAVELL: Right. But what might be the expected effects?

MR. ANDERSON: I wouldn't know. We've never studied it, just because in commercial practice, that's not the way it's

sold, distributed. So I don't have an answer for that.

MR. FOSTER: Go ahead, Zea and then Calvin.

MS. SONNABEND: My question is similar to what I asked Dr. Anderson and Dr. Bhatia. If you put in beta carotene to get, enough to get Vitamin A activity, would that also be enough quantity as an antioxidant, or is it a different quantity that you're adding for one or the other?

MR. ANDERSON: Typically, they're different quantities, because antioxidants is a very complex system. Sometimes, if you add more of these substances, that can serve as a pro-oxidant. It's very complex and there's many, you know, there's many combinations, I should say, of these substances added.

But the level that you find typically in our product will be in a range of two to four hundred IUs per liter. That level would be similar to that found in human breast

milk. It may have some antioxidant effect, but typically antioxidants by definition are added at very low levels.

MR. FOSTER: Thank you. Calvin.

MR. WALKER: If these two materials are voted down, what would be the impact? What would you do in terms of an alternative?

MR. ANDERSON: For ascorbyl palmitate, there isn't any. That's the honest answer. There is none. It's a very, very critical part of protecting this product. So if the committee were to vote ascorbyl palmitate out, we'd have a serious problem with the viability of this product, commercial availability.

MR. FOSTER: And last call? All right. Thank you very much.

MR. ANDERSON: Thank you.

MR. FOSTER: Next we have Eric Lien or Lane. I apologize for not getting one of those right, and then Diane Wilson on deck.

DR. LIEN: Good morning. It's a pleasure to be here to address you today. I am currently adjunct professor, Department of Food Science and Human Nutrition at the University of Illinois. Previously, I was Vice President of Nutrition Research at Wyeth Nutrition and have more than 25 years of experience in pediatric nutrition.

I'll provide a very brief introduction to infant nutrition, talk about three components of interest, taurine, nucleotides and carnitine, and draw some conclusions.

Birth weight of term infants typically doubles in the first three to four months of life. We realize that either breast milk or formula may be the only source of nutrition during this time. So it's important that we find complete feeding systems.

What we realize is that human milk is by far the preferred means of providing nutrition to infants. If the mother cannot or

chooses not to breast feed, then substitutes of the highest quality must be available. Infant formula is really the only choice and must meet all nutritional needs of the infant.

Let me move to components of interest. Taurine functions. Taurine is essential for retinal function. It's a component of the predominant bioacid required for fat absorption in term infants. As you see in the draft here, it's found in exceptionally high concentrations of human milk, and exceptionally low concentrations in both cow's milk and formula.

If we look at plasma taurine levels during the first 12 weeks of life in term infants, we see that breast-fed infants have a substantial increase in taurine levels during that time, and unsupplemented formula-fed infants have a substantial decrease, with a highly statistically significant difference at the end of 12 weeks of life.

If we look at taurine function in

the retina, retina function deteriorates during taurine deficiency, and this is most often seen in either pre-term infants or individuals receiving total parenteral nutrition.

Taurine supplementation can reverse these abnormalities, and we can come to the conclusion that taurine does play an essential role in normal visual development. There's also data that indicates that taurine supplementation or taurine plays a role in cognitive, that is mental development, in infants.

Let me briefly move to nucleotides. These are simply the monomers of RNA, so RNA being important in all genetic expression. Nucleotides, when added to infant formula, have three roles. They have a GI anti-infective effect, less diarrhea during the first year of life.

Immune system is closer to breast-fed infants, improved immunoglobulin

production to vaccines, for instance, and the GI maturation effect, which permits nutrient absorption, especially in small poor gestational age term infants. A dietary supply is essential during the first period of rapid growth, such as during infancy.

Finally, carnitine is essential for the metabolism of fat. Carnitine couples to fatty acid in the cytosol of the cell. That transports the fatty acids into the mitochondria, where fatty acids then are burned for energy.

Carnitine deficiency results in increased urinary excretion of unburned fatty acids, soy formulas and some milk-based formulas require supplementation, and for instance, the EU requires supplementation at one point, two milligrams per hundred kcals of soy formulas. Insufficiency may result in hypoglycemia and failure to thrive.

So I just will bring to conclusion human milk and formulas must be complete

feeding systems. I've discussed three nutrients, taurine, nucleotides and carnitine. Taurine and carnitine have been added to formulas for more than the last 25 years.

So we will not see deficiency syndromes coming from feeding systems. These nutrients support essential bodily functions, and they should be included in infant formula. Thank you for your attention, and I'd be happy to answer questions you may have.

MR. FOSTER: Questions? Zea.

MS. SONNABEND: Thank you. We heard from our experts earlier that carnitine is not required by the FDA, but L-methionine is. One of the reasons cited was that if you received enough L-methionine, your body could make L-carnitine.

I'm wondering if what your perspective is on that subject, and whether an infant can create enough L-carnitine from an L-methionine supplementation.

DR. LIEN: This is a matter of

maturation. Certainly as adults, who are eating mixed diets, where we see dietary carnitine. But vegetarians and vegans are also capable of synthesizing L-carnitine.

Carnitine will increase in production as the infant matures, but it is my opinion in current infant formulas, if carnitine is not present in sufficient amounts, it should be added, to cover any synthetic immaturity of the infant.

MR. FOSTER: Jean.

MS. RICHARDSON: My question is on taurine. If, you stated that taurine is essential, but it's not required. So can you help us to understand why it's not required if it's essential?

DR. LIEN: It's clear in experiments in taurine deficiency that there are problems of fat absorption and also of visual maturation. The FDA approved taurine for use in infant formulas in 1984, and it has been added to all formulas since that time.

We will not, under these conditions, see taurine deficiency. Dr. William Heird at the USDA Children Nutritional Research Center in Houston, has indicated it's his opinion that it would be at this point unethical to do further experiments into taurine deficiency, because it may lead to untoward consequences, which I've indicated here.

So it will be a very difficult nutrient to remove from formula. We really don't know what kind of situations we may put infants who have true taurine deficiency in, without that added component.

MR. FOSTER: Thank you. Additional questions? Colehour.

MR. BONDERA: Sorry about that. Thank you. I apologize, and thank you for your testimony, Dr. Lien. I just, I apologize that I may have missed this at the beginning.

But according to my sheet, and according to what you're presented, I'd like

you to not necessarily repeat your qualifications, but who you're here representing or what brings you here today?

I understand and appreciate your, you know, experience and presentation.

DR. LIEN: Thank you. I did indicate in my qualifications that I am retired Vice President of Nutrition Research for Wyeth Nutrition, who was a manufacturer of infant formula, and I have been here at the request of the formula manufacturers.

MR. BONDERA: Thank you.

MR. FOSTER: Additional questions. Harold.

MR. AUSTIN: On these three materials, are you aware of any formulas right now, currently on the market, that do not include these three products?

DR. LIEN: No, I am not. I should indicate that for carnitine, there are some milk-based formulas that have sufficient endogenous carnitine, which is present in

cow's milk. Not to add it, but they would have more than the required amount for soy formula already endogenously provided by bovine milk.

MR. AUSTIN: Thank you.

MR. FOSTER: Thank you. Last question, Calvin.

MR. WALKER: As it relates to infants, does these deficiencies continue after the infancy or breast feeding or milk feeding period, these deficiencies that you mentioned?

DR. LIEN: As we move through the weaning process, introduction of what we'd call complementary foods, these foods will start to introduce these components to the infant and young child through other sources.

The critical period is the time of exclusive feeding. So that as long as six months, and that's the time when we would be most concerned, as a sole source of nutrition. We as adults have a mixed diet. If we're

insufficient in one nutrient from some component of our diet for a few days, it's truly immaterial.

This very rapid growth rate may be supported by only one source of nutrition. It must be complete.

MR. FOSTER: Thank you. All right. I appreciate your time. Next, we have Diane Wilson with John Ashby on deck.

MS. WILSON: Good morning, and thank you for letting me be here today. I'm Diane Wilson. I am Director of Nutrition Services for Nature's One, the manufacturer of organic pediatric medical nutritional products.

I would like to remind this Board, as I did at the May Albuquerque meeting, that I'm not talking about infant formula; I am talking about medical nutritional enteral products. These are products that are for medically nutritionally fragile children.

Our products are specifically for

children, toddler to 13 years of age. These are products that must be usually fed either tube-fed by nose or through the stomach, in order for the child to receive appropriate nutritional care.

My comments are that if a nutrient is essential for infant nutrition, then it obviously is going to be essential for a child who requires medical nutritional care. My request is that you amend your proposals to include infant nutrition or infant formula rather, and medical nutritional enteral products.

In addition, the proposal for soy isolate should be changed to soy protein. Our products for older children, even though tube-fed, contain soy protein concentrate and not soy isolates. So please consider that recommendation also from me.

Next, I want to remind you that at the May meeting, the question arose as to whether we would continue looking for organic

alternatives to these essential nutrients that unfortunately are synthetic.

My answer was of course we would. I used a different term, which I think got a chuckle out of the group. But we did, and we are. If you remember, choline was one of the topics for the last meeting.

Since that time, we have found that our toddler formula with DHA, which I will remind you is not the algal fungal sources of DHA and ARA, but egg phospholipid source, a natural source, we have found that we do not need to add choline bitartrate to our formula with DHA, because the egg phospholipid source provides the natural choline needed to meet the child's nutritional needs.

With that, I will close my comments and then be more than welcome to answer any questions. Thank you very much.

MR. FOSTER: Thank you. Do we have questions? Jay.

MR. FELDMAN: Thank you. Are your products used by prescription only?

MS. WILSON: No.

MR. FELDMAN: So when you say "medical," who's determining the medical need?

MS. WILSON: Well, they're not exclusively used under medical --

MR. FELDMAN: I'm sorry. So can you describe that product line that is -- is there any product line that's prescribed?

MS. WILSON: I wouldn't say they're prescribed. They're recommended, but obviously for a child that's being tube-fed, there are many alternatives.

But most of them are non-organic. I would say just about all of them are non-organic, except for ours. So they would be recommended by the health care professional.

MR. FELDMAN: Thank you.

MS. WILSON: I believe Dr. Bhatia would agree. Hopefully you and your Committee on Nutrition would agree that for a child in

need of a medical nutritional enteral product, these essential synthetic nutrients are extremely important.

MR. FOSTER: We'll certainly put that question in the queue for later questioning. Thank you. Do we have more questions for the commenter?

(No response.)

MR. FOSTER: Okay. Thank you very much.

MS. WILSON: Thank you.

MR. FOSTER: Next, we have John Ashby, followed by Peggy Miars.

MR. ASHBY: John Ashby with California Natural Products. Once upon a morning dreary, while I pondered weak and weary; over many a quaint and curious volume of the CFR, while I nodded, nearly napping, suddenly there came a tapping, as of something gently rapping, rapping at my chamber door.

'Tis Other Ingredients tapping, tapping at my chamber door, only this and

nothing more. But that is enough, Lenore. How distinctly I remember it was back in bleak October when each separate incidental wrought its ghost upon our door.

From my books surcease of sorrow, sorrow for the incidentals. Harmless barely even present, whom the angels named Lenore, called incidentals now and forevermore. In the silken, sad uncertain future of processed organics thrilled me, filled me with fantastic terrors never felt before.

So that now, to still the beating of my heart, I stood repeating "processed foods, they are the gateway, in our now organics heyday. Can they really be destroyed? Our enemies won't be annoyed."

605 keeps processed growing, unprocessed if we close the door them, growth organics nevermore. Presently, my soul grew stronger, hesitating then no longer. Sir, said I or Madam, truly your forgiveness I implore.

But the fact is we've been growing, and so gently you came rapping, and so faintly you came tapping, tapping at my chamber door, that I scarce was sure I heard you, processed organics on the floor; growth organics nevermore.

Perfection just cannot be met. We go that way, we lose the bet. That feeds our enemies and we have them. Think otherwise and you will let them beat us. Please make no mistake; the risk is real, this is the stakes. When we were small, we were no threat. Who cares? So what? Big deal, no sweat.

But now it may just be our time, and if we really mind the store, then growth organics evermore. And organics never flitting, still is sitting, still is sitting on the milestone of our successes, just beyond our reach and grasp.

But we must be both wise and reasoned, careful, balanced, cautioned, seasoned. If we do, then we can have, what it

is we most desire, what can be weakened nevermore, growth organics evermore.

Now I can't explain incidental ingredients or technical effects in the food if you wish. My bias is really so strongly, does it increase or decrease organic acreage, while keeping within whatever we define as the sphere of maintaining that organic aspect well enough.

But also don't let the perfect be the enemy of the way better. You know, let's remember there is a 100 percent category for people who insist upon this. Processed growth is the gateway, and I want to mention, this opens in and it opens out.

A positive list of incidentals runs the risk of wiping out huge sections of processed foods, for reasons I'm happy to go into. Okay, here it goes.

Option A, I think legally suffices. This is a food. Food has specific way. It deals with the word "ingredients."

I agree with Zea. I think we need some lawyers to get in on that.

Reviewing these things when we go through it is just a wonderful, is a wonderful idea. This is a good thing. It's the risk of having a positive list that holds the specter open for finding something at parts per trillion in a product, which then causes a recall. You cannot build brands with that kind of risk; you just can't.

By the way, the meter is trochaic octameter.

MR. FOSTER: Well, let this former Literature major say, thank you for that. It warms my heart, and certainly appropriate in the -- just down the street from the birthplace of Edgar Allen Poe, of course.

MR. ASHBY: And in a ghost hotel.

MR. FOSTER: Indeed, indeed. Do we have questions for Mr. Ashby? Yes, you will be needing to use iambic pentameter for your questions. Or free form. Free verse is

fine. No questions.

I would ask for a copy in writing of that little diddy, if you don't mind.

MR. ASHBY: Okay. I'll get it to you. Okay, thank you.

MR. FOSTER: Thank you very much. Next we have Peggy Miars, followed by Gwendolyn Wyard.

MS. MIARS: Thanks, Michelle, for putting me after that.

(Laughter.)

MS. MIARS: Good morning. My name is Peggy Miars, and I'm Executive Director of OMRI, the Organics Materials Review Institute. My comments today will focus on the Other Ingredients discussion document that was brought by the Handling Subcommittee.

OMRI provided written comments on this subject as well, and as a participant in the Materials Working Group, OMRI also provided input to the various options presented by the Subcommittee, including some

of the pros and cons that were listed for each.

My comments today address two specific points about the importance of adopting a policy, and carefully considering the evidence that's presented to you by various stakeholders with experience on this issue.

First, I want to reiterate the importance of adopting a policy to address this issue. However, before doing so, the NOSB should understand the scope of Other Ingredients currently being used and their purpose, as some commenters have suggested, to understand the impact of your recommendation on the organic marketplace.

The presence of Other Ingredients and their allowance has been a source of confusion or inconsistency for many years. Although OMRI has been consistent in our approach to this issue, our daily interactions with certifiers discussing Other Ingredients

tell us that there is a range of approaches to, and interpretations of this issue.

The NOSB has not been consistent in how it has recognized, reviewed and annotated other ingredients. So we're happy to see you address this issue and treat it as seriously as it deserves to be treated.

We hope that you will take into account the many opinions and comments, and decide on a reasonable policy that's both practical and that protects the integrity of the organic label.

OMRI's policy on Other Ingredients is actually a combination of Option C that's presented in the discussion document, and Option D, as presented in some organization's public comments, including the Cornucopia Institute and Beyond Pesticides.

We would like to offer our experience as one of the few organizations that has practiced the alternative Option D. This alternative option proposed by these

organizations stipulates in a nutshell that Other Ingredients be organically produced or be on 205.605 or 205.606.

OMRI's policy has always been to require that Other Ingredients be organically produced, or be provided for in the annotation, or be on 605 or 606. In rare cases, we've allowed Other Ingredients that have explicitly appeared in the technical review.

OMRI lists processing inputs that are generally comprised of 605 or 606 materials, such as yeast ingredients, defoamers, food sanitizers such as fluorine and peracetic acid, and formulated ingredients such as fruit coatings.

OMRI's list of processing inputs is meager compared to the possible thousands of ingredients in processing aids used in organic foods today, and we attribute this lack of growth in our list to two reasons.

One, the policy for allowing Other

Ingredients from the NOP and NOSB has been inconsistent and led to varying interpretations, and two, most ingredients and processing aids do not comply with OMRI's strict interpretation and policy.

So the NOSB may want to consider OMRI as a real life example of how Option C and Option D may play out if implemented. I want to make it clear, OMRI takes no position on the appropriateness of any specific policy. However, we do urge you to look at the evidence presented, to formulate your final recommendation as soon as possible. Thank you.

MR. FOSTER: Thank you for that. Any questions? Zea.

MS. SONNABEND: Thank you, Peggy. I'm wondering how comfortable OMRI reviewers feel with going back to look for potential Other Ingredients in the TRs and petitions, as opposed to having a centralized database through the NOP, where those things would

exist?

MS. MIARS: I'm sorry. I'm not quite sure I understand that question. Can you restate it?

MS. SONNABEND: Well, do you find that it's a problem to have to go searching through a lot of TRs and petitions when determining if Other Ingredients were reviewed in the initial review, versus the convenience of having everything in one place, which may or may not be, have the funding to be kept up, for instance, or have other issues?

MS. MIARS: Well obviously, it would be much easier just to go to a database or spreadsheet. However, I do know that our reviewers do go back to technical reviews on a regular basis, to do as part of the research for our product reviews.

MR. FOSTER: All right. There's some more questions. Jay and Nick. MR. FELDMAN: Thanks, Peggy. This is a question for OMRI. I'm hoping we can get an answer

before we have to vote or in further discussion on this issue of soy protein isolate, and these distinctions being made between isolate and concentrate, and how it's derived, how it's formulated. Is that something you can help us with?

MS. MIARS: Well, that's not an area that I'm knowledgeable of, so I would defer technical questions to my colleague, Lindsay Fernandez-Salvador.

MR. FELDMAN: Okay, thank you.

MR. FOSTER: Nick.

MR. MARAVELL: Yes. Just out of curiosity, at OMRI, you wouldn't happen to have your own little personal crib sheet or cheat list that would sort of serve the secondary purpose of a database, as you go through and review materials, and review the technical reviews, et cetera.

Do you actually sort of keep a tally of what we might be calling Other Ingredients, with annotations as to under what

circumstances these surfaces, et cetera?

MS. MIARS: Sure. We do keep detailed information like that in our database, because we do see certain materials come up time and time again. So it does make sense for us to maintain those records and refer back to them on a regular basis.

MR. FOSTER: Thank you. Last question. No? Thank you, Peggy.

MS. MIARS: Thank you.

MR. FOSTER: Coming up is Gwendolyn Wyard, to be followed by Britt Lundgren.

MS. WYARD: Okay, top of the morning. Mr. Chairman and OP staff and ladies and gentlemen of the gallery. My name is Gwendolyn Wyard. I'm the Regulatory Director of Organic Standards and Food Safety for the Organic Trade Association, representing over 6,500 members across 48 states.

I also serve on the OMRI Board, and I'm co-chair of the Materials Working

Group. First, I want to thank you so much for your dedication, and for the 239-page proposal packet that was prepared for this meeting. I truly appreciate the full time job security your voluntary positions provide me.

(Laughter.)

MS. WYARD: We did submit comments on ten of the proposals. You have those in writing. My comments today will focus on Other Ingredients, Other.

First and foremost, I want to be perfectly clear that OTA supports a careful and thorough review of Other Ingredients. How that review is documented and how allowances and prohibitions are communicated to certifiers and material review organizations, MROs and industry is the crux of our challenge.

Historically, the review of Other Ingredients contained within petitioned substances was part of the overall review process. In most instances, the substance and

the other ingredients were specifically or generically acknowledged, and the entire substance in its totality was evaluated against OFPA and the National List criteria, and added to the National List.

Over the years, the Board has proposed several multi-ingredient or multi-component substances to the National List. Examples include enzymes, vitamins, dairy cultures and natural flavors.

These substances are functionally dependent on other ingredients, meaning they cannot be used, they cannot exist, they cannot be used for food application without them. If you purchase Vitamin D, you would never purchase Vitamin D by itself. It would always come with a dispersing agent.

The problem is that the review of generic materials at the NOSB level has not been consistently carried out and documented, as Zea pointed out, and accordingly, certifiers, MROs and industries face

uncertainties when trying to figure out which other ingredients are allowed in brand name products.

The good news and an important bit of perspective is that not all substances on the National List depend on other ingredients. In fact, most do not. Out of the 139 handling materials on the National List, there are about 12 that require other ingredients.

But they're a critical 12, and they're commonly used in the organic foods that we love and consume daily, and they've been allowed for over ten years.

A large majority of the substances on the National List were reviewed and added as single component substances, and they should remain just that. Any other ingredient would need to be organic or on the National List, because they were not reviewed or considered by NOSB.

As for the multi-component substances, we believe we need to take a case-

by-case approach, just as they have previously been reviewed, and we have our work cut out for us. OTA's comments present a seven-step procedural plan, spread out over the next three NOSB meetings.

I don't have time to discuss each step, but I will say that the first step needs to begin now, and it needs to be an assessment. We need to invite industry to go back and look at their products, and look at what other ingredients are being used.

Separate single component substances out from the multi-component substances. Examine the collected information from industry and address each multi-component substance accordingly. For the 12 or so listings that require other ingredients, use annotations to set restrictions and prohibitions when it's appropriate.

This is consistent with historical practice, and we believe NOSB has the authority to continue this discretion. Take

natural flavors, for example. In '95, the Board considered the fact that carriers and preservatives, which are Other Ingredients, are always added to compounded flavors.

They didn't say they all needed to be on the National List. Instead, they said they needed to be non-synthetic, and they annotated the material as such and added that material in its totality to the National List.

In conclusion, you cut off my mic? Oh, sorry. Well in conclusion, thank you very much. This is the nuts and bolts of our policy, and we've basically taken elements of Option A, B and C, and pointed out the key factors that we'd like to see worked into our policy. Thank you very much.

MR. FOSTER: Thank you. Questions? Mac.

MR. STONE: So I'll ask you this incidental additives that don't have a technical or functional effect. How are they there, and again the confidentiality in

developing these products, or disclosure of confidentiality?

MS. WYARD: Okay. I'll take that in the two parts. So why they're there. In a finished, certified product, the other ingredients are these incidental additives. They are present by way of an ingredient that's been added to that finished product.

So the finished product, the consumer's looking at the finished product. They're reading the ingredients statement, and the ingredients statement will read "Vitamin D." Within that Vitamin D, you may have dispersing agents or stabilizers or preservatives.

They were added to the Vitamin D during the manufacturing of the Vitamin D. They were not added to the milk, for example, but they're present in the milk by way of being carried in through the Vitamin D.

So in the finished product, which would be the milk, they are present at

insignificant amounts, and they do not have a technically functional effect on the milk. They had a technically functional effect on the Vitamin D, acting as other stabilizer preservatives, et cetera.

Confidentiality for most of the substances on the National List, for 605 and 606, really is not that big of an issue. Unlike crop products, where trying to get disclosure of the inerts is very proprietary, the specification sheets that come along with the ingredients that are being used by certified handlers, those specification sheets list the other ingredients that are in that ingredient.

So if you are using an enzyme, you're going to get a specification sheet that's going come in with that enzyme, and it's going to list the other ingredients that are there. Certifiers can readily look at them. The manufacturer of the ingredient is required to provide the handler with an

ingredient list of those other ingredients.

There are some exceptions, and those exceptions would largely be natural flavors, very proprietary. You will actually get the list of the other ingredients in a natural flavor. What you won't get is the proprietary formulation of all of the flavor constituents.

But even in natural flavors, you will, you know, they'll disclose the glycerine is being used, for example, as a carrier, or maltodextrin is being used as a carrier. Colors, you would run into also some proprietary information. But again, that would be for the specific color constituents and not so much the other ingredients.

MR. FOSTER: Thank you. Additional questions? Nick.

MR. MARAVELL: I'm going to change the subject here Gwen, and go a little philosophical. I'm going to quote from your conclusion of your prepared remarks. In

effect, you're saying we believe that NOP certified products should be nutritionally equal to their conventional counterparts.

For me, the philosophical part of that comes in. Does there need to be a conventional, I mean an organic product sort of standing analogous side by side with every conventional product, and is that sufficient justification for adding things such as synthetic preservatives?

So let me go one step further. So how, what's the impact on the industry if your conclusion is not one that is accepted, versus accepting that conclusion? What's the impact, the positives and the negatives, on the organic industry?

MS. WYARD: Well I think, you know, OTA has gone on record several times, stating that, you know, we support consumer choice. We support consumer preference, and we envision the day, and I think we're getting there, where organic products are a

significant part of our everyday life.

So to every extent that it's possible, there's going to be caveat here, and a huge one. But to every extent possible, I would hope that we're all striving to create as many organic products as we possibly can, and that we would create an organic counterpoint to every conventional product out there.

Now I know this gets into the organic Twinkie argument, and I'm not going to go there fully. But the caveat is that we have to do this in full compliance with OFPA and the regulations. There is no skirting around that. We would never suggest that we'd do that.

If you look at the criteria that are listed out in OFPA for putting materials on the National List, we all know they're rigorous and it's -- here we are going through this process.

So I think if you follow the OFPA

criteria and the National List criteria and the regulations, then we should have a list of ingredients that are consistent with organic principles, and we should be able to make products that comply with the regulations.

I think bringing personal choice in to the matter, in terms of whether you believe infant formula is right or wrong is irrelevant. It's whether or not the product complies with the regulations, and the screening step that takes place prior to that is the, this process that we're all here going through right now.

MR. FOSTER: Harold.

MR. AUSTIN: I think you partially answered this, Gwen. But on one of your slides, how would you suggest that we conduct assessment of the National List, and what would this ultimately do for us, as we're trying to work through and develop this policy?

MS. WYARD: So the first step is

to begin this assessment, and I think this assessment should and can happen now, and OTA is absolutely ready and willing to help with that process, in terms of outreach to industry and notification to industry, to go and conduct a very thorough assessment of the non-organic ingredients that they're using in their certified products, and then going back to the manufacturers of those ingredients and finding out exactly what other ingredients are in those approved substances on the National List.

I think we need to understand the universe that we're operating in, in the same way that has been conducted for the inerts. For the inerts, you know, you have an idea of these 126 inerts that you're working with, broken into their classes.

We have no idea how many other ingredients are in use out there. So I think that's a first step and also, you know, we have the work that's already in the discussion

document, the spreadsheet at the end that goes through and it did a review of all of the technical reviews and the petitions.

So we have a pretty good idea, and so that's what I base that number 12 on. As far as this list right here, these are the multi-component substances. These rely on other ingredients. We already have a lot of information. They were approved in 2000, well '95, and they've gone through a couple of sunset processes.

We have a lot of information, but we don't have a thorough assessment of what is being used out there. But we can at least say, you know, let's focus on this 12, and let's verify that it is just 12 that we're talking about. What have we missed, waxes, et cetera, et cetera.

I haven't included the sanitizer, disinfectants and cleaners here. That is another issue, certainly all one in the same topic. But I think that's the first step, is

to conduct this assessment, and you know, at that point, if we're only dealing with 12, it kind of helps to find our universe. It makes it a little bit easier.

Then you can take it, you know, one by one, because if you're talking about vitamins and minerals, and this would also apply to vitamins and minerals used in certified livestock feed. So in that case, it's not going to be just human foods.

If you want to say that every other ingredient needs to be organic or on the National List, and all the vitamins and minerals that are being used in processed food for humans and for livestock, that's going to be a huge train wreck. It's also going to be a regulatory bottleneck, to try to go through a petition process to deal with all of those other ingredients, and that's just in vitamins and minerals.

So that's why we're recommending that we use annotations, and I think this

assessment and looking, doing a case-by-case review of these 12 substances, can help us define and say well, let's do what we did with natural flavors. We say only non-synthetic other ingredients can be allowed.

Or maybe in one instance there's, you know, a few enough other ingredients being used that you can put it in the permitted substance database, or just document in the background. The point is that there are 12 different substances, and they really need to be dealt with on a case-by-case basis.

So and I think if you look between now and spring of 2014, you can get that work done maybe. This is just a suggestion for a road map. But it's just a way to start thinking about this process.

MR. FOSTER: Terrific. Thank you. Jay, this will need to be the last one.

MR. FELDMAN: Okay, thanks.

MR. FOSTER: We only have ten minutes here.

MR. FELDMAN: Okay. Just quickly, then. I'm just trying to decipher how you're looking at the listing, the word "listing" on the National List. So there's that footnote in the discussion document that, you know, recited the findings of the court, you know, on this question of Other Ingredients or processing aids, and basically said that, authorized the use of synthetic substances when ingredients or processing aids for use in handling operations, so long as they appear on the National List.

So you're equating this sort of grouping as a listing. Is that how you're interpreting that, compliance with that finding by the court?

MS. WYARD: I wouldn't call it a grouping. I would say a substance. A substance can contain multiple ingredients. So if you, you know, OFPA states that a handler must use ingredients that are either organic or on the National List.

So dairy cultures, that is an ingredient. So if a handler is using a dairy culture, the handler is using an ingredient that is on the National List. Further on in OFPA, it states that NOSB needs to add substances to the National List.

So now we've moved into, you know, we were using ingredients earlier on, and now we're talking about substances. But there's also further on and off where there's -- and I think that Zea put it up in her introduction, where it points out that a substance can be a multi-component substance. It can contain other ingredients.

So this is where we get in to these two school of thoughts that Zea presented in her presentation. What does it mean if an ingredient is on the National List? If a substance is on the National List, does that include, in its totality, those other ingredients?

The only thing that I can tell is

clear is that it's not clear, just as Zea presented, and I won't comment any further there. I think it does definitely get into legal land, and I'm not a lawyer, and that's, I think, where that needs to go.

MR. FOSTER: Thank you very much.

MS. WYARD: Thank you very much.

MR. FOSTER: And just while we're changing here, Britt's coming up, I've already had four requests for John Ashby's - four email requests for John Ashby's, so make it five. Yes, Yes. So you may want to print it in a pamphlet or something.

John Ashby will have a signing party in the lobby in the Renaissance Room after the proceedings. So Britt, thank you for your indulgence of our jocularity, and then next up is Elizabeth Johnson.

MS. LUNDGREN: Hi. Thank you for this opportunity to comment. My name is Britt Lundgren. I'm the Director of Organic and Sustainable Agriculture at Stonyfield, which

is the world's leading organic yogurt company.

At Stonyfield, we appreciate that the NOSB has decided to look more closely at the use of other ingredients in substances allowed on the National List.

We agree with the Handling Committee's assessment that while the overall ingredient review process is already quite rigorous, improvement and harmonization of this process would be beneficial.

We support the establishment of a more clear and consistent process to review other ingredients, because it will promote even greater transparency within the standard, and also provide greater certainty for processors such as ourselves.

In general, I think our position on this could be best described as Option B of the Handling Subcommittee's options, with variations. As Zea said earlier, a lot of us have tweaks to that.

We believe that this is the best

way for NOP to ensure that all other ingredients are evaluated in the process of evaluating substances for inclusion the list, without creating an onerous new set of requirements.

We believe that Policy Option C does nothing to advance the actual integrity of organic products, but could create a regulatory bottleneck for the agency, and thus hinder the future growth of organic agriculture.

Before NOSB settles on a policy for evaluating other ingredients, like OTA we suggest that the first step is to conduct a more thorough inventory of other ingredients that already in use in allowed substances.

In many cases, these other ingredients have already been reviewed as part of approval and sunset processes, while in some cases we may not be aware of the other ingredients that are in use in a substance.

By defining and thoroughly

investigating the scope of this issue first, NOSB can then design a policy that is more appropriate for the problem in hand. For some substances, it may be most effective to specify the allowance or prohibition of individual other ingredients.

In others, it may be more appropriate to allow or prohibit a functional class of other ingredients, or to allow other ingredients based on regulatory reference under another government agency. The point is that a one-size-fits-all policy for evaluating other ingredients may be inadvertently restrictive, or it could result in NOSB having to review many individual other ingredients, when a simple annotation to approve a functional class of ingredients would suffice.

For certain proprietary formulations, it may not be possible for NOSB to have full access to a complete list of other ingredients used, and in this case, it should be up to the certifying agency to

evaluate these other ingredients.

By first reviewing all allowed substances to determine which are likely to have other ingredients, and which of these are likely to be of a proprietary nature, the NOSB can be in a better position to provide appropriate guidance to certifying agencies about how to evaluate these other ingredients, as they have done in the case of natural flavors.

Once the review of other ingredients is complete, the NOSB can use what they have learned in this review to develop a policy for evaluating other ingredients. This policy should be designed to foster more transparency within the standard, by requiring the technical evaluation report and any other review done by NOSB, to always note any presence of other ingredients, and establish either specific allowances or restrictions as appropriate.

NOSB should also develop guidance

for certifying agencies on how to evaluate these other ingredients. That's it. Thank you.

MR. FOSTER: Thank you. Do we have questions?

(No response.)

MR. FOSTER: All right. Thank you very much.

MS. LUNDGREN: Thanks.

MR. FOSTER: Next up, we have Elizabeth Johnson, followed by Deborah Trinker.

MS. JOHNSON: Good morning. I'm Elizabeth Johnson from Tufts University, where I work in the Carotenoids and Health Laboratory, and where I've been working for more than 20 years, looking at the role of carotenoids in human health.

There's been a lot of talk about lutein this morning, and I'm here to tell you what it is and where we find it in the body. Lutein is a plant pigment. You find it common

in our diet. It's part of the carotenoid family.

There are hundreds of carotenoids in nature. We see them this time of the year, the reds, the yellows, the oranges. But of those hundreds, only two get in the eye, lutein and its isomer, zeaxanthin. In the eye, it has a role as an antioxidant in vivo. It's an anti-inflammatory and it's a blue light filter.

So that lends a lot of strong biological plausibility that it's important. What really makes a lot of plausibility to its biological importance is that we find a specific binding protein for lutein in the eye, and in biology, when you find a specific binding protein for something, that really lends support for it being important.

In the eye, the concentrations of lutein are 500 to 1,000 times more concentrated than anywhere in the body. The only way you get it in there is if you eat it.

Now the role for lutein in neural health, a lot of that comes from what we know in adults.

We know that lutein preferentially accumulates not only in the eye, but in the brain as well. There's a lot of double-blinded placebo-controlled trials, which are the golden standard when it comes to nutrition research, that show that if you give lutein, you improve cognition, you improve visual function.

So we know a lot of the epidemiology, we know the clinical work, we know the intervention trials support a role for lutein in eye health and in cognitive function in the adult.

Now a lot of what we know about lutein as an in vivo antioxidant, as an inflammatory, as a structural role, a lot of what we know in the adult, we can really expect that to be true in the infant. Its role as an antioxidant and anti-inflammatory is structural.

So in the adult, when we look at lutein status, whether it be in diet, whether in blood, whether it be in brain, we have data. More lutein in the brain, better cognitive function. Those roles of lutein should apply for the infant as well.

Now when we look at brain tissue of the adult, the major dietary carotenoid in brain is lutein. It's not beta carotene, it's not lycopene. Despite having increased levels of these other carotenoids, the brain takes that lutein out, just like it does in the retina.

For the infant, it's the same story. We've analyzed infant brain that died of natural causes, mostly SIDS, and when we look at the all the carotenoids in their brain, 60 percent is lutein. We analyze these brains in the first year of life, and we know they're not eating lutein in their diet. It's probably taken up in the brain, where we think it's function.

There have been studies defined that if you give lutein to infants that are on formula, that otherwise wouldn't have lutein, better antioxidant function. Then that implies there's going to be less formation of something called lipofuscin, which is a long term increased risk of eye health towards later in life.

So there's a functional role that we know, of lutein in the eye, that we can really apply to what's going on in the brain as well. So knowing that breast milk contains lutein, that without lutein in early life that you'll see decreased levels of lutein. This really has implication for its role being added to infant formula. So I thank you for your time.

MR. FOSTER: Nice timing. Questions from the Board? All right, Zea.

MS. SONNABEND: Thank you. Do you know how the lutein is made?

MS. JOHNSON: It's a plant

pigment, very common to our diet, our green leafys. And when we look at it not being in the diet, the studies we've done in monkeys, if you don't have it there, you see some abnormal morphological differences in the retina that are related to worse functioning.

MS. SONNABEND: But do you have any knowledge of whether the lutein that would be fed to the infants is the same exact lutein that's in the plants?

MS. JOHNSON: That's where almost all of our lutein comes from, is a plant extract. It's pretty expensive to synthesize, so you really want to go for a plant extract, and I don't know anyone that synthesizes it for commercial reasons.

MR. FOSTER: Additional questions? Harold.

MR. AUSTIN: Based off of all of the research that you've been doing with it in the University, what do you feel the significant impact to the infants would be if

they were lutein-deficient during their growth development?

MS. JOHNSON: Well, our best evidence comes from the work that we've done in primates and monkeys, where they actually never, ever were exposed to a carotenoid in their life. When you look at their retinas, it's not normal. It's not normal at all.

But when we fed lutein back to those retinas, there's these certain cells in the retina that they kind of traffic the nutrition coming in, the waste products going out, and that profile becomes distorted.

When we add lutein back to their diets, you can repair that. To me, that's pretty compelling, to see something like that going on.

So it's, you know, it's pretty important, and to find that there's this specific binding protein, which I had mentioned earlier, that to me is pretty strong biological evidence that it's important, when

we have evolved to have this protein to zap, to bring it out of the circulation, to put it in the retina exactly where it needs to go.

I mean most of us in the room are thinking more about preserving the neural tissue that we have, and one of the major problems we have right now is age-related macular degeneration. I bet everyone in this room can raise their hand, because they know someone who has this.

Lutein is in the macula. It's 500 times more concentrated there, where it is a blue light filter. The light coming in is blue light. It's a yellow pigment. It grabs that blue light, so it can't go on to those photoreceptor cells and damage them. Light is damaging.

The eye is very vulnerable to light damage. It's not like your liver or bones. It's damaging. So we want to protect it with a blue light filter, with an antioxidant, with an anti-inflammatory.

MR. FOSTER: Any additional questions?

(No response.)

MR. FOSTER: Great. Thank you very much. Next up, I'm showing Deborah Trinker, followed by Helen Kor.

MS. TRINKER: Good morning. My name is Debbie Trinker. I'm the Vice President of Regulatory Affairs for Kemin Foods, LC.

I appreciate this opportunity to appear before the Board, and to provide this statement in support of the addition of lutein USP to the National Organic Standard Board's list for use in organic formula.

We're in the manufacture of Floraglo brand of lutein, and we are the petitioner requesting this addition under Section 205.606.

My comments this morning will address some of the new scientific and other information that I was disappointed to see was

not in the Technical Report, that we think is relevant to your review of this ingredient.

Also, when I look at your definition of an accessory nutrient, if it provides an optimal health benefit and there is no viable organic alternative, then this ingredient should be considered and included on the list. Those are the points I'd like to make today.

I'd also like to take a little bit of time to discuss some of the issues that came up that are not in my prepared statement, regarding why we listed this ingredient under 205.606.

We believe that lutein USP is an agriculture product under this section. It's derived from a botanical source, marigold flowers, with minimal processing, and it retains its essential agriculture characteristic.

It is a pigment, a xanthan-filled pigment, and in fact under FDA regulations, we

are required to label it when it appears in the supplement as lutein, identifying its botanical source and part of the plant, i.e., the marigold flower.

When we prepared the petition, it was our understanding, and we did provide quite detailed information on our manufacturing process, and some of that was labeled as CBI, and it was our understanding that that would be reviewed and would be considered.

In the interest of transparency, I can briefly summarize how we process this. There is a solvent used. Hexane is used to extract the xanthan fills from the marigold petals, to create the oleoresin, and this is necessary.

The use of synthetic chemicals or solvents under this Board's recommendations would not in and of itself render the substance as synthetic, and I refer to the NOSB recommendation for classification of

materials in 2009, and unless there is a chemical alteration of the substance or the synthetic material occurs in the resulting product and is not removed.

When we test our crystalline material, we find that the hexane is not detectable. There's a second step in this process, and it's de-estrification step.

And if I can go back for a minute, we've also looked at these steps in terms of other substances that you've allowed under this listing, and we find precedent with unbleached lecithin, where hexane is used as a solvent.

A second step that is of interest to this discussion and this Board's review is the de-estrification step, and that provides lutein in the free form in which it appears in breast milk.

This step uses a processing aid that appears on your list as a substance that may be used in processing, as a processing

agent organic handling under 205.605, and the precedent here would be the HMP and LMP pectines, which are proposed to be consolidated under 7 C.F.R. 205.606.

Such that our conclusion, to be consistent, is that the de-estrification process, in and of itself, does not render this as a synthetic product.

I want to talk briefly about essentiality. I'm a food and drug lawyer. That's been the bulk of my practice, and the listing of ingredients that are allowed in fortification are based on having DVs.

That doesn't mean that this ingredient, per Dr. Johnson, is not critical to infant development. Just as one final comment that I'd like to make, because there's been a lot of discussion of EFSA, we define infant formula specifically under our laws, under the Food and Drug Act, and infant formula is supposed to simulate human breast milk, and lutein is in human breast milk at

significant levels.

So this is consistent with the statutory definition that the Food and Drug Act has, that FDA uses, not what FC uses. Thank you very much.

MR. FOSTER: Thank you. Do we have questions? Harold.

MR. AUSTIN: Thank you for coming and clearing up some of the complications that we are running into a little bit.

MS. TRINKER: Sure.

MR. AUSTIN: I know your original petition was for 606. We moved it to 605(b) because of, you know, because part of the information was classified confidential. We then were removing from an agricultural product down to a synthetic material or an ingredient.

So that's why we chose to move it there. I do appreciate you coming and clarifying that for us, because that does help. I think most of our Subcommittee would

have, at the time we were deliberating on it, which we still are, would have voted in favor of it, if we could have felt comfortable enough to classify it as a non-synthetic.

So I think you have helped clear it up a little bit, for at least some of us. So thank you.

MS. TRINKER: No, you're welcome, and on the record, in the interest of transparency, we can provide more information on that process. And I apologize. It was my understanding that the discussion and the petition would be subject to review. So that's my fault. I thought that discussion and the petition was sufficient.

And there's just one other point too, that I thought the Technical Report did not list any of the new studies done in infants since the EFSA decision in 2008. They're in the petition. They show favorable impacts in infants, in moderating reactive protein that is a mark of anti-inflammation.

They're also summarized in my statement, and I'd ask that you all look at these and review them carefully.

MR. FOSTER: Thank you. Thank you for your time. John. Oh, I'm sorry. Jay, did you have a question?

MR. FELDMAN: Yes, I had one more question. Sorry.

MR. FOSTER: I'm sorry I didn't see you, Jay.

MR. FELDMAN: When you talk about these ingredients, do you have -- are there published levels in the product that are either assumed or -- I mean since we don't have a standard, I don't believe, how does the industry determine the level of these substances that are added, in this case, lutein?

MS. TRINKER: The level of the substance, the amount of lutein in infant formula?

MR. FELDMAN: Yes.

MS. TRINKER: That's a very good question, and if you look at our petition, we think that there's some safeguards that address your specific point.

Lutein, our lutein has gone through the GRAS process, and it cannot be added in infant formula for term infants at levels that exceed 250 micrograms per liter.

So by law if we -- and it wouldn't be us; it would be the company, the customer. So if they were to exceed that, legally the ingredient would no longer be GRAS, and the product would be adulterated. So that's a pretty strong deterrent against excess levels.

MR. FOSTER: Thank you.

MS. TRINKER: Thank you.

MR. FOSTER: Next, I'm showing Helen Kor, followed by Troy Aykan.

MS. KOR: My name is Helen Kor. I'm a nutritionist with the Hain Celestial Group. My company advocates breast feeding as the first and best choice for infant feeding.

However, for mothers who cannot breast feed, my company offers milk based and soy based organic infant formulas, and the precise formulations reflect the combined knowledge of the FDA, international regulatory agencies, professional associations, and the leading experts in the field of infant nutrition and health.

I am here to support the petitions for the nutrients used in infant formula. I will focus my comments today on the petitions for methionine, carnitine and taurine. But first, I want to correct some misinformation.

It has been stated by some commenters that organic soy-based infant formula contains hexane-extracted soy protein isolate. This is not true, because synthetic solvents may not be used in organic ingredients.

Organic soy protein isolate is used in our soy-based infant formula and is certified by an accredited certifier under the

NOP.

L-methionine is an amino acid that is vital for growth and development of infants. Because soy-based infant formulas do not provide sufficient methionine without fortification, soy-based formulas must be fortified with L-methionine to meet the protein requirements of the FDA. We could not sell or organic soy-based formulas without it.

We strongly urge the NOSB to approve the petition to add L-methionine to the National List. L-carnitine is another amino acid that is found in breast milk, and is vital for infant growth and development.

An inadequate carnitine intake may result in failure to thrive, low blood sugar and cardiomyopathy. Therefore, carnitine fortification of infant formula is recommended by both the EU and the Life Sciences Research Office, operating under contract with the FDA.

Initially, carnitine was only added to soy-based infant formulas, but

starting in the 90's, some milk-based infant formulas began to be fortified, to ensure that they meet the minimum recommended level.

We strongly urge the Board to approve the petition for L-carnitine to the National List for both soy-based and milk-based infant formulas.

Taurine is present in significant amounts in breast milk. Taurine is needed for proper functioning of the retina, for proper digestion and absorption of fats, for heart and motor function and other important physiological functions.

Infant formula needs to have added taurine to match the levels in breast milk. This is why taurine has been added to both milk-based and soy-based infant formulas all over the world for decades. We urge the Board to approve the petition for taurine.

Some of the people opposing the petitions for infant formula nutrients acknowledge that there are no available

substitutes for these nutrients. But their solution, that women should only breast feed, is not feasible, due to physical problems, their jobs and/or upon advice from their health care provider.

My son had a slower growth rate than is expected in his first few months of life, and so my pediatrician advised me that my son must be fed infant formula, because breast feeding alone could not provide the calories and nutrients needed for optimum growth and development. This was the best choice for my son.

As a nutrition scientist and a mother, every child deserves a formula that delivers adequate nutrients needed for optimal growth and development. I implore this Board to approve all the petitions for nutrients added to organic infant formula. Thank you.

MR. FOSTER: Thank you. Do we have any questions for the commenter? Jean, Jay.

MS. RICHARDSON: Thank you for your comments. One of the other public comments that we received in the written material before the meeting included a statement that L-carnitine is required in the European Union, for addition to organic formula.

Can you tell me if that's correct from your knowledge in the manufacturing process?

MS. KOR: I'm not familiar with the EU regulations. I work for a U.S.-based company. But through my understanding and what was written in the petitions, that is indeed the case, that there is a requirement in the EU for carnitine.

MR. FOSTER: Thank you. Jay.

MR. FELDMAN: Thank you for your statement, and your clarification on the extraction process for the soy isolate. What is the process? Can you explain the process that is currently used?

MR. FOSTER: I'm not a food scientist, so I don't know the process for extracting --

MR. FELDMAN: Somehow we'll get the answer to that by the end of today, I hope. Thanks.

MR. FOSTER: I'm sure it can be. Additional questions?

(No response.)

MR. FOSTER: All right. Thank you very much. Next up, Troy Aykan, followed by Zareb Herman.

MR. AYKAN: Good morning. My name is Troy Aykan. I'm a food scientist and an attorney, specializing in food laws and regulations, and a professor. One of the questions asked by the NOSB is whether a material is essential for organic production.

If a material has been shown to be essential for proper growth and development in infants, then it should be considered essential for infant formula. The Infant

Formula Act was passed in 1980, and a list of nutrients was codified in 21 C.F.R.

Some people erroneously believed that if a nutrient or substance is not listed here, it's not essential for infants. This is not correct. This list is not intended to be only ingredients necessary for infant formulas.

There have been many advances in nutrition science since 1980, and other ingredients have been introduced to provide nutrition that infants need.

Before a non-listed nutrient can be used in infant formula, it must go through a thorough GRAS notification process with the FDA. After it's granted GRAS status, before the nutrient is used, the component must document the benefits of the nutrient to the satisfaction of the FDA.

Every infant formula then is supported by clinical trials, and is thoroughly reviewed by FDA before it can be

even sold. It's important to note that many essential nutrients don't even have daily values, such as numerous amino acids, fatty acids and other nutrients.

The ingredients in infant formula have nutritional or functional properties that provide for a safe and complete formula. To limit the ingredients to just those nutrients from 1980 will result in an outdated incomplete, unstable nutritionally inferior formula.

Consumers expect organic infant formula to be the best formula that they can buy for their babies. To deny the use of these substance will place organic formula at a competitive disadvantage, when compared to non-organic formulas, and more importantly, it will place the health of babies at risk, and could result in the elimination of organic infant formulas altogether.

Actions by this Board can have serious consequences. For example, oxidation

of essential fatty acids is a major challenge. Oxidized or rancid fats smell terrible and can cause serious diarrhea in infants.

If the petition for ascorbyl palmitate is not approved, the shortened shelf life will make infant formula commercially unbuyable. Our products must travel from the production site to our warehouses, then ship to distributor warehouses until orders come in, and then it ships to other warehouses or to the retail stores, which might require shelf lives of up to 15 months.

With ascorbyl palmitate, there is a good chance that oxidative destruction of essential fatty acids and vitamins will occur. This may cause the levels of these nutrients to fall below the levels that are required by federal food laws.

Such products could be considered adulterated, due to rancid fats, or misbranded, due to insufficient levels of nutrients. Actions which violate the above-

mentioned laws and regulations may also be a violation of OFPA, which states in relevant part that "nothing in this chapter shall alter the authority of Secretary of Health and Human Services under the federal food laws."

If certain nutrient petitions are denied, this will impact international trade. Without carnitine, we could not sell our formula in the EU. Similarly, without taurine, we could not sell our organic infant formula in Canada, which is a major trading partner.

For these reasons, and many more, we urge the Board to approve the petitions for these important nutrients. Thank you. Any questions?

MR. FOSTER: Thank you, Mr. Aykan. Questions? Mac?

MR. STONE: You had in bold on the previous slide that it could eliminate organic formulas on the market, but it didn't say it "would." What would you have to do to not

have it eliminate infant formulas?

MR. AYKAN: I don't see the gentleman asking the question. Could you repeat it please? I'm sorry.

MR. STONE: On the previous slide, you had a bold statement, said it "could" result in the elimination of organic infant --

MR. AYKAN: Yes sir.

MR. STONE: It doesn't say it "would" eliminate. So what would you have to do to adjust for this, if the Board were to deny any or all of these?

MR. AYKAN: Yes, great questions. There are, with the denial of the petitions, there are two problems, okay. One is oxidation of essential fats. As the previous experts testified, that infant formula contains about 25 to 28 percent fat.

Not just VHA. VHA is a very small portion. But a lot of other fats, because linoleic acid is required by law to be there. So to protect these fats from oxidation, we

need to have the system of ascorbyl palmitate and tocopherols and beta carotene.

If you're asking me what is it that can be done, is that I don't know how science could come up with something, another oxidation system that would be acceptable. But in any case, as you may realize, we're already selling these formulas. They are available.

They're available in the U.S. as organic infant formulas. We sell these in Canada. We started selling them in China and Hong Kong. And to think, of course they have different local regulations.

That is of no concern here, but it requires some study and I don't know how soon that could be done. Three years, four years. I don't know, but these oxidation systems already exist.

The second problem would be the lack of important nutrients, such as taurine, carnitine and methionine, which was, you know,

explained in detail by experts.

MR. FOSTER: Thank you. Jay. Oh I'm sorry. I thought you -- you have no idea how much I'd love to have you do that. I want to be mindful of time. People are getting hungry. We have a few more speakers. I want to make sure we make sure to get to them.

So choose your questions wisely, that's all. I'm happy to go through it. I just want to make sure we're aware of that. Nick's promising me very short. Okay, Nick, Jay and --

MR. MARAVELL: The question's short.

MR. FOSTER: Nick, Jay and Harold.

MR. MARAVELL: No. The answer should be short too. You said you're selling your product abroad now, Canada, China and perhaps other markets. With regard to ascorbyl palmitate, it's our understanding it's not permitted under the Canadian standard for organic infant formula.

I'm not familiar with the Chinese situation, and I would -- so I'm asking has that been something that has been brought to your attention with your product, and then the final one is would you anticipate any problems selling your product in Europe? So I'm just trying to get an idea of how that works.

MR. AYKAN: Yes. You just switched from Canada to Europe. In Europe, yes, I understand it.

MR. MARAVELL: No. It's multiple questions.

MR. AYKAN: Yes, I understand it.

MR. MARAVELL: I'm a globetrotter, okay.

MR. AYKAN: Okay. In Europe obviously, ascorbyl palmitate is approved for use as a proper Vitamin C source, as I looked it up personally myself. As far as the Canada and ascorbyl palmitate, I don't have the answer, but I'll defer to one of my colleagues that may come up after me.

As far as these formulas, and let add this too, is that our organic infant formula is made right there in New England, in Vermont, by Vermont dairies, 100 percent, and locally, and we'd like to keep this business here.

As far as the Canadian question, I have to check our formula, to see whether there's an ascorbyl palmitate. That's a really good question to know. Yes, yes, I agree with you.

MR. FOSTER: Thank you. I have Jay there.

MR. FELDMAN: Thank you. With all the expertise -- John, this is actually a question for you, because I don't know how you want to handle this, with all the expertise in the room and the references to GRAS among many of the commenters.

I'm wondering if we could have a definition, both by FDA and maybe Mr. Aykan, on what exactly GRAS means. It's been used.

We know what it stands for, Generally Recognized as Safe. But this process of FDA granting GRAS status, what exactly does that mean, and does that conform to our standards under OFPA.

So if we could use the expertise in the room, I'd appreciate it.

MR. FOSTER: My instinct would be going to our guest from the FDA, would be my sense. Does that sound reasonable?

MR. FELDMAN: Cool.

MR. FOSTER: Okay. Then I had Harold, I believe, had a question.

MR. AUSTIN: Just quickly. In regards to taurine, you mentioned that without it, you could not, your formula could not go into Canada? Could you clarify that, or did I mis-hear what you were saying?

MR. AYKAN: Yes sir. Taurine is required in Canada, so it must be added to the Canadian formula, and also -- that's my understanding. Yes, just been confirmed. It

is required, and I want you to please also understand that if possible, you know, we'd like to use the same formula for our friends in Canada and here, if possible, obviously.

But because as you guys know, there's a certain organic equivalency agreements and all that stuff. But yes, taurine is required in Canada, yes.

MR. AUSTIN: Thank you.

MR. AYKAN: Mandatory.

MR. FOSTER: Follow-up, Harold? One more quick one.

MR. AUSTIN: Would you happen to know the regulations that are guiding the nutrients required in Canada, how current those are, when those were established, versus 1980 for ours, or 1985?

MR. AYKAN: My, the answer is that I do not know. My thinking is that they are more recent, but by the day is over, we could give you a report on that as to the date, as information. But I don't have it in front of

me.

MR. FOSTER: I'm sure that someone's Googling it right now. All right. No more questions? Thank you very much for your time. Next up, thank you, thank you. Next up, I see Zareb Herman, followed by David Cockram.

MR. HERMAN: My name is Zareb Herman. I'm a nutritionist with the Hain Celestial Group. I am here to support the petitions for the nutrients used in organic infant formula, because these ingredients are found in breast milk and the science supports their importance for infant growth and development.

When the Infant Formula Act was passed in 1980, I was living in Berkeley, California. My graduate advisor was one of the leading experts in maternal and infant nutrition. In the last 30 years, nutritional science has advanced greatly.

Infant formula manufacturers have

a tremendous responsibility to provide the most current and best possible nutrition for infants during the most crucial stages of their development. When it comes to what is necessary in infant formula, we need to trust the infant formula experts.

I prepared a handout for the Board. I don't know if they received it, but I don't have time to go into it. But I would ask you to look at it, because it sort of condenses what would happen if you took each nutrient out of infant formula.

And also on the handout, I show this particular slide, and it shows the continuum of views on non-organic ingredients in processed organic foods. On the far right are the people who say heck, add anything you want.

On the far left are people who say organic foods should have only organic ingredients, nothing else, no National List. In the middle are people who support a

reasonable National List. They support necessary non-organic ingredients in processed organic foods such as infant formula.

It is important to remember that over 50 percent of the organic market is processed food. The vast majority of these products require some non-organic ingredients. Without them, these products could not exist. Consumers want organic infant formula.

I know this, because organic infant formula is a major portion of the organic foods market, with annual sales of $500 million. Many organic farmers and many other people make their living because of organic formula.

A no vote on these petitions will almost certainly wipe out organic infant formula from the marketplace. The organic regulations provide for the use of synthetic ingredients when necessary. This is why we have Section 605(b) of the National List.

We don't live in a perfect world.

The reality is that some nutrients are only available in synthetic form. They are identical to the molecules in breast milk. Being synthetic does not make them evil. The rejection of a substance just because it is synthetic is not valid.

Some people who oppose these petitions argue that there are substitutes that can be used. However, these substitutes must actually exist, and they must work and be available to be considered viable alternatives.

Some people want to keep the National List small. They kind of lean to the left a little. I want to remind that these petitions are not for all organic foods. The petitions are for a small but very important group, with special dietary needs, infants.

We all need to stand back from the politics and ask what is really important here. The answer is the health of babies. We should all want what is best for babies, and

not sacrifice their health by denying them these nutrients.

Lastly, I'm not trying to be funny when I say this, but please, don't throw the baby out with the bath water.

MR. FOSTER: Thank you. Questions for Zareb?

(No response.)

MR. FOSTER: Thank you very much. Next up I see David Cockram, followed by Robert Rankin.

DR. COCKRAM: Hi. My name's David Cockram. I'm representing Abbott Nutrition, makers of Similac organic infant formula. I'm a nutrition scientist and a registered dietician. Have had over 25 years of experience developing infant formulas and adult nutritional products for people with a variety of conditions.

Breast feeding is clearly the number one option, the best option for nursing infants in the first year of life, but it

isn't always possible or chosen. An infant formula that complies with the Infant Formula Act's requirements for composition, pre-market notification, quality and documented safety is the only appropriate substitute for human milk.

The compositional requirements, as you've heard in the Infant Formula Act represents minimum standards for infant formula. However, the Infant Formula Act nutrients have not been updated since the 1980's, and I would suggest to you nutrition knowledge has grown, and the Infant Formula Act nutrients no longer fully reflect contemporary nutrition knowledge.

Lutein and lycopene are good examples of this. The dietary guidelines for Americans, which have incidentally been updated six times since the Infant Formula Act nutrients were established, encourage us to make half your plate fruits and vegetables, and to eat red, orange and dark green

vegetables.

The dark colors in these foods are the result of the carotenoid content. Carotenoids are a collective term for, as you've heard, for a number of structurally-related compounds.

Some, like lutein and lycopene, are the focus of very intense research efforts, and there's throwing recognition of the role of these substances in human nutrition, especially infant nutrition.

I'm going to focus on lutein, but the story is fairly similar for lycopene as well. Diets contain over 50 carotenoids, of which about 20 can be found in the blood. Of these, they are highly concentrated in certain tissues, those being the eye, that bright yellow spot there in the eye, is primarily lutein, and then in the centers of the brain that are associated with learning, memory and vision.

Carotenoids are transferred from

mom's diet to the infant via breast milk. Early breast milk or colostrum has a very high lutein content, which decreases over time and in breast-fed infants, blood lutein normally rises over the first month of life, something as you see on the right doesn't tap into infant-fed formula without supplemental lutein.

Until infants begin consuming complimentary foods, infants only get carotenoids from fortified formulas. Studies now in both term and pre-term infants show that lutein levels approximate those in human milk-fed infants when supplemented formulas are fed, but not when unsupplemented formulas are fed.

The brain grows very rapidly, as we've heard, in the first six months of life. This shows relative development of neural pathways in the visual cortex of the brain, and as noted earlier, lutein is highly concentrated in this part of the brain.

Evidence from a recent study in premature infants suggests that lutein accumulation early in life may be physiologically important.

These are data from premature infants fed a carotenoid-supplemented formula, and showed signs of improved neural retinal health or eye health, based on a sophisticated measure, rod photo-receptor sensitivity, which highlights the role and potential benefit of lutein in infant formula. I'll stop.

MR. FOSTER: Thank you. Question for the commenter? The best four minutes of your life, huh?

DR. COCKRAM: I'm sorry?

MR. FOSTER: Fastest four minutes of your life.

DR. COCKRAM: It was a fast four minutes. Can I volunteer the answer to the question of the difference between soy protein isolate and concentrate?

MR. FOSTER: Yes.

DR. COCKRAM: Since 18 people have asked and nobody's really answered?

MR. FOSTER: And you're willing to answer it. Go for it.

DR. COCKRAM: Basically, the difference is the concentration of protein. I can't speak to the details of the manufacturing, because I don't know. But soy protein isolate usually has a higher concentration of protein, less fats, carbohydrates, minerals with it.

Soy protein concentrate is generally a little bit lower, is lower and it's over a range of protein concentrations. But the tradeoff is with a concentrate, you tend to have more of the other stuff from soy that's still there, the minerals, the electrolytes, etcetera.

MR. FOSTER: Thank you. Okay, Jay.

MR. FELDMAN: Well, just to follow up. Thank you for asking yourself that

question. I guess the question is what is typically used in the industry. I mean somebody is --

DR. COCKRAM: In terms of the concentrate versus isolate?

MR. FELDMAN: In soy --

DR. COCKRAM: I can't speak to that. We don't use that for -- I mean it's isolate in infant formulas for certain.

MR. FOSTER: Thank you for your time.

MS. SONNABEND: I have a question.

MR. FOSTER: Oh, I'm sorry. I'm sorry. David, would you come back? Zea.

MS. SONNABEND: Your company manufactures infant formula, not the components of the infant formula; right?

DR. COCKRAM: You are correct.

MS. SONNABEND: Okay. To your knowledge, are there more than one company that make lutein and lycopene and those types of products?

DR. COCKRAM: There are several manufacturers of lutein in particular, as well as lycopene. To my knowledge, there is only form that has been reviewed by FDA for infant formula use, and I guess that kind of gets me to the point I had up on the slide, or that I didn't get to, was other sources certainly have ingredients.

Could be developed, but the issue is it just takes a very long time, and it's a fairly painful process to do that. Goes through the, you know, two sequential FDA reviews for ingredient safety, the GRAS part, and then clinical or the appropriateness for infant formula.

MR. FOSTER: Thank you. I have a question from Jean.

MS. RICHARDSON: We've heard from the commenters that many of these ingredients, if not most of them, are considered by the producers of the formula to be essential for the infant, and yet they're not required by

FDA.

As you're pointing out on this slide here, that the infant formulas are highly regulated and closely scrutinized. So we have the challenge sitting here, deciding what to do with it. Why are they not required if they're so darned essential? Could you help us with that?

DR. COCKRAM: That's a good question, and I guess one that on occasion I've even debated a bit with Dr. Anderson. But you know, frankly, the FDA -- in order for FDA to or actually any regulatory body, and I would submit to you this is probably a good thing, in order for any regulatory agency to change a regulation, it's a fairly cumbersome process and requires a lot of work.

Goes through notice and comment rulemaking, gets input from all sides, just like we're getting here today, and you know, it's a major chore for the regulatory agency to go through that.

And you know, there are a lot of priorities and under the current regulations, there's really nothing that absolutely forces a manufacturer to limit themselves to -- well obviously there's nothing that forces a manufacturer to limit themselves to only the IFA nutrients.

You are obligated to go to FDA and convince them that in fact you will be doing no harm and hopefully some good, and you know, at this point, that system has worked reasonably well with FDA and, you know, Dr. Anderson certainly can comment further on that.

But I think we have, you know, I think because of the burden of changing regulations, you know, certainly public health guidelines and recommend, you know, the recommendations for nutrient intake have changed over time. But the regulations, probably as a good thing, haven't.

MR. FOSTER: Thank you. Just to

follow up on that Jean, my hope is that shortly, the Handling Committee will come back from lunch.

We go, according to the agenda, to an immediate Handling Subcommittee break, and so we have -- we will need to get with Dr. Anderson, I believe no later than 1:30, in order to make sure she can leave on her schedule.

So my hope is that Handling Subcommittee can get back -- at least Handling Subcommittee can get back by 1:30, so that we have time to take advantage of Dr. Anderson's knowledge with respect to the GRAS question perhaps Jean, as well as the question you just asked, and the rosemary extract.

Any -- okay, thank you for your time.

DR. COCKRAM: Thank you.

MR. FOSTER: Next up, I have Robert Rankin and then the last speaker scheduled is Marsha Walker.

MR. RANKIN: Good morning. My name is Robert Rankin. I am the Associate Director of the International Formula Council. The IFC is an association of manufacturers and marketers of formulated nutrition products, including infant formulas, and we appreciate the opportunity to speak today.

I would like to thank the NOSB and the NOP for your hard work on these activities. These are a lot of difficult decisions you will need to make. As has been stated today, and we didn't make it any easier with our petitions that we submitted.

However, I think it makes an important point, in terms of what has been discussed today, related to what we knew in 1980 versus what we know today. So I'll be speaking about that in a second.

As stated in our petitions and written comments, the ISC supports the continued use of all nutrients in organic infant formula. They have been reviewed and

accepted by the U.S. FDA and regulatory agencies around the world for use in infant formula, and with the exception of ascorbyl palmitate, they're all found in human breast milk.

Because there were so many petitions and so many nutrients to discuss, I will not be commenting on each one individually. Instead, I'll be providing some contextual comments, which I hope will help the NOSB in your evaluations.

First, the ISC supports the American Academy of Pediatrics' recommendations regarding breast feeding. Human milk is the gold standard for infant nutrition, and provides specific maternal and infant benefits.

The ISC also supports positive efforts to support and promote breast feeding. Every mother should breast feed if she can and chooses to do so. The reality is not all mothers can and want to breast feed. There

are a variety of reasons for it, be it maternal health, infant health, adoption, lack of workplace support, cultural reasons, a mother's choice and many others.

The NOSB was not created, nor are we here to discuss how infants should be fed. What we believe we should be discussing is how to ensure infants who are not breast fed receive the most complete, optimal nutrition possible.

As has been said before, U.S. regulations define infants as persons no more than 12 months old. Infants are a very critical population, and require specific nutrients to ensure proper growth and development, and these needs are met through breast milk, infant formula, or a combination of both.

U.S. regulations also define infant formula as a food solely for infant use, as a complete or partial substitute for human milk. Infant formula is the most highly

regulated food in the world, and is recognized as the only appropriate alternative in meeting the nutritional needs of infants, of mothers who cannot or choose not to breast feed.

It is important that infant formula be as nutritionally complete as possible, to ensure proper growth and development.

Because infant formula is the sole source of nutrition for many infants, academicians and industry researchers recognize the importance of continuously conducting scientific research, and evaluating results, to ensure and constantly improve the nutritional quality and performance of infant formulas.

The primary goal of the infant formula industry is to ensure that infants who are fed infant formula receive a product that is nutritionally close as possible to human breast milk. This requires research and investigation into the composition of human

milk, as well as the mechanisms of the benefits associated with breast feeding.

When existing data and new research provide a reasonable basis to conclude that a new ingredient is safe and provides a benefit, the manufacturers are required, as has been said, to provide FDA with documentation of that information, to establish its safety and suitability.

It can take decades of academic and industry research to result in a nationally or internationally adopted requirement for a particular nutrient. So while it would be nice to be able to do that on an as-needed basis, it's not practical and feasible, as has been discussed.

So that brings me to the discussion being had here today, where it's been suggested that infant formulas may only need to include ingredients listed in the Infant Formula Act from 30 years ago.

The Infant Formula Act reflects

the nutrition science known at that time, and over the past 30 years, significant improvements have been made in learning about infant nutrition and the composition and benefits of breast milk, which has resulted in the products you see today. So I'd like for you to take that into consideration as well. Thank you very much.

MR. FOSTER: Thank you. Questions from the Board? Calvin.

MR. WALKER: How does the -- if by chance these particular materials are voted down, what kind of impact would that affect your particular business?

MR. RANKIN: Well, I'd probably want to refer that to the manufacturers who use the ingredients and manufacture the products. However, I can volunteer a couple of opinions.

Obviously, a lot of research and development has gone into the ingredients that are currently used in infant formula. As I

said before, they've been reviewed and accepted by the FDA. They've also been accepted by regulatory agencies around the world.

So they are safe, they are suitable, and based on the information that is required by manufacturers to submit during the review process, they do show proper growth and development. So those nutrients are researched and proven to be safe and suitable for infants.

If any of these ingredients are, especially those which provide a function, such as antioxidant and what have you, manufacturers, if they were no longer allowed to use those ingredients, they would be forced to research and develop alternatives, if those exist.

That would require, I think the previous speaker had a table which showed a pretty long time table for what goes into researching, studying alternatives, going

through clinical trials, which is required for infant formulas, to show that the ingredients are safe and suitable.

The GRAS approval process, which I think it would be great for FDA to discuss a little bit more, because I believe one of the comments I heard from another commenter, in my opinion it kind of -- in my opinion, it downgraded FDA's role in reviewing these ingredients for their safety and suitability.

I really believe that the process is robust and it is working, as far as we're concerned, with regards to infant formulas. But then so the manufacturers would need to identify alternatives, determine that they are suitable, determine that they are viable, and then determine if that's something that they want to pursue, in terms of staying in the market.

But as I think, as you have heard, there's at least one nutrient for which there is not a suitable alternative. So and I think

that affects the antioxidant properties. So that as some have said, could potentially affect the category, although I can't speak to that, because I'm not a manufacturer.

MR. FOSTER: Thank you. Additional questions? Nick and then Zea.

MR. MARAVELL: Yes. I was wondering if you have a feel for what percentage of infant formula currently sold in the United States is labeled as organic, and if you had a feeling for how much of that is soy-based and milk-based?

MR. RANKIN: I actually don't have information on the percentage of organic infant formula. I think the manufacturers might have an idea, because they would produce those.

I would like to say, though, that in my opinion and in my history, my wife buys a lot of organic products and my understanding is that those who are interested in organic products are very passionate about having that

option.

And so I think if you get into a situation where the organic option is not as nutritionally complete, perhaps, as a conventional formula, then they may deselect that product and go with an alternative that is not safe and nutritious and recommended, such as a home-made type of product.

And that, I think the FDA would agree and the AAP, is definitely not where we want to go with that. Breast milk and infant formula are the two safe nutritious recommended options, and it's my opinion that that option of an organic product for those consumers, and mothers who want to provide that for their infants, should be preserved.

Then as far as soy, again Dr. Bhatia made some comments about the needs for soy formula, and I don't disagree with his comments. But I would like to say that with regards to soy, just like with organic and with everything else the consumers have the

opportunity to purchase, we believe that that option should remain available to consumers, because it is an important category for those who want to provide their families with vegetarian options.

So we strongly believe that soy formula has its place and it's very important.

MR. FOSTER: Thank you. Last question, Zea.

MS. SONNABEND: Thank you. In looking at alternatives, particularly to the ascorbyl palmitate and beta carotene, which appear to be preservatives, we're wondering if any of your members or colleagues have looked into the possibility of refrigerated infant formula without preservatives?

MR. RANKIN: One of the speakers mentioned that they weren't aware of any research that's been done. You might ask the other manufacturers. But I'm not aware of it myself. Just it's apparently not the way that it has ever been done, and so it's not been

considered, and I know if the AAP would have any comments on that either.

MS. SONNABEND: A follow-up to that. Would -- you were talking about you need to go GRAS approval if you're adding other ingredients. But if you were just making refrigerated formula without ingredients, would that still need certain FDA or GRAS approvals?

MR. RANKIN: As long as it doesn't include an ingredient that has never been used before and never been reviewed. That GRAS review is for any nutrient that's not considered, you know, on the regulatory list, and has not been used before.

So it would need to go through that GRAS approval process. So a short answer, if it's a new ingredient, yes, it needs to go through the GRAS process.

MS. SONNABEND: Refrigeration isn't an ingredient, so it's just a process or a product?

MR. RANKIN: Right. If you're talking about taking out ingredients, I think that would be considered a new formulation. So that would need to go through the FDA approval process again. But as long as there were no new ingredients, it would not need to go through the GRAS review process, just the pre-market notification process.

MR. FOSTER: Thank you for clarifying. We have one more speaker, according to my schedule.

MR. RANKIN: Thank you.

MR. FOSTER: Thank you very much for your time. I had Marsha Walker. Is Marsha in the house? Okay. Marsha's not here. That concludes the public comment that I have on the schedule here.

At this point, I need a lot of clarification on the timing of the breaks, because the agenda I have is not clear to me. So I'm going to need help. I want to make sure that we accommodate Dr. Anderson's

departure schedule.

So I know we need to be back to ask some questions of her by 1:30. But beyond that, help me understand what's in the agenda. When does everyone need to be back, versus when does the Handling Committee need to be back, because there appear to be a difference in the agenda I have.

I'm going to hand this over to -- yes, go ahead. I'm listening.

CHAIRMAN FLAMM: Well, will it meet our guest's time table if we returned on the scheduled time of 1:30, John. We're almost there right now, so it would be just a little over an hour break.

MR. FOSTER: Okay, returning at 1:30.

CHAIRMAN FLAMM: And then you'll have the opportunity to get together with your Subcommittee after we have the chance to ask some more questions. Is that okay?

MR. FOSTER: That's fine. So back

at 1:30, everyone.

CHAIRMAN FLAMM: We'll take a break now for lunch, and be back here at 1:30.

(Whereupon, the above-entitled matter went off the record at 12:23 p.m. and resumed at 1:43 p.m.)

A F T E R N O O N S E S S I O N

1:43 p.m.

MR. FOSTER: All right. Thanks everybody for coming back. I hope you got some provender to keep you going for the rest of the afternoon. We are moving back into the portion of the agenda that's dealing with Handling Subcommittee activities.

We had scheduled on the agenda to go directly into additional subcommittee deliberations, which I know the gallery would find fascinating. But instead, we want to accommodate some travel schedules for Dr. Anderson.

So with -- Barry, with your okay, I'd rather move straight into the Board members' ability to ask some specific questions of Dr. Anderson. Is that all right with you? Okay. Thank you, Barry. Thank you, Mr. Chairman, I should say.

We have a number of questions that came up in the context of earlier dialogue,

that we want to reiterate. Jay, I know you have a question about GRAS notifications. Jean, I know rosemary extract is one and oh, it looks like I am buying someone's round tonight. There you go. That's me. That's my fault. That was me. I'll claim it.

We had a couple of additional questions that came up in the context of a very unofficial lunch, a fast-paced lunch meeting. So we'd like to move straight into questions of Dr. Anderson and others, if we need to.

So with that, Zea I know you had a specific question, and if it's okay with everyone, I'll go Zea, Jay and then Jean, and then take other questions from the Board.

MS. SONNABEND: Thank you. Dr. Anderson, my question is following up on what one of the commenters said about going through the FDA process, to get approval for a refrigerated version of an infant formula that did not have preservatives.

Could you describe what that would involve? If it didn't have a new added ingredients, but it was just for refrigeration.

DR. ANDERSON: That would involve a new processing entirely, and the safety of that processing would have to be evaluated. It would also have to be evaluated for the microbiological quality, the nutrient quality, and they would have to provide an infant formula notification before they go to market, and they would have to show that they were complying with good manufacturing practices, that they were not producing product that could be considered contaminated or adulterated, and that it would support normal growth in infants and be well-tolerated.

So they would have to give us an infant formula notification, to give us assurances that the product was being produced in a way that is following good manufacturing practices, and that will meet the needs, the

nutritional needs and the safety needs of the infant.

One thing we do not approve, these notifications. Congress did not give us approval authority. If an infant formula company comes to us and gives us a notification, they have to do so 90 days before they go to market.

But on the 90th day, they are free to go to market, even if we have serious questions about the product. Congress didn't give us approval authority.

MS. SONNABEND: Dr. Bhatia, could you address that question?

DR. BHATIA: I have a more practical point. Let me, if you take sterile formula, with a long shelf life, what have you. I'm not here representing anybody who manufactures, and open that can or bottle or refrigerate it, you have to throw it away in 48 hours.

So if you only have non-

preservative, refrigerated milk, not only are you reducing shelf life; then you have to prove that the formula, as prepared, is good in the refrigerator, even for that 48 hour period. So it has got a lot of implications and one simple step.

MR. FOSTER: Jay.

MR. FELDMAN: Thank you. Dr. Anderson, thank you. The earlier question I had was about the standards for FDA, and the actual process that the FDA goes through when a manufacturer lists as GRAS.

DR. ANDERSON: Okay. As indicated earlier, GRAS stands for Generally Recognized as Safe, and that's a category of food ingredient. There are two categories of food ingredients. One is food additives, and that has to have food additive status. A compound has to be petitioned to the agency.

The agency approves or not approves the petition, and a regulatory decision is made and that has the force of

law. For a Generally Recognized as Safe substance, the agency provides a different mechanisms for establishing the Generally Recognized as Safe status, and I should emphasize that the -- it's not the substance that has GRAS status; it's the substance for its intended use that has the GRAS status.

So if it's for use in infant formula, that's the use that has to be evaluated in any evaluation of safety.

The process that is used for evaluation of Generally Recognized as Safe Ingredients by the Office of Food Additive Safety is a voluntary process, in which infant formula manufacturers, food manufacturers, ingredient manufacturers come to the agency and say that we have self-determined that this substance is GRAS for use in infant formula or whatever, and we base this on either history of use or scientific substantiation, scientific evidence, and in addition, it's recognized in the scientific community by

experts qualified by training and experience, that this is indeed a use that is safe for the particular substance.

Now with the provision of a GRAS notice, the information all has to be publicly available. The agency cannot consider proprietary or confidential data as primary evidence for the safety of the compound for that particular use, and the agency does not make its own determination of the safety.

At the end of the review of that notice, the agency will issue a letter saying either we have no questions of your self-determination, or we do have questions and these are what the questions are.

So it is incumbent on the manufacturer to provide the, for the safe use of the ingredients in their products. Neither the infant formula notification process, which is mandatory, nor the GRAS notice process, which is voluntary, are approval processes.

And so that in a nutshell is what

we, what the process is for new food ingredients for infant formula.

MR. FOSTER: Thank you. Follow-up, Jay?

MR. FELDMAN: Yes, thanks. I actually had another question after that, but is part of the assessment, it sounds like there's an assessment in there somewhere. In other words, the company or institution is self-certifying, subjecting their information to some review process at FDA by somebody or some panel of people, and then they get a letter of some sort. Is that accurate? Am I summarizing that accurately?

DR. ANDERSON: Pretty much so. As you've said, FDA does not make its own independent review of all the data on its own. FDA relies on the information that's provided in the GRAS notice, and other information that's available in the publicly available literature.

MR. FELDMAN: Okay.

DR. ANDERSON: If there's issues that they have questions about, they communicate those questions to the notifier during the review, and they can provide supplemental information. However, it's not an independent review of the safety of the use of a particular substance.

MR. FELDMAN: Okay, and just one other thing on that point. As a part of the information that is submitted to FDA, does any of that information include data or other types of information on the manufacturing processes that are used to produce this?

DR. ANDERSON: Oh yes. Yes, it does. It includes information on the composition of the substance, on the manufacturing process, on any toxicological tests that have been done, any clinical tests that have been done, any scientific information that's available on the substance, and I think that pretty much sums it up.

MR. FELDMAN: Okay, thank you,

thank you. John, I have another question if there's time.

MR. FOSTER: Okay, yes. We'll go to Jean and then round back if we have time. Thank you, Jay. Jean.

MS. RICHARDSON: Yes, I have two questions. The first question relates to the use of rosemary as a potential antioxidant in infant formula. Do you know if rosemary extract -- some of the technical report information suggested that rosemary extract could be permitted as an antioxidant, and if it is used, does it have any other use that you're aware of?

DR. ANDERSON: The only use that I'm aware of for rosemary extract is as a flavoring agent. I'm not aware that it's ever been used in infant formula as an antioxidant. FDA has certainly never evaluated that use for safety.

Addition of a new antioxidant system in infant formula would require a pre-

market notification for the new infant formula, and in our review of that infant formula notification, we would want to be certain of the scientific basis of the safety for that use of rosemary extract, or any other new antioxidant system in infant formula.

Like I said, rosemary extract is generally recognized as safe for use as a flavor, in accordance with good manufacturing practice in FDA's regulations. Whenever we get an infant formula notification that might involve use of a new ingredient, we consult with the Office of Food Additive Safety, which is responsible for the review of GRAS notifications and has the expertise on evaluating food safety, ingredient safety questions.

We always encourage infant formula manufacturers to submit a food additive petition or a GRAS notice to the Office of Food Additive Safety, and to work with that office to resolve any safety issues about use

of ingredients new to infant formula, before they come to us with an infant formula notification.

Just one additional word here, is that the time line for review of a GRAS notice is 180 days. The time line for review of an infant formula notification is 90 days. So if an infant formula manufacturer comes to us with a GRAS notice for, I'm sorry, with an infant formula notification, for which they haven't resolved safety issues of a new ingredient, then that really creates problems getting a review or consulting with the Office of Food Additive Safety on an accelerated time line.

MS. RICHARDSON: Thank you. My second question relates to essentiality. As you know, we have to try to determine if anything that's going into the infant formula, is it essential for that formulation, for that product.

We know that these items that

we're looking at today are not required by the FDA at the present time, but as you heard from the presentations this morning, they are stated, many of them, as being essential for the formula to make a whole food for that infant.

So could you help us to understand why if they are indeed essential, why are they not on your -- on the FDA list?

DR. ANDERSON: The term "required" is a legal term that's used in our regulations and in the law, to indicate the 29 nutrients that are required in infant formula. The term "essential" is used by the nutrition community to recognize that substances are needed in the diet of humans.

The Institute of Medicine of the National Academy of Sciences is an authoritative body that provides information on the essential, on what are essential nutrients. Like I said earlier, it requires a formal rulemaking procedure, which is very

long and involved and complicated, to change a regulation.

For us to change or update the list of 29 required nutrients and their minimum values would require that formal rulemaking process. However, in another part of the infant formula regulations, there is allowance for addition of other substances in infant formulas.

For example, selenium has -- in the time between 1985 and now, selenium was recognized as an essential mineral. It has not been added to the list of 29, and primarily because of agency priorities and the cumbersomeness of rulemaking.

However, infant formula manufacturers do add selenium to their products, and they are -- the do so on the basis that the National Academy has found it to be essential in human nutrition. So I hope that answers your question.

We don't -- although we have a

list of 29 required nutrients, we don't have a list of mandatory ingredients or a restricted list of ingredients that can be added to infant formula.

MS. RICHARDSON: Are you aware then if the National Academy has said that any of these ingredients we're looking at today are essential?

DR. ANDERSON: No. The-- no.

MR. FOSTER: All right. Are there questions from others on the Board? I have one. I think -- I don't think it will be a long one; then we can get back to others. What, in this GRAS notification process, what happens if an operator were to, you know, give you this notification and you've got 180 days to respond to them.

What happens if they've provided some information to you that's incorrect or inconsistent with guidelines or standards ore requirements? What can happen them in the context of infant formula, where they've just

misreported something?

Like if they're trying to pull the wool over your eyes, what happens when you catch them doing that?

DR. ANDERSON: If there are safety issues involved, it would be regarded as an adulterated product, and there would be compliance issues with that, and so -- and there could be -- it would be a prohibited act to market that, and there are criminal penalties involved with that.

MR. FOSTER: And so what's the consequence to the supplier of that information, if you find something out that they were trying to hide, or if something was bad, something was wrong? So what compliance? What do you mean by compliance action?

What happens? Does that mean show up at their house or --

DR. ANDERSON: Well, a warning letter could be issued. Product could be seized, an injunction could be issued.

MR. FOSTER: That's what I was looking for. Thank you. Questions from others on the Board?

DR. BHATIA: It also appears on a FDA warning list.

MR. FOSTER: I'm sorry, what appears on a warning list?

DR. BHATIA: Not FDA, but when some of these infractions occur, FDA issues a warning that is public domain. So that actual list which is kept forever, saying so and so has manufactured X and Y. So there's an actual warning published to the public domain about any infraction which the FDA is against.

MR. FOSTER: The old version of shunning back in the day. Thank you for that. Questions from others on the Board for either of our guests? Then we'll go back to Jay for a last one.

MR. FELDMAN: Okay. So this is a question about the levels, the nutrient levels that would be allowed in these products. I

assume whether it's organic or not, the levels that would be used would be uniform across conventional and organic products.

But if FDA is not setting a level as required or essential, because somebody else does that, where do these levels, these nutrient levels that actually end up in the final product come from? Who makes the determination as to whether the levels are the right levels, or that they, somehow children are being over-exposed or there's a risk factor there that's not being considered fully?

DR. BHATIA: Well, it's interesting you ask that question, because right now the NIH has convened a body. NIH, FDA, USDA, AAP, all these different people, to ask that very question. What are the questions from 0 to 24 months which would include the period you're talking about, the infant formula would be the key question.

A lot of the requirements at not

known. These are best estimates made from epidemiology, are the classic nutrition principles of defining a requirement. So either you find a population that was sufficient, or you find a population that had excess, or you find a population that's deficient, and you guess that it is somewhere between the deficient and the excess.

Then a best guess is made. That's one way of looking at nutrients. So we really don't have evidence, informed guidelines for every nutrient that's already there, and that's where the struggle is now, to put together some body of evidence which says this is a human requirement. This has been a slippery slope.

DR. ANDERSON: And I can add to that as well. In the GRAS notification, in the GRAS notice process, one of the elements that's required, and I neglected to mention, is that there has to be an exposure estimate, of exposure of -- what the exposure will be,

and why that exposure will be safe, and there --

In each GRAS notification, there is an upper limit that is specified for the exposure, and that that exposure will be safe.

MR. FELDMAN: But again, that is not independently reviewed by FDA, as to whether in fact that level is either effective or potentially problematic?

DR. ANDERSON: Yes. FDA does not do its own independent review. However, all of those decisions or all of those no further questions are time-dependent, and if any information becomes available after that letter is issued, FDA would reconsider any updated information.

MR. FELDMAN: Thank you.

MR. FOSTER: Mac, I saw your hand.

MR. STONE: I have one question in reference to rancidity. We heard about the oxidation and rancidity of the oils. If you have -- who determines that shelf life, and if

in fact it is a food safety issue? Does the manufacturer determine the date that it should be removed from the shelf, or does anybody verify the preservative value or that length of shelf life?

DR. BHATIA: I can't get too technical on this, but I can tell you from my own what the shelf life means. The shelf life specifies that the nutrients on the label, the minimum amounts of nutrients on the label are still present at the end of shelf life.

The other issues of being rancid, coloring, all that, that's determined way before the formula is even submitted to the FDA for review. In fact, if you go to any of the manufacturing places, a lot of people from Abbott can confirm what I'm saying, the whole shelves, there are whole shelves of formula that are kept for time to see what happens to formula over time.

But that claim is only based on that the formula will have the minimal amounts

of nutrients specified in the label. So as a matter of fact, each manufacturer adds much more than the minimal level to assure minimum label is still there one year later.

This is especially true for vitamins, which are photo-sensitive and decay over time.

MR. FOSTER: All right. I had Nick there, but it seems he's out for a sec. I'll ask for others. Jean, did you get what you need? Okay. All right. I'm assuming Dr. Anderson had to leave; clearly she did.

But I'm assuming she had to leave the premises actually, to catch her next appointment. So with that, if there's no more questions, we'll move into a 15 minute break for the Handling Subcommittee, to get our heads together, see what changes, if any, we need to make and then reconvene at -- let's make it 2:25 as a full board. Thanks.

Oh, I'm sorry. Thank you Dr. Bhatia. Thank you for being here. Thank you

for your -- we found, actually we talked about this at lunch. This was very valuable to have you here, and we'll be recommending to the program that we have more regular interactions like this during our Board meetings.

So I thank you for that, for setting an excellent precedent. It was very, very helpful to have you here. So thank you very, very much.

DR. BHATIA: Thank you for the kind comments, and appreciate the invitation.

MR. FOSTER: Thank you.

(Whereupon, the above-entitled matter went off the record at 2:10 p.m. and resumed at 2:36 p.m.)

MR. FOSTER: Barry, I'm handing the virtual gavel back to you.

CHAIRMAN FLAMM: Thank you, John, and I believe we're ready to proceed. The Handling Committee is ready to vote on all of its proposed -- shh, shh, shh. Can't hear myself think.

The Handling Committee is ready to proceed on all their petition materials, except for nucleotides, which is being postponed until tomorrow. I think the voting will proceed in the same order that it was presented this morning, and so I'll entertain a motion on the first material, and that is --

MR. FOSTER: The first item is ascorbyl palmitate. Nick, I believe you have the goods on that.

MR. MARAVELL: Where am I?

MR. FOSTER: Ascorbyl palmitate.

MR. MARAVELL: Are we entertaining motions?

MR. FOSTER: We are accepting motions about the petition to add ascorbyl palmitate to the National List.

CHAIRMAN FLAMM: But we need the motion.

MR. MARAVELL: The first motion would be a listing, a classification motion?

CHAIRMAN FLAMM: That is correct.

MR. MARAVELL: Okay. So I am willing, I am going to make a motion that ascorbyl palmitate is synthetic.

CHAIRMAN FLAMM: Do we have a second?

MS. FULWIDER: I second that.

CHAIRMAN FLAMM: We have a motion that's been seconded to classify ascorbyl palmitate, CAS No. 137-66-6 as synthetic. Discussion?

(No response.)

CHAIRMAN FLAMM: Hearing none, I'll proceed with the vote. The vote will begin with Jean.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

MR. BONDERA: Yes.

MS. TAYLOR: Yes.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

MS. SONNABEND: Yes.

MR. STONE: Yes sir.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: Yes.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

CHAIRMAN FLAMM: And the chair votes yes. We have 15 yes, 0 no's. The motion to classify the material as synthetic passes. I'm going to entertain a motion to list.

(Off record comments.)

CHAIRMAN FLAMM: So we can entertain a motion on listing the material.

MR. MARAVELL: I'd like to make a very brief clarification and then go forward with the motion. In the materials prepared by the Subcommittee on Ascorbyl Palmitate, we did reference the fact that rosemary extract was something that this Board had approved with regard to DHA and ARA, which was for use in infant formula.

In a private conversation with Dr. Anderson, I asked how that came about, given that FDA has never reviewed rosemary extract, and she had a very straightforward and simple answer. What we approved was not what Martech had submitted to FDA for their GRAS listing.

And so indeed, our statement is correct, but it would lead one to believe that perhaps rosemary extract had also been in some way reviewed or submitted to FDA, and that is not the case. On behalf of the Committee, I apologize if we misled anybody, even though our statement is technically correct.

Now I'll proceed with a motion. I make a motion to add ascorbyl palmitate, CAS No. 137-66-6 to the National List, Section 205.605(b) for use as a preservative in infant formula.

MS. RICHARDSON: I second that motion.

CHAIRMAN FLAMM: Who seconded it?

MS. FULWIDER: Jean.

CHAIRMAN FLAMM: Jean seconded the motion. We have a motion, which has been seconded, to add ascorbyl palmitate, CAS No. 137-66-6 to the National List, Section 205.605(b) for use as a preservative in infant formula. Discussion? Zea.

MS. SONNABEND: Thank you. For the purposes of everyone in the audience, and so that everyone is clear on this point, I would like to ask the NOP to state what would happen if something that has previously been allowed in infant formula comes off the list, because we don't vote for it at this time. Could you just say what people can expect from that?

MS. BAILEY: Thanks, Zea. So as people are well aware, the Department published a proposed rule in January of this year, with a proposal to amend the listing for nutrient vitamins and minerals on the National List, and we proposed what new language would be.

That new language would not provide for the use of the nutrients that are petitioned before you today. So in September, we published an interim rule to continue the listing as it is currently codified in the regulations, which essentially maintains the status quo.

We are taking comments on that interim rule for 90 days until December 26th. In the proposed rule, we explicitly asked for input from commenters on the proposed length of the compliance period, which would have been two years after the issuance of any final rule on the matter.

So at this point, the interim rule maintains the status quo. We have not issued a final rule, based on the comments that say what the intention of the agency is as far as a compliance period. But we did ask for those comments and would address any comments about compliance in any final rule that we would do.

CHAIRMAN FLAMM: Follow-up?

MS. SONNABEND: Well, I have one additional clarification. For these particular first two items that are able to be used as vitamins in the proposed rule that already is out, the vitamin, ascorbyl palmitate is a source of Vitamin C and beta carotene is a source of Vitamin A.

If we are not voting for them here, that means they can still be used as the source of Vitamin A or Vitamin C, because what we are doing is voting them off for the petition use as a preservative.

MR. FELDMAN: And can you verify that -- I'm sorry.

CHAIRMAN FLAMM: Jay.

MR. FELDMAN: Could you verify the citation under where that fits? Is that just under the general Vitamins and Minerals? Okay. Okay.

CHAIRMAN FLAMM: Nick.

MR. MARAVELL: Yes. Just to amplify one point on what Zea said, the

ascorbyl palmitate, which is the motion that we're considering right now, was petitioned as an antioxidant, which functions as a preservative, and Dr. Anderson clarified from her point of view that antioxidants were a subcategory of preservatives. But the actual petition was as an antioxidant.

CHAIRMAN FLAMM: Any further discussion of the material? There's no further discussion, I believe we can proceed with voting, beginning with Calvin.

MR. WALKER: No.

MR. BONDERA: No.

MS. TAYLOR: No.

MR. MARAVELL: No.

MR. FELDMAN: No.

MS. SONNABEND: No.

MR. STONE: No sir.

CHAIRMAN FLAMM: Wendy?

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: No.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: No.

MS. RICHARDSON: No.

CHAIRMAN FLAMM: And chair votes no. How many yes's do we have? Four. 4 yeses, 11 no's. The petition does not pass. The motion does not pass. We can proceed for the next material. John, you're just going to make a motion for --

MR. FOSTER: We'll hear a motion regarding beta carotene from Tracy.

MS. FAVRE: I make a motion to classify beta carotene as petitioned as synthetic.

MR. BONDERA: I'll second that.

CHAIRMAN FLAMM: We have a motion and it's been seconded, to classify beta carotene as synthetic. Discussion? Tracy.

MS. FAVRE: I would just like to reiterate that the same conditions exist for beta carotene, synthetic beta carotene as

petitioned. It is approved for pro Vitamin A use, and it has been -- should we vote this down, it would still be allowed for vitamin use.

CHAIRMAN FLAMM: Any other comments?

MR. FELDMAN: I'm just -- sorry guys. I'm a little confused on this, because my understanding is that these are not -- if I heard correctly today, neither the Vitamin A or the Vitamin C in these forms are allowed in infant formula. That's what I heard today.

So we would not want to give the organic community the impression that we were allowing something in the form of a vitamin through this listing or any other listing that wasn't approved by FDA. So that's just a clarification. I'm probably misinterpreting.

CHAIRMAN FLAMM: I think Tracy had her hand up first.

MS. FAVRE: Jay, it's my understanding that it is allowed, but it is

not typically chosen for use. Vitamin A isolate was used -- Dr. Anderson remarked that Vitamin A isolate was typically used for Vitamin A in infant formula, rather than beta carotene.

CHAIRMAN FLAMM: Nick.

MR. MARAVELL: By way of clarification, Jay, that, I would not agree with your statement. What we heard and what was contained in the TR is that ascorbyl palmitate is a source of Vitamin C and is approved as such by FDA for infant formula.

However, if you look at practice in the industry, the TR states and Dr. Anderson stated that you would use ascorbic acid, because it -- ascorbyl palmitate, when it enters the body, in order to be Vitamin C, it has to hydrolyze and become, part of it, ascorbic acid.

So why not just put the ascorbic acid in, if you're looking for the Vitamin C action. However, it is permitted to be used

as a source of Vitamin C.

MR. FELDMAN: Thanks for that clarification.

CHAIRMAN FLAMM: Further discussion?

(No response.)

CHAIRMAN FLAMM: If not, we can proceed with the voting on the motion to list the material. Beginning with Colehour. Colehour.

MR. BONDERA: I apologize this is a classification motion, not a listing motion; correct?

CHAIRMAN FLAMM: Yes, sorry.

MR. BONDERA: I vote yes.

MS. TAYLOR: Yes.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

MS. SONNABEND: Yes.

MR. STONE: Yes sir.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: Yes.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

CHAIRMAN FLAMM: And the chair votes yes. 15 yeses, 0 no's. The motion to classify beta carotene is a synthetic passes. Do we have a motion to list beta carotene?

MS. FAVRE: Yes. I'd like to make a motion to add beta carotene as petitioned to 205.605(b) for use in infant formula.

CHAIRMAN FLAMM: Do we have a second?

MR. FOSTER: Second.

CHAIRMAN FLAMM: It's been moved and seconded to add beta carotene as petitioned to 205.605(b) for use in infant formula. Discussion.

(No response.)

CHAIRMAN FLAMM: I guess we

already had so much discussion on this, under the synthetic part that I almost forgot. I believe then we can proceed with the voting, beginning with Jennifer.

MS. TAYLOR: No.

MR. MARAVELL: No.

MR. FELDMAN: No.

MS. SONNABEND: No.

MR. STONE: No sir.

MS. FULWIDER: No.

MR. AUSTIN: No.

MS. FAVRE: No.

MS. BECK: No.

MR. FOSTER: Yes.

MR. DICKSON: No.

MS. RICHARDSON: No.

MR. WALKER: No.

MR. BONDERA: No.

CHAIRMAN FLAMM: And the chair votes no. 1 yes and 14 no's. The motion to list beta carotene fails. So what's next, John?

MR. FOSTER: We will be having a vote on adding lutein to the National List. Harold.

MR. AUSTIN: Okay. I would like to make a slight clarification before we make the motion. After listening to the manufacturers' information and presentation, we went back, the Handling Committee went back, took another look at the TR, because we were on the fringe of deciding whether or not to list this as a synthetic, or to reverse our previous decision.

But based off of the information and based off of her presentation, the registrant's presentation, and then going back and revisiting the information, and looking at the process actually is through saponification, estrification and de-estrification, actually as it's determined by our process, does classify that as a chemical change.

So our motion will be to list

lutein as a synthetic.

CHAIRMAN FLAMM: Could you restate the motion, Harold?

MR. AUSTIN: The motion would be to list lutein, CAS No. 127-40-2, as petitioned, as a synthetic.

CHAIRMAN FLAMM: Do we have a second?

MS. FULWIDER: I second that motion.

CHAIRMAN FLAMM: We have a motion, which has been seconded, to classify lutein as CAS No. 127-40-2, as petitioned, as a synthetic. Discussion.

(No response.)

CHAIRMAN FLAMM: Would you want to restate what you said previously before the motion was made, Harold, or does anybody feel it necessary to -- are they clear on it? I guess everybody's clear. I guess we can proceed with the vote then. There's no desire for further discussion, so begin with Nick.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

MS. SONNABEND: Yes.

MR. STONE: Yes sir.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: Yes.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

MR. BONDERA: Yes.

MS. TAYLOR: Yes.

CHAIRMAN FLAMM: And the chair votes yes. 15 yes, 0 no. Entertain a listing motion on the material.

MR. AUSTIN: Okay. The Handling Subcommittee would move to add lutein, CAS No. 127-40-2, to the National List, 205.605(b), for use in infant formula only, lutein using approved organic delivery ingredients.

CHAIRMAN FLAMM: Do we have a second?

MS. RICHARDSON: I second the motion.

CHAIRMAN FLAMM: Jean seconds the motion, to add lutein, CAS 127-40-2 to the National List of 205.605(b) for use in infant formula only, lutein using approved organic delivery ingredients. Discussion. Jay.

MR. FELDMAN: This is a broader discussion. Obviously, you know, we don't want to spend a lot of time on this. But I think I'd start with the premise that organic is held to a higher standard in the marketplace, that the expectation is higher, for better or worse.

That's the burden and the challenge that we have, I think, as a community, and this area of accessory nutrients in infant formula is really troubling to me, especially because of the way Dr. Bhatia answered the last question that I

asked.

And that is the recognition or the understanding that a lot of what we're discussing here is really outside the scope of FDA. I mean FDA is in a situation where they're operating under an old statute. They haven't updated their requirements.

Our law talks about requirements, for the most part, and we are then being asked to add materials for which the academic and scientific community have not yet agreed on even what the appropriate levels are of these things including lutein.

So I think it's unnecessary to put the organic label in the middle of all of this for soy product at this time, and I view this as protecting the label, so that we can grow acreage, by the way.

So I see this as our opportunity to say we are about protecting the label and growing acreage. So I think we have to keep that in mind when we vote on these materials

cross the board, at this stage, given where we are, and given the lack of scientific cohesion on the value of these things, and the long-term impacts, etcetera. Thank you.

CHAIRMAN FLAMM: Further discussion? Zea.

MS. SONNABEND: Thank you, Barry. This one, I would have to say, is the toughest one for me to make a decision on. You know, what we've heard today is how valuable it is to developing infants. But when we look at the extraction process and the manufacturing process, which has finally been disclosed to us, we find that this truly is a plant derivative. It's made from marigolds.

The great irony of our little corner of the world here is that the reactions that cause it to come out of the marigolds and become lutein would cause it in our definition of thinking to be synthetic.

But if the marigolds were grown organically and treated with other compounds

on the National List, it could be certified organic product. So oddly enough, I'm going to go along with Jay here, and wait for the organic marigolds to get grown, and expand the acreage and vote against it.

(Laughter.)

CHAIRMAN FLAMM: Well, when we get done laughing, I'll call on John.

MR. FOSTER: On that note, I believe I did just see a pig fly right by that window.

(Laughter.)

MR. FOSTER: Right as Zea was saying that.

CHAIRMAN FLAMM: Organic pig?

MR. FOSTER: Absolutely, of course.

CHAIRMAN FLAMM: Is that your comment, John?

MR. FOSTER: That's it. That's the best I've got right now.

(Laughter.)

CHAIRMAN FLAMM: Any other discussion? It doesn't appear we have any more comments. We'll proceed with voting on the motion, beginning with Jay.

MR. FELDMAN: No.

MS. SONNABEND: No.

MR. STONE: No sir.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: No.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: No.

MR. BONDERA: No.

MS. TAYLOR: No.

MR. MARAVELL: No.

CHAIRMAN FLAMM: And the chair votes no. I'll have to wait for a tally here. The vote is 6 yes, 9 no's. The motion to list fails. We have next material, John.

MR. FOSTER: Yes, we do.

CHAIRMAN FLAMM: What is it, lycopene.

MR. FOSTER: We do. The next material we'll be voting on is lycopene. Nick, would you go forward?

MR. MARAVELL: I make a motion. I move that crystalline lycopene be classified as a synthetic material.

MR. BONDERA: I'll second that.

CHAIRMAN FLAMM: It's been moved and seconded that lycopene be classified as a synthetic material. Discussion.

(No response.)

CHAIRMAN FLAMM: Doesn't look like there's need for any further discussion, so we can begin with voting. Zea, you may start the voting.

MS. SONNABEND: Yes.

MR. STONE: Yes sir.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: Yes.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

MR. BONDERA: Yes.

MS. TAYLOR: Yes.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

CHAIRMAN FLAMM: And the chair votes yes. We have 15 yes and 0 no. So the motion to classify as synthetic passes. Do we have a motion for the lycopene to be listed?

MR. MARAVELL: Yes. I move that crystalline lycopene, CAS No. 502-65-8, for use in infant formula be added to the National List, Section 205.605(b).

CHAIRMAN FLAMM: Do we have a second?

MR. AUSTIN: Second that.

CHAIRMAN FLAMM: Harold seconds.

The motion that crystalline lycopene, CAS No. 502-65-8 for use in infant formula be added to the National List, Section 205.605(b). Discussion on the motion?

(No response.)

CHAIRMAN FLAMM: No discussion on the motion? We can proceed with the voting, then, beginning with Mac.

MR. STONE: No sir.

MS. FULWIDER: No.

MR. AUSTIN: No.

MS. FAVRE: No.

MS. BECK: No.

MR. FOSTER: No.

MR. DICKSON: No.

MS. RICHARDSON: No.

MR. WALKER: No.

MR. BONDERA: No.

MS. TAYLOR: No.

MR. MARAVELL: No.

MR. FELDMAN: No.

MS. SONNABEND: No.

CHAIRMAN FLAMM: And the chair votes no. Do we have any yeses? 0 yes, 15 no. The motion fails. Let's see, carnitine. Next John on the list is, I believe is --

MR. MARAVELL: Carnitine.

CHAIRMAN FLAMM: Carnitine.

MR. MARAVELL: Indeed. Zea, would you go forward with the motion?

MS. SONNABEND: I'll make the motion that L-carnitine, CAS No. 541-15-1, as petitioned, is synthetic.

CHAIRMAN FLAMM: Is it --

MS. FAVRE: I second the motion.

CHAIRMAN FLAMM: It's been moved and seconded to classify L-carnitine, CAS No. 541-15-1 as petitioned, as synthetic. Discussion?

(No response.)

CHAIRMAN FLAMM: I don't believe there's any desire for further discussions, so we can proceed with the vote, beginning with Wendy.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: Yes.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

MR. BONDERA: Yes.

MS. TAYLOR: Yes.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

MS. SONNABEND: Yes.

MR. STONE: Yes sir.

CHAIRMAN FLAMM: And the chair votes yes. So 15 yes, 0 no. We can proceed with the motion to list the material. Who wants it?

MS. SONNABEND: The motion is to add L-carnitine, CAS No. 541-15-1 to the National List, 205.605(b), for use in infant formula only.

CHAIRMAN FLAMM: Do we have a second?

MR. BONDERA: Second that motion.

CHAIRMAN FLAMM: It's been moved and seconded to add L-carnitine, CAS No. 541-15-1 to the National List, 205.605(b), for use in infant formula only. Discussion please?

(No response.)

CHAIRMAN FLAMM: No discussion. No need for further discussion, so we can begin with the vote, beginning with Harold.

MR. AUSTIN: Yes.

MS. FAVRE: No.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: No.

MR. BONDERA: No.

MS. TAYLOR: No.

MR. MARAVELL: No.

MR. FELDMAN: No.

MS. SONNABEND: No.

MR. STONE: No sir.

CHAIRMAN FLAMM: And the chair votes no. I'm sorry, I did that again.

MS. FULWIDER: Okay, yes.

CHAIRMAN FLAMM: And the chair votes no. Let's see, 6 yeses and 9 no's. 6 yeses, 9 no's. The motion to list fails. Next material is --

MR. FOSTER: L-methionine.

CHAIRMAN FLAMM: L-methionine, I believe.

MR. FOSTER: We have a motion for you. Tracy, would you be so kind?

MS. FULWIDER: Make a motion to list L-methionine on 205.605(b) as synthetic, non-agricultural.

CHAIRMAN FLAMM: Do we have a second?

MR. FOSTER: I'll second.

CHAIRMAN FLAMM: We have a motion that's been seconded, to list L-methionine as

synthetic. Is there discussion? Question or --

MS. BRINES: Just a clarification from the program. It seemed like it was a combined classification and listing, from the wording of the motion. I just want to be clear. The classification motion is first. Thanks.

CHAIRMAN FLAMM: All right. We're just doing the --

MR. MARAVELL: I would agree.

CHAIRMAN FLAMM: Restate it.

MS. FAVRE: If I'd just strike the words "non-agricultural," is that sufficient? Is that what the complaint, the comment is?

MR. MARAVELL: No, I think the word "list."

MS. FAVRE: Oh, I'm sorry, yes. Make a --

MR. MARAVELL: Motion to classify.

MS. FAVRE: Yes, got it.

CHAIRMAN FLAMM: Oh, I get it.

MR. MARAVELL: I think we just used the wrong word.

MS. FAVRE: Got it, got it, sorry. I make a motion to classify L-methionine as synthetic. Thank you.

CHAIRMAN FLAMM: Thank you. I didn't notice it either.

MR. AUSTIN: I'll second that one.

CHAIRMAN FLAMM: I think I said it right, but I didn't read it right. Okay. Where are we now?

So I'll restate the motion for, to make sure it's clear, that the motion is to classify, I mean yes, to classify L-methionine on 205.605(b) as synthetic, non-agricultural. We don't need the non --

MS. FAVRE: The motion is to list L-methionine as synthetic, period.

CHAIRMAN FLAMM: As synthetic, period, okay.

MS. BRINES: Did you guys say "list" again?

(Laughter.)

MS. FAVRE: I make a motion that I need a cup of coffee before I make any more motions.

MR. AUSTIN: I'll second that.

CHAIRMAN FLAMM: And I need a new pair of glasses.

MR. MARAVELL: I want one of Zea's apples.

MS. FAVRE: I make a motion that L-methionine is synthetic.

CHAIRMAN FLAMM: To classify it.

MS. FAVRE: The classify it as synthetic. I'm scared to death to say anything else.

CHAIRMAN FLAMM: Okay. Is there a second?

MR. FOSTER: Yes, second.

CHAIRMAN FLAMM: Okay. It's been moved and seconded to classify L-methionine on 205.605(b) as synthetic. Discussion, Zea.

MS. SONNABEND: I'd like to

suggest that L-methionine as petitioned, there are non-synthetic forms of L-methionine. So L-methionine as petitioned is synthetic.

MS. FAVRE: I would accept that friendly amendment.

MR. BONDERA: Excuse me, Mr. Chair.

CHAIRMAN FLAMM: All right.

MR. BONDERA: I suggest that you have the motions that are on the table withdrawn before they're added to at this point in time.

CHAIRMAN FLAMM: I think that would be --

MR. BONDERA: Because we have a number of motions on the table at this moment.

CHAIRMAN FLAMM: I think that probably would be wise, just to clear the slate. Could you do that, Tracy, and then we'll start all over again. I'm sorry for the confusion. Withdraw your motion.

MS. FAVRE: I withdraw my multiple

goofy motions.

CHAIRMAN FLAMM: We're getting tired, I think. Okay. Would you like to -- will you agree to it being removed and we'll start over?

MR. FOSTER: I withdraw all my seconds, except the one for her and coffee. But yes I do, all of them. They're all gone.

CHAIRMAN FLAMM: Okay. Let's start over, Tracy.

MS. FAVRE: I make a motion to classify L-methionine as petitioned as synthetic.

CHAIRMAN FLAMM: And okay. Got it? Is that good, Zea? Okay. Do we have a second?

MR. FOSTER: I will second that.

CHAIRMAN FLAMM: And John is seconding, and I'll re-read it again for the record. Okay. The motion is to classify L-methionine on 205.605(b) as petitioned, as synthetic, and this has been seconded. Do we

have any discussion? Sorry for the mix-ups.

(No response.)

CHAIRMAN FLAMM: No discussion now? Got it all cleared. So we can begin the voting with you, Tracy.

MS. FAVRE: Yes.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

MR. BONDERA: Yes.

MS. TAYLOR: Yes.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

MS. SONNABEND: Yes.

MR. STONE: Yes sir.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

CHAIRMAN FLAMM: And the chair votes yes. So it's 15 yes, 0 no's, to classify L-methionine as synthetic, as

petitioned as synthetic. We can now proceed with the motion to list.

MR. FOSTER: The next one up is going to be in the same order we did it before, will be -- sorry, listing motion. Back to Tracy.

MS. FAVRE: I make a motion to list L-methionine for inclusion on 205.605(b), for use in infant formula made with soy-based protein. Excuse me. L-methionine, as petitioned, for inclusion in 205.605(b) for use in infant formula made with soy-based protein.

MS. FULWIDER: I second that motion.

CHAIRMAN FLAMM: Who seconded? Okay. We have a motion that's been seconded, to list L-methionine, as petitioned, for inclusion on 205.605(b), for use only in infant formula made with isolated soy-based protein.

MR. FELDMAN: We took isolated

out.

CHAIRMAN FLAMM: Oh that's, sorry. Just soy-based protein? Yes, okay. Correction. I'll re-read it. Motion to list L-methionine, as petitioned, for inclusion on 205.605(b), for use only in infant formula made with soy-based protein. Is that right? Okay. That's a motion. Discussion on this motion? No discussion? Zea.

MS. SONNABEND: Thank you. Because this is the one of the group that is truly mandated by the FDA for soy formula, much as I hate to do anything to encourage anyone to use soy formula, I feel like I have to vote for this, because if anyone did use soy formula, I wouldn't want the babies to get an incomplete protein.

This one, unlike L-carnitine, cannot be made once they have -- in the digestive system, once they have enough of something else.

CHAIRMAN FLAMM: Colehour, please.

I'm sorry, were you finished?

MR. BONDERA: Yes, you can go ahead, Jay.

CHAIRMAN FLAMM: Colehour?

MR. BONDERA: Yes, thank you. Just in terms of clear understanding, like you just stated Zea, since FDA requires, since it's not a choice; therefore, the conclusory part of your clause isn't accurate, because there never would be a soy formula sold without it. It just wouldn't be organic.

It's not that someone's going to be able to buy one, because it's required. So there couldn't be one without it. So therefore, it's not as if any customers are ever going to purchase one that doesn't have, because it's never going to exist that way.

It's just not going to be organic. That's the differentiation. Just the way that it came across to me, the way you said it is that --

MS. SONNABEND: Conventional, soy-

based formula has to have L-methionine too. You could not buy any without it.

MR. BONDERA: Right. That is what you said, and the way you said it is that you didn't want people to be buying it without. Well, they're not going to ever be able to, which is the first part of what you said.

MS. SONNABEND: I think you misunderstood it. I don't want people to ever buy soy formula.

MR. BONDERA: I understand that too. You said that. That's true. That was the very first part of what you said. But in any case, thank you.

CHAIRMAN FLAMM: Jay.

MR. FELDMAN: Thank you. So this is a little complicated for me, and I wish we had more time to sort through this. First of all, as far as I can tell from reading the literature, when we're talking about soy-based formula, we're talking about isolated soy-

based formula. If someone can help me with that, and tell me that's really not the case, I'd appreciate it.

But unless we can distinguish here what we're talking about, I think we do a disservice, again, to the organic community, which is held to a higher standard in the marketplace than the conventional side.

So I recognize that -- I take this deletion of the word that was in the original listing motion that came out of the Subcommittee as an indication that there's some awareness that there might be a problem with isolated soy-based protein, both in the way it's extracted and because of its reliance on the addition of other synthetic materials, to deliver product that is considered adequate for the infant.

Whatever the reason is, I think we should share that with the full Board, why the term was removed from the original listing motion, and I would like to get some technical

support, if the chair thinks that's appropriate, on some of the underlying issues associated with the extraction of isolate soy protein and what that means to an organic product, whether in fact we, as a Board, feel that that base product meets the standard that we are charged with enforcing under the law.

So again, sort of a request for assistance here.

CHAIRMAN FLAMM: Let me take Tracy's question. I'll get back to you, Jay. Tracy?

MS. FAVRE: Actually, it's not a question. Jay, I just wanted to let you know that the motivation behind that was that we had received some information that there are some formulas used for later stage infants that are not isolated soy. They're just concentrated soy protein.

Therefore, we didn't want to exclude that from the possibility. Rather, we had specific concerns about the isolated soy

protein.

CHAIRMAN FLAMM: And Jay, were you making a request in that statement you made?

MR. FELDMAN: Yes. Well, you know, I don't want to hold the Board back. But I do believe that if we're talking about concentrated soy protein and isolated soy protein in this motion, we need to understand, you know, the differences.

Are they made differently? Are they produced with different extractants? Are there issues around our criteria as it relates to health and safety and so forth. So I don't know if we could get a quick rundown on that from one of our esteemed experts in the audience, or if anybody else feels they need that kind of information to vote on this.

You know, at this point, I'd just think, share my thought process with you all. I think that if -- I understand that without methionine, this product couldn't be marketed as organic. That's essentially what -- I was

asking the chair, I'm sorry, of the Board. No, no. I was asking the chair, if the chair felt it was appropriate.

So do you use what I'm saying? So if that were the case, without that kind of information, I feel that it would be appropriate to not allow, recognizing that it would impact on the market availability of this with the organic label.

I understand that it's having that effect, but I think we have a duty to first ensure that the product to which we're adding this to meets the standards of the statute.

CHAIRMAN FLAMM: Jay, I do think we had experts here this morning that were, that we more or less cleared, could present us with impartial answers to questions, and I don't know. Bringing others, I don't know if you could get the answer in the time we have, since we had that opportunity for several hours this morning.

So I'm reluctant to -- I think

unless -- I'll entertain other thoughts, but I don't know we can get what we're asking for. Zea, do you have a comment?

MS. SONNABEND: Yes. Jay is asking for someone with organic expertise. Our people this morning had a lot of additive expertise, but couldn't explain necessarily how an organic soy formula would be made, whereas either the formulators in the audience or OMRI would perhaps tell how the soy is extracted, or someone like that, to explain how soy could be extracted for organic soybeans, which may be different than conventional soybeans.

CHAIRMAN FLAMM: So is there a person that could briefly give that, that's here?

MS. SONNABEND: I would recommend Lindsay, if she's in the audience, or Gwendolyn also could do that.

CHAIRMAN FLAMM: Lindsay, would you be willing to come forward and -- that's

short notice, I know, and that's -- we'll just --

MS. FERNANDEZ-SALVADOR: The other politics that are going on around here. Get out and vote, folks.

Okay. So soy protein isolate is -- it is a process extract of soy protein, and from what I understand and the form that OMRI reviewed many, many years ago, the form that we reviewed was being used in a fertilizer, and this conventional soy isolate was extracted using hexane, and then further processed to isolate the protein further and separate it from the carbs and the fats and the fiber, through an acid-based precipitation.

However, under organic production, and I'm not privy to confidential business information, so I don't know the exact formula by which you would get an organic soy isolate, but it would likely be either through a water or a certified organic ethanol extraction,

with a citric acid and sodium hydroxide acid.

But it would likely be either through a water or a certified organic ethanol extraction, with a citric acid and sodium hydroxide acid-based precipitation.

CHAIRMAN FLAMM: Does that answer your question?

MS. FERNANDEZ-SALVADOR: He says I'm on the right track. Without knowing the exact soy isolate, it's hard to say.

MR. FELDMAN: Thank you.

(Off record comments.)

MS. FERNANDEZ-SALVADOR: I don't work for a certifier. I have never seen an organic certified soy isolate manufacturing process.

CHAIRMAN FLAMM: Please. Thank you very much, Lindsay. I appreciate you doing this for us.

MR. FELDMAN: I have a follow-up question for the Board, or the Committee, Subcommittee.

CHAIRMAN FLAMM: Okay. Any other --

MR. FELDMAN: So --

CHAIRMAN FLAMM: Thank you Lindsay.

MR. FELDMAN: Okay. So that then raises for me the question as to whether we need to annotate the extraction process. If there is an organic way of doing this or one that is viewed as acceptable under organic standards, I know we don't have an extraction policy yet.

But there have been a number of votes that have debated the methodology by which we extract, and hopefully will be incorporated into a larger policy at some point.

But lacking that policy, it is my preference to try to exclude the volatile synthetics, and it sounds like what Lindsay described did just that. Okay. I take that back, yes. Okay. So we're still dealing with

volatile synthetics when we're talking about extraction. Is that the case? Okay.

CHAIRMAN FLAMM: Okay. You can --

MR. FELDMAN: Any other comment, discussion? Yes, okay. Lindsay, you can --

MS. FERNANDEZ-SALVADOR: Yes, sorry. I just wanted to clarify one thing, because Jay said something and it wasn't what I said. Lindsay Fernandez-Salvador for OMRI. It's not with the volatile synthetics; it's with certified organic ethanol would be one way of doing it.

That's not synthetic. It's volatile, but it's not synthetic. So that's the difference there.

MR. FELDMAN: Thank you.

CHAIRMAN FLAMM: Thank you for the clarification. Okay. Any other? Jay.

MR. FELDMAN: My question for the record is whether in voting this motion, that are we allowing a broad range of processes in its production of the soy isolate, or are we,

because of other limitations, narrowing that extraction process to the one Lindsay described, to the non-synthetic ethanol process?

I just want to be -- I just want to clarify that we are indeed, through this listing, narrowing that extraction process.

CHAIRMAN FLAMM: Does anybody on the Subcommittee wish to tackle that question? Zea.

MS. SONNABEND: The extraction process is being limited to things which are organically produced or on the National List. So organic, non-synthetic ethanol or sodium hydroxide, which is on the National List or, if you figured out how to make it with pectin, it would be allowed, because it's on the National List.

Anything, you know, that's the rule. That's the basic thing in the rule, and that is limiting what types of agricultural, organic products can be treated with.

MR. FELDMAN: Thank you for that clarification.

CHAIRMAN FLAMM: Thank you. At one point, I saw somebody. Lisa, did you have a question or clarification you wanted to make?

MS. BRINES: No. Zea provided the clarification we were looking for. Thank you.

CHAIRMAN FLAMM: I'm sorry. Oh, okay. Thank you. All right. Any other discussion, questions on that? Okay. I believe we can proceed with the vote. Yes, and we're on the motion, aren't we? It's been so long.

Okay. We can proceed with the vote on the listing motion, beginning with Carmela.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

MR. BONDERA: No.

MS. TAYLOR: No.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

MS. SONNABEND: Yes.

MR. STONE: Yes, sir.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: Yes.

CHAIRMAN FLAMM: And the chair votes yes. What's the count? 13 yes, 2 no's. The motion to list passes, and we're due for a break, but I suggest we just continue and finish these materials. Is that all right, John, with you?

MR. FOSTER: It's okay with me.

CHAIRMAN FLAMM: Okay. I believe the next proposal is taurine.

MR. FOSTER: It is indeed taurine, and Jean, would you, do you have a motion?

MS. RICHARDSON: Yes. I make the motion to, the classification motion for

taurine, CAS 107-35-7, as petitioned, is synthetic.

MR. BONDERA: I'll second that motion.

CHAIRMAN FLAMM: Okay. We have a motion which has been seconded, to -- let's see. We've got a motion on taurine, CAS No. 107-35-7, as petitioned, to classify it as synthetic. I can't quite read that. Right. Discussion?

(No response.)

CHAIRMAN FLAMM: Doesn't appear to be any discussion, so we're going to vote on the motion to classify taurine as synthetic. I believe we're beginning with John.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

MR. BONDERA: Yes.

MS. TAYLOR: Yes.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

MS. SONNABEND: Yes.

MR. STONE: Yes, sir.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: Yes.

MS. BECK: Yes.

CHAIRMAN FLAMM: And the chair votes yes. I believe we have 15 yes, 0 no. You know, to classify taurine as synthetic. We can proceed with a motion to list taurine.

MS. RICHARDSON: I make a motion, a listing motion, to add taurine, CAS 107-35-7, to the National List 205.605(b) for use in infant formula only.

CHAIRMAN FLAMM: We have a motion, which has been seconded, to add to taurine, CAS No. 107-35-7 to the National List, 205.605(b) for use in infant formula only. Can we have discuss on this motion?

MS. FAVRE: I second the motion.

CHAIRMAN FLAMM: You second the

motion. Thank you, Tracy. It was seconded. Discussion on the motion?

(No response.)

CHAIRMAN FLAMM: No discussion on the motion. We can proceed, then, with a vote on the motion, beginning with Joe.

MR. DICKSON: Yes.

MS. RICHARDSON: No.

MR. WALKER: No.

MR. BONDERA: No.

MS. TAYLOR: No.

MR. MARAVELL: No.

MR. FELDMAN: No.

MS. SONNABEND: No.

MR. STONE: No, sir.

MS. FULWIDER: No.

MR. AUSTIN: No.

MS. FAVRE: No.

MS. BECK: No.

MR. FOSTER: No.

MR. DICKSON: No.

MS. RICHARDSON: No.

CHAIRMAN FLAMM: And the chair votes no. We have but 1 yes, 14 no's. The motion to list taurine fails. I believe that completes what you were prepared to vote on today, and so we can take a break and be back here in 15 minutes.

(Whereupon, the above-entitled matter went off the record at 3:41 p.m., and resumed at 3:56 p.m.)

CHAIRMAN FLAMM: Board members, please return to your seats. We're running behind. The next and last session for today is for the Policy Development Subcommittee to present their proposals, and I will turn the gavel symbolically over to Colehour to proceed.

MR. BONDERA: Thank you. Thank you, Mr. Chair. Sorry my microphone is being funny. Very good. If Michelle, you could put up -- no, sorry. It's a little confusing. We have a couple of different PowerPoints in our hands over there.

So I'm going to just go through briefly the Policy Development Subcommittee generally and our topics, and then we'll be trading back and forth among three of our members. At that time, the first thing I'll talk about, and whether or not it's up there, it'll be up there in a minute, is really what we do.

We're providing guidance, clarification or proposed standards of NOSB operations, policies, and procedures. We're maintaining the content and updates to the NOSB policy and procedure manual and the new member guide, and we're working with other Subcommittees to develop joint proposed recommendations, where policy issues are involved.

So it looks like I'm just going to read to you rather than you seeing as well, the other part of that slide, which is the members. The members are myself, Joe Dickson, Jay Feldman, Barry Flamm, Jean Richardson, Mac

Stone, Jennifer Taylor, and C. Reuben Walker.

So we have, and again I apologize that they're not up on the screen, but we have three proposed recommendations, and we will be hearing about them in that order. Thank you. Sorry, thank you. It's all good.

There they are. Conflict of Interest or COI, Public Comment and Public Communications. So you know, this is just the background reality and actually, I presented this, a version of this same slide that's up there right now at our previous meeting.

But I think that, you know, I think it's worth reiterating the fact that these topics came up because of a combination of requests from the NOP, from the public and from within the NOSB for reviewing and updating the policy procedure manual.

And the updated reality is the fact that the conflict of interest was put forth at both the Savannah, Georgia and Albuquerque, New Mexico meetings, and quite

honestly -- quite frankly has been substantially revised, you know, like I just said, not once, but multiple times, and I think that that's worthy of note.

The public comment that you're going to see was a discussion document at the Savannah meeting, and then it went to the Albuquerque meeting as well, and the public communications, proposed recommendation is, you know, it has some of that same history, but it's to establish a policy that doesn't exist.

So at this point in time, what I'd like to do is, and I will be frank and honest with you. Our most complicated of these three, in various ways for various reasons, is the conflict of interest. But due to the way we had the schedule already, that's going to be the very next one, and that's --

What I'm going to do is turn it over to C. Reuben Walker, and he's going to lead us through the conflict of interest. So

thank you.

MR. WALKER: Thank you, Colehour. I would like to begin by saying that conflict of interest, as I mentioned in New Mexico, has been a problem since the beginning of humankind, and today, it is no different.

We hope that as we leave from here, that a decision would be made on conflict of interest up or down, and we can move on to something else. Primarily, the conflict of interest was brought about by I call it the "Organic Nation," several groups making a request for more transparency and things centered around conflict of interest.

As Colehour, the chair, had mentioned, we went through probably at least 30 iterations of this particular document since last year. We have even went as far as requiring the declaration of interest form. No board member can lobby the Board until two years afterwards.

We had a financial, we had all

kinds of things in this document, and but what we found in doing this is that, and rightfully so, some board members seem sometimes to be, I call it maybe somewhat unfairly picked on, and this is a very sensitive topic.

So we decided to take our time, and make sure we get something that hopefully that we can come to a consensus. I believe the attorney from WDA mentioned that at some point, instead of fighting all the time, at some point a consensus need to be done.

My view of a consensus is that each side is still pissed off. But we agree to move it along, just for the good of the whole group. So I guess I'll just go the public comment. This is the public comment that was put out.

Table 1 shows that it was 104 entities or individuals responding to our document. Some of these were form letters. As you can see, no one supported the document, for various reasons. What the Policy

Committee said that we just wanted to get it out, to let the organic community weigh in on it, because it was changed from the New Mexico meeting.

Table 2, if you chisel down, if you take away the form comments, we had roughly 25 different commenters, groups or individuals, and again, zero percent was for what was placed out there for various reasons.

Another question we wanted to know was in our current policy and procedure manual, and we have seen quite a few former Board members, and when they was on the Board, conflict of interest were mainly led by the Board itself, and that particular writing it still is in our policy document, on pages 9, 10 and 11.

So essentially with this new document, we have agreed to keep it that way, that the Board maintain that particular wording, that NOSB determine a conflict of interest. But we know that AMS and NOP is the

final arbiter of anything that we might do. That's a fact. So that's where we're at.

That will take care of that, and what I would like to do next is Michelle will go, will assist me here. This is the document that was put out for public comment. It's eight pages, and this shouldn't take long, because I'm going to go through it pretty fast.

Page one, there was no change. So we can go down to, Michelle if you don't mind, to the recommendations. What we wanted to do as a Committee was to show what was placed out for you all to review. Then we wanted to show in yellow -- I had some problem with some of this. Some of it was in green, but anything colored is what we changed.

How did we change it? We changed it based upon the public. NARC, Cornucopia, OTA, WDA, and essentially what I did, I made a grid for all the objections. Some of the trade groups said keep the conflict of

interest policy as it was.

If that be the case, we have that in this document. The NOSB Board make the initial determination, and the NOP will be the final arbiter.

So Recommendation 1, everyone agreed to that one, of all the stakeholders. Recommendation No. 2, there was an agreement. Simple. We just wanted to add the word "proposed inclusion" into the language.

So Recommendation 3. In Recommendation 3, with respect to Michael Jackson, we moonwalked back on this one. The issue we had here, what the public had was it said that all of us was to represent the interest of the entire organic community.

But what stakeholders said, that we was placed on this Board to represent the interest in which we was appointed. So essentially, we put the language back.

Organic farmers should represent the interests primarily of organic farmers,

retailers, retailers, handlers, handlers. But not to overlook the entire organic community, but we was primarily to represent the interests in which we was appointed, and what we had out there was different.

So we just essentially placed back what we had in the policy manual, and that's been there for the last, since 1999. So what's in yellow is what we placed back. Instead of saying "board members," I just said his or her, to try to be more personable. So we essentially changed the language back to what we had.

What you see in blue redacted is what we had out there, that stakeholders did not like. So we've just taken that back out, kept the policy.

Recommendation 4. That was okay. Recommendation 5, disclosure of financial interests. What we decided to do here was to say that in our policy manual, it says "recognize corporate opportunity."

So we wanted to change that to "disclosure of financial opportunity," because when you say "corporate," it seems like, you indicate that you're picking on those who may have a corporate leaning, and that is unfair and that is unjust.

So what we tried to do was to say we all could have a possible conflict of interest, and we need to disclose it. So what the Committee decided to do was let's remove the term "recognize corporate opportunity," because it seemed to be, give the indication you're singling out a particular group.

Recommendation No. 6. Let's see here. Essentially, this goes back to the first one. It says "NOSB members shall, with the various backgrounds, are recruited to provide a balance to the Board." While the individual NOSB members represent the segment of the population from which they were selected.

They are also to represent the

greater good of the population as a whole. You can see what was redacted. Essentially, it said that we all was to represent the entire community, and we were not appointed by the Secretary of Agriculture and AMS and NOP. We was not appointed for that. We was appointed for a particular, to advocate for a particular position.

So we essentially put the language back that we have in our policy manual. To me, our policy manual is the NOSB Board's Bible. So we don't want to change the bible too much, that it would take away from its effect.

Recommendation No. 7. We have 11, so it won't be long. Number 7, essentially where we had "NOP," we returned that back to "NOSB," the language that we had at the New Mexico meeting and Savannah meeting.

So what's in yellow, a conflict of interest. The long and short of this is the definition was quite lengthy. It had

entities, it had organizations. In Louisiana, we call it, it was a gumbo. It had some of everything in it.

What we decided to do was to deal only with a direct financial gain, as opposed to a direct financial interest and affiliates and all those things. So in essence, Recommendation 8 was we reduced it to a direct financial gain.

Also, potential conflict of interest was redacted. No one seemed to have liked that in the public comments, trade associations and the public interest groups. Now bear in mind that this doesn't mean that it will not show up again, because the NOP will begin with ethics, to make sure that this is proper.

Immediate family member. This was added. What you all read was it was in the definition of a conflict of interest. So what we decided to do was actually just pull that definition out, as opposed to just keeping it

in the definition of a conflict of interest.

And also, immediate family members is also in our policy on page 11. So the term in the definition of immediate family member is not new. It's already existing in the document already.

Okay, number 9. No one seemed to like this one. I was surprised on this one. They didn't like the direct financial interest. So trying to build a consensus at our level, we decided to put the term back, what we originally had in Savannah and New Mexico, which was "direct financial gain."

Stakeholders said that direct financial interest was too broad, why did you cut it off, those sort of things. So we thought at our level, we'd just return it back to what we have in our policy.

Number 10. Essentially, we returned back and added. What we returned was that we wanted to show that NOSB is, I would say "will take the lead" in determining if

there's a disclosure. The Subcommittee or this Board will make that first determination.

But we do know that if the program object, they would be the final arbiter, because that just the way it is. So essentially at the Subcommittee level, when work plans are done and for those of you who are not familiar, at some point after this meeting, we would get together and determine -- - I think we already determined that now right, work plans?

Work plans are actually decided, and as November, December, January go along, we'll determine if all these things going to stay on each of the subcommittees' work plan. We are asking that fellow Board members and subcommittees disclose early on if they have a conflict of interest.

If they do, then happens to be determined at the subcommittee level, and it need to be documented in the minutes. This would be done in conjunction with the program.

At the Subcommittee Level 2, that's the next page, and all you're seeing in blue is what we kind of redacted.

Yes, this one here. Yes, okay. At the biannual meetings, at the beginning of each subcommittee, we are asked -- the chair is to ask committee members or Board members if they want to disclose any potential conflict of interest, any conflict of interest, as we did somewhat during this meeting.

So it need to be disclosed in the public, and not at a level where one do not know. So what is in blue, I apologize for not being able to read it, but the scratch-through is what we put out, that individuals tended to have a problem with. So essentially we kind of returned this back to what we had at a previous Board meeting.

Next recommendation, or going further down the next page. I think one of the problems that I would like to note here,

we had an issue of three days that the program will decide if there was a conflict.

That was an error. That was taken out. We also said that if there is any revote, that would be not retroactive. Several groups did not like how far do we go back.

Do we go back to 2002 and revote on an issue, and the Board, the committee decided that the revote would only come into play if necessary, and determined by NOP, once this particular document is finally approved at a level above us.

And recommendation No. 11. No one liked this particular recommendation. Whether it was trade association or community-based groups or individuals. So essentially what we have here is that we just returned the language of Recommendation 8 back to where it was in our policy manual.

The last slide, oh I see. I didn't have it on the other one. It's not

there. But that's it. So essentially we are putting before the Board as a whole and the organic community, because what you've seen out there, you have expressed to us that you didn't like it.

So essentially we have went back and made quite a few changes, substantial changes as Mr. Colehour mentioned, and we are hoping that this Board tomorrow will digest it, and maybe we can move something forward. There's no guarantee that it would be accepted all by the program.

But if we can get a strong vote up or down, a strong vote would be better for NOSB. If it's voted down, it may not be as good.

So that's where we're at, and my collaborator here was Mr. Joe Dickson, and the reason why we like it is because when you get a public interest, you get the retailer, you get the environmentalist, you come up with a pretty good document.

So we're hopeful that, tomorrow that we can get this through in some form. Thank you.

MR. BONDERA: Very good. Thank you very much, Mr. Walker, and I appreciate the complexity of what you were presenting. So we will keep working on that.

The next thing that we're going to do is go ahead and listen to the presentation of the next recommendation that's on the table, which is -- the title of it is public comment, and I am going to present that to you.

So hopefully here it comes. So the truth is that this is going to be -- what Calvin just took us through, he has notably and significantly modified from what was put forth to the public and the realistic truth is that this particular one does not have any changes at all.

So we're just going to go through it, and I think pretty quickly. This is about

the policy for public comments at NOSB meetings, and I think honestly, Calvin went through the process very well, and I appreciate that he thanked Joe for his help on the conflict of interest one, and I'd like to start out by doing the same with Jean, who -- Jean Richardson, who really played a significant role in helping me work on this, and get it to where it's at. So thank you, Jean.

I have led the efforts on this particular topic, both through the discussion document form and as well as to our last meeting in Albuquerque. The goal of this is to amend Section, I guess it's Section 6 of the policy procedure manual, which is entitled "NOSB Policy for Public Comment at NOSB Meetings." These are the new words that we have put forth.

So I'll just go ahead and read them to you. There's ten points. The first one is "All persons wishing to comment at NOSB

meetings during public comment periods must sign up in advance, per the instructions in the Federal Register notice for the meeting."

Number two is "All presenters are encouraged to submit public comment in writing according to the Federal Register notice. Advance submissions allow NOSB members the opportunity to read comments in advance electronically, and decrease the need for paper copies to be distributed during the meeting."

Number three is "Persons will be called upon to speak in the order they sign up. Persons called upon who are absent from the room could potentially miss their opportunity for public comment."

Number four. "Time allotment for public comment per person will be four minutes, with the options of reducing to a minimum of three and extending to a maximum of five minutes at the discretion of the NOP, working closely with the NOSB chair, in

advance of the meeting."

Sorry. Yes, next slide. Sorry, I didn't say that. Sorry, I'm looking at my screen and not up there. I apologize. Too many things going on, and I'm tired like all of us. So I hereby take full responsibility for that error, and I hope you'll all just deal, as I read through them, even if they aren't on the screen.

Number four. Time allotment for public comment -- I already read that.

Number five. "Persons will give their names and affiliations for the record at the beginning of their public comment.

Number six. "Proxy speakers are not permitted."

Number seven. "Public comment requests may be scheduled by major topics under consideration, as we have -- my comment on that is as we have eased into doing, starting at the Albuquerque meeting, and now it seems like that is our modus operandi." So

that's how people are grouped together.

Number eight. "Individuals providing public comment will refrain from any personal attacks and from remarks that otherwise impugn the character of any individual."

Finally, number nine. "The NOSB will attempt to accommodate all persons requesting public comment time. However, persons requesting time after the closing date in the meeting notice or during last minute sign-up at the meeting, will be placed on a waiting list, and will be considered at the discretion of the NOP, working closely with the NOSB chair, depending on availability of time."

Number ten. "Members of the public are asked to define clearly and succinctly the issues they wish to present before the Board. This will give the NOSB members a comprehensible understanding of speaker concerns."

And so I think like I wrote here, we didn't receive that many written comments on this topic, and really, all of them were supportive, even when there was a little bit of reluctance in the comments we received, in terms of I think notably the amount of time involved.

I think that the other thing worth noting, in terms of written testimony that we've received, is that the one thing that is sought in that testimony is that there would be no restrictions on questions and discussion by NOSB members.

I think the honest truth is that, you know, that's going to have to be worked in as is viable, depending upon what our volume of people is and what our topics are. You know, these little -- they aren't quotes actually. These highlights that I've put on this slide are actually from the Albuquerque meeting, not from comment from this meeting.

But I think that they all pretty

much still apply, since we haven't really modified the document very much at all in fact, and I think they still are all relevant. Allow more time for public commentary is a general feeling that people who comment and communicate about this want and seek.

That's why we have public meetings, and you know, so I want to let that proxy topic totally drop, just because it does have history within the NOSB and I think that noting that people do feel like it's helpful for public interest organizations is relevant.

What I just said, I think, is also notable, in terms of the fact that the circumstances go into define how things really are played out, and I think in my opinion, as organics grow and, you know, as a meeting plays out, what is anticipated if it's a heavily attended meeting, where a lot of people are interested in the subject areas, and/or it's held in an area where there's a lot of, I don't know what descriptor to use,

but vibrance about the topics at hand, then I think that we may have, you know, an issue in terms of how many people have to speak and how much time.

I think that those issues will have to just be dealt with, and we all will need to be flexible, according to the circumstances. So I think that that highlight really still pertains.

I also do think it's still worth noting that like I alluded to earlier, the reluctancy of the support that the written comments that came in on this, you know, were not exclusively and not solely, but were related to, you know, the five minutes instead of four minutes.

Then with the concept of adjusting it downward rather than upward. So I just thought those were worth repeating for you all. The final words I want to just share with you are, you know, the reality is that --

Well, I'll be honest with you all,

and I don't feel bad about it, but you know, Barry Flamm served as the chair of the Policy Development Subcommittee for four years, and you know, he's not the easiest act to follow.

I think that that's, you know, I respect and think that Barry deserves the honor that he has earned. But I think that the truth is that I have tried as hard as possible to work with the National Organic Program, and get their input, and they have worked with us and have chosen to, you know, point out some of the clear facts, that the truth is that the Designated Federal Officer is ultimately responsible for the NOSB meeting schedule.

I think that that is the truth. No matter how this plays out or what the process is, you have to fit all the things into the reality. I think that that is critical.

We're going to have, after our third presentation, we're going to have live

testimony and, you know, the live testimony can also affect both the full NOSB discussion and then the final vote on the proposed recommendations.

So I encourage those that are going to provide testimony to recognize that, and I'll just finish up with that. Thank you. Mahalo. At that moment then, what I want to do is ask -- Jennifer is going to present the third subject to us, and her topic is public communication.

Like I said before, it's something that doesn't exist per se in the policy procedure manual. So it's a new subject, although she has in Albuquerque already presented it to us. So it's not all fresh and new, but I'll turn it over to Jennifer. Thank you.

MS. TAYLOR: Thank you, Colehour. Okay. We will review and now discuss as well the public communications document. Okay.

"A primary role of the National

Organic Standards Board is to advise and counsel the Secretary, to represent the segments of the population from which they were selected, and to treat the business of the Board as fiduciaries for all members of the organic community and public at large." That's coming from the Policy and Procedures Manual.

The Organic Foods and Protection Act states that "The statutory mission of the NOSB is to assist in the development of standards for substances to be used in organic production, and to advise the Secretary on any other aspects of the implementation of this title." Okay, thanks.

Okay. Can we go to the next slide, please? Thank you. Again as stated, within the Policy and Procedures Manual, the NOSB mission statement is to provide effective and constructive advice, clarification and guidance to the Secretary of Agriculture concerning the National Organic Program, and

the consensus of the organic community.

The Federal Advisory Committee Act meeting obligations to the public suggests that any member of the public is permitted to file a written statement with the advisory committee during meetings.

In addition, the NOSB infrequently receives public communications outside of the designated public comment period. These communications include verbal and written information.

Due to the opportunities that the Board has to hear from the organic community, in the course of fulfilling its mission, it has both an opportunity and responsibility to bring to the Secretary of Agriculture information that it believes may impact on the implementation of the Organic Foods Production Act.

This communication may, by necessity, extend to organic standards and practices, as well as related issues that may

affect those standards and practices.

Therefore, based on the communications and input it receives from the public, the National Organic Standards Board may provide effective and constructive advice, clarification and written information as it deems necessary directly to the Secretary of Agriculture after each of its Board meetings.

Additionally, and as a part of its responsibility to communicate with the organic community, pertaining to the implementation of the Organic Food Protection Act, the Board must receive and review information from the NOP and other sources during its deliberations.

As a stakeholder board, the input from the organic community is valuable in the deliberations of the Board, and the community decision-making process. The procedures of the Board should facilitate public communication to inform these deliberations, and we'll follow with recommendations.

The public, I'm sorry, the Policy and Procedures Manual, Section 6, Miscellaneous Policies, page 26, is amended by adding a new subcategory that states "The NOSB policy on its advisory role in communications with the Secretary of Agriculture. Based on the communications and input it receives from the public, the National Organic Standards Board may provide effective and constructive advice, clarification and written information as it deems necessary directly to the Secretary of Agriculture, after each of its Board meetings.

"This information is intended to facilitate public communication with the Secretary on critical issues that may emerge, that it believes are important to the implementation and integrity of the organic standards and practices under the Organic Food Protection Act.

The policy and procedures manual Section 6 is amended by adding a new

subcategory. NOSB policy for public communication between NOSB meetings. "The NOSB seeks public communication outside of the Board meetings and public comment periods, to inform the Board and program work.

"The Policy and Procedures Manual, Section 2, role of the executive director, is amended to include the following language: "Identify, implement, administer and maintain a year-round mechanism by which public feedback can be received, posted and archived for viewing by the NOP, the NOSB and by the public itself."

Now this document has been before the public before, and we received several comments from the public, all in support of the document. We received comments also from the program that were in support of the document as well.

This is a representative comment from the public. "I support both aspects of the proposed public communications policy.

The ability for the NOSB to inform the Secretary of the organic community's views is critical, particularly for views that are contrary to USDA's other policies. It is also important that NOSB members be able to receive input from the organic community during all stages of deliberations."

Another method that was used was to state "We fully support the following additions to the policy manual, as proposed by the Policy Development Subcommittee."

We also received a question during this period, during this fall meeting period, and the questions were "Will NOSB members have to check or will they receive the comments in their email. Will someone alert them if something is posted?"

We thought about that same thing actually, and what we're hopeful of is that the communication that we've established with a program through the docket system, we will receive an alert and we will receive an alert

that the information is being deposited there.

"Is there an opportunity for the NOSB members to respond? Two-way communication is important." We also realize that two-way communication is important, and we're hopeful that we'll be able to respond as well to those comments that we receive.

The Subcommittee vote on this particular document is reported as you see. We had a vote of eight in support of the proposed document. Colehour, I return.

MR. BONDERA: Thank you very much. Very good. At this point in time, even though we are running slightly late, I would like to turn to the people that have signed up to provide us with live public testimony, and the first one that I have on the sheet is Marnie Karlin, followed by Andy Pollock.

So if you can be ready, I will be corrected if it's inaccurate. But the third one I have is Rosemary Galiani. So in that order, if you will please share with us.

Thank you.

MS. KARLIN: Thank you. Good afternoon, and thank you for the opportunity to comment today. My name is Marnie Karlin, and I am Associate Director of Legislative and Legal Affairs of the Organic Trade Association.

Just by way of background, I came to OTA after nearly four years as counsel to the United States Senate Judiciary Committee, and before that I practiced law in Washington, D.C. for almost eight years.

I also bring with me a little food cred, as I hold a degree from the Cordon Bleu Culinary School, and now I'm here, commenting at my first NOSB meeting. Unfortunately, OTA could not support the proposed changes to the COI policy circulated before the meeting.

But we thank you very much for the changes that Calvin explained, that address many of our concerns, and leave me with very little to comment on. I'll just outline some

of our concerns, just to add a little color, as to perhaps why some of those changes may have been made.

NOSB is a FACA board, an advisory board prohibited from creating policy or issuing regulations. Actual decision-making is done by USDA officials, who are subject to strong COI policies.

Your purpose is to provide advice from the perspective of interested parties, which only happens when you each represent your constituencies.

You are all chosen because of your professional expertise in a particular area, selected to provide particular points of view. The Board as a whole represents the entire organic industry, but for you to function as Congress intended, each member must represent his or her particular constituency.

This leads us to what I see as a misunderstanding between a conflict of interest and an interest. Some commenters

suggest that any time a Board member has an interest, he must disclose it for analysis of whether a conflict exists.

That is belied by the purpose of the Board. Each of you brings a set of interests -- that is exactly why you were appointed -- to bring your relevant interests to bear as you advise the Department. You were each selected to represent your constituency, farmers, handlers, scientists, and you would not be doing your job if you did not represent that interest.

Now a conflict of interest is different. It arises when a member's interest conflicts with his official responsibility. When serving on a FACA board such as NOSB, your official responsibility is to have an interest and represent that interest.

It is only when your personal interest conflicts with your ability to represent your constituency's interest, that any conflict would arise. It is important

that we not show having an interest, but regulate only conflicts.

I'd also like to talk for a minute about transparency. Some commenters suggest that transparency requires open discussion of individual Board members' personal interests. Respectfully, this misunderstands the transparency requirement.

Transparency is absolutely important, but does not require or even suggest public discussion of Board members' personal interests. FACA's transparency requirements are that Board advice is accessible to the public, and committee meetings are open to the public.

As we've seen this week, NOSB meetings, deliberations and votes are public, and public comment is welcome. FACA-required openness already does what a stringent COI policy must do in less open government processes: it shines light on and makes transparent the process, so the decision-maker

and the public know what interests were represented.

Finally, I'd like to thank you for a couple of changes in specific areas where the original proposal went too far. First, it allowed application of a new COI policy retroactively to votes or deliberations taken before adoption of the new policy.

Not only is that a bad idea, but U.S. jurisprudence is clear that retroactively is not favored in the law. Finally, we oppose the terms of "potential or perceived conflict of interest," which are uncertain, vague and overbroad. So we appreciate them being stricken as well. Thank you for your time.

MR. BONDERA: Thank you very much. Any questions for Ms. Karlin? Jay.

MR. FELDMAN: Thank you for your statement. Do you have any comment on the revisions that -- I know it's --

MS. KARLIN: So I just heard them, you know, five minutes ago. At first blush,

they look like a much-improved proposal. I would love to have a moment to actually read through them before I make an official, you know, have an official statement on behalf of OTA. But I'd be happy to do that if I could take a read on them.

MR. BONDERA: Thank you. Any other comments? Harold.

MR. AUSTIN: I know you haven't had a chance to see some of the revisions that they just made. I'd be interested in your feeling on the conflict of interest policy where we're putting the verbiage back in, that that, those decisions would be controlled by the NOSB Board itself, rather than being directed firsthand through the NOP. What are your thoughts there?

MS. KARLIN: That tends to concern me a little. I tend to feel that there is an opportunity for NOSB members to have their own interests in whether or not something is determined a conflict of interest.

That raises a bit of concern for me, in terms of that being where the decision is made. So I generally prefer seeing an objective, outside body of the NOP making that decision.

MR. BONDERA: Any other questions?

(No response.)

MR. BONDERA: Very good. Thank you very much.

MS. KARLIN: Thank you.

MR. BONDERA: Do we have Andy Pollock present?

(No response.)

MR. BONDERA: Okay. Hearing and seeing no response, Rosemary Galiani. Thank you. Please introduce yourself.

MS. GALIANI: Hello. You got my name correct. My name is Rosemary Galiani. I am general manager for the Alternative Food Coop.

We're located in Wakefield, Rhode

Island, which is just about 30 minutes south of here. We've been in business for over 40 years, we have 600 members, and I'm here today as the manager, to urge the NOSB Board to keep the organic standards clean.

Our members and our shoppers want to know what is in their food. I am also a member of the Cornucopia Institute, and I'm here today as a citizen lobbyist. Cornucopia believes that the conflict of interest proposal is a step in the right direction in the current policy.

We are especially concerned with the suggestion that the Board members disclose conflicts to the NOP, but not to the public. Organic stakeholders would like to see greater transparency, not less.

Since the NOP has demonstrated it is unlikely to ask a Board member to recuse him or herself, as happened at the last meeting with the carrageenan vote, this could lead to a situation where the NOSB itself has

no control over the conflict of interest, and the public might not even know whether potential conflicts were declared.

We question where this change in the proposal came from. We support keeping this important responsibility with the Board. We also note that the contracts for technical review are still missing from the proposed conflict of interest policy, despite repeated requests by numerous public interest organizations to add them.

Currently, even the identity of technical reviewers is not publicly available, much less the potential conflicts. Technical review essentially happens behind closed doors.

We urge you to add a line in the proposal to require technical review contractors and researchers to sign the conflict of interest statement prior to commencing work on the TR.

We also question the claims made

by some groups and individuals in public comment that the Board is supposed to represent people with different points of view within the organic community, and that a stronger conflict of interest policy is therefore not needed.

This system is simply not working as is designed. We have seen too many corporate representatives, all with conflicts, vote on issues while they are serving in seats legally reserved for farmers, consumers and scientists.

When the system breaks down, as it has, a conflict of interest policy is needed to provide checks and balances. For example, in recent NOSB history, we have seen an employee of General Mills, a $16 billion corporation in the scientist's seat, who failed to disclose a conflict when her employer had a license agreement with the petitioner for the very same substance that was being petitioned. That's Martek DHA.

We have seen the CEO and employer of an individual in a pharma slot directly contact NOSB members to lobby for a yes vote for carrageenan, while the NOP decided that this pharma Board member had no conflict.

If that -- your own boss actively lobbying other Board members -- doesn't constitute a conflict of interest, than what does? The system is clearly broken and needs to be fixed. We would like to see more transparency, not less; more integrity, not less.

With regard to your public comment proposal, please allow for unlimited questions and answers. Experts often travel great distances to attend these meetings, and Board members should have the opportunity to publicly engage with public presenters until their questions have been answered. I thank you for your time. I'll answer any questions.

MR. BONDERA: Thank you, Ms. Galiani. Any Board member questions?

(No response.)

MR. BONDERA: Very good. Thank you for your time. I do thank you. This microphone and me are not having the best time, and I apologize. It keeps considering not being on.

At this point in time, we have finished with the Policy Development Subcommittee's presentations and testimony, and I would like to call a 15-minute break so that the Policy Development Subcommittee can huddle together and regroup about our voting process, so we can finish up this day.

So if that's alright with you, Mr. Chair, I would like to reconvene at five after 5:00.

CHAIRMAN FLAMM: That is fine. We'll reconvene at five minutes after 5:00.

(Whereupon, the above-entitled matter went off the record at 4:49 p.m. and resumed at 5:03 p.m.)

CHAIRMAN FLAMM: We've got the

chair of the Policy Subcommittee, and I guess we can resume now.

MR. BONDERA: Very good.

CHAIRMAN FLAMM: Colehour, I understand that the committee has made some decisions on how you wish to proceed for the rest of the afternoon.

MR. BONDERA: Yes. Thank you very much, Mr. Chair. At this point in time, based on the discussion within the Policy Development Subcommittee, we have decided that we would like to move forward with our recommendation on public comment and our recommendation on public communications, and postpone our conflict of interest topic until tomorrow so there's more time for discussion about the changes that have happened to the proposed recommendation as it was put forth to the public, since as you saw, there's a fair number of lines crossed off and a fair number of new ones.

I want to give the opportunity to

entire NOSB members who are not on the Policy Development Subcommittee an opportunity to be prepared with their discussion points and questions when we deal with that, and you have, according to my watch, you know, well over 12 hours to do so. So I'm sure that that's enough time for everybody involved.

In any case, so that's our intention, and we have, like I said, two subject areas, and I would like to start out the process, before a motion is made, by asking the NOSB members if there is -- and I do hope we can all, we all already know the answer to this.

But nonetheless, just to give the opportunity, in case there is any rationale or logic for any recusals or information-sharing on conflict of interest related to the policy development, this is an opportunity to do so. So I welcome anybody who has something to put forth in that regard.

Very good. Hearing and seeing no

reaction or action on that, I will move us forward to considering the recommendation, and first the one that I presented on public comment, and so like I said, the recommendation is to amend Section 6 of the PPM, and I don't know if Michelle wants to put it up on the screen, because I didn't prep her put it up on the screen.

But know, the actual wording of the actual recommendation, the motion, because otherwise, I have to read through the whole motion again to present it.

So it's the same one that's in the, what was publicized too. I don't know whether you have it. Sorry. I apologize for that delay.

In any case, I will actually make that motion at this point in time, that we do amend the policy procedure manual as that reads, and would be happy to entertain a second to that motion.

MS. RICHARDSON: Second the

motion.

MR. BONDERA: Thank you very much.

CHAIRMAN FLAMM: It's been moved and seconded.

MR. BONDERA: Thank you.

CHAIRMAN FLAMM: Colehour? It's been moved and seconded. If I understand, your motion is to change the -- to add to the Section 6 of the policy and procedure manual, the following recommendation, and those recommendations are numbered 1 through 10, as shown on the screen.

If everybody is satisfied with reading it themselves, rather than have Colehour re-read it. Is there any desire to have Colehour read the full motion?

(No response.)

CHAIRMAN FLAMM: If not, is there any discussion? Mac.

MR. STONE: I haven't asked presenters specifically, but from this vantage

point, it seemed like the presenters were more comfortable with a four-minute delivery. I thank Michelle for the little beeping light thing. I think that gave them some time to help their cadence.

So obviously I want the public to know too that there's uniform interest for this Board to maximize public comment time because it is deemed extremely valuable. But I think the four minutes was way better than three.

CHAIRMAN FLAMM: Any other comments or discussion by the Board? John.

MR. FOSTER: Thanks. So on point number one, it says -- basically it says you've got to sign up ahead of time, and then in number nine it says you can do something else. So I'm wondering if there's a way to reconcile that.

Number one just says very clearly everyone who wants to speak has to sign up ahead of time. Number nine, I think, it says

that, well, actually you can sign up according to certain, if certain criteria are met. I'm wondering if we can change number one to be something other than absolute because clearly we don't want it to be absolute. You know what I mean?

MR. BONDERA: So you're specifically referring to the word "must" in that sentence?

MR. FOSTER: Yes. Sounds pretty absolute, and maybe it's no big deal. Maybe no one else is worried about it, but I just hate putting something in one part of a new document, and then somewhere else in that same document we're saying we're not going to follow what we just said.

Maybe no one else -- I don't know. It doesn't, that's not my preference. Anyway, if no one else is worried about it, I'll pass. But it seems like you could build, you could put all that into one point, and then be not contradicting yourself. That's my first

question.

Or if there's a reason to do it this way, tell me what that is, please.

CHAIRMAN FLAMM: Nick. I'm sorry, John. Have you finished?

MR. MARAVELL: I agree with John, and I was about -- he stated what I was about to state. It might make sense just to put it all in one point. I would hate to sit here and wordsmith, but I would leave that to the discretion of the Subcommittee, to get the commas and the tenses and everything else straightened out.

But I would say we should encourage, you know, we encourage everyone to sign up in advance, and then go on for point number nine, saying if you don't sign up in advance, then this is what happens.

CHAIRMAN FLAMM: Colehour, would you like to respond to --

MR. BONDERA: Yes. I think in one second I will, sorry. I'm just looking at

the screen, I apologize. Yes. I think that in my opinion, and I thank you for your comment, John. I think if that word "must" were to change to the word "should," and number nine was simply put as a continuing, just take everything that's in number nine, no wordsmithing at all except for that one word I just mentioned.

Take number nine and put it directly after number one, as part of number one. So eliminate number nine and put the text of it at the end of number one.

The word "should" means that's what you should do, but that we're going to accommodate people if they otherwise fit in, and then not change any of those other words. I don't know if that addresses your question sufficiently or not John, but that would be how I'd handle it.

MR. FOSTER: Yes, it does.

MR. BONDERA: Okay. Did you have some other points? Sorry.

MR. FOSTER: I did. I know this kind of language often uses the word "impugn," but it's not uncommon to have impugning going on at these proceedings. So by definition, I know we all think it means one thing. It means a little more general than we actually assume it to be.

So I'm not suggesting we change it, but those of you who know me know that there's certain words that I like to be very precise about, and impugn has a much more general kind of challenging connotations to it than what we mean, which is don't bad-mouth someone and don't personally attack them. That's what we mean, and I get that.

But impugn is more general. I'm not necessarily saying we change it. I just want to call it to everyone's attention that impugn is a very broad -- it's a very broadly applicable challenge or attack. Accusing something, in this case, a person's character as being false.

That's a very general statement, and I just want to make sure we know what we're doing when we say that, because we're trying -- I mean this will be a continuously improving document. I'm sure we can always make it better, and I just want to make sure we mean what we say when we say it, that's all.

CHAIRMAN FLAMM: Colehour, I think if we're going to do any wordsmithing, we don't have time to do it here. If you wish to do that, I would withdraw your motion and fix it and come back tomorrow, and we can vote on it. We have time tomorrow. John.

MR. FOSTER: I want to just make clear, I'm not saying we have to do this in order for me to vote for it or against it or anything. I'm just, I want to get it out there, that this clearly has -- this is a very useful concept to include in our Policy and Procedures Manual.

So when we put something in it, I

just want to make sure that we're using the words we mean to use. If no one else, or if we don't -- if there's not general consensus that we need to worry about that, then you know, go with the will of the Board.

CHAIRMAN FLAMM: I'm just giving Colehour that option, as the maker of the motion.

MR. BONDERA: Thank you. I think, Mr. Chair, what I would like to do at this time is, and thank you again, John, for your comments, I would like to see if there's any other comments. So that if I make that decision, then I know -- or if I want to withdraw that, that I know what I'm considering.

But I think that it does make sense to me. But I'd appreciate wrapping up any other comments, if there are any more.

CHAIRMAN FLAMM: All right. Any other -- yes, I got your point. Any other comments or discussion, and if those were

corrected and brought back tomorrow, would that satisfy the Board? Hearing none, I -- we got one.

MR. FELDMAN: Yes. I don't have a problem with the word "impugn." I think that's -- we discussed it as a subcommittee, and I think that's what was intended, that there not be any, as you say, broad attack on people.

I just think we have other things to do tomorrow, and I also think the issue of aligning number one with number nine is rather simple. We could just say, you know, instead of the word "must," if people feel uncomfortable with that, we could say "must as a general rule," and then add the rest of the sentence in number nine to that paragraph and say "However, if," and then just connect those two thoughts, as you're suggesting, and be done with this, because I think we have other things to do tomorrow, and I think we all basically agree with this.

CHAIRMAN FLAMM: Okay. Colehour, I give you the option, Colehour, of either withdrawing it and fixing it and coming back tomorrow, or restating the motion, with the suggested changes.

MR. BONDERA: Thank you. I would like to modify my motion that's on the table, to change number one and number nine, as Jay just presented as a suggestion, and I'm sorry I don't know if I should ask --

CHAIRMAN FLAMM: Read the changes out.

MR. BONDERA: So, can I read this? May I read it? "All persons wishing to comment at NOSB meetings during public comment periods must, comma, as a general rule, comma, sign up in advance per the instructions in the Federal Register notice for the meeting."

Number nine could remain or could become a part of number one, which I would suggest. "However," and this would become the last sentence in number one. "However, the

NOSB will attempt to accommodate all persons requesting public comment time, comma, delete "however." "Persons requesting time after the closing date in the meeting notice, comma, or during last minute sign-up at the meeting, comma, will be placed on a mailing list and will be considered at the discretion of the NOP, working closely with the NOSB chair, depending on availability." Renumber number ten to number nine, period.

CHAIRMAN FLAMM: Do we have those changes, proposed changes recorded? Colehour.

MR. BONDERA: Yes, but I don't have them in electronic form.

CHAIRMAN FLAMM: I'm taking -- the motion's been withdrawn and a new motion's on the floor. Is there a second?

MS. RICHARDSON: Yes, I second the motion.

CHAIRMAN FLAMM: Does the Board understand now the changes that were made? Any questions? Discussion?

(No response.)

CHAIRMAN FLAMM: I call for a vote then. Where are we? The vote begins with Jean.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

MR. BONDERA: Yes.

MS. TAYLOR: Yes.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

MS. SONNABEND: Yes.

MR. STONE: Yes sir.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: Yes.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

CHAIRMAN FLAMM: And the Chair votes yes. 15 yes, 0 no. Thank you. Your next proposal, Colehour, and that will finish the afternoon.

MR. BONDERA: Yes, very good. I would like to turn it over to the lead on this. Jennifer, if you would present a motion for us, please?

MS. TAYLOR: Thank you. Thank you, Colehour and Barry. I would like to motion that the proposal, Public Communications, be accepted. Is that the word? That it be adopted. Thank you.

CHAIRMAN FLAMM: We need to either see it or you need to read it, so we know what words.

MR. MARAVELL: I think -- let's see if we can get it. Do we have a copy of it for the screen? Yes, that's what we're waiting to see, if we can get a copy of it.

MS. TAYLOR: The recommendation is Roman numeral IV. Want me to read it, Barry?

CHAIRMAN FLAMM: Well, I think if we could show it on the screen, it would probably be easier for the Board to -- we don't have it.

MS. TAYLOR: We also have it in our agenda items.

CHAIRMAN FLAMM: Well then go ahead and read what the recommendation is, so we can get it in the record.

MS. TAYLOR: Yes sir, thank you. "Recommendation 4. PPM Section 6, Miscellaneous Policy, page 26, is amended by adding a new subcategory in italics. NOSB policy on its advisory role and communication with the Secretary of Agriculture.

"Based on the communications and input it receives from the public, the National Organic Standards Board may provide effective and constructive advice, clarification and written information as it deems necessary, directly to the Secretary of Agriculture, after each of its Board meetings.

"This information is intended to facilitate public communication with the Secretary on critical issues that may emerge, that it believes are important to the

implementation and integrity of the organic standards and practices under the Organic Foods Protection Act, Production Act.

PPM Section 6, Miscellaneous Policies, page 27, is amended by adding a new subcategory in italics. "NOSB policy for public communication between NOSB meetings. The NOSB seeks public communication outside of Board meetings and public comment periods to inform Board and program work."

PPM Section 2, page 13, Role of the Executive Director, is amended to include the following language, in italics. "Identify, implement, administer and maintain a year-round mechanism by which public feedback can be received, posted and archived for viewing by the NOP, the NOSB and the public itself."

CHAIRMAN FLAMM: Thank you. Do we have a second to the motion?

MR. FELDMAN: Second.

CHAIRMAN FLAMM: It's been

seconded to amend the Policy and Procedure Manual to add communication material. Unless any Board member is unclear on what was read, I'll just -- I'll leave it at that. Is there any need for clarification on what we're about to discuss and vote on?

(No response.)

CHAIRMAN FLAMM: Hearing none, discussion? Any discussion. Thank you. Zea.

MS. SONNABEND: Well I've read this a few times in Albuquerque and now, while I don't really support the bottom part of the recommendation, I just don't understand the point of the first part of the recommendation.

So I guess I'm going to abstain, because I just -- I'm afraid that it's -- I mean I don't understand what "effective and constructive advice" means. How do you give the Secretary effective advice, by saying that in advance and it's not really public communication you're talking about. It's NOSB communication with the Secretary.

What you get from the public, I don't know. So I'm having trouble like really understanding the point of it. So I'm going to abstain.

CHAIRMAN FLAMM: Let's see. I think, Nick, you had your hand up first, I believe.

MR. MARAVELL: Yes. I think what we're looking at here is the intent. This is establishing sort of the rationale for what we're trying to do. We're trying to provide effective and constructive advice. It's the intent. We can't guarantee it.

It's to establish the intent of why we are trying to, in effect, take what we have received from the public and communicate that as part of our responsibility in the statute, to advise the Secretary on any aspect of the National Organic Standards Program. So it's just showing intent. Sort of a rationale.

CHAIRMAN FLAMM: John, a comment?

MR. FOSTER: I'm a little with Zea on this. I think our mission and mission statement are pretty clearly defined, what this body is about. It says that. I don't perceive that we have a problem delivering information to the Secretary, either directly or through the NOP, and I guess I am puzzled.

This feels like a solution in search for a problem to me, and I don't -- I think what we see here is already covered actually more clearly. I don't see the need for it. Then also, I'm with Zea on the effective advice part. That's been a long-time bugaboo for me.

But the way this is phrased makes it sound like we are to base our input, our effective and constructive advice, clarification or written information, based on the communication input it receives from the public, and I think we should be basing our advice on not just that.

This makes it seem like it should

be just that. So that I'm uncomfortable with that. It's very limiting, and I don't think we make our decisions based on one avenue of information.

Historically, we certainly haven't, and I think it's pretty clear in our policy and procedures, as well as other guidance we've gotten from the program, and I think the FACA rules are pretty clear.

We're getting information from more than there. So I don't like being limited by this, by what this says, irrespective of not knowing what effective advice is, like Zea said.

And then -- well, I have something to say on the second part too, but I don't know if you want me to stop there and we can cover that.

CHAIRMAN FLAMM: Go ahead. You can finish your comment and then I'll call on Tracy next.

MR. FOSTER: Okay. The second

part is I don't think we have an executive director anymore. I know there are a lot of references to it in the Policy and Procedures Manual, and I assume the PDC is going to be -- or PDS, rather, is going to be working on getting those changed out to current job titles and what-not.

But so I recognize here -- I don't know if we want to continue talking about the executive director, where we're making amendments to the Policy and Procedures Manual, or whether we want to change, use language that's more appropriate for current conditions. That's more a question.

CHAIRMAN FLAMM: Thanks, John. Tracy.

MS. FAVRE: I would like to get some clarity around what is the mechanism by which we communicate with the Secretary of Agriculture, and, as well as receive the public communications. Jennifer, you mentioned something about the public register.

But is that the only means by which you intend for NOSB members to receive public comments outside of the specific meeting procedures?

CHAIRMAN FLAMM: Nick, you want to respond to that?

MR. MARAVELL: Yes, and to John's concerns about the executive director. I think, you know, what we're talking about is house cleaning, and I think that's going to take place at a subsequent time, and really it's not part of this proposal.

With regard to the other concern that John had, it's my understanding, and correct me if I'm wrong, is the way you interpret it is correct. We are commenting and this is why I say the intent here is, should be stated.

We can communicate with the Secretary for a variety of reasons, you're absolutely correct. But what we're saying here is it's going to be our policy that we

intend to provide an avenue specifically for public input, that to the extent we feel it's appropriate, to inform the Secretary of what we have been hearing.

Now I'm going into history, and I may not be exactly correct on this. But I know, I was informed that in the early days of the NOSB Board meetings, that it was not at all uncommon for the Board at the end of the meeting to draft a letter to the Secretary.

Now I'm not saying I know what was in those letters or anything else, but I understand that's what happened. I don't know if anyone could fill me on this.

But the intent back then was because this was a new program in formation, et cetera, was to bring forward public comment, and that was part of the statutory authority, was to advise the Secretary on any matter concerning the implementation of the program. So that's why that was done a long time ago.

And Tracy, you had a concern too? I forget what.

MS. FAVRE: About public communication with Board members outside of meetings.

MR. MARAVELL: Right. So I don't, you know. This is, this would cover communications that we, you know, we've had with the public, whether it's through a working group or through a request for information. It wouldn't have to just be at this type of a meeting.

So I don't, I mean I don't think this is a big deal personally, but maybe I'm missing something here, that we're just saying from time to time, we may want to inform the Secretary of things that we have heard from the public concerning the operation of the program, and that's the way I interpret it.

CHAIRMAN FLAMM: Miles or Jenny, do you want to make a comment or ask a question?

MS. TUCKER: Hi. A couple of comments. This is Jenny Tucker. In terms of the policy on communication with the Secretary, the Secretary delegates authority for the NOSB to the National Organic Program. So we would request that any letter that is sent directly to the Secretary go through our Designated Federal Officer, who is Michelle.

As an example, at the last Board meeting, you passed the motion to send the GMO-related letter to the Secretary. That was submitted through the DFO and it was in the Secretary's hands within 24 to 48 hours. So that's an appropriate chain of command to submit information to the Secretary.

On the second point related to the public communications capability, a number of questions have come up in terms of, for example, email notification and will Board members be able to respond.

The motion here is you're -- would be to state that you want this kind of

capability to exist. The program would then come back to you with an implementation plan, in terms of here are the different tools that could be used to accomplish that kind of goal, and that would lead to an implementation and rollout plan that would roll from a recommendation you would make today.

But some of those answers have not been answered yet. We have to decide first that you want the capability.

CHAIRMAN FLAMM: I think Jay had his hand up next, though. Thank you, Jenny.

MR. MARAVELL: Yes. I don't think anybody has a problem with that, Jenny. But I just want to say that we're both a National Organic Standards Board and a federal advisory committee or advisory board.

So we're just simply looking for the way to provide our advice. So it would be -- our physical method of doing this is within the constraints of the Department's policy. So I don't see a problem with any of that.

CHAIRMAN FLAMM: Jay.

MR. FELDMAN: Well, the Subcommittee discussed the issue of how this wording should appear, and felt after discussion that we should just repeat the statutory language, and leave the implementation, as Jenny mentioned, the mechanics of how the thing gets delivered to the program, but that the language in terms of the direct communication, as indicated in the statute, between the Board and the Secretary, be preserved and memorialized in the PPM.

To answer John's earlier question, you know, this grew out -- or John's statement that this is a solution in search of a problem: this actually grew out of a problem. As you recall, there was some interest on the part of Board members to communicate with the Secretary after the Seattle meeting.

There had been a, what, 50 or some-odd comments on GMO issues, and it felt like, to some Board members, the

responsibility of the Board was to make the Secretary aware that the Board had been hearing from the organic community on this issue.

So a one-paragraph letter was drafted, and that then turned into a year-long project. But there could be opportunities here to keep the Secretary informed as to what is being heard at the NOSB meetings, to the extent that the Board comes together and feels there is something important to report to the Secretary.

So that's the intent here. In some cases, that may be a year-long project, to work something up. But in other cases, it may be a simple note, hey, this is what we heard at the meeting. We wanted to make you aware that this, that we heard x number of comments on this issue. It may affect your thinking one way or another. Sort of a factual communication that again, as Nick said earlier, is intended to be constructive, and

is intended to be helpful in terms of the overall program, USDA meshing with what happens here during the NOSB meetings.

So that was the intent, and it grew out of a sense that there was a need for this, and I personally believe the need may exist at some point in the future, where the Board feels it's necessary to bring that.

I don't see anything particularly at this meeting where this arises, but the authority we know is there, no matter who is managing the program or who's sitting in the Secretary's seat. It's just an ongoing, it reaffirms the ongoing ability of the Board, per the statute, to engage in that type of communication.

CHAIRMAN FLAMM: Nick, I'll recognize you in a minute. But I want to give the lead person on this an opportunity to speak, if she wants to. You are the writer. You ushered this through, and I think maybe you should have the opportunity to answer

questions.

MR. MARAVELL: Yes. I'd like to just state my understanding of this so that we're all clear. We're not talking about providing recommendations to the Secretary here, that would, you know, those go through a different process.

This is primarily informational. There may be some advice in it. But we're not providing recommendations under that type of authority.

The statute said we're authorized to provide advice. So this is what I would consider to be a lower-level type of communication, rather than saying we recommend this for the National List or something like that.

CHAIRMAN FLAMM: Harold.

MR. AUSTIN: I guess to me, it would appear that there's already a vehicle and a means and a method in place right now.

I think the process in the Board

and the communication between the program and the Secretary and the NOSB seems to have been able to function in the past, or we wouldn't probably be to where we are right now.

I think this does open up the potential for issues. I don't think it's clearly defined as what the vehicle will be or who will deem it necessary. Is it the entire Board that makes the decision on what communication? It doesn't state that.

Is it, you know, are those issues decided by a majority of the Board, or by individuals of the Board. I think if we're going to put something like this into the Policy and Procedures Manual that's going to replace what is in existence today, we need to be a lot more clearer and a lot more specific than what's on there right now.

I could not vote for this as it is written right now.

CHAIRMAN FLAMM: Colehour, as chair, I want to give you an opportunity to

speak before we -- we're past recess time now, so but would you -- you want to address the concerns that some Board members have stated?

We have a motion, and we'll need to either -- we need to either vote on it soon or withdraw it, and that's your call.

MR. BONDERA: Yes, very good. Thank you. Like when I introduced this, I will just remind the NOSB members that this is nothing new, and this, in this form, has been presented for quite some time.

But I appreciate people's responses nonetheless. I think it's relevant to speak about it. I do also, however, want to remind people what the program just told us, which is that they understand that we're seeking ways to achieve these goals, and their understanding is they would work with the NOSB to, like Harold just referred to, lay out the specifics, because that is some of the questions at hand, and I think it --

I acknowledge the fact that it

does say executive director, and there are other -- there's actually verbiage in the statute that, as John alluded to, is a little bit -- needs updating. But we're not in a role to be playing those kinds of roles very viably or in this context.

So that said, I would like to ask you, Jennifer, if you would like for us to -- you know, you're the one that made the motion. If you would like to withdraw this motion and we can continue this discussion tomorrow, I think that would be fine, and if you feel otherwise, I'm willing to entertain continuing with it at this moment. But I will ask you that question.

MS. TAYLOR: Colehour, I'm hoping that we will be able to go ahead and vote on it. I believe it's been properly seconded, the motion has. Yes. I'd like to continue our vote, to vote on it, please.

CHAIRMAN FLAMM: There is a motion that's been seconded on the floor, and we can

proceed with a vote, if that's what you would like to do. Any further comments or discussion?

If not, we'll proceed with a vote, beginning with Calvin.

MR. WALKER: Yes.

MR. BONDERA: Yes.

MS. TAYLOR: Yes.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

MS. SONNABEND: Abstain.

MR. STONE: Yes sir.

MS. FULWIDER: No.

MR. AUSTIN: No.

MS. FAVRE: No.

MS. BECK: No.

MR. FOSTER: No.

MR. DICKSON: No.

MS. RICHARDSON: Yes.

CHAIRMAN FLAMM: And the chair votes yes. Let's see what we have: 8 yes, 6 nos and one abstain. We have insufficient

votes for the motion to pass, and it fails. That's the end of the session today. We'll recess until eight o'clock tomorrow morning. Have a good evening, everyone.

(Whereupon, the above-entitled matter went off the record at 5:47 p.m.)

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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 my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R. Gross

Court Reporter

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

MEETING OF THE NATIONAL ORGANIC
STANDARDS BOARD (NOSB)
+ + + + +
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

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, CACS, 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

Richardson to present a summary of the calculating percentage of organic ingredients discussion document, and summarize the public comment that the Committee has received to date. Jean?

MS. RICHARDSON: Thank you. I'm going to try to be relatively brief on this very complicated topic. So, bear with me, and then of course, there is time for questions later on.

So, the problem, as presented to us, basically is that there may be a lack of uniformity amongst the accrediting certifying agencies, the ACAs, in their procedures for verifying the verification of the calculation of percentage of organic in multi-ingredient products.

And so, what happened was that the NOP asked us, the NOSB, if we would develop a discussion on this issue and seek public comment, in order to get a clear understanding of what the situation was, and if we could

scroll through that, Michelle, to where the relevant area of the rule is, just so that -- not everybody is necessarily familiar with it. Yes, if we could just scroll that up and then just sort of leave that up there, for your reading, while I talk.

So, here is the relevant area of the rule, of how to calculate the percentage organic in multi-ingredient products.

It's relatively straight forward on the surface of it, take out the water, take your liquids, take your dries, add them up and it should be relatively straight forward to do.

But the NOP had found, in doing their audits around the country, that there was a lack of consistency from their perspective.

So, we sort -- so, we worked on this ourselves, on the NOSB Subcommittee. We sought information from -- well, I'm an inspector, John is in inspection and Zea and

other people on the Board have some experience, obviously, in just doing this themselves, from different perspectives.

So, that was helpful, and then we talked to some different major certifying agencies, and got copies of their forms and so on, and then developed a set of questions to send out to the broader community.

I should say at this point, that we received an absolutely excellent response from several major certifying agencies. It was in fine detail.

They spent a long time, helping us to understand more clearly, the issue from their perspective, and we also got them from Organic Trade Association, excellent detail that we -- was very useful, from a major processing company and from Organic Valley, as well as from individuals from individual people, and they were just really, really useful.

So, basically, what I'll try to do

is summarize, using some of these documents, just summarize sort of the findings.

Generally speaking, if you just put it into one paragraph, in most cases, the ACA, the Accredited Certifier's Association, the Association of all of the accrediting agencies, they really feel, from their perspective and all the work that they've done, that there is training that goes on, and not everybody goes to the trainings, however.

But by and large, most of the certifying agencies are doing a relatively consistent job, if not, a very consistent job, obviously amongst the large certifiers, but processing, especially for multi-ingredient processing, has grown so fast, that some inconsistencies may have sort have been built in, as the industry has grown.

And so, therefore, they appreciated, apparently very much, the fact that we were putting out this discussion document, and came back with some excellent

recommendations to us, as to what to do, including especially, that there should be a large amount of training and information materials placed on the NOP website, that would be easily available to the larger, the smaller ACAs, whoever they are, whenever they feel that they need some information, together with specific examples of what you do in this situation.

How do you actually develop a specification sheet? How do you deal with the individual materials that are not properly described on their certificates, and examples of better ways to do this, and then they provide some specific examples, which we will be putting into our recommendation or guidance, as we begin to develop it.

So, some of the other -- we posed a series of questions, and I'll just sort of give some of the answers that we got from all of the public comment.

Nobody seems to want there to be a

standardized form, and by that, you know, there is like a -- you know, we looked at these in our Committee, this was a simple, self-calculating sort of Excel spreadsheet type form that the larger accrediting agencies use, where you just type in the numbers and magically, the organic percentage appears at the other side, which makes for relatively easy verification, when you're an inspector, and it puts the burden where it should be, on the processor and the handler, in terms of keeping track of that information.

The complexities come in, of course, when you have sub-ingredients and sub-ingredients, and you go back through the system, trying to track all of those percentages, narrowing it down to less than one percent of some minor ingredients, as you're trying to do the calculation, and that's where we need to have some of these specific examples put onto the website.

But there was a general feeling

from everybody that we didn't want just one form, that there is enough subtle difference between the way in which the different accrediting agencies do their forms for their calculations, that they should be -- have their own forms, as long as they meet the letter of the law, in terms of the ability to verify the percentage organic.

So, in fact, the statement was, "It's not the form itself that's important, it's the method of calculating, is what is really important," and guidance is really needed for that.

Same thing with specification sheets, which came up from several of the commenters. If you have sub-ingredients, and you know, you're doing a cookie mix and you've got a bunch of flavors and chocolate chips and all kinds of stuff that are going to go in, each of those need to have specification sheets that would make it much easier, as that product goes through from the processor to the

handler/distributor, through the processing system.

On salt, we asked them if the only salt that was used in their calculation -- excluded from the calculations was sodium chloride, and the answer to that was, yes, sodium chloride is the only salt that is used to be excluded from the calculations, and that needs to be clearly stated on our guidance document and on the NOP website.

Let's see, other things, yes, there is -- very often, when a certificate comes out, like for example, there is a producer that has -- they're producing apples and lettuce and a whole range of vegetable crops, sometimes, those certificates say 100 percent on it. Other times, they just say 'organic', and they may or may not have an addendum that goes with their certificate.

It may just be a general certificate that says fruits and vegetables organic, and that is not very helpful, if that

product is going to go into a multi-ingredient processing product to be developed, because you don't know whether you're dealing with 100 percent, or are you dealing with 95 percent.

Are processing aides being used? Has there been any post-harvest handling that would indicate that the product was less than 100 percent?

So, we need to have clarification on what would be -- what is needed on the certificates, to make sure that that label, that the consumer sees at the end, clearly reflects what the percentage organic was that went into that, because sometimes, these aides that are used or post-harvest treatments or the manner in which the raw ingredients is handled, sometimes those become ingredients and not just processing aides and not just -- like the citric acid that goes into the tomatoes.

So, we need to have examples, specific examples of when you need to have --

what you need to have on those certificates, that will allow for clarity.

Let's see, other things. Yes, it was pointed out that most of the ACAs do not include processing aides in their calculations. They will be on the back sheet, or they -- and they may be on the calculation sheet itself, just as an aside, but they're not normally -- they're not used in the calculations, but then some of the ACAs do.

So, again, we need information about what -- we need to be sure clearly, that we've expressed request to be sure that the processing aides used, are listed clearly, so that the handler, the processor can clearly demonstrate the extent to which there is a lot of that processing aide, a little bit. Does it -- when does it become an ingredient, in order to again, determine if it should be counted in the organic calculations or not.

So, like here is one statement from ACA, "Based on the results of our survey,

it appears certifiers could use guidance in determining when a processing aide is considered present in the finished product, at an insignificant level versus present at a significant level, and when a processing aide warrants re-classification as an ingredient, counted in the organic calculations, and listed on the finished product label," and it's those subtle nuances that the small numbers below five-percent and often, below one-percent, that become kind of critical between -- because if you don't do the calculation properly as you obviously know, then your product will drop down from being -- from the organic category into the 'made with' category, which is not what a processor necessarily wants.

There was general consensus that we didn't need a rule change for the fact that in the present language, the language of the law at Section 205.302A, one, two, three, wherever that is, up there, is that the -- in

regards, the finished product versus the use of all ingredients, it was considered that that would just be a very simple minor change to make, and the accrediting agencies felt that simply a recommendation or guidance from the NOSB would help to clarify that, since it is, indeed, that we calculate the ingredients based on all ingredients, and not just the finished product numbers.

The salts, we did that. Yes, there was -- another one is that we need to clarify when we're presenting our guidance, our recommendations, whether water that comes in with the processed ingredient is removed from the calculation of the organic content in a finished product.

For example, chicken broth. You don't consider all of the chicken broth, only the solids in the chicken broth, and not the water.

So, at what point -- if you're adding chicken broth to your multi-ingredient

product, you've got to be sure you've taken out the water of the chicken broth that you're adding in, before you make your final calculation.

And again, we'll need to have specific examples of these, when we put them on the -- when we put out guidance and when we put them on the website.

Let's see, and we could -- and would we please -- another question or statement was, "Could we please provide specific examples that would demonstrate the impact of failing to exclude water and salt on the proper labeling category?"

All of these are just very doable and very straight forward things, I think, that the NOSB can certainly work on in this coming semester.

Okay, so, sort of in sum, that we've got a lot of encouragement from everybody to move forward with a detailed recommendation, as soon as possible, regarding

a need for clear and comprehensive guidance document, and to request that additional webinar style training for ACAs be done by the NOP, on a relatively regular basis, so that as this burgeoning and fast increasing market really, means that there is an increasing level of confidence of the consumer in what that label actually means at the end, that says percentage organic.

So, that's, I think basically, all I really need to do on this topic, and take questions from the Board.

MR. DICKSON: Thank you, Jean. Are there questions or discussion from the Board?

MR. STONE: I'll just add that we intend to engage the certifier's ACA on some of these judgement calls, if you will, that the folks that are using and that help all the time, working with handlers, so, the people that are close to the decision making can advise us in the best way.

The people that are close to the decision, help make that decision and engage them very closely, so, we don't kind of sit in a -- we're not going behind the curtain to finalize this recommendation, I guess is what I'm saying.

MR. DICKSON: Any other questions from the Board?

As far as next steps on that discussion document, our work plan is currently to take the feedback that we received and fashion a recommendation on this topic for the Spring 2013 meeting.

Next, we have Barry Flamm presenting the discussion document on biodiversity.

Barry?

CHAIRPERSON FLAMM: Thank you, Joe. This discussion document is about implementing biodiversity conservation in our organic agricultural systems.

The purpose of the document was to

review progress in implementing the Board's recommendations on biodiversity conservation, which was made back on May 6, 2009, and approved by the Board, by all, but also, to identify other aspects of implementing biodiversity conservation standards that may require further attention, and by seeking the input of the organic community, and another purpose was to further call attention to the importance of biodiversity in organic production systems.

As a way of a little background, which isn't really needed with this group, I think, because I think the value of healthy agriculture and for society at large, depends on protecting biodiversity, and this is reflected in a number of places in the -- in our organic regulations, and in response to this, the NOSB issued guideline statements in 2004, 2005 and again, in 2009.

And during all this period, there has been tremendous, outstanding work done by

the organic community. Much of that is -- really, great work has been done by the Wild Farm Alliance, the International Organic Inspector's Association has done a lot of work on training inspectors, and we got help from ATTRA, providing producing guidelines and so forth.

My first meeting in May 2008, five years ago, Lynn Coody, representing her -- both herself, and the Wild Farm Alliance, called to attention to the Board, the -- a need for some follow up action by the Board, and this ended up with the Board -- the Board agreed with these comments, and established a joint CACC then, and Crops Committee, to look into the problem and issue a statement.

There was a draft document produced, that received lots of comments, lots of ideas, and that led to the recommendations and guidance that was produced in the following year, in May 2009.

That document sort of divided the

issue up into two parts. One dealt -- one part -- the first part dealt with what the Board itself could do, and that dealt with a material review and looking at our checklist and so forth, and see how biodiversity could be better addressed.

The other dealt with the organic system plan, which is so key to the whole -- our whole system. That's what gives us both a way of implementing organic standards and guidelines, but it allows for the flexibility to fit the situations, and certainly, biodiversity is a case where every -- practically every farm is a little bit different. So, you're going to have different solutions.

The recommendations there, again, under the plan, the recommendations were divided up for the certified producer, what they could do, what the inspectors could do, what certifiers could do, and what the NOP could do.

And in this review, we looked at each segment of this, and asked them some questions that -- of each, not only, we wanted to find out what the progress was, but also, whether there was other things we could do, and then -- and in this process, there were a few questions asked that we were trying to get some response to.

Just those -- under the material review, a question that was asked was, originally in the first -- and the Board had added questions about biodiversity conservation, the impact, but this was sort of a negative statement.

The question was, what are the positive impacts a particular material might have on biodiversity, and that was a question.

One of the issues that was raised as an issue, but without any proposed solutions, really in the 2009, was a high value lands, you know, natural lands, high value conservation lands, that might be

converted to organic production, and you know, those lands might -- they can be tempting, for one thing, because you don't have to wait for the transitioning, if they're natural.

So, there was some issues there, and we -- the Wild Farm Alliance, besides some 39 other groups working with them, had made some recommendations, and we raised the question about their recommendation, what the whole organic community thought of that.

Then there is -- I think the other question was about handling operations, and we had heard that some certifiers didn't think that asking -- that handling operations had any impact or needed to pay any attention to biodiversity. So, we asked questions about that.

We really got some really good written comments back from -- we got excellent comments back from all these people, the ACA, Beyond Pesticides, Center for Food Safety, Cornucopia, NOC, OCA, Oregon Tilth, Wild Farm

Alliance and several individuals, and yes, I found this one a little late, but QAI had comments also, and I hope I didn't miss anybody else.

The way it's organized between general and specific topics, it takes a little bit of searching.

But these are excellent comments, and I think we'll give these, all of them, further review in the Committee, and then we got some very excellent comments during the meeting, the session, and I'm personally looking forward to Lynn Coody's comments today.

So, I think it's sort of appropriate, five years, 10 meetings later, that she starts it off and has, not the final word, but today, because there is no final word on biodiversity. It will be something we're always going to be -- if we're diligent, we'll always be working on it.

I think, as I said, this -- the

comments are, you know, really very useful. I think the -- everybody, all the comments acknowledges and recognizes the value of biodiversity. I think everyone thought the approach that was taken into those recommended in 2009 were the right approach.

I think everybody agreed that, you know, we ought to address the positive impacts of a material on the -- when we review it, on material checklist.

I believe the only comment we had that questioned doing that was Oregon Tilth. I think there was agreement on conversion of high value conservation lands, as really, an important issue.

There wasn't universal support, but there was strong support for the approach that Wild Farm Alliance made, and those recommendations actually were in a package of other recommendations to the National Organic Program.

Not surprising, there was

universally strong support for the need for further education and training, and I think there was agreement that handling operations can affect biodiversity, and that is something that cannot be ignored, and finally, I think several commenters pointed out the importance and need for further National Organic Program guidance, in order to achieve better implementation.

There has been excellent progress in that area, and much of the recommendations were -- that had been made in 2009, either have been accomplished or are being implemented or on the work plan to be done, soon.

So, I think Joe, that is the summary, and I hope we, you know -- I think we need, as a Committee, to study these comments and look at what we got out of that and figure out in the Committee, you know, what further action or how we should proceed. So, that concludes my comments.

MR. FOSTER: Thank you so much, Barry, for keeping up the momentum on this important issue.

Is there discussion from the program or the Board, on this particular discussion document? Questions?

All right, thank you, Barry. Now, we move on to public comment on the CACS work plan.

We have Lynn Coody up first, followed by Bonnie Wideman, on deck.

MS. COODY: Good morning. My name is Lynn Coody and I'm commenting on behalf of the National Organic Coalition, a national alliance of organizations representing farmers, environmentalists and other organic industry members and consumers who are concerned about the integrity of the national organic standards, and today, I'm commenting on the biodiversity discussion document.

NOC concurs with the CAC that both the NOP rule and the principles of organic

farming recognize the value of fostering biodiversity in organic production systems.

NOC has consistently supported the NOSB's recommendations that have encouraged NOP to implement the existing standards on biodiversity and nature resources conservation. We're pleased that the CAC has developed a discussion document to assess the progress on this topic.

On the topic of the NOP instruction on biodiversity.

CAC reports on NOSB's earlier discussion for the need of additional guidance on biodiversity and nature resource conservation, because both operators and certifiers and have expressed that more information would be helpful to them, in implementing NOP standards on these topics.

NOC thinks that some further explanation from NOP about its expectations, with regard to implementation, will serve to both clarify and standardized certifier's

approaches to these topics.

NOC favors development of an NOP instruction that would be framed as a requirement for certifiers under Section 205.501-A21, which is the provision on other requirements for certifiers. This would make it a mandatory requirement.

Applicability to handling operations. NOC notes that the regulation requires that operations of all scopes of certification address biodiversity. So, instruction on the NOP's expectations with regard to assessment of handling operations would be especially helpful.

Although handling operations deal mainly with indoor environments, NOC suggests that there are many opportunities for addressing biodiversity in natural resource conservation, such as, here are a few examples.

Landscaping methods and materials around processing facilities. Management of

nearby lands, to mitigate the loss of natural environments, such as wetlands or other sensitive environments, when building processing facilities.

Pest control systems that are sensitive to non-target species. Wastewater treatment systems that protect both water quality and quantity.

Air handling systems that shield natural systems from dust and fumes, and plantings that create shelter and food for beneficial insects, bats and birds.

Audit checklist. NOC notes that the NOP previously recommended revision of the checklist used to audit certifiers, so that the checklist include questions about NOP's biodiversity standards in every assessment of certifiers.

We are pleased to see that the NOP recently posted revised checklists that do implement this recommendation.

Now, that NOP has taken that

positive step, we endorse a further step, recommended by the NOSB, that is including the topic of biodiversity standards in trainings that NOP provides for the accredited certifiers.

Finally, penalty matrices. NOC continues to review new policies of the NOP with an eye to evaluating their sufficiency for supplementing the standards on biodiversity and natural resources. In September 2012, NOP issued an instruction, and NOC reviewed the penalty matrix associated with this instruction for the requirements of implementing biodiversity.

We concur with the comments of Wild Farm Alliance, about the importance of specifically mentioning biodiversity and natural resources in the penalty matrix, as NOC thinks that the current mention of soil and water quality is not broad enough to address operators compliance with all elements of Section 205.200.

Thank you. Just perfect. The only other thing I'd like to say is, again, thanks so much to Barry, for spearheading this great effort on biodiversity. It was really great to be there, making my presentation and having Barry as his first meeting, really speak up strongly and help out. So, I appreciate it.

MR. DICKSON: Thank you, Lynn. Any questions for Lynn? Jay?

MR. FELDMAN: Thanks, Lynn, for all your work on this.

What should -- what do you think the NOSB should expect, in terms of things moving forward?

You know, if you were to lay out a time line for things to happen vis-a-vis training and certification in this area, what should be the expectation of the NOSB, for that time line?

MS. COODY: Well, I think that we've come a long way and we have a lot of

pieces that the NOP, itself, has actually worked on.

So, I would like to see -- I mean, there is a great training coming up in January, and I think there could at least be an initial review of what is in place now, and what -- how certifiers can implement this.

Of course, many certifiers are already implementing this, you know, they have taken steps voluntarily to include biodiversity in their OSP forms and things like this.

But as far as the penalty matrix and the expectations about the way that certifiers will be assessed in their accreditation audits, I think that would be really great topic for including in the NOP's training in January.

So, I don't think it would be that hard, and they are already obviously, doing these assessments. So, just letting certifiers in on what to expect, would be

great.

So, that is one -- that is -- you know, I'd like to do that. I'll be at the training, and I'd love to see that.

MR. DICKSON: John, did you have a comment?

MR. FOSTER: Yes, a question, actually. Thank you, Lynn. That was very good.

My question, not surprisingly, is on the handling.

MS. COODY: Yes.

MR. FOSTER: Kind of the expectation. So, do you see that eventually ending up in the form of standards, regulation or is that guidance or -- because that -- the options that you laid out there are all very sensible, you know, thoughtful and likely, doable kind of things.

MS. COODY: Yes.

MR. FOSTER: Where, in that hierarchy, do you see that falling and what --

you know, how do you see that playing out?

MS. COODY: Well, I think, John, it could easily be included in this instruction, that I recommend that the NOP use to help certifiers understand exactly what is expected.

So, some certifiers have already included, as I said, they already include this in the handling inspections. But others, it's a new area for them.

So, I think it would be a good thing, to have a specific area in this instruction, about handling -- the applicability of these standards to handling operations.

It would help, not only certifiers know how to implement this, it would give handlers an idea of, you know, what they could actually put in on their -- how they could fill out the portion of the OSP and what is -- many handlers are already doing things like this.

So, they can kind of get biodiversity credit for some of these activities that are already occurring.

MR. DICKSON: Thank you, Lynn.

MS. COODY: Okay, thank you.

MR. DICKSON: Next is Bonnie Wideman, and on deck is Marty Mesh. Don't leave the room, Marty.

MS. WIDEMAN: Good morning. I'm Bonnie Wideman. I'm the director of Midwest Organic Services Association, or MOSA, and we certified 1,500 operations in 20 states. I'm also the steward of the land at Pine Knob Organic Farm, and I raise sheep, beef and have organic wool and lamb skins.

I'm retiring at the end of this year, and I'm going to be able to devote myself to my farming, and because I'm retiring, I'm at a point where I can look back and I look forward, and I want to express my concerns, that are joined with the concerns of other farmers, in that we are being

overwhelmed with paperwork and the need for documentation.

And also, at the same time, I think many farmers would agree with what Vashi said, about the floorboards of organic being taken out, but the ceiling not being raised, and I think the biodiversity is a really, really important area.

On my own farm, I have it in a conservation easement, no mining, no development, no conventional farming. I'm going to read to you, a comment by an outstanding conservation farmer that we certified organic, and when I read it, I don't want it to come across as anti-biodiversity, but what I want to stress is that we're not following through on this age of enforcement by increasing the length of the organic system plan.

What we need is guidance from the NOP, as to what we are to look for in biodiversity.

I would love it, if we didn't certify corn that was planted on land coming out of CSP. You know, but give us the tools to enforce. Empower the certifiers. You could do the same with animal welfare. We don't need to lengthen the OSP. We need to feel empowered.

So, here is a statement, and again, this is from a farmer whose family, generations back, were leaders in conservation farming, in the Coulee Region of South Western Wisconsin.

"Well, Bonnie, I am," this was in 2006. We had included a few questions on our OSP, suggested by the Wild Farm Alliance. I took them out the next year.

"Well, Bonnie, I am about done with my MOSA application, and I have to confess, I hate it more every year."

"Nowhere in bureaucratic heaven or hell are there more extensive or more complete collections of inane, pointless, redundant,

stupid and just plain impossible questions. Like, have you assessed the farm for biodiversity problems and greatest opportunities, then developed goals and a time line for biodiversity conversation, then please describe or explain."

"To make the point of how stupid your question is, you give me one quarter-inch of unlined paper for an answer that the EAP would spend $3.6 million in four years, answering."

"The final insult is when you are done with this monstrosity, the organic application, the instructions say, take your 47 pages, pull out the staples and make two-sided copies of everything. MOSA needs to review this process. I have spent two days on it, and I am sure, I am going to be told it is incomplete. Compliantly yours, Vince."

So, I made it before the buzzer. So, thank you, all. Any questions?

MR. DICKSON: Thank you, Bonnie.

MR. MARAVELL: Thank you for your comments. I know that many farmers share the sentiment of the quote that you just gave, and they are sincerely trying to meet the goals of biodiversity.

So, to the extent that we can come up with the type of flexibility that a farmer is willing to respect, in dealing with a certifier, would be great, because I must -- I guess I should -- for full disclosure, it takes me more than two days, to fill out my OSP, and it's getting longer, each year.

So, I applaud you on your courage and for the goals that you stand for, and please, help us come to -- give me the time to go out and do the work of biodiversity, get me out of the office.

MS. WIDEMAN: Thank you.

MR. FOSTER: Bonnie, one more. Bonnie, one more question.

MS. RICHARDSON: Bonnie, I want to thank you very much for your comments, and

they're really right on point.

You know, I've been doing organic inspections for the last -- and this is to the Board, too, for the last 13 years, and when we started doing the inspections 13 years ago, we had like three sheets was the OSP, and our inspection report was maybe two sheets.

I mean, it was really, pretty much, check off, and there was a lot of exchange, and just -- I mean, there was probably more discussion than Miles would have liked us to have had, but you know, we -- it worked pretty effectively and it was very sort of educational and empowering to the farmers.

But then now, when I go there, their OSP's are usually, I don't know, 25 pages long and plus, all the necessary attachments they have to put in, and then my inspection report is usually, I don't know, 25 pages long for a vegetable farm. I mean, it is excessive, to put it mildly.

And I really agree with you, and I

think it's an important thing for us to be looking at on the NOSB Board, as we begin to work to exchange information with the ACAs, to say, you know, all those folks sitting in the accreditation offices, you know, the kind of people that are there, and I mean, I know lots of these nice people, but they're very focused on forms, and they don't necessarily go out on the field and do a lot of the actual inspections, perhaps as much as they ought to.

So, to try to reduce the amount of paperwork, and that just doesn't mean turning everything into computer systems, I'm not sure that that is the answer, either, because I think we have to remember, as you're pointing out in your presentation, that these farmers are human beings trying to make a living, and we do have to be empowering and helpful in every -- in many different aspects.

So, I think greater exchange between what the accrediting agencies feel that they need, what NOP thinks that they need

to do their audits right, remembering that we're dealing with either processors and producers or farmers who are trying to make a living by working with a system, which has become increasingly complex, especially as we begin to add in things related to gap certification, as well, and all the other things that are coming in.

So, I really appreciated your comments, and I hope you stay, even though you're going to retire, I hope you'll continue to give us some specific examples and feedback, as we try to come up with some useful guidance that doesn't swamp the processors and producers, anymore.

MS. WIDEMAN: Right, I think it needs to be -- farmers have commented that inspectors don't inspect anymore, they just review the paperwork.

But biodiversity should be inspected and enforced, and it needs to be done on the farm, not on the paper. Thank

you.

MR. DICKSON: Wait, don't go anywhere, yet.

Zea?

MS. SONNABEND: Thank you for the comments, Bonnie, and in general, we at CCOF completely agree with you, and really hope the NOSB, in the future work plans, will get around to working on some issues regarding how much paper is appropriate.

However, in my long experience as a farm inspector also, I know that just as biodiversity encompasses a great deal of different types of systems, there are a great deal of different types of farmers, and those questions which are irrelevant to, you know, many, many farmers, will be really significant for some farmer with some type of farming system, somewhere.

And so, at some point or another, you know, all of those 25 pages come into play, although not all on the same farm, and

that is what we have to struggle with, to make sure we can encompass all the situations we find out there in the farming world.

So, we hope you will continue to participate and help with that, as we struggle with that.

MS. WIDEMAN: I certainly will.

MR. FOSTER: Hey, Bonnie. I think we have one more question, sorry.

MS. WIDEMAN: It's getting embarrassing.

MR. DICKSON: Barry?

CHAIRPERSON FLAMM: I don't want to wear you out, but I just want to -- as sort of lead person on this, thank you for those comments, because we did get those kind of comments back on -- in 2008 and 2009, from farmers, and we're --

But I think what you said is a good reminder to keep it down to earth and what we all want is the -- is to be able to help the farmer do a better job in

biodiversity conservation, because that will help him, in the long run on his farm.

And I thank you very much for reading that and reminding us of the realities and impacts, and we don't want more paperwork. We want better practices, and to help the farmer do it. So, thank you very much.

MS. WIDEMAN: You're welcome.

MR. DICKSON: All right, I think you can go now. Thanks, Bonnie, and Marty Mesh, with the last word.

MR. MESH: I'm Marty Mesh, the executive -- you don't have to be sorry, they all appreciated it, actually.

I run a non-profit called Florida Organic Grower's, just a credit, Florida Organic Grower's, our certification program, quality certification services. I think, I didn't prepare written comments, because I didn't even know how long you get with these things, whether it's three or four minutes, and I was too busy.

But I think the overarching thought that I had is to thank the Board, obviously, for all the work. It's a tremendous amount, on behalf of everybody. I think, Barry, the other night -- and the biodiversity stuff, we certainly were supportive of, although our certification program, Bonnie articulated it all well, and I didn't know what she was going to say, beforehand.

You know, I was scared when Barry no longer has a valid certificate, but wanted to keep his old certificate, you know, during the reception the other day, I that I heard, I came up to him and asked, "I hope that you didn't give up your certification because of the expectation of increased paperwork related to complying with the biodiversity standard," and so, Bonnie's comments, I just want to echo and reiterate.

I've expressed concern that, you know, our certification program again, while

it's supported, biodiversity had a real fear of increasing the amount of paperwork in time, and sometimes, it feels to me like, you know, we're our own worst enemy, as far as the goal of growing organic agriculture, and I see it sometimes in materials review, changing the landscape, changing the rules, you know, you encourage.

You know, when I buy a product personally, I really look at, you know, what effect does it have on the farm workers, farmers, the environment, and I want to support that product, and that is why, you know, I choose to buy organic products a lot, and so, to have something that is, you know, 99.9 percent organic product, I look upstream, and I don't really care that it has some little thing in it, and I wonder sometimes, on the process of it.

I also, you know, I am scared somewhat, I heard the talk about inerts ingredients reviews, which I know are

important, you know.

But you know, the amount of work and materials reviews that I think the staff -- I don't know if you guys even talk about to the National Organic Program staff, or your own materials review committee, about what the inerts review will entail. It seems just a tremendous amount, and so, the whole thing seems to be getting not only paperwork-y, but you know, top heavy in the sense of the program.

And you know, when I think back years ago, that was what my farming partner said is, you know, when he didn't support the National Organic Program and I did, he asked me, "You know, tell me one thing that the U.S. Government has done, that has been good for organic farmers like us," and it was deathly quiet in the watermelon field that day, because I couldn't think of it, and I said, "I'll make this one different."

But you know, I see farmers

fleeing now, from organic because of not so much that they're running away from farming organically or the commitment to environmental stewardship, but from the paperwork and the bureaucracy and stuff like that.

But I wanted really, to make sure that I was the last public commenter that Barry ever heard, sitting on the Board, so, I signed up for the last slot, and I just wanted to say thanks, and we have a little parting gift for you, a little DVD from a film that has biodiversity methods in it.

MR. DICKSON: Thank you, Marty. That concludes the compliance -- that concludes our part of the meeting. Barry, I return the imaginary gavel to you.

CHAIRPERSON FLAMM: I've been asked to make an announcement, that the Board should sign the 10-year anniversary poster. It's in the back there, and so it can be put up.

So, everyone, when we have our

upcoming break, please, if you haven't signed it, sign the board back there, and Michelle can put it where you're going to put it.

Anyway, I think we're scheduled for a break, now. We may be a little ahead of schedule, but we'll take our break, and then we'll come back to address the proposals that were deferred. We have four proposals from, I guess, three committees that will be further discussed and voted on, this morning.

So, let's take a 15-minute break and be back here at, let's see, 10 after the hour.

(Whereupon, the above-entitled matter went off the record at 8:57 a.m. and resumed at 9:17 a.m.)

CHAIRPERSON FLAMM: Board Members, please take your seat.

Our business now is to address the deferred proposals, from the last several days.

We have four deferred proposals

for the final vote, and beginning with the Crop Committee.

Crop Committee, do you have a motion on any of your deferred proposals?

MR. FELDMAN: Yes, Barry, thank you very much.

CHAIRPERSON FLAMM: Do you --

MR. FELDMAN: I have the motion on rotenone here.

CHAIRPERSON FLAMM: Okay.

MR. FELDMAN: Okay, sorry for the delay. Appreciate your indulgence.

The classification motion, first. I move that rotenone is a natural substance. Can I get a second on that?

MS. SONNABEND: I'll second.

CHAIRPERSON FLAMM: It's been moved and seconded to classify rotenone as a natural substance. Discussion? Any discussion by the Board?

To clarify the motion, if you'll agree, Jay, it's to add rotenone to the

National List 205.602 as a prohibited natural substance. No, that is the next part, sorry, I'm ahead of the game.

MR. FELDMAN: You're ahead.

CHAIRPERSON FLAMM: Excuse me.

MR. FELDMAN: Yes, that's where we're headed.

CHAIRPERSON FLAMM: Okay, sorry. Any discussion?

Hearing no discussion, I think we can proceed with a vote, beginning with Colehour.

MR. BONDERA: Yes.

MS. TAYLOR: Yes.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

MS. SONNABEND: Yes.

MR. STONE: Yes, sir.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: Yes.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

CHAIRPERSON FLAMM: And the Chair votes yes. So, we have 15 'yes', zero 'no', and the motion to classify rotenone as a natural substance passes.

Okay, now, for the listing motion.

MR. FELDMAN: I move that we -- the motion -- the following motion, to add rotenone to the National List 205.602 as a prohibited natural substance, effective January 1, 2016. Second, please?

MS. SONNABEND: I'll second.

CHAIRPERSON FLAMM: We have a motion, which has been seconded, to add rotenone to the national list 205.602, as a prohibited natural substance, effective date -- effective January 2016.

Discussion on the motion? Hearing none --

MS. SONNABEND: I'll discuss.

CHAIRPERSON FLAMM: John?

MR. FOSTER: I'm surprised I'm the only one, but so far.

So, I've kind of gone back and forth on this, and I mentioned some of my concerns, the other day, about the optics of it.

But I want to at least, talk a little bit about the process of it, you know, having not been a petitioned move, and how that impacts timelines in people's minds, and that it was something we brought forward, as opposed to a different process that we're more used to, and I really -- I would like to be more comfortable with that process, and where we all feel -- how we're feeling about that.

Because I haven't been involved in a lot of those conversations, so, I wouldn't mind hearing how people are feeling about the process of it.

CHAIRPERSON FLAMM: Jay or Zea,

would you like to address that?

MR. FELDMAN: Okay, just to clarify, John, I'm sorry, I was a little distracted.

You want to hear about a discussion on the process?

MR. FOSTER: Just that this came about --

MR. FELDMAN: Okay.

MR. FOSTER: -- you know, as a result of an atypical process.

MR. FELDMAN: Yes, yes, yes.

MR. FOSTER: And you know --

MR. FELDMAN: Yes, exactly.

MR. FOSTER: And I would like to have more thoughts on that.

MR. FELDMAN: Okay.

MR. FOSTER: Because I'm a little sketchy about that.

MR. FELDMAN: Well, I think this is -- good point.

This has been a learning

experience. This was a Board initiated action, essentially. A Committee member brought this issue to the Crops Committee.

Based on, almost a housekeeping issue, that rotenone had been voluntarily cancelled for use in the U.S., by the registrant, by the manufacturer, and it was being phased out and it was determined that even though there is an existing stocks provision of rotenone, that there was -- it was still legal to use in the U.S., and it was confusing that it was not prohibited on our national list, given that there was no longer any use.

Now, because it was initiated through the Committee process, there wasn't a full petition, and as you -- as we all know, the petition process essentially, is public notice. It is posted -- the petitions are posted on the NOP website, and gives the public an opportunity to first of all, be aware, and then bring information forward, et

cetera.

So, and prepare, really prepare for a potential outcome that might change their practices.

So, since we didn't have that process, I think there is a feeling that more time is needed on the back end, as almost a notice to folks, to let them know.

But that is why the date certain was added to this provision.

Now, you know, there is also the feeling that when you take an action, that requires people to plan, change their practices, their tools or whatever, that giving them a date certain is a very helpful tool.

We recognize that dates cannot always be met, and it's hard to predict when something will actually work its way through the regulatory process, but that a three-year time frame sets the right tone and message, that there is concern, as there was within the

EPA regulatory process of the harm associated with the use of this thing, and that the organic standard should not counsel the use of this -- of a material with these sorts of hazards.

How that gets implemented around the world, domestically and around the world, is hopefully in a uniform way. We're leveling the playing field for everybody that is growing under the organic standard, to ensure that a material that does not meet the criteria of our statute is being following, and we realize at this point in time, that the remaining users are in developing countries, in banana growing regions of the world.

But again, our role here is to establish a uniform standard that we believe is in compliance with the organic law, and we hope that folks in Latin America and around the world can find a -- we trust they will find an alternative to address the thrip problem that they're struggling with in

production, and Zea, I guess has more to say.

MS. SONNABEND: My personal agenda, in coming onto the Board, has a lot to do with being very familiar with the history of this Board and the 20 years that it's been around, for which I've been privy to most of, and there are a lot of loose ends that have occurred over that time.

Petitions that were tabled, never to be seen again, and things that got resolved in different ways, at different times, and past arguments that really got resolved by the Board saying, "We'll take a look at this in another five years," and then it never happened, and that is what this is.

In 1994, there were people at the equivalent of this table, screaming over this, and the review at the time was not really that complete by today's standards.

I quoted the entire review, in our document, the one paragraph, that made it into the transcript.

So, it's really worth honoring the sense of the previous Boards, by taking another look at something like this, and also, the fact that we get questions from consumers and constituents all the time, concerning this, and so, that is why it got brought up.

But that being said, I agree with Jay, it's very important that the organic community at large has plenty of notice about pending actions, and that is why we feel like we've chosen a sufficiently long time frame, but have a certain date on it, so, rather than just open-ended for however long the rule making takes, because the certain date enables people to get ready and start doing the work on alternatives.

CHAIRPERSON FLAMM: Harold?

MR. AUSTIN: While I support the motion as it's been presented, I would like to point out, on behalf of that stakeholder group, that we sprung this upon them pretty unexpectedly.

The regulatory process, for goodness sakes, we know is slow enough in our own country, let alone if we go into a third-world country.

My concern is that the expiration date that we've given will possibly not be sufficient for them, but at the same time, I think it does engage them to the fact that there is a pending drop-dead date out there, and it will then, help them to get involved and start the process moving forward.

I would suspect that they will come before us at some point in time, and ask for an extension of time, and I hope when that point in time comes, that does not fall upon deaf ears, and we give it full and due consideration, when they come and they, as a stakeholder, as for our help and consideration, because I think a part of this, the time frame that we've done is also part.

Our lack of doing our job as a Board, and not -- and we ignored outside of

our country, stakeholders that are certified by the program, that we are still -- that are also engaged and follow the same rules that we all follow.

CHAIRPERSON FLAMM: Nick?

MR. MARAVELL: Yes, thank you, Barry. I'd like to draw a little bit of a parallel to tetracycline and streptomycin, in this situation.

I think it's appropriate to consider an extension of timeline, but not without certain considerations or conditions.

One is that for the date certain, this gives them the ammunition or the sense or urgency in their own countries, and number two, if people come back to us without a report of what they've done, the progress that they've made, the actions that they've taken, and to justify an extension, I would hope that any future Board would not look too kindly upon that.

Then again, I harken back to

streptomycin and tetracycline. We can put date certain's in there. We can make our intentions known, but we're flexible, and but when you come back, you better have something to say.

And so, I think that should be in the record, that in deed, we're not trying to be unreasonable here, but we expect responsible action on the other side of this recommendation.

CHAIRPERSON FLAMM: Further comments? Mac?

MR. STONE: I remember hearing in past meetings, that program is -- has asked for specific dates when they're shorter than the normal five-year, and just make sure that everything is in line, or it doesn't hinder the process by some date.

CHAIRPERSON FLAMM: Was that a question you were wanting a response to, or just a comment?

MR. STONE: If they didn't raise

their hand, then I guess it's okay.

CHAIRPERSON FLAMM: Okay, John?

MR. FOSTER: So, the time line that you're talking about here, 2016, that we're talking about here, 2016, is -- if part of the intent of that is to allow time for research to be done, to explore the alternatives, and allow for, you know, perhaps another material registration process to unfold, registration process, I can see, but my experience is that three years is not an adequate period of time to generate the kind of data that would convince this body, one way or another.

I just don't see how that -- unless it's already studies that have been done, to say, now, go, complete something in three years, and bring us back the data, I just -- that feels unreasonable to me.

Knowing the standards that this body has, with respect to the data they expect, in order to change a date,

empirically, it's pretty clear, we expect some pretty hardcore data, and certainly, the public demands that.

So, I'm not sure how genuine in feel about saying, well, you got three years to generate the data, and you got to meet a pretty high bar, so, I'm uncomfortable saying that with a straight face, because I don't feel like -- I don't feel like that is something they can be successful at, and if I'm off-base on that, let me know, but that's been my observation over the last couple of years, anyway, and if I'm wrong, please tell me.

CHAIRPERSON FLAMM: Nick?

MR. MARAVELL: No, John, you're not wrong. I share your concern, and that's why I drew the parallel to tetracycline and streptomycin.

That is why I think we should have it in the record, that we can be flexible, but we need to see some action on the other side.

As simple as that.

I mean, we're not asking for things that are un-achievable, but they need something on their side, to go back to their country and to their interests, and say, "We got to move."

CHAIRPERSON FLAMM: Any further comments? Zea?

MS. SONNABEND: I would just ask John if he has a better suggestion of a date?

MR. FOSTER: I mean, it's -- at that point, it's kind of splitting hairs, 17, 18, 19, I mean, right, I get what Harold -- what you were saying, I get about, you know, having a date. I understand the rationale for that. I think that is probably sensible.

But four years is -- it's only marginally better than three, and so, I -- I still haven't made up my mind on the vote yet, but I don't want to put things out, that people can't be successful at, knowing that they -- and then if everyone is in agreement,

that they can't be successful at that, then -- and providing, you know, the data we need, then I don't know, that seems -- that feels very disingenuous, to me, and if there is -- I wish I could come up with a better date. I can't, and still be kind of responsible to the -- obviously, the data that shows that health impacts are a problem, and -- but I am very reluctant about this, but I -- so, anyway, no, I don't have a better date, other than one -- you know, one more year.

CHAIRPERSON FLAMM: Miles, would you like to comment?

MR. McEVOY: Yes, you're -- I think you're mixing up a few things, here.

The notification to foreign governments and to the community is done through the Federal Register Notice, when we put out a proposed rule to add rotenone to the prohibited list.

So, your recommendation here is not an official notification, and there are a

lot of people that will not note this. Some will, for sure, but there will be a lot of stakeholders that won't note this, until there is Federal Register Notice and the foreign governments are officially notified through the WTO process, where we have to notify them of these types of changes.

So, the other thing you have to keep in mind is that this is -- you're adding -- you're making a recommendation to add something to the prohibited natural list, and so, the expiration date is not as critical.

It would give an indication to the program of what your recommendation is for that effective date, but this will be determined by the proposed rule that we would put out and the comments that we would receive.

We would try to mirror the intent of the recommendation, but this is not a sunset, where -- or an annotation that you're adding to a recommendation for an expiration

date.

So, it's a little bit different than that.

CHAIRPERSON FLAMM: Thank you, Miles, for that explanation. Zea?

MS. SONNABEND: And I just wanted to reflect to John, about my thinking on this and why I think it's quite substantially different than the antibiotic argument.

In that case, there are few, if any, alternatives to be looked into. There is one promising one, but there isn't a range, yet the list that I read of possible alternatives for thrips control, which are well studied in this country, offer many opportunities for them to look into a lot of different things down there, that may not have been looked into, yet.

And so, I think that there is -- it's not just a long road, as it is on a tree crop, with very few alternatives. There is plentiful research to be done in those three

years.

CHAIRPERSON FLAMM: Harold?

MR. AUSTIN: Earlier, in our meetings, I made a comment regarding the alternatives that are available.

Just because a product is listed as an available alternative material, does not necessarily mean that it has true efficacy and control on that insect species.

Thrip, I think will find that a lot of the materials, a lot of the products that are listed will give minimal control, at best. Spinosad will be, by far, the best approach that they'll have, if they can get that certified in the country.

But a lot of the alternatives, based off of use here in our country on other crops, are relatively non-effective.

So, I think we have to be cautious, when we're looking at any material for review or for addition to the list, that just because there is natural or organic

alternatives available, just because they're classified, and the comments made that they're available, does not necessarily mean that they'd have true efficacy for what they're being called -- they're claimed for.

CHAIRPERSON FLAMM: Okay, Jennifer?

MS. TAYLOR: Thank you, Barry. I think we also need to remember some of the health concerns and health issues that were brought about, that have to do with not only the environment of the applicator, but probably the environment of other workers, within the distance of the application.

CHAIRPERSON FLAMM: Further comments? Further discussion? Harold?

MR. AUSTIN: I would agree with Jennifer's comment, that we do need to look at those type of concerns and issues, but I also reflect back onto the information that was provided to us, and I know that it was an isolated snapshot of one company and what they

were doing, but what we saw here, during Luis' presentation and the following presentation, showed an extremely solid process, where adequate -- where it looked like they had adequate PPE in place, protected -- personal protective equipment.

The application method looked to be a very specific zone was not an air-blast, cover all of the tree canopy, cover all of the rows, like we do in a lot of our crops here in the country.

So, it was very controlled, environmental controlled application, so, I was -- and I can't say that this is the only method being used. I don't know what the label is, in the countries in question.

But the process that we saw presented to us made me feel a lot more comfortable than if I would have seen an air-blast speed sprayer that was putting material on at 400 gallons and going up into the air and covering the entire canopy.

So, I was a little more comfortable with the application and the process that I saw, but that doesn't necessarily mean it's the only application technique that they're using.

CHAIRPERSON FLAMM: Further comments? Discussion?

I think we've had a very thorough discussion on this material, and I believe we're probably ready for the vote, and I think the begins with -- am I correct? Anybody else have anything else to say? I don't want to shut anybody off.

Okay, we can --

MR. BONDERA: Can you repeat the motion, please?

CHAIRPERSON FLAMM: I'm sorry?

MR. BONDERA: Can the people that made the motion, repeat it, please?

CHAIRPERSON FLAMM: Okay, I can read. The motion is to add rotenone to the National List 205.602, as a prohibited natural

substance, effective January 2016. Do I have the correct date?

Okay, is that all clear? That is what we'll be voting on, beginning with Jennifer.

MS. TAYLOR: Yes.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

MS. SONNABEND: Yes.

MR. STONE: Yes, sir.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: Yes.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

MR. BONDERA: Yes.

CHAIRPERSON FLAMM: And the Chair votes yes, 15 'yes', zero 'no'. The motion passes.

The Crops Committee, you have another proposal to present to the Board?

MR. FELDMAN: Yes, thank you, Barry. The Crops Committee has a proposal on the petition material biodegradable mulch film made with bio-plastic and -- or made from bio-plastics, and Carmela is going to lead us through that. I think there is a PowerPoint.

MS. SONNABEND: Thank you, Jay. Well, I was trying to figure out how to prepare for this, last night, and when I started thinking about the overall philosophy behind organic farming, I think it goes much beyond the details of how to review materials and categorize ingredients, to the positive effects that we can have on the land through fuzzy concepts like stewardship or nurturing.

We wouldn't all be here if we didn't think that less pesticides and petro-chemicals weren't a good thing, and farms should achieve ecological balance with their environment.

There are times when a broader concept can take precedence over the minutiae of our daily work, and by using the precautionary principle on a global level, we can forgive the taking of a risk on something new, that all the data is not quite gathered for.

Biodegradable, bio-based mulch is one of those opportunities to make a real difference in reducing pollution in the whole world, without sacrificing our principles.

It's an interesting concept here, to me, between -- or dichotomy I guess, between long term thinking of trying to reduce the plastic burden on landfills worldwide, with the lack of fully long term information on these products.

Okay, our studies of the materials over the last several months has led us to want to pursue a recommendation at this meeting.

That being said, we've tried to

write an annotation that is as tight as possible, while still allowing the best of these products to be reviewed and allowed in organic farming.

Our recommendation is set up, so the first several criteria -- okay, wait, we're going to skip that for now.

The first several criteria refer to those certifiers and MRO's who will figure out which products are allowed.

Our last clause is the only one that refers to what a grower has to do, and correspondingly, what their certifier will have to evaluate.

It is anticipated that the NOSB and the NOP together, will work on a guidance document that will come out accompanying the final rule, that will outline what the appropriate actions in our annotation are, for the large variety of environmental conditions in soils, that are governed by this regulation.

So, Carmela is going to read our recommended motion and annotations, and needless to say, I skipped the slide that our first motion will be determined, these products are synthetic, but we'll go into the listing motion.

MS. BECK: All right, so, that's a long one.

So, to list on 205.601B2 mulches, biodegradable, bio-based mulch films, to be reviewed and meet the following criteria.

A) completely biodegradable, as shown by one, meeting the requirements of ASTM standard D6400 or D6868, specifications or other international standards specifications, with essentially identical criteria, that is to say EN13432, EN14995, ISO17088 and two, showing at least 90 percent bio-degration -- bio-degradation, absolute or relative to micro-crystalline cellulose in less than two years in soil, tested according to ISO17556 or ASTM5988.

B) must be bio-based with content determined using the ASTM D6866 method, C) must be produced without organisms or feedstock derived from excluded methods, D) must be produced without engineered nano-materials and E) grower must take appropriate actions to ensure complete degradation.

MS. SONNABEND: Thank you. So, here is our analysis of the annotation and some of the accompanying issues.

First of all, the title, biodegradable, bio-based mulch film reflects our intention to define bio-based, so that this category would not allow products made from AAC, which come from petroleum, originally.

Carmela, you want to read that definition?

MS. BECK: All right, bio-based. The ASTM definition of bio-based material is organic material in which carbon is derived from a renewable resource via biological

processes.

Bio-based materials include all plant and animal mass derived from carbon dioxide, recently fixed via photosynthesis, per definition of a renewable resource.

Bio-based materials are certified using the ASTM D6866 method, which certifies the biologically derived content of bio-plastics.

MS. SONNABEND: Thank you. We have chosen not to use the word bio-plastic, so, that it makes it easier for the NOP to jump through whatever hurdles they're undoubtedly going to encounter in writing this regulation.

The Committee also feels that the process of bio-degradation is equivalent to removal of the substance at the end of each -- the growing season, as is stated in the rules.

Okay, back to -- now, Clause A, we believe the standards referred to here will cover the range of products in the range of

temperatures in environments.

We also acknowledge that the ASTM 6400 will involve testing for any residues and eco-toxic effects.

We welcome the creation of a certification program to these standards, but we cannot endorse such a program ahead of its creation.

Clause B, must be bio-based. We feel that with a good definition of bio-based, we are making sure that this testing protocol means something.

C), we have decided to be specific about our excluded method language, and we wish to -- I believe we wish to change just slightly, what this says on the screen, but right now it says, "Must be produced without organisms or feedstock derived from excluded methods," and I think we want to at least say and/or, because we don't want either of them. We don't want someone to choose between one or the other, but we definitely intend to keep

these out.

Our feeling is that in the -- let's see, while we have some concerns about consistency between this and the excluded methods in other soil inputs, since this will be a brand new category of materials, we wish to shut the door to GMO's at the outset.

The annotation regarding the feedstock is not to be construed as carrying over to other soil applied materials.

D), must be produced without engineered nano-materials. In the absence of an overall NOP written statement on this subject, we are putting this clause in, to make sure that we keep these out.

If the previous NOSB recommendation on the subject gets formally acknowledged before this rule comes out, then it may be removed, and E), the only clause that applies to growers and the certifiers who monitor them.

Growers must take appropriate

actions to ensure complete degradation.

As mentioned above, we'll be -- previously, we'll be issuing a further guidance, we hope, on what actions growers need to take, what certifiers need to do with those actions.

We do think that there may be situations where the use of this mulch is not appropriate, because soil can -- or other conditions will not allow it to break down, and we hope to have -- use the next year or more, to explore those situations, look at the ongoing research and come up with some guidance.

Okay, I want to just flag a few other concerns that have been brought up, and this is referring back to the TR, in some cases.

This is from lines 592 to 597 of the TR.

Researchers have argued for more extensive research into the bio-degradation

pathways of the various bio-plastics for a more complete understanding of potential impacts, citation given.

Complete degradation of the bio-plastics depends on blending polymers to maximize degradability, and depends on the composition of soil micro-organisms.

Due to the biodiversity of bio-plastics currently being developed, testing is necessary to determine which polymer mixtures are degraded completely and what effects incomplete degradation will have on the agro-ecosystem.

This, as we know, is true. There could always be more testing and more study done on bio-degradation pathways and the potential impacts.

We feel that by removing the petroleum source films from this recommendation, that we'll have less to study about residual components and less testing to be done on fewer chemicals.

From lines 649 to 654 of the TR, comprehensive studies were not found that describe the environmental impacts of the use of bio-plastic mulches. Most researchers concluded that the mulches would degrade to carbon dioxide, water and soluble bio-mass, citation given.

Due to the wide variety of potential chemicals released from incomplete degradation of bio-plastics, this is a data gap.

Some reports have shown that bio-plastics containing terephthalic -- well, some stuff, acid, at concentrations over 50 percent do not completely bio-degrade in soil.

While of the 14 chemicals named in the TR, six of them are from the AAC source, including this one that I can't pronounce. Therefore, they would be ruled out from materials.

Two of them are the pigments. Three of them are the polymers, themselves,

and three of them are the plasticizing agents that break down completely.

There are slight data gaps here, but we see no red flags by prohibiting the petroleum source product.

Okay, conclusion. Very clearly, our work on this subject is not over, by passing this recommendation. We need to keep investigating this until a proposed rule comes out, and if red flags arrive during that time, we can point them out during the proposed rules comment period or before, potentially.

We are suggesting putting this on our work plan for grower certifier guidance document and putting the unanswered questions into our research priorities for the coming year, as a high priority topic.

We understand that the work plan is not finalized on this subject, until the NOP and the Executive Committee takes a look at it, after the meeting.

We hope all of us on both sides of

this table will bring a positive message about true sustainability and stewardship motives behind this recommendation, and help inform your constituents about this positive step for the future of our planning. Thank you.

CHAIRPERSON FLAMM: Thank you, Zea. That was an incredible statement. Thank you. Jay, where are we?

MR. FELDMAN: Well, I think we are at the discussion phase of this. I think we should treat this as a listing motion, and begin the discussion on it.

CHAIRPERSON FLAMM: Yes, we have to have a classification motion.

MR. FELDMAN: Yes.

MS. SONNABEND: Carmela, do you want to make the motion?

MS. BECK: So, I'd like to make a classification motion, that biodegradable, bio-based mulch film is synthetic.

MR. FELDMAN: Second.

CHAIRPERSON FLAMM: We have a

motion that has been seconded, that biodegradable, bio-based mulch film is synthetic.

Further discussion? Colehour?

MR. BONDERA: Yes, thank you. I just want to say, and I think that in Zea's presentation, it was already addressed, but to reiterate the -- what I personally and I think is received as a little confusing, in terms of the -- what is being, in this case, classified not-listed, but it applies to both.

And while I fully understand the conceptualization, I do not think it would hurt if it were repeated, that biodegradable, bio-based mulch film, as the listing, is leaving out reference directly, to what is being considered, which is -- which is the point of why it says it is synthetic, which is the bio-plastic part.

And so, I just would like to ensure that that is, at minimum, recognized, that we have removed the word bio-plastic in

this, and I think as Zea said, you know, changes could happen, through this whole process, but your title is unlikely to get very changed.

So, I just wanted to say that. Thank you.

CHAIRPERSON FLAMM: Further discussion or comment or response to Colehour's statement?

MR. FELDMAN: Thank you. Yes, I agree with that, Colehour, you know, and we did hear from the industry, the bio-plastics industry, which has that exact word in its name, and recognizes the process that produces this material to be a plastic process. We talk about plasticizers, and so forth and so on.

So, this is a problem. You know, we all want to be transparent. That is one of our cornerstones, and but you know, this is where it seems like the majority wants to go, the decisive majority wants to go.

I'd feel more comfortable if we had bio-plastics in the title, but the critical thing is really how we manage this material, at the end of the day.

CHAIRPERSON FLAMM: John?

MR. FOSTER: This has been such an interesting dialogue on this material, and I've really appreciated the opportunity to kind of come around and to appreciate different nuances of it.

I was very taken by the long annotation, as I mentioned, and it was -- I thought the process actually did exactly what it was supposed to do, which was present a platform for exchange of ideas, and everyone comes to the table with an open mind and argue points and business.

I always pick one material, at every meeting, that exemplifies for me, the process by the -- that I think this is supposed to be, and this was the one for me, where I felt like it was very smart,

respectful exchange on the material.

I definitely came around to different points of view then I started with, and I wanted to point that out, including the kind of the nomenclature, with respect to plastics being out, I thought that dialogue was really very well informed and mature, and I really appreciated that.

So, this was exactly what this process -- our process was supposed to be, for me, and I think we came to a very good place that is mindful of all of the considerations, and maybe I would go so far as to say, you know, like Calvin, where everyone is a little pissed off about the outcome. I don't think it's quite there.

But I think everyone came to it with an open mind, and I'm -- I was -- I felt actually, very privileged to be part of the discussion. So, I wanted to throw that out there, because this is the best that -- I think this represents our best work. So,

thank you for that.

CHAIRPERSON FLAMM: Additional comments on the classification motion? We're talking about the classification motion, right now.

If there is no additional comments, we can proceed with the vote, with Nick leading off.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

MS. SONNABEND: Yes.

MR. STONE: Yes, sir.

MS. FULWIDER: Yes.

MR. AUSTIN: yes.

MS. FAVRE: Yes.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

MR. BONDERA: Yes.

MS. TAYLOR: Yes.

CHAIRPERSON FLAMM: And the Chair votes yes, 15 'yes', zero 'no'. The motion to classify the material as synthetic passes.

Now, we're ready for the motion to list. Jay, who would you -- Jay?

MR. FELDMAN: Yes, sir.

CHAIRPERSON FLAMM: How would you like to proceed on the motion to list, and we'll then open.

MR. FELDMAN: I was going to suggest that Zea read or cite, what she has already read, the listing, proposed listing motion.

MR. FELDMAN: Carmela, do you want to read it?

MS. SONNABEND: Okay, the listing motion. To list -- the motion is to list on 205.601B2 mulches, iii, biodegradable, bio-based mulch films to be reviewed and meet the following criteria.

A), completely biodegradable, as shown by 1) meeting the requirements of ASTM

standard 6400 or 6868, specifications or of other international standard specifications, with essentially identical criteria, such as EN13432, EN14995, ISO17088, and 2) show at least 90 percent bio-degradation, absolute or relative to micro-crystalline cellulose and less than two years in soil, tested according to ISO17556 or ASTM5988.

B), must be bio-based with content determined using the ASTM6866 method, C), must be produced without organisms and/or feedstock derived from excluded methods, D), must be produced without engineered nano-materials, and E), growers must take appropriate actions to ensure complete degradation, and that is the definition part of the motion.

I believe we want to read the definition into the motion, to also add the definition to the rule in the appropriate place, bio-based.

The ASTM definition of bio-based material is organic material in which carbon

is derived from a renewable resources via biological processes.

Bio-based materials include all plant and animal mass derived from carbon dioxide recently fixed via photosynthesis, per definition of renewable resource.

MR. FELDMAN: So, that would be 205.2.

MS. SONNABEND: Okay, 205.2 for the definition.

CHAIRPERSON FLAMM: Do we have a second?

MR. AUSTIN: Second.

CHAIRPERSON FLAMM: It's been moved and seconded, to -- now, I've got switched here.

Could we go back to the first screen?

MS. SONNABEND: Which first screen?

CHAIRPERSON FLAMM: The listing motion. So, I won't reread this, unless you

request it.

Is the motion, the listing motion clear, and then we'll look at the definition, which will be added. Does anybody object to -- or unclear, I should say, about what we're about to -- we will vote on? No question? Does the program have a -- Miles?

MR. McEVOY: Yes, we have a comment. If you want these, what you're calling biodegradable, bio-based mulch films to be allowed to be used in organic production, within the -- a shorter time frame, we would suggest that you remove the Clause D, must be produced without engineered nano-materials.

We have a recommendation from the Board on nano-materials, that we're working with. We'll be meeting with OMB and other agencies, to look at the implementation of that particular recommendation.

But part of the problem with that recommendation is, there is no Federal

definition, consistent definition of nano-materials.

So, in order for us to incorporate that particular clause into this rule making action, would significantly slow down and potentially, even stop the ability to get this substance listed. It's just going to make it very, very difficult and slow down the process.

So, if you want that to happen, if it's that important, leave it in, but if you really want these substances to be allowed by organic farmers, then I would suggest taking it out and working on nano-materials through other mechanisms.

CHAIRPERSON FLAMM: Sort of a two-part thing. The first part is that the Board is clear on the motion that is now before us. If they're clear, I'll -- I'll move the discussion, and Miles has made a comment on the motion, and what he has identified as a problem with the motion.

So, first of all, I want to be sure that everybody understands what the motion is before us.

So, I think everybody is acknowledging, they are clear on the motion, and so, I'll open it to discussion, and perhaps, the first -- I think I'll just ask either Zea or Jay, to respond or open the discussion with a comment on Miles' comment and the concerns that he expressed.

MS. SONNABEND: Okay, Nick, did you want to say something?

Let me, okay. We wanted to ask Miles if instead of this clause about nano-materials, if we referred to the NOSB's own recommendation about nano-materials, would that help solve the problem at all, because we have our own recommendation, and if it's internal, maybe that would help.

MR. McEVOY: Yes, the problem is putting it into the recommendation, because that is what would have to be in the

regulatory text, that we would have to get through all the various legal and clearance processes, and it's a complicated situation, without -- with a lot of agencies involved, in terms of nano-materials, the definition of nano-materials, how they're overseen and regulated by the Federal Government.

So, if you had it in your -- the body of your recommendation, that would be different, but having it in the actual annotation, is where it would cause us significant difficulties in getting this approved and through the clearance process.

MR. MARAVELL: Miles, I completely understand, and I'm just wondering if there is a way to indicate that it would be produced without nano-materials, when such definition is promulgated, you know, but it would not be effective until such definition is promulgated.

I mean, would that give you enough of an out? I think we need to be able to tell

the community, fairly definitively. So, does that work?

So, that is just a question you may want to think about it, before you get back to us, on that, but we clearly, do not want to hold this up, and if this will hold it up, we can take other action, but if there is a middle ground there, we would be willing to consider that, too.

MR. McEVOY: Yes, well, we can consider that, but again, that would slow it down.

You've already made it -- you already have a final recommendation on nano-materials. You've made it -- you've proposed a -- or made a recommendation on a definition for nano-materials. So, we have that.

So, the problem is, is if you put it in the annotation, we're going to have extreme difficulty. There is just -- the difficulty, it's just going to take a lot of time, where there is a lot of different

entities that we'll have to work with, to get that through the process.

It's going to take a lot more analysis, a lot more staff time, to do that.

Now, nano-materials is not a recommendation that we're ignoring. We are moving forward on that, but it is a final recommendation. There is many NOSB final recommendations that we still have to work on and implement.

What we're suggesting is that this is not the place that you -- in order for us to effectively move forward, if you leave it in the annotation, it will make it extremely difficult for us to move forward in any kind of expeditious way.

CHAIRPERSON FLAMM: John?

MR. FOSTER: So, this is kind of the discussion I was referring to earlier, where this kind of dialogue is just, as some would say, a natural and zesty enterprise.

But my -- anything having to do

with holding this up, and this came up in our Subcommittee meeting last night, was my biggest concern, other than what I have already said about making preferable materials easier to use than the less preferable materials, is that every month, every day, every year, this doesn't move forward, is that much more un-biodegradable plastic in the environment, and it ends up everywhere, we know.

We all know where it ends up, and I don't -- we're so close to giving -- to putting a dent in that, I think it's really, really important that we design this, so that it moves as quickly as possible.

That is a big priority for me, and as I said last night in our evening Subcommittee meeting, but so, if that is a hazard, and it's going to postpone this, it sounds like it is, then I want to avoid that hazard.

It's predictable, and as my mom

would say, therefore, it's preventable. So, I think we should prevent that.

CHAIRPERSON FLAMM: Further comments? Jay?

MR. FELDMAN: Thanks, Barry and Miles, for your comment.

I'm trying to understand the process here, and I, you know, I know that as has been mentioned, we, as a Board, adopted in 2010, unanimously, as you know, the definition of engineered nano-materials, and we appreciate the program working -- moving that forward.

Then in December of that year, 2010, you wrote a memo, that really, I hope, could be used in this instance. It ended with -- you know, you explained the uncertainty and the lack of Federal guidance and so forth on this, and then you ended with something that I really appreciated at the time, the NOP accepts the NOSB recommendations and tends to gather additional information about how nano-

materials are regulated and used in the agricultural production process.

So, I guess my point here, or question maybe, is if the program accepts the process that the Board went through in defining this thing, and the Board, as you know, worked a long time and heard a lot of public testimony on this issue, is there a way we can incorporate that statement that the Board adopted, as guidance, and then add Nick's language, you know, pending some other action by the Federal Government, or by USDA, so we can expedite this, just so that, you know, we can do this in a way that, as John says, moves this along quickly, but also gives the Board some assurance that there won't be plastics folks jumping all over this thing, with nano, because we know that there are folks out there that would like to do that kind of thing.

So, it's just a way of almost setting a moratorium, until the USDA comes up

with a definition, that it feels is appropriate.

MR. McEVOY: Yes, well, you already have the recommendation -- final recommendation on nano-materials defined, nano-materials and consider nano-materials to be a synthetic substance. We've accepted that.

So, that is the way that the program and the, we expect certifiers and companies to accept that, as well, that nano-materials are considered synthetic substances, and therefore, not allowed unless they're added to the national list.

So, that is the concept, and that is what some of the power of your final recommendations can do. They set the tone.

For us to issue various documents, requires different levels of clearance and approval. So, for us to issue a memo to the Board, that we accept your final recommendation on nano-materials, sends a

statement, but it's not a regulatory text. It hasn't gone through public comment and rule making.

So, it doesn't have the same level of authority, as a rule on nano-materials or putting nano-materials and prohibiting nano-materials into the USDA organic regulations would have.

That is going to take a lot more time and a lot more work, because there is a lot of affected parties there, and a lot of people that probably will have comments on that particular thing.

So, my suggestion would be that the -- if you want to have this particular substance be available to organic producers, that you remove that clause, and you include that in the background information that you have around this particular recommendation.

But if you leave it in, as part of the annotation, that means that we have to do all the rule making around your particular

final recommendation on nano-materials, which is very complex. It's not an easy task for us to do that.

We have recommendations from the Board, from 10 years ago, that we still have not implemented. So, and nano-materials is not an easy one.

We have accepted. We do recognize that the Board considers nano-materials as synthetic and therefore, they're not allowed in organic production or handling.

But to raise it into the rule making process will delay that in very substantial ways.

CHAIRPERSON FLAMM: Thank you, Miles. Nick?

MR. MARAVELL: Yes, Miles, maybe the easiest way to do this is put it in the positive.

Can you explain to the Board, if we drop that clause, let's say we just take 'D' out, how the program would proceed and how

that would have an impact on the review of this material, and what would be permitted under your understanding of how you would proceed?

In other words, tell us how it would play out. What would be the impact, if we dropped that and put it in the -- and put it in the background material, just say how -- how would you then review materials? How would you expect materials to be reviewed? How would this have an impact?

MR. McEVOY: Well, we would expect these materials would be reviewed by material review organizations, and that they would -- once this was added to the national list, that they would then review these materials, based on the annotation.

Then if there were particular questions about, let's say, the clause and nano-materials is removed, if there were questions that a manufacturer was using nano-materials, they would go to the final

recommendation from the NOSB on nano-materials to say that those are synthetic substances and are not allowed in those substance -- those products that are being approved.

So, they could rely on the background information on this particular recommendation, as well as the final recommendation on nano-materials. That would be their guidance.

MR. MARAVELL: And at this point, we have no reason to believe that nano-tech materials are included in the substances that are included in the petition. Is that correct?

Right, so, we are not approving nano-technology materials. We are approving what is in the petition? Would that be also, a correct statement?

MS. SONNABEND: There were -- there are no -- none of the products submitted in the petition are made using nano-materials, at this time, and to our knowledge and asking

the petitioners, none are planned.

So, I don't -- you know, this is not something that we have to keep out, because it's in there on a day-to-day basis. This is a protective clause, and as a protective clause, it is my opinion that we shouldn't bog the whole thing down by keeping this in. We should just put it in the background material, just as we're putting in the clause about, that we interpret the bio-degradation to be equivalent to the removal step.

I think if we also put a sentence in the cover, saying that we fully expect that these materials will have to meet the NOSB's recommendation on nano-materials.

MR. MARAVELL: But weren't we also going to be making a statement that what we have reviewed in the petition, is what we are approving, and that people can't just use the moniker of a bio-based, bio-film mulch, to put any synthetic that they would desire into that

product, is that also correct?

Weren't we planning to make that statement? Yes, so, this might work.

CHAIRPERSON FLAMM: We have other Board members that would like to ask questions. Jean, please.

MS. RICHARDSON: I was looking forward today, to voting on something that is actually going to give something to the organic farming community, because we always seem to be voting 'no' on everything.

So, it is important to me, if I want to get back to Vermont and the Northeast alive, that we do vote on this today in a positive way, and so, I would actually encourage a modification of the listing motion, to remove the line 'D', a this time, on the clear understanding, obviously, the issue on engineered nano-materials will be within the body of the general statement that is attached to the listing motion.

CHAIRPERSON FLAMM: Tracy?

MS. FAVRE: Thanks, Barry. Jean, I would -- actually, I was just getting ready to make a similar comment.

I feel as though that if we don't remove it, we are essentially, creating a backdoor veto to the listing of the product itself, and I think as long as we have sufficient intent expressed in the background materials, that will then be used in combination with the nano-technology materials recommendation, that should be sufficient, and I, personally, would like to see this move forward, as well.

CHAIRPERSON FLAMM: Zea?

MS. SONNABEND: As the maker of the motion, I would like to accept what Jean and Tracy said as a friendly amendment, and remove Clause D of the annotation, to be put in the background materials, appropriately. Does the second agree?

CHAIRPERSON FLAMM: Okay, just a technical point, there is -- Robert's Rules of

Order doesn't recognize friendly amendments, but if the Board, as a whole --

MS. SONNABEND: What is that?

CHAIRPERSON FLAMM: I'm just about to tell you. It's a technical point, but let the record show that we follow Robert's Rules of Order.

If it's a -- if the Board does not disagree, we can accept this change. So, it's a full Board decision, not an individual decision.

Seeing no objection to the change, I believe it's accepted. So, would you briefly restate what the change is, so everybody is clear on what we're voting on?

MS. SONNABEND: The motion on the floor then is the entire thing you see on your screen, except for Point D.

But be assured that Point D will appear in our narrative that accompanies this.

CHAIRPERSON FLAMM: And do we have -- does the -- do we have a second to this

motion?

MR. AUSTIN: Second.

CHAIRPERSON FLAMM: It's been seconded, that the listing motion, plus the definition, which has not changed, minus what is the number now? Minus 'D', is every -- is the Board clear on what we're -- we will vote on?

Jay, do you have a -- further -

MR. FELDMAN: Yes, thank you. I realize the sense of urgency to move this, and we'll talk about that a little later, when it comes down to another text change that we've discussed.

But on nano, specifically, and this particular amendment, or this motion, I hope we can include in the statement, the background material, the actual policy itself, so that the Board is aware of what, at least has been established by the Board previously, as the responsibility for recognizing the unique properties of nano, that distinguish

them from all other listings of this substance, sort of in the realm of what Nick is saying.

That we understand, we're approving, in effect, non-nano forms of this bio -- I can't say bio-plastic, can I? Biodegradable mulch film, and that they are not allowed, that is the nano-form of this material, should it become available, are not allowed by a listing of the bulk form of the substance, on the national list, and that, in effect, serves as a prohibition of the engineered form, the engineered nano-material form of this listing.

So, I hope we can be more -- I am just hopeful and maybe we can get an agreement here, that we will re-list that, so that everyone is clear on -- as to what the policy says, and how it is intended to function.

CHAIRPERSON FLAMM: Jay, I want to -- I'm not clear myself, on that. Maybe others aren't.

We have a motion on the floor.

MR. FELDMAN: Well, the motion included -- well, the motion was to take this out, but as it was described to us, it included the incorporation of the no-nano clause in the recommendation, itself.

So, I just to amplify on that -- Zea's proposal on that, to suggest that we actually include and cite the policy that was adopted by the Board, previously.

CHAIRPERSON FLAMM: So, this is for the background statement, and not changing the motion?

MR. FELDMAN: Background, yes.

CHAIRPERSON FLAMM: I'm just trying to --

MR. FELDMAN: In the background statement.

CHAIRPERSON FLAMM: I am just trying to clarify that for the record --

MR. FELDMAN: Yes, in the background statement.

CHAIRPERSON FLAMM: -- that that is what you're doing.

MR. FELDMAN: Yes, yes.

CHAIRPERSON FLAMM: Okay, further discussion? Nick?

MR. MARAVELL: Yes, Jay, I just think we need to be a little bit flexible. I'm not sure we want to prohibit nano. I think we want to just say, "We have not approved any nano in our review of this petition, if the program needs such flexibility, in the way they proceed."

So, you know, do you -- well, let me ask the program. Do you care whether we say, "We would prohibit nano-technology," or simply that it is not in this petition, we did not review it, and we are not approving it?

CHAIRPERSON FLAMM: Miles, would you respond to that question, please?

MR. McEVOY: What we are saying is that if you leave Clause D into the motion, that that would significantly decrease our

likelihood of getting this listed in the near future.

CHAIRPERSON FLAMM: Mac?

MR. STONE: Shift gears a little bit. So, from the certifier point of view, couple of thoughts.

The word 'complete degradation', I have a little concern that if a grower is in a dry climate or an environment where he is having trouble, they try it and it doesn't work the way they hope it does, for various environmental conditions, that they, or the certifier/inspector is not in a position of dinging the farmer, even though they're assuring appropriate actions are be taken, but completeness didn't happen.

So, I guess some guidance is necessary around that, which in conversation with the program, that is behind the scenes of this, the guidance behind that.

But just to make people aware, that that could be an issue for somebody, and

since it's not a plastic, it doesn't fall into the 'must be removed' thing.

So, I think that language helps for that side, but 'complete' is a little bit worrisome, I guess, not to -- I am not amending the motion, I'm just acknowledging that.

CHAIRPERSON FLAMM: Further questions and discussions on the motion that is before us?

If not, we can proceed with the voting.

MR. FELDMAN: Well, yes, I have another issue, I'm sorry.

MR. MARAVELL: Point of clarification. Are we just voting on the motion to take 'D' out of the proposal, or are we voting on the entire proposal?

CHAIRPERSON FLAMM: We already --

MR. MARAVELL: Took 'D' out?

CHAIRPERSON FLAMM: -- did that. We already did that.

MR. MARAVELL: Right, well, then I think there is additional discussion, before we call the vote.

CHAIRPERSON FLAMM: Okay, that's what we've been doing, I thought.

MR. MARAVELL: Yes, yes, yes.

CHAIRPERSON FLAMM: Okay.

MR. MARAVELL: I'm just saying, I think there is quite a bit more, yes.

CHAIRPERSON FLAMM: Okay, I assume if you -- then you want to make another comment?

MR. MARAVELL: I want to give others an opportunity to speak, but I have more points.

CHAIRPERSON FLAMM: Okay, I think I tried to give everybody an opportunity, and if you go ahead, Nick, if you've got further discussion.

MR. MARAVELL: Yes, well, first of all, I want to associate myself with the -- with Mac's comments, as it -- as a farmer,

you're going to read this and it says 'complete degradation'.

Well, I know that in regulatory language, 'complete' may mean something else, but a farmer says, "That means 100 percent," and I hope that in the guidance, it will be clear, that nothing is 100 percent, and we're not going to scare people from using this product, because they're going to say, "Does that mean I've got to cover it up and bury it, so that nobody can possibly ever see it," and actually, that may -- if they cover it up and bury it too deep, reducing moisture, oxygen and temperature to the product, it may actually retard its degradation.

So, I would like to know what other think about this, in terms of what message we're sending, and whether or not the program has any views on, if they anticipate putting out guidance on this particular aspect that Mac raised.

CHAIRPERSON FLAMM: Any other

questions? Discussion by the Board? Miles, do you want to respond to Nick's question?

MR. McEVOY: Okay, so, Nick, you're asking what -- about the grower must take appropriate action to ensure complete degradation, and part of this proposal, I heard was that the Crops Committee would want to work on developing guidance for how that would be implemented, is that correct?

MR. MARAVELL: Yes, yes.

MR. McEVOY: So, it seems like it could be handled through that process, of working with the Crops Committee, on what the appropriate guidance or instruction to certifiers would be, to meet the intent there, that the growers, which is the active word there, they're the ones that have to take the appropriate actions, yes.

CHAIRPERSON FLAMM: Jay, and then Mac.

MR. FELDMAN: Okay, thank you. Okay, so, here, I'd like to follow up on your

comment, Jean, about sort of weighing the need and the need to go forward with this, in an expeditious manner, and our need, as a Board, to make sure that we are evaluating this thing under our criteria.

I understand there are always uncertainties and I think we have to bring -- you know, address those uncertainties in ways that -- best ways we can.

I, for one, am willing to accept some uncertainties, if there are threshold issues that I think we, as a Board, have adequately addressed, and on the science here, I'm willing to accept some of the uncertainties that we've heard about, that Zea actually referenced, in terms of the unanswered questions that are in the technical review.

And I think that is something that we all have to come to, maybe in a different way, but understand what those things are.

So, I want to put that context

around what I have to say about the last clause in the listing motion.

One of the things I've learned, being on the Board for three years now, is that it's very hard to get the horse back in the barn, after the barn door is open. I mean, we all know, we've experienced that probably, literally and figuratively.

So, the issue with something like this, where there is a fair amount of uncertainty still, everybody acknowledges that, and there is a need to do more research, there is a need to develop guidance, there is all kinds of needs.

My feeling is that we really need to start with the narrow, a narrow -- get this -- get a foot-hold with this material, get it going, but do that in a narrow way, and expand on it.

It's easier, much easier to expand on something, in a deliberate way, with better information, than pull something back, once

it's out there. We've experienced this over and over and over again.

So, with that being the theme, I -- - when we started this discussion, the Crop Subcommittee, we started with the presumption that -- and looking at the data from the manufacturer, that we would be able to assume compliance with the degradation, or the removal, equal in degradation, within the time frame that was envisioned by the law.

At that time, since the manufacturer petitioned as a bio-plastic, we evaluated as a -- we evaluated it as a plastic and we looked at OFPA, and OFPA says removal, at the end of the growing season, or -- yes, at the end of the growing season.

So, or the harvest season. So, that obviously, has changed. We're now talking about this not being a plastic, even though I reiterate again, that the industry itself has called this thing a bio--plastic.

I think at the end of the day,

legally, we're going to find that this will be called a plastic, whether we rename it or not.

You know, if someone chooses to sue on this material down the road, there will be no question, in my view, that this will be deemed a plastic.

So, it's within our responsibility, I believe, to try to manage this thing, within the frame work of the law, which -- and get it on the market, because I believe the product we're -- that would -- that I believe would at least, one, would qualify would meet this standard, at least in terms of most of its applications at this time, is the -- is our -- does suggest that biodegradation within the growing or harvest season, by the end of the growing or harvest season, with it -- is the one year time frame within the statute.

There may be some outliers there. The certifiers can manage those outliers, in the short term. If we find out through more

and more experience, that in fact, that cannot be done, they can come back with a petition to expand on that. By then, we'll have more data.

But we have gotten a foot-hold with this. We will be forward thinking. We will be reducing plastic substantially, but we wouldn't be trying to get the horse back in the barn, after the door was open.

So, that is my -- I just wanted to explain my philosophy, my sort of strategy would be to start narrow, limit the uncertainties to the degree that we can, build on that over time, as we get more data coming in.

So, in that respect, I would like to propose, I know this isn't a form of proposal, Barry, but I'd like people to consider putting back in, that language at -- let's see, let's just see, on the last 'E'.

The original language for 'E' was, "Grower must take appropriate actions to

ensure complete degradation at the end of each growing or harvest season."

Now, having said that, I'd like to hear, if anybody has a comment in response to that, I'd like to hear it, but I'm also interested in hearing from the program on this element of our proposed listing motion.

You know, what are the constraints, given the law, given the nature of this material? What are the constraints, in terms of removal equals degradation, equals one year, et cetera?

I hope that is clear. I just want to throw that out. Thank you.

CHAIRPERSON FLAMM: Mac? Okay, Jean, you had a follow up question?

MS. RICHARDSON: Yes, and I tend to agree with you Jay, actually, it would be good to see some -- the careful use of that 'end of the growing season phrase'.

But do we need the word 'complete' in the last sentence, under 'E'? I'm not

certain about that, either, quite frankly.

I mean, but let me tell you from the point of view, if I am the inspector, because I think if we're going to make proposals, that have to be able to be verified in the field, if that grower is utilizing the bio-mulch, this year and next year, in the same field, before they move into, perhaps some different kind of rotation, from a verifying point of view, it's going to be very difficult for me to be sure, when I go into that field, is this mulch a little tiny bit that I might see, left from this year or last year?

So, from the -- so, I do think we have to be careful, if we're going to make language, that you've got to say how are we going to have that verified in the field, in that -- at the end of that growing season?

Having seen the mulch being used all over New England, I mean, obviously, if the farmer is not going to use it in the same

field for two crops in a row, or two growing seasons in a row, then it wouldn't be an issue.

But if they -- but you know, we don't dictate their rotation that they have.

CHAIRPERSON FLAMM: Yes, I'll call on Tracy next, and then Harold, but I've got to remind the Board, we do have a motion on the floor. So, let's keep the discussion germane to the motion that's on the floor, and we may -- and then if you have a proposal and want to amend the motion, we have a procedure for doing that.

But I'm just saying, this is not a complete free-wheeling discussion, because we've done that previously, in Committee, and I think we've got to get some closure on this, and with that, Tracy, would you proceed?

MS. FAVRE: I was going to only ask the question, if we have a standard, which it looks like 90 percent biodegradable per ISO 17556 or ASTM 5988, is there some description

in there, that describes what degradation would be, that would also be applicable for the field verification, rather than using some word that is absolute?

I mean, is there some criterion that is used? No, I'm seeing 'no'.

CHAIRPERSON FLAMM: So, shaking the head, but that doesn't make it on the record. So, you know, yes, Zea or Jay, would you answer the question Tracy posed?

MS. SONNABEND: No, that 90 percent is for products being tested in the controlled environment of the standard testing, not for verification in the field, because you would never be able to assess what 90 percent was, in the field situation.

CHAIRPERSON FLAMM: Harold, I believe you had a question or a comment, I should say.

MR. AUSTIN: Yes, I think part of it, too, we mentioned earlier that we have suggested that this be added to our research

priority list.

So, I think some of the answers could be sought out through how we pose that research priority project.

So, some of these may be some uncertainties, but I agree, we do have a motion on the floor. So, I think we've got some guidelines, that the certifiers and reviewers could be following, as it exists, and if we need to modify that, I think based off of research and information that we do not have at this time, we can better adapt the policy, as we move forward, based off of science, not based off of human assumption.

CHAIRPERSON FLAMM: Nick, you have a comment?

MR. MARAVELL: Barry, I would respectfully request the chair, a little forbearance, here. I have more than one comment, and I'm certainly willing to give others plenty of opportunity to comment.

But I think this is an important

material decision, in that the complete reasoning and rationale of the Board should be put on the record. It should be placed, so that there can be responses to this, later on.

So, I ask a little bit of forbearance on this one material, to perhaps extend the discussion, and I would like to introduce a comment, now, is that okay?

CHAIRPERSON FLAMM: That's okay. I was just suggesting, we try to stay at least around the motion, itself.

MR. MARAVELL: And I take we -- yes, we'll stay within our time constraints.

I would like to address a couple of issues, in a little bit of a round-about way, and just say what we're looking at here, and why we're looking at it.

In the deliberations to pass the original Organic Foods Production Act of 1990, the statute contains a provision, which clearly states, "If you're going to use plastic mulch, that you remove it at the end

of the year."

At that time, the only mulches available were made from petro-chemicals, and that was what was in everybody's mind.

So, I just want to state that I don't think there is any intention here, of going back on that original intent of the law, but we have substantially different material to deal with now.

Now, I want to deal with the end of the growing season, or the complete degradation issue, and I see it coming about for two reasons, and one of them goes back to the original law, where clearly, there was no intent to leave a black plastic mulch made from petroleum products, down on the ground, year after year, but you would remove it at the end of the growing season.

So, part of the rationale of the Committee, in terms of degradation, was to show that the removal of a bio-mulch, and I'm going to just abbreviate here and call it a

bio-mulch film, the removal of a bio-mulch film can be accomplished through the degradation of that film, and I think that -- so, that one, put that out as one criteria that we are trying to achieve, in trying to meet a definition that was intended for black plastic coming from petroleum source.

On the other side, and now, I'm speaking as a farmer, there is something called organic matter, and organic matter is managed, and I think what, you know, where Mac and I are having a little bit of an issue here is, I don't consider it mandatory, if plow down my corn stover or my cover crop or whatever additions I'm adding to the soil, that it be 100 percent completely bio-degraded at the end of a year or two years.

In fact, I consider it sort of a bonus if I have different carbon fractions of most recent to least recent, adequately mixed in an active, biological soil, in the top layer.

And so, I think from an agronomic -- from a farming standpoint, I don't think it's imperative that 100 -- if we were using newspaper, or more appropriately in my case, if we were using straw or stover or other types of materials, that they necessarily be 100 percent degradable or 90 percent degradable in a particular period of time.

So, having said that, what I would urge the program, is to -- we are trying to fit this into existing law and existing regulation. The regulation contains and additional prescription, not in the statute, with regard to other synthetic mulches.

And so, I guess my point here is that if our intent is clear, that we see this as a bio-based mulch, made out of -- now, I'm saying organic matter, but not certified organic matter, but made out of a material that came from recently alive material, if you will, then it might be necessary to review other sections of the regulations, to make

sure that we are -- we have -- and maybe modify those, so that this, in deed, does fit within the program's definition of adequate removal of the synthetic.

So, I'm desperately trying here to outline the thinking of the Committee, in putting this forward. Are we creating a conflict, or is this something that the program can accommodate, in terms of the removal of a synthetic mulch?

CHAIRPERSON FLAMM: John, you had one.

MR. McEVOY: It just seems like that was a question for the program, and we don't see a problem with making the necessary changes, based on what we see in front of us.

I mean, just one thing that we see here, if we take your recommendation and go through the regulatory process of review, to ensure that it fits into the complete picture of the regulation.

So, for instance, up here, you

have, "Grower must take appropriate actions." We would change that to 'producer', because we don't define grower in the regulation. We define producer.

So, it's things like that, that we do with all of your recommendations, as we go through the proposed rule, as we then put out something that may not be exactly the language that you choose, but it is -- it gets your recommendation.

CHAIRPERSON FLAMM: Thank you, Miles. John, you have a comment or a question?

MR. FOSTER: So, with respect to my previous comments, and my mellow is getting harshed a little bit here, on the process, can we -- I'd like to call the question on this issue.

CHAIRPERSON FLAMM: The question has been called. Is there -- there needs to be a second to the question.

MS. RICHARDSON: Second.

CHAIRPERSON FLAMM: The question is to call for a vote, to end discussion.

I'll just ask for votes or objections to the question. Any objections?

MR. MARAVELL: I would object. I think there is legit -- no, but I'm saying, I would object to the motion, if I were asked. There's been not adequate discussion, in my mind, yet.

CHAIRPERSON FLAMM: Since there is -- I'll rule that since there is an objection to the question, I'll let the question continue, but I would hope we could end this fairly soon, because I think we're covering some ground, again, that was at least been discussed in Committee.

I'll recognize Jay, right now.

MR. FELDMAN: I'm just trying to get clarity on Nick's question.

Looking at the rule, we're talking about 205.206C, "Weed problems may be controlled through six, plastic or other

synthetic mulches, provided that they are removed from the field at the end of the growing season."

Miles, I didn't quite understand your response. Maybe I was a little distracted. So, help me out here, I apologize.

This is a rule that was adopted by the Board, I mean, it was proposed by the Board, adopted by the program, incorporated into the rule, presumably, and maybe we can get a correction.

But in any event, it's a -- in my view, it's a principle of soil management, you know, because when we look at the other elements of 205.206C, we're talking about mulching with fully biodegradable materials, mowing, livestock grazing, hand-weeding and mechanical cultivation, flame, heat or electrical means, or the plastic, provided it's removed. Disease problems may be -- and then 'D', Disease problems.

But in any event, plastic or other synthetic mulches is the last on the list. You know, obviously, it's not necessarily a prioritized list, but the presumption here is that this is a principle of soil management, that we don't leave synthetics or put synthetics into the soil, and that if we do use synthetics as mulches, we remove them.

This is, again, what I'm talking about here is specific to weed problems, we're talking weed management.

So, I mean, I'm not sure how much leeway the program really has, to redefine what we remove or don't remove, in the terms of synthetic mulches.

The Committee, the Subcommittee has been working under the presumption that first of all, the material does degrade within the time frame of the law, and of this rule, and that removal or degradation equals removal.

To change this underlying

principle is what I thought I heard you say, to change this principle that synthetic mulches may remain in the soil, or i.e., not degrade, as ASTM suggests they would degrade and as the manufacturer testified to their degradation, seems to me, over-reaching, if I'm interpreting this correctly, over-reaching the intent of the existing standard, as supported by the NOSB.

MR. McEVOY: Okay, it think it seems like your question is, is whether or not 205.206C is relevant, and it definitely is relevant to this particular proposal.

If this proposal is adopted and is a final recommendation from the Board, then that is our responsibility, is to take that and then add this particular material to the national list, and make sure that it doesn't conflict with other parts of the regulations.

So, that particular clause that you're referring to would have to be amended, most likely. I mean, looks like it, in terms

of, to be compliant.

So, what we do is, we take your final recommendation and make changes to 205.206C, so that it is compliant with the final recommendation of this Board, that is recommending that this particular substance is added to the national list.

It's a normal part of our process, to do that.

MR. FELDMAN: Okay.

CHAIRPERSON FLAMM: Okay, can you make one more -- can you wrap up with another question? We have a couple other people who want to talk.

MR. MARAVELL: Okay, well, no, but this is direct follow up on this, but I can --

CHAIRPERSON FLAMM: Well, if --

MR. MARAVELL: It's short.

CHAIRPERSON FLAMM: I'll take that, you make yours now, if it's a direct on this.

MR. MARAVELL: Yes, in effect, I'm

going to restate this another way. We already saw that fully biodegradable mulches are permitted. We didn't specify in that, you know, they can't be, it's only non-synthetic fully biodegradable mulches are permitted, and I think where we're trying to get, in my mind, Jay, is that this really qualifies.

This is a material that was never really anticipated in the formation of law or the regulation. So, this -- we're now finding a material that is fully biodegradable.

So, I could almost make the argument that it's covered above, as a fully biodegradable mulch, but I do certainly not want to second guess the program on that.

So, that is where I'm heading with this, and I think it's important to have this discussion.

CHAIRPERSON FLAMM: Mac? Mac doesn't have any further questions. Nick, do you still have a question? Comment?

MR. MARAVELL: I have one closing

comment. I say, I have one closing comment.

CHAIRPERSON FLAMM: You have a closing comment?

MR. MARAVELL: Yes, if you --

CHAIRPERSON FLAMM: Okay, and then we're going to proceed to -- if nobody has any comment or question, after Nick makes his final comment, we'll proceed to the vote on the motion.

MR. MARAVELL: Yes, I would simply like to thank Carmela and Zea, for sticking with us, through all of this. This has gone through many twists and turns, and they have valiantly kept us on track, and steered the course for us.

I would also like to thank all the members of the public, who have commented on this, because this is what we need, as a full and open discussion, when we're trying to move forward, and I really feel that we have benefitted greatly from the public comment.

MR. FELDMAN: May I have a closing

comment, too, just one second?

CHAIRPERSON FLAMM: You're going to vote.

MR. FELDMAN: I'm going to vote, but I'm going to --

CHAIRPERSON FLAMM: Jay, go ahead.

MR. FELDMAN: I also want to thank the Subcommittee and all the commenters for participating in this process.

I really feel like we're close on this. Unfortunately, I'm not going to be able to support this with these last outstanding questions.

But please don't take that as my lack of enthusiasm for getting to a place where this material can be used safely and effectively.

Again, I appreciate everybody's work on this.

CHAIRPERSON FLAMM: We're ready to begin the vote with -- on the motion, it's been a long time, so, anybody -- is everybody

clear on what we're voting on?

I'm taking the silence is that everybody is clear on the motion.

MR. BONDERA: Barry?

CHAIRPERSON FLAMM: Yes?

MR. BONDERA: Sorry, I was raising my hand, sorry. I just want to verify that the motion, even though the screen shows it with Item D, "Must be produced without engineered nano-tech materials and," that's not -- that is not the motion being voted upon.

CHAIRPERSON FLAMM: That was --

MR. BONDERA: That was removed and now there is --

CHAIRPERSON FLAMM: That was removed and --

MR. BONDERA: There is no -- yes, I just want to --

CHAIRPERSON FLAMM: The motion on the floor does not contain 'D'.

MR. MARAVELL: Barry, also, when

we read the motion, with regard to bio-technology concerns, it was 'and/or', and I don't know if that -- does that -- is that on the screen? Oh, it's on the screen? Okay.

CHAIRPERSON FLAMM: Any other questions about the vote, the motion we're voting on.

Hearing none, I'll proceed with starting the vote with Jay.

MR. FELDMAN: No.

MS. SONNABEND: Yes.

MR. STONE: Yes, sir.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: Yes.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: Yes.

MR. BONDERA: No.

MS. TAYLOR: No.

MR. MARAVELL: Yes.

CHAIRPERSON FLAMM: The Chair votes yes. Three, let's see, 12 'yes', three 'no'. The motion passes.

That concludes the Crop Session. I think we deserve a little break, 15 minute break, and then we'll move to handling proposal.

(Whereupon, the above-entitled matter went off the record at 11:06 a.m. and resumed at 11:31 a.m.)

CHAIRPERSON FLAMM: Board Members, please take your seat.

Okay, the Board's back in session. Our next business matter is the Handling Subcommittee's proposal that was deferred on nucleotides.

John Foster, Chair, would you proceed, please?

MR. FOSTER: Yes, we have one remaining item from our agenda yesterday, and that's the subject of nucleotides, it was

petitioned item, I believe Lisa Brines, if I speak slowly, has time to -- you already introduced it.

Lisa, you've already introduced the material of nucleotides. You need not do it again, excellent.

One remaining material. Again, I'll give them on to Zea, who did some heavy lifting on this, and Michelle has already put up the current, what will be the current motion on the screen. So, Zea, if you would.

MS. SONNABEND: Thank you, John. As we discussed yesterday, the Committee, based on public comment, has -- is likely to change our vote because we think the nucleotides are non-synthetic.

We held this back from voting yesterday, though, primarily to make sure that we were creating a listing motion in the right way, and so, we have added, since yesterday, to the listing motion, instead of just saying, "Motion to list nucleotides for inclusion on

the list," we're saying, "Nucleotides as petitioned," to add to the list.

The reason for this is, there are several different nucleotides and their salts. They are spelled out in the TR, and we just want to -- and in the petition, and we want to make sure that the correct reference to the correct materials is given.

So, with that, I'll go ahead and make the motion to classify nucleotides as petitioned, as synthetic.

CHAIRPERSON FLAMM: Do we have a second?

MR. BONDERA: I'll second that.

CHAIRPERSON FLAMM: Okay, discussion? Jay?

MR. FELDMAN: Thank you. So, I've heard some discussion about how this is manufactured, and I wanted, if you could -- I don't know, Zea, you may not be able to do this, but if somebody could enlighten us, as to the manufacturing process and the

crystallization process, and how people are thinking about that, and whether or not it's viewed as a synthetic process.

If you go to line 258 of the technical review, it says, "Nucleotides are processed and prepared for packaging using filtration crystallization, centrifuging, drying, sizing, milling and blending."

So, if you could help me, or just get on the record, at least, what that process is, so that we understand it to be a natural process, as some people have described it.

MS. SONNABEND: Well, I would refer you to OMRI's and Rich Theuer's comments on this, and I'm looking for them, but does someone else on the Board have them more accessible, and could explain to Jay?

MR. FOSTER: I'm looking for them. I'm trying to get there, too.

MS. SONNABEND: Okay, or we could call up an audience member, although Lindsey has left, but there are other audience members

who could explain it, if that's acceptable to Barry.

CHAIRPERSON FLAMM: What would be the --

MS. SONNABEND: Jay is asking for an explanation of how those terms that he just read off in the processing of it, made it non-synthetic, and it was in our written comments, but it's going to take us a bit to find them, but someone from the audience, such as Gwendolyn or -- no, or someone else who maybe has the handling comment.

Okay, Emily, thank you.

MR. FELDMAN: Thank you.

CHAIRPERSON FLAMM: Thank you, Emily. You may proceed.

MR. FELDMAN: I can read in the record, what OMRI said, now.

Just so the Board is aware of this, they restated that crystallization is used in the manufacturing of nucleotide, in the final mix, classifying such materials that

go through this process, as synthetic because the resulting material was created via synthetic systems, to generate large volumes, is not in keeping with the criteria set forth in OMRI' synthetic/non-synthetic decision tree, nor with common understanding of the definition of synthetic.

"Using the same reasoning on a number of other materials, such as yeast extract, some amino acids, citric acid, et cetera, these substances would have to be considered synthetic because these substances are generated in large volumes via synthetic systems."

We asked the NOSB to reconsider this classification for the sake of consistency.

So, that answers OMRI's position. If Lindsey were here, I would just ask a few more questions about what that crystallization process is, but thank you.

MS. BROWN-ROSEN: Can you hear me?

Well, our concern was just that when we looked back at the petition, that I agree that the, you know, the explanation is basically biological processes of enzymes extracting the yeast, but the actual final product, which I believe the petitioner -- no, I'm not sure if they're -- did they comment or not? I don't know if they did.

But anyway, the petition actually asked to include nucleotides, isolated from yeast RNA, hydrolyzate on the national list, and specifically, it says it requested the listing to be nucleotides from yeast, RNA hydrolyzate, identified as the following, and their sodium salt. So, then it listed the five different nucleotides.

So, once, you know, these yeast bits are extracted into the adenosine, cytodine, guanosine, uridine, inosine-5, then you know, what they're actually asking to be listed is adenosine diphosphate and sodium salt.

So, that process has not been like well elucidated in the TR or in the comments, and we feel like there are similar salts of other possibly natural materials that are on the national list as synthetic, as well. That was the concern there.

CHAIRPERSON FLAMM: Yes, I'll call on you.

MS. SONNABEND: But Emily, isn't that creation of the salt is the crystallization that Jay is referring to, because it's just precipitating out at a certain saturation point.

MS. BROWN-ROSEN: You know, it's not clear. We don't have a clear definition or description of the final processing phase there, I don't think.

MS. SONNABEND: What do you suggest we do?

MS. BROWN-ROSEN: That's a judgment call, to you. If you think that renders it synthetic or not, it's -- you know,

there seems to be that it's a salt formed through -- you know, a basically natural extraction, but then there is a salt form.

So, you don't have -- I mean, it's based on your own recommendation on classification.

CHAIRPERSON FLAMM: Emily, could you --

MS. BROWN-ROSEN: It's up to you.

CHAIRPERSON FLAMM: Could you repeat what you said, and speak up? At least, I couldn't hear it, so, we can be sure we get it on the record.

MS. BROWN-ROSEN: Just saying that it's -- you know, there is a lot of -- this is sort of a borderline call. You know, it's extracted from a natural product, using a biological process. So, that is all considered non-synthetic, in your position.

It's just that the formation of the final salt, there must be an added synthetic phosphate source or sodium source,

to get the final salt.

So, normally, that is considered a chemical reaction, but it's, you know, not a -- you know, maybe you might not consider that a fundamental change. It's up to you guys.

CHAIRPERSON FLAMM: Anymore questions? Discussion on the topic? Zea?

MS. SONNABEND: So, I know we decided that saying 'as petitioned' would cover this issue, but now, I'm feeling that if we -- no matter which way we vote, it will be confusing to the likes of OMRI and other professionals, who are trying to look at these materials.

And so, now, I feel like maybe we need to change the classification motion to say, "Motion to classify nucleotides (including their salts) as petitioned, as synthetic." So, that's extra clear, that that is what our concern may be. Does that make sense to anyone?

CHAIRPERSON FLAMM: John, do you

have a comment? No?

MS. SONNABEND: I made the motion, so, if the second agrees, I guess I'll amend my motion.

CHAIRPERSON FLAMM: Why don't you just withdraw your motion and restate it?

MS. SONNABEND: Okay, I'll withdraw my motion and make this new motion.

CHAIRPERSON FLAMM: So, would you state your new motion?

MS. SONNABEND: Okay, classification motion, "Motion to classify nucleotides (including their salts) as petitioned, as synthetic."

CHAIRPERSON FLAMM: Is there a second?

MR. BONDERA: I'll second.

CHAIRPERSON FLAMM: It's been moved and seconded. In a moment, I'll -- it's moved to classify nucleotides -- what is this? Including their salts, as petitioned, as synthetic, is that correct? Further

discussion? Is there further discussion? Do you want to ask a question?

MS. SONNABEND: Tracy has her hand up.

CHAIRPERSON FLAMM: Tracy?

MS. FAVRE: Zea, as you know, we've gone back and forth on this, in the Subcommittee, a couple of times, and I guess I'm a little confused now, in regards to the process, specifically, that has caused us to sort of reverse this decision.

CHAIRPERSON FLAMM: Zea, would you like to respond to that question?

MS. SONNABEND: I don't consider it reversed, before we vote, but what caused us is, the department flagging it, that it wasn't properly annotated to include the salt forms.

CHAIRPERSON FLAMM: Does that answer your question, Tracy?

Further questions? If not, we'll proceed with the vote on the classification

motion, beginning with Zea.

MS. SONNABEND: Abstain.

MR. FELDMAN: We can't vote, if we abstain.

MS. SONNABEND: You don't have to abstain. I will.

CHAIRPERSON FLAMM: Everybody else abstains?

MS. SONNABEND: Okay, yes.

MR. STONE: I guess yes.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: Abstain.

MS. BECK: Yes.

MR. FOSTER: No.

MR. DICKSON: Abstain.

MS. RICHARDSON: Abstain.

MR. WALKER: Yes.

MR. BONDERA: Yes.

MS. TAYLOR: Yes.

MR. MARAVELL: Yes.

MR. FELDMAN: Yes.

CHAIRPERSON FLAMM: And the Chair votes yes. We have a record number of abstentions, I think. I'll give you the count on whether it passed, in a moment. I've got to look at this tally, what constitutes --

I have to refer to the table, to see that. What is your tally? Okay, give me the count again.

MS. FULWIDER: Eleven.

CHAIRPERSON FLAMM: Eleven 'yes'.

MS. FULWIDER: One 'no'.

CHAIRPERSON FLAMM: One 'no', and three abstentions. The motion passes. Sorry for the time element, but I had to double-check the chart that we had the right amount for passing.

MS. SONNABEND: Okay, in light of it passing, Barry, the listing motion needs to be changed back to, "Motion to list nucleotides, including their salts, as petitioned, for inclusion on 205.605B, instead of A, allowed for infant formulas labeled

'organic' or made with organic specific ingredients or food groups, only in the organic and made with organic categories."

CHAIRPERSON FLAMM: Do we have a second?

MR. FOSTER: I'll second.

CHAIRPERSON FLAMM: It's been moved and seconded. If I can -- I'll make sure I've got all the changes, before restating the motion.

MS. SONNABEND: Michelle needs to remove the strike out from B. Okay, I see, there is a new B.

So, yes, I believe that is correct.

CHAIRPERSON FLAMM: The motion is to list nucleotides, including their salts, as petitioned for inclusion on 205.605B, allowed for infant formulas labeled 'organic' or made with organic specified ingredients or food groups, only in the organic and made with organic categories."

Discussion on the motion? No discussion?

Okay, we will proceed with the vote, if there is no discussion. Starting the voting with Mac.

MR. STONE: Yes, sir.

MS. FULWIDER: Yes.

MR. AUSTIN: Yes.

MS. FAVRE: No.

MS. BECK: Yes.

MR. FOSTER: Yes.

MR. DICKSON: Yes.

MS. RICHARDSON: Yes.

MR. WALKER: No.

MR. BONDERA: No.

MS. TAYLOR: No.

MR. MARAVELL: No.

MR. FELDMAN: No.

MS. SONNABEND: No.

CHAIRPERSON FLAMM: And the Chair votes 'no'. Seven 'yes', eight 'no', the motion fails.

I believe that completes the Handling Subcommittee options and actions.

MR. FOSTER: Yes, it does, and again, I'd like to thank the Subcommittee for a lot of hard work, lot of hours on conference calls, and again, the program, for their excellent support.

CHAIRPERSON FLAMM: We'll break for lunch now, and return at 1 o'clock. Thank you.

(Whereupon, the above-entitled matter went off the record at 11:52 a.m. and resumed at 1:18 p.m.)

CHAIRPERSON FLAMM: The meeting will come to order. The next item on the agenda is the -- is for the Policy Committee and to address their deferred proposal on conflict of interest, and I'll turn the gavel and the microphone over to the Chair Colehour Bondera.

MR. BONDERA: Thank you very much, Barry. At this moment, I request that in order

for us to best be able to address the conflict of interest proposed recommendation that is on the -- that was presented yesterday, that the Policy Development Subcommittee have a short meeting to discuss our options.

So, I hereby request 10 minutes to do that, if you can so.

CHAIRPERSON FLAMM: The request is granted.

(Whereupon, the above-entitled matter went off the record at 1:19 p.m. and resumed at 1:30 p.m.)

MR. BONDERA: Board Members, please be seated.

Thank you very much. Thank you all, for the time. I apologize for the impacts of things that needed to be further considered.

So, at this point in time, because -- the Policy Development Subcommittee just got together, and we're dealing with the topic, which is on the table, which is our

conflict of interest proposed recommendation, and because of the fact that the conflict of interest document that was submitted for public input and to be considered has received -- and also, from NOSB members, has received such substantial changes, at this point in time, from where it was, and to properly deal with that fact, and separately and in addition from talking to the program people on this topic, we have decided that the best approach is what I am going to do at this moment, which is to table the motion, table the topic of the conflict of interest and pull it off of our plate, at this point in time.

So, that said, I would like to turn the gavel back to you, Barry. Thank you.

CHAIRPERSON FLAMM: Thank you, Colehour, and I understand that completes not only the Policy Subcommittee's work and proposals, that we have no other deferred proposal for consideration and voting? Am I correct?

I think we've completed -- yes, Zea?

MS. SONNABEND: I would just like to say that I think the public communication portion about the open docket should come back up at this meeting, that part of it, because I think we really need an open docket, and we're delaying it for six more months.

CHAIRPERSON FLAMM: I understand that has been discussed, but it's going to be -- probably be somewhat reworked and brought up at the next Board meeting.

Okay, that completes the work on the proposals, and I think we're -- the next order of business is election of officers.

So, I'll turn that over. Wendy, are you going to distribute the ballots?

MS. FULWIDER: I have already distributed the ballots. You all have three cards. So, we'll use one for Chair, one for Vice Chair and one for Secretary, and it doesn't matter which one.

CHAIRPERSON FLAMM: And just, if I could, a reminder of the procedures.

There will be separate votes on the -- the first vote will be for the Chair, and after the vote is taken and tallied and the winner announced, then we'll proceed to the Vice Chair position, just for clarification. That's the order, and I don't have any voting cards.

MR. McEVOY: Do you not need to nominate people for these positions, to start with?

CHAIRPERSON FLAMM: Yes.

MR. McEVOY: Okay.

CHAIRPERSON FLAMM: We'll have to have nominations.

MR. BONDERA: Excuse me, Wendy.

CHAIRPERSON FLAMM: Okay, Colehour?

MR. BONDERA: Yes, I unfortunately need to not turn this ballot, which turned into a card from a friend, who came to find

me, into a ballot. So, I wonder, can I please request a replacement and leave this on the table? I apologize. Thank you.

CHAIRPERSON FLAMM: I thought you were going to make a nomination, Colehour.

MR. BONDERA: I apologize, that's why -- so, this is sitting here. I'm not double-balloting. It will still be sitting here, sorry. Thank you.

CHAIRPERSON FLAMM: Okay, thank you. So, is there a nomination for the position of Board Chair? Zea?

MS. SONNABEND: I'd like to nominate Mac for Board Chair.

CHAIRPERSON FLAMM: Mac, you've been nominated for Board Chair. Do you accept the nomination?

MR. STONE: Could we take about a 10 minute break for me to think about that?

CHAIRPERSON FLAMM: Chair refuses.

MR. STONE: I'll accept that.

CHAIRPERSON FLAMM: Okay, is there

further -- further nominations for Board Chair?

I think the normal procedure is, ask that question three times. I only got two more.

Is there nomination for Board Chair?

One more time, is there nomination for Board Chair?

Hearing none, we just saved a bunch of paper and cardboard. Congratulations.

We can proceed for the nomination for Vice Chair. Nomination for Vice Chair?

MS. FULWIDER: There is a question.

CHAIRPERSON FLAMM: Question? I'm sorry? This glare, I can't see, right now, the people. Who?

MS. FULWIDER: Miles.

MR. McEVOY: I think you still need to vote, or at least do an acclamation

for --

CHAIRPERSON FLAMM: By acclamation, that's what I -- I didn't use the proper word, I'm sorry, couldn't think of it.

But yes, it was by acclamation. So, with no other -- with three requests for nomination, if there is no other nomination, you can declare the vote by acclamation. That's what I did, but I might have missed the terminology.

MR. BONDERA: That is correct.

CHAIRPERSON FLAMM: Yes, I'm having -- I'm getting blinded, looking off that way. As much as I like the sunshine, I couldn't see.

Are we all clear then? Mac is the new Chair, and then we -- I'm looking for a nomination for Vice Chair.

Nick, I believe you had your hand up?

MR. MARAVELL: Yes, I nominate Colehour.

CHAIRPERSON FLAMM: Colehour, you've been nominated for Vice Chair. Do you accept the nomination?

MR. BONDERA: Yes, I will accept that nomination. Thank you, Nick.

CHAIRPERSON FLAMM: Is that 'yes'?

MR. BONDERA: Yes, it was.

CHAIRPERSON FLAMM: Okay, and I saw that Jennifer had her hand up.

MS. TAYLOR: I was going to nominate the same person.

CHAIRPERSON FLAMM: All right, Harold?

MR. AUSTIN: I nominate John Foster.

CHAIRPERSON FLAMM: John Foster has been nominated for Vice Chair. John, do you accept the nomination?

MR. FOSTER: I accept.

CHAIRPERSON FLAMM: Okay, we have -- at this time, we have Colehour Bondera nominated for Vice Chair and John Foster,

nominated for Vice Chair.

Any additional nominations? Any additional nominations? Any additional nominations?

Okay, not hearing any, I think we can vote.

I have counted the votes and it's been verified by the program, by Miles, and John Foster is the next Vice Chair. Congratulations, John.

Okay, we have the important position of Secretary to be elected now. Do we have -- is there a nomination for Secretary of the Board? Harold?

MR. AUSTIN: I'd like to nominate Wendy.

CHAIRPERSON FLAMM: Wendy, you've been nominated to serve as Secretary, for a third term. Do you accept?

MS. FULWIDER: I accept.

CHAIRPERSON FLAMM: Are there further -- is there additional nominations?

Yes, Wendy?

MS. FULWIDER: I'm going to nominate Calvin.

CHAIRPERSON FLAMM: Calvin has been nominated to serve as Secretary. Calvin, do you accept the nomination?

MR. WALKER: Wendy, you are running?

MS. FULWIDER: Yes, but I feel that you should run, as well.

MR. WALKER: I decline. I respectfully decline.

MS. FULWIDER: You're hurting my feelings.

CHAIRPERSON FLAMM: Calvin, I understand you do not accept the nomination to be Secretary?

MR. WALKER: That's correct, I would not want to run against my Chair of the Livestock Committee.

CHAIRPERSON FLAMM: Is there any further nominations for the position of

Secretary?

Is there any further nominations for the position of Secretary?

Yes, would you like to make a nomination for Secretary?

MR. MARAVELL: Well, what I'd like to do is just to point out the general policy of the Board, and I think it may be in the policy and procedures manual, that we encourage a turnover, and I think that's what Wendy is indicating here, and I would ask Calvin to reconsider.

But I'm just going to indicate that the policy is generally, to encourage, you know, not a lot of consecutive terms.

So, Calvin, would you possibly reconsider?

CHAIRPERSON FLAMM: I could -- I just reread the procedures of the manual position. Consecutive terms are allowed, however, I would say that more than two terms aren't, by the language, not particular

encouraged. But it's not -- no prohibited.

I just wanted to clarify that. It's not prohibited.

At any case, I want -- okay, I'm asking for one more time, for nominations. Wendy, do you have a nomination?

MS. FULWIDER: Under, you know, the situation, you know, if Calvin is not going to run against me, I feel that I should decline.

CHAIRPERSON FLAMM: So, we've gone from two nominations now, to no nominations. Most unusual, I would say, at elections, but okay, I'm going to accept that Wendy has declined.

So, I'm going to ask for nominations for the office of Secretary. Colehour?

MR. BONDERA: Yes, I would like to nominate Calvin to serve in that role.

CHAIRPERSON FLAMM: Calvin?

MR. WALKER: I accept.

CHAIRPERSON FLAMM: Will you accept the nomination?

MR. WALKER: Yes, sir.

CHAIRPERSON FLAMM: Okay, Calvin has accepted the nomination to be Secretary of the Board. Is there additional nominations? John, do you have a nomination?

MR. FOSTER: I feel like there is a full circle thing here, that needs to happen, and I'm going to nominate Wendy, and she can do as she wishes.

CHAIRPERSON FLAMM: Wendy, are you going to accept or decline that?

MS. FULWIDER: I will accept, providing Calvin does not decline.

CHAIRPERSON FLAMM: Most unusual.

MR. WALKER: I will not decline.

CHAIRPERSON FLAMM: Okay, so, as I understand, we have Calvin has accepted the nomination to serve as Secretary, and Wendy has accepted the nomination to serve as Secretary. Do we have further nominations?

Okay, hearing none, I'll ask it, now. Do we have further nominations? Do we have further nominations?

Hearing none, we'll proceed with the vote.

I've counted the votes for the position of Secretary of the Board, and it's been confirmed by the program, by Miles, and Calvin has been elected Secretary, and congratulations, Calvin.

I want to extend my thank you to Wendy, for her great service over two years. That's a tough job, so, thank you very much, Wendy.

At this point in time, I'd like to restart a tradition that was on the Board when I joined it, and that is that I pass the gavel to the new Chair.

I want to thank the Board for their honoring me with serving as your Chair, and I appreciate all the cooperation and good work you done, and now.

MR. STONE: The first order of business is not only thanking Barry, and I'm humbled by the shoes that he has filled, but Barry, you've got a new name tag, and we'll have this one framed and sent to the house for you.

CHAIRPERSON FLAMM: I love that, and you can't believe how truthful that is.

MR. STONE: Well, it's again, Barry, I know that following your footsteps of, you know, a lot of people were very comfortable with your leadership and steady guidance.

So, I do have a strong sense of responsibility, obviously. There is a lot of very strong and passionate and caring people, and we can agree to disagree, but then we agree to go forward, in a unified voice, after some -- we made some very tough votes this past week, but we still have to look forward and at the end of the day, come together and do what we all think is best for the industry,

if you will.

I think we have work plans, next. I don't know, Michelle, if you have that to put up, or if each Subcommittee Chair has their own, and maybe we'll just go in the same order that they're in on the screen.

Looks like starting with certification, Joe, if you want to reference the document.

MR. DICKSON: Thank you, Mr. Chairman. The Compliance Accreditation and Certification Subcommittee's work plan for 2013 for the Spring meeting has three items on it.

The first of which is the extension of the calculating percentage of organic ingredients items, which we presented the discussion document for today. We will take that feedback and work as a Committee, to assemble that into a concrete recommendation for the next meeting.

We will also be exploring the

issue of the use of sanitizers, as they relate to 100 percent organic products, based on input that we should be receiving from the National Organic Program, in the near future.

Finally, we will be rekindling the issue of retail certification. It's an issue that came up back in 2007 and 2008, with the previous Board. There was an earlier discussion document on the sort of question of the retail exemption, the extent to which retailers are able to use it, what happens when a retailer opts to become a certified entity.

There are these sort of grey areas of the certification policy around retail stores. So, we will be dusting that discussion document off and fashioning that into a recommendation from the Committee for the Spring meeting, as well.

Those are our three work plan items. Thank you.

MR. STONE: Thanks, Joe. Are

there any questions or discussion for Joe, around that work plan?

Okay, scrolling up, does that say GMO? Yes. Zea?

MS. SONNABEND: Okay, the GMO ad-hoc Subcommittee will be discussing all of the comments we received about purity and GMOs, and possibly, having a recommendation, or at least a proposal for moving forward at the Spring 2013 meeting.

We are going to take up the issue of some of the terms used in plant breeding, to clarify whether they're GMOs or not, things like mutagenesis, cell fusion, micro-encapsulation, and then on the longer term work plan, I think Fall 2013 is optimistic, but we're going to try to get a handle on it, tracing GMOs back in the input and ingredient chain.

MR. STONE: Any questions for Zea, over members of that Committee?

Okay, crops?

MR. FELDMAN: Thank you, Mac. We have a number of petitions that are pending before the Subcommittee, polyoxine D zinc, as a folier spray for fungal disease, vinasse as a soil amendment, tetracycline as a petition, streptomycin, we expect to receive a petition, and then we have a number of aqua-culture petitions, related to plant material and aqua-culture, CO2, chlorine, micro-nutrients, vitamins B1, B12 and H, lignin sulfonate, as a chelating agent.

We also have a petition for carbon monoxide, exhaust gas, add to Section 205.601 petition, and we will be working on plant breeding issues, related to GMOS, and let's see, inerts, also as a -- we'll have to take a look at, you know, the policy of past and coordinate with the program, on how to move forward on that.

Finally, I guess it hasn't been approved yet, but it seems as though we may be working on a set of proposed guidance, or work

with the program on guidance, related to the biodegradable mulch, film mulch. Thank you.

MR. STONE: Very good, Jay and his Committee. It's quite an aggressive agenda, but I think with the quality of the members, you can work through that. Any questions for Jay?

MR. FELDMAN: Excuse me, I guess Zea is saying we have some sunsets, which I wasn't aware of, I must admit.

MS. BAILEY: Mac?

MR. FELDMAN: Okay, these are -- this one is --

MS. BAILEY: Mac, sorry. Yes, Jay, we think Miles showed this to you this morning. Those weren't on the Crops Subcommittee list, but we know we're going to have to deal with them next year.

So, we had added the three sunset 2015 materials onto the Crop Subcommittee work plan, for the Fall.

MR. FELDMAN: Okay, so, sulfurous

acid, sodium carbonate and not a -- you can pronounce that last one for me, and aqueous potassium silicate. Did I get that? Okay, sorry, Mac, I wasn't aware of that until just now.

MR. STONE: All right, any questions or follow up for Jay or that Committee?

Okay, next up is Handling, that is Mr. Foster.

MR. FOSTER: Thank you. We have a number of petitioned items.

First, on this will be gibberellic acid, re-visitation of that, and its current status as determination of whether or not there is substantive new information, as compared to the last one. We haven't made that determination yet. But we'll be looking at that, to see if it needs to go through.

We also have petitions for sulfuric acid, barley beta fiber, sugar beet fiber, DBD/MH, and then we're thinking of a

proposal, based on this discussion document around auxiliary/other ingredients.

Then following something we talked about the last meeting, hopefully getting a jump on Sunset 2015 items, gellan gum, marsala, sherry and tragacanth gum. Those are mostly 606, but the gellan gum will be 605 material.

So, the farther we can get on those, you know, ahead of the deadline for Sunset, the better. So I'd like to work pretty hard to make sure we cycle through those. That's it.

MR. STONE: Any questions for John, not that I knew what all of Jay's were, but what is DBD/MH, whatever it was? What was that one?

MR. FOSTER: Really? You're going to ask me that? It's a multi-syllabic word, I do not have in front of me at the moment, and I am not going to guess, right now.

MR. STONE: Okay.

MR. FOSTER: If you'd like, I'll be happy to tell you perhaps, after the meeting.

MR. STONE: No.

MR. FOSTER: Actually, Lisa Brines may be able to help. She is good, like that.

MR. STONE: Okay.

MS. BRINES: For the record, that is dibromo-dimethyl-hydantoin. Thanks.

MR. FOSTER: Does that make you feel better?

MR. STONE: Yes, like that helps, yes. All right, you better be careful, I'll end up on that Committee, if I'm not careful.

Livestock, Ms. Wendy.

MS. FULWIDER: Thank you, Mac. We have quite a list of aqua-culture petitions for Spring.

We have tocopherol, vitamins, trace minerals, lignin sulfonate and chlorine.

We also have a little diversion of chickens. We have a methionine petition

coming back, and we also may have a proposal for the omnivore diets, as a follow up to the discussion document.

For Fall 2013, we have acidified sodium chlorite and a working group update for the GMOS vaccines, and I would also like to go on record that at some point, I would like to know when we would be able to do the animal welfare guidance, because when we passed the recommendations for animal welfare and animal handling and transport, it was with the understanding that we would have strong outcome based standards to go with that.

And so, I would just like to know at some point, you know, when the program would expect we would be able to do that, and we could also take that up on the Executive Committee call. I don't expect an answer today.

MR. McEVOY: Yes, we're still working with the animal welfare recommendations that were passed by the Board.

So, we still have a lot of work to do, to work on that, and what we requested from the Board was to give us a little bit of time to figure out how we're going to move forward with that, before you developed more recommendations that could potentially complicate our ability to move forward on the original animal welfare recommendation.

In addition to that, this is a very lengthy, ambitious list that the Livestock Committee has on their work plan. So, especially for the Spring. I think it's something that we certainly can continue to discuss, how the additional guidance on animal welfare might fit into the work plan for the Livestock Committee in the future.

MR. STONE: Okay, any questions, Wendy? Okay, next? I'm sorry, Colehour?

MR. BONDERA: And I apologize if I missed it, but I wanted to ask, at the bottom, I think, was a, yes, GMOS vaccines, and my question is, and I don't want to put anybody

on the spot, but I'm just going to raise it as a question, which is right now, we're in Fall of 2012.

I personally, based on my input and experience with the GMOS vaccine, am a little bit concerned that there wouldn't be a working group update all the way for a whole other year.

And so, from a scheduling perspective, I wonder if that could or should say both Spring and Fall?

MR. STONE: All right, that's a good point, and we'll talk about it, at the Executive Committee and work with the program, and see how fast that is moving with the working group and certainly, an abbreviated update, if nothing else, I'm sure. So, good catch.

Materials, Ms. Jennifer.

MS. TAYLOR: Thank you, Mac. Our work plan for the Spring and Fall will include examining update petition, technical review

process, define production aides, how to address scientific uncertainty, which is a new item that has been added to our work plan.

The confidential business information transparency and its process, and research priorities.

MR. STONE: Thank you, Jennifer.

MS. TAYLOR: Thank you.

MR. STONE: Any questions for Jennifer? Very good. That's one more, Policy, Colehour.

MR. BONDERA: Yes, thank you. Yes, the Policy Development Subcommittee will work on reviewing and updating the manual, the policy and procedure manual, doing the same with the new member guide, and ideally, we will have put notable energy into those, and there will be something to consider at the next meeting.

A threshold two-stage technical report, which we have talked about before, but it's currently targeted for Spring, as well,

and then working with the Materials Subcommittee, as the supporting Subcommittee, but we will lead the material initiation or substance annotation clean up policy and we'll work on the title of that, as necessary.

A decisive/indecisive determination of NOSB votes, and finally, convening of technical Advisory Boards, the policy on that.

So, those are the things that we have on our sort of, I guess short term agenda and/or like I said, a few of them aren't scheduled, but that is what I have to share. Thank you.

MR. STONE: And I guess with the tabling of the conflict of interest, we can add that back in there, as well, I guess.

MR. BONDERA: I think that is a good point.

MR. STONE: Yes.

MR. BONDERA: We may well do that, so, thank you.

MR. STONE: All right, well, thank you, all, for that. We all have a lot of work to do.

So, just a few sort of remarks. I'll kind of go around and I know the program may have some closing remarks, no particular order, but those of you, the Committee Chairs, get your final recommendations. Michelle sent the new form around, so get those finalized and to her, so that she can complete our work for this week. It's not technically complete until she gets all the paperwork.

Rookie mistake, on my part. Those actually go to Barry, for his signature, before they go to the program.

So, thank you, and I hope you'll join me next year, when we -- next Spring, keep me on track.

So, Lynn, I just wanted to follow up with you, that Barry may not be on the Certification Committee, but we have his phone number, and we will continue with the

biodiversity, because we know how to a hold of him, and I'm sure he'll still be interested that we do follow through on it.

So, I just want to say some thank yous, but Michelle, do you have any housekeeping or anything that you need for us to know, before we part?

MS. ARSENAULT: I don't have housekeeping, but I just wanted to kind of address everyone. I didn't do that at my first meeting, because I was on the job for three weeks, at that time.

Most of you guys know I've been -- I'm new to the program. I've only been here seven months, but I have a few impressions. This is the most incredible group of people I have ever worked with. I spend an awful lot of time with them on the phone, and I'm incredibly impressed by how respectful and thoughtful and hard working everybody is, staff included.

If you guys have received emails

from me, you may have noticed weird time stamps, like late at night, weekends. I wouldn't take my work home with me, if I didn't really love my job.

But I am probably the least hard working person in the office, because it's definitely a team effort, and everybody works really hard around the office.

The Board, they're amazing. I was welcomed with open arms, and they're very gracious and patient with all the mistakes, as I fumble my way through, learning my new position, and I just wanted to say thank you to everyone, which I don't say often enough. So, thank you.

MR. STONE: Our thanks to you. Well, now, we have a couple of presentations to make. Is there any comments or anybody want to bring something before the Board, for discussion, before we -- and we also want to get a group picture, as well.

So, I see Miles has a plaque

there, so, if you'd like to present that.

MR. McEVOY: Yes, actually, I'd like to also just say a big thank you to Michelle. She does all the logistics and the background work to support your work, and all of her work supports the NOP, as well, and she has just been so great to work with and just, we couldn't do it without out. Thanks so much, Michelle.

Okay, so, I have a bunch of plaques to distribute, and first of all, to Barry Flamm. As I said on my opening remarks on Monday, Barry is an amazing individual, has a lifetime of achievements before he came here to the NOSB.

He has contributed so much to the NOSB and the organic community, and we're going to miss you a lot, Barry. We just really appreciate your leadership. Thank you.

CHAIRPERSON FLAMM: Miles and staff, and Michelle, as everybody has attested on the Board, that she has been terrific and

you out there, it's hard to say you're out there, you're in here, we're all a community and a team, trying to work to further organics, that we all have such a passion for.

So, it's been great meeting all of you. Thank you.

MR. McEVOY: Thanks, Barry, and then I have plaques for all the new Board Members. You're not so new, now. This is your second meeting, but we failed to give you your plaques and your letters from the Secretary.

We actually got a call this Summer, kind of an angry call from the Secretary's office, saying, "Why didn't the Board get their letters, before they started their appointment in May?"

So, the Secretary's office takes it really seriously, your appointment, and really honors your contribution to the organic community and American people, by serving on this Board.

So, this is just a small token of recognition for your service, through a plaque, and hopefully, you've already received your letter from the Secretary.

So, first of all, for Tracy Favre.

I guess I could just do this all together. For Andrea Sonnabend, or Zea.

For Carmela Beck, thank you so much for your service.

For Harold Austin, thank you, and for Jean, for Dr. Jean Richardson.

MR. STONE: Good, thank you, I appreciate that. In a word that I hear most often in the Certification Accreditation Committee with John and Joe is awesome. It's awesome to serve on this Board and many of us feel like we -- as much work as it is, we still benefit more than we can contribute, because of the people that are in the room, not just the people at this front table.

You know, you all are here for four days and you're on the phone and the

email is almost as much we are, around these topics, and we couldn't do our work without what you all provide to us.

So, there being no other business to attend to, I guess I'll officially declare the Fall meeting of the NOSB adjourned.

(Whereupon, the above-entitled matter concluded at 2:19 p.m.)

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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: 10-18-12

Place: Providence, Rhode Island

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R. Gross

Court Reporter