

**United States Department of Agriculture  
Agriculture Marketing Service (AMS)  
National Organic Program (NOP)**

**Meeting Of The National Organic Standards Board (NOSB)**

**May 22, 2012**

Hotel Albuquerque Old Town  
800 Rio Grande Boulevard NW  
Albuquerque, NM 87104

The National Organic Standards Board convened at 8:00 a.m. with Barry Flamm, Chairperson, presiding.

**Members Present**

Barry Flamm, Chairperson  
Harold Austin  
Carmela Beck  
Colehour Bondera  
Joe Dickson  
Tracy Favre  
Jay Feldman  
John Foster  
Wendy Fulwider  
Nick Maravell  
Jean Richardson  
Zea Sonnabend  
Robert "Mac" Stone  
Jennifer Taylor  
Calvin Reuben Walker

**National Organic Program Staff**

Miles McEvoy, Deputy Administrator  
Melissa Bailey, Director, Standards Division  
Dr. Lisa Brines, National List Manager  
Emily Brown-Rosen, Agricultural Marketing Specialist, Standards Division  
Michelle Arsenault, NOS Advisory Board Specialist

\*\*Note: This is not a certified transcript, and may contain errors or omissions.

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Barry Flamm: Meeting will come to order. Welcome to the NOSB meeting here in the Land of Enchantment. This week we will be hearing important comments from the public that will guide the final recommendations that the Board will make. We have already received around 1700 written comments, will be considered equally. Next on the agenda is the approval of our agenda. Are there any changes that the Board wishes to make to the agenda? The Board recognizes Madame Secretary.

Wendy Fulwider: Thank you, Barry. In response to public comment, the Livestock Committee intends to seek additional input from interested individuals to clarify the issues at hand relative to GMO vaccine use under the NOP. It is clear additional information is needed for the committee to deliberate in making a final recommendation. We will keep an active conversation open by tabling the vote at this meeting. We will bring back a refined recommendation at a future meeting of the Board for final vote. Timely, active deliberation is necessary to address the ruling of the OGC on this issue. It is vitally important to capitalize on the expertise assembled at this meeting to further a workable recommendation. We look forward to your input during the Livestock Committee's discussion session on the agenda. Thank you.

Barry Flamm: Without objection, the change is accepted. Is there any other change to the agenda? Since there is no other change to the agenda, the agenda is approved.

I have a couple of announcements to make. Ben, who is doing the recording for us, has asked the members to speak into the microphone. I have already violated this several times, as you noticed. It takes a little getting used to. He is over there and is ready to help us at any time. Also, I would like to alert the Board that there is a New York Times photographer here. He will be taking, at various times during the day, will be taking pictures, which will apparently appear in the New York Times.

Next on our agenda is the introductions. I would like to lead off with having former Board members in the audience to stand and be recognized. These people have done tremendous work for the organic community in the past. Don't be bashful. Where are you? I know you are here. [Applause] Thank you very much. Next, I would like the new Board members to introduce themselves, and just say a few words about their background and what they would like to achieve. If I could, I would like to start off with Tracy.

Tracy Favre: I'm Tracy Favre with Holistic Management International. I come from an environmental engineering background, and I now work for an organization that trains people on systems approach to agricultural management. And I hope to bring a balanced view and pragmatic approach to the Board.

Barry Flamm: Thank you, Tracy. Zea, would you introduce yourself?

Zea Sonnabend: [Indiscernible -- low audio]

Barry Flamm: Thank you, Zea. [Indiscernible -- low audio]

Zea Sonnabred: [Laughter] Okay.

Barry Flamm: By the end of the week, we will all get used to the mics. Herald, would you introduce yourself, please?

Harold Austin: Good morning. My name is Harold Austin. I'm the Director of Orchard Administration with Zirkle Fruit Company in the state of Washington. I oversee our food safety Programs, all of our quality Programs. I am directly involved with the management of our organic Program from growing to the packing side of it. We grow, pack, and sell apples, cherries, blueberries, pears, and wine grapes. I'm also involved in the advisory Board for the Washington State Department of Ag's organic Program as well. I've been involved in our area in organics for almost 20 years now. What I would like to do here is to represent the stakeholders from my area and across the country as a handler representative but also I bring to the Board, I think, a long line of experience in the farming side of it. I have grown up in the orchard industry my entire life. I look forward to serving on the Board and working with the stakeholders. Thank you.

Barry Flamm: Thank you, Harold. Carmela, would you introduce yourself please?

Carmela Beck: Good morning. My name is Carmela Beck and I work for Driscoll Strawberries Associates. I'm on the producers' seat. I have about eight years of experience in the organic sector. I started out with QAI doing review of files. At Driscoll's, I manage the organic Program. I work with all of our independent growers to maintain their organic certification, their OSPs. I also work with our handlers to maintain their organic certifications. I look forward to representing our constituencies and learning from all of you and also learning from all of the expertise of the Board members.

Barry Flamm: Thank you, Carmela. Finally, Jean, would you introduce yourself?

Jean Richardson: Good morning. I am Jean Richardson from Vermont. I have been an organic inspector for about the last 12 years in all kinds of farming and processing as well. I'm presently also an organic maple sugar producer, maple syrup that is, a sugar maker as we are called. With my family I started a family farm about 35 years ago in Vermont and grew everything that there was. And I started a lot of the early intensive pasture grazing systems which are now so common, of course, across all of the United States. Also a professor of environmental studies and environmental law at the University of Vermont with a background in biological sciences, bio-geography, Earth sciences, strong environmental interest, a lot of research in that area. And I am very much a pragmatist, a lot of practical experience, good background in both science and law that I think will help me a great deal as I try to represent consumers in this important arena. Thank you.

Barry Flamm: Thank you, Jean. And now I would like the Board members who have been working diligently the last two, three years to introduce themselves starting with Jay, and then we will go around the table. Thank you.

Jay Feldman: Good morning, everybody. My name is Jay Feldman. I am the Executive Director of Beyond Pesticides, which was an organization founded in 1981. Our goal is to bridge the interest of farmers and consumers and environmentalists. Our Board is composed of a variety of people in the medical field, researchers, farmers, farm workers. Organic, we really view, is the solution to pesticide pollution. Quickly, I feel, given my history on this, having sat around the table when the actual Organic Foods Production Act was written, that my role is to focus on the law. And what our responsibilities are as the Board vis-à-vis the law. But more than that, the core values and underlying principles that have driven that law and driven the market from zero almost when we started, to what it is today. So I am really excited about working with everybody on issues of integrity and growth under the banner of strict compliance with the law, the principles and the values. Thank you.

Barry Flamm: Thank you, Jay. Calvin, would you introduce yourself please?

Calvin Walker: Yes, I would like to say good morning, everyone.

Crowd: Good morning. [Laughter]

Calvin Walker: I was appointed to the Board in the slot of public interest. As USDA celebrates 150 years of service, all of us here in this room certainly hope that organics will be a major part of the next 150 years. I look forward to a productive meeting. Thank you.

Barry Flamm: Thank you, Calvin. I think John is back there in the corner. I can't see you, John. Would you introduce yourself?

John Foster: My name is John Foster. I'm -- this is my fifth meeting on the Board. I'm sitting in the other of the two handler positions. I am the Director of Compliance for quality food safety and organic integrity at Earthbound Farm. Grower, packer, shipper of organic produce. All we do is organic. We started in '84 on 2.5 acres of raspberries, and now we grow and market for approximately 200 growers of all manner of organic fruits and vegetables from many countries. So we focus more on marketing now. We also have our farming division that I don't oversee, but I'm pretty connected to also. I'm looking forward to another no doubt interesting meeting. This is one of my favorite activities, to get to spend time with this community. Thank you.

Barry Flamm: Thanks, John. Joe, would you introduce yourself please?

Joe Dickson: Good morning. My name is Joe Dickson. I'm Global Quality Standards Coordinator at Whole Foods Market. We are a retailer operating about 300 organic and natural foods stores. My job at Whole Foods is to set standards for the products that we sell in our stores. I advise the company on food policy issues, organic compliance and manage our Programs related to organic certification and integrity. I occupy the retail seat on the national organic standards Board and I also serve on the Livestock Handling and Policy Development Committees as well as chairing the Compliance, Accreditation and Certification Committee.

Barry Flamm: Thank you, Joe. Mac, would you introduce yourself please?

Mac Stone: My name is Mac Stone I'm a certified organic farmer from Kentucky. I sit on the certification rep. seat, and the Certification Committee, Livestock Committee and Policy Development Committee.

Barry Flamm: Thanks, Mac. Wendy, would you introduce yourself please?

Wendy Fulwider: Thank you Barry. I own a third generation family farm that has been recently certified organic. My son is home making hay today. It is a diversified livestock operation, and we will be transitioning the dairy herd beginning in the fall. This is my fifth meeting on the Board. I am on the Livestock Committee and the Materials Committee. And I also work full-time for Organic Valley. So I look forward to having a really good meeting here, and very productive, this session.

Barry Flamm: Thank you, Wendy. Colehour, would you introduce yourself please?

Colehour Bondera: Yes, Hello. My name is Colehour Bandera, and I sit in one of the producer seats on the NOSB, and I think it's worth mentioning the fact that in my opinion, from my small-scale farm in Hawaii, but also from my perspective and background and constituency, I really see the fact that since the vast majority of farms in the entire world but definitely in the United States are small scale, I try to make sure that our discussions on the committees I'm in and in general accommodate recognizing the impacts and the realities for small-scale farmers when we are making choices and putting forth recommendations.

I think that it is worth mentioning that I sit in this position from that perspective but also from the perspective of standing up for and standing with the background of organic integrity and seeking organic integrity is one of my driving forces. I really appreciate working with, like you have already heard, diverse perspectives and experiences on the Board, and that's what I anticipate continuing to do, henceforth. So thank you.

Barry Flamm: Thank you, Colehour. And, Nick, would you introduce yourself please?

Nick Maravell: Hi. My name is Nick Maravell. I'm a certified organic producer for more than the last three decades. I hate to admit it. I started out all in vegetables, and now we have a diversified operation that includes vegetables, crops, livestock, organic seed production, poultry feed production, et cetera. And I am located in the state of Maryland.

Barry Flamm: Thank you Nick. And I am Barry Flamm, chair of the Board, as you may have suspected, for this year. And I see my job as working to coordinate this great group of people we have on the Board. In an effort to get the most out of them, I try to work them hard, and that is not hard to do because they are all hard workers. I am in my last year on the Board. I serve also on the CAC Committee, and the Crops, and Policy Development, and I was chair of that for the past four years, and I handed the reins over to Colehour a

few months back. I am particularly happy to be here in Albuquerque, in New Mexico. This state was my first job after graduating in forestry. When I came out of what was then Colorado A&M, I end up on the Gila National Forest. I've worked all over the state and I spent a year here in Albuquerque. Like everywhere else, it has changed a lot. [Indiscernible – low audio] That's the trouble sitting here. I missed a very important Board member everybody is pointing out to me. And I will complete my comments to say I am delighted to be here and work with this great group of people. And glad to see all of you in the audience. Jennifer, my sincere apologies.

Jennifer Taylor: No problem. Good morning. My name is Jennifer Taylor. I'm from Florida A&M University where I am coordinator of small farm Programs. I develop education and hands-on training opportunities, experiences for farmers that are interested in organic production and alternative kinds of production and management strategies as well as providing information and training for conventional farmers, assisting them to transition to organic production. Thank you. [Indiscernible – low audio] on the Board is to represent the public, to represent consumers. And I appreciate that. Thank you.

Barry Flamm: Thank you, Jennifer. You got the last word in for the Board. Next, I would like our deputy administrator, Miles McEvoy, to introduce himself and his staff, please.

Miles McEvoy: Good morning. Miles McEvoy, Deputy Administrator for the National Organic Program, part of the Agricultural Marketing Service. It's great to be here, and I will have more remarks in a few minutes. So I would like to introduce the staff here from national organic Program.

On my right I have Melissa Bailey who is back from maternity leave. She is our standards director and keeps all the rules going through the process of development, proposal, through the Office of General Counsel, back through the long and torturous path of clearance, which seems to get more and more complicated as the months go by. She is the one who makes that happen. On my left I have Dr. Lisa Brines, National List Coordinator for the National Organic Program. Dr. Brines will be presenting background information on petitions and technical reports as we move through the meeting the next few days. Next to Lisa is Emily Brown-Rosen, who says she has been to every National Organic Standards Board meeting except one, is that right? One or two. Just a couple she has missed over the last couple -- I guess it's been 20 years now, the National Organic Standards Board. So she is the historian of the Board for the Program. She has a wealth of experience in organic certification and standards and the history of the Board. So she will be very valuable as we continue through the week. And finally we have Michelle Arsenault, one of the newest members of the NOP family. Michelle is the special assistant to the Board, who does all of the work on logistics, supports the Board in all the things that they do, keeps the subcommittee minutes, and she will be the one that handles all of the public comment in terms of scheduling the time and things like that. So, Michelle, welcome to the National Organic Standards Board meeting. Thank you.

Barry Flamm: Thank you. I think those of you who have been to previous meetings notice now a change in format of the agenda. And this is a trial to see if we can become even more

efficient and make better decisions. So we are hoping that this will be an improvement. We think it's a step forward.

Another change you may notice from at least recent meetings is the arrangement at the table. And at least for my time on the Board, the NOP and the staff sat with their backs to the audience. And when there is questions or dialogs, I think it was difficult for all of you to really hear or appreciate what's going on. So this is a little change in layout of the tables is so that we can all see each other better. We can see the NOP staff, and I think most of you can see them pretty well. And also double screens are an attempt to improve the visual effect.

It's been a tradition of the Board to remind ourselves and remind the participants in the meeting of the mission of the Board. And if you will give me a few moments, I would like to read from our policy manual on what the Board says its mission is. Of course, we have a statutory mission. And I think you are probably familiar with that. But let me read the mission that we have given ourselves. The NOSB's mission 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. We will do this by several key activities. Assist in the development and maintenance of organic standards and regulations, review petition materials for inclusion or deletion on the National List, recommend changes to the National List, and communicate with the organic community. And this is probably one of our most important roles. And also communicate with the NOP staff. Next on our agenda is the Secretary's Report. Secretary Wendy Fulbright, please.

Wendy Fulbright: Thank you, Barry. The transcript and voting record of the previous meeting has been distributed to the Board. Are there any corrections or additions?

Barry Flamm: Hearing none, the voting record and transcript of the last fall meeting is accepted. Next, Brett Baker, organic Program manager, I hope I have the title right, from the State of New Mexico, would like to welcome us. And Deputy Administrator Miles McEvoy will introduce Mr. Baker.

Miles McEvoy: We will get nice and formal here. Brett has been working in organic certification for a long time and he is the chief inspector for the New Mexico Department of Agriculture. I think that's a great title. He's been that chief inspector for a long time. Inspection is really the key element in terms of the organic certification process. So welcome Chief Inspector Brett Baker to welcome us here to New Mexico.

Crowd: [Applause]

Brett Baker: Thank you, Miles. Thank you everyone for coming here. Bienvenidos. Welcome to the Desert. Keep in mind this is mild spring weather. Drink lots of water. Remember that the more chili you eat, the more you perspire, and it acts as an evaporative cooler. It will keep you cooler that way. I've been working with the State of New Mexico's Organic Program since 1990, when Jay Friedman, who some of you might know, was still in law



school and he was writing a bill to pass an organic rule for the State of New Mexico. I was minding my own business, growing heirloom native seeds when Jay called me up and asked if I wanted to be an inspector. Now since that time, little by little through attrition, the people who were the reviewers and certifiers slowly disappeared. And all of a sudden I looked around and found out that I was in charge of running the certification Program, which I still I'm doing. For many years, we were the New Mexico Organic Commodity Commission, an independent agency under the State of New Mexico. It was a little bit difficult and a rocky road just being basically a line item on the governor's budget, subject to any kind of veto and things going on in the Legislature. And just about a year ago, the administration of the state said that, well, we really don't have the money to fund your Program anymore. If you can bring in your own money, fine. Or if the New Mexico Department of Agriculture will take you on, you can continue. Otherwise, you are not getting any more money from us. So thankfully, Secretary of Agriculture Jeff Witte agreed to take us on along with the Director of the Marketing Division, David Lucero, even though they had absolutely no budget to take on our Program at all. So we feel very fortunate that we have a good home under the Department of Agriculture, which is under New Mexico State University, which is about three hours south of here, which means all of my bosses are about three hours away. So that works out pretty well.

Crowd: [Laughter]

Brett Baker: I would like to introduce a couple staff members. First is Craig Maple, who was our coordinator. Craig was on the commission, our Board of Directors for many years. He has helped us through this change. He is really invaluable in getting us into the Department of Ag. and keeping us there.

And also Joni Quinn. Joni is our education Department, basically. When our legislation was written by Jay Friedman, it said that we would have an Education Department, someone who could answer the questions that a certifier is not allowed to. So when people ask me a question that is more than a "yes" or a "no" answer, they are directed to Joni for any help in meeting their corrective actions, non-compliances, anything like that.

And I don't think he is here right now. Martin Sanchez is our newest reviewer, certifier. Oh, there he is. Good morning, Martin. Martin has been with us for a little while now. He is a certified organic farmer as well as inspector/reviewer and certifier.

I want to say welcome, everyone. If there is anything anyone needs, information, directions, whatever, please call on any of the department staff. Again I want to thank the Board for being here. This is my first time at a NOSB meeting because we were always too poor to send most of us anywhere out of the state. So thanks for coming. Thank you.

Crowd: [Applause]

Barry Flamm: Thank you very much Brett. Next on our agenda is the NOP report. Miles McEvoy, please.

Miles McEvoy: Okay. Good morning again. I have a lot of things to cover. So I think I will just get started. Why don't we go with the first slide here? We have about 1.5 hours for this. There are 4 parts to this particular presentation. And after each part I'm going to stop and ask if the Board has any questions or comments about each a section of the presentation. There is a lot of things here. I will try to take my time, but there's a lot to cover. So the first part is about the National Organic Program. What we have accomplished, what we are planning on working on. The next part, National Organic Standards Board, the role of the National Organic Standards Board, a lot of information that we have, that we have learned recently, about the Federal Advisory Committee Act and how that relates to the NOSB. Next, how we can best utilize our limited resources that we have in the Program and the limited resources that the Board has in terms of time and energy as volunteers. And then finally how we can work together to achieve common goals. Next slide.

So the National Organic Program is responsible for oversight of the global organic system. There are 93 certifying agents. We have four recognition agreements and two equivalency arrangements. There's about 30,000 certified organic operations around the world in 133 countries. We are responsible to ensure all those operations, all of the certifiers, are complying with the USDA organic regulations. Exports are really important. We've been working on acceptance in foreign countries for USDA organic products. We have the new US/EU organic equivalency arrangement to open up markets for organic producers and handlers in the US. And then for imports we have to ensure that all imports that come into the US meet the USDA organic regulations. Next slide.

A little bit about the 2011 accreditation audits. We did 29 audits in 2011. We had 93% compliance with all the criteria. We have a new system in place where we identify all the various criteria within the regulations in the certification and accreditation sections, so there is many, many different data points on the requirements that certifiers have to meet. We did 11 domestic certifiers and 18 foreign certifiers and recognition agreements last year. And we looked at all of the various audit reports and found some common problems that certifiers are having. They include incomplete organic system plans, that is, that certifiers are accepting system plans that are not complete. Organic certificates that lack required information. That some certifiers were not adequately identifying operations non-compliances when they had identified those in the field. Not taking follow-up action. And then, not submitting required information to the National Organic Program. These are all, for the most part, correctable issues that we identified most commonly. For certifiers, we are developing corrective action plan to continue that concept of continual improvements so the certifiers can improve their process.

And so for 2012, next slide, we have a lot of audits that are occurring this year. More than 50 audits that will occur this year. This is a renewal year. The first set of accreditation was issued in 2002. They are renewed every five years, so this is the second cycle, 2012. The focus this year for all of those audits is pasture rule implementation, grower group certification, materials review and approval process to ensure that there is consistent application of that through all of the different certifiers that are operating around the world, conflict of interest provisions that they have in place, and then their compliance procedures. We really want to make sure that all certifiers are following the

same compliance procedures so that when they do identify non-compliances, corrective actions are taken and they are resolved, or that the suspensions or revocations are done appropriately and timely when necessary. So audits are occurring in many foreign countries, China, South Africa, Egypt, Mexico – you can read the list - and over 25 states. What we have been doing is expanding the number of witness audits that we do. Instead of just going to the home office and operations close to the home office, we will be doing witness audits in many different countries and many different states where the home office of the certifier is not necessarily located.

Next, going to talk a little bit about OIG audits and the peer review process. These are really important for the Program to continue to improve the quality of their services, to protect organic integrity. It ensures that the NOP is meeting the requirements under the Organic Foods Production Act, and so I'm going to talk briefly about these different reviews that are going on.

So the Office of Inspector General, we have three audits that I will cover: the comprehensive 2010 audit, the organic milk audit that is partially complete, and the National List audit that is underway. And then also the National Institute of Standards and Technology that is doing the peer review.

So for the first audit, this is the comprehensive audit I have reported on before. It was conducted in March of 2010. It looked at many aspects of the Program including compliance and enforcement, our oversight over state organic Programs and certifying agents, and our statutory requirements under OFPA. For this audit, all the corrective actions are complete including the peer review. There's only one outstanding item and that is removing the FACA requirement from the peer review part of the National Organic Regulations. So that's in process.

The second audit is on organic milk. The scope there is to evaluate whether milk marketed as organic meets USDA organic requirements. The Phase 1 findings were released this winter. It had four findings. One was around GMO testing, which I will talk a little bit more this afternoon about during the GMO Subcommittee report. List of certified operations: the OIG identified that the Program had provided more transparency in terms of the list of certified operations that is on the NOP website, but that there is a lot of room for improvement for that list. The list is a point in time of a list of certified operations. And as soon as it's published, it is out of date. So you can find operations on there that are no longer certified, or you can find certified operations that are not on list. So improvement needs to happen there. The need for unannounced inspections and handling of bulk commodities were two other findings. And this is where the Board is very important in terms of the work of the OIG audit and the work of the Program is. We have already made recommendations on these two different areas. And so, with those recommendations and with the information from the OIG audit, it makes it easier for us to implement those recommendations. And Phase 2 of the organic milk audit is underway so we'll have findings of that later this year.

Next we have another audit that is underway on the National List and the National Organic Standards Board. So they are evaluating the process for adding substances to the National List of allowed and prohibited substances. The findings of that particular audit should be released relatively soon.

Next we have the National Institute of Standards and Technology. So part of the audit from March of 2010 was that we had never conducted -- the National Organic Program had never conducted -- a peer-review. So we contracted with the National Institute of Standards and Technology to do a peer review assessment of the Program. The first phase was completed last July. They had 28 findings and four observations. And our corrective actions have been accepted and we are just about ready to complete those corrective actions.

Overall, NIST found that the NOP is designed to fulfill the requirements of the USDA organic regulations and that our actions are aligned with ISO 17011. ISO 17011 are the general requirements for accreditation bodies. So what we have done to address the findings from the NIST audit was: we revised our work agreement with the NOP auditors, we have improved our web content, we've drafted proposed regulations to remove the FACA requirement related to accreditation, and we have improved control procedures for documents and records.

A brief overview of the NOP budget for fiscal year 2011, just to give you some sense of where the money goes. We were appropriated \$6.97 million, a little under \$7 million for fiscal year 2011. This year we have a little bit less than that, \$6.92 rather than \$6.97. Our largest expense categories are \$3.8 million for salaries and benefits. We have \$1.6 million that are for contracts and agreements. And I will talk a little bit more about those particular contracts and agreements that we have engaged in. Almost \$800,000 for agency overhead, which includes the Administrator's Office for Agricultural Marketing Service, our human resources, our support for human resources, the Congressional affairs office, communications office, civil rights offices, training, and IT. So there's lots of things that -- lots of uses that that \$7 million goes to, not just directly into the NOP for our use. We have overhead expenses. And we have about \$175,000 for other USDA services, for facilities, lights, power, mailroom, security. And then about \$165,000 for travel, which includes the travel for the Board.

So in terms of contracts and agreements, a lot of the contracts and agreements go to support the work of the Board. Technical reports for the NOSB - a couple hundred thousand dollars for that. The NOSB public meeting webcasting is a contract that we issued. Hotel contracts and transcripts for the NOSB are part of that money. The NOP Appeals Staff is separate from the National Organic Program, so we fund the NOP Appeals Staff, which is 2.5 people. We had a contract for permitted substances list that we are hoping to publish later this year that will provide a permitted substances list for crop inputs. We are currently doing an economic impact analysis for the animal welfare recommendation from last year to see what the economic impact is on the organic poultry industry. We have an organic literacy project we are doing and will be rolled out to USDA later this year. This is where we are providing information about certification in

the organic standards to other USDA agencies and field offices in particular, so that information about the opportunities in organic agriculture can be provided to farmers and handlers all over the country. So we are very excited about that particular project. We have an inspector reviewer criteria development project that we hope to provide further instructions to certifiers about the criteria for inspectors and reviewers, the qualifications that they need to have. And then we are working with NCAT, the National Center for Appropriate Technology, which has the producer/handler workbooks that will be updated. So lots of things going on through those contracts.

So accomplishments for the Program, in terms of accreditation and international activities, we continue to do audits of domestic and foreign certifying agents. We established the trade partnership with the EU. We streamlined our trade of ruminant livestock products to Canada. We demonstrated that the pasture rule meets or exceeds the Canadian stocking rates. So that now, for ruminant livestock products going into Canada under the Canadian equivalency arrangement, they no longer have to demonstrate that the stocking rates are being met. As I said, we have aligned our accreditation processes with ISO 17011. And we have revised our audit checklist on certification to include all the various components of the certification and accreditation criteria.

In terms of -- next slide -- compliance and enforcement, as of the middle of this month, we completed 162 complainant investigations which is 26% more than all of last year. So we made a lot of improvements in terms of our timeliness of closing those complaints that come into NOP compliance. We have issued \$54,000 in civil penalties this year. We published nine fraudulent organic certificates online. And we continue to have our efforts to streamline investigations and make enforcement more effective. So a lot of things are going on in compliance and enforcement. We have a new Director of our Compliance and Enforcement Division, Matthew Michael, who comes from FSIS. And he has got a lot of experience in conducting investigations and bringing a lot of that experience to the National Organic Program and things are going really, really well there. We've also worked a lot with our NOP appeals team and reduced the appeals time from 698 days -- was the average time period from the filing of an appeal to the issuing of the appeal decision, that was in 2009 -- down to 256 days in 2011. So great improvement there, but we are not done yet in that regard. We hope to get down to about 90 days as the target over the next couple of years, for appeal decisions. We really feel like this is important to get those appeals decisions done as per OFPA. It says "an expedited appeals process". So we will continue to work on improving in that the area. Next slide.

In terms of standards, we have implemented the pasture rule. We have new policies on GMOs, textiles, and residue testing. And we have published many things, many National List amendments, and guidance to implement the National Organic Standards Board recommendations: Sunset 2011 final rule, crops and handling materials, Sunset 2012 proposed rule; vitamins and minerals proposed rule, parasiticides proposed and final rule, methionine and tetracycline proposed rule. So lots of things are going on in that arena.

And then in terms of NOP-wide activities, we have improved our website and communication. We have the NOP Organic Insider that is now a standard part of our

communication strategy. And then we have also increased participation in the organic certification cost share Programs over the last couple of years by 20%. More organic producers and handlers are now participating in that Program and getting the cost share assistance that they deserve.

Okay. Now moving on to some of the challenges that we face, some of the things we have identified as challenges. One is geographic. If you look at a map of the United States and the number of certified organic operations, you can see that some states, there's a lot of adoption of organic agriculture. California, Washington, Wisconsin and New York lead the pack. But then if you look at the southeast part of the US, there's many states that have very little adoption of organic agriculture or certified organic agriculture. And there's no lack of markets in the South. Organic markets are very strong in the retail category in those states and the cities in that region. And there's no lack of great farmland. So what are the barriers that are there that are not allowing farmers - organic farmers - in that area to participate in the opportunities that organic offers? We would really like to address that to see if we can get more adoption of organic agriculture in the South.

Next challenge that we have identified - next slide - is not applying the standards uniformly. We see this when we do the audits of certifiers -- that certifiers are still making different decisions in terms of implementing of the standards. So we still need to work on consistency in terms of how the standards are applied in this global system. Next is lack of data. As we work on our rulemaking and our guidance, we really lack a lot of data on the number of operations affected and the economic impact of the rulemaking that we are conducting. It is really an impediment for us to move quickly with our rulemaking is that lack of data. Insufficient technology in terms of -- as we identified in the OIG audit -- insufficient technology of our list of certified operations is out of date. We really need to ramp it up a bit in terms of information technology. And finally, we have limited resources. We have -- the US is in a tough budget times. It is really difficult budget scenario in Congress. And so we have a \$7 million budget. We cannot get it all done. We are getting a lot done, but taking on more activities is really challenging.

So we have four initiatives that kind of summarize where we are heading around clear standards, consumer protection, market access, and information technology.

So the first one is around clear standards. We think that this is essential in terms of fairness and transparency, to level the playing field. So continue our work to publish clear standards. Address those gray areas, in terms of implementation and ensure consistency. Ensure our continued collaboration with the National Organic Standards Board to clarify those gray areas. And make sure that this is a transparent process throughout.

The areas of focus that we have are residue testing - getting our final rule out on residue testing. Origin of livestock is a priority - to get that out this year in terms of a proposed rule. We are working on getting the permitted substances list published for crops. Pet food, aquaculture, apiculture, and mushrooms are other practice standards we would really like to move forward.

The next major initiative is around consumer protection, which leads to consumer confidence. This is really the core of the whole system - the organic regulatory scheme. We need to protect the integrity of organic products, whether they are grown locally and sold locally or grown in a foreign country and enter into the global organic market. Continue our rigorous inspections and investigations. Conduct more audits. We would really like to initiate a market surveillance Program. Enhance our enforcement actions. And ensure terms of our trade partnerships are being met. In terms of enforcement actions, just to make you aware, that in the Farm Bill that the Senate has adopted, there are a couple of amendments that are being proposed to the Organic Foods Production Act to provide stop sale authority and subpoena authority to the Programs that would enhance our ability to take enforcement actions. And, of course, we have no comments on the Farm Bill, but just to let you know that that is out there.

Market access is really key to provide economic opportunity. We think of market access not just in terms of market access to foreign markets, but market access for local and regional farmers to get organic products into their farmers market, into their local and regional stores. Why in the South is there plenty of organic products being sold, but those farmers are not – or don't have access -- to the market. What are the barriers? Why are there very limited certifiers -- local certifiers -- available in the South? What information do they need to overcome those barriers -- to be successful in getting into the organic market? So we want to enhance our USDA technical and financial assistance. We do want to continue to provide access to foreign markets as well. We feel that's important. And we want to make the organic certification process accessible to all in the US. Affordable so that small and medium-sized farmers can afford it. And attainable so that we don't make the process so difficult that people cannot attain the certification.

And finally, information technology, which we believe it is very much tied to organic integrity. We do have a list of certified organic operations on the website. We get a list of all the certified organic operations from the certifiers once a year. And it takes us a little while to put that together into a comprehensive list. There's a lot of great information there. It's actually a searchable spreadsheet, so if we go to the next down arrow, if you were a producer in Alabama, and you were interested in organic livestock production and you were looking for organic hay, you could put in the state of Alabama and hay and you would come up with two producers. So there is two producers you could potentially identify. The next slide shows this farmer in Alabama, let's call him Marcus. What kind of questions would he have? So I'm looking for organic hay. I want to get in organic livestock production. I found this list of certified operations. But what do I need to know?

I needed to know whether or not -- next -- is this operation still certified? Since we get this list of certified operations one time a year, it is already out of date when we publish it. So they would have the question, whether this operation is still certified? Have they been suspended or revoked? And whether or not they have any organic hay available? So we really want to work on this organic database. Next slide.

So this would better connect the organic community, a modernized database. Provide historic and current information on the certification status. We would like to display the search results in list or map-based formats. And allow certifying agents some kind of interface so that they can efficiently provide updates, and that this could be a real-time database.

For example, with a map, you could list the particular operations that are currently certified, where they are located. But we would also like to provide information on here, what certifying agents are available in this region. How do you get in touch with the organic certification cost share Program? What kinds of organic input supply companies are around, or what kinds of market opportunities are there? So, there's a lot of things that we could do through this database that could provide more information, and make it more accessible to protect organic integrity.

So the benefits: enhanced oversight of certifying agents; increased transparency. We have a number of separate spreadsheets currently on our website. We would integrate all those different spreadsheets into one source. And streamline the certification process, especially for export markets. We could provide export certificates in a timely fashion for Japan, Korea, or the European Union.

Okay. So those are the four areas that are our initiatives: clear standards, consumer protection, market access, and information technology. And we do that to level the playing field, protect organic integrity, increase the number of organic farms and businesses, and connect the organic community via integrity.

So that's the end of the first section. Any comments or questions from the Board on what the Program is up to? Could be a chance to get a drink of water here.

All right. So we will just move on to the next part. What is the role of the National Organic Standards Board? This is what we will talk about the Federal Advisory Committee Act. Next slide.

So the Organic Foods Production Act establishes the framework for the National Organic Program, and the National Organic Standards Board, the roles and activities. It establishes the NOSB to assist in developing the proposed standards for substances for use in organic production and advises the Secretary on other aspects of OFPA. It establishes the National List, which is based on proposals from the National Organic Standards Board and it outlines the NOP and NOSB roles.

So a brief history of the Board: It is a very active, self-empowered organic community. It existed before the Organic Food Production Act. OFPA was established in 1990 but there was little funding, initially, to support the work. There was a tough learning curve faced by both the NOSB and the USDA in establishing the National List and the NOP role. USDA had a lot of cynicism about the organic community. That has changed dramatically over the last 20 years. But when I started, for instance, at the Washington State Department of Agriculture in 1988, there was a lot of jokes about organic



agriculture. Things have really changed. We've really come a long way, that organic agriculture is very well accepted within both the federal and state departments of agriculture. So I would also like to say that this is the 20th anniversary of the National Organic Standards Board. I would just like to read off the names of the original National Organic Standards Board. Craig Weakley, who just retired recently from Cascadian Farm/Small Planet Foods; Don Kinsman; K. Chandler; Dean Eppley; Margaret Clark from Washington State; Merrill Clark from Michigan; Michael Sligh, that might be here somewhere -- Michael, thank you for your service; Nancy Taylor, who unfortunately passed away earlier this year, which is quite sad. She was from Utah and Idaho. She actually worked as an inspector for Washington State Department of Agriculture for a while. Rich Theuer, who might be here as well. Maybe later. Bob Quinn from Montana; Tom Stoneback; and J. Friedman, who helped to start the New Mexico Department of Agriculture's New Mexico Organic Commodity Commission. Thank you for their service and thank you for the new Board and all the time in your service as well. Okay. So where was I? So as NOP implemented the rules, -- let's step back a minute.

So the NOSB recommendations have often been viewed as default answers by the organic community, especially in the '90s, as the Program was being developed. And as NOP implemented the rules, the focus shifted more and more to the NOP and certifying agents. And we have formalized the process. In this phase, NOSB worked on many issues but NOP really lacked the resources to respond to many of those things. So you saw the development of many, many NOSB recommendations that the Program just did not have the resources to implement. And at times the National Organic Program released directives without adequate input from the NOSB or the organic community, and that led to community conflict.

So now we have a new balance. There's increased funding for the Program, which allows better management and rulemaking. There's more frequent and structured communication between the NOP and the Board. We provide regular feedback to the National Organic Standards Board on your recognition and the management support for your work. We regularly request your advice on materials issues and practice standards and we want to continue to do so.

So our current challenges are that industry growth and new technology options have led to increases in the number of public comments and to public scrutiny. The rulemaking and guidance implementation is very lengthy and resource intensive. And it is getting more and more so. The process of getting things through clearance is just -- it takes a long time. There's a lot of people we have to satisfy to get the NOSB recommendations implemented and through the rulemaking process. The NOP and the NOSB are both governed and overseen by many offices and interests. The NOSB activities and NOP's management, we must comply with the requirements of the Federal Advisory Committee Act, as well as with OFPA.

So the Federal Advisory Committee Act: what is that? It governs how all advisory committees provide advice to the federal government. It has specific requirements. It requires that advice is objective and accessible to the public. It provides for the

government-wide oversight of those advisory committees. And it establishes a framework covering the creation, management, operation and termination of those committees. The goals of FACA are to enhance public accountability. Requires balanced committee membership to control undue influence, and to maximize public access to committee deliberations through public meetings, and through the public comment process. Another goal of FACA is to reduce wasteful spending, to monitor and reduce costs, to reduce redundancies, and to maintain accountability of this process through our annual report of accomplishments. So we have to report back to the FACA folks every year on the accomplishments of the Board.

So FACA defines a committee as any committee, Board, or other similar group, which is established by statute for the purposes of obtaining advice or recommendations. So we call it the National Organic Standards Board, or you are also an advisory committee. So you will notice on the agenda that we have changed the standing committees to the term “subcommittees” because committees in FACA language equals -- has certain requirements, has certain standing. All committee meetings have to be public, have to be accessible to the public. So that's why we are now, from this point forward, going to be calling the previous NOSB committees “subcommittees”. Functionality-wise, it is going to work the same way. But we are just going to call your previous committees “subcommittees”, because the National Organic Standards Board is a committee under FACA. So, federal advisory committees exist to advise and recommend and not to decide. So your job here is to advise and recommend actions for the National Organic Program in relationship to OFPA.

So, does FACA conflict with OFPA because OFPA has specific requirements as well? It does not. OFPA does not direct the NOSB to decide. OFPA asks the NOSB to assist in the development of standards, to provide recommendations, to evaluate substances, to develop a proposed National List, and proposed amendments to the list for submission to the Secretary. The Secretary retains that decision-making and rulemaking authority.

So government oversight of the NOSB is through the Government Services Administration, which administers FACA. At USDA, we have a dedicated Committee Management Officer that oversees all the advisory Boards, all of the federal advisory Boards, at USDA. And we are held accountable to that group for the governance of the Board, for the activities of the Board, and for the budget of the Board.

Our responsibilities are to establish uniform administrative guidelines and management controls, maintain systematic information on committee operations, exercise control and supervision over committee management Program, and make sure that the advice of committees is not inappropriately influenced.

Our responsibilities, through our designated Federal Officer – and Michelle Arsenault, the Special Assistant to the Board is the designated Federal Officer for the Board -- is to call, attend, and adjourn those committee meetings, to develop and approve agendas, to maintain those required records and budgets, to ensure efficient operations and adherence

to FACA and other laws, and to develop committee reports for the Committee Management Officer.

So the success factors: Our success is measured in part by our success in managing the National Organic Standards Board. Are Board and Program resources being used effectively and efficiently? Is the NOP asking for advice that it can then act upon? It wastes time and resources for the Board to work on items that we cannot implement. So we really want to collaborate and work very closely with the Board and on the work plan of the Board, on the agenda of the Board, so that we can work together to build the organic sector, to build the National Organic Program. And then finally, are appropriate management structures and processes in place and are they functioning?

So, a little bit about the budget for the National Organic Standards Board. There's \$190,000 for direct NOSB expenses in our budget. That covers the salary for our Advisory Board Specialist and the travel for Board members and staff. There are additional expenses that are related to the Board as well: The meeting contracts and transcripts, the technical reports, which is quite a bit; Webcasting; and all of the staff subcommittee support that we provide to all of the subcommittees. So all in all, there's quite a bit of our budget, of our \$7 million budget, that goes to the -- to support the work of the National Organic Standards Board. Very critical work, very important work for the success of the Program, the work that you do. But we want to make sure that we are collaborating on that work to make the best use of our limited resources and to make the best use of your time, which is also limited.

Okay. So FACA meeting rules: open meetings are required with the opportunity for public comment. Meetings must be announced 15 days in advance in the Federal Register. The meeting minutes are required and have to be publicly available. And the meeting must be accessible.

Ethics: Board members speak for "we" not "I". They represent and are appointed to represent the points of view of recognizable groups: growers, handlers, consumers. It is expected that members will represent a particular bias, driven by the group that they represent, not by your personal views. So try to keep that in mind as you're deliberating on these very important matters: to keep the perspective of your particular group in mind as you deliberate. Members must disclose interest for any specific votes and abstain from voting where conflict exists.

Some of the key roles for the Board: provide recommendations to the Secretary regarding the Organic Foods Production Act, develop the proposed National List or proposed amendments to the National List for submission to the Secretary, convene the technical advisory panels to provide scientific evaluation of materials. This is something that has not been done for a while by the Board. It's something that I think would be really important for the Board to take up again, the creation of these technical advisory panels. Specifically, review botanical pesticides, which is in OFPA, and then advise the Secretary on product residue testing for unavoidable residual and environmental

contamination and emergency spray Programs. Those things are all outlined within OFPA.

In terms of the National List: The National List is established by the Secretary, shall be based on the proposals developed by the Board. The proposals must be published in the Federal Register with public comment period. This notice must include any changes to the proposed list that is provided by the Board or amendments that are recommended by the Secretary. The NOSB also establishes procedures for how people can petition the Board for evaluating substances for inclusion on the National List. So that is also your responsibility, to establish those procedures around the petitions process.

Your activities and parameters: National List activities defining the petition process, considering proposed substance petitions, proposing new National List items to USDA, that is your responsibility, and completing the Sunset evaluation process that you must do every five years for all substances that are listed on the National List. Key parameters within OFPA: a quorum is defined as the majority of the NOSB members. And then it also talks about decisive vote: that a two thirds of the members present is a decisive vote. We will go into that in a little more detail in a moment here. And then it also spells out the criteria for evaluating substances for the proposed National List or proposed amendments to the National List.

Okay. So that was a lot about FACA. I will stop there and pause. Are there any questions, comments, on this section?

Barry Flamm: Colehour has a question.

Colehour Bondera: Yes. Thank you. Yeah, it was a lot and I don't know that I feel that I'm totally adept to inquire, but I'm curious about some of what may or may not be easier issues which are: you laid out some of the budgetary topics and -- I don't know if you can clarify more. I have two questions. One is, you said that there is \$190,000 that's -- sorry I'm not going to get the word right -- but is direct expense. But then you said additional expenses. And you referred to, in what you presented, that it was "quite a lot". But I wanted to have a better sense of if it was - just to get a scope of the whole picture - if I get a better sense of those additional expenses that are incurred.

Miles McEvoy: Right. For budgeting purposes, we budget \$190,000 for the Board. USDA has limits on how much money it can spend on advisory boards in general for the whole department. And the National Organic Standards Board is a significant amount, of that total amount, that is allocated by the federal government, by USDA, for advisory boards. So there are additional costs, additional time that also goes into supporting the Board. Besides Michelle on the subcommittee calls, there are NOP staff members that sit in on all those subcommittee calls to provide technical assistance, to do some background work for the subcommittees as necessary, to provide you all with the information that you need to make good decisions. So there's that cost. There's the cost of the technical reports, so that is a separate contract not included in the \$190,000. I think we spent -- Lisa what was it? - about \$200,000 for technical reports from our last year's budget? Webcasting and --

I can't remember the other part, but there are other costs as well. We figure somewhere between half a million and \$600,000 total cost to support the Board, which is a significant part of a \$7 million budget. But really, it is a very critical part of this whole public-private partnership, the Board. We really rely on your work, so it is important for us to invest in good deliberations, good decisions so we can move forward with the Program. But there is cost involved in supporting that work.

Colehour Bondera: Yeah. Thank you. That gives me a better sense. And leads to my second question, which was: You said that the NOSB could, as it has in the past, convene Technical Advisory Boards - that maybe we should be doing that - you alluded to that in what you were saying. And I'm curious - again from a financial perspective - is there, since we don't have a budget, we don't, I don't feel -- from my perspective -- it's like, well, is there money to be convening Technical Advisory Boards? And who is doing that? Where that fits into this whole picture is a little bit unclear, at least to me. I don't know. I have not discussed this with people. I would like it if you would address that a little bit more detail. Thank you.

Miles McEvoy: Yeah. If the Board wanted to restart technical advisory panels, there would be a cost involved, but we already have a lot that are invested in the technical reports. We also are working with the Agricultural Research Service in terms of them providing assistance in terms of peer review of the technical reports to ensure the quality and completeness of those technical reports. There might be some ability of USDA working with the Agricultural Research Service to help to convene technical advisory panels. So I don't think you should get hung up on the cost of implementing a technical advisory panel. Because first you would want to scope out what it would look like. But it is an important part that was envisioned within the Organic Food Production Act that there would be these technical advisory panels that would be feeding in information to the National Organic Standards Board to provide you with better, more complete information so you can make your final decisions on the National List.

Colehour Bondera: Thank you.

Barry Flamm: Are there any other Board -- Jay has a question for you.

Jay Feldman: Thank you, Miles. Thank you for your comments and interpretation of the statute. I particularly appreciate the emphasis on collaboration with the Board and the need to work together in moving the Program ahead on behalf of all of the stakeholders that have a real interest in seeing organic grow and seeing it grow with integrity.

One of the elements, one of the elements that you mentioned, which I think is key to our better understanding of the responsibilities that we have in carrying out the statute, is this overlap or cross authorities of the FACA law and the Organic Foods Production Act. And you pointed out, rightly so, that this Board has specific statutory authorities that are distinct from, and perhaps complement and may amplify, the FACA statute.

And one of the things that the statute talks about, which Colehour mentioned just now, is the authority of the Board to convene technical advisory panels, which is an important authority and I think goes back to some of the history, that you yourself mentioned, in terms of the recognition that was afforded the organic sector back when the law was established. And that lack of recognition in some circles, and that today has been corrected, and now we see much more acceptance and support from USDA and from state agricultural agencies. But nevertheless, that was envisioned by the drafters and by Congress as an authority that was vested with the Board. To, by virtue of convening, to essentially direct how those technical panels were put together, who served on them, what their backgrounds are, whether there are conflicts of interest, the range of issues that one would bring to a deliberative process around the act of convening. So I think the Board, in my view, should exercise that authority. And I would like to ask the Chair of the Policy Development Committee to put this on the work plan in terms of figuring out ways to exercise that authority in a collaborative spirit with the Program, which is key to the statute working.

The other element that you didn't mention, which I was surprised not to hear you mention, is the section in the law that is entitled "No Additions to the National List", which I know you are familiar with. I just want to make sure the Board is aware that in addition to this authority that the Board has. And if we are to do our job, we find we spend a lot of time on this, and that is making proposals and recommendations, as was stated, to the Secretary on the formation of this National List. But there is a key limitation there, which is very distinct to the NOSB. And you will not find in other FACA committees, that I'm aware of any way. And that is that there's a limitation on what the Secretary's authority is with respect to the National List. And that is just to read this, just so that I don't misinterpret it, I will read the language to you. "The Secretary may not include exemptions for the use of specific synthetic substances in the National List, other than those exemptions contained in the proposed National List or proposed amendments to the National List."

So those proposals obviously come from this Board and the Secretary may not create exemptions from that list. What flows from that is pretty substantial authority to manage that list. Now, we can make a proposal, the Board can make a proposal to add something to the list and the Secretary may choose not to add that substance. But the Secretary may not remove something that we have added to the list. Or, no, I'm sorry. The Secretary might not add something that we have not proposed for the National List. And please correct me, I will stop in a minute here, but please correct me if I'm wrong in terms of this interpretation. I just want to make sure that as we move forward and as we carry out our responsibilities, vis-à-vis work plans and agenda items to carry out our statutory responsibility, which is unique to this Board, that we have sufficient authority to manage that list in a way that enables us to hear from the community of people that we represent in our various sectors, and carry out that statutory responsibility as it was intended by the lawmakers and the public that got behind it. Thank you.

Miles McEvoy: Yeah, you are absolutely right, Jay, I'm going to cover that in the next part of the presentation.

Barry Flamm: Zea has a question for you, Miles.

Zea Sonnabend: Thank you, Miles. My question has to do with what you said about the FACA Board as it relates to what you said about the OIG auditing the National List procedures. And will the OIG audit be oriented towards NOSB procedures or only how the NOP implements NOSB recommendations in terms of rulemaking? And along with that, do you expect that to come out before the next NOSB meeting in the fall?

Miles McEvoy: Yeah. I actually can't provide any details because we actually don't have the details. We know the report is going to be out fairly shortly. It will be out before the next Board meeting. And we will certainly share it with the Board as soon as it is available, but I don't have any details that I can share with you.

Zea Sonnabend: But will the corrective actions be only for NOP to correct, or will the NOSB have to take up some of the things that are in there to correct our procedures? Do you have any idea?

Miles McEvoy: We don't know what the findings are yet, so we can't, I can't, provide you with any information at this time.

Zea Sonnabend: Thank you.

Barry Flamm: Are there any more questions from the Board on this part of the presentation? John has a question for you, Miles.

John Foster: Thank you. Miles. On your areas of focus that are coming up, there's a pretty long list there. Can you help us understand how those are prioritized? How you prioritize those? Apiculture first, or aquiculture first, or mushrooms, or...? What are the criteria that you make those priorities?

Mile McEvoy: We have lots of areas of focus. I wasn't sure if you are talking about we are focusing on for accreditation audits or ...? So you are talking about for standards development specifically?

John Foster: Not necessarily, although that was my main point. We can focus on that. Standards development prioritization would be great.

Miles McEvoy: How do we prioritize? Ah, that is a good question. We try to listen to the various stakeholders, the Board ... So, there's a lot of different factors. So let's just look at that list of items that we have for prioritizing standards development. The residue testing rule is a priority because that's part of an OIG audit. It was a finding from an OIG audit that we were not meeting a requirement under the Organic Foods Production Act. So that goes was up to the top of the list. That is why that's at the top of the priority list.

The origin of livestock is at the top of the list because we know it's really, really important to a large segment of the organic community. We have a recommendation from the Board from years ago that we know we want to move forward as quickly as possible.

The rest of those items on the list, we pretty much tried to date order them from the oldest NOSB recommendation forward. But you will see that they are not quite in that order. So it has to do partially with resources and the size of the economic opportunity for developing standards in those particular product categories. And Melissa has something to add here on that.

Melissa Bailey: Thanks for the question, John. I would also just add to what Miles said in that a number of our priorities are sort of driven by the nature of the National List, of course. So we've been heavily involved in a lot of Sunset work over the last year. Any work that has, sort of, a time-sensitivity to it. So things with expiration dates really jump to the top of the list and push down a lot of those other priorities just because of the time sensitive nature. So I think Miles will also address expiration dates a little bit later in the presentation.

Barry Flamm: Are there any other questions from the Board on this portion of Miles' presentation? Jay has a follow-up question, Miles.

Jay Feldman: I was hoping someone else might ask this, but... First of all, I want to preface, Miles, what I'm saying with extreme happiness and enthusiasm around the strength and growth of the National Organic Program. It's institutionalization within USDA and the work that you're doing and the Program staff are doing with respect to implementation of this law. But you heard the "but" coming, right?

Crowd: [Laughter]

Jay Feldman: One of the things that I'm hearing – and it is sort of a subtext of what you have been saying in this presentation -- is that somehow in carrying out our work plans and in thinking about the decisions the Board makes, the NOSB makes, that we should recognize that the Program has financial challenges, and budgetary restrictions in terms of how it can move and so forth and so on. And I certainly, I hope, you believe that I appreciate that struggle and that limitation and that I'm sure all of the other Board members do as well.

I want to get your thoughts on this, because I think it's something that we have to be clear about. And that is whether this Board, in carrying out its statutory duty to propose changes under all the procedures that we have in place, including annotation process under the Sunset reviews, whether we should consider issues of budget and financing within the Program when we are deliberating on a particular action that we think is necessary to carry out our statutory responsibilities as a Board. And I raise this because it has come up in your talk today and also in other discussions that we've had. And my feeling is that that would be outside the purview of this Board. That our Board has a duty to evaluate these based on the standards and statute and that is as far as we go. We hand it



off to the Program. The Program is then in a tricky spot. We recognize. And that goes to the question of budget allocations.

I close saying that, in talking with people in other agencies on this very question, where we all know we are struggling as a government to meet obligations and so forth, that the one thing I hear over and over again is that, where Programs have statutory duties to fulfill, the government is very sensitive to funding those Programs. Because the government recognizes that they are vulnerable to litigation should they not meet their statutory duties. So I want to put that on the table because we will have a lot of issues coming up over the course of this meeting, as you know, that obviously affect the Program's use of funds and prioritization and so forth. But I just wanted to get your perspective on whether you thought it was appropriate for this Board, the NOSB, to curtail its decision-making in any way relative to budgetary issues. Thanks.

Miles McEvoy: Yeah. I wouldn't use those particular words, but I think it's very important for the Board, if the Board wants to be successful in terms of implementing your recommendations, making them actually be implemented and followed by the Program and implemented by the organic community worldwide, you have to keep in mind what our resources are and what is possible.

We have a full plate. And a lot of things are not under our control. We have very good control over the accreditation process and the compliance and enforcement process. And we are making great strides in that area. But in terms of rulemaking, guidance development, there's a lot of other factors that come into play.

Office of General Counsel, they have limited resources for reviewing the things that we send down there. So that is the major bottleneck at this point is the Office of General Counsel just does not have enough attorneys to crank out the work. So they are slowing down the process.

And then you have our ability to get things through the clearance process. There's only so much capacity that USDA has for rulemaking. And we get so many cards to play during any particular time period. We can't do it all at once. We have those limited resources. If the Board wants to be successful in implementing your recommendations, you should realize the capacity of the Program, of USDA, to implement these recommendations. Okay.

Barry Flamm: I believe that's all the comments for this section. If you want to continue on the next, Miles?

Miles McEvoy: Let's move onto the next section. The next section is how can we best utilize our limited resources? Perfect segue, Jay. Thank you. Next slide.

So, a little bit about the process from work plan to rules. The work plans are the things that the Board develops. They are basically their agenda for what they are going to work on during the various sessions. So the NOP and the Board agree on that particular work

plan. Those subcommittees engage in the work of developing those work plan items. And they develop proposals. That takes between three and nine-months depending upon the particular issue. There are things that the subcommittees worked on this last few months that they decided not to bring to the meeting here in Albuquerque. And will most likely be on the agenda for the Providence meeting. Next slide.

So next, those NOSB proposals from the subcommittees are posted for public comment. There's a public meeting. The NOSB considers those public comments that come in in written and oral form. Revises those proposals and votes, and makes a final recommendation. Those recommendations are then provided to the National Organic Program and USDA. And that takes about three months from the publication of the proposals to the final recommendation coming out.

Next, we consider those recommendations and we respond to those recommendations. We engage in rulemaking for development of whatever is necessary, whether it's guidance or policy statement or proposed rule. And then anything that we would do, for the most part, would then come out as another proposal that would be subject to public comment. And then would be finalized to the rulemaking process or the guidance process based on that public comment.

So rulemaking for National List takes from six months - if we are really pressed for time for particular things, like we did with the interim and final rule on methionine - to eight years it took for moxydectin from a final recommendation to a final rule.

So, the types of proposals that the Board comes up with: National List petitions, to add, remove, or change the listing for a National List. You also have Sunset proposals to determine if a current listing should be renewed, or whether it should be removed, or whether that should be amended. And then you have your non-National List proposals. So those are practice standards or clarification of the USDA Organic Regulations or other areas involved in implementing OFPA.

So the process for the National List petitions is that you review the petitions for completeness. That is done in concert with the Program. You request a technical report. You review the technical report and the petition. The subcommittee develops and votes on the proposal. We post those subcommittee proposals for public comments. Written and oral public comments are considered by the subcommittee and the Board.

Then, in terms of decisive votes -- sorry for the small print here. But, in terms of National List petitions, a decisive vote is a two thirds majority. The Board votes to classify a substance as synthetic or natural. That would also require a two thirds decisive vote to proceed. The failure to obtain a decisive vote on classification would stop the process. So, if the Board fails to make a decisive vote on synthetic versus non-synthetic for a petition, the process would end at that point. You would have to go back to subcommittee, try to figure out if there's a way to get to a consensus on that or a majority vote. Not a majority vote, a two thirds vote.

Next, the Board votes to list, not to list or change the annotation or to remove the listing. That also would require a two thirds decisive vote to proceed. And then NOP considers the recommended action and responds with our intended next steps. We can accept that recommendation, we can further restrict the addition of something to the National List, or we could choose not to take the recommended action. And, Jay, as you pointed out, NOP cannot expand the use of a substance without the NOSB decisive vote. Next.

So in terms of Sunset review, the NOSB reviews the history. The subcommittee may request a technical report. The subcommittee then develops a proposal. That is posted for public comments. The Board would then vote to renew, to change, or remove the listing. If the NOP cannot renew... let's see. The NOP cannot renew the listing without a two thirds majority. If two thirds majority is not achieved, the listing would be removed. Again, this is where the decisive vote comes into play on a Sunset material. If there's not a two thirds vote to relist, then that substance would not be... we would not have the ability to move forward to relist that substance on the National List. So NOP then again considers that recommended action, that proposal from the Board, and responds with our intended next steps. We can either accept, further restrict, or choose not to take the recommended action, but we cannot add to the National List.

Non-National List Proposals: The NOSB and the NOP agree on the work plan. The subcommittees develop the proposal. The subcommittee proposals again are posted for public comments. The Board votes to recommend action. Again it requires a two thirds majority vote for that decisive vote. And then NOP will take those recommendations under advisement, but we are not restricted to the recommended language or actions. So for non-National List recommendations, we are not restricted. We can change those recommendations based on other input.

A little bit of data here. This just shows the number of petitions that have come in over the last 10 years. And you can see that there was a big jump in 2007. This was part of the Harvey lawsuit with the 606 materials. So I can't read the small print there, but lots more came in in 2007. And then you will see pretty much a steady number of petitions and then another uptick in 2011 in terms of number of petitions that are coming to the Board.

The number of technical reports, there was a number in 2002 and then another uptick in 2006 related to the Harvey lawsuit. And then you can see that a lot of technical reports have been done over the last two years. In 2011, it has some number there, what -- 30 technical reports were conducted in 2011. So we are putting more resources into those contracts to provide more technical reports to the Board.

Number of NOSB recommendations over the years. There was a peak in 2007. These were the 606 materials. And many recommendations -- where is that? Around 40 to 50 recommendations per year? 2007? -- 63 recommendations in 2007 which is the high water mark. And as you know there still are many National Organic Standards Board recommendations that we have not implemented. Mostly those are practice standards. They were working on them but again the limited resources come into play there. Next slide.

Just shows the Federal Register activity. The types of Federal Register notices that we have published from 2001 to 2012. We will have this PowerPoint available on our website later today, I believe. So you can get a copy of this later. Next slide.

So from recommendations to final rule: So there's the step between when you make your recommendation to when the Program actually publishes the proposed rule. And that can vary a lot in terms of the amount of time. It can be six months for us to develop that proposed rule, or three years for fenbendazole, or it was eight years for moxydectin, from the time there was a recommendation to when we had a proposed rule out on moxydectin. And then the next stage is from proposed rule to final rule. On average for a National List substance, that is 10 [sic]. For Sunset rules, from the recommendation to the final rule on Sunset, it's usually about three years and for non-National List recommendations, the pasture rule took nine years from the first Board recommendation to the final pasture rule. And we don't actually have any other examples, which tells you something right there.

So details are important. But so is the big picture. The Sunset process enables the NOSB to review all materials on a five-year cycle. It's in the statute in terms of what's the responsibility of the Board. This is where we make our plea to the Board. That these additional expiration dates for National List substances present incredible timing and resource allocation issues for us to deal with in our rulemaking process. And we have so much work to do that we really would ask the Board to really restrict your use of expiration dates because of the extra work that occurs. We are not getting other work done. You already have a process through the Sunset review process to review these things on a five-year basis. Please restrict your use of that, of expiration dates, to that Sunset review process.

And then think about strategic rulemaking. For instance, pet food. A recommendation from the Board from a number of years ago projected sales of organic pet food are \$300 million by 2015. We don't have any specific USDA organic practice standards for pet food. National List annotation changes are important, but so are practice standards. We really want to get to some of this -- what we think are fundamentally more impactful work. The National List is really, really important, but give us some time to work on some of these other things as well.

Okay. So that's a little bit about how best to utilize our limited resources. Any comments or questions on that section?

Barry Flamm: Jay?

Jay Feldman: Thank you. Thank you, Miles. As you know, I was hoping we could have a community-wide discussion on the effect of non-decisive votes on synthetic/non-synthetic determinations at this meeting because I think there are a variety of opinions and insights that could be brought to the Program's interpretation on how to carry out this exercise in a way that is most protective of organic integrity and/or the growth of organic.

And so I would urge that we put that issue on the work plan. Again, giving the Chair of the PDC a lot of work.

But for the next meeting, because I think that we have, as a community, we have a problem with this. And the problem -- tell me again if I am misinterpreting the problem -- as I see it, that is, we have a lot of, from time to time, I wouldn't say a lot but from time to time, the Board is really dealing with issues of material allowance retrospectively. In other words, the material is out there. It has been used at one time. A MRO, a material review organization, may have said to a user that it was okay to use as a non-synthetic. And then had to re-, you know, there's new literature, new determinations, new information. And the MRO decided this is synthetic and it should go to NOSB. Or we are dealing with vaccines, or something of that nature, where we find out that there may be some GMOs in the mix. So it is suggested often by the Program that the NOSB take a look at this and effectively make a determination retrospectively on the use of those materials.

So we have had situations where the Board cannot make a decisive vote, reach a decisive vote on synthetic/non-synthetic. And the question before the Board is: is the material non-synthetic? Which is always the default question, as you know, before the NOSB. And so the Board, failing to make a non-decisive vote - in this case on a material that is in commerce and being used - is a critical question because it is a question of on-going use. It was -- many of us believe it was the correct interpretation would have been to disallow the use of that material by virtue of a failed vote on determination of non-synthetic. And so that creates a framework around which we, as a Board would know, that we are moving forward. In this case, the Program took the position as I understand it that because the material was in use, the Program would allow the material to remaining use. Sort of the inertia theory. You know: A chemical in use without scrutiny shall remain in use? Unless the NOSB can reach a decisive vote on non-synthetic.

Miles McEvoy: Or you could say a natural substance in use would continue to be allowed in use without....

Jay Feldman: This is why I want the community discussion, because the Board was unable to reach a decisive vote on it being a natural. That's why...

Miles McEvoy: That's exactly how OFPA is set up. You did not make a decisive vote. It then means you did not make a decision, so it goes to the Program to make a determination which we make every day on a multitude of issues, on materials every day. Certifiers are making those decisions every day. The Board's responsibility is to make -- your authority rests with when you make a decisive vote. You need two thirds of your members to make a decisive vote. What we have agreed to is that we will provide a document to the PDC around this issue of decisive votes. And we will have further discussions of that with the PDC. But it's not on the agenda for this meeting.

Jay Feldman: Right, I understand it's not. Here's what I'm hoping we can get to, Miles, and that is a better understanding of how the Program makes that decision. In other words, what are the criteria that are used?

Miles McEvoy: Yes

Jay Feldman: What are the determinations based on? So that I don't, as a member of the public and as a member of this Board, feel that those decisions are arbitrary and capricious? I don't believe, finally, I don't believe that just because a material is in use and the Board cannot make a determination that the material should remain in use, whether synthetic or non-synthetic in that context. And so all I am asking for, and I hope we can get some consensus on this at some point, that we have a set of understandings as to the process that the Program goes for -- goes through, I should say -- when it is taking the authority on a question for which the NOSB could not reach a decisive vote.

Miles McEvoy: Right. We will be going through that in some detail on the classification of materials tomorrow morning, which is based on the NOSB recommendation on classification of materials. We will be presenting that tomorrow morning. That is the basis of how we would make that determination. So we look forward to further discussions on that.

Barry Flamm: Any further Board questions on this portion of Miles' presentation? Would you like to proceed?

Miles McEvoy: Yes. Okay. Last part. I think this is a little bit shorter. So how we can all work together to achieve common goals. Ground rules for the meeting: All public and Board comments must be respectful. No personal attacks. This is standard Board process. No interruptions from the audience while the Board is speaking. No interruptions during public comment. We allow the public to speak. No intimidation, profanity or any language or activity that threatens openness.

This is a federally sponsored meeting. The meetings are managed using Robert's Rules of Order with the caveat around decisive votes as per the OFPA requirements. The NOP will intervene if the ground rules are broken, and may ask anyone who disrupts the meeting to leave. So we are many voices joining to form one community. Let's have a great meeting together.

This is a public-private partnership. We commend the NOSB for their public service, the countless hours that you have devoted to the Board. We know how much work you do. We really, really appreciate it. We really rely on your recommendations for the success of the Program, for the success of the organic community. Your diversity of perspectives, this vigorous public debate, it really strengthens our outcomes, strengthens our community. So thank you for that.

Just remember that the scope of organic is very, very broad. We have livestock feed to frozen beef skilllets, apple seeds to hard apple cider, small local CSAs to large

multinational corporations. All have to meet the same standards. All have to live under the same standards. Whether they are here in New Mexico or in Ghana, or China, they all have to meet these same standards, this world of organic farmers, world of organic agriculture. Let's celebrate this diversity to help us all achieve something much larger.

I just want to show a few slides from some of the audits that we've been on in the last few years. The next slide shows an organic cacao cooperative in Ghana. This is a group of 150 growers that are part of a grower group. We arrived on the day that they were making their first organic sale to a European buyer of organic cacao. They are all very, very excited about this opportunity to enter into the organic market.

Next slide shows the truck that was being loaded up. Big celebration for this community that gets to benefit from this organic market.

The next slide shows the alternative. The alternative to organic cacao in Ghana is this young man or teenager, possibly, with a backpack sprayer spraying chemicals without protective gear. In Ghana, the government subsidizes fertilizers and pesticides to cacao growers to try to up production. They don't subsidize organic production. They subsidize non-organic production. And organic holds so much promise for environmental stewardship, for getting toxins out of the environment. We really need to work on ways to promote and to support these kinds of efforts.

So next slide shows a young man, benefiting from the wonderful taste of fresh organic cacao.

And the next, I have a slide of a Veterans Sustainable Agricultural Training Program in Southern California. This is a thing that Karen and Colin Archipley have started. Colin Archipley is a decorated Marine veteran, served three tours of duty in Iraq. When he came back after his third time there, his wife really did not want him to back a fourth time. And they decided to buy a small piece of land and get into organic production. They have developed this organic hydroponic system which produces a lot of organic vegetables using 87% less water than a non-hydroponic system in that same area. And then they really wanted to give back to the veterans in that community in Southern California. So they started this Veterans Sustainable Agricultural Training Program to train other veterans on how to get into organic agriculture, how to get into the organic food business. So they teach them how to do organic hydroponics, business planning, financial planning. And it's really a wonderfully inspiring story of getting more young and beginning farmers into organic agriculture.

The next slide shows Mike Haynes, who was a homeless veteran. A lot of veterans suffer from post-traumatic stress disorder. And he certainly did. He was homeless for two years, participated in this Veterans Sustainable Agricultural Training Program, put together a business plan and now he has a successful hot sauce business that is part of the organic community. I think this is some of the things that really inspire me every day that I go to work of what we are all about in this organic community to really help build this organic

movement. So thank you very much and look forward to a number of good days of discussions.

Crowd: [Applause]

Barry Flamm: We will take a break now, recess until 10:15. Then we will begin our first public comment period.

[BREAK]

Barry Flamm: Our first public comment is by Alexis Baden-Meyer from Organic Consumer Association. And Jo Ann Baumgartner, Jo Ann will follow her. Alexis, would you proceed, please?

Alexis Baden-Mayer: Okay. Alright. So I am Alexis Baden-Mayer. I am the Political Director of the Organic Consumers Association. I appreciate the opportunity to present public comments before you.

The Organic law is great. It is just not always followed and it is not being fully enforced. And unfortunately, in most instances, when the refusal to obey the law has been widespread, the response from Congress, from the National Organic Program and from the National Organic Standards Board has been to change the law and regulations to match non-compliance rather than to strengthen enforcement.

The most striking example of this was in 2005, when the Organic Trade Association went to Congress to overturn a federal court ruling in favor of organic blueberry farmer Arthur Harvey.

Another more recent example is DHA and ARA. The National Organic Program admitted that these synthetics used in baby formula were illegally approved for use in USDA organic products. But instead of enforcing the law, which would have only meant changing the certification of these products to "made with organic", the NOP asked the manufacturer to petition the products for placement on the National List, and the National Organic Standards Board approved them at the last meeting, even though it was clear that the NOP had not properly vetted DHA and ARA to determine whether they were produced using excluded methods of genetic engineering.

Two more examples of the organic industry's refusal to obey the law, and the NOP's unwillingness to enforce the law, are open questions before you: GMO vaccines and animal welfare standards. Now I understand that you have tabled this issue, but I'm going to give my comments as prepared because I'm not exactly sure why you tabled. So I will just let you know what I think.

Under the regulations, GMO vaccines cannot be used unless they are successfully petitioned for use on the National List. To date, no GMO vaccines have been petitioned, so one would assume that they are not being used in organic.



In reality, we know that they are being used. This was first admitted publicly by the National Organic Program staff at the May 2009 meeting of the National Organic Standards Board. Richard Matthews announced to the Board that in fact, since the beginning of the Program, all vaccines have been routinely allowed in organic without a review as to whether or not they were genetically engineered. And he recommended that instead of the NOP enforcing the law against this violation, the NOSB should recommend a change in the law. And that is what NOSB did.

Deputy Administrator McEvoy wisely rejected that recommendation, but the NOP still has not made any attempt to enforce current law. The NOP should have immediately collected information on which vaccines are used in organic, and informed certifiers and producers of which of those vaccines were genetically engineered. At that point, prohibited GMO vaccines that had been used in organic could be petitioned, and we would be back on track with the current law.

Instead, the NOP seems to have left the ball in the NOSB's court, and we still have an acknowledged failure to follow the law and to enforce the law. This is not right. I urge you all to stop your work on the GMO vaccine recommendation until you get some assurances from the Program that they're going to actually take steps to stop the illegal use of GMO vaccines.

We have a similar issue in animal welfare. You all are trying very hard to establish some measurable standards for animal welfare. But the irony is that, while you try to improve animal welfare standards, the current regulation is being violated. The Livestock Living Conditions Regulations and Livestock Health Practice Standard Regulations – they are in my comments, and ... Okay. I am done. You can read those. But I encourage you to encourage the NOP to follow the law before you produce any more standards on animal welfare.

Barry Flamm: Thank you. Are there any questions from the Board?

Jay Feldman: Thank you, Barry. Thank you, Alexis. I appreciate your comments. You put your finger on an issue that concerns me as well in terms of how we get ahead of the curve on issues of compliance. Have you had any direct communications with the Program on ideas of how they might enforce this? My understanding is it is complex – this I am talking about the GMO vaccine – it is complex in terms of even knowing what is out there in the market now, as you know, with proprietary control that these companies exert over their genetic engineering technology.

How would you suggest we move forward as a Board? In what timeframe? And what is your expectation on behalf of consumers as to what we need to do as a Board? I mean, obviously you know, we do not enforce the law. So that talking to the Board about that isn't that helpful in terms of our ability to set priorities. But, what you think the Board should be doing next and in what timeframe?

Alexis Baden-Mayer: I don't think the Board be acting on GMO vaccines except to encourage the Program to enforce the law. And I think to come up with recommendation after recommendation on this issue isn't very helpful. I think that the Program has the responsibility. And I understand that the companies that produce GMO vaccines don't want to explain whether their vaccine is GMO or not, but if they want to use it in organic, they need to. And it is incumbent upon them to prove that their vaccine is non-GMO before it is used in the Program. So that should be the message of the NOP to the manufacturers of vaccines. And I think it is more honest, as a Board, to acknowledge this failure of enforcement and the law, rather than trying to help the NOP to put together some change in the law that would make enforcement easier.

Barry Flamm: Calvin, I believe you had a question for Alexis.

Calvin Walker: I do. Alexis, would you... what is your view on the Board having more time to digest complex issues like DHA, corn steep liquor, and others? Because many times, a lot of written comments are provided. We need more time to digest it because consumers put a lot of thought into writing. And we come to meetings and, as a new member - not as new as Tracy and Camilla and others - is that we hear expert testimony, consultants. And we have such a short time to actually vet or determine if this information is correct before we vote. Do you think your recommendation such as these need to be deferred after hearing oral testimony and then maybe, at the next meeting, bring those issues up for a vote?

Alexis Baden-Mayer: That is not a bad idea, I think you all should take as much time as you need, and gather the information that you need, especially on complex issues. I think that that would have been very helpful at the last meeting on ARA and DHA. If the open questions had been answered before the Board made a decision. And, as far as I know, there was... you know, you all are not under a deadline. These substances have to be properly vetted before they are approved for use in organic. And you can take the time that is necessary to do that.

Barry Flamm: Alexis, is there... Nick has a question for you, Alexis.

Nick Maravell: Yes, Alexis. You are recommending here that the Board stop any work on the issue of vaccines containing GMOs. You don't see any valuable contribution that the Board could make in cooperation with the Program to move forward on this issue? I am not quite sure what you are implying by "the Board should stop work" on this if this is indeed an important issue for the organic community.

Alexis Baden-Mayer: The law, as it stands, certainly protects organic integrity and it protects consumers. The law, as it stands, requires every single vaccine that is genetically engineered to be individually petitioned and reviewed by the Board. And we haven't seen that. And we know that there is an outstanding violation. And we know that many GMO vaccines are being used in organic. And we don't know anything about them. And that is a very bad place to be.

And I think it is really important for the NOSB to acknowledge that. And I think that in 2009, when the Program came to the NOSB and said we are violating the law, there should have been some measure of outrage. And there should not have been such an effort to change the law to help the NOP with enforcement. And, you know, the most recent recommendation is not offensive to me. I think it is in good faith and you are trying to figure out these things for producers. But I think that we need to enforce current law. And on something like this, it is totally jumping the gun to see how we can enable farmers to use GMO vaccines in emergency situations, where they might be needed, when we don't even know which vaccines are GMO and the Program is not enforcing current law.

Barry Flamm: Thank you, Alexis. I don't believe we have any additional questions.

Nick Maravell: Do you have suggestions on ways in which the organic community can work with the Program and with the National Organic Standards Board to identify the very information you are talking about, and to move this issue further down the road in terms of resolving it and making it clearly legal, and clearly understandable to everyone? Do you have specific suggestions on who might participate in that?

Alexis Baden-Mayer: The manufacturers of the vaccines have the information that we need. And it is incumbent upon them to petition their vaccines that are GMO to the Board. That would be what would happen in a perfect world. That may not be what happens here. But I think that if that doesn't happen, if GMO vaccine manufacturers are not coming forward, then the directive from the NOP has to be "if you want to use a vaccine in organic at all, you need to show us that it is non-GMO". So if they won't come forward with the information about whether it is GMO, we need to require each of them to prove that it is not.

Nick Maravell: That places organic livestock producers in a quandary. So we are trying to move forward in a way that is equitable to all sides. So I guess that's what I am looking for: some way in which the information can be collected, and better inform us as we try to make policy. I am not sure that the Program can require a manufacturer of a vaccine to do anything, if they don't want to submit a petition. So I am not quite sure how we are going to get there without cooperation. That is, I guess, what I'm saying is.

Alexis Baden-Mayer: I am not suggesting that we decertify livestock operations that are using vaccines for which we don't know the GMO status of. The proposal that I'm making is just that the current mess that we have be cleaned up. Not that anyone get decertified. Not that vaccines stop being used. Let's just get into compliance with current law. I'm not asking for anyone to be punished for the non-compliance.

Barry Flamm: Thank you, Alexis.

Alexis Baden-Mayer: Thanks.

Barry Flamm: Jo Ann Baumgartner is the next speaker. From Wild Farm Alliance.

Jo Ann Baumgartner: Hi. Oh, good. There it is. Hello, everyone. I am Jo Ann Baumgartner with Wild Farm Alliance. And I'm going to talk about biodiversity conservation in the NOP rule. Next.

Biodiversity conservation is part of the NOP definition of organic farming. There is a major standard, 205.200, that says operators must maintain or improve the natural resources including soil, water, wetlands, woodlands, and wildlife. The preamble says farmers must initiate practices to conserve biodiversity. And twice the NOSB has made recommendations. The most current recommendation was for the NOP to comprehensively address biodiversity conservation. Next.

So, we, along with many others in the organic community, have come up with biodiversity guidance that we are proposing that NOP consider adopting and putting in the national handbook. It will help certifying agents. It will help farmers. It will help them with complying with regulations in crops, livestock, and handling. Next. This addresses the NOP stated commitment to biodiversity as a priority, and the NOSB recommendations. Next. It is easily adopted. We use the same terminology as what is in the handbook right now. It gives definitions. It gives examples of actions that can be taken.

So, what is biodiversity? It is the inclusion of diverse flowering plants and habitat for pollinators and other beneficial insects. Next. It is conserving and restoring habitat like on this organic farm. Next. It is conserving wetland and riparian areas, sensitive areas that need protection; planting diverse systems and pastures. Next. And rare seeds and breeds. Next.

There is also government information that is tied into this along with the NOP's... it ties into NOP's model organic system plan. Next. And addresses land conversion. Next. And gives all of these other standards that address biodiversity.

The other thing we want to talk about was accreditation. Next. We need the 205.200 standard in the accreditation checklists, both this file review checklist. Next. And the witness checklist. It is missing. It would be really simple to include. So we would love to see the NOP consider that, and consider adopting and/or editing and adopting the guidance into the handbook. Thank you.

Barry Flamm: Jay has a question for you, Jo Ann.

Jay Feldman: Thanks, Jo Ann. Thank you for the work you are doing. Obviously, I am interested in how your work can be better incorporated into the work of the Program. And it sounds like you feel the handbook is adequate on many levels. I guess what I'm interested in is what actions, additional actions you feel are necessary to help promote the adoption of biodiversity guidelines or operations. And then what are the hurdles that a certifier faces when they are trying to enforce biodiversity guidelines or biodiversity practices as you

see it? And what should we be doing as a Board in terms of taking additional action with regard to all of this?

Jo Ann Baumgartner: First of all, I think the handbook would be much improved with the adoption of this guidance. But the most critical thing is to add the biodiversity standard, the 205.200, where “operators must maintain or improve the natural resources including soil, water, wetlands, and wildlife” into that checklist. Because that would mean that all certifiers across the board would be addressing this. Right now, there are several certifiers that do. And they have figured out how to build this into their programs. And they still have vibrant programs. Like CCOF is an example. As you know, they are the biggest certifier and they helped with this guidance. And I think it is fair to say they would like to see a level playing field for all certifiers. And that would move the issue forward significantly. And what would be great, is for the NOSB to look at the accreditation checklist and help make a recommendation to the NOP.

Jay Feldman: Thank you.

Barry Flamm: Other additional questions? Thank you very much, Jo Ann. Our next speaker is Lisa Bunin.

Lisa Bunin: Good morning. My name is Lisa Bunin. I’m the Organic Policy Coordinator at the Center for Food Safety. My remarks address multiple issues.

GE contamination of organic: CFS is pleased to see the formation of a GMO ad hoc Committee and we support its letter to the USDA Secretary Vilsack raising concerns about GMO contamination of organic. We agree with the letter's conclusion that the USDA's actions to date on GE crops have been insufficient to protect organic integrity. The burden for preventing GMO contamination continues to unfairly rest on the organic industry, even though the technology provides them with no benefits and only costs. We urge the NOSB to pressure USDA to require those who profit from GM technology to demonstrate whether contamination prevention is possible. This proof is essential to protecting organic integrity.

GMO vaccines: CFS does not support the recommendation. We share concerns about the potential lack of non-GMO vaccines to combat a severe disease outbreak or an emergency. However, permitting the use of an un-reviewed GMO vaccine will not protect valuable livestock genetics if an unanticipated health problems arise as a result. There is a noticeable absence of peer-reviewed studies to demonstrate the safety of GMO vaccines for humans, animals and the environment. Unfortunately, the TR fails to shed any light in this regard. A list of non-GMO vaccines and their uses must be published to prevent accidental use by farmers. GMOs are not seen as functionally equivalent by consumers or in the legal interpretation of the NOP regulations. We urge the NOSB to reject the proposal.

Aquaculture: CFS supports the development of organic aquaculture regulations for land-based, closed loop, recirculating systems. We do not support open ocean facilities like

those allowed in the new Canadian trade standard. Such facilities contravene OFPA because fish escapes are impossible to control, and because they disrupt natural ecosystems by releasing foreign matter, species, and disease into the ocean. CFS opposes harvesting wild fish to feed farm fish under any circumstance, as allowed by the Canadian Standard. Organic aquacultural systems must never compete with marine life for food. It is ecologically unsustainable and inconsistent with the principles of organic. The courts have ruled that livestock must eat 100 percent organic feed, not wild fish. We urge the NOSB and NOP to develop organic aquaculture rules that truly support organic integrity and to resist pressure to make US rules equivalent with Canada's weak, voluntary standards.

Inert: CFS supports reviewing Formula List 3 by 2015, and developing a concrete plan for reviewing Formula List 4, beginning with 4B which includes acutely toxic and endocrine disrupting chemicals.

Conflict of interest: CFS supports the proposal and urges disclosures by contractors, public communications. CFS supports the proposal and agrees that the Board benefits from stakeholder input in between meetings. And we support...

Biodiversity: We support putting biodiversity guidance in the NOP handbook and including biodiversity in the accreditation checklist. Thank you.

Barry Flamm: Thank you, Lisa. Before I ask Jay to ask his question, I have a request of the people that are scheduled to speak. If, when you are next on the list, if you would come up and sit in the chair right next to where Lisa was, that will help us out a great deal.

Male: [Indiscernible -- low audio]

Kathryn Grant: I'm right here.

Barry Flamm: Thank you, Kathryn. Again I... You were blocked out, so thank you. And the next person on the list, if you would be prepared to come up, that would be great. Jay, will you ask your question?

Jay Feldman: Yeah. Thank you. And thank you, Lisa, for your work and the work of the Center for Food Safety, and advocacy work on genetic engineering. I think what you, along with the community, did to advance this issue within the NOSB is critical to the process and shows that public input into this process is critical to the outcomes of the Board's work. Thank you for that. On the aquaculture, I know you among many others on the consumer side are basically asking the Board to revisit a policy that was adopted – what? – 2008 or so. And I just wanted to get clarity because we have a lot of new Board members here. And there is a basic tenet under which many have operated in the past. And that is, you know, a previous policy should really not be revisited except under extreme, pretty extreme circumstances. And I would like to just hear if you think we have met that threshold of extreme circumstances that would require the Board to revisit it. That is the first part of the question. Second part is we are being asked by the Program to move

petitions for materials that would be used in aquaculture systems before we have actually seen the final rule on this and I was interested on your thoughts on how or if we should move in that direction.

Lisa Bunin: The 100 percent feed rule is definitely violated by the regulations. So I would definitely encourage this new Board to revisit that before really moving forward too much further in aquaculture. A 100 percent is legally required and so, allowing less the 100% organic feed for aquaculture systems should not be allowed. And the second part of your question was about moving forward with materials. As you have seen in our remarks, we really are supportive of moving forward with aquaculture but in a very careful and measured way. And we believe that open ocean systems are detrimental to the marine environment. And we have said, submitted many comments on the record including resubmitted a list of escapes and what the potential effects are in the marine environment. We would recommend moving forward with land-based inland recirculating systems where they can be tightly monitored and tested and a trial system be put in place to really get the system right. I think this is a really important new area and we want to make sure that organic integrity is upheld.

Barry Flamm: Thank you. Nick has a question for you.

Nick Maravell: Yes, Lisa. I have two questions. And you packed a lot into your presentation. I know we limit them to three minutes. So I was wondering if you could expand on two points that you raised with regard to GMO vaccines. One is: you said the un-reviewed GMO vaccines will not protect valuable livestock genetics - I see that as one half of this one question - if unanticipated health problems arise as a result. Can you extrapolate on that a little bit and say fully what you mean there?

Lisa Bunin: We have been looking for data to see really: has anybody really studied the health and environmental effects of GMO vaccines? And so they really haven't. And so I guess we would be looking for is some side-by-side comparisons where you took a look at a conventional vaccine and a GMO vaccine and maybe a control group. And there was some sort of... I don't know if there is data that we are not privy to because it is confidential business information. But from the information that we have been able to obtain, we just don't feel confident that GMOs are safe. And we feel that, given that lack of information, it would be extremely inappropriate for the NOSB to recommend the allowance of GMOs even in emergency situations.

Nick Maravell: You anticipated my second question. I will just mention that the committee recommendation as it was formulated would not have changed any behavior on the ground in the event of an emergency. If the specific vaccine were required by a federal or state official empowered to declare an emergency, it is still going to be used under existing law or under the committee's recommendation. We simply were providing a different status of the resulting product which under current law would be declared not organic. Where did you look trying to find information on the health effects, the impact on the environment, the impact on humans, of GMO vaccines? Where were you looking?

Lisa Bunin: Medical Journals. I had a list in my longer testimony. Animal husbandry journals. You know, what we could get access to. But if I could just go back, and addressing what you were saying in the case of an emergency: I understand that there are certain laws that take precedence and, of course, under those circumstances, the Program has to agree with those laws. On the other hand, I keep grappling with myself, is how do we push back, particularly on the GMO issue to USDA or FDA to really take a harder look at the safety of these drugs for example, or GMOs in particular. And so that was why I phrased it that way in hopes that the NOSB would be proactive and aggressive in asking these other agencies to really take a harder look at the environmental and public health/safety of releasing GMOs that we do not feel have really adequately been studied. Thanks.

Barry Flamm: Thank you, Lisa. There is another question for you from Calvin.

Calvin Walker: You mentioned in your written comments Canadian aquaculture is not the best model.

Lisa Bunin: No. Not at all.

Calvin Walker: Could you recommend to us, the Livestock Committee, maybe a particular aquaculture regulation that may be pretty decent?

Lisa Bunin: I think it is the one that we are going to put together here. I really do not believe that there is anything out, that I have seen, that really does a good job of regulating organic aquaculture. And I really would urge you to begin with the inland, closed-loop, recirculating systems. And I think, if you do that, you are going to find that we are maintaining and charging ahead with the organic gold standard of the National Organic Program of the United States of America.

Calvin Walker: That is good. That is the same comment that Mr. Lockwood, that was his same response when we asked that question in the Livestock Committee. Thanks.

Barry Flamm: Is any other questions for Lisa? Thank you, Lisa. Katherine DiMatteo is our next speaker.

Katherine DiMatteo: Thank you. Good morning. My name is Katherine DiMatteo. Welcome to all the new members of the Board. And thank you for the energy and time commitment you give in service to the organic community as members of this National Organic Standards Board.

Wolf, DiMatteo and Associates is a small consulting business that has served hundreds of farms and businesses with their organic production systems and regulatory compliance, both nationally and internationally. Our written comments and these oral comments are not made specifically on behalf of any one of our clients. But do represent the opinions of my partners based on our personal values and experiences, and on our work with both current and past clients. There is not enough time now to restate our written comments. So here are some of our overarching thoughts behind the comments that we have written.



The Inerts Working Group should complete its recommendations as soon as possible in order to avoid confusion that may result from short-term solutions made in the absence of an overall policy on the approval of inert ingredients, and also to end the regulatory uncertainty that is disrupting the development of new inputs suitable for organic production. As well, the framework document, Classification of Materials, recommended by the NOPB, should move forward as NOP guidance before new discussion proceeds on solvents and extractants, and on the definition of insignificant, uh, of significant residues.

We live in a polluted world. The proposal that any detectable level of synthetic is significant is in direct conflict with the interests of the organic farmers. Allowed synthetic materials and natural materials that have long been used by organic farmers, such as adjuvants, pH adjusters, plant animal meals, botanical pesticides, beneficial microbial inoculants, compost, processed and raw material, uh, manures, mined rock minerals, micronutrients, and plant extracts, would be lost and, in turn, would result in the decline of the numbers of organic farmers and acres in organic productions.

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. This approach should be continued rather than individual reviews of such substances. The organic label and NOP Seal are allowed on products with up to 5% non-organic, non-synthetic, and synthetic substances. Don't sacrifice the producers of the 95% organic ingredients by overzealous interpretation of review criteria based on personal opinion about the essentiality of the 5% substances, or other concerns that fall outside the scope of the National Organic Program, such as chemical sensitivities or allergies.

The very existence of Certified Organic Farms, organic processing, the National Organic Program, and input and ingredient suppliers who provide compliant materials, has been continuous improvement from business as usual in the farm and agricultural product sector. Please provide them with the tools and time to build on what has already been accomplished and increase adoption of organic methods. Let's get beyond the 1 percent of worldwide agriculture that we currently have.

Barry Flamm: Thank you, Katherine. Is there questions for Katherine from the Board? I guess there is no questions, Katherine.

Katherine DiMatteo: OK. Thank you.

Barry Flamm: Thank you. Gang... how do you pronounce your name, Kristine [*sic*]?

Kristin Gangwer: [Laugh] It's "Gan-gwer".

Barry Flamm: Gangwer. Thank you. Excuse me.

Kristin Gangwer: [Laugh] No problem. My name is Kristin Gangwer. And I'm a consultant to agricultural non-profits and CSA's in Albuquerque, New Mexico, where I also live. I'm a

member of the Cornucopia Institute and I'm here today as a citizen lobbyist. Today I'm going to read a proxy letter that thousands of individuals have now signed.

Dear Secretary Vilsack and Chairman Flamm,

The will of Congress, and the rule of law, has been ignored for too long in the management of the USDA's organic program. This problem predates the Obama administration. But after the election of President Obama, we had hopes for "change" at the USDA.

We ask that you both immediately take charge of investigating improprieties at the National Organic Program and address the following problems and issues:

1. Based on intentional misinformation provided the NOSB, and incompatibility with the Organic Foods Production Act, we ask that the National Organic Program return to the NOSB, for reconsideration, its recommendation approving Martek Biosciences' genetically mutated algal and fungal oils, containing many synthetics.

The NOSB should remove carrageenan from the list of approved non-organic food substances due to serious health and environmental concerns, including being classified as a "possible carcinogen."

3. The Technical Advisory Panel review of carrageenan, and a subsequent review at Sunset, took an industry-friendly perspective by ignoring well-documented health and environmental concerns. Because these reviews by agribusiness-affiliated scientists were not aberrations, we request that all future Sunset reviews be required to include new Technical Reviews, until the integrity of the process can be assured.

4. The process of choosing individuals or organizations to conduct future Technical Reviews needs to be revamped to assure reviews by truly independent scientists. The current contract with The Organic Center, an offshoot of the industry's largest trade/lobby group, must be immediately discontinued.

All future NOSB appointments should be made respecting the letter of the law and congressional intent. Farmer board representatives must, as is written in the law, own or operate a certified organic farm. Further, the independence of NOSB members must be maintained by refraining from appointing farmers, scientists, environmentalists, and consumers who are simultaneously employees of corporate agribusiness.

We call on the Secretary to immediately remove the new NOSB farmer representative who in reality is a full-time employee of Driscoll Strawberry Associates, Inc. and replace this individual with a legitimate farmer meeting the definition of the law. We have no objection to her future appointment to a board seat reserved for a handler.

8. Recent rules reducing individuals of public interest groups to three minutes of public testimony during NOSB meetings, and limiting direct correspondence with NOSB

members, give corporate agribusinesses a disproportionate advantage, since they can afford to be represented by numerous executives and lobbyists. Public participation should not be shortened. The process should be more inclusive.

And, finally, two square feet for poultry outdoors, and other woefully inadequate animal husbandry recommendations, need to be revisited.

Thank you for considering my concerns. I urge you to take action to prevent embarrassment to the USDA and the organic industry, preventing organic stakeholders from being compelled to sue the USDA to enforce the law.

And again, that was a proxy letter signed by thousands of individuals and I also thank you for your time.

Barry Flamm: Thank you for your comments, Kristine. Is there questions from the Board? Calvin has a comment for you, Kristine.

Calvin Walker: The proxy letter of a thousand individuals/stakeholders, are they all from New Mexico? What is the range in states?

Kristin Gangwer: [Inaudible] Fair enough. Yeah, sure enough, Mark.

Mark Kastel: I can help you with that, Calvin. There have been somewhere upwards of 20,000 proxies. Dr. Joe Mercola put it on his website as his lead story to 22 and a half-million interested parties last Sunday. He gets 25 million visitors to his website, even more than the Cornucopia's website. And so that would be from all over the country including this individual who signed it, thank you, from New Mexico.

Barry Flamm: Harold has a comment, a question for you, Kristine.

Harold Austin: Kristine, one of your comments was about the appointment of individuals to this Board that might represent larger stakeholder groups. Would they not still be considered a stakeholder?

Kristin Gangwer: [Inaudible] Yeah.

Crowd: [Grumbling]

Mark Kastel: Thank you. Thank you. Ladies and gentlemen, I am going to take advantage of the opportunity that this Board afforded William J. Friedman, the attorney for...

Miles McEvoy: Mark, it's not your time. You need to sit down. Mark, you need to sit down.

Mark Kastel: To answer any questions, Miles, you allowed Mr. Friedman to come and ...

Miles McEvoy: You have your time. You need to sit down. It is her time.

Mark Kastel: So the court... Don't touch me. Don't touch me. Thank you. You can argue with me. But, Barry, I'm going to appeal to you since you a chairing this.

Crowd: [Applause]

[Off microphone discussions]

Barry Flamm: Kristine, Harold would like to... Excuse me, Kristine, Harold would like to rephrase his question in a way to get your reaction and personal response.

Kristin Gangwer: Sure, and I am happy to respond to the question as it was posed before as well.

Harold Austin: Thank you and my apologies for putting you on the spot. Let me rephrase the question to go to your comments. Wouldn't it be, wouldn't you think it would be fair though to consider appointments for this Board or any other part of our organic industry to consider all stakeholders and not limit specific stakeholders? Irregardless of size?

Kristin Gangwer: Sure and I am just going to speak to my understanding of the system. But in this situation, what this comment was addressing, I see as a certified organic farmers in that position being... they must own or operate a certified organic farm. And so I guess, for me right now, that is all I am really able to speak to. That this individual, as far as I know, does not actually farm. But any other questions, more detail, can definitely be directed to Cornucopia staff in their allotted time.

Harold Austin: Fair enough. Thank you.

Barry Flamm: Are there any other Board questions for Kristine *[sic]*? Greg Herbuck *[sic]* is our next speaker. Did I come close, Greg?

Greg Herbruck: Close. Good morning. I don't know how to follow that up. But thank you for your time. My name is Greg Herbruck. I am an organic and conventional egg producer in Michigan. Since the vaccine issue was withdrawn, I will just make a few comments that... As Nick had mentioned, please don't put egg producers and specific poultry producers in a tough spot by changing things in the middle of the game. We have an issue, for instance, we don't... Vaccines are critical to life of the bird as well as the product they produce. For instance, an egg, we give salmonella vaccines to prevent infections that wind up in the egg itself and could wind up in the human food chain. And I hope that we are not using as a criteria down the road, a human illness infection as the time we could use this kind of a vaccine. So I would encourage that we move carefully and slowly, that we don't cause collateral issues on downstream.

I would also like to bring up the methionine issue. I know there has been an agreement to move it ahead at a 2-pound static recommendation. I would encourage the NOSB and the NOP to consider recognizing, as they have done in many other times, the stage of life. A bird does not need a static inclusion of amino acids in its diet when it is young. Coming into peak production, it has a much higher level. The static number does not fit. We are

under feeding. We are not meeting the birds' needs for that stage of life. And so would strongly encourage recommendation that we consider it an averaging effect over the life of the bird.

And then, finally, I just want to conclude that I would elicit caution as we move forward. I have had the chance to travel a fair amount in Europe and watch, in looking at different systems that they have as far as the living system for the hens. And what I am seeing is organic is disappearing greatly. It is a miniscule portion of the commerce of egg production in Europe anymore, because they have overdone some of these standards and restricted. And I just encourage caution that we move forward, that we don't wind up with the same thing here. Because in Europe, it is a very... it is disappearing very fast and I just don't want to see that happening here. Thank you.

Barry Flamm: Thank you, Greg. Mac has a question for you. Right here.

Mac Stone: What's the... how you determine the regiment of vaccines? And is it different from your conventional versus your organic? And does the system that is in place create a different regiment?

Greg Herbruck: I'm going to let our veterinarian Mohamed speak to that later but, generally, it is a slightly different. Some of the same experiences, a bird dealing with viral infection risks we deal with are very similar. The bacterial is more significant in organic because the birds are in a cage-free environment, where they are in a more – we call it – dirtier environment. They are more exposed to agents in the environment and so it is a more strict regime.

Mac Stone: With the outdoor access, does that change the regiment?

Greg Herbruck: Yes, it does in some degree. We had – we have not done it yet – considering a second possible killed salmonella vaccination just to further protect the chick, the hen and then the eggs it produces. Have not yet.

Barry Flamm: Nick has a question for you, Greg.

Nick Maravell: Could you just comment on the size of your operation? And whether or not you think there would be any value - if you can respond to this - any value in exploring autogenous or customized vaccines for your flocks that might be equally as effective as what you are using now?

Greg Herbruck: Some of these autogenous are very narrowly focused. And what you run into – the problem is – some of the commercially available ones are designed for a broader spectrum, so you get a broader range of protection for the bird.

Nick Maravell: So you don't think autogenous vaccines would be appropriate for your operation? It would be specific to your operation. And could you comment on the size of your operation in terms of size of flocks?

GregHerbruck: We have roughly 1 million organic hens and roughly 5 million conventional hens. And autogenous, again, it is a very focused. And again, I may defer to Mohammed, who is going to be coming on later. He is our expert on that and can speak to the details of that situation.

Barry Flamm: Jean has a question for you also.

Jean Richardson: Yes, thank you for your comments. I do want to make it clear that we are interested in seeking input on GMO vaccines throughout this meeting. And it is important to us because, even though we have tabled a vote this week, I think it is reasonable to assume that we will try to come up with a good recommendation within a year. So my question to you is: have you read the TR? And, if so, are there specific areas where you've found error or specifics which you would like to draw to our attention at this time, especially perhaps with regards the avian salmonellosis vaccine?

Greg Herbruck: I think that would be... The main concern is that thinking of... That we would be able to have some of these restricted vaccines in the event of an outbreak. OK? If it is an outbreak in a bird, then it is a localized. If it is an outbreak in a human population, we waited and... Are we putting ourselves and our companies at risk because we allow, we produced a product then. And then it is too late. And that was my comment there: on using a vaccine in the event of... petitioning for it after the fact.

Jean Richardson: Again, did you get a chance to review the technical report?

Greg Herbruck: Not all of it. No.

Jean Richardson: OK. Thank you.

Barry Flamm: Calvin has a question for you, Greg. [Inaudible]

Jay Feldman: OK, thank you. Apologies if I'm asking you to repeat something, but did you say that you are aware of using GMO vaccines in your operations?

Greg Herbruck: I am not aware. We are using what has been approved by through the organic certification with QAI. We submit our vaccine regiment to them.

Jay Feldman: Okay. The proposal that was before the Board linked the use of the vaccines to a declared emergency. In your experience, have there been emergencies? Does that make sense to you, that linkage? And are there any examples of emergencies having been declared and by whom?

Greg Herbruck: Well some of... We worry about animal welfare and bird care. Would we wait 'til... I mean, the reason we give vaccines is to prevent disease. Do we want to wait 'til a disease has caused illness and injury to a bird or a animal, and then wait... In the case of salmonellas, if the salmonella infection winds up in an egg, do we want to wait 'til a

human outbreak? And therefore I think that we need... That was my point of caution, that we make sure we don't open ourselves up to a high risk situation, where we wait, we react instead of prevent.

Jay Feldman: Thank you.

Barry Flamm: Thank you. Greg. I believe that is all the comments that we have.

Greg Herbruck: Thank you.

Barry Flamm: Liana Hoodes is our next speaker.

Liana Hoodes: Good morning. The National Organic Coalition appreciates the work of this Board and the NOP in clarifying definitions and adding consistency to the standards and the National List. This Program is one of the most exceptional at USDA, and OFPA is one of the most forward thinking pieces of legislation in all of government.

However, the innovations and complexity inherent in the law and Reg.'s also present significant challenges in implementation. Ten years on, there are naturally issues that need clarification and prior decisions that may be inconsistent with the intent of the law or other decisions. This Board must not shirk from facing them head-on. And we indeed see that some of those tough issues are addressed here.

It is the statutory requirement of this Board as well as NOP to complete this work. It is not unusual for government to claim poverty or politics for not getting the job done. But it is up to citizens to continue to push for their interests to be met. Organic needs you at this critical time. Consider the law first and the regulation as a vehicle to its implementation.

Aquaculture: Consider the whole organic system first. Implement the biodiversity guidance and checklist. Evaluate all synthetics and provide practical, consistent definitions across all categories, even if it calls for midcourse corrections - as it would in ARA and DHA, which we believe you must revisit, or for carrageenan, which needs to come off, or by refining Classification of Materials by tackling the issues of significant residues.

In obtaining clear, scientific and consistent definitions and reviews, reformulations may be necessary and are welcome in facilitating increased organic commerce. Confusion and un-clarity of definitions around materials is bad for business.

Please move forward on inerts and GMOs despite the fact that you may get push-back up the line. It is clear that USDA from the top does not want to do anything regarding organic and genetic engineering, so you must be the place to do it. Please clarify both definitions around excluded methods as well as the effects of GE contamination on organic. Send the Secretary your letter, clarify existing regulation, and set a course for keeping GE out of organic.

Similarly, deal with inerts immediately. We understand the enormity of the task but through the years NOSB has been crystal clear that inerts must be reviewed. Use... Group them, but they each must be reviewed. Why the delay?

Many of us advocate for NOP in every budget and farm bill. And it is much better for the integrity of the label and all of organic that, having done the hard work to remove unsafe materials from organic, you are waiting for USDA way up the line to complete the regulation, rather than for this topic to languish.

We must remind ourselves that organic is the only food or agricultural label with such demanding mandates as well as public transparency. Where our flaws are laid bare to the public, our only defense must be that the federal government has never embarked on such a task and it takes time to get it perfect. But we must show that we are on the road to continuous improvement, not that we are thwarted by those who may wish to destroy it through weakening or confusing the standards.

In the end, organic is about the health of humans and the environment and it is the future for all of food and agriculture in the US. And thank you for holding that true.

I just want to note that the yellow comments do have some additions from what we submitted to the docket in research priorities, significant residues, biodiversity standards, and conflicts of interest policy. Thank you.

Barry Flamm: Thank you, Liana. Board, questions for Liana? Colehour has a question for you, Liana.

Colehour Bondera: Yes, thank you, Liana, for your presentation and for handing this out. You potentially raised a second question for me, but I will stick to my first question and we will see. And my first question is somewhat general. I recognize that, in the amount of time that you are testifying, you can't get into much detail. But I guess it is seeking you to go into a little bit more detail potentially, even though it is not an easy question. Because you suggested or referred to the idea that the NOSB should, and this is not a quote, but should strive towards or be ensuring consistency in the various decisions we are making across the different recommendations and different topics. And I hesitate a little bit, as the chair of the Policy Development Committee to ask this, but do you have a more specific suggestion as to how that can be achieved? Or what actions we might strive to take? Or what, like I said, what policies we might have in place in order to go down that path?

Liana Hoodes: I think that inconsistencies have occurred through unclear definitions or moving forward - and not just this Board but through the first 10 years of implementation - through making decisions without good definitions. So where you are able to define terms, then do it. Take that time to do it. And then don't be afraid to go back when materials come up for review, review them in light of your new, consistent definitions. So I am not sure it is a policy that the PDC takes. I think that it is to acknowledge that there



were some places, where definitions were not clear in previous years, led to decisions that are not consistent across different categories or whatever.

Barry Flamm: Jay has a question, and then Calvin.

Jay Feldman: Thank you. Thanks, Liana. Again, I appreciate the work that NOC is doing is doing on all of this and in the context of NOC being a brain trust, of sorts, in the organic community and crosscutting in terms of bridging farm-environmental consumer interests. I would like to focus my questions on the public engagement part, or the public communications issues, and ask you: how important you feel that is? We all, as Board members, are aware that NOC attempts to communicate directly with Board members to share the expertise that makes up the coalition. Some Board members feel overwhelmed by that process of direct communication. The proposal on the table makes some other suggestions as well as mechanisms for receiving the kind of valuable information that NOC provides on an ongoing basis throughout the deliberations of committee work, or subcommittee work. So I guess my question is: can you shed some light on the importance or lack thereof of the recommendation coming out of the Policy Development Committee?

Liana Hoodes: Yeah. First of all, public participation is really important. And we haven't actually been communicating with the Board for that long of our history. We felt that we should not. And only in the past year or so have really stepped up communicating throughout the whole year and not just on the docket, because we felt that, when it came time for the comment period, it was a little too late for your decision-making. And so we have stepped in. But we actually think it needs to be institutionalized.

There is a long history of industry having access in USDA and us advocacy groups have also stepped up our ability to have input. But everyone needs to be able to have that input. And so something like a continuous docket that is separate from the comment period would help. But it is crucial because there are so many interests. This is a big Program, as you know, and there are a lot of different areas that practical experience, as well as good science, would inform your decision-making. And how can you all be experts in all of these fields? So I think the more transparency for you receiving information the better.

And, obviously, it must get overwhelming. So I would say that something like an open docket where you can have access to it might help. My feeling is the more consistency, so it is not that I know I can get to you, or that an industry member knows that they can get to you, but that a citizen knows they can get... That we all have the same ability to this and it needs to be there to help inform your decisions. I am trying to see if I said anything - particularly in our written comments - that I need to reinforce. But we do really endorse your clarifications on public communication.

Jay Feldman: OK, I need to clarify something. I just want to put my glowing comments in context and disclose that my organization is a member of NOC, so said take whatever I said with a grain of salt.

Liana Hooded: [Laugh]

Barry Flamm: Calvin?

Calvin Walker: My remarks is just a comment. Again, I would like to express what you all do as – NOC, Cornucopia, OTA – I'm just impressed when I read documents from the different organizations that I have named and have not named with so much thoughtfulness that you all have placed in the written comments to give to the Board. I guess my question would be: do you feel that, as a Board, are we adequately addressing oral comments because we have so much sometime coming before us before we make a decision?

Liana Hooded: I think... I do really think it seems you are definitely addressing oral comments. I hope that you are able to be a little flexible in the amount of time that is given. Three minutes is just not enough to say very much. But I have been at NOSB meetings where it ran on until 9 o'clock at night. That is not acceptable either. So is there a way to say that... to look at the number of people who are commenting and say, OK, there is less than we thought; you can now all have four minutes. Okay, it doesn't get in the Federal register that way. I am not sure how that all gets dealt with. But can't there be a way for flexibility to add minutes and to have a commitment for a little bit more time when it is available. Three minutes is not reasonable. But the question and answers that you do I think really help to drag it out of us after we fast talked for 3 minutes.

Barry Flamm: Nick has a question for you, and then Jean, please.

Nick Maravell: Yes, Liana. Thank you for your comments. I have some questions about the GMO vaccine issue, specifically with regard to some comments that you were not able to make verbally, but were in your written statement. And you are suggesting that the NOSB and the NOP write to the Secretary of Agriculture. Oh, and, I wanted Miles to hear this, but it looks like... Well...

Crowd: [Laugh]

Nick Maravell: I'll have... Who is standing in for Miles, because I am going to ask for a comment from the Program? Melissa, are you standing in? Well, okay. I will give you plenty of time. One is you are suggesting that the NOSB and NOP write to the Secretary of USDA and APHIS, the Center for Veterinary Biologics who registers vaccines, requesting that there be mandatory labeling of all vaccines. I assume you mean mandatory GMO labeling of all vaccines. This is an issue that goes well beyond, that is an agriculture-wide issue. That is not... this is not restricted to just organic agriculture here.

Liana Hooded: Right.

Nick Maravell: And I'm sure we, the NOSB, have that in our purview to advise the Secretary. I guess I would like to get a comment out of the Program whether or not this seems to be within the authority of the Secretary of Agriculture to make a mandatory requirement

across all agricultural areas that GMO vaccines be labeled as to their GMO content? You can duck or whatever you want, but I need to ask that and see what the...

Melissa Bailey: Sure, no. I can give you some sort of answer. If Miles wants to contribute to that, he can do that when he gets back. I think... So to repeat back your question, you are asking if the Secretary has the authority to require mandatory labeling?

Nick Maravell: Of the GMO content of the vaccines.

Melissa Bailey: Of the GMO ... for vaccines. I think what we would have to do from the Program's perspective is bring that kind of question to both APHIS, probably through the... there is a biotechnology working group that is an interagency group at USDA, to see where their authorities lie. It is certainly not under the NOP's authority. So I would not want to speak for APHIS specifically on that particular issue. But if that is something the Board wanted information on, we could certainly pursue and find that information for you.

Nick Maravell: Yeah, I think it would be a very useful piece of information to have, and maybe something that the ad hoc GMO Committee may want to consider as well. The second question...

Liana Hoodes: Nick, can I just comment on that? I believe it is the duty of every citizen of the United States to demand that our government label all GMOs. That would be GMO vaccines and GMOs everywhere else. And therefore, I understand the difference that it may not be the purview of the NOP to be able to ask for that. But I do believe that it would then be the purview of the NOSB to be able to ask for labeling of GMO vaccines. And it is necessary that we demand of our government that there is GMO labeling at every turn.

Nick Maravell: The second question I had was your point was: require livestock producers to find out if any vaccine is GMO and certifiers to request that information. Do you have any indication that that is currently being done or it is possible or is not possible? What are you hearing from the field?

Liana Hoodes: I am currently hearing that it is not possible.

Nick Maravell: It is not possible?

Liana Hoodes: Yeah. There is not clarity that a particular vaccine is GMO or not GMO. It should be down the line, when we get all of this GMO labeling that we are going to get when we ask for it, that it happen. But it is not possible and, you know, we are adamantly against the use of GMOs in organic yet we presented to you some alternatives because we're really worried about the effect on farmers here of outbreaks and of what happens if GMO vaccines are not available in specific instances so we have sort of capitulated - gone a little bit both sides here - but it is really about, we don't want to cause problems for farmers. It is very serious and you have noted that to other commenters.

Nick Maravell: We have gotten some indication at the Livestock Subcommittee level – I'm now informed – that some producers have been able to inquire manufacturers about but, generally speaking, that we have not found that as a trend. The third thing I wanted to raise is that you are suggesting the NOP should compile a list of all non-GMO vaccines and their use. I guess what I would like to inquire would be a comment from the Program whether or not – and Miles, you missed the first half of this – but whether or not that is indeed a realistic request: that the NOP could compile, has the authority, and has the ability to compile a list of non-GMO vaccines and their use and appropriately update it.

Miles McEvoy: Ah, it is an interesting idea. My understanding is the way the vaccines are being utilized through brand-name products. And, in general, the Program has stayed away from any kind of any brand-name review. We leave that up to the certifiers and the material review organizations to look at specific brand names. We know that APHIS has a list of what they consider recombinant varieties of vaccines. But that does not easily translate into the commercial available varieties of vaccines that farmers use. So it is unclear exactly what it would be that you are asking. You are asking for a list of brand-name product products that are non-GMO, or a list of vaccines that have not been genetically modified? And then providing that list of vaccines that are not genetically modified would only be part of the process, because from there then you would have to see whether or not they are part of a commercially available vaccine.

Nick Maravell: We haven't gotten to commercial availability. [Laugh] Let me ask Liana, and Miles, if you would want to comment on this too. Would maintaining a list of brand-name vaccines that did not contain GMOs, is that something that you think a material review organization might be able to accomplish?

Liana Hudson: I am not convinced. That seems like it is a hard slog for everybody to get this done. So, to start at APHIS and with what information they know and working down, I think is a better way to go. And to say that we can't figure out if there are GMOs in vaccines is not a reasonable answer for organic. We must find out whether there are GMOs in vaccines. So we have to propose a lot of different paths to try and get there. For the MROs, and I'm thinking of my own small certifier that I am on the Board of, it would be a really tough thing to do that - to require each one to do it - but I think it has to happen on a number of fronts. And we just can't say that we can't do it because that is not appropriate for organic.

Nick Maravell: Miles, would you like to comment on the appropriateness of a materials review organization maintaining a list, perhaps under contract from the USDA, that would evaluate materials specifically with regard to excluded methods?

Miles McEvoy: Well, that could be a very good way to go once you have the criteria set up so that the material review organization knew specifically what they were looking for. So the best information we have currently is the APHIS list of recombinant varieties. And that's... we need a lot more information to see how that can be provided to producers and certifiers to provide clear information. So, it just seems like there is a lot more

information that is necessary. The best information is the APHIS list, and it opens up a number of additional questions.

Barry Flamm: Thank you. Jean has a question for you, Liana.

Jean Richardson: Hi. I appreciate your very short, your concise verbal comments, and the fact that you also were able to give us additional yellow sheet of information. On the additional material you gave us, you have expressed concern over the use of gibberellic acid in post-harvest handling for bananas. And I would like to know a little bit more from you about that. Obviously, when the Handling Committee got the TR and they went through all the details, they would have spent a great deal of time working to come up with this recommendation that they are putting forward. And I wonder if you could provide me with some of the additional information you have which would lead to suggesting that it may have some human health impacts as a biologically active plant hormone?

Liana Hoodes: I refer you to the Organically Grown Company's comments, but then also to Lynn Cody, will be speaking for NOC on gibberellic acid on Thursday. And she will be the person to talk to. And by the way, Nick, Harriet will also be speaking about livestock issues and GMO vaccines, and you all can ask Harriet. She is better at livestock stuff than I am. Those are two NOC folks who will be speaking later. Sorry to put you off on that.

Barry Flamm: Thank you, Liana.

Liana Hoodes: Thank you.

Barry Flamm: Patricia Kane is our next speaker.

Patricia Kane: I would like to thank the NOSB and NOP for the opportunity to provide these public comments. My name is Patricia Kane. I am the coordinator of the Accredited Certifiers Association. We represent 43 foreign and domestic accredited certifiers, and we also have supporting members.

We did submit written comments on various topics but I'm going to just touch on a couple of our comments. I'm also going to talk about GMO vaccines a little bit. I would like to thank the committee for withdrawing the recommendation. We would really like to have additional work done on this. We have also suggested that the NOSB, the NOP, and APHIS work together to provide some sort of list that is usable for certifiers and producers on this really important topic. We also do not want to have producers penalized by eliminating these tools. Since the recommendation was withdrawn, I'm not going to give any additional comment on that.

We also commented on the criteria for materials review by material review organizations recommendation. And we were in general support of the recommendation. We did have a question. On bullet 2, regarding the requirement that ACAs, or MROs obtain ISO 65 accreditation, we would like to ask the committee to consider distinctions in the various

types of MROs. We feel there are three distinct types of MROs. One is an independent MRO that reviews materials and publishes a publicly available list of approved materials - which is... and this activity is conducted outside of the scope of certification; ACAs that conduct certification activities and also provide a publicly available list of materials; and then there are ACAs that review materials within the scope of organic system plan and do not offer a publicly available materials list. The ACA believes that the independent materials review organizations and ACAs publishing materials lists should obtain ISO 65 accreditation. We also believe that requiring ACAs who only review materials in the context of an organic system plan should not be required to have ISO 65 accreditation in addition to their NOP accreditation. This is redundant and very costly. As written we believe the recommendation would require all ACAs to obtain ISO 65 accreditation. In our written comments, we did have some suggested wording for revision of bullet 2, so we hope you can take a look at those.

We appreciate and thank you for your work on these issues.

Barry Flamm: Thank you Pat. Does the Board have questions for Pat? Joe, please.

Joe Dickson: Hey, thank you, Pat. I don't have a question. I just have a quick comment on bullet 2. We read your written comment, and others like it, and we will be voting on a version of that recommendation this afternoon that does clarify the ISO 65 requirement to only apply to entities that publish lists.

Patricia Cana: Great. Thank you.

Joe Dickson: Thank you.

Barry Flamm: Jay has a question for you, Pat.

Jay Feldman: Thank you, Pat. I am interested in the 100% issue and this distinction between processing aids and sanitizers. Your comments in the, I guess, the response to the survey questions that went out, indicate this distinction that suggests that the sanitizers don't come into direct contact with food, whereas the processing aids are somebody... I guess they are referred to as transformative possibly, and do come into contact with food. I was wondering if there are examples of sanitizers where there is direct food contact and whether, in fact, that is not an accurate distinction, such as a chlorine dip or something of that sort.

Patricia Kane: I think that you probably need to talk to some of the certifiers that are here. I don't deal with this on a day-to-day basis, so I am not familiar with specific sanitizers.

Jay Feldman: Thank you for sending out that survey. It is very interesting.

Barry Flamm: Mac has a question for you, Pat.

Mac Stone: Pat, kind of a follow-up to Jay's referring to the survey: There was... several of the questions, the survey results were quite varied and lack of consistency, I guess, to say the least. How can we work with the certifier community to help develop a standard, if you will, that can get to the clarity to eliminate some of these of variances of the current interpretation? How do we work together as a Board, as a Program, as a certifier, community?

Patricia Kane: I think working through your, you know, your work plan and the process that you use, the topics that you are discussing. And we are really willing and able to formulate working groups. That is how we arrive at the comments that we submit. We have working groups. And we can provide you with information as you are going through the process before you come to, you know, the conclusion on a recommendation. Certainly the question you ask, how can you work with us to provide standards and consistency could be a working group discussion. And we could start that.

Barry Flamm: Any other questions for Pat? Thank you very much, Pat.

Patricia Kane: Thanks.

Barry Flamm: Mark Kastel is our next speaker.

Mark Kastel: Thank you, Mr. Chairman. My name is Mark Kastel. I am the co-director of the Cornucopia Institute. My message today is: party is over. Party is over. The systematic corruption, secrecy, violation of the letter of the law and the intent of Congress, in reviewing synthetics and organics with the Board's concurrence, will end in here in Albuquerque. The blatant illegal stacking of the NOSB with agribusiness executives, consultants, and agents has to end or we are headed to court. Nominating a consumer representative from General Mills is illegal. Likewise, appointing agribusiness executives to the farmer slots when they do not, as OFPA requires, own and operate an organic farm is likewise illegal and a betrayal.

Furthermore, under the last Board chairman, chairperson, going from public comment representation, affording five minutes a year ago to speak before the Board with an additional five minutes as a proxy down to a mere three minutes is a gross suppression of public input. Why do we at Cornucopia and other public interest groups need proxies? Who is in this room? Who is in this room every meeting? At the Cornucopia Institute, we have many imminently qualified organic leaders who have important contextual information to share with the Board. Unlike corporate executives, consultants, lobbyists, lawyers, we do not have a travel budget underwritten by agribusiness. Among those speaking for corporations in the Martek case at the last meeting, as you recall, was a physician, in the best tradition of doctors hired by tobacco companies to contest the preponderance of published peer-reviewed literature. It was true that we challenged Dr. Alan Greene to identify his conflicts of interest. And we told him if he didn't, we would.

He registered to speak before you folks as a quote "public citizen". And even though he was paid to appear by Dean Foods, he told the Board he was a consultant just answering

questions about DHA. In reality, he was doing promotional work for their brand. He did work for Mead Johnson in promoting DHA for Martek and their conventional infant formula, and even sold, partnered with Twin Labs selling DHA supplements under his name.

Going forward, the NOSB needs to require all individuals presenting testimony to this Board, to fully disclose who they are working for currently and in the past. Who is paying the bills? During the Martek debate, after four years of research, Charlotte Vallaey's had three minutes to present her findings to you folks. With all the consultants and people they flew in, Martek and Dean Food had almost 55 minutes. Does the imbalance serve the Board in building your knowledge base necessary to make good decisions? I hope the Board members will ask our position on technical reviews because I am out of time. Thank you very much.

Barry Flamm: Thank you for your comments, Mark. I believe Calvin had his hand up first for a question for you.

Calvin Walker: Mark, you asked that we ask you... your last statement. So what is your position on TRs?

Mark Kastel: And we had it on our printed comments. I hope you will consider. The Martek situation at the last meeting was a wake-up call for Cornucopia.

We never considered ourselves a quote "materials group". We depended on other folks and now we are learning that there might have been biases involved. The technical review system over the last... during the history of the NOSB has been inappropriately influenced by the competition of this Board in reviewing. And I have already illustrated that some slots that are reserved for independent voices have been filled by corporate representatives.

But we need to demand that all the individuals producing the technical reviews are fully identified, not just, as I referred to, the testifiers before this panel who are giving expert advice, but the conflicts of in... First of all, this is being done in secret. We know the firms that the department is contracting, the Program is contracting with. We don't know the authors of the technical reviews.

We have looked at this and have every reason to believe that we would all be disturbed by the identity of some of these individuals. So, number one, they have to be made public. Their backgrounds have to be made public and any conflict of interests have to be disclosed.

Most importantly, OFPA gives the authority to secure technical reviews, not to the NOP but to this body. Congress encharged you with making sure you are educated. This is not, with the exception of Zea, this is not a scientific panel. You have to be able to depend on the independence and quality analysis that is presented to you. The Board of Directors at the Cornucopia Institute choose our auditor. Chase Bank, or whatever the whole



conglomeration is called now, their Board of Directors chooses the auditor, not the staff. So you folks need to vet those experts. You can collaborate, certainly, with the staff but it needs to be your choice and they have to be identified to you, identified with you.

The final thing on TRs, Calvin, is that because - if you read the organic Watergate document that we just recently made public - because of the fact that the authors all had an agribusiness relationship, some of them are still working as consultants, testifying before you on the issues that they have critiqued, I think it is very important to look back by requiring TRs on all Sunset-ing materials. The recent committee decisions, one of them suggested a material remaining on the list because no new information has come forward to contradict what was originally presented to the Board. Unless you do a literature review, unless you have someone do a literature review, how do we know if there is not new scientific basis, as in the case of carrageenan, that new, very serious, deleterious impacts to health or the environment have come to light.

Barry Flamm: Jay has a question for you, Mark.

Jay Feldman: Mark, I have a couple of questions. But I just want to sort of address the Board quickly on.

I appreciate the passion that you bring to this. I think there is a fine line between passion and disrespect and emotion and I think just, as you may be aware, some people are very uncomfortable with where that line is. I personally have experienced the passion in that people that walk that line over the course of my responsibilities at my organization. So I have learned to wade through the weeds on issues of emotion and passion which I think are incredibly important to understand when we are dealing with the public. And I urge Board members to cut through all of that and get down to the kernel of the issues that are being discussed here because, despite that passion-slash-emotion-slash-disrespect that you might be seeing or feeling, that there is a lot of good critical important information that is being put together by a extremely capable staff that has spent hours and days and months researching issues in what I think is a very laudable way and scientific way. So I just want to put that out there because I know there is some discomfort among many, both in the audience and on the Board here.

OK, so having said all that, I... You have been raising this issue of proxies which, up until very recently, was considered important to the Board's functioning and hearing from the community. And I just want to hear your viewpoint on the whole proxy system as a part of public comment, and how important you may view that as a part of the process, and why it is important.

Mark Kastel: Sure. I actually think your first comments dovetail perfectly into that.

I want to really clarify for the Board and my fans out in the audience what this little confrontation today was all about.

I talked about the fact that Dean Foods and Martek have the budget to fly in farmers, to fly in consultants, to have lobbyists and lawyers at this podium before you, whereas a public interest researcher did not have that availability. At one juncture in the last meeting, an executive was standing at this podium with Martek Biosciences Incorporated and could not answer a question from the Board. I think, Jay, the questions you ask are probably more important than our testimony because it is the missing piece of the puzzle that you have to find to make your informed decisions. And since that executive could not answer the question, their lawyer William J. Friedman, walked up to the podium and said, I can answer that question, and did so.

Now we don't have \$400 an hour lobbyists. But we had in this case, and a few other, volunteers that are organic stakeholders. And if the Board has a legitimate question, I was standing ready and prepared to answer that. Now when Miles came up to me - Miles, I said very respectfully, you are not chairing this meeting, Barry is - and that is why I went over to Barry. And Barry assured me that myself and the other Cornucopia staff members would have an opportunity to answer some of those questions after we do our presentation. I appreciate that opportunity.

So the dovetailing into the proxies is that we have this leadership - I'm just going to mention a couple of people because I have presented proxies in the past and other Cornucopia staff members that presented from Goldie Caughlan, Bill Weish (who passed away last year I'm sure you folks know), Kevin Engelbert, and Merrill Clark - all former Board members who are intimately involved in Cornucopia leadership and monitoring what is going on here. They are active in their communities. They are working farmers. Their voices are equally as important as the lobbyists that appear before you.

The problem is, they can't afford. We can't afford, as Cornucopia, to pay those lobbyists. And Goldie, Bill, and Merrill, they can't afford the... It costs us - and most non-profits don't have as many people attending - \$1500 to \$2000 to fly here, to rent a room, to have meals, for transportation on the ground. And there are some really important voices in the community, not just associated it with Cornucopia, Jay, but not associated with the corporate entities that can underwrite their participation. And so I think that is why their proxies are so fundamentally important. And that is why someone like Liana, who works so hard to be up to speed on these things, to be allowed five to 10 minutes to present something. In our case, we have about 7500 members - thought to be more organic certified farmers than any other policy group in the country. Their voices are funneled through Will or Charlotte or myself. Three minutes is a joke. I am sorry. Thank you for the question, Jay.

Barry Flamm: Jay, do you have a follow-up question?

Jay Feldman: Yeah, I also... I have many questions. I'm just going to ask this one more. You know, I know it is difficult to confront - not for you obviously, but for some people - to confront, you know, individuals on issues, especially when they are sitting there, and they are representing a sector as we understand it to be in the statute, and then they, of no fault of their own, got an appointment outside that sector. So I just want to clarify. I mean, you

are looking at the statute, you are looking at the... You don't have a beef with the statute obviously. You believe that those categories are valuable to the process. And so, what are you looking for the community to do, or this Board to do, in that respect?

Mark Kastel: Well, the first of all, I want the Board, hopefully, to go on record with the Secretary that you want OFPA respected, both the letter and the spirit of the law. So first let me talk about the letter of the law.

No. When it comes to individuals, we don't have a beef with anyone on this Board, anyone who has served on this Board. And, an individual who does not qualify as a farmer, if they were chosen to represent, to sit in a handler seat, we would certainly have no objection to that individual serving. But you are right, Jay. You know, speaking truth to power is highly uncomfortable. But that is our job. Because you folks, I don't think, know the scorecard all the time, because... The perception becomes the reality.

So we talk about the letter of the law, but let me talk about the spirit of the law too. When the representative from General Mills was first nominated by the Secretary to serve in a consumer slot and was later withdrawn, that was illegal. When she was put in a scientist slot, I would testify to you that, although technically she qualify with her PhD, that the spirit of Congress was to create a very diverse panel that represented all kinds of interests. And the scientist spot wasn't scientist hyphen corporate agribusiness. It was scientist. So I think that if we... I think that we want to as a community, reinforce the spirit of what Congress tried to do.

This is a highly unique Board. There aren't other Boards at USDA that have statutory authority. If it is stacked with corporate voices... And I'll use one last example. The past chairperson was the number one champion and lobbyist for the Martek proposal on this Board. What slot did she hold? Do you remember? She was the consumer representative. Every single public interest group that commented formally, in writing and orally, 100% opposed the Martek petition. Was she representing the interests of consumers in the United States? I don't think so. Thank you.

Barry Flamm: Thank you, Mark. I believe Jennifer has a question for you.

Jennifer Taylor: [Inaudible]

Mark Kastel: I can't hear you, Jennifer.

Jennifer Taylor: [Inaudible]

Mark Kastel: You're still ...

Jennifer Taylor: [Laugh]

Mark Kastel: Okay, now I can hear you.

Jennifer Taylor: OK, I just want to say this is true. And we appreciate your insight and your willingness to take on the rally of the organic community. Thank you. Could you please address the concern that you had in your document that dealt with the concept of conflict of interest within the commenters? Could you please talk about that a little bit more?

Mark Kastel: Sure. First of all, let me just tell you that we are concerned with conflict of interest and transparency in all areas, that this very unique community comes together. So that means Board members need to declare, as you folks have been discussing. But I think appropriately that people in the audience who are aware of conflict should bring that up. For instance, in the last meeting, General Mills has a contractual relationship with Martek Biosciences to help them produce the materials that were being petitioned. Their representative on this Board did not mention that. It was, there was knowledge of that in the audience. We don't have the ability to bring that forward. But I think this Board has to operate with full knowledge.

In terms of the Board members, the technical review folks, and people who are standing up here, who are representing to you, that they are coming to you and giving you factual information. I don't think anyone should be disqualified from standing at this podium regardless if they represent corporate interests or public interests, but you should at least have that transparency. So I think, at a very minimum, the consultants at the last meeting - and this was where this big wake-up call was from us - waltzed up here without saying anything but identifying they're name, and saying I'm a consultant to the community. You need to know who is paying their meal ticket, who flew them here. So that is number one.

But I think it is just as important to ask them: have you have done any professional work, either for the petitioner or in this area of science or in this area of commercial interest. So as an example, Doctor Alan Greene who worked for years who, while he was testifying on Mead Johnson major pharmaceutical manufacturer, on their website still listed him as a consultant and reference. The website, one of the medical peer reviewed literature sites... I'm sorry, they publish peer reviewed literature, but they have a advisory panel. Doctor Alan Greene sited on that website in real time as he was speaking to you folks, that he was working for Earthbound Farms. There were two representatives from Earthbound Farms on this panel. And I respectfully think that people need to be transparent about their financial interests. They need to share that with the community and that might elicit questions from the Board but at least you can put their testimony into context. I hope that answered your question. Thank you.

Jennifer Taylor: Thank you.

Barry Flamm: Thank you, Mark. Is there any other questions? Nick has a question for you, Mark.

Nick Maravell: I'm going to ask about GMO vaccines. I'm sorry but I'm going to be very pointed in my focus during these proceedings. You are suggesting that the committee recommendation with regard to the use of GMO vaccines in an emergency situation needs to be tightened up, clarified, etc. Could you give us some specific ideas as to what

your concerns are? And I will just state that the concerns of the committee were parallel to yours. And it is in our expanded comments that we did not want to see this emergency provision abused. We don't think it would be abused. But I wanted to hear your viewpoint on it, given that we saw a declared emergency as something that affected all livestock farmers. It has nothing to do with organic or non-organic, and you were required to obey the direction of a federal or state official. So could you clarify how you might want to see that tightened up? We certainly, on the committee, would not want to see it abused.

Mark Kastel: Nick, I think we had a kind of a divided, rigorous discussion on the Cornucopia Board and within our policy advisors also. I can hear Kevin Engelbert's you know voice in my ear here that there are legitimate emergencies. Part of Kevin's... this is why I kind of wish I had a proxy from Kevin here because he could have written this out a little more eloquently than I am going to deliver it. But part of his concern was that, if we have to wait for a declared emergency, that if there are individual epidemics on a farm, let's say, that something has to be controlled, we are taking that tool away. So I really have sympathy. On the other end of the spectrum, we are talking about a whole new area of technology. And we are talking about muddying up, our really militant anti-GMO staff in giving consumers a pure option in the marketplace. And I do not think that will serve us well.

So I really support Mac's comments too in that, as we understand it right now, there are only two GMO vaccines that are commonly in practice being used for salmonella in dairy and in poultry. And I think you heard Mr. Herbert speaking in the poultry arena. The dairy, it's a, it is a very low utilized product, almost nonexistent. I was not even aware of it until we started doing research. So by looking at these as individual materials, by the Board reviewing them, and then putting in realistic restrictions, if you approve them, I think you are preserving the integrity of the process and still making sure the safety and well-being of our livestock and the livelihoods of our family-scale livestock producers are protected.

Nick Maravell: Thank you. I think some of the sentiment that we are hearing here goes to the use of vaccines as they are normally used, which is as a preventative. And I believe what the committee's view was, is as a preventative, that we were open to petitions. There is a second use, much less desired, and that is an emergency use. And under those circumstances, we felt other things would come into play. So I think we share your concerns here and we are quite willing to entertain petitions to look at specific needs.

Mark Kastel: Nick, I want to emphasize one thing if I may. And that is this, you know, if we put this into the restricted category, restricted use, and then here is the caveats. This has been horribly... and the reason I want you folks, just not on this subject but in general, to really view restricted use in a much more judicious manner is that, because of the track record of abuse. For 25 years, I was an independent consultant working primarily for farmer owned cooperatives in the organic movement and dairy interests. And one of my clients was NC+ Organics which, at the time, was the largest independent seed house in the United States - the largest. They have since been purchased by Monsanto. And I helped them launch their organic seed division. It is now Blue River Hybrids. Maury

Johnson used to be on our Board of Directors. When I was doing the market research for NC+ Organics - it is a cooperative - and I went out in the field and I talked to certified organic farmers about what seeds they were choosing, they told me that they had a letter from the... They were using treated seed because the untreated variety wasn't available. And they had a letter from their supplier, and their supplier was NC+ Organic, or oh, I'm sorry, NC+. They had all of them available in untreated, and some of them available in certified organic, but they had gotten one of the field salesmen to write them a letter saying it wasn't avail... So the potential for abuse is there. So I am just kind of giving you that warning. I am shooting the flare up in the air to make sure that, if you do that, it is tight enough that it gives farmers the tools but not license to abuse it.

Nick Maravell: Thank you for those comments. That is one of the issues that we constantly grapple with when dealing with commercial availability. And so I appreciate those comments.

Mark Kastel: Thank you.

Barry Flamm: Thank you, Mark, we appreciate your comments.

Mark Kastel: Thank you, Mr. Chairman.

Barry Flamm: Patty Lovera. And Patty will be our last speaker before we take a lunch break.

Patty Lovera: Hi. My name is Patty Lovera. I work for an organization called Food and Water Watch in Washington, DC. And we are a consumer advocacy organization. So I am going to try to quickly cover some concerns about aquaculture and then several other issues.

For those of you that have been coming to these meetings for a while, it is not a surprise that we do not like the last recommendation NOSB made on aquaculture, specifically, allowing open net pens and the use of wild fish as feed for organic aquaculture products. We are still very concerned that that is what is guiding the regulation making process. And we think that that is worth talking about again, worth reconsidering. And I think that it is just really important - and Lisa brought this up earlier from the Center for Food Safety - to think about starting in a more restricted way. To do it properly and to build up organic aquaculture on a really firm foundation that is compatible with other organic standards for livestock. We think the way to do that is in the closed, recirculating, inland systems, not in the open net pens, not with wild fish as feed at all.

And then as the Board is, you know, taking into consideration this request from the Program to look at materials, we think it is kind of hard to evaluate these materials without knowing what systems are going to be allowed to be organic. One material in a closed system, it is going to behave very, very differently, serve a very different purpose, than the same material in an open net system in the open ocean. And so we just really throw that out there - to think about that. We submitted a much longer comment about this to the docket that kind of reiterates points we make in the fall about specific materials

with some of that thinking about open systems, closed systems, and some things that should not be allowed in any aquaculture system for organic if it is being used for a crutch for a poorly operating system to deal with the negative effects of too high a density or things like that.

So on a few other topics with the time I have left. I think the other major thing for the consumers, you know, who support Food and Water Watch is really in the vein of what Liana was talking about from the National Organic Coalition. And Food and Water Watch is a member of the National Organic Coalition. And what it boils down to is that each of these individual decisions you are making, often on materials or vaccines or things like this, in the consumer perception we are now at a point where it is kind of like the net effect of all these decisions together is really greater than the sum of the parts.

So we have this continual perception problem we have to answer for consumers and explain to consumers who are confused about what is happening to these standards. And it may be not just the decision on corn steep liquor or ARA-DHA but the net perception we really have to deal with as a community. And I just urge you to keep that in mind as you think about many of these topics.

So, super quickly, we support the letter to the Secretary Vilsack on GMOs. It is long overdue for this community to talk about the impact biotechnology is having on it.

We urge the Program and the Board to think about getting biodiversity into the mix the way that the Wild Farm Alliance has suggested.

We believe that carrageenan, it should not be used in organic products. So we do not think it should be listed.

And finally, on inerts, we think that has to be dealt with as soon as possible. It is one of these integrity issues for consumers. It is one of the reasons they come to organic and they are learning more about how... what the wild west of inerts. How they are not regulated. We don't know what they are. And so organic should be a place where they can be assured they are not going to have them. So if you separate of those lists to finish... Evaluate them individually and finish List 3 as soon as possible, and List 4 as soon as possible after that.

Barry Flamm: Thank you, Patty. Any questions for Patty? Calvin.

Calvin Walker: Food and Water Watch is for open and closed systems, or just closed systems?

Patty Lovera: We are essentially for recirculating, closed systems. We have not seen any open net systems that are not damaging the environment. So, yeah, we think we have to start and then probably stop with closed recirculating systems.

Calvin Walker: Thanks.

Barry Flamm: Colehour has a question for you, Patty.

Colehour Bondera: Yes, Patty, thank you for your testimony and I appreciate your work. I think my question is actually very similar to, or a repeat to, the question I heard Calvin ask when there was testimony about the aquaculture question related to closed systems and it is: whether or not you have any examples that you might call upon or references of experiences - not necessarily Food and Water Watch's - but that we might look at when we are considering this aquaculture question. If you have anything to add from a more, I don't know, yeah, reference perspective. Thank you.

Patty Lovera: Sure. So when you're asking questions in the fall, the Materials Committee, about how do we start to look at these materials, I think the question on there was: has anyone done this well? And our answer in that comment was "no". We don't think that the EU standards, you know, that the new Canadian proposal - we don't think that they are there yet on how to evaluate materials. When it comes to the bigger question of what is a responsibly operated, you know, low impact et cetera system for closed recirculating systems, there is a new coalition of producers in the US who are interested in this exact type of aquaculture. They are moving right along. There is a... So it is called the Recirculating Farms Coalition. You know, the woman who is the executive director of that has commented in the past. She could not make it to this meeting, but she would be a really good resource for the future. Her name is Mary Ann Cufone. I know she would be happy to talk to folks. And I actually emailed with her this morning. She is visiting some closed recirculating farms in Milwaukee, you know, who are figuring it out on the ground. And, if organic can develop a standard that they see working for them, I think they would happily embrace it. If it does not and it is very much open net systems and going the way of organic salmon, quite frankly, they are just not going to bother with it. And they are going to do their own thing because they are figuring it out right now.

Barry Flamm: Jay has a question for you, Patty.

Jay Feldmen: Thanks, Patty, and thanks for the work that you do. You know, this might be a really good opportunity for the NOSB to get it right, you know, at the front end. And Calvin actually made a suggestion after some of his first year of experiences around a process that would enable the Board on questions of materials, which is typically where this does not happen, to bring a discussion document on materials to the community before we actually are faced with voting. The aquaculture working group has 10 synthetic material petitions before the Board right now. And if we proceed as I understand the Program would like us to proceed, we will be here at the next meeting in the fall with recommendations on those 10 materials.

We have not yet seen any guidance on the 2008 policy. Some people have told us that parts of that policy may be illegal, unlawful. We don't know how the materials fit the into the larger policy framework. This might be an example, Calvin, of a situation where you would want, the Board would want to get the material discussion out in front of you and the community before we actually, you know, vote on allowing materials.



One of the things we have not had real good access to yet is the kind of independent science that you are suggesting be developed, or is being developed. We have heard from the aquaculture working group, industry-related people who are, you know, include scientists to the industry but we have not heard necessarily yet from independent sources on that. So it sounds like you are willing to assist and bring the resources that you guys have to this process.

What would you recommend the course of action be in terms of Board action, given that we are facing 10 petitions on synthetics in aquaculture perhaps at the next meeting? What would you recommend the chair of the Livestock Committee do if indeed that is where all this ends up? It has been in Materials Committee up until this point. What would you recommend we do in terms of process? Chart out for us where you think we should take this process next.

Patty Lovera: That is a good question. It is kind of the ultimate question for this issue, I think, and it is kind of intertwined with what the NOP is doing. I mean if I was on the Board, I think I would be really asking the NOP frequently: what are these regulations going to look like? Are we looking at open systems or closed systems? You know, we have an opinion is should not be the open net systems.

If that can't happen, if you don't get that clarity, I think sadly you have to evaluate these materials on two tracks. So I know that in the comment that we submitted, there are just a couple of examples. Where, for example, using a vitamin or a nutrient in a closed system, you probably use it in a very small amount as a supplement. If you use iron in that way in an open system to fertilize growth, you are also fertilizing, you know, growth for free for everything outside that net too. You know, fish that you are not going to harvest. You are changing the environment for them.

So the same material could be very different in two different settings. So I think it kind of doubles the work for the Board. But I think that is what has to be done if you don't know what you are looking at for what an organic aquaculture operation is going to be.

Barry Flamm: Follow up, Jay?

Jay Feldman: Here is one more question for you. One of the things the aquaculture working group has said to the Materials Committee is, on this question of release, is that any release of vitamins, nutrients, would be an adventitious presence, which sort of rang a bell in the back of my brain which didn't sound too good. But their argument is that the release would be helpful to the environment and that is something we have not heard the other side of the argument on.

Patty Lovera: I think that is overly simplified. To act like adding nutrients of any kind to a ecosystem is beneficial all the time. So, you know, in different parts of the world, there are well documented cases where sharks are drawn to open net pens because there is like a salad bar for them. There is food floating out all the time. There is fish escaping all the time. Other organisms are coming in to eat the waste. But they are building up an

unnatural food chain there. And then the sharks get a little greedy, and they start to attack cages, and then more fish get out. So I mean this is not a controlled option – an open net ocean systems. And to act like it is that simple, like you are just fertilizing the ocean, it is never that simple in natural systems. So I don't think that is a good baseline to start from. And we are happy to try to find... You know, we have been, I think about a year ago we submitted quite long comment with some of the ecological concerns we have. And I'm happy to resubmit that and get our folks to update it if there is more stuff.

Barry Flamm: Miles?

Miles McEvoy: Yeah, just an update on aquaculture: The Program has put together a work group working on aquaculture to develop a proposed rule to come out hopefully next year. This is based on the NOSB recommendations. The NOSB has put in a lot of time and energy into developing your recommendations over a period of years. We are in the process of implementing those recommendations. Those recommendations, final recommendations from this Board included open net pens. So we are not asking the Board to reconsider recommendations that you have already finalized.

What we are asking the Board to do, just like you do with many other systems, is to evaluate petitions for these systems. You evaluate materials for aquaculture, for instance, and you have added things to the National List even though we don't have specific aquaculture standards. For aquaculture, you have your final recommendations that the Board passed. You can utilize those recommendations to move forward with evaluating the petitions for aquaculture.

It is just like how the rule was originally developed. There was no standards when the National List was first being proposed by the National Organic Standards Board. You use your recommendations that you have to evaluate these substances for aquaculture, as we move forward to implement organic aquaculture standards based on your work and your recommendations. So, to reconsider them at this point is really inappropriate.

Barry Flamm: Thank you, Miles. Any other questions? If not, we are going to break for lunch at this time and be back here at 1:30 pm. We will continue with the public comments under the general category. We have 12 to go yet, so we are running one hour behind schedule and I ask the Board just to stay here for a minute. I need to talk to you all before we break up for lunch.

[BREAK]

Barry Flamm: We are back in order. We are going to have to change the rules a little bit this afternoon for a while. There will only be one question per commenter coming from the Board until we get back on track. We could end up being two, three hours behind schedule the way things are going. Hate doing it, but that is what we are going to do for a while. So, Johanna Miranda is our first speaker for the afternoon.

Johanna Mirenda: My name is Johanna Mirenda. I am materials review specialist for Pennsylvania Certified Organic and I would like to comment on recommendations from the Livestock Committee and from the Compliance, Accreditation and Certification Committee.

Livestock Committee, after a quick rewrite of my comment this morning, I would like to thank you for withdrawing the recommendation on vaccines from excluded methods from this meeting's agenda. PCO strongly feels that additional research, discussion and clarification, is needed on this topic. The recommendation, as is currently written, would pose significant challenges to both producers and certifiers. PCO has certified hundreds of poultry houses and has reviewed thousands of livestock medical treatment products. Many of our certified poultry producers rely on vaccination as part of their preventative health care management program. Vaccines for several diseases are currently not available in non-GMO form. If organic producers were not able to use vaccination as a preventive health care management tool for these diseases it would not only prevent, present a significant food safety risk in itself, but it would also conflict with other industry regulations that require producers to take preventative measures, including vaccination, to ensure food safety. Organic egg producers have told us that they would not be able to enter some markets without a vaccination program for salmonella, one of the diseases for which a non-GMO form is not available.

As the Livestock Committee continues to work on this recommendation, we urge you to think critically about the areas that the public has identified that require further research and clarification. PCO has identified several of these areas in our written public comment, and we would be happy to participate in future discussions on this topic.

Compliance, Accreditation, and Certification Committee, we strongly encourage the Board to pass the recommendation on criteria for material review organizations. And allow NOP to move forward in providing detailed material review criteria to be followed consistently across all certifiers and material review organizations. Consistent material review is critical to providing quality and consistent certification services to all organic producers and processors. Thank you, all the committee, for your hard work.

Barry Flamm: Thank you. And, Board, raise your hand if you have a question and Mac Stone will decide who will get to ask the question. You got a question?

Mac Stone: I think they were all scared so I will be first. How much variation do you see in the vaccine programs based on size or the types of operations you see? How much variation in the vaccination schedules do you see?

Johanna Mirenda: I would estimate, at best, that our larger poultry producers are the ones maybe using the vaccines but overall, most of our poultry producers are routinely using a salmonella and E. coli vaccine.

Barry Flamm: Thank you very much. Steve Mojo.

Steve Mojo: Mojo

Barry Flamm: Mojo. Thank you, Steve.

Steve Mojo: Thank you. I am Steve Mojo. I am the Executive Director of the Biodegradable Products Institute or BPI. The BPI is a not-for-profit trade association started in 1999 and represents the major manufacturers of biodegradable mulch films in the United States. Our primary goals are, one, to demonstrate and educate consumers and others the role of biodegradable products of today's society and, secondly, to promote scientifically-based standards that ensure these products will fully and safely biodegrade in their intended disposal avenues, such as soil, marine, or compost. Today, the BPI consists of 140 companies located around the world, including suppliers of biodegradable mulch films.

This is my first visit to the NOSB meeting. Besides introducing the Board to the BPI, I hope to observe and better understand your process in preparation for the review of our petition - biodegradable mulch films made from bio-plastics. And then, as this petition moves forward, to offer any assistance that the Board may need.

Four months ago, the NOP accepted our petition for biodegradable mulch films. And, according to the USDA website, the technical evaluation report is being prepared. At a future meeting, the BPI will ask that our petition be placed on the National List under the crop section 205.601(b): Mulch.

Our goal is to enable organic growers to use these films if they wish. In fact many growers have already encouraged the BPI to submit this petition rather than give up there organic certification as a few have done. These useful products can improve the environmental stewardship of organic production as they provide a more effective tool for growers while helping the US organic community reach its stated production and growth goals.

I believe that biodegradable mulch films represent a significant improvement to polyethylene plastic mulches and, as such, are compatible with organic farming. In fact, other organic standards, such as those in Canada, already allow these biodegradable mulch films to be used. Then these Canadian products can be sold in the US and display the USDA organic seal.

Biodegradable mulches provide weed control, moisture retention, and soil warmth and, unlike polyethylene mulches, they decompose naturally into carbon dioxide and water just like the crop residues that are plowed back into the soils at the end of the growing season. The performance of these materials has been documented by research at Rodale Institute as well as other organic farms. I look forward to working with the NOSB as this petition moves forward. Thank you very much.

Barry Flamm: Thank you, Steve. Question? Thank you, Steve.

Steve Mojo: Thank you.

Barry Flamm: David Moore.

David Moore: Good afternoon and thank you for this opportunity to address the Board. My name is David Moore. I am a California licensed pest control adviser, qualified applicator, and I work for Neudorff. Neudorff is the registrant and manufacture of Sluggo, the ferric phosphate snail and slug bait, an NOP compliant pesticide. Sluggo is OMRI and ECOCERT listed. It is allowed in organic production in the EU, here in the US and elsewhere.

I would like to thank the Board for their recent unanimous vote to recommend the relisting ferric phosphate for another five years and for their careful consideration of a petition to remove ferric phosphate from the National List. I also want to thank members of the Crops Committee for their diligence and patience as they review the technical materials associated with that petition.

Slugs and snails are a direct challenge to the basic practices of soil fertility management and conservation. Fallowing, cover cropping, and minimum till production systems foster huge pest mollusk populations that not only damage cover crops but which persist to damage or, in some cases, destroy subsequent crops. Many agronomically-challenging, high-value crops depend on an effective molluskicide to remain economically viable as both conventional and organic crops. Economic viability is one of the pillars of sustain... one of the three pillars of sustainability, and if organic growers of crops such as leafy greens, soft fruits, artichokes, citrus, and ginseng are deprived of Sluggo, these acres will likely return to conventional production and these crops will become organic rarities or luxuries.

Remember, the crop pests and diseases are, in themselves, disruptions of the ecological balance of the farmer ranch and that growers face three major challenges in correcting this imbalance. First, the solution must be effective. But it must also be compliant with all laws and regulations, and it cannot compromise food safety. Ferric phosphate is the only effective, economically viable organics treatment available for slugs and snails. This is clearly established by the market, which has... which as growers have rejected alternatives and embraced Sluggo. Indeed the organic community has so far expressed only support for this important material. So-called alternatives are not embraced by commercial growers. Most are economically impractical. Some are violations of the NOP and basic food safety best practices. At least one is a illegal application of an unregistered, illegal material. And one or two are pure fantasy.

Ferric phosphate alone is an effective solution that is consistent with organic agriculture and with the Organic Foods Production Act of 1990. Everyone in this room has heard it said that organic food, organic agriculture cannot feed the world and we all want to be part of refuting that challenge. But if organically produced food becomes, is a luxury, offered only to and afforded only by the affluent, then organic agriculture surely will not feed the world. This Board's duty of care is to the organic community and that includes dedicated, organic growers that depend on an effective organic molluskicide. But, for

organic agriculture to feed the world, that duty of care must also be extended to millions of people that want to be organic. Thank you.

Barry Flamm: Question?

David Moore: Thank you.

Barry Flamm: Thank you. Cam Wilson?

Cam Wilson: Thank you. I am also here from the company Neudorff. My name is Cam Wilson and I am here to talk about ferric phosphate.

Dear NOSB members, You are probably very familiar with the ferric phosphate issue. It has been going on for a couple of years now within the NOSB. A couple of background points to talk about first. The active ingredient in the ferric phosphate is on the National List for the control of slug and snails in crop production.

I realize we have submitted a lot of information to you over the last couple of years. I have been told voluminous amounts, in the size of a phone book. I would just encourage you to take the time to read through the science. The science is there to refute any of the allegations that have been made by the company that wants to delist ferric phosphate.

First and foremost, we support the continued listing of ferric phosphate on the National List. Just a bit of background information for you: In 1997, the EPA confirmed that the active ingredient in our product Sluggo is ferric phosphate. They registered for the first time in '97. Our product: the recipe itself has not changed since that original registration. In 2005, the NOSB voted "yes" to add ferric phosphate to the National List as a molluskicide and, as such, it has become now on the National List as a result.

In 2008, the EPA asked for additional information on our ferric phosphate bait. The question they put forth to us: is ferric phosphate truly the active ingredient or is it iron EDTA? We submitted the science, the same science that has been submitted to the NOSB and, as a result, the EPA confirmed that the active ingredient was in fact iron phosphate.

EDTA, which is in the product, is an inert, acts as an inert. And, as a result of that, they gave us the NOP language and the OMRI language on that stamped-approved label. In other words, they would not be able to do that if they did not believe that we did not show without a shadow of a doubt that ferric phosphate was in fact not the, the active ingredient.

A little bit of information about inerts I just want to say for the record: The EPA defines an inert as any substance other than an active ingredient, which is intentionally added or included in any pesticide product. An example is in a solvent that allows a pesticide's active ingredient to penetrate a plant's outer surface. EDTA is a List 4 inert. List 4 inert ingredients are defined as inerts of minimal concern and, specifically, as ingredients for

which the EPA has sufficient information to reasonably conclude that the current use pattern in pesticide products will not adversely affect public health or the environment.

In 2010, the NOSB voted, as part of the Sunset review process, to relist the existing List 4 inerts for five more years. As well, in 2010, as part of the Sunset review process, the NOSB recommended to relist ferric phosphate as part of the National List. And I am being told to stop. Okay. I am obviously a slow talker. I will just conclude then. We have had similar allegations like this put forward in Europe. The results were ferric phosphate is the active ingredient. EDTA or anything else in the product is an inert, and just...

Barry Flamm: Cam, will you wrap up? You are over your time limit.

Cam Wilson: We just ask that the NOSB look at this from a point of view of what the other countries in the world have done, and the science that the EPA has done, and we just ask you to consider the science. And thank you for your time.

Barry Flamm: Board questions? Thank you, Cam.

Cam Wilson: Thank you.

Barry Flamm: Michael Potter, next.

Michael Potter: Good afternoon, ladies and gentlemen. I am Michael Potter, Chairman and President of Eden Foods, in the organic food industry for 43 years. We are not an OTA member.

I must object to the greenwashing for more, easy and cheap to produce, quasi-organic food. Should organic food be better for large corporations or better for the people? Self-proclaimed organic leaders - self-proclaimed by those in, to those in Washington - long ago abandoned quality for quantity - quantity in cash flows, profits and, overall, quantity in and of numbers.

They have adopted the Wall Street ethos that bigger is better and so have completely abandoned the organic truth that small is beautiful. Organic food is supposed to be an alternative to industrialized food. It is supposed to be the antithesis of commercial food. Yet how can it be an alternative to junk food when it is being measured for success with the same yardstick used for and by Wall Street rascals?

The NOSB was designed to be a gatekeeper in order to preserve organic authenticity. To do this, they must employ the precautionary principle, always being certain that what they do is appropriate for organic food. There is a huge need for something to control the inputs into organic food. There is need to offset the efforts of those simply want to make as much money as possible doing it the easiest and cheapest way.

A character of organic agriculture is that it must encourage life in soil. Anything that diminishes or limits vitality of soil life ought to be avoided. Anything that stresses or destroys soil life must not be used in organic agriculture.

USDA organic food has a reputation as needing only comply with the paperwork scheme, a scheme that invites and encourages fraud. It is urgently important than something developed to off...something developed to offset this and the role of the NOSB ought to be this offset.

Chemical manufacturers can lay hundreds of pounds of documents before us claiming their additive is safe and suitable for organic. Who can counter such a presentation? An individual? Objective academia? Is it the people's job to prove them wrong when they simply say they are right? They should have to prove beyond a shadow of a doubt, until the due diligence of their precautionary principle is entirely met.

Definition of organic food ought to be similar to that of organic agriculture. Anything that causes physiological stress in a healthy person eating it should not be added. And the handling and processing of organic food should be done to protect and enhance vital forces inherent in it.

Food is a life force and growing and handling and processing it must be looked at in its entirety not in the myriad of small pieces. First, principles must be set for organic food and then the small details looked after accordingly. Looking after small details without overriding principles is a recipe for disaster - a disaster where organic food no holds credibility with the public.

At Eden Foods, we hear of trade association's grandiose numbers touting tens of billions of dollars in organic food being sold. This is usually met at Eden with sarcastic comments about organic junk food. Organic foods that by no means ought to be called or sold as organic food. Thank you for my three minutes.

Barry Flamm: Questions? Thank you, Michael. Whoops, oh, excuse me.

Jay Feldman: Thank you, Michael. Thanks for coming to the NOSB. Welcome. Appreciate you being here. I am really interested in getting, since you are such a large producer and have a very important presence in the market, the organic marketplace, I am interested in getting your specific input on specific materials that we are reviewing. And are you going to have, or do you have, specific positions on the materials we will be reviewing over the next couple of days? And can we call on you as those come up?

Michael Potter: Eden Foods is a very resourceful company. We welcome being utilized as a sounding board. You know, the driving force, I heard someone testify earlier today, that you have to hurry up. We need to be bigger. My God, that is not what this is about - hurry up. We need to do it right. And size is not everything. You know, healthy development is what we need. And I am more than willing to participate in any way that the Board would deem useful. Thank you.



Barry Flamm: Thank you, Michael. Our next speaker is Alexis Randolph.

Alexis Randolph: Good afternoon. My name is Alexis Randolph, and I represent QAI, an organic certification agency. QAI submitted written comments on several different committee issues, but I am speaking publicly today to request the NOSB take up the new work plan for future meetings. It is very ironic, given Miles' opening presentation so please prioritize this as you see fit.

We ask that the Board develop criteria for implementation of rule changes. To illustrate the necessity for improved guidelines in this area, I will discuss the recent rule change for lecithin, and explain challenges certifiers and organic operators are now facing. There is exactly 30 days from the Federal Register publication announcing the rule change for lecithin to the implementation date in March. Many operators did not prepare to source organic lecithin prior to the rule change.

As you know, the NOSB has made many recommendations to the NOP that have not yet been implemented. If companies made changes to their operations based solely on NOSB recommendations, they could easily be wasting time, money, and in some cases, even find themselves out of compliance. Preparation goes far beyond identifying a supplier. Samples need to be obtained, months of R&D need to be conducted, consumer taste tests are performed and then, if all goes well, labels are redesigned. Thirty days was not enough time to effectively implement this rule change.

On March 15<sup>th</sup>, companies stopped organic production. Because 205.606 and commercial availability does not apply to products making a "made with organic" claim, some companies have continued to use non-organic de-oiled lecithin and reduced products to the "made with organic" claim in order to get back into production as fast as possible.

The "made with organic" claim means that certifiers have to verify agricultural status of lecithin, which speaks to another topic at this meeting. We would like the NOP to urgently move forward publishing guidance on the classification of materials. I was very happy to hear earlier that Miles will be speaking on this topic tomorrow.

Those companies able to start using organic lecithin are faced with costly label revisions just to add an organic designator for the ingredient on their label. QAI expects the average manufacturer to take six months in R&D, and one to two years using up labels as a result of rule changes.

Lecithin is just one example. Many National List changes result in organic operators performing R&D and making label changes. Additionally, producers and livestock operators may find they have spent precious dollars on inputs that they can no longer use.

We ask the NOSB to consider the impact of rule changes, especially the necessity of those changes. And, knowing that some of will be made, we ask for some criteria for

implementation timelines that the NOP could provide to certifiers in the form of guidance.

On a different topic, I would like to briefly mention that QAI submitted written comments to the Handling Committee in which we bring up the concern that the NOP regulations stay in step with international regulations where equivalency agreements have now been forged. The NOP regulation, especially the National List, needs to provide a level playing field for organic operators to produce the same products in the United States as are allowed to be produced in Canada or the EU for import to this country. We ask you to consider equivalency agreements as you vote in this meeting and future meetings. Thank you for your time.

Barry Flamm: Question? Zea.

Zea Sonnabend: Thank you. This isn't quite so much of a question, or maybe it is a question, but as much for Miles as it is for you, Alexis. To me, it would be the NOP's purview as to a grace period for changing labels or a sourcing period when there is a rule change like that. But I agree with you. This is something that has worried all of us certifiers for a long time - that we are told, time and again, an NOSB recommendation is not law until it becomes a law. So you had several years on lecithin to think it was coming, but we have been told to not recognize until it becomes a law, and then you only have 30 days. And you are absolutely correct. That is not enough time for a reformulation. But I don't think it is necessarily the NOSB's job to determine those details, and more the department. And I am wondering if Miles has a response to that.

Miles McEvoy: Yeah, we learned a lot from the rulemaking with lecithin. When it went into effect, this is one of the few times that a widely used substance has come off of the list or changed its allowance. We had some questions and answers concerning the effectiveness of the change. That is on the website. But this is an interesting situation that seems ripe for the Board to take a look at. Of when things are coming off the list, things that have been in common usage within organic production or handling, what is that transitional time period? And how do we work that into the rulemaking process to make that transition be as seamless or not disruptive to the industry. So we learned things with this lecithin. We will bring back some more information on that to see if we can come up with better procedures for changes like this in the future.

Barry Flamm: Thank you. Terry Shistar is our next speaker.

Terry Shistar: Hi. I have a PowerPoint here. Okay. I am Terry Shistar with Beyond Pesticides. We submitted several written comments on a number of issues before the Board. Right now I'm going to talk about a few crosscutting issues.

The NOSB has a duty to review each synthetic material allowed in organic production to determine essentiality, environmental and health impacts, and compatibility with organic principles. It is a big job and we really do thank you for volunteering to do it. The

proposed public communications policy would help make the NOSB's job more efficient by encouraging timely input.

Your action is urgently needed to begin a review process that was called for over a decade ago. As a background to the List 3 inerts recommendation indicates, the Board has been aware of the need to review these ingredients and, in fact, set itself a deadline of January 1st 2002, more than 10 years ago, for doing so. It is time to do it now.

The Board must also adopt a clear and consistent policy on extractants as a first step in addressing the other ingredients in processed organic products. The issue of unexamined so-called inert ingredients is immensely important to environmentalists and consumers. One of the first lessons in Pesticides 101 is that inert ingredients are not biologically or chemically inert, but are only those ingredients not claimed to have pesticidal action against the target pest. You can find the same lesson in publications for hospitals, and from the National Pesticide Information Center, or ExToxNet.

EPA, realizing that the term "inert" is misleading, now calls them "other ingredients". The agency no longer supports the system that NOP uses. NOP cannot rely on EPA's evaluation of any material under FIFRA, which has very different standards than OFPA. But in the case where the evaluation consists of a list that EPA no longer supports, the reliance is completely untenable.

For the environmental community, the issue of so-called inerts is fundamental. It is about exposure to toxic chemicals without informing us. It is about toxic chemicals posing as harmless fillers. It is a basic right-to-know issue. We in the environmental community believe the organic community should be with us unequivocally on this issue. In the same way, other ingredients in processed organic foods are important for the same reasons. Thank you.

Barry Flamm: Thank you, Terry. Question? Brise Tencer is our next presenter. Thank you, Terry.

Brise Tencer: Thank you. My name is Brise Tencer, and I am the Director of Policy and Programs for CCOF Inc., which is the CCOF Trade Association. And I am happy to be here just to provide a couple of general comments today.

First, I would like to start with our kudos to the Board. First, we would like to express our very enthusiastic support for the new Committee's ad hoc Committee on GMOs. We think GMOs have presented problems for a long time. And we are really happy to have a venue where they can be looked at more thoroughly. We are also supportive of the letter to Secretary Vilsack regarding GMOs.

On another positive note, we want to express our support for the research priorities in that framework. Research, of course, is absolutely critical to the organic sector as a whole. And we have so many critical issues in front of us that can't be addressed without thorough research.

Looking forward, we do have a couple of thoughts. I want to be on the record of our support for organic standards better addressing biodiversity. It is a critical and integral part of organic farming systems. We support both guidance and there being a checklist for accreditation.

I want to make a point about unannounced inspections. CCOF continues to try to be a leader on unannounced inspections which, we think, is absolutely vital to real enforcement and real verification of what is happening. And we strongly encourage guidance or rulemaking on this, in the hopes that it can be an integral ongoing part of organic certification.

In general, we think there is a need for continued improvement and clear and consistent recommendations on materials that certifiers can understand and enforce. This applies to a wide variety of issues from GMO vaccines to the 100% organic label and other topics that have been brought up at this meeting.

On that point of the 100% organic label, I do want to share that we have had conversations internally and there is a strong sense that the 100% organic label is confusing, it has been difficult to explain, and really difficult to implement consistency.

Lastly, I want to just mention regarding livestock scorecards that we support strong animal welfare that is clear and enforceable. We believe organics should be the gold standard in animal welfare, and that there should be no need for any additional animal welfare standards. We are prepared to do the work to help get us there, but we need clear standards.

And lastly, please continue to work with the organic community to have a viable public input system. It is difficult to do as the industry continues to grow and more people are interested in these issues. Three minutes is an awfully short time, but we are all doing our best. Thank you so much.

Barry Flamm: Thank you very much for your comment. Question? Thank you. Chris Wilcox is the next speaker.

Chris Wilcox: Good afternoon. I am representing Wilcox Farms, a fourth-generation 103 year old family business in Washington state. We are a poultry, egg company. I brought some pictures. I'm supporting the, and advocating the aviary system. All of our organic facilities are in the aviary system.

Here is a picture of what our farm looks like. You can see the organic growth should promote outside access. We should allow for a alternative aviary system. Next, please.

This is a typical poultry house at our farm. The key factors are training the birds actually to go outside. Every day we kind of herd them out and they go out. And then the exits: we have 67 linear feet of exits alongside the poultry house and on the back. Next, please.

You can see the inside space calculation needs to allow for square foot created by aviaries. Aviaries allow for about an extra 30% square feet. The perches are a natural resting space and they should be included. The current wording uses the house's footprint to calculate the inside space. This would make aviaries uneconomical. Next, please.

It is inconsistent: The current recommendations are not consistent with European or Canadian organic rules. Our farm builds all of our poultry houses to European standards. The maximum flock size: If the committee is worried about big flocks, perhaps you should have a maximum flock size.

And these are just some suggestions. Don't ban a great alternative production system. Thank you.

Barry Flamm: Thank you. Question? Thanks.

Chris Wilcox: Thank you.

Barry Flamm: Darryl Williams?

Darryl Williams: Good afternoon, Darryl Williams, representing Oregon Tilth Certified Organic. I am the handling technical specialist.

Carrageenan is used by a wide variety of certified operations. Amongst other uses for its stabilization, emulsification, and protein binding properties, it is notably used by many organic soymilk producers because of its vegan and vegetarian sources, and in beer manufacturing for its ability to bind with proteins so they can easily be removed. Without a proper substitute for all applications in organic production, it should continue to be listed on the National List. According to the evaluation criteria identified in 205.600, its immediate removal without a suitable replacement would be extremely disruptive to organic manufacturers.

Oregon Tilth agrees with the committee's decision to not vote on GMO vaccines proposal at this meeting. We feel that there is many refinements needed in order to ensure that the policy is sufficiently enforced by certification agents without creating an undue paperwork burden on certified organic producers. We are excited to hear your discussion this week, and your next action steps for an updated proposal in the future. We did submit written comment on this topic, and would welcome any request to discuss this topic with you or provide further information.

We do not feel that a non-organic food contact sanitizer should prevent a product or ingredient from being labeled as a 100% organic. National List sanitizers are used for packaging and for cleaning of equipment without a rinse. If product is run directly after sanitation has occurred, there will be a residual sanitizer left on the package or equipment unless completely rinsed and tested to show the absence of residual sanitizer. When organic production commences, the sanitizer residues left on the package or surface will come into contact with organic product. To recommend that a sanitizer used in direct

food contact will prevent an organic product from being in the 100% category when a sanitizer used on a surface which could then be transferred to a product via residual contact will not prevent an organic product for being in the 100% category is not consistent.

Not allowing sanitizers to be used on 100% organic products risks bringing more negative media attention to the organic movement. We do not believe that this will benefit the US organic market. Nor do we believe that allowing the use of sanitizers to be used on 100% organic products presents adding any adverse risks to consumers who purchase organic products.

Oregon Tilth's farm and livestock clients do not utilize the 100% organic category but our handlers do. All product are assumed to be 100% organic leaving the farm. Of the 626 handling clients we currently certify, 159 clients (25%) utilize the 100% organic category on their certificates. There are 34% of products certified in the 100% organic category. It is worth noting that the vast majority of our clients that utilize the 100% organic claim are for the calculation purposes for their buyers who are purchasing certified ingredients for further processing and handling.

Barry Flamm: Darryl, would you please wrap up?

Darryl Williams: Yes. Also, the 100% organic content claim is allowed on products. I will just end with that.

Barry Flamm: Thank you. Question? Thank you, Darrell. Our next and last public commenter is Marty Mesh.

Marty Mesh: Howdy. I thought I was going to be the last one before lunch so I was going to make it light, but it is after lunch. I should wake you all up I guess. So my name is Marty Mesh. I am executive director of a non-profit called Florida Organic Growers. We operate an organic certification program called Quality Certification Services. I have been involved in organic farming and the industry since 1972. So I have had the pleasure of seeing the frustrations and the growth within it.

So, welcome to the new Board members. Thanks to Miles and his staff for the good work and the report. Look forward to being able to read the report 'cause I was sitting way back there when y'all post it.

The GMO letter to Secretary Vilsack, I want to express our thanks and support for it.

We see Bt resistance no longer as something in the future but something that is here now. Bt is a valuable resource and tool for organic farmers and regular farmers and it is on its way to being ineffective. We support the concept that the patent holders need to be held responsible - and we were glad to see it kind of alluded to in the letter. I think it could be made better, even stronger - and that buffers should be really the responsibility of those utilizing technology or chemicals, not organic farmers.

We, I had written the disagreement with Alexis about their GMO vaccine. And then she clarified her stance in a letter. And so I will just skip that part, to say we are glad you all are tabling it. And that we don't think it is really ready, as it was presented, to go further.

Concerning Miles' report, we stand ready to help grow organic agriculture in the south. It reminds me that, yes, okra still grows well. And we still have never heard from those companies who tried to put okra on the non-commercially available list. Even though they are not still on the Board, I thought I would just go ahead and mention it.

Food safety is coming up. And we look to the Board, as well as the Program, to weigh in. And organic farmers are hopeful that the Program will weigh in on behalf of organic agriculture and ensure that the use of compost and manures that meets the organic regulation will not become collateral damage by FDA.

We did not sign the biodiversity letter due to my travel schedule, but we certainly support it. FOG has worked with Joanne for a long time. And we are in fully support of it although we remain concerned about what Miles alluded to is the organic certification process continuing to be attainable. And so, in that context, we want organic farmers to be able to farm, and afford to be able to be certified, and have the time and the capacity to do both. And we see the increasing amount of verification required for organic certification and paperwork as a weight that organic farmers are starting to just throw off.

Man, are you kidding me? If you want to ask me about aquaculture, I would say something, or calcium sulfate. I don't know. It is just an idea.

Barry Flamm: Thank you, Marty. Marty, I may be the only one left on the Board that knows your okra story. They were sitting in the audience. Question for Marty?

Marty Mesh: There are three.

Mac Stone: Zea.

Zea Sonnabend: Marty, tell us about aquaculture.

Marty Mess: Since we certified, according to the regulation, aquaculture when it was allowed by the USDA, and have seen those two aquaculture operations go bankrupt once the ability to use the logo was pulled from them and have advocated for standards development for years and years, we are happy to see organic aquaculture getting some attention. We support the idea of standards. I had a conversation with Lisa and, although she talked about recirculating things, I think we are in agreement with the fact that recirculating may not have been the right term. That they are supportive, as well, of managed pond systems and that is what we had certified before in the two domestic shrimp producers that USDA drove to bankruptcy. So we are glad to see aquaculture standards move forward and question the idea of materials before the standards as well.

Barry Flamm: Thank you, Marty.

Marty Mess: And then... was it about calcium sulfate? I don't know.

Barry Flamm: No. That is the only chance. Thank you, Marty.

Marty Mess: And we will submit written comments in the future given that three minutes goes oh so quickly.

Barry Flamm: We are going to move directly into Compliance, Accreditation and Certification. Joe Dickson, chairperson, I will turn over to you.

Joe Dickson: Thank you, Barry. I believe we have an hour and a half on the schedule here and I think we could probably cut that in half and get us back on schedule. We have two very straightforward discussion topics today. One is the recommendation of materials review organizations, which we will vote on. And the other is the discussion paper on sanitizers and the 100% organic category of products. I have asked John Foster first to just give us a quick recap of that discussion document. If you are ready to do that?

John Foster: I can get ready. Alright. So this is for those of you have been out in the audience or up on the Board actually for the last, any of the last three or four years. This is some... This will be a little familiar for some of you. It has had a few different iterations over the last few years. That is, I think those are described in the document so I will not belabor that.

But essentially, the question is around the use of sanitizers and the resulting eligibility or lack of eligibility for 100% organic claim. The...this kind of presupposes a potential distinction between sanitizers and processing aids, which is not necessarily common parlance. But in FDA language there is a difference. And how those terms have been used in organic production has not been so distinct. So this is an opportunity to dig into that a little bit more and provide the community an opportunity to weigh in on that, if they choose to.

The... Kind of in keeping I think, Joe, with not, with trying to get us maybe back on schedule, the paper that we, the discussion paper we put out was pretty straightforward. It speaks also to some of the past discussions that have been had. Some of you in recent memory will remember a discussion that ended up focusing on argon and how that is an oxygen displacer in some bottling, bottled product manufacturing. That actually started as a discussion around this topic and it evolved over the months, actually a little over a year, to being something a little different. So this is getting back to a previous version of something that we talked about although it does not look like that. I did reference that, we did reference that in the discussion document.

Let me scroll to our discussion here. The... let me get back to that. For those of you who want to look it up, it was the 2009-2010 NOSB discussions around inert gas packaging



and the use of the 100% organic claim. A lot of background information is in common if you want to look that up.

There was quite a bit of public comment that came in on this. The... it is variable like everything this community tends to speak to. There is a little... there is some people who are adamant on one side and those who are adamant on another. So no surprises there but we are very appreciative that once again I think CAC has done a good job of using discussion documents to flesh out comments ahead of a recommendation if there is one. I think this is another good example of using that.

We had some good discussion amongst the committee. We generated a list of questions and many of the commenters dealt with those questions one by one. That was very helpful. As were the comments that did not deal with them one by one but took the larger approaches to the answer, like questioning the need for the 100% claim. That to me is very, that is very helpful. Not... wasn't necessarily the intended outcome, but I think that is really important to the discussion and so we recognize that as a potential. We are glad to see a lot of commenters speaking to that. This, as this is a discussion document and not a recommendation, I can go into a little more detail on public comment if you want, if Chair, you would like that. If not...

Joe Dickson: I think we have time for a little more details ...

John Foster: Okay, and then discussion...

Joe Dickson: and summary of the public comments received and then a discussion.

John Foster: Okay. We had a number of certifiers speak to this, a number of whom took the time and the effort to survey their client base, which I thought was very helpful, a very efficient way to get a lot of people who use these materials to weigh in on it. That was very, very helpful. We also got a nice constructive criticism with OTA's comments that made a minor correction on one of the statements we had made relative to current guidance and what NOP have to say about it. That was very helpful. Thank you for that.

Several... one thing that emerged amongst certifiers was that some certifiers do use the 100% claim on raw agricultural commodities, and some certifiers don't use it at all on agricultural commodities and use it only in a processed context. And that is very interesting to me that one certifier, who has a lot of processed items and a lot of raw agricultural commodities, has just chosen not to get into the 100% claim on anything that comes from the field. And for some crops that makes sense, like I can imagine alfalfa makes sense. You're not going to have that issue, certainly not with sanitizers coming for the alfalfa coming from the field.

But I can speak with some experience on lettuce coming from a field or broccoli or any number of raw agricultural commodities that are field packed. Right now, a great – I should not say that – a number of customers and buyers of those products expect good agricultural practices to be present in the field. Not only expect it, but demand it as a

contractual obligation. When you are harvesting those kind of agricultural commodities, it is expected again and, in some cases, mandated that, for example, the belts on which lettuce is dropped to be packed into cartons in the field, which is quite common in California, that those belts are sanitized with chlorine or peracetic acid or..., generally it is one of those two. Well, right there you have a field packed what we called a raw agricultural commodity and, the moment it hits that belt, it contacts some chlorine residue. Well, the question is should that or should that not exclude that lettuce, or that broccoli, or that cauliflower, or whatever, from then being used to..., then being eligible for a 100% organic claim.

That was one of the things that got me interested in this question. Not so much on lettuce, but on the results of, say, fruit packing. And very often, in a lot of fruit operations, the dump tanks at the packing shed will have chlorine or peracetic acid in it, and all of the sudden an apple coming from the field being 100% organic - even if it is not certified to that, it is eligible for that. As soon as it goes into a dump tank, it loses that eligibility. That is very, that is interesting if that pack shed now wants to sell the fruit as an ingredient. If the buyer needs to claim a certain percentage in their..., in my finished, say, orange juice that I want out of those oranges, I need to know exactly what that... what I am able to claim the organic content of those oranges is and it is apparently not 100%.

There is different scales of that and there is... what I have noticed and what I have talked to certifiers and inspectors in the industry, are that there are some certifiers who are not, that is not common for them to do and so I think mostly based on inexperience, it is hard for processors, handlers to get the kind of numbers, like is it 99% organic? 99.9? 99.99? That kind of information is hard to get from certifier... from growers typically.

So that started ask... We started getting a lot more of these questions. That is why the list of questions is pretty long. As I said, some certifiers were, if I had to pick one category of commenters, it was certifiers, as a... I am very... I am always proud of that one, certifiers speak their mind, having been one for a while. And lot of folks were okay with, a lot of certifiers were okay with the idea of sanitizers that were on the National List not removing the eligibility or cancelling the eligibility for 100% claim. Others were not.

The public commenters that I could not discern a certification link to or a corporate or a company link to, which I think is generally called consumer representation or consumer voices, tended not to like that. The most pronounced voices were very clear that, if it is 100%, it needs to be all 100%, all the time, every bit of. So, and that was very clearly stated too.

I would say, so then, then the last kind of general comment was this question around whether or not 100% claims needed to be around at all anyway. And a lot, and there were a few folks who went into the origins, and certainly a lot of private standards prior to the NOP did not address that at all. And then there are some international issues that are worth talking about probably in a broader context. But I thought that was an interesting outcome also that it is starting to ask the question for whom does this have value? How valuable is this claim? And several of the comments spoke to that from their position.

I think that is a good summary.

Joe Dickson: Thank you, John. Questions or discussion from the Board? Mac?

Mac Stone: There is a little bit about now with the EU equivalency that now that sort of came to bear on some of this for processors. Can you explain to me better that current situation?

John Foster: I could go on for a long time. But I think it is better to just note that while our kind of production and handling standards are part of that equivalency agreement all labeling that is mandated in the EU would still have to be met. So we would have to, our products even, though they are manufactured, grown, handled, et cetera, they would still have to meet all of the standards that the EU has. Yes.

Mac Stone: I guess I meant relative to the 100% label versus the not 100% label. Wasn't there some question the commenters were referring to that?

Miles McEvoy: Yeah, just a point for clarification: You said "all standards". You are referring to labeling, you have to meet the labeling conditions of the importing country. So, in order to ship products to Europe under the equivalency arrangement, you need to meet the EU organic labeling requirements and they have to do the same. For them to ship products into the US, they have to meet US organic labeling requirements. It is the same with our equivalency arrangement with Canada. So it is the labeling standards of the importing country needs to be met.

Joe Dickson: Zea

Zea Sonnabend: The main issue I have with this whole discussion is that it fails the common sense rule of organic in any way, shape, or form. Which, for example, if I grow apples and I wash them in chlorinated water, then they cannot be called 100% organic apples because there has been processing aid, sanitizer - whatever you want to call that - involved. But then, if I sell those apples to an apple juice maker, and say they are certified by someone different than I am certified by, they can make those apples into juice and call it 100% organic apple juice because they don't have to go back and look and see whether I washed my apples in chlorinated water. They just know that it is 100% apples, no matter whether I call them 100% or not 100%. You see what I am talking about?

This is one reason why I do not think there should be a 100% label to start with. We should just get rid of 100% because it means to most people that the single ingredient is 100% of what you say it is going to be. And so it means that the apple juice is made of 100% apples. And they are organic apples, not that a processing aid or a sanitizer may or may not have been used. So, you know, our organizational position is get rid of it. It is too confusing. It just does not make sense to consumers and any, no matter what policy you adopt. But good luck adopting a policy.

Joe Dickson: Zea, I have a question back at you. We heard from a couple of commenters and I have heard over the years from different organizations, that the 100% category has the potential to be a really good resource for consumers who are looking to avoid organic products with no synthetic ingredients, with none of the 5%. Do you see that argument as having any validity? Or do you think otherwise?

Zea Sonnabend: I do see that as having validity, but then you have to make a clear-cut statement that it applies only to ingredients and not sanitizers.

Joe Dickson: Jay, did you have any questions?

Jay Feldman: Yeah. [Inaudible] I sort of agree with Zea on this. I think, if you go back historically and look at how we got to this 100%, I think it is fair to say that it was a trade-off on allowing 5% - of the 95-5 - to be synthetic, recognizing that the initial law was intended to really only allow non-organic non- synthetic in the 5%. And creating the 100% category enabled the NOSB then to offer, as you are suggesting, to consumers a product that did not have synthetics in it. And was really the only opportunity at that point to get products without synthetics in it.

So, you know, I agree if we go down that route we would have to be much more specific on the labels to how we are defining 100%. Otherwise, the presumption is going to be that there are no residues added, purposefully added. And along those lines, it is not clear to me - you know this is outside my area really, but - whether product that comes, is used and comes into contact or directly with food as opposed to surfaces, then which our food is exposed to or raw agricultural commodities are exposed to. Are we making that distinction here? For instance, are there sanitizers that are used in a manner that, to which food is directly exposed, dunked for instance? And that is still not clear to me whether we are making that distinction. So if we were to put a label on there that said 100% organic, which does not include sanitizers, which people can, I think, can understand on some level. What do we mean by sanitizers really? Is it just food contact substances? Or is it materials to which food are, or can it include materials to which food are directly exposed? Not through a surface exposure, but directly. And that you can, maybe you can help clarify that for me.

John Foster: I would go with what the FDA definition of sanitizer is when I would define it. I don't know that we are going to do it any better than that. They have been at it for quite a while. The distinction: I am not quite sure what the distinction you are drawing between direct versus contact. I'm not... We can get into that later. But I think it is worth clarifying. But the definition, FDA's definition, is pretty clear, and that is how I, that is where I would start anyway.

But what I was going to say earlier was another interesting comment was pointing out, this is an old, I'd say not the first time I have heard but it but it has not got a lot of press lately, is that the category heading of 605 is about ingredients. And what is odd about the list in 605 is that there are many things that are never going to be ingredients and yet the header of 205.605 says ingredients. And I don't know, back in 2001 or somewhere in

there, at one of the trainings - it might have been in 2000 in Atlanta actually - that I remember that question coming up with, I think, Keith Jones. And the list - I don't have it in front of me - but the list says something like "ingredients in or on" and the use of the proposition "on" there then implied that it was anything that might go on to, and somehow the word ingredients got, kind of, it got forgotten.

So one of my questions over the years has always been to what extent should that 605 be ingredients versus processing aids and sanitizers and whatnot? Or that's... I keep looking over at the Program and, I'm sorry, I don't want to put you in that spot but it... that... A couple of commenters brought that up again and I think that is going to be part of this discussion as it keeps rolling is to what extent is that list meant to be ingredients versus processing aids, versus sanitizers. And that... It has been floating around for at least a decade, that I can remember, so might as will put it on the list.

Barry Flamm: Joe, since this is a discussion document, and we do have a voting document, perhaps we ought to move on to that.

Joe Dickson: Did the Program have anything to add before we go on to the next item? OK.

Miles McEvoy: I am going to have Emily comment on this please.

Emily Brown-Rosen: Which... Hi, this is Emily Brown-Rosen, NOP staff. Which question do you want me to answer first? Could you... The ingredients versus processing aids on 605?

Joe Dickson: That is a really important question. This sort of... If you can parse the heading of 605 which, you know, is substances allowed as ingredients in or on processed products and how that sort of bears on this discussion of sanitizers and processing aids.

Emily Brown-Rosen: Well, sort of structurally, the list has always said that in the title of 605 ingredients. The NOSB made a recommendation a long time ago - probably 2002 or 3 - to change the title to say used in or on, not just say ingredients but substances used in or on organic food products or something to that effect. And we have not made that change at this point. But that was the understanding as to what 605 means. It is the universe of synthetic, non-synthetic substances allowed in organic food.

And there was a legal precedent after the Harvey suit. I think in the Harvey second... One of his appeals contended that processing aids were not covered under the court ruling. And therefore all processing aids were prohibited. But the court rejected that and said that it was really clear from the record in Congress et cetera that intended all substances whether they were to be... They did not make a distinction at the time between ingredients and processing aids. So they are, in fact have always been, considered important.

So I would think, you know, I think we could look at, you know, at some point, and there was a proposal a long time ago also to divide up the list differently. That is something we

could, you know, to have a separate section on sanitizers. That might be very useful thing rather than the way they are kind of lumped together with processing aids in future. But at this point everything that is basically in direct contact with organic products is appearing on the National List. That has been the precedent. OK.

Joe Dickson: Emily, one more quick question and then we can move on. Is the Program's thinking that substances in direct contact with organic food, is there any differentiation between materials used on food contact surfaces and materials applied directly to the food? Like the difference between a chlorine dip and a, say, cutting board sanitizer?

Emily Brown-Rosen: That is a very good question, Joe. Thank you for that question. Yes, we do. And I realize this has been unclear and I realize, after we read your proposal, that even certifiers are still unclear about this and I know there has been conflicting information in the past. But at this point, our position on sanitizers in direct contact is that, yes, there would be two categories.

The sanitizers that are used in direct contact with food, which are normally called antimicrobials. They are in dunk tanks. They are on carcass washing. They are in egg washing. They are either regulated by FDA or EPA. They have a complicated breakdown on who regulates what. But those are classed as secondary direct food additives. They are regulated generally at 21 CFR 173 or they might have a specific food additive listing in the CFR. And we consider them processing aids. And therefore those would be, if they are in direct contact, then that would preclude the use of a 100% label.

However, sanitizers used on food surfaces, like belts, bins, dairy pipelines, those are considered indirect food additives. And NOP at this point does not consider that would affect the 100% label claim. That is an equipment cleaning procedure. And it is not, you know, does not rank at the level of being a direct food contact. Usually you have good agricultural, you know, you have your required sanitizing practices. We did clarify this in the chlorine guidance that we issued earlier last year. So...

Joe Dickson: Great. Thank you, Emily. I could ask a million more questions on this which means it will be a really fine conversation between now and Providence.

Emily Brown-Rosen: Yeah, we could work with you on revising this.

Joe Dickson: Yeah, we look forward to working with the Program on this issue as it turns in a recommendation for sure.

So, moving on to material review organizations. This is now the third meeting in a row where this has been an item on the agenda. Prior to the Seattle meeting, we received a request from the Program asking the CACC to do some thinking and recommending on how the Program should oversee independent organizations that review materials for compliance with the standard. Following that request, we issued a discussion document in Seattle in April 2011, which asked a series of very specific questions to the organic community about how we should fashion this recommendation, and how the Program

should oversee and evaluate these organizations. Our main concern, of course, being that there be some consistency between the materials decisions being made by these organizations as there had been a few high-profile situations where there were inconsistent decisions made by these organizations and obviously that was a problem.

So we issued a discussion document in Seattle. In Savannah we issued a recommendation which laid out some very broad guidelines for the NOP to use in overseeing these organizations, ensuring that their materials review decisions made by these organizations were consistent with each other and well communicated to affected stakeholders in the organic community. At that meeting we got a few really good comments, specifically from OMRI and WSDA and the Accredited Certifiers Association, noting that we had answered most of the questions that the USDA had asked us, but we had skipped sort of the most important one which was: what are the specific protocols and procedures that should be followed within the organizations while they are reviewing specific materials. So this sort of phase two of that recommendation is an attempt to answer that question posed by the NOP which we did not quite nail the first time.

The recommendation that we are making today received a pretty decent amount of public comment from the organic community. To summarize, the Accredited Certifiers Association, as Pat mentioned this morning, thought that the recommendation overall was very good but that we were inadvertently requiring ISO 65 accreditation from entities that were not publishing lists. And that was an oversight and not the intent of the committee.

So we have edited the recommendation to reflect that. Michelle, would you scroll down to that one modification we made? Or one of two modifications we made?

Michelle Arsenault: [Inaudible]

Joe Dickson: Yeah. Do you have that version? Or I can just describe them, if not.

Michelle Arsenault: [Inaudible]

Joe Dickson: OK. Well in it's... I can just keep talking while you find that. The same feedback as we received from ACA about that ISO 65 requirement, we received from OMRI, from MOSA, from WSDA. PCO expressed their support of the recommendation provided that it is only effective if it is swiftly implemented by the National Organic Program. OTA strongly supported the recommendation and proposed one additional minor change, which we will also review once we have that version on the screen, and that is just a really simple clarifying change to basically empower the Program to begin working on the issue immediately and, while they are developing an accreditation scope for materials review organizations, allowing them to still immediately begin to provide some basic guidelines to those organizations.

Michelle Arsenault: [Inaudible]

Joe Dickson: Yes, that is the one. Ah, actually I am sorry. There are three modifications. The one on the screen now shows that, based on feedback we received from one of the organizations, to also ask the Program to clarify not only how far back to reach in determining the absence of excluded and prohibited methods, but also to very explicitly clarify whether or not and exactly to what extent prohibited methods are permitted in the production of inputs for organic agriculture in different categories.

Michelle, if you would scroll down under recommendation to the next edit I made there.

This is the OTA's recommended language change, which basically inserts the language "in conjunction with and in parallel to NOP's work in creating an accreditation scope for materials review". NOP should provide detailed guidance and criteria on the material review process, etc. Simple but important clarifying change.

And then if you scroll down to the second bullet on the following page? The change that we made there is simply to insert the language "who publish materials lists" to clarify that materials review organizations who publish materials lists should be required to obtain and maintain ISO 65 accreditation.

And that, those are the only changes that we made. The Board did re-vote on this this week and accept this, a modified version of the recommendation. Are there questions or general discussion from the Board? Zea?

Zea Sonnabend: CCUF submitted comments on this document concerned about the language contains... a bullet point that reads "contain a mechanism to ensure consistency in decisions across MRO's" was not sufficiently clear enough and that the language should be modified to talk about an appeal process in that the appeal process could be accessible to both MROs, ACAs, and manufacturers of the inputs. And I think it was a valid concern about the document but you haven't mentioned it.

Joe Dickson: Yeah, well, CCUF commented in general. And, you know, to paraphrase your comments, that, you know, in a lot of different areas this recommendation did not go into enough detail so as to be successfully implemented by the Program. And in our committee discussions, we felt really strongly that this recommendation should be as general and, sort of, abstract as possible and give the Program the latitude it would need in order to determine how best to implement it. So, in some of those areas, we felt that, you know, we were more comfortable expressing our general intent to the Program without being overly proscriptive about how the Program should implement our guidance. On that particular issue, I don't, you know, I don't think it is objectionable and I would be open to an amendment if other members of the Board are interested and don't see an issue there.

Are there other questions about this recommendation from the Board? Or the Program?  
Or Miles?



Miles McEvoy: Yeah, we just had a couple of comments that we already shared with the committee. In the proposal, it claims that on numerous occasions certifiers are making different decisions regarding allowed input materials. We certainly have seen that from time to time when we do our audits that... And we would say that occasionally certifiers are making different decisions but, for the most part, the decisions on the allowed inputs that certifiers are making are very consistent across the board. There are some instances where it is not consistent.

Then the other claim in the proposal is that certifiers are continuing to allow substances that NOP has specifically disallowed. And, if that is the case, if you have any specific information on that, that would be a serious violation of the standards of the accreditation agreements that they have. And we would like that information to be submitted to the Program, so we can take appropriate enforcement action.

So, in general, it seems to leave a lot of the specifics to the Program, which is fine. We know there is more work that needs to be done in this area. We have the situation where we have two organizations that are fairly well recognized, OMRI and WSDA, that publish lists. And you have the State of California that is in the process of doing organic input material review under their state authority. But we had notified California that we do not recognize the organic registration, their organic input program, that they are creating because they are not ISO Guide 65 accredited, and they have not asked for that program to be part of their state organic program purview. So we don't have direct oversight over the implementation of that program. So that particular program that is going into effect, that is registering products, supposedly in compliance with the NOP regulations, is outside of the recognition system that we currently have. I just wanted to make the Board aware of that situation.

Joe Dickson: Thank you, Miles. I think on your first clarification there, as far as the characterization of the occasions in which a material has been allowed by one agent and prohibited by another, that could certainly be amended to more accurately reflect the reality there, without substantially changing the recommendation and I would support that.

On the second item, I need to look more carefully at the roots of that language. But my understanding is that came largely from characterizations that were brought to us by different certification organizations during the last cycle. And we, again as a committee, can look at ways of, you know, massaging that language to make it more accurately reflect the reality as well.

Barry Flamm: Joe, are you through with your part of presenting the discussion documents and proposal? Next on our schedule is to hear public comments on the CACC proposal. So...

Joe Dickson: Yeah, let's...

Barry Flamm: If you are through, I will ask for the public comments.

Joe Dickson: Yes, I am through presenting. I think we should move on to public comments.

Barry Flamm: Thank you. I have on my list, Tawnya Laveta, I hope I'm... Oh, and Peggy Miars. Thank you. Peggy Miars is first. That is the reason I have this guy here.

Peggy Miars: [Inaudible] I'll start over. Good afternoon. I am Peggy Miars, Executive Director of OMRI, the Organic Materials Review Institute. And for those unfamiliar with OMRI, we are the material review organization, or MRO, that is not a certifier and that publishes a public list.

Thank you to the CAC Subcommittee for your continued discussion and recommendations regarding criteria for recognizing MROs and the criteria that MROs should use in evaluating input materials. We at OMRI agree that there is a clear need for more uniform and consistent policies governing material review organizations. We also agreed that all organic stakeholders would benefit from a clearly defined NOP guidance around the qualifications and activities of organizations conducting material reviews.

It is obvious from questions, answers, and discussions on the accredited certifiers' association listserv that there are varied degrees of material review being conducted by ACAs. At last fall's NOSB meeting, OMRI presented examples of various things that different ACAs may look for and not look for when conducting material review because of the varying interpretations, policies and procedures.

As stated in our written comments, and as Joe stated, we do agree that criteria needed for how MROs should verify the use of prohibited materials, such as genetic modification, and we also believe that clarification is needed for whether such prohibited materials are even allowed for use as inputs in organic production.

The Board should clarify whether requirements for ISO 65 accreditation are sufficient to address some of the subcommittee's recommendations or whether you are suggesting that the NOP specifically dictate them. For example, the appropriate education, training and experience levels for personnel conducting material review. Or, for example, the appropriate levels of personnel resources, infrastructure and documentation to engage in on-site inspections. And we request clarification regarding what is specifically prescribed and what is open to interpretation by MROs.

We have heard some comments that ISO 65 accreditation should not be required for ACAs that do not publish a public list, and Joe just showed us that the committee has included that in a revised recommendation. I understand the concern about added time and expense for those certifiers, and I urge the committee to include in your revised recommendation that, for those ACAs that do not publish a public list, during the material review portion of their NOP accreditation audit, the NOP should address some of the same criteria that are covered under ISO 65 accreditation that will be required of the MROs that do publish a public list. In other words, whether you are IOS 65 accredited or not, all MROs should be held to the same requirements and should be audited in similar

ways. And you should also consider that ISO 65 audits are required annually whereas the NOP accreditation audits of ACAs are conducted every five years.

And we look forward to NOP guidance on this topic and to more consistency in material review for the benefit of the organic industry and organic consumers. Thank you.

Barry Flamm: Thank you, Peggy. Question? Jay?

Jay Feldman: I will defer to somebody else if we are only asking one question. I was curious as to whether you have any specific language that could be incorporated into this recommendation?

Peggy Miars: Unfortunately, I don't but we could put that together if you would like us to.

Mac Stone: Joe?

Joe Dickson: Thank you. As far as specific language you would propose, would that be regarding... just further clarifying the ISO 65 bullet and just clarifying that, for ACAs that don't publish lists, the NOP should still look at similar criteria as part of the accreditation audit?

Peggy Miars: Yes. Correct. Yes.

Joe Dickson: OK. Great.

Barry Flamm: Thank you, Peggy. Now, Tawnya Laveta.

Tawnya Laveta: That is pretty good for not being from New Mexico.

Barry Flamm: I spent enough time here. I should do a lot better.

Tawnya Laveta: Oh, okay. Well, thank you. Thank you, Chair. And good afternoon, Board members. My name is Tawnya Laveta. I am a consumer and I also work with local farm to market programs here in New Mexico. I live in Santa Fe and I am also a member of the Cornucopia Institute. I'm here today as a citizen lobbyist. Since public interest charities don't have the same resources as corporate agribusinesses to hire lawyers, lobbyists, and expert witnesses, I have volunteered my time to be here today.

The proper food safety environment and meticulous sanitation: Those should be the hallmarks of all production systems, conventional and organic. However, the rule says products labeled as 100% organic, if processed, must be processed using organically produced processing aids. And I do like that idea of separating the sanitizers in that other 5-0-something.

We are also concerned about problems with mislabeling non-organic products as organic, which the Cornucopia Institute has identified on store shelves and bulk bins in stores

around the country. They have communicated these concerns to the Board, and would like to bring this issue to your attention once again.

When food manufacturers, who were once committed to the organic label, discontinue sourcing organic ingredients and they downgrade their products to 70% - “made with organic”, or [cough] “made with organic” or conventional - they should ensure that retailers are aware of this change and their products are not incorrectly labeled organic by in-store signage or by advertising.

This is especially true for the bulk bins. The Cornucopia Institute has sent numerous complaints to the NOP, each one identifying about a dozen retailers that continue to mislabel Golden Temple bulk bin granola even after being notified about the change. But many stores had mislabeled Golden Temple bulk granola for months, just unknowingly. Golden Temple had neglected to notify the retailers that their granola was no longer organic. Customers who bought this bulk item - [cough] – excuse me - purchased a non-organic product thinking it was organic and that no way... there was no way of independently verifying the product’s organic status. And this constitutes consumer fraud in my mind.

To prevent these, this unintentional in-store mislabeling of products that were once organic, manufacturers should be required to change their product’s Universal Product Code, the UPC, and the accompanying barcode when they downgrade their product from organic to “made with organic” or conventional. Whenever a product’s organic status changes, the package must be redesigned and reprinted anyway. The organic label and USDA seal must be removed or added.

We urge you to consider recommending a rule change to require the product’s UPC barcode on the product package to change when the product’s organic status changes. This would alert the retailer that a change has occurred and ensure that they can [cough] change their in-store signage and bulk bin labels.

We hope that the current Board members will concur with this proposed rule change which will have a significant impact on protecting organic consumers like myself from mislabeled products with virtually no cost or downside to reputable purveyors of certified organic products. And I think it will also protect the integrity of the organic label and the food manufacturers, farmers, and retailers who are committed to organic foods. Thank you.

Barry Flamm: [Inaudible]

Tawnya Laveta: Thank you, Board.

Barry Flamm: Thank you. Joe, I will turn it back to you for the subcommittee consider whether you want to make changes and then whether you are ready to present, to make a... have some... make a motion and have it seconded and present for Board vote. But remember that the motion needs to be in writing, passed to the secretary, and I will look it over.

Joe Dickson: Yeah, I guess I have a procedural question. I would like to propose a couple of changes to the recommendation, sort of following the public comment and Miles' feedback. To do that most appropriately, do we need to ratify that as a committee, as a subcommittee before it goes to the full Board?

Barry Flamm: [Inaudible] You can...

Joe Dickson: Question?

Barry Flamm: If you can poll the... yes, and this is the first time we are doing it this way so let's see if you can try, if you have, try to poll the committee in a brief amount of time and see if you can do that.

Joe Dickson: And should we do that during a break or just right now?

Barry Flamm: Right now.

Joe Dickson: OK, so I will just talk through... and this all...

Zea Sonnabend: Can ask a point of order about this?

Joe Dickson: Yes, please.

Zea Sonnabend: At some point, is there time for more discussion among the Board, when... either now or when they come back with their modifications to further discussion based on public comment?

Barry Flamm: When the motion is made and seconded, I will read the motion and then open it for discussion.

Joe Dickson: So the compliance, the CAC Subcommittee will discuss a few more potential changes, vote as a subcommittee, and then move to vote as a full Board and then there will be discussion. Okay? This is a whole new world here. So in addition to the changes I presented before, I would like to stick in a few more. First of all, Miles made two really good points about some of the language in the challenges section. Michelle, would you scroll to that section with the numerals 1, 2, and 3, etc.? Yeah, exactly. Just down to bullet number two there/ I would like to change the word "numerous" to "limited" or "certain". Just to... What's that?

Michelle Arsenault: [Inaudible]

Joe Dickson: You are right. The second sentence: "on numerous occasions" to change that to "on limited occasions" to more accurately reflect that the occasions have been few. Any objections there from the committee? Okay.

Miles McEvoy: We need to provide a point of clarification here. Lisa.

Lisa Brines: Sorry for the interruption. We just had some discussions about process. So it is our understanding that the subcommittee would not need to vote separately on these proposed amendments. So the committee has provided their proposal to the Board for consideration. You are welcome to make amendments to that procedurally, but we don't think it needs a separate subcommittee vote to move forward.

Joe Dickson: That is great. Thank you. Jay?

Jay Feldman: So who would the proposal be coming from? Would that be the chair or...? It's a question, process question, to you Barry. Because normally what the chair does in a situation like this, or his... previously, is bring it back to the committee, the committee deliberates, and then brings it back.

Female: [Inaudible]

Miles McEvoy: So you are in full Board session now. You have a proposal that the subcommittee has presented. And you haven't had a motion yet, or you are working on a motion. So you are, the full Board is making this work happen, not the subcommittee and so at a certain point you will finish this and then you will as, someone will make a motion to move forward and the Board as a whole will then take it under consideration. So you are in full Board session at this point.

Barry Flamm: But the... the agenda calls for the subcommittee to modify its proposal, if needed. That is what they are in the process of doing. And then it can go to the full Board. I suggested they just poll. They should have an agreement before they bother making a motion. That way... I think we should...

Crowd: [Whispering]

Lisa Brines: Okay, let me take another stab at this. So under Roberts' Rules, generally debate would follow a motion. So that, in general NOSB procedure, you generally discuss the motion before somebody actually makes, you discuss the proposal before somebody actually makes a motion. Because this has come out of a committee, you know, generally under Roberts' Rules, it is sort of assumed that that is a motion that has already been seconded because it is within a committee. So I think the discussion that you are having right now, I would suggest that somebody perhaps make a motion to... for this particular and then, this particular proposal. And then we can have a secondary motions to make whatever amendments that might be needed. It would be a more efficient way to progress.

Barry Flamm: We are charting new ground here, for the audience, in terms of this arrangement. And I think since we are already past our 3:15 break, I am going to call for a 15 minute break. And we will reconvene and continue this committee's action.

[BREAK]

Barry Flamm: Board, please take your seats. I think I am going to have to get a hearing examination for these people. Okay. The Board meeting is back in session. Joe, will you continue with your committee action?

Joe Dickson: Yeah. Thank you, Barry. So, we are going to continue to just briefly discuss, as the Compliance Subcommittee, a few additional edits to the document.

Michelle Arsenault: Do you want the document up?

Joe Dickson: I would love the document up. Thank you. Can we now go down to the challenges again? We would like to change the word “numerous”, the second occurrence of the word “numerous” in the second sentence of number two, to “limited”. Are there any objections from the committee? Thank you.

On number three, I would like to insert the language at the beginning of the sentence “There is no formal mechanism to prevent”. Oh, you lost your... And then, delete from “prevent” to “material review organizations” at the... So that it reads “prevent material review organizations”. Yes. And then, delete the word “continue” and insert the words “from continuing”. And so the sentence should now read: “There is no formal mechanism to prevent material review organizations from continuing to list or register these materials as approved for use in organic production and handling.” And that I think more accurately describes the limitation of the current model without misrepresenting the sort of extent of potential issues there. Miles, does that address your concerns with that sentence?

Miles McEvoy: Yeah, the first one works. The third point... I am not sure if I understand what is being said there. “There is no formal mechanism to prevent material review organizations from continuing to list register these materials”?

Joe Dickson: Oh, okay. Let's say “the materials disallowed by the NOP”. You know what I'm trying to say? I'm changing the sentence so that it does not imply that there is some massive crisis out there.

Miles McEvoy: I don't think that is correct. I think the OMRI, and WSDA, and others have ways of disallowing materials that the NOP directs them to.

Joe Dickson: I guess what I'm trying to say there is that the NOP has no way under the current model of compelling OMRI.

Miles McEvoy: Oh, okay.

Joe Dickson: That is what that sentence was trying to do. So let's just say there is no formal mechanism to allow the NOP to compel material review organizations to no longer...

Miles McEvoy: I would suggest that point number three may not be necessary for getting your point across. I would just...

Joe Dickson: I would actually agree that we have covered point number three extensively in the earlier two versions of this recommendation and it is really kind of... So let's just delete it.

Mile McEvoy: Yeah. When you can't figure it out, just delete it.

Crowd: [Laughing]

Joe Dickson: Any objections from the committee? Awesome. Cut it.

Let's skip all the way down now to just above the recommendation section. That change we have already discussed as a committee. Keep going down. "In conjunction and parallel to" has already been voted on and approved by the committee.

Bullet two. On that... So "who publish materials lists" - that edit has already been voted ne by the Board. I would like to insert some more language after "transparency" in a new sentence. "For ACAs or other entities that do not publish public lists..."

Male: [Inaudible]

Michelle Arsenault: Say it again. Sorry.

Joe Dickson: You, in the word "other" have a "p" instead of an "o".

Michelle Arsenault: Oh. I'll tidy it up.

Joe Dickson: I'm sorry to copy edit before an audience. I know that is awkward.

"For ACAs or other entities that do not publish public lists" comma "the NOP should still include similar criteria as part of the accreditation process." And that's...

Michelle Arsenault: Other criteria? Say it again?

Joe Dickson: "accreditation process". Period.

Any discussion or questions or objections from the committee on that one?

That is the final edit that we have as a committee to that document. If there are no objections from the committee to those changes, I would hand it back to the general Board. And Mr. Chairman, I would like to make a motion that the Board accept this recommendation as amended by the committee.

Female: Second it.



Male: You [Inaudible]

Female: Want me to second that, Mr. Chair?

Barry Flamm: No. We have a motion and a second to accept the document that has been presented on the screen. Is there any discussion on this motion?

Colehour Bondera: [Inaudible] Not exactly a discussion but could you scroll back up so I could read the change that was made in the second paragraph of the recommendation? Yes, that one. Thank you. Because it wasn't up on the screen last time long enough for me to read. Thank you.

Barry Flamm: Are you okay with it, Colehour?

Colehour Bondera: [Inaudible] Yeah, so far. If you can just see if other people have comments, I just wanted to be able to look at that. Thank you.

Barry Flamm: As there is no further discussion, I call the question. And we will start with voting with Jay Feldman.

Jay Feldman: Are you... Point of order. Are you going to ask for conflicts of interest?

Barry Flamm: Oh, golly. Thanks. My partner here, he wrote me a note and I forgot. Are there any conflicts of interest? Anybody want to recuse themselves or abstain? Zea?

Zea Sonnabend: I don't know if you consider this a conflict but I do feel the need to disclose that I work for an ACA who makes materials review decisions and also a bit for OMRI on a stipend basis for conference call, not for material reviewed on the review panel. So you tell me if I should not vote or not.

Barry Flamm: I will defer to the Program. Is there any problem with Zea voting on this?

Miles McEvoy: You know, it's a... For, Zea, if you're working for an organization that is affected by this, directly affected by this particular proposal both for your work with OMRI and your work with CCOF in terms of reviewing materials – this is... directly affects that organization has well. I think it would be best to recuse yourself from this vote.

Zea Sonnabend: Okay. Although I do not benefit financially directly, because I am just paid per hour, rather than per thing, but I will recuse myself.

Barry Flamm: Your decision stands - that she should recuse herself?

Male: [Inaudible]

Miles McEvoy: Yes.

Barry Flamm: OK. Zea, would you please recuse yourself from voting?

Harold Austin: Point of disclosure. I sit on the Organic Advisory Board for the WSDA. I don't stand to any financial benefit but just a point of disclosure at least.

Miles McEvoy: The Program would say you do not need to recuse yourself because of that relationship.

Barry Flamm: Anybody else that needs to declare? Jay?

Jay Feldman: Well, I just... Again, point of order. I feel as a Board member I need clarification on the standards that are being used here, because many, as we have discussed many times, many Board members work for organizations that have an interest in the materials and the processes that we discuss and vote on. And I... And yet do not have any personal financial gain associated with that decision. So I feel that... I would like to see more clarification on how these determinations are being made, so as to not create a precedent that would preclude other members down the road from voting even though they have a perceived vested interest by virtue of being an employee of a company or organization that is involved with, may benefit from in somehow – through increased sales or what have you – of those materials. So I don't know, Mr. Chairman. I guess that is just a point of concern and hopefully the Board can pursue a process that offers more clarity to the Board members on how decisions are being reached, with some sort of checklist perhaps. I don't know.

Barry Flamm: I agree. Would you like to address the Jay's comments, Miles?

Miles McEvoy: Yes, this is going to be point of discussion during the Policy Development Subcommittee's time on Thursday, I believe. The conflict of interest: so we will get into this in some detail at that point. This is an area that we have learned a lot about learning more about FACA committees and how conflict of interest and ethics affects this Advisory Committee. And so for this particular situation... Well, in general, what we want to do is make sure that the decisions around when we would want people to recuse themselves because of their interests, is it a conflict of interest, are done consistently and fairly. We want to have a diversity of interests being part of the vote, part of the discussion. We need those perspectives. In this particular case, Zea is very involved in both of those organizations around those particular issues of material review and approval of materials and the criteria. And so her intimate involvement in that part of those organizations is, I guess, the criteria where it seems best - because of that impact on those organizations - that she recuses herself from this particular vote because of her involvement in that aspect of those businesses that she works for.

Barry Flamm: [Inaudible]

Jay Feldman: I believe that... I'm sorry.

Barry Flamm: Do have another question?

Jay Feldman: I would just like to say that I don't believe that that interpretation is in conformance with our PPM and that - our Policy and Procedures Manual - and that our Policy and Procedures Manual talks about a personal financial gain - which Zea does not have in this case. And therefore this is a new, obviously a new interpretation of conflict of interest which, quite frankly, has caught me by surprise. I can't imagine other Board members are not being caught, being taken by surprise here. So again, I would just like the record to reflect that, and hopefully down the road we can get more clarity on this. Thank you.

Barry Flamm: Thank you for your comments. I think we definitely need more clarity on this. Any other... Alright. We will proceed with the voting beginning with Jay Feldman.

Jay Feldman: Yes

The Entire NOSB Board: Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes, sir. Yes. Yes. Yes.

Barry Flamm: And the Chair votes, yes.

Crowd: [Laughter]

Male: Jennifer.

Barry Flamm: Boy, am I in trouble.

Crowd: [Laughter]

Jennifer Taylor: Yes.

Barry Flamm: I thought I heard you. Sorry. The ... 14 yeses, zero noes, and of, course one, recusal. So, I believe that completes the CAC report. We can move directly now to the GMO ad hoc Committee. [Inaudible]

Zea Sonnabend: Are you turning it over to me, Barry? For the GMO Committee?

Barry Flamm: Yes.

Zea Sonnabend: OK. Thank you. We decided – just slightly different than the agenda – but Miles will talk first about what the NOP current GMO policy is. And then, after that, we will talk about our committee and where we go from here. So, Miles?

Crowd: [Laughter]

Miles McEvoy: Okay. I'm going to present the NOP policy on GMOs. This is a policy that we issued last year that reflects, basically, a reiteration of the letter that was sent to NASDA back in 2004. Basically, I'm just going to read through the policy. We thought that this

would be a good place to start to understand where the Program's policy is on GMOs as this GMO ad hoc Committee gets started - to understand those parameters, and then get the feedback from the Board on the policy, and work that needs to happen with GMOs and organics.

So, next slide. I wish this was a little larger, but... The Overview: The Organic Food Production Act of 1990 does not mention biotechnology, genetic engineering, or genetically modified organisms. OFPA prohibits synthetics unless they are allowed and allows natural substances unless they are prohibited, but it does not make any mention of biotechnology or GMOs because they were not really in commerce or being widely used at that time.

The first National Organic Program proposal, which came out in 1997, did not prohibit GMOs or GE substances. And, as you all know, there was a huge public outcry because of that - against having GMOs being potentially allowed in organic production and handling. Unprecedented number of public comments came in, and the proposed rule was withdrawn, and USDA went back to the drawing board. So the second National Organic Program proposal, proposed rule, which came out in 2000, excluded the use of GMOs in organic production and handling. Next slide.

So, the way that the rule looks at that, that they are, GMOs are prohibited as excluded methods – and that is under 7CFR 205.105 under the section of allowed and prohibited substances, methods, and ingredients in organic production and handling. It specifically says, to be sold or labeled as “100% organic”, “organic”, or “made with organic” specified ingredients or food groups the product must be produced and handled without the use of, specifically without the use of – under Sub e – excluded methods except for vaccines provided the vaccines are approved in accordance with 205.600(a). And that is a discussion for the Livestock Committee, that they are working on, with GMO vaccines. But excluded methods are the things that are prohibited. That is how GMOs are prohibited under the USDA organic regulations.

So then you have to go to the definitions to look to see how GMOs are defined. It is actually, GMOs are not defined but excluded methods are defined. And they are defined in three separate sentences. The first sentence says “a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes, and are not considered compatible with organic production.” So a couple of key concepts there: not possible under natural conditions or processes, and not compatible with organic production. And that is where the Board would most likely come in – defining what is not compatible with organic production.

The second sentence says “such methods include cell fusion, micro-encapsulation, and macro-encapsulation, and recombinant DNA technology, including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology.” So, a lot of use of the term recombinant DNA technology, moving genes around, and then these other terms – cell fusion, micro-

encapsulation, and macro-encapsulation – that are no, there is no further clarification or definition of those terms anywhere in the USDA organic regulations. And that is causing some questions of interpretation that we want the GMO ad hoc Committee to take a look at.

The third sentence says that “such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.” So again those things are not further defined either. And, in some ways, the second sentence somewhat conflicts with the third sentence because some things that are used in traditional breeding could be considered cell fusion. And so we really need to work on this definition. This definition was developed many years ago to really define more clearly and specifically some of the provisions of these different terms that are used in this definition.

Okay. So then NOP Policy: This goes back to 2004 when the NOP responded to a letter from the National Association of State Departments of Agriculture, NASDA, regarding the use of GMOs in organic production and handling. So in September of 2010, the NOP published the Program Handbook: Guidance and Instructions for Accredited Certifying Agents and Certified Operations. And then, in April 2011, we issued Policy Memo 11-13 to address GMOs in organic production and handling. And this policy really just reiterates the policy that was outlined in the 2004 letter to NASDA and clarifies some additional questions concerning GMOs in organic production and handling. And that is what I will present now.

So, unfortunately, I can't read this and that is going to be a problem because I don't remember this in detail. So...

Crowd: [Whispering]

Miles McEvoy: Okay. You certainly can all read this. It is on the website, but we do think it is important to read through this and answer any specific questions that the Board has. So the first issue: Is the inadvertent presence of GMOs in organic seeds a violation of the NOP regulations? Can organic producers use seeds that contain the inadvertent presence of GMOs? The reply is that 7CFR 205.105 of the NOP regulations prohibits the use of GMOs as excluded methods in organic production and handling. The use of excluded methods, such as planting genetically modified seeds, would require a specific intent and would render any product ineligible for organic certification. However, the inadvertent presence of GMOs in organic seeds does not constitute a use because there was no intent on the part of the certified operation to use excluded methods. The presence of detectable GMO residues alone in an organic seed does not constitute a violation of the NOP regulations. It is the same as if you had an organic seed that had pesticide residues in it. The presence of pesticide residues in an organic seed does not make the organic seed non-organic unless it exceeds 5 percent of the EPA tolerance level, or those pesticides were applied in violation of the standards. If the standards were being used, or being followed, then the inadvertent presence of GMO residues, or unavoidable residual environmental contaminants, do not render the seed non-organic.

So, how do organic producers avoid contact with GMOs? The reply is: Organic producers utilize a variety of methods to avoid contact or the unintentional presence of GMOs including testing seed sources for GMO presence, delayed or early planting to get different flowering times for organic and GMO crops, cooperative agreements with neighbors to avoid planting GMO crops adjacent to organic crops, cutting or mowing alfalfa prior to flowering, posting signs to notify neighboring farms of the location of organic fields, and thorough cleaning of farm equipment that has been used in non-organic crop production. So there many practices that organic farmers utilize to minimize and to avoid contact with GMOs. And conventional farmers, in most situations that I have been involved with, are very willing to do things to also try to mitigate that contamination as well. But more work certainly could be done in that area.

What are organic producers required to do in order to avoid the presence of GMOs in their products? Reply: In order to become a certified organic operation, a producer must submit an organic system plan to an NOP accredited certifying agent for approval. The producer's organic system plan must include a description of management practices and physical barriers established to prevent contact of organic crops with prohibited substances. So that is one part of the organic system plan is to have systems in place to avoid contact with prohibited substances. So certifying agents evaluate those preventative practices and buffer zones, to determine if the producer has taken reasonable steps to avoid contact with GMOs. That is what is required by the regulations.

Next issue: Could a farm's organic certification status be threatened if sufficient buffers and barriers are not established and inadvertent contact with GMO material occurs? The reply is that organic producers that implement preventative practices, preventative measures to avoid contact with GMOs will not have their certification threatened from inadvertent presence of the products of excluded methods. But crops grown on certified organic operations may be sold, labeled, and represented as organic even with the inadvertent presence of GMOs provided that all requirements under 7CFR Part 205 have been followed. So if a organic farm does not take actions to establish buffers and barriers then that could be a violation of the standard. But, as long as they do, and there is that inadvertent contact, they can retain their certification and sell the crop as organic.

Next issue: Is there a working definition of the word "contamination" within the NOP? The reply is there is no definition in the NOP regulations for the word "contamination," even though it is mentioned frequently in the standards. The use of excluded methods in organic production is prohibited, as cited in 7CFR 205.105. And as an aside, we... In the US-EU organic equivalency arrangement, there is certain appendixes to that arrangement and the third appendix is to establish an organic working group, to share information between the EU and the US on organic production, to learn from each other, and continually improve our systems, and to do mutual assessments of each other's programs. But one of the provisions in there is to share information on ways to avoid contamination from genetically modified organisms. And, because of that, that we put the word "contamination" in the agreement, we got some pushback from some various parties, the biotech industry in particular, that they were concerned that we were using the word

“contamination” in a Federal document and that we were changing federal biotech policy which we are not. It was just a simple way of sharing information and continuing to share information with the EU. But that word “contamination” is a trigger word for many in this particular debate because the biotech industry sees the word “contamination” meaning that the food, the product, would be unfit for human consumption, not in the terms of how we look at it in the Organic Program whereas “contamination” means that the product does not meet the organic standards and can't be sold as organic. So it is just a different meaning of the term in those two different perspectives.

The next issues: What actions are authorized or required when organic crops or products are found to contain unintended or inadvertent genetically modified substances? Reply: The inadvertent presence of genetically modified material does not affect the status of the certified operation and does not result in loss of organic status for the organic product, provided it was produced in accordance with all of the organic requirements under 7CFR Part 205. So we do not want to punish the certified operation if they are following the requirements. Certifying agents are responsible for working with organic producers to identify the source of the inadvertent GMOs and to implement reasonable steps to avoid contact with GMOs in the future. So we don't want certifiers to ignore this. We don't want the farmers to be penalized. But if GMOs are found, we want the certifiers and the farmers to work together to try to further mitigate the presence of inadvertent GMOs in the future. That is the whole concept of continual improvement.

The next issue is: Are organic products tested for genetically modified substances? Reply: Under 7CFR 205.670(b), certifying agents may test organic products when there is reason to believe that excluded methods were used in the production or handling of an organic agricultural product. So certifiers have the authority to test. Certifying agents may also collect and test organic products from organic handlers to ensure that practices are in place to prevent commingling or contamination during handling and processing. So they can test in those situations as well.

Next issue: Are organic products free of GMO contaminants? The reply is: Organic standards are process based. The NOP regulations prohibit the use of genetically modified organisms. They prohibit commingling or contamination during processing and handling, and they require preventative practices to avoid contact with GMOs. Organic agricultural products should have minimal, if any, GMO contaminants. However, organic food products do not have a zero tolerance for the presence of GMO material.

The next issue is: Has a tolerance level, for example 5%, been established for the presence of GMOs in organic agricultural products? Reply: The NOP regulations do not establish GMO tolerance levels. The NOP regulations establish a tolerance for the presence of pesticides that are registered by the U.S. Environmental Protection Agency and that is set at 5% of the EPA tolerance level for the specific residue detected. No federal agency, including EPA or USDA has established tolerance levels for the inadvertent presence of the products of excluded methods, GMOs.

Next issue: Processed food sold as “organic” must contain at least 95% organic ingredients. Are GMOs allowed in the remaining 5% of ingredients? Likewise, processed food sold as “made with organic”, specified ingredients or food groups, must contain at least 70% organic ingredients. Are GMOs allowed in the remaining 30% of ingredients for these products? The reply: The use of GMOs is prohibited in all ingredients in “organic” and all ingredients in “made with organic” specified ingredients or food groups. There is no provision within the NOP regulations that allows the use of excluded methods in ingredients or processing aids under the “organic” or “made with organic” specified ingredients or food groups label categories.

Okay, so that concludes the NOP policy on GMOs. I just wanted to briefly touch on the OIG organic milk audit and the GMOs there, if that is okay, Zea.

So the organic milk audit, phase one, had some findings around organic feed and forage. They were looking to see whether or not there were any issues with organic feed and forage that were received by organic dairies. What they found was that there was no testing that they found that certifiers were currently doing for GM material. But they also did not find any evidence that GM material or GM inadvertent presence was a problem in their findings. So their finding was that the lack of GM testing does not provide assurance that feed and forage is not contaminated with GM material. So they use the term “contaminated with GM material”. They, however, did not define what they meant by “contaminated with GM material”. So they are finding that this lack of testing was a problem and we have come up with a response to their finding.

Our response is that GM testing is allowed when certifiers have reason to believe that the use of excluded methods has occurred. And we expect certifiers to conduct GM testing if they suspect that an organic dairy has used a GM soybean or a GM alfalfa. We do recognize that limited testing is currently being done by certifiers. And that there needs to be a distinction in that testing between violations, which would mean that the GMO was being used, versus the inadvertent presence of GM material in an organic feed or forage. And that is where it gets really tricky of: how do you make that distinction? Our plan is to analyze GE testing methods, their costs, their reliability, the very sampling methods that could be conducted. Where would you sample? Would you sample at the dairy farm? Would you sample at the feed supplier? Would you sample at the farm that is growing the soy or the alfalfa? Would you sample the seeds? Would that be the best place to sample? We will analyze the results and how that might inform whether the presence of GE material would indicate either a violation, which would be the use of GMOs, versus inadvertent presence. And then we would determine whether guidance is needed. So we will be working on this analysis report. We want to work with the NOSB on that. And we have to have our report back to the OIG by February of 2013.

So that is a quick summary of the policy and our response to the OIG audit.

Zea Sonnabend: Thank you, Miles. Now, while Michelle pulls up my slides, I will mention that since that definition was crafted by the NOSB with what became “excluded methods”, back in the mid-90s – ‘96 or ‘97 it was finalized – the NOSB has done very little work on



the issue of GMOs. And I can't even tell you how many times I have personally have stood in public comment in the past and urged for certain things to be done about GMOs, to very little avail. And I'm sure many of you have also. So at the time that I was appointed to the Board, I decided that that should change. And other Board members were feeling a similar amount of frustration. And so, Barry and the Executive Committee created the NOSB ad hoc GMO, and I guess it should now say Subcommittee, although my slide still says "committee". Michelle, the slides I sent you about the committee, could that come up?

Male: [Whispering]

Zea Sonnabend: What? Oh. OK, in a second I will take questions to Miles, if there is any questions to Miles. I am sorry I did not do that. But, well... Since we are on pause here, does any Board member have a question for Miles? Nick.

Nick Maravell: Miles, I just want to get a clearer understanding of the current policy. With regard to testing for GMO, which I know is a very sticky wicket so to speak. But you said one of the control measures or avoidance measures or mitigating measures was for organic producers to test their inputs for GMO, particular seed. However, that is not a requirement. Is that correct right now? That as part of your organic system plan, you do not have to run a test on all of your seed certified organic and other seed purchased.

Miles McEvoy: Yes, that's correct. What the requirement is, is that you have procedures in place to prevent contamination, to avoid contamination from adjoining land use to prevent commingling. So those are the specific requirements. You have to prevent contamination from GMOs but also from pesticides and other potential contaminants. So you can do that through a variety of mechanisms which may include testing. But it is not required that that is one of the mechanisms.

Nick Maravell: If an organic producer were to test and find the presence of GMO in their seed stock, what then is the producer required or advised to do?

Miles McEvoy: Well, that would be dependent upon their organic system plan and how they would be implementing their organic system plan. So if they were doing testing, then they would have then procedures in place, what they would do if they found presence of GMOs. So the one farm that I know of that does GM testing is that they would, they accept organic feed and forage if it is below, if it meets the non-GMO project's standards, which is point 9 percent for feed and forage, and I think point 5 percent for seed. So if it is below those thresholds that have been established – I don't think they call them thresholds, but – below those levels that the non-GMO project uses, then that organic producer would continue to use that. If it was above that, then they would reject that product.

Nick Maravell: OK. So then the organic producer establishes their organic system plan and establishes their own criteria for evaluating, if they test, whether or not they would use a product that had some presence of GMO.

Miles McEvoy: That is correct.

Nick Maravell: OK. Thank you.

Zea Sonnabend: Are there other questions for Miles? Colehour?

Colehour Bondera: Thank you. And, thank you, Miles. I appreciated that presentation. I did write down several different questions and I am going to try to just ask one. And I will hold the other ones 'til the future. But I was just curious: you mentioned something that I wrote down as "GMO working group" in reference to the EU and USA. And I would like at least another sentence on that if that exists and who serves on that and what you said.

Miles McEvoy: No. If I said "GMO working group" that was a bad mistake. It is an, the Organic Working Group is the title of the group and it consists of USDA and the US trade representative on the US side and the Director General for Agriculture under the EU Commission. So those are the two, the parties that are involved in the Organic Working Group. And they are involved in implementing the US-EU Organic Equivalency Arrangement, working out the details of that. A part of that is also, as a partnership between the EU and the US, is to share information on organic production. For instance, they do not allow methionine to be used in organic poultry production. How did they do that? So we can learn from them. We don't allow antibiotics in organic livestock production. How do we do that? 'Cause they allow antibiotics in organic livestock production under the European standards. So the idea is to share information and learn from each other and get that information out to our respective organic communities. One of the, one little line in that appendix is that we would also share information about methods for avoiding a GMO contamination. And that is the little line that caused some consternation from our friends in the biotech industry.

Zea Sonnabend: Other questions for Miles? Okay. Thank you. Okay. So as I was saying, we, the Board set up an ad hoc GMO Subcommittee to take another look at some of the things that had been sitting around wanting to be looked at for the last decade or so. And I am the chair of it. So, I could have the next slide?

Before we get into the substance of the committee, because I sat out there in the audience for 20 years now and occasionally had a say, but relatively rarely, I thought it would be a good time to just have a moment of audience participation. And so what I would like to do is, when I count to three, everyone who thinks there should not be GMOs in organic agriculture can join me in saying "no GMOs". Okay. One, two, three.

Crowd: No GMOs!!!! [Laughter]

Zea Sonnabend: Thank you.

So, the new committee was set up because the organic industry is very concerned about keeping GMOs out of the organic food supply. Manufacturers and consumers alike need

greater visibility from the leaders of the organic movement, the NOSB, on this subject. Excluded methods and the accompanying issues of where to draw the line for exclusion, how to provide leadership in this area, and how to monitor compliance have not been examined since the rule came out.

The GMO Committee, our first job was to write a mission statement and here is the mission statement up on the board. The NOSB accepts responsibility for making recommendations that pertain to excluded methods to ensure that genetically modified organisms are prohibited in organic production and handling and don't contaminate agricultural products. The NOSB ad hoc GMO Committee will examination all the areas where GMO contamination poses a threat to organics and will provide leadership in clarifying what excluded methods actually are, and how compliance to the provisions of the rule can be monitored. Next slide.

So we recognize that this is an issue that cuts across all of the committees. And so, as an ad hoc group, our work will be to sort of tie together and keep moving forward the work of all the different committees. So some examples, and this, you know, my appointment is five years and so I'm working, we as a committee are working on a five-year work plan. Hopefully, it will keep going on beyond then, in case we don't solve all the GMO issues in the next five years and get rid of them completely. There will be more work to do.

So examples of some of the things that we will do include: examining the GMO definitions and regulations in other countries and CODEX to see if we can learn anything from them and harmonize better with them. To provide oversight on GMO issues as they cross the committees. So certain things, like GMO microorganisms will be used in farm inputs as well as in processing ingredients. And we may choose policies that, choose to look at policies that apply to both crops, livestock and handling. And then to look at the language in the rule that Miles has read about excluded methods in relation to other concepts that are also in the rule but not so clearly stated how they relate - concepts like unavoidable residual contamination, residue testing and preventative measures to keep GMOs out. Next slide.

So the five-year work plan: These are some of the first-year highlights that we hope to start working on right away. And we have started on a few of these. We are going to put forward, I hope, a seed purity discussion paper. And this is the step that we like to take before we proceed to a recommendation, so that we can gather information from the organic community about what type of measures might work for this issue, what type of data is out there about the purity of seeds, and other issues related to seed, because after all it all starts with the seed and, if we can take some measures in assuring seed purity, we will have a jump on assuring everything else about GMOs. So we hope to have a discussion paper with questions that members of the public can write in on in the fall.

We also, as Miles mentioned, will be providing some input to the NOP on their response to the OIG audit on the role of GE testing in food and forage. We are going to take up some plant breeding issues, such as cell fusion, mutagenesis, which have been bandied

about without having very clear direction or policy on where they are going. And we are going, the CACC may take a look at increasing consistency among certifiers and the overall committee about the concept of using decision trees and guidelines for preventative measures. And there are some examples that we will have to look at.

So, the first step, which Colehour will present in a moment, will be the letter to the Secretary from the NOSB stating that we are claiming responsibility for our part of the problem and they need to also claim responsibility. I would like to thank everyone for the public comment that we did receive and, in particular, to those of you who submitted some future ideas for our upcoming work plan; such as, Jim Riddell who gave us a very nice pamphlet about preventative measures, and OTA who put in a lot of points about their GMO policy. And we encourage you in future public comments to keep those coming because we have a lot of work ahead of us and a lot to do.

So, with that I will turn it over to Colehour to talk about our letter to the Secretary.

Colehour Bondera: Very good, thank you. Michelle is going to put up my simple and brief presentation on this topic. But, not the letter my PowerPoint slide 13.

Which is the, like Zea said, thank you, it is our one recommendation that we are putting forth, our first one as a committee and we will be carrying on. The first thing – I guess I will start talking about it while she is pulling it up, so we can move on – is really the – yeah, the next slide – is the importance of the letter. And I just, you know, try to reduce that down to a few points, essentially coming from the fact that the public, in many ways, over a lot of time, was requesting that the NOSB make a statement on integrity of organics in relation to GMOs. As is referred to in OFPA, in the Organic Food Production Act, the duties of the NOSB include advising the Secretary of Agriculture about important issues. And, you know, organics has a stronger voice by using communication with the Secretary of Agriculture through the NOP to ensure that time sensitive, these time sensitive topics are granted the needed attention.

Yeah, you can go to the next slide, which is just a copy of the letter. I'm not going to read the letter in its full. I will, I mean, I assume you have read it. I think I... Yeah, I mean I will take a moment and read a couple of paragraphs but I think that because it will stand out. But I think it is a pretty straightforward letter.

Paragraph four says: "The NOSB ad hoc GMO committee will examine all the areas where GMO contamination poses a threat to organics and will provide leadership in clarifying what excluded methods actually are, and how compliance to the provisions of the rule can be monitored. We see the potential of contamination by genetically engineered crops as a critical issue of organic agricultural producers and to the consumers of their products. There are significant costs to organic producers and handlers associated with preventing this contamination and market loss arising from it."

And I think, you know, it is worth, as a side comment, especially after what Miles did but even what Zea did and even what is here in this, that paragraph of mentioning that really

there is an interesting both use and reference and time point of the phraseology “excluded methods” and then we have formed an ad hoc GMO Committee. We have not formed an ad hoc Excluded Methods Committee. So I think that there is still some fine-tuning to be working on on these topics. And, you know, they are not exactly synonyms I think is worthy of note. But this is how we have moved forward for a variety of reasons and I think it is a logical place.

In any case, going to move to the next slide because, you know, Zea mentioned the general reality of the public comment and it all was a hundred percent supportive. I note that of approximately 35 written comments, 11 of those were specifically about the letter to Vilsack, and all were supportive entirely. So I don't have to differentiate really. Really a wide range of people though and groups were represented from trade associations, public-interest groups, individuals, organizations involved with agriculture from farmers to farmer advocacy. I just think a lot of players are making their voices heard and I think that that is worthwhile.

I actually – the next slide – I have even noted a few quotes here, not particularly any bias but I just chose a few to highlight, you know, that support. “...strong support for the NOSB’s proposed letter to the Secretary”. This next one is a more general one about GMOs in general, not specifically about the letter but... “We must protect the integrity of organic foods. The consequences of the rapid manipulation to, of genetics as opposed to selective breeding are not fully understood, and endanger the whole concept of the organic food production, as well as the environment.” Another quote was “...fully supports the letter drafted...”. And a final one was again general but “keep GMOs out of organics”.

And I will just go to my final slide, which is my final words on this. The integrity of organic standards needs to be clear about excluded methods which includes GMOs. Really a letter, you know, from the perspective of our committee is really raising the topic and pointing out the willingness, you know if you read the letter, the willingness to engage in dialogue with the Secretary of Agriculture. I view it as a first step towards conclusions which we all, both the organic and the non-organic, can comfortably share. And one could argue, I realize, that that is maybe a way of saying that we are open to discussing coexistence even though, you know, that is not how I phrased it, not how I see it. But I think that the point is that let’s be talking about these issues and not just be relying on what is put forth. And I'm happy to, you know, if there is any clarification questions, respond. That is all I wanted to present.

Zea Sonnabend: Okay. Is there Board discussion before go to public comment? Nick?

Nick Maravell: Yes, this letter is oriented primarily towards crops and contamination in crops. Is that correct? And the reason I am asking this is because we are facing a GMO issue with regard to animal vaccines where there may be instances where we, the NOSB, might recommend the introduction of GMO technology into organic production. So what I guess I am asking here is we may need to either seek the help or give advice to the

Secretary on animal issues as well with regard to GMO. Are you seeing that as a possibility in the future or is this sort of our one and only shot so to speak?

Zea Sonnabend: Oh, no. Certainly the letter was not just for crops. It was intended to address everything. But recognizing that was actually in the rule besides exclusive methods it gives us specific exemption to excluded methods for GMO vaccines to be put on the National List. And so that is in the rule, and so, you know, we follow the rules, so if that is the way it goes, then we will go there.

Nick Maravell: That is not exactly what I was getting at, but we may need either the assistance of the Secretary; because the issues that we're dealing with go beyond the Organic Program.

Zea Sonnabend: Yes, we may. And we were trying to position the letter to not be antagonistic to the Secretary but to just claim some leadership in it. Other question? Okay, let's have public comment.

Jay Feldman: [Whispering]

Zea Sonnabend: What? Oh, Laura is out for this. Okay. Christine Goodman?

Michelle Arsenault: Zea, I think they just went to look for her, because the person prior to her canceled and she did not quite know she was going now.

Jay Feldman: [Whispering]

Zea Sonnabend: Alright. We will go to the next person. Isaura Andaluz? Thank you. Go ahead.

Isaura Andaluz: Good afternoon. My name is Isaura Andaluz and I am here on behalf of OSGATA, the Organic Seed Growers Trade Association and as a public citizen.

As OSGATA: We have concerns. The first one being that we only have three minutes to express our concerns for the participation is essential to enhancing organic stakeholder's involvement.

Two, all future NOSB appointments should be made respect with to the letter of the law and Congressional intent. Farmer Board representatives must, as is written in the law, own and operate a certified organic farm. Further, the independence of NOSB members must be maintained by full disclosure by farmers, scientists, environmentalists and consumers who are simultaneously employees, contractors, or consultants of corporate agribusiness. All interests must be transparent and members should recuse themselves on issues where there is a potential conflict of interest.

Three, the NOP final rule 205.204 must have a deadline to require organic seed with no exemptions. We also need a threshold of zero GE contamination to maintain our foundation seed clean of any GE material.

Four, GE contamination is a risk to organic integrity. The result is a loss of consumer confidence in our products, whether it is through seed contamination, GMO vaccines, organic production, handling, or processing, this contamination dilutes organic integrity. Coexistence is not possible with biotechnology until flow and/or contamination is controlled.

Finally, we are in support of the biodiversity guidance submitted and the checklist.

Now as a citizen independent of OSGATA: the word “GMO” should be changed to “genetically engineered”. Everything is genetically modified. What we are dealing here with is genetically engineered. It does not occur in nature.

Secondly, if this Board continues to allow materials, GMO vaccines and other elements to be allowed in organic production, then as a consumer I have no need for organic certification. For these same reasons, all the young farmers I am working with are all dropping their organic certification.

Organic products are considered to be receiving a price premium. The truth is organic has higher cost productions, employs more people, and implements truly sustainable stewardship practices. Organic is the fastest growing agricultural sector and the US cannot meet its own market demand. USDA must support, at the same level as biotechnology, the organic sector in funding, research, and marketing.

Thank you for your time, and your, all of your work.

Zea Sonnabend: Are there any questions for our commenter? Okay. Thank you very much. Okay. Christine Goodman. Is she here yet? Okay. We will go to Angela Anirton? No? Okay. I guess that is all the public commenters that I have on the list for this. Correct? Okay.  
So, I guess we are ready to proceed with further Board discussion. And to do that, perhaps, Colehour, do you want to put the motion on the floor to adopt the letter? And then we will have discussion.

Colehour Bondera: Yeah. I move to adopt the letter as presented.

Zea Sonnabend: Second. Oh, it doesn't need a second because it is from the committee. Okay. Further Board discussion. Okay, we are... Nick.

Nick Maravell: I am still a little troubled by this letter and might suggest a two word change because I think we need to foreshadow the possibility of going up to the Secretary. On, when you say, in the, the letter says in the last paragraph, we intend to keep you informed of our recommendation on this issue. The preceding paragraph is about genetic drift between farms and mitigation. And I guess my concern is that we keep this open enough to say we intend to keep you informed on our recommendations on this issue and other GMO related issues.

Zea Sonnabend: This and other issues?

Nick Maravell: This and other GMO, or however you would like. I just want to make it clear that this goes beyond genetic drift between farms.

Zea Sonnabend: Okay. Does the maker of the motion accept that?

Colehour Bondera: Yes.

Zea Sonnabend: Okay. Further discussion? Okay. I guess we vote. But, Barry, do you lead that?

Barry Flamm: Yeah, I will. If you are ready for the vote, we will begin with you, Zea.

Zea Sonnabend: Okay. I vote yes. Oh, conflict of interest? We won't have a conflict of interest?  
[Laugh]

Crowd: [Laugh]

Barry Flamm: ... conflict of interest.

Zea Sonnabend: I vote yes.

The Entire NOSB Board : Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes, sir. Yes. Yes. Yes. Yes. Yes.

Barry Flamm: The chair votes yes.

Zea Sonnabend: Okay, that is unanimous. Without further ado, I am going to bring the hardcopy letter up to our Chairman to sign, although we will have to make a wording change and have him sign it over again but that concludes our presentation.

Crowd: [Applause]

Zea Sonnabend: There are two copies, and I just hand wrote the little change so that means we will have to do it again. Sign right there.

Barry Flamm: Okay. I am signing this letter with great pleasure and I thank the Zea and the committee for all there their hard work. Believe it or not, we finished the day's agenda a little ahead of schedule. And we recess until tomorrow at 8:00.

[Event concluded] (End)



Meeting Of The National Organic Standards Board  
May 23, 2012

**United States Department of Agriculture  
Agriculture Marketing Service (AMS)  
National Organic Program (NOP)**

**Meeting Of The National Organic Standards Board (NOSB)**

**May 23, 2012**

Hotel Albuquerque Old Town  
800 Rio Grande Boulevard NW  
Albuquerque, NM 87104

The National Organic Standards Board convened at 8:00 a.m. with Barry Flamm, Chairperson, presiding.

**Members Present**

Barry Flamm, Chairperson  
Harold Austin  
Carmela Beck  
Colehour Bondera  
Joe Dickson  
Tracy Favre  
Jay Feldman  
John Foster  
Wendy Fulwider  
Nick Maravell  
Jean Richardson  
Zea Sonnabend  
Robert "Mac" Stone  
Jennifer Taylor  
Calvin Reuben Walker

**National Organic Program Staff**

Miles McEvoy, Deputy Administrator  
Melissa Bailey, Director, Standards Division  
Dr. Lisa Brines, National List Manager  
Emily Brown-Rosen, Agricultural Marketing Specialist, Standards Division  
Michelle Arsenaault, NOS Advisory Board Specialist

\*\*Please note that this transcript may contain errors or omissions and does not represent an official record of all proceedings that took place on May 23.

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Barry Flamm: Members please take their seat. The National Organic Standards Board meeting is back in session. First on the agenda this morning is Materials. And to begin the conversation on materials, Lisa Brines, National Organic Program Manager will lead off with a little explanation of the process. And then, I will turn the rest of the material discussion over to the Committee Chair, Jennifer Taylor. Lisa, please?

Lisa Brines: We are just waiting on slides, so it will be just a moment.

Crowd: [Mumbling]

Lisa Brines: Alright, thank you, good morning, everyone. Okay, so the purpose of the overview today is to give an update on the Program's work on the development of draft guidance related to classification of materials.

So, as many of you are aware, classification has been an ongoing project within the NOSB for a number of years now. And, recently the Program has indicated its intention to move forward with draft guidance. So this is to provide an update, sort of, on where we are in the process. Here we go. So, I know the text is a little small, so I apologize for that.

So, as background, the National Organic Standards Board has issued a number of recommendations over the years regarding the classification of materials. A most recent one was issued in April of 2011, but they date back to August 2005. So, it has been on the work plan for the Board for a number of years. Most recently, in a memo to the NOSB regarding recommendations made at a recent meeting, the Program had indicated its intention to move forward with draft guidance based on the last recommendation that had passed the Board. So, that was that was the November 2009 NOSB recommendation. And there were some minor amendments that were made in 2011. So, as many of you know, we have not yet published this draft guidance, so the intent today is to provide as much detail as we can in terms of the Program's current thinking on what this draft guidance will ultimately look like. We are pretty far along, so I feel reasonably confident in sharing all these details, in terms of what the final project will look like.

Okay, so, why is this classification guidance needed? So we need a framework to be able to classify materials for inputs, to ensure consistency on decisions that are made as classifying things as synthetic or non-synthetic. For other substances, it is important to be able to classify them as either agricultural or non-agricultural. For placement on the National List, it is very important to know how the substance is classified, so we can ensure that it is in the proper placement. But, it is important to note that the classification decision is a separate decision from the Board's motion to list a substance on the National

List. So, it is related, but it is a separate decision. So, they are both important, but a classification decision does not necessarily mean that the substance is compatible with organic agricultural, agriculture or handling or not. So, the guidance is also needed to implement the outstanding NOSB recommendations on this topic.

Okay, so, from NOP's perspective, the purpose of the classification guidance will explain the NOP's policy as related to classification of materials, will describe in detail the procedures that should be used to classify substances as either synthetic or non-synthetic, or as agricultural or non-agricultural. And, the guidance will be published in conjunction with another guidance on permitted substances, which is also in development. So, this is a project that we have talked about at past meetings, that the Program is intending to publish a guidance at least for crop production inputs of a list of allowed substances. So, we have the National List which allows, which indicates the synthetic substances that are allowed in organic crop production. But at least to date, there has not been a comprehensive list in the regulations of allowed non-synthetic inputs for crop production. So we hope this permitted substance list in conjunction with the classifica- guidance will provide the clarification which is needed for the industry for those consistent decisions.

Okay, so, what will the guidance document actually look like? We anticipate it will be published as three separate related documents. So, the first document is the... will contain most of the text, which will be the guidance for classification of materials. And there will be two related documents, which contain the decision trees. So the first decision tree will include the synthetic, non-synthetic decision tree procedures, and the second decision tree will be for agricultural and non-agricultural substances. So I know within the discussions that the Board and others have had on this topic, there has been some discussion on whether additional decision trees might be needed in order to give the detail list needed for some materials. At this point, we anticipate just the two decision trees. There is just currently one definition for synthetic and non-synthetic in the regulations, and a definition for agricultural and non-agricultural. So having two different decision trees that might have two different outcomes for the same defined terms did not seem consistent. So at this point, we anticipate just those two decision trees to be available.

Okay, so, definitions. A number of new definitions have been included in the NOSB recommendations regarding classifications. At this point, because we are issuing this as a guidance document, rather than a change to the regulations, we are not anticipating the need to include those new definitions within the actual rule. So, some of the definitions will be included within the scope of the guidance to provide clarification where needed or guidance to the users of the documents, but we are not actually anticipating making changes in the rule to add those new definitions. The one item that I anticipated a question on was that there were proposed changes to the definition for non-agricultural within the NOSB recommendation. This is a term that is defined in a different way under the NOP rule currently. So, in order to move forward the guidance, we do not anticipate at this point amending the definition for non-agricultural. We know that there have been some inconsistencies identified with some materials using the current definition. But, at this point, in order to move the guidance forward and to get it out, we do not anticipate

making that change to the regulation. We could revisit that in the future, but that is our current plan.

Okay, so just a couple notes on some of the definitions. And I realize for the audience you may not be able to read these definitions. But, this presentation will be posted on the NOP website so you can look at it more detail. So want to, there are a couple of definitions that we are proposing slight changes to, mostly for clarification. I do not think it changes the original intent of the NOSB's definitions. So, one of those changes is for the definition of chemical change. So I have the existing definition out there, and I will just read you the proposed clarification that we anticipate to include. So, we anticipate defining chemical change as a process, for example, a chemical reaction, whereby a substance is transformed into one or more other distinct substances. So, it is a little bit different, but I think it provides additional, provides clarity that will be helpful.

And the next definition is extract. So, the NOSB definition is on this screen. I will just read our proposed clarification. So, we would define extract: "to separate, withdraw, or obtain one or more constituents of an organism, substance or mixture by use of solvents, and in parentheses, dissolution, acid-base extraction, or mechanical or physical methods." So, the one change from the proposed or recommended definition is we are striking the word "essential". So, it can be, you can extract non-essential substances, as well. And, the addition of acid-base extraction as a method used to extract substances.

Okay, next would be the definition of substance. And just a note on this one, because this term is not defined within the regulations currently, but, it is used extensively, both in terms of the National List of allowed and prohibited substances, but also elsewhere throughout the rule. So again, we are not anticipating adding this to the regulations, but I will just read you our proposed clarification. And I think this will broaden the scope little bit to capture some of the materials that are on the National List, but wouldn't necessarily fit within the NOSB's proposed things. So, something like newspaper or compost, which are substances. So the proposed clarification would be a substance would be defined as a generic type of material, the new text, such as an element, molecular species, or chemical compound that possesses a distinct identity, for example, having a separate CAS number, CODEX international numbering system number, or FDA or other agency standard of identity. Just a minor change, but I think it will be more clear for some of those other substances.

Okay, so that is the definitions. Get down, I think I am going to go through type of production, just, so bear with me a little bit. This is going to be background information as well. But, for crop input specifically, the synthetic/non-synthetic classification, as you are aware, is important to determine whether a substance is allowed, whether it is prohibited, or whether it needs to be on the National List. So again, for crop inputs, natural substances are generally allowed unless specifically prohibited, and then the allowed synthetic inputs specifically need to be listed on section 205.601 of the National List.

So, terms of related to classification, the NOP guidance will state that classification should be made according to the decision tree, NOP 5033-1. That is the synthetic/non-synthetic decision tree. And again, we are developing draft guidance for permitted crop inputs under a separate guidance document number, which will list the allowed non-synthetic and synthetic inputs, so, a comprehensive list of inputs that are allowed for crop, organic crop production. So, we understand that some substances may not fall on this list, and may not have been previously looked at by the Board or by a material review organization or certifying agent. So, our intent is that, for substances that are not classified on the permitted substance list for crop inputs, we will have to establish a separate review process for that. So we anticipate when we publish the permitted substance list as final, it is possible we may get new requests to add things to that permitted list as non-synthetic. We do not currently have a process for petitioning the Board for that type of synthetic/non-synthetic decision. If there are some sticky issues, we may have to address those on a case-by-case basis. But, we will at least be able to accept the request for additions and then decide how to move forward from there.

Okay. So, for substances that would be considered non-synthetic, one of the tools that is available is there is other substances listed elsewhere in the National List that have been previously classified. So, even though something may be classified one way for handling or for livestock, we know that that does not necessarily mean it would be allowed as a crop input. However, we can take advantage of that work that the Board has done on classification to have consistent decisions across the different types of production system. So what will be clarified in the draft guidance is that for substances that are already classified as non-synthetic on 205.605(a) of the National List – those are the non-synthetic handling inputs, it can be assumed that those are non-synthetic for crop inputs. So, those again would be allowed unless they are specifically prohibited on the crop section of 602 of the National List. And likewise, for things that are already classified as synthetic on section 205.605(b) of the National List, again it is assumed that those would be also classified as synthetic for crop use. So they would be prohibited as synthetics unless they were listed on section 205.601 of the National List. And then finally, for substances that are classified as agricultural on 606 of the National List, the presumption would be that those would be permitted as crop inputs, again, as natural materials, unless they were specifically prohibited.

Comment [JMS1]: 00:15:00

Okay, so moving on to livestock. So again, similar to crop inputs, classification is needed for livestock inputs to determine again whether the substance is allowed or whether it needs to be on the National List. For livestock feed ingredients, classification as agricultural/non-agricultural is important to determine whether the substance needs to be certified organic. And again, 603 would be the allowed synthetic livestock inputs, 604, the prohibited natural inputs. Again, for livestock, other natural substances are generally allowed for use, with the exception of things that are included in livestock feed and are agricultural, those have to be certified organic.

Okay, so again, the procedure to be used that will be in the guidance is that, for livestock inputs, they should be made according to the same decision tree used for crop inputs for synthetic/non-synthetic classification decisions. And again, for things that are not

previously classified, they need a separate, may need a separate review process. At this point, the draft guidance for permitted substances is only going to cover crop inputs, rather than livestock inputs. So, we will not have that additional resource. But, there will be some of the same decisions that can be taken advantage of.

And this, okay, sorry, is very small. But, similar to crop inputs, again, things that have already been classified as natural for handling would presumably be natural for livestock inputs and allowed unless prohibited. Things that, again, are non-synthetic on the permitted substance list, that is the crop inputs list, would be presumed to be also non-synthetic for livestock inputs and, again, allowed unless prohibited. Again, synthetic substances that are classified for handling as synthetic would not be allowed as livestock inputs unless they are specifically listed on the livestock section. And finally, things that are agricultural on 606, those that are used as livestock feed ingredients, they would need to be certified organic.

Okay, so moving on to handling. So again, handling is a bit more complicated because of the additional details that are, the additional breakdown, in terms of how substances are classified for handling use. So again, classification is important to determine placement of those non-organic substances on the National List. It is also important for products in the "made with organic" category, whether a substance is agricultural or non-agricultural, will have some effect. So again, I have listed the references there, and will come up in discussions later today. So, 605(a) would be the allowed non-synthetic substances, 605(b) allowed synthetic, and 606 is the allowed non-organic agricultural ingredients, which again are only allowed when the organic version is not commercially available.

So in terms of the classification decision process, the guidance will indicate that classification of materials used in handling should be first made according to the decision tree to classify them as agricultural or non-agricultural. If a substance is class-, and again, there is the decision tree number. For substances that are classified as non-agricultural, those would need to be further classified as synthetic or non-synthetic, and again, using that same decision tree used for crop or livestock inputs.

Okay, so notes on a couple of issues about separation methods, solvents in handling, which will be a topic discussed later today within the Materials Committee, eligibility for organic certification, and timeline and next steps.

The separation methods: So, within the guidance, we know that there is, there has been some concern in terms of what separation techniques would be allowed or change the classification decisions. So, we recognize that for some substances, they might be isolated from mixtures using a variety of different separation techniques. So, those could include things like distillation, also solvent extraction or acid-base extraction, physical or mechanical methods like filtration, crushing, centrifugation, gravity separation, there is all sorts of methods. The isolated substance could fall under a number of different classifications. So depending on the process used and the starting material, that could be certified organic, could be non-synthetic, synthetic, agricultural or non-agricultural. So I will get into a little bit more detail on what we anticipate putting in the guidance.

So this is just for a comparison. It is not really within the scope of the guidance. But, just to compare classification work from the... is different than the process used for certified organic substances. So, for certified organic substances, materials used as ingredients, extractants, or other processing aids must be organic or must comply with the National List. So for example, you can have a certified organic substance that might have been extracted with organic ethanol, it might have been extracted with sodium hydroxide which is an allowed synthetic, citric acid, carbon dioxide, anything that is, anything that had been reviewed by the Board and is on the National List, or any organic ingredients or processing aides. So, we had clarified this at the last meeting, but, just so as a reminder: under 205.270, the use of volatile synthetic solvents or other synthetic processing aids are prohibited for certified organic substances, unless that solvent or processing aid is on 205.605.

So what does this mean for solvents used in handling is that no synthetic solvents or other synthetic processing aids in or on organic products, or in or on organic ingredients, can be as used unless they are listed on 605. Solvents can be considered a part of the manufacturing process for non-organic substances for those listed on 605 that may have, that have been reviewed by the NOSB and not further restricted. So examples would be lecithin, in the past, pectin or shellac. Non-organic agricultural ingredients in the "made with" products may have also been produced with the synthetic processing aids or solvents. And non-organic ingredients listed on 606 for use in organic products may have also been produced using synthetic solvents or processing aids, unless specifically annotated otherwise.

So again, here is the regulation 205.270. The bold is just for emphasis. So the handler of an organic handling operation must not use in or on agricultural products considered to be sold, labeled or represented as "100% organic", "organic", or "made with organic specific ingredients or food groups", or in or on any ingredients labeled as organic. And there is the citation for the prohibition on volatile synthetic solvents for those particular types of products.

Okay. And so in terms of classification of materials, the use of solvents for non-organic substances: So talk a lot about solvents used for extraction, but it is helpful to recognize that solvents are used in many different ways during manufacturing process. So they may be used as reaction media. It can be used as an extractant, but they can also be used for purification or crystallization, for concentration, standardization, serve a number of different roles. Seem to focus on the extraction a lot, but there are other uses for solvents in production of materials. So, the NOSB in reviewing petition materials may always consider the use of any substances used in the manufacture of particular materials, including solvents, as part of its review of petition materials. So again, the guidance does not change any of this, it just clarifies what particular things would be allowed. So, again volatile synthetic solvents are prohibited for handling organic products under 205.270, unless those specific processing aids would be listed on 605. And according to the draft guidance, the use of the synthetic solvent in the process would not necessarily result in a substance being classified as synthetic. So, it does not automatically change the



classification, you have to look at more detail to determine whether the substance classification should change.

So, what are the criteria? We have a number of steps that I will go through, in terms of what things that would be considered in terms of whether the separation technique involved would result in the substance being classified as natural or non-synthetic. It would need to meet all of these criteria in order to be considered natural. So, the first criteria would be at the end of the extraction process, the substance has not been transformed into a different substance via chemical change. So again, chemical change will be defined in the guidance using the NOSB recommendation. So, as an example, something like citric acid, which is listed as non-synthetic on 605(a), so that is a substance produced by microbial fermentation of a carbohydrate substance, then is isolated and purified through various techniques, but, again, at the end of the process, and isolation process, it is not transform into a different substance, so it is classified still as non-synthetic on 605(a).

Okay, so the second criteria would be that the substance has not been isolated in a form that does not occur in nature. So again, using citric acid as the example, it is natural when produced by microbial fermentation, but something like potassium citrate, which is potassium salt of citric acid, would be classified as synthetic on 205.605(b). So that is consistent with the Board's recommendation and the current placement on the National List.

The third criteria would be that any synthetic materials used to separate, isolated or extract the substance have been removed from the final substance, for example, through evaporation, distillation, precipitation, or other means, such that they have no technical or functional effect in the final product. So the example here would be pyrethrins, and many botanical pesticides are extracted from the natural materials. So, in the case of pyrethrins, they are extracted from the flowers with a synthetic solvent, but the solvent is removed prior to product formulation. It does not serve any technical or functional effect in the final product. It is just used to extract the pyrethrins from the natural material. So that was, again, consistent with how that material has been previously classified. It would still be considered non-synthetic.

The fourth criteria for substances used in crop or livestock production: The substances used for formulation would need to be non-synthetic or included in the appropriate section of the National List. So, for the example here, again, natural botanical pesticides: Even though the active ingredient would be natural, any inerts used for product formulation, they would either need to be natural or comply with the National List. The current placement for those inerts would be at 205.601(m).

For handling substances, for those non-organic substances used in handling, those substances used in the formulation would need to be provided for in NOSB review of the substance or included in the substances annotation on the National List. And we understand that the NOSB has on their work plan a recommendation, or is planning a recommendation, to clarify other ingredients allowed in handling inputs. So we

understand that this particular provision might change as a result of that work. But, this is our current understanding of practice.

Okay, so, one item that has come up, particularly with respect to the Boards' deliberations on what an appropriate definition of chemical change would be, is that there was a concern about crafting a definition that would not result in processed agricultural products being classified as synthetic, and potentially ineligible for organic certification. So what we anticipate putting in the guidance is the guidance is really just for classification. It is not really to be used for determining the eligibility of a substance for organic certification. So, assuming a substance contains or is made up of agricultural ingredients and can meet the NOP requirements for production, handling, processing and labeling, it would still be eligible to be certified under the NOP regulations. So the classification guidance is just for classification, it is not as a substitute to determine the eligibility of any particular material for organic certification.

Okay, so, a few details on the decision tree: I do not have this in decision tree format, but these are the questions that we anticipate putting in the tree. And they should be familiar because they are fairly consistent with the last recommendation that came out of the Board. So the first question would be, is the substance manufactured, produced or extracted from a natural source? Does the substance undergo a chemical change? And that will be a defined term. Is the substance created by a naturally occurring biological process, such as composting, fermentation, or enzymatic digestion, or by heating or burning biological matter, matter? And the last piece of that - heating or burning biological matter - is a new addition from the, a new addition that the NOP is proposing to include in the draft guidance. And that would be consistent with materials, such as ash, which are classified as non-synthetic on 602.

Comment [JMS2]: 00:30:00

Okay, next question on the decision tree would be is the substance created by a naturally -- oh, I am sorry, that was a repeat of the second one. Sorry. Is the substance combined with other materials to produce a commercial product? And, are those components present in the generic substance non-synthetic? So again, some of this is targeted to organizations that would be reviewing those inputs for compliance with a producer's organic system plan, but they might also come up during Board deliberation as well.

Okay, so in addition to having a table with those decision points, we also anticipate including a table of example classification decisions with explanations. So, this will give some guidance to users of the document on how the decision process should work, with specific examples of where the NOP chose, the NOP sees where the line would be, in terms of making a particular decision. So I know that for the audience, you cannot read all these examples, but again, they will be on this slide, and so it will be listed as substance, what the classification decision would be according to the decision tree, and then just a brief explanation of where on the decision tree that substance, how that decision was made, what the final step was.

For the agricultural/non-agricultural decision tree, it will have its own set of questions. So, starting with, is the substance derived from a plant, animal, microorganism or

mineral? Is the substance a microorganism, for example, yeast, bacteria, or fungi, or an enzyme? Or, is the substance isolated from the product of a microorganism or an enzyme? Following that, has the substance been processed to the extent that its chemical structure has been changed?

If there has been a change, is the chemical change a result of naturally occurring biological processes such as fermentation, use of enzymes, or a result of mechanical or physical processes? And again, have any other, for reviewing of formulated products, have any other ingredients been added to the substance that remain in the final product, and are those ingredients consistent with the National List for handling? And again, as a result of the Board's work on this issue, that might evolve a little bit.

So again, similar to the classification decision tree for synthetic/non-synthetic, we will include a table with example substances, those classification decisions, and an explanation of how we got there using the tree.

Okay, so that is the overview of the document. In terms of next steps, we hope to put the draft guidance into clearance this summer. Again, it will be hopefully published in conjunction with the draft guidance for permitted substances for organic crop production. That way, its... we can make sure those two documents are consistent with each other. And, like any draft guidance, it will be open to public comment. This one we anticipate at least 60 days for public comment. And as a result of that comment, we will review those comments, amend the text and publish the final guidance. And then, the final document would be incorporated in the Program Handbook and available to the public.

That is it. I am happy to answer any questions you might have.

Barry Flamm: Any questions for Lisa? Zea.

Zea Sonnabend: Thank you, Lisa. That was very informative. Have you anticipated at all that the publication of the guidance will necessitate a re-review of some things that are already on the list but may not have been classified in alignment with the new guidance?

Lisa Brines: Yes, we have anticipated that question. We are not clear exactly how many substances might need additional review. We anticipate that the guidance will be consistent with most of the decisions that are already on the list, but there might be a few outliers that need to be looked at by the Board again.

Barry Flamm: Jay?

Jay Feldman: Thank you. Thanks, Lisa. On the issue of significant residues, could you go over that again? Or I am not sure I caught what you are saying on that, if anything.

Lisa Brines: Sure. Yeah, so, you may have noticed that we did not indicate, use the term significant residues at all in this presentation. We do not anticipate using those terms within the guidance. So, I know this will be on the, this is on the agenda for later this

morning to talk about significant residues. But, we think that we can meet the intent of the Board's recommendation on classification without the need to define what a significant residue is.

Barry Flamm: Any other questions for Lisa? Thank you, Lisa. Next, Jennifer Taylor, Materials Chair, will present the initiatives and proposals from the Materials Committee.

Unknown Female: [Inaudible]

Jennifer Taylor: Thank you. Thank you, Barry. Lisa, could you please provide the update on the petitions?

Lisa Brines: Sure. Thanks, Jennifer. I guess you are not done with me yet. You can go back to the slide, please. Thank you.

So, in general, at each of these meetings, the Materials Committee, within the section of the Materials Committee, we give an update to the Board and to the public on what petitions have come in since the last Board meeting. So that is the purpose of this, and to just to give a couple of reminders on process.

So, for the Crops Committee at this meeting, they will be addressing the one listing for Sunset, which is still remaining for Sunset 2013, that is the List 3 inerts. There is still an out-, one outstanding petition to remove the material, which is ferric phosphate. There is two petitions outstanding for inert ingredients. And then for petitions to add a new substances, 601, those include bio-plastic mulch, oxidized lignite, polyoxin D zinc salt, and propylene glycol monolaurate. Technical reviews for all those petition substances are in development. The one for propylene glycol monolaurate has been recently accepted by the Crops Committee, so that is available to the public on the NOP website. Currently, there is also a supplemental report in development regarding the petition to remove ferric phosphate, but that is of limited scope.

For Livestock Committee, they are not addressing any petitions at this meeting. There is one petition to amend an annotation under consideration which is for methionine. There are two petitions to add a new substance. One is nonanoic acid, which is also known as pelargonic acid, and there is a petition for pet food amino acids as well. There is one technical report in development for the pet food petition. The nonanoic acid technical report was accepted by the Livestock Committee and is available to the public on the website.

For the Handling Committee: addressing several substances at this meeting, both petitions and Sunset materials. We are still waiting for a petitioner response on the petition for Caramunch malt, which has been outstanding for some time, and since the last meeting, the petition for dextrin has been withdrawn voluntarily by the petitioner. And then there is a long list of outstanding petitions for the Handling Committee as well. For 605, we have ascorbyl palmitate, beta-carotene as a nutrient which is separate from its allowance as a color, L-methionine, lycopene, nucleotides, sodium gluconate, sulfuric

acid, and taurine. And for agricultural substances with the petitions outstanding include barley beta-fiber, bergamot bitter orange power, lutein, and sugar beet fiber. And many of these are in process for technical reports. Just one note on the technical reports for all the petition nutrients, those drafts have all been provided to the Handling Committee, although they have not all been finalized yet. So that, when they are, they will be available to the public.

And, one update on, for the aquaculture petitions, and this will be discussed later this morning. We received a number of petitions from the Aquaculture Working Group regarding materials for use in either aquatic animal production or aquatic plant production. A majority of these are still under review by the NOP so they are not posted on the website yet, with the exception of chlorine and carbon dioxide.

And this is just a reminder for the benefit of the audience, and I guess for the Board members as well. The criteria used to review these petition substances and the National List come straight from the Organic Foods Production Act and the NOP regulations. And I will not read these to you, but these are the criteria from OFPA are what forms the basis for your checklist, in terms of filling those out. They are straight from the Organic Food Production Act. And then there is additional criteria for the use of processing aids or adjuvants that are listed on 205.600.

We do have two petitions this meeting for 606 materials, which are the agricultural. So the Board does have criteria for evaluating those substances that might be potentially commercially unavailable in organic form.

For the Sunset materials, just as a reminder, the reason that the Board is looking at these again is because, under OFPA, there is a requirement that the Board look at these existing listings every five year to determine whether they should be renewed or not.

And so, for the voting procedure for petition substances, those... the first motion will generally be for classification, either as synthetic/non-synthetic or agricultural/non-agricultural. The second motion would be for listing. And those listings are always made in the affirmative. So even for things that do not pass, the original motion is to list the substance on a certain section of the National List. And those, either motion would require a 2/3 majority to pass the motion.

For Sunset substances, the classification vote is generally not needed since the substance is already classified unless a change is needed. The relisting motion again would be made in the affirmative. For our Sunset materials, where a change to the annotation is proposed, the Board, according to the procedures, would vote on that proposed amendment first, but also vote on the existing listing as a back-up to allow the NOP, if we need the time for rulemaking, to have that as an available option. And again, the 2/3 the majority would be required for those motions as well.

And I think that is it, just as a reminder, unless there are any questions.

Jennifer Taylor: Are there any questions? Okay.

Lisa Brines: Thank you.

Jennifer Taylor: Excuse me. I am sorry. I had, I am having computer problems at my computer work this morning, and it is not working now so. I have got a small PowerPoint presentation. Thank you, Lisa. Thank you, Barry.

I thought it might be good to start this morning with a review of some of the general comments. The comments found in the general category. These are written comments that the public, consumers, stakeholders provided in regard to our recommendations and discussion documents in regard to the Program in general. And I won't read them all, but I'll start off with this one. "Please ensure that the language of the organic standards guarantees that organic farming products will not be harmful to human health or the environment." "I would like to state that I feel the organic standards should continue to be strong to protect the consumers who choose to use the products." "There are many of us that wish to limit the chemicals and toxins that are currently pervasive in the food supply, and reduce the amount of pollution that accompanies conventional agriculture." "We must preserve high and strict organic standards that allow farmers to grow food the way it was meant to be, the way nature, not man, made it." "Food without chemicals should not have to be asked for." And this is an excerpt. "All I want to express is to please keep it simple, keep it honest, and keep it up front." "Please help keep our food safe and clean by maintaining organic integrity. Thank you."

Comment [JMS3]: 00:45:00

The members of the Material Subcommittee include Jay Feldman, Zea Sonnabend, Calvin Walker, John Foster, Wendy Fulwider, and myself, as chair.

We have worked really hard this year to identify issues that are important to the organic community, and to the Program. And, to examine and identify themes that are foundational to organics, themes that are foundational to the integrity of the USDA organic seal.

So, the topics that we will discuss today will include aquaculture petition update presentation - Jay will provide that discussion; research priorities framework proposal, provided by Zea and Calvin; two discussion documents, extractants and solvents discussion document, and significant residues and classification materials discussion document, both provided by Jay.

Unknown Male: [Inaudible] Sounds pretty boring to me.

Jennifer Taylor: Okay, we will begin with Jay.

Jay Feldman: Thank you. We are going to start with the aquaculture update. And as you all know, this is just an update. I guess what we are going to do is run through these various presentations, and then we will have time for discussion, I hope, at some point. Okay, thank you.

So, this is just some background for you, for everybody. The definition of livestock is in OFPA. OFPA provides for a possibility of allowing wild seafood to be certified. The '97 proposed rule allowed certification of confined aquatic systems, but not wild fish. The 2000 rule removed fish from livestock. And in 2000, USDA began a process of developing rules for certified organic aquatic animals.

This is how things played out in that regulatory and statutory context. An Aquatic Animal Task Force produced a report in 2001, based on organic principles for livestock management. The NOSB accepted the report of the task force and approved the following recommendations. No standards be developed for wild caught aquatic animals; standards be developed for the production of farmed aquatic animals that reflect an innovative approach to organic certification while remaining fully consistent with the statutory requirements of OFPA; and three, if standards are developed for farmed aquatic animals, the NOP and the NOSB should use the task force report as guidance.

As a result of work by the AWG, composed of NOSB members and outside people with experience and expertise in the field, a series of detailed recommendations were passed by the NOSB between 2007 and 2008. Except for aquatic plants, which was bought by a Joint Committee of Crops and Livestock, all were brought to the Board by the Livestock Committee.

Petitions: The AWG has submitted petitions for the use of 10 synthetic substances or classes of substances in aquatic agriculture. Three of these, chlorine, carbon dioxide and vitamins, have been sent to the Materials Committee for consideration. The Materials, I mean the Committee has considered the petition for carbon dioxide and vitamins, has found them insufficient, and awaits further documentation. So, that process is ongoing. We expect that soon.

As noted in the discussion document in 2011, the Materials Committee learned this from petitions. We need different criteria for open as opposed to closed systems. Petitions need to include the use pattern of the material, quantity, how it is added to the system; aquaculture-specific information, for example, on environmental fate, interactions with other substances and organisms; and aquatic, sorry, aquaculture-specific reference to applicable law and regulations.

We learned from petitions regarding carbon dioxide and vitamins two other things. Petitions should cite references that are relevant to the use of the material in an aquatic system as well as petitions and TRs for crops and livestock. We need to deal with specific materials, not categories, at least until we get the material evaluation process worked out.

And this is what we heard from the public. That... We summarized this in Savannah. So we have that on the record, that commenters urged the NOSB to review aquaculture materials using organic principles, particularly the concern for the surrounding ecology, use of synthetics in non-routine situations and not for systems functions, and using the underlying ecology to feed plants and animals.

Commenters strongly urged the NOSB to distinguish between closed and land-based systems in evaluating materials, and we were urged to consider differences between herbivorous and carnivorous – I did that last time too – fish in feed requirements and potential for bio-accumulating toxic chemicals.

Commenters urged the NOSB to evaluate materials in light of properties of aquatic systems, in addition to questions normally asked when examining materials. Questions must be interpreted to include impacts relevant to an aquaculture system, such as bio-accumulation, oxygen depletion, chemical changes that could lead to the need for intervention, and depletion of ambient nutrients, as well as impacts to non-aquatic organisms attracted to a water source.

The Materials Committee may continue to work with the AWG to ensure sufficiency of petitions, on the work... or the work may be transferred to the Livestock Committee and the Crops Committee for the plant materials, which seems to be the direction things are headed in right now. Committees will incorporate public response and advice of experts in aquatic biology and aquaculture into development of questions for TRs for aquaculture materials. TRs will be requested as needed. The Materials Committee will work with the CC and LC on materials.

So, that is the update. And I think we will leave it there. I will hand the gavel here over to Zea, who will talk about research priorities, and then I will come back and talk about extractants and significant. Thank you.

Zea Sonnabend: Thank you. Michelle, could we have the research document up, perhaps? Well, I have been in the fortunate position so far of being the point person on things that have had relatively little opposition. The GMO letter, I think, was crafted in a way that everyone could agree with. And likewise, this research priorities document, which has been quite some time in development, has reached the stage where pretty much everyone is happy with both the criteria and the procedures of it moving forward.

So, just to tell you how we arrived at this place, I mean, you can... I am assuming that everyone who was interested read the document, and perhaps you read the discussion document from the previous meeting. But, we looked at the few public comments from the previous meeting, which had some very good suggestions. And, that resulted in us – where did my mess go? – okay, could you scroll down to the recommendation part of it, Michelle? That resulted in us using the same criteria that were in the discussion document with one more added to it, which it would be to particularly focus on things that are, research needs that are relevant to assessing the need for alternative cultural, biological, and mechanical methods for materials on the National List. Because, after all, that is usually where our lack of research comes up in discussion when we are discussing a material and we do not have a good handle on what the alternatives really are, and what they can do. For... And then, we need more research on it.



So, we recognized that there..., not only are we identifying research topics, but, along with those topics, a lot of times, we have to frame questions. And these questions may be framed for all different types of researchers to do research on. So, I use the example of, from a couple of meetings ago, the antibiotic use in apples and pears. And so, someone could do market research on consumer acceptability of different, of resistant apple varieties, for instance. And then, apple breeders could do research on finding resistant varieties. And agronomists or chemists could do research on, you know, other materials that may be used, useful, maybe microbiologists would get a role. So that there are some key, targeted questions framed, so that if I am any type of researcher, and I am looking around for a high-priority topic to apply for a grant, I can develop a research project, and then I can submit this as evidence to the granting agency that the NOSB really needs this research done. And hopefully, that would carry some weight with the funders who like to fund organic research.

So, we created a little structure which would be under the heading Process Framework. In this, the Materials Committee will collect all the research topics as they come up in meetings, and from the other committees, referred from the other committees. Each NOSB committee will have to identify their research questions on their own topics that they have been uncovered in the course of doing the committee business, and for the amount to the Materials Committee.

We will keep... We, the Materials Committee, will keep a running list of all the different topics. And then, once a year, before the fall meeting, we will try and identify the top priorities of that list. I did not put a set number of top priorities in there, but, I expect that we are going to try and definitely keep it under 10, and, you know, maybe as few as five – somewhere in the five to 10 range. And we will flush those out with some appropriate research questions in conjunction with the committees.

We will keep the rest of the list and make that public, also, the things that did not make our top five or 10, because there may be some obscure topics that come back in the future that rise to the top, shall we say. And, we will make that public for researchers and the public to use. So then, at the fall meeting each year, we will present the top topics. And, ratify them. And then, we have a dissemination phase of how we are going to make those topics and questions known to the organic research community. And so, that is presented here.

Now, Calvin is going to talk a little bit about what types of public comment we got on this, and how the proposal will move forward.

Calvin Walker: Thank you, Zea. I will be very brief. Zea actually capsulized we have seen in the public written comments, and it is definitely good to be on a committee where the public was 100% for what we was trying to do. Not a lot of acrimony. And I think, the key thing that came out of this is that stakeholders want to see research. And, we have seen two different tracks. One dealing with a individual material topics, such as GMO, terra-cycling, etc. But, there was a large number of stakeholders also ask that we look at organic management systems. Look at cultural, biological, and mechanical type research

Comment [JMS4]: 01:00:00

that deals with organics. So, I think that those comments was very valued. So we hope that we will be able to do that.

Also, as I note, we can actually start doing some of these things right now. For a person who have had three organic grants funded, and those of us who know, many times your topic is actually -- when it goes through reviews, the topic has a lot to do with it. And, I found it very helpful to put the word organic in it. As opposed to, if I am doing something with animal science, it may not be the best to not put organic in that topic, because, it may get to reviewers who may be conventional agriculture. And many times, these agencies select reviewers based on your topic. Or what you determine where they should go. So, I think research priority will go a long way in dealing with a lot of these substance that we see coming in on the..., that we have been asked by stakeholders to take off the list, or add to the list. So, I think two tracks research priorities need to be a look at the organic management system, as opposed to individual items. [inaudible]

Zea Sonnabend: Okay, thank you, Calvin. Are there any questions from the Board before we move on? Okay, thank you. Oh, question down there.

Nick Maravell: Yes, Zea, I just had a question on one of the criteria relevant to assessing the need for alternative cultural, biological, and mechanical methods to materials on the National List. I am to understand that what you are saying is assessing, what are the alternatives to materials on the National List that could be achieved through cultural, biological and mechanic methods? Or am I reading that incorrectly?

Zea Sonnabend: Well, it is not just what are they, but how well do they work. And that is why we say relevant to assessing, not assessing, because, many of the alternatives are very situation specific, especially biological methods. So, a certain method might work in one enviro- , in one microclimate, and not in another, or in one region, and not in another. And so, we wanted to encompass all of that, all of those types of work, research in that criteria.

Nick Maravell: I am in total agreement. I might suggest a few more words to make that clear and to particularly, the concept of systems work within regions or localities or whatever. I see that as a systems oriented type of situation. And, we need not debate that any further. But, I would be happy to discuss that with you, in terms of how to tease that out a little bit more.

Zea Sonnabend: Okay, but are you saying we should delay the vote on this to re-craft some wording on it?

Nick Maravell: Not at all. What I am suggesting...

Zea Sonnabend: I do think...

Nick Maravell: As we move forward, this would be kept in mind, because...

Zea Sonnabend: Yeah. Absolutely. We, Our committee strongly has a systems approach in mind. All of us who discussed it are definitely thinking...

Nick Maravell: Right, and that is what I would like to see, you know, highlighted here. I think there will be plenty of opportunity in the future to do that.

Zea Sonnabrand: Okay, thank you. Mac?

Mac Stone: Are you all going to take this and craft a request to the public and the industry to seek topics and kind of formalize the request in preparation for the fall meeting?

Zea Sonnabrand: It will be on the fall agenda, yes. However, what we will be presenting for the fall agenda is the research needs that have come in from the past year, and people can submit more during the next docket. But, we won't be able to incorporate them until, if they are brand-new, until the next year's thing, because we will be sifting through what we already know about. We will be putting in an internal call to committee chairs to, you know, collect and move forward their research team that they have developed so far for the fall meeting. But anything submitted in the next docket will have to move forward on the list until the next year. And actually, some of the public comment from this meeting on other subjects that are on our agenda said, this would be a really good topic to do more research on, and so, we will collect those things that have come in on this docket and move those onto, into the fall pile.

Miles?

Miles McEvoy: Just a process question here. In your process framework, you are proposing that this would go to the list of priorities or the recommendation would go to NIFA, ARS and NRCS and OFRF and other private foundations. In terms of the mechanism for the Board, the priority list would come to the Program, and then what would be a more impactful would be for then the Program to then send that list of priorities to these institutions within USDA in particular, because that is both the process that we would need to follow, and it would have a greater impact by following that process.

Zea Sonnabend: I figured it would be something like that. And that is why it says the Chair of the Board will make sure it is sent, and that means, of course, we will send it through the NOP. But, I did not know exactly how to word that. We did not have any guidance from NOP at the time we were developing the recommendation. So, do you think that is okay to say, make sure it is sent, in number six?

Miles McEvoy: Well, again, you can provide it to the NOP, and then we will make sure that it is sent to the appropriate [inaudible].

Zea Sonnabend: Okay, so we will make that wording change, and I do not even have a hard copy. But, Michelle, can you note down that we will say, in number six, after the

recommendation is finalized by the NOSB each fall, the Chair of the Board will send it to the NOP who will make sure it is sent to primary organic research. Thank you.

Anyone else? Okay, thank you very much.

Jay Feldman: Thank you. We had eight questions that went out for public comment on this. And just to put this in context at... Well, I can start the slides actually. At the time that we began this process, we had reached out to the NOP to identify this as an issue, and we... At that time it seemed appropriate to go ahead with this. I still think it is a valuable exercise.

And my hope is that we could even develop a side-by-side that incorporates some of the issues that are raised in this document and puts them side-by-side with the NOP guidance, and even with the material working group proposal, as well as the NOSB recommendation or policy that was passed by the Board, so that we can see which pieces are there, which pieces are missing. Because, what this document tries to get at is a comprehensive approach to this extractants issue. And, I believe there are some issues addressed in this document that were not addressed today in the NOP presentation.

So, this is the way in which we approached this whole issue. That there are limitations on the use of extractants and solvents used to produce materials used in crops, livestock and processing that are not uniform or consistent across the rule. The lack of consistency leads to problems in classification and listing. The Materials Committee seeks to clarify the issues around the use of extractants and solvents to ensure more informed and logical decision making across numerous NOSB committees and materials review. The Materials Committee asked the NOP if the committee could continue to work on this issue, at least at the time, the response was yes.

So, we addressed eight questions. What is a volatile synthetic solvent? What does the use of a solvent or a synthetic solvent change, or when does it change the classification of the material? Does the use of a volatile synthetic solvent in an ingredient mean that the ingredient is not permitted in organic food? This has to do with the heritage of an input: does a prohibition against its use carry back to the origin of the ingredient or ingredients?

The limitations on the use of extract – oh, I went the wrong way, sorry. Okay, when does the use of a synthetic solvent change the classification of the material? The use of a solvent, synthetic or non-synthetic, may result in production of a non-agricultural product from an agricultural substance under the definition, under the current definition. Though, if the definition passed by the NOSB in 2009 were written into the regulations, it would not. And again, we have to weigh this or compare this to what was presented to us earlier in this session. The use of a synthetic solvent can change the classification of a material from non-synthetic to synthetic, if the addition of the synthetic solvent results in chemical change, or if the material contains a significant level of the synthetic solvent. And that is the NOSB policy. It uses those two concepts of chemical change, and significant level of synthetic.

Does the prohibition against... Does the prohibition against the use of volatile synthetic solvents carry back to the origin of ingredients? And this is where 205.270 – two seventy – comes in. It is not clear whether the use of a volatile synthetic solvent in an ingredient that is subsequently used in another product disqualifies the second product as being labeled organic.

Public response: We have got several individuals who advocate for clarifying the policy and maintaining a prohibition on the use of volatile synthetics. CCOF says any policy made must be achievable by certifiers and MROs. Several groups urged, public interest urged the Board to make the prohibition on volatile synthetics solvents in processed foods clear and consistent, to clearly define volatile synthetic, and re-write 270. The trade groups, for the most part, asked to postpone consideration until the guidance is published.

So, the first question was around this issue of should volatile synthetic solvents be defined, especially in relationship to 270? Should we make a distinction between different types of solvents? If possible, reference to a standard scientific or regulatory definition is preferred. Should the toxicity of a volatile synthetic affect how it is treated in classification? And does the supercritical carbon dioxide meet the definition?

And we received a fair amount of good response to this, I think, from across the groups. Beyond Pesticides, NOC, and Cornucopia supported the suggested definition. Beyond Pesticides suggested a clarification of “a volatile synthetic solvent is a synthetic chemical with a boiling point of less than 287 degrees Celsius at standard atmospheric pressure that can dissolve another substance”. All three organizations and Equal Exchange agree that supercritical carbon dioxide is not a VSS.

OMRI says, since handlers – oops – of “organic” and “made with organic” products can only use synthetic ingredients and processing aids on 605(b) and 270(c)(2) establishes that an organic handler may not use, as Lisa told us, a synthetic volatile solvents in producing a final certified organic product, a definition for volatile synthetic solvent would only be needed if such a substance was petitioned for addition to the National List under 605(b). OTA reminds us that 270(c)(2) applies to synthetic processing aids as well as volatile synthetic solvents, and referred to a clarification formerly posted on the NOP website. OTA urges the NOP to formally clarify 270(c)(2).

Question two: is there distinction between volatile synthetics for extraction versus volatile synthetics used for other purposes? Solvents are also used for purposes other than extraction, such as purification of a substance via crystallization. Solvents can also, are also common inert ingredient in formulated pesticide products.

Beyond Pesticides and Cornucopia answered that the prohibition is against volatile synthetic solvents, however they are used. OTA points out that historically in the context of making synthetic/ non-synthetic determinations, the focus is on extraction and manufacturing and whether or not a synthetic substance **chemically** changes the non-synthetic substance.

Comment [JM55]: 01:15:00

And then Question three: Should the process of extraction change the classification of an ag product? Does it matter whether the extractant is synthetic or non-synthetic? And we did not get much response to that. We did not get any response to that, I guess, because people integrated answers to that in their other responses.

Since – this is question four – since 270 organic handling requirements explicitly prohibits VSS, oops, the handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented “100% organic”, “organic”, or “made with”, or, in or on any ingredient labeled as organic. A volatile synthetic solvent or other synthetic processing aid not allowed under 605.

Except that non-organic ingredients in products labeled “made with”, are not subject to the requirement should consumers expect that non-agricultural ingredients identified as “organic” be produced or extracted with the same restriction. And that becomes a key issue, I think, given the range of issues we have heard about today. So, I am going to repeat that. Except that non-organic ingredients in products labeled “made with organic” are not subject to this requirement, should consumers expect that non-agricultural ingredients identified as “organic” be produced, inorganic, be produced or extracted with the same restriction. And then we asked for rationale.

And this is where the public interest side basically said that we should re-write 270, which has been referenced today extensively, skip down, to a volatile synthetic solvent or other synthetic processing – this is the last paragraph – aid not allowed under 605, except, that non-organic ingredients in products labeled “made with specified ingredients or food groups” are not subject to this requirement if the use of the volatile synthetic is revealed in the ingredient statement –which is not happening now.

So, Beyond Pesticides put this in their testimony, which I think helped me, I mean, you know, I did not... When we sat down to really figure out what is going on here, this is all complicated mumbo-jumbo to a lot of us. What is happening here? And there are two tracks happening. If you start at the top, and this is something that we experienced with DHA, actually. We start with any agricultural material. We use a vola- – go to the second box – we use a VSS, right? Then we have the next material, the extracted material. Okay? That extracted material either goes to a certified handler, or goes to a non-certified handler. If it goes to a certified handler, we have heard today very clearly, it cannot go into, it cannot be labeled as “organic”.

But, if it goes to a non-certified handler, as I understand it, as Beyond Pesticides explains this, it goes to, it can end up in a USDA certified product. So, that is what the public interest side was saying. Well, what... Is this fair? Or I mean I do not know if that is the right word. But, shouldn't we have some equality of attention to the extractant or the extracted material whether it is handled by a certified handler or it is handled by a non-certified handler? In the case of DHA extraction, as you recall, it was handled, as I understand it, by a non-certified handler, so it ends up an organic product without any discussion as to whether – okay, we can discuss that. Okay.

And here we have it on the non-, oh, that was an agricultural. So, here we have it on the non-ag side. So, you are right, it was an agricultural. So, DHA would be the second example. We start with a non-agricultural material. We applied a VSS. We then have an extracted material. What we start with in that case, algae or whatever. And then, it is handled by a non-certified handler, and then sold at some point to a certified handler. But, we are talking about the heritage here. We are talking about the original ingredient. It is... The VSS, in all these cases, is applied to the original ingredient. If it is handled by a non-certified handler, it ends up in an organic product. If it is handled by a certified handler, it ends up in a certified product. And you can clarify this later. Or, do you want to do it now?

Zea Sonnabend: A non-certified handler cannot make a product labeled organic on the front label.

Jay Feldman: Right. We are talking about the ingredient, ingredient B, put into a certified organic product. That is what this chart is talking about. Not the... The product itself cannot be labeled organic, we understand that. It can be put into...

Zea Sonnabend: A made with organic.

Jay Feldman: Right, it can be into a product that is made with organic. So, the question is, should we try to fix that? Or, does it need fixing? And that is what we are going to hear from later today, I guess. The solution being proposed here is that whether it is ag or non-ag, if it is extracted with a VSS, whoever handles it, it needs to, you know, it needs to either get on the list or it should not be used, or, we have to have some process of keeping it out of organic. Or, some people believe we need a process of keeping it out of organically-labeled products.

Okay. We are obviously not going to get through all of this. So, that was the main distinction I think I wanted to bring up between this issue and some of the other issues that have been raised by the Program this morning. But, I just want to provide you with the OTA response, which we will hear directly hopefully from them, and OMRI. OTA says that this does not make sense because non-agricultural ingredients are not identified as organic. And we will talk about what we are trying to identify as organic. But, OTA says it is important to note that the heading of 605 refers to ingredients only. Under this section, a certified handler is allowed to use the listed substance referred to as ingredients in the 5% or 30% of the certified product. So, it would be the "organic" or "made with organic" label. The reference to 270(c)(2) is significant to the handler of a certified operation because it clarifies that synthetic solvents and synthetic processing aids used in or on products labeled "100% organic", "organic", or "made with", must also be on 605 of the National List.

I am going to stop there because I want to run quickly through the significant discussion piece as well. And I think the rest of this presentation overlaps, to some degree, with the significant issue, which may be a non-issue, given that the NOP believes that we may not

need to be concerned about that word. I am going to be really interested to hear from the industry side on whether they feel comfortable with dropping the significant language.

Jennifer Taylor: Excuse me. Excuse me, Jay. The Program has a statement.

Jay Feldman: Okay.

Emily Brown-Rosen: We would just like to reiterate what was said before in Lisa's presentation about the use of synthetic solvents under 270(c). So basically... And I think the little diagram there which made a distinction between the certified handler and non-certified handler was pretty confusing and inaccurate. Basically, a non-organic ingredient, you can if it is on 605 and is reviewed by the National Organic Standards Board, you consider solvents in the manufacturing process. There is no prohibition – [cough] excuse me [whisper: could you get me some water?] – there is no prohibition if you review it as part of the process, if you do want to restrict solvents in a non-organic, non-agricultural substances on 605, then you need to annotate that on the list. In non-organic agricultural ingredients and made with organic products, so, in the 30%, they are not restricted either. They can have been produced with synthetic solvents. This is the way the rule is written now.

Non-organic ingredients that are listed on 606 for use in organic products, they may have been produced also with synthetic solvents or processing aids unless the NOSB specifically annotates it. So, the NOSB has moved to annotate things like colors on 606. So, that is the framework we are working with now. So, you know, we do not need to make suppositions about if the handler is certified or not. That does not seem relevant.

Jay Feldman: Right. Well, what this discussion document is trying to get at is whether this should be a uniform restriction. This was the question that was asked in using volatile synthetic substances in extraction. And, if there was to be a uniform prohibition or restriction, we would not, as a Board, be negotiating between hexane and some other equally hazardous synthetic, volatile synthetic organic - It would not matter who... - material. It would not matter who handled it, whether it was a certified handler or was a non-certified handler.

There is a distinction in the law, which has really not been fully vetted, that allows ingredients in organically labeled or certified products - these are heritage ingredients, precursor ingredients - that have been extracted with volatile synthetic organic. And I think it, we experienced, I experienced a frustration on this Board in getting to a discussion point, finding out that there was a long list of volatile organic, or volatile synthetic substances utilized in the production of this ingredient, even though there was another equally effective ingredient that was produced without that long list of volatile synthetics.

And we, yeah, we checked one off on the list. But, what this discussion document was asking the community is, whether we could come up with a uniform way, across the board, of addressing the use of volatile synthetic substances. So, yes, it is confusing. But,



this is a reality, unfortunately. And the distinctions that are in the rule, I think, make it confusing. What we could discuss here today is whether we could eliminate those distinctions, so that the consumers know that volatile synthetic substances are either not used or prohibited, or are used in some way that this Board deems acceptable in a uniform type of way. And I hope we can discuss that further as we move through this.

But, I have four minutes to go through the other document, which I am obviously not going to get through. But, I do not want to hold this up. So, thank you for that, and I hope that we can discuss it further, Emily. I appreciate that comment.

So, again, what we are faced with as a Board is the fact that we have a policy on the books that is very clearly stated that chemical, that chemical change is, or synthetic is defined, synthetic substance is defined by two elements. One is whether there is chemical change, and two whether there is a significant residue of a synthetic in that product that we are reviewing. Those are two elements.

And, the Program, this is the first I am hearing of this, so I may have it a little bit wrong, of course, but the Program is suggesting that we can define chemical change, certainly, and that instead of specifically identifying some significant residue that would deem a product synthetic. So let me say that again, instead of using the term significant residue in a product we determine to be organic, that we can determine that there is some language we could utilize that identifies removal of that product to the extent that it does not have a technical or functional effect. Okay? So, that is the substitution for significant. I am going to be really interested to hear what the industry has to say about that.

This presentation was really an attempt to provide for the Board the background history, especially since we have many new Board members here. But, you are getting a sense of the context, I hope, that this Board passed a policy in 2009. The Board came back, the Materials Committee came back to the Board in 2010 and asked for a definition of synthetic. We were unable to reach a decisive vote on that question. And, we were left with this question in the Materials Committee as to whether we should take this up again, given that we were unable to resolve it in 2010, again, consulted the program, and the program said, if you want to keep beating your head against the wall, have at it. But, that is what we did, instead of coming back with a proposal, we came back with a discussion document that really opened this issue up, again. And, I think we will hear from OMRI later in terms of the, in terms of the process that they use.

And, I just want to show you quickly here. We will see this flow chart. I hope you all saw this in Lindsay's testimony from OMRI, how they, and a hope that she can walk us through this process, because I think it will help us to understand this concept of removal to a functional or technical or functional effect level. But, at the end of the day, there is no distinction in this flow chart that OMRI uses on this question of significant. It is simply a review. Now, I wonder whether we, as a Board, would need to revise our policy on this. And, I would be interested again to hear from the industry on, and the people associated with the Materials Working Group on this. So, I will leave it there, Mr. Chair, Madam Chair, and I appreciate the time to go through these.

Comment [JMS6]: 01:30:00

Jennifer Taylor: Thank you, Jay. Are there any questions? Okay. Thank you. I believe we need to proceed with the public comment period. Is Grace here? Grace Marroquin? Please come up.

Unknown Male: [Open mic; Inaudible]

Jennifer Taylor: Followed by Lindsay Fernandez-Salvador. [Inaudible]

Unknown Male: [Open mic; Inaudible]

Grace Marroquin: Okay. My name is Grace Marroquin, and I am President and CEO of Marroquin Organic international. We are an organic and non-GMO ingredient supplier. We have been working with farmers and suppliers from around the world for the last 22 years.

Today, I am here to talk about yeast. Naw, I am just kidding. I promised I would come back once our yeast petition had moved through the Board. Today, I am here to give the NOSB and Program a progress report on the results of some decisions and changes.

I want to say thank you for doing the right thing with the organic lecithin. Rule change went into effect February of 2012. I am happy to report that, as of today, there are now three suppliers of organic lecithin and, in six to twelve months, there may be another two. Bravo. This is how it is supposed to work. The petitioner was not so happy, but as he shared with me, it is the pioneers that take the arrows and the settlers that get the land.

Our yeast petition took almost 7 years to move through the review process. Finally, an annotation went into effect and stated that, if yeast was being used for human consumption, organic yeast must be used if available. This rule change goes into effect October 2012. As expected, I am now pulling an arrow out of my back, because another yeast company is close to launching organic yeast.

I applaud the Board and Program for taking the steps to uphold the principles of organic preference, which results in the growth of the organic industry, supports continuous improvement, and in the end, benefits and supports our organic farmers and consumers and the planet.

With that said, I want to recommend that the Board exercise caution when reviewing ingredients to be taken off the National List. Many of us can appreciate the complexity of reviewing materials and applying the criteria required by OFPA and the NOP regulations. We urge you not to take an overly proscriptive approach and be sure that alternatives are widely applicable and viable when considering renewal or approval of materials.

Thirdly, research and evaluate the impact of the removal of one ingredient will have on the farmers and on the trade. Please keep in mind that you are not just removing one

ingredient, but there is a watershed effect, such as in the case of carrageenan. If there are no alternatives and if companies cannot make a final product organic, they may downgrade the product. This could affect sales of organic sugars, soybeans, rice, almonds, milk and fruits, just to name a few. And who do you think loses besides the manufacturers? Yup. It is going to be the farmers, and consumers, and in the end, it is the planet. Please hold on decisions until you are truly sure you are making the right decision.

The use of annotations can be positive actions towards continuous improvement. It is not fair to hold organic ingredients in limbo while we decide the meaning of life, ag versus non-ag, synthetic versus non-synthetic. Flavors are an example of an ingredient being held in limbo. Keep up your efforts to develop balanced, pragmatic recommendations and come to decisions that stimulate growth and integrity within the organic sector. Please do not let the perfect be the enemy of the good. The future of the planet is at stake. The future generations will appreciate –or suffer – our legacy. Thank you for all your hard work and consideration.

And I may add three minutes is way too hard to do this. It is stressful for us slow talkers. Thank you.

Jennifer Taylor: Thank you. Any questions? Thanks. [Inaudible] Could Dragon please come up? Thank you.

Lindsay Fernandez-Salvador: Thanks. Well, first of all, I would like to say thank you for providing this little stepstool for us short people. [Laughing] I did not want to be a bobble head here.

Unknown Male: [Laughing]

Lindsay Fernandez-Salvador: While they are getting up my presentation, that is supposed to start with a comic so that we can get through this difficult stuff with laughter, I will introduce myself.

My name is Lindsay Fernandez-Salvador. I am the program director at OMRI. I wanted to talk a little bit about significant residues and about how OMRI currently thinks about significant residues. And I also see OMRI's role today as providing real-life examples so that some of you that are not familiar with this type of process and thinking can wrap your head around these really difficult complex issues. Next.

This may look complicated, but this is how I train a lot of industry members about how to do material review, what material review looks like. Thank you. We are not going to go through this entire thing, but I wanted to show it to you to show that there is an actual step-by-step process that one can take to determine how significant residues come into play during material review and during the process in general. And I am going to give an example of how we look at it in two different aspects.

So we are really going to just use question number one there: are there ingredients within ingredients, and follow that flowchart through to the end.

How do you -- I really do not know. I cannot see this. Sorry. Thanks. Okay, next, thanks. Oh, that is a happy thing. I am so [Laughing] Just go through to the next slide. Just keep clicking. Sorry, folks. I completely forgot about that animation. Okay.

So, in the one example, feathermeal is used as a compost feedstock. And the feathermeal has potassium sorbate. It is a preservative. Okay? So are there ingredients within ingredients? The answer is yes. Is that ingredient synthetic on the National List? Is potassium sorbate on the National List? No, and it is not non-synthetic. So, you want to go to number two and you ask, is it present in the final product? If it is using as a compost feedstock, it is going to be consumed during the composting process. That is called a removal step for OMRI, so we would move on to question number two next.

Yeah. Okay. Thanks. Okay, and that is it. Keep going. Sorry, folks. I completely forgot about this.

So, the removal step can be anything, based on chemical properties of the substance. Right? So, it would not be an analysis after the removal step. We would not look at the lab analysis for most cases. So, it could be evaporation, acid-base precipitation; it could be consumption; it could be metabolism by microbes; washing. A lot of different things act as removal steps for lots of different materials. It is based on knowledge of the material, plus the specific manufacturing process, which it is being removed from. And, it requires deep chemical knowledge of chemistry, biology, and geology. I did not get to go through that. Thanks.

So, this is just feathermeal as a compost, as an ingredient in...

I have got to stop, sorry. I cannot get through this. I am sorry. So we can go through it in general if people want to ask me about it later. Sorry.

Jennifer Taylor: Okay. Thank you. Jay?

Jay Feldman: Could you continue?

Lindsay Fernandez-Salvador: Could I continue? Okay, thanks.

So, feathermeal used as an ingredient in a blended fertilizer: If it is being mixed into a blended fertilizer, there is no removal step for that potassium sorbate. So therefore, it is just been diluted down. So, OMRI would currently prohibit this particular ingredient, okay, or this particular product. Because, it is not removed, it is in a presence of 4 to 5 parts per million. So, the next slide.

So, our really significant question for us is, is 4 to 5 parts per million significant? Is it a significant residue? And so, what we really want you to take home today is that OMRI

does support evaluating residues based on the functional and technical effect on the final product. So if you were to look at both types of compost feed stock versus blended fertilizer with feathermeal, both of those would have insignificant residues based on this new approach of looking at it from a functional and technical effect on the final product.

I think that is it. Yeah. Well, those are take-homes from other things. So, I won't spend time on that.

Jennifer Taylor: Thank you. Zea? Do you still have your question?

Zea Sonnabend: It was the same as Jay's, to just ask Lindsay to continue.

Jennifer Taylor: Oh, okay. Thank you. Max?

Mac Stone: Lindsay, can you give me a visual of a part per million? Like, one dollar bill and a million would be a stack how high? Or one marble would fill this room? Do you have some sort of visual on what parts per million looks like?

Lindsay Fernandez-Salvador: Yeah, it is a needle in a haystack. [Laughing]

Crowd: [Laughing]

Jennifer Taylor: Okay, I am sorry. Jay? Thank you.

Jay Feldman: So do we need a definition of technical and functional effect? Is there something that you reference when you use those terms?

Lindsay Fernandez-Salvador: Well, currently we do not use these terms, okay. But if we were to use these terms, we would look at the technical and functional effect of that particular ingredient. So, in the case of potassium sorbate, say, the functional effect is a preservative. So if it was having a preservation effect in the final blended fertilizer ingredient, then we would prohibit it. But in that case, at 4 to 5 parts per million, that is just below industry standard for any preserving effect.

Unknown Female: [Inaudible whispering]

Jay Feldman: Okay, so it does not apply to a technical effect, say, on environmental impacts or human health effects? I mean, you know, from the consumer's perspective, there is a concern about an effect to the organism, to... Whether you have a visual of one drop in an Olympic size swimming pool or the Atlantic Ocean, you know, science can hopefully now tell us that the exposure level has some effect. There may be uncertainties in there, but you know, we... To answer the consumer question, I understand the issue of effect on the product's operation or, you know, how it functions, but... Do you see what I am getting at? Do we have a way of evaluating the effect on organisms and the environment?

Lindsay Fernandez-Salvador: That... You know, I really cannot answer that question because currently that is not how we review. I am just saying that we could support that going forward. If that was part of the technical and functional effect, that adds a significant level of complexity that would require some significant research on our behalf to determine, what are these substances that have some environmental effect, and at what level do they have that environmental effect?

Jennifer Taylor: Yes, Zea?

Zea Sonnabend: Lindsay, would you describe how OMRI would treat the same 4 or 5 parts per million of potassium sorbate if you were to review it for a handling material, say an enzyme used in processing, where that preservative would fall under the other ingredients?

Lindsay Fernandez-Salvador: Yeah. That is a good question. Currently, OMRI... Because they are a little bit different in the handling ingredients the way that the standard of identity works for those sorts of types of materials, we understand that a lot of time there are other ingredients in there. So, what OMRI does is that we look back to the TAP review or the technical review, and we look at what the NOSB reviewed and we try to understand, were there other ingredients as part of the review. And, if the NOSB did in fact review preservatives as part of that ingredient, of enzymes or possibly agricultural ingredients, and they chose not to annotate that material, then we will allow those other ingredients.

But, if the technical review does not make any mention of other ingredients, like the enzyme technical review does not, we would not allow that material, that extra other ingredient.

Jennifer Taylor: Any other questions? Jay?

Jay Feldman: I am really trying to understand this handler issue, and the ingredient within ingredient, which I do not think is still clear to many of us.

Are there indeed two paths one can go through to get into an organic, to be an ingredient in an organic product? One through a certified handler, and one through a non-certified handler? And, are those two paths subject to different degrees of review and allowance at the end of the day in a certified organic product or made with?

Comment [JMS7]: 01:45:00

Lindsay Fernandez-Salvador: I am sure there is. I am sure there is because certifiers are human beings. They are all human beings reviewing these materials and one certifier may look at something and then put it differently. So I am sure that there are different pathways.

Jay Feldman: Yes, I mean, I guess I would like to get at this question of whether this is a real issue or not, that there could be a need for uniformity across the system of review when it comes to volatile synthetic substances. That indeed, we do not have uniformity now, in terms of how we review ingredients within ingredients, and that for us as a Board to review each volatile synthetic every time it comes up in every material before handling or

crops or whatever. It seems to me we could as a community agree that regardless of how it is used and applied, you know, used in extraction for non-ag or ag, that at the end of the day, even if you go to the functional technical equivalent definition, hopefully applying to adverse impacts on organisms and environment in addition to impacts on the functional effect in the product itself, even if we were to agree on that, could not we still benefit from a uniform definition and application of VSS review and restriction across the board? Ag, non-ag.

Miles McEvoy: Just to clarify, there is one standard, one regulation. We expect the certifiers to follow that for all ingredients, whether it is coming through a certified handler or there is an intermediate non-certified handler involved. There is one standard. There may be different ways that certifiers are conducting their reviews, but, there is one standard. They are expected to follow that. So if there is inconsistency, we will work with the certifiers to ensure it is a consistent process. But, there is not two ways that ingredients are allowed in organic products. There is only one way.

Jay Feldman: Do you believe that this Board should be reviewing individual volatile synthetic substances and each handling product as we looked at one of many in DHA, which seemed difficult and confusing and unsatisfying, in terms of the end result? Do you think there is a better way of creating some uniformity in how we look at volatile synthetic substances?

Miles McEvoy: As we wrote to the Board in the fall, we want the Board to work on a comprehensive policy on other ingredients, which would include synthetic solvents that are used in creating products that are on 605. So, yes, it is important to have a comprehensive way of approaching other ingredients on 605 materials. It really has not been done in the past. It has been a case-by-case basis. In the meantime, you need to look at it on a case-by-case basis as you are reviewing substances for either Sunset or addition or withdraw from the National List. So, both are true. You should look at other ingredients for all categories. Comprehensive policy on that is also important.

Jay Feldman: Okay, well that helps because I did not realize, I was not clear that solvent or extractants were included in the other ingredients discussion. And hopefully, we can put that on the work plan for the Board. Or someone said it might be on the work plan already. So thank you.

Jennifer Taylor: Thank you. Dragan. Could Robin please come forward?

Dragan Macura: My name is Dragan Macura. I am the Chief Science Officer and part owner of AgroThrive Incorporated. We are a small organic fertilizer manufacturer that can very much be affected by the decision on the significant residues that is in front of you. Could you have the slide please?

AgroThrive Incorporated produces organic fertilizers from food industry and other organic wastes. We are very small, seven employees in all, including myself. We pioneered the food safety and organic integrity programs in our industry, advocating full

transparency, plant audits, and a clear way out of the wilderness that our industry was in only a few years ago.

We must accept waste streams of organic materials as they come, contaminated or not. We apply microbial and enzymatic digestion technologies to convert an environmental hazard – that is organic waste – to a valuable agricultural commodity – that is organic fertilizer – thereby, significantly improve the impact of the organic waste on the environment.

Our operation takes organic wastes and other ends, that often, that often end up in the landfills, and converts them to materials that are excellent, that are excellent fertilizers and improve, that improve plant and soil health. Fertilizers drive, drive food and fiber production, organic and conventional. NOSB decision on significant residues will have huge impact on our business, thus, I offer several points of, for consideration when deliberating over this very important issue. Next, please.

Consider the system in question. Feedstock for composting or organic fertilizer manufacturing process should be looked at differently than the food for human consumption. Number two.

Consider mitigating or amplifying circumstances. Is there anything in the process that renders the substance in question more or less dangerous? For example, composting and or microbial enzymatic digestion will often inactivate the offending substances. If so, allow for the transformation or decontamination. Is anything in the process of making the material more dangerous? If so, take that into account. Number three.

Consider the point of significant engagement as major point of evaluation. At what point in the process and at what concentration does the offending material become dangerous to the environment, handlers or consumers? Consider the point of significant engagement at the point of food consumption. Next, please.

Do not needlessly reduce, this last one, our feedstock options as we already have a severe shortage of organic inputs. Please remember, everything that is organic, has to be fertilized first. We need more organic fertilizers, not less, in order to grow the whole organic industry.

Jennifer Taylor: Thank you. Any questions? Thank you. Could Gwendolyn please come up?

Robin Seydel: Good morning, my name is Robin Seydel. I am the Membership and Community Development Manager of La Montanita, a consumer co-op owned by over 17,300 New Mexicans. And I am a member and supporter of Cornucopia, NOC, the Wild Farm Alliance, Beyond Pesticides, Food and Water, and the Center for Food Safety. And RAFI too.

A businessperson, I recognize that you are in the weeds of rule-making minutia, and that some of your deliberations are beyond my expertise. I urge the NOSB and the NOP to take the technical testimony of the above mentioned organizations as my



recommendations, but, would like to thank you for the discussion of extractors and solvents.

The current rule which prohibits the use of synthetic volatile solvents only by certified organic handlers is extremely misleading to consumers who rightfully expect all ingredients in a certified organic product be produced without their use. Cornucopia notes the annotations to prohibit specific volatile synthetic solvents for some materials on the National List, but not for others, is inconsistent and adds to confusion among consumers. The prohibition of hexane and Martek DHA oil production, but continued use of synthetic isopropyl alcohol, makes no sense and shows why clarification is needed in the rule.

Please support the definition of volatile synthetic solvent as a synthetic chemical with a boiling point less than 287 degrees Celsius that can dissolve another substance. Cornucopia points out language in the rule prohibiting certified organic handlers from using volatile synthetic solvents but allowing them to purchase ingredients from non-certified handlers who do use volatile synthetic solvents is a loophole with serious implications for organic integrity. Organic products should be produced without the use of synthetic volatile solvents and this prohibition should apply to all ingredients. Please support the change to the language in the rule as proposed by the above groups.

Any residue of synthetic is significant with significant defined as any known level of a synthetic substance in the final material, or in the environment as a result of manufacture, use and disposal, and should trigger review. Any materials that are produced with the use of synthetics must be classified as synthetics to trigger the required NOSB review under OFPA.

Mr. McEvoy yesterday used the phrase consumer trust in organics. Thank you, very much. I could not agree more. Thanks to my decades of work in the retail organic food sector, I know this trust is based on consumer perception of the safe process and materials inherent in organic production.

As market research shows, organic consumers are a highly educated and discerning population. Every time you approve a possible carcinogen or an endocrine disrupting chemical or a genetically engineered material for use in organics, you erode that trust. And hence, threaten the vitality and viability of all our organic businesses. Because, sooner or later, we, consumers will find out that we have not met their expectations. And, as any business person will tell you, not meeting consumer expectations is not good for business.

I most respectfully request that in all of your deliberations, you go slow, as they affect all of us. You hold ourselves to the highest standard of ethics, integrity and transparency in the face of any and all political or financial pressures, because, our shared organic future is at stake.

Sorry I went a little over. But, three minutes, just could not get it in in three minutes.  
Sorry.

Jennifer Taylor: Thank you. Any questions? Jay.

Jay Feldman: Welcome, real consumer.

Robin Seydel: Thank you. It is a pleasure to be here. Thank you all for the opportunity to be here.

Jay Feldman: And how many members are part of your co-op?

Robin Seydel: 17,300. We have five locations in New Mexico. We work with 900 local producers around the state and have a food shed warehouse that runs trucks every day. 20% of everything we purchase and sell is local and organic, or organic.

Jay Feldman: I know you have been around some of the meanings of the last couple of days, and sessions. You know, you may have heard people say that if you do this to organic or that to organic, if you restrict this input or that input, you will restrict the growth of organic. You will hurt organic. You will hurt our ability as a community to grow and expand. How does that comment sit with you? And how would you respond to that? Or, how do you think I should respond to that as a NOSB member?

Robin Seydel: It is a really good question, Jay. And I understand the viewpoint of people who say that we will limit the growth of organic. But, I think that if we do not maintain the integrity of organic, as I said in my comments, consumers will know. And we are already seeing consumers say, oh, organic, you know they allow all of this stuff in it now. It is not really organic any more. I am not going to buy organic. I am going to go local or I am going to go sustainable because organic does not mean anything anymore.

So, I think, you know, we... it is a tightrope that we walk. It is a really fine line. And I would urge this committee to maintain the strictest standards. Go really slow. We have to be careful. You know the carrageenan thing. People will find out. In our next co-op newsletter that goes out to all those consumers, I feel held to my integrity as a person and in our organization to let them know that carrageenan is a possible human carcinogen, and that if they see that in the ingredient list in a certified organic product, they shouldn't buy it if they care.

And so, I think we have to be really careful. And I think of many of our organizations and many of the people here feel strongly about that, that we must maintain our integrity, because if we do not, we have nothing. And, people will find out, and if they do not trust us as Mr. McEvoy, you know, most astutely pointed out, then we have nothing when we lose that trust. And I, for one, am all for maintaining that trust as we look at these solvents, and look at these chemicals and these possible carcinogens and these additives and, as you pointed out, these ingredients within the ingredients. That was totally new to me.

Comment [JMS8]: 02:00:00

Jennifer Taylor: Okay, thank you. Any other questions? Thank you again.

Robin Seydel: You are welcome.

Jennifer Taylor: Gwendolyn, please come forward. And followed by Sarah? Sarah Ann.

Gwendolyn Wyard: Thank you. Lisa, are you my timekeeper? Okay. I want to get ready to set and go here. So I can just give myself a moment to time, because I really tried to time this to stick right to three minutes. Okay, one, two, three. Go.

Good morning, Mr. Chairman, NOSB board members, NOP staff, and ladies and gentlemen of the gallery. My name is Gwendolyn Wyard. I am the Associate Director for Organic Standards and Industry Outreach for the Organic Trade Association. And, for the new members, welcome. I am also co-chair of the Materials Working Group and I serve on a OMRI Board of Directors. I have been in certification for 15 years with a focus on materials, and I have a food science degree. My comments today are on behalf of OTA, representing businesses across 49 states, and we represent over 6500 members. OTA is respect – Okay, next slide.

OTA is respectfully asking the Board to please pull back the discussion documents on synthetic solvents and extractants and significant residues, and reserve any further work on these topics until after the NOP has released draft guidance on classification of materials. The questions raised in both discussion documents address very critical yet very specific challenges that are housed within the larger classification of materials discussion that led to a recommendation that was finally passed in 2010 after ten years of NOSB, NOP and public collaboration. We are concerned about the discourse and the confusion that may be created, especially for the new Board members, if these topics are revisited without the full context of the 2010 recommendation, and the subsequent NOP draft guidance. So, let's call the 2010 recommendation the whole pie. Next slide please.

So here, this is really intended to overwhelm you. It is only half the pie. And you can see the arrow in the red box is pointing to a couple questions, and those couple questions are what resulted in the discussion documents that are coming out of the Materials Committee. This is a decision tree, the tree that was drafted by NOP in 2005. It is being re-worked. This is not the decision tree that is coming out of the draft guidance from NOP. I want to be clear. We believe it is confusing and counterproductive to discuss these topics without understanding how they fit into the whole pie, and then how that whole pie fits into the feast, if you will, the entire evaluation of materials in general both at the NOSB level as well as at the MRO and certifier level. In our comments, we took the opportunity to answer the questions by reviewing the work that has been completed since 2005. Would you go ahead and just flip through those next two slides?

If you just go through, that is a lineup of all the documents that have been produced since 2005. Go onto the next one. And I hope that you carefully review all of those documents

and, for the new members, that you really take the time to study this topic, because it is critical to your rule, obviously, as the NOP presented this morning.

This is a picture of some products here – chocolate milk, chocolate pudding. All of the ingredients that you see up here, they are hydrocholates. They are gums. We see that they have similar functionality. They are produced in a very similar fashion although we see them placed on the National List as non-synthetic, synthetic and agricultural. Their placement seems to be very random so we really urge the Board to hold back on classifying these materials. Also relevant to these discussion materials, hold back on classifying them and take the opportunity to look at all these materials as examples and deal with them all at once and see what – and this is after the NOP has released their draft guidance.

And then I just have a couple take-home messages that if you just move on to the next slide.

We really urge the Board to request a training on classification materials. And, urge the Board and thank the NOP for the work they have done on putting together draft guidance and we look forward to that coming out and all of us collectively as a community commenting on that draft guidance. Thank you very much.

Jennifer Taylor: Thank you. Any questions?

Gwendolyn Wyard: Oh, could you put that slide back up there?

Jennifer Taylor: Okay.

Gwendolyn Wyard: Could you... Oh, thank you. Questions? Yes, Jay?

Jay Feldman: I am just interested in your response to what you heard this morning from the Program, especially on the issue of significant and the functional and technical effect level or whatever.

Gwendolyn Wyard: Well, I am absolutely pleased. I am excited about what we heard this morning. It is great to see the progress that the program has made. I think that, as they pointed out, they did not use the term significant. But, certainly they have addressed the question of the use of synthetic processing aids and synthetic volatile solvents. And, this idea of a removal step and a technical or functional effect, as we also heard from Lindsay, that is consistent with the practice of OMRI, which as we know, many, many of the materials that out there in use today have been reviewed by OMRI and that is the criteria that they have been applying. So, I appreciate what is being presented because it is consistent with practice, which I think is very important.

They have also, it is draft guidance, and so, they have picked a path, and so it provides us with a great opportunity to comment on what they have put out there. So, that is what I

am really looking forward to is really, you know, all of us being able to take a look at these questions in that greater context.

Technical or functional effect, I think there is regulatory references that we will be able to look to when we are talking about crop materials. We have, we have certain regulations in place. We have the, we have the inerts to look to. When we get into handling materials, we have regulatory references that are set, that determine, you know, whether or not a certain material has to be declared on the, an ingredient statement. There also have undergone a number of evaluations from FDA, USDA, in terms of their safety. So I think we have a lot to look at.

Certainly, there is a refinement. And I can, you know, I can see where we may have to come up with some definitions of technical or functional, or at least lay out specifically what regulatory references are out there that we can look to.

But, I think that we are, we are going in the right direction and we are closer than we have ever been before.

Jennifer Taylor: Thank you. Jay.

Jay Feldman: Just a follow-up to that. You know, as you have heard from the consumer side, the environmental side, the issue of studying effect, at least as I understand, the responsibility of this Board is to look at effects on health, on human health, on biodiversity, on in this case we are talking about a food, a processed food commodity, you could be talking about, I guess, an extracted material that is a crop material. But, the consumer message that I am hearing is that the expectation is that these materials be reviewed for an effect through the National List process, and that anything that would circumvent that review would be problematic. Do you, as an industry representative, are you concerned that the people that ultimately are needed to make this industry grow are raising concerns that some ingredients may not be subject to full review for their human health, biodiversity, environmental effects?

Gwendolyn Wyard: So, in this situation, OMRI would be reviewing a otherwise non-synthetic material. And, but, they are going through an evaluation of synthetic or non-synthetic. They see that a synthetic processing aid is being used. It is not just a volatile synthetic solvent, it is any synthetic that is used in the process. And, it is used during the process. It does not remain in the product in a, at a sig-, or have a technical or functional effect.

I think that we have to take into consideration the consequence of what we are really talking about. I mean, we cannot separate out crop materials from handling materials. If it remains in the product at any known level, it is going to be there. So, that would also include pyrethrins. I do not know how you are going to be able to separate out, and if you want, if you want to drill down to that level, I think we just need to, you know, if this is the concern, if this is where the organic sector wants to go, then we will see a lot of materials go away.

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And I think we just need to be prepared for that outcome if that is the direction that we want to go to. I do not think that, I think the law requires that synthetic materials are, be put, be placed on the National List, but, the situation we are talking about here is whether it is synthetic or non-synthetic. And if a synthetic is used during this process, it has not resulted, we do not have a synthetic process so it is not subject to review. So, I think if we just stick to the law and the regulations, we have not violated anything in OFPA, as they are currently written.

Jennifer Taylor: Any further questions? John? John? No? Okay. Thank you, Gwendolyn.

Gwendolyn Wyard: Okay. Thank you.

Jennifer Taylor: Barry?

Barry Flamm: We will take a 15 minute break now and be back at 10:30 am.

[BREAK]

Comment [JMS9]: 02:11:00

Crowd: [Background noise; Indiscernible conversations]

Barry Flamm: The Board is back in session. Jennifer Taylor, please continue with your committee business.

Comment [JMS10]: 02:38:25

Jennifer Taylor: Thank you, Barry. We have a proposal before us that needs a motion. Go ahead. Yes, Zea?

Zea Sonnabend: I would like to make the motion to approve the recommendation for research priorities as posted.

Unknown Male: Second.

Wendy Fulwider: Second.

Unknown Male: [Indiscernible]

Wendy Fulwider: Second.

Barry Flamm: There is a motion on the floor to approve - motion and second - to approve the research proposal. Is there ---

Zea Sonnabend: We should call for---

Barry Flamm: -- any discussion?

Zea Sonnabend: Yeah, discussion.

Barry Flamm: Got any questions from the Board?

Wendy Fulwider: Colehour.

Barry Flamm: If not, we will proceed with voting.

Wendy Fulwider: Colehour has a question, Barry.

Colehour Bondera: Yes, just for the sake of verification. During the presentation process, there were a few words added to number six, and what has been moved did not include that. And I wanted to know if it is going to be modified at this time or not as a motion.

Zea Sonnabend: Nick did not really add words. He suggested something conceptually, and then I asked him about wording changes and he said he did not have any at this time.

Oh, Myles. Myles did have words. Yes, sorry. Thank you for that correction. So with the correction to, the motion then is, with a correction to point number six as explained in when we were talking about it before, which was to send it to the NOP and they will disseminate it. Does the second agree with that wording change?

Wendy Fulwider: Yes, I do.

Zea Sonnabend: Okay. Thank you. Sorry, Colehour.

Colehour Bondera: Thank you.

Barry Flamm: Thank you. Any other questions or discussion? If not, we will proceed with voting. First of all, is there any conflict of interest among the Board? Anybody want to declare a conflict of interest? Hearing none, we will proceed with the vote. Calvin, would you start please?

Calvin Walker: Yes.

The Entire NOSB Board : Yes. Yes. Yes. Yes. Yes. Yes. Yes, sir. Yes. Yes. Yes.

Barry Flamm: The chair votes yes.

The Entire NOSB Board: Yes. Yes.

Barry Flamm: Excuse me. I will revote and be last. I vote yes. The motion passes. 15 yeses, and zero noes.

Unknown Male: Excuse me.

Zea Sonnabend: Barry. Correction, 14 yeses, zero noes, one absent.

Unknown Female: Nick is missing.

Barry Flamm: Thank you. I did not know he was gone. So, the record should be corrected, it is 14 yeses, and zero noes, 1 absent.

Nick Maravell: I just returned. [Indiscernible] Okay, I can record my vote if you would like.

Barry Flamm: Okay, that completes the Materials work. Next on our agenda is Crops Committee and Jay Feldman will take over.

Jay Feldman: Thank you all. We are going to discuss the, an item for which we will be voting, which is the List 3 Inerts Sunset - List three inerts and passive pheromone dispensers. Hopefully, everybody has had a chance to look at this but I am going to run through the background on this and then we will get an update from Emily on the task force, the Inerts Task Force.

In terms of where the actual rule is now, 601, synthetic substances allowed for use in organic crop production. This is where the inerts fits in as one of the list of materials. (m) As a synthetic inert ingredient classified by EPA for use with non-synthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitation on the use of such substances. And, it is this next section that we are looking at. EPA List 3: Inerts of unknown toxicity for use only in passive pheromone dispensers.

So, here is some background on this, just so you, we all are understanding where this has been over the years. This has been an issue that has gotten significant amount of discussion on the Board. As you probably know, OFPA, in establishing the National List, creates a list of exemptions for prohibited substances in organic production and handling, and lists the categories of substances that must be reviewed by the NOSB if they are to be listed. Section 2118(c)(1)(B)(i) – little i – creates a category of active ingredients that may be allowed, and (B)(ii) – little 2 i – creates a category of inerts that may be allowed, those found by EPA to be, to not be of toxic, inerts of toxicological concern. The categories of active and inert ingredients establish an NOSB duty to review substances.

Comment [JMS11]: 02:45:00

Okay. So, here is where the Board started getting engaged on this issue back in 1999. The NOSB recommended this: inert ingredients on EPA's Lists 1 and 2 shall be prohibited by use, or for use in organic production and handling effective on the date of implementation of the final rule. This goes way back. Synthetic inerts on EPA's List 3 shall be prohibited if not specifically approved by NOSB. The approval process will be completed and published by January 2002.

Any inert currently in use in organic production that is not approved by the NOSB will be banned within 18 months after the review is completed and published. To that goal, inerts on EPA List 3 used in products that have active ingredients approved for organic production shall be reviewed by the NOSB on a case-by-case basis for possible inclusion on the National List.



In October of 2002, the Board passed the motion to list pheromones, which results in a current listing for List 3 Inerts which we are voting on today. At the same meeting, the Board also passed a motion temporarily allowing the continued listing of certain List 3 inerts. The NOSB recommends that any List 3 inert material forwarded for a technical review be allowed for use until that material is approved or prohibited by the Secretary of Agriculture.

When the List 3 inerts came up for Sunset in 2007, the summary of the recommendation said: future petitions to add, remove or renew an inert ingredient to the National List will need to reference a specific inert ingredient. That was the Board policy at the time.

In then the 2007 recommendation was affirmed again in 2008 in presenting the discussion paper on List 4 inerts in November 2008, NOSB member Gerald Davis said, about List 3 inerts used in passive pheromones dispensers, quote, they – and this is List 3 inerts – need to be petitioned individually and are subject to regular Sunset re-evaluation that has already been in place as an NOP policy for a couple years now, since we were first notified about the EPA change.

So there was a notification that came out of from EPA that they were dispensing with the list process. So these lists that we actually reference no longer exist at EPA any longer. They have just, they are just put them all together in one list and class, evaluate them as other ingredients, which, actually in my other, in my other world, I have been advocating for for many years. So, we view that as a positive change. And part of what we are trying to do here is bring ourselves into compliance with this new world where we are not listing inert ingredients any longer in this list format.

At this point, I am going to turn it over to Emily who will talk about how we are trying to deal with that issue overall in the Working Group on Inerts.

Emily Brown-Rosen: Thanks, Jay. I am just going to quickly update what the Inerts Working Group has been doing since the last meeting in December. So, this is similar PowerPoint. I will just skip through a few of these slides, but I have updated a couple points here I wanted everybody to see.

So, this is our Inerts Working Group. We now have Dr. Lisa Brines, myself from the NOP, from the EPA, we have Chris Pfeifer and Kerry Leifer, and from NOSB Jay and Zea Sonnabend is our new member. So I am going to skip this background because Jay just pretty much went through this.

Current timeline: We are working on a proposal, we have been, you know, it is working for a couple of years on this collecting information and trying to figure out options. But, we hope to have a proposal to give to the Crops Committee by this September. Then, NOSB will work with that proposal and develop a formal recommend, or, the Crops Committee will develop a formal recommendation for the full Board. Then, NOP needs to receive a proposal from NOSB so that we can complete rulemaking no later than

October 17th, which is when the Sunset date for List 4 is. And that was, that was the original goal for the Inerts Task Force, or I should say Inerts Working Group. So that we, the next time that Sunset comes around, we do not have to refer to this obsolete reference in our CFR.

Right now, EPA does not use these lists, as Jay has mentioned. They have instead set tolerance exempt, tolerances or exemptions from tolerance for pesticide residues and inert ingredients, and it is, whoops, it is all at the, in the 40 CFR, their part. And they have, in this review process, they have drastically cut down on the number of inerts available. So, the whole List 4 is not even available anymore. They also have a new classification. Well, it is not new, but they expanded it a little bit of inerts as permitted for use in minimal risk products, and it includes what is called FIFRA 25(b) products. And it includes most of the former 4a's but not a lot of the 4b's which are still in current use for organic.

This was a diagram I showed last time. The old List 4 has around almost 900 substances on it. We did a survey from OMRI and WSDA and EPA and we think we have only, you know, less than 300 in use. And most of those are non-synthetic. But, half of them are in 25(b). And then we have about, in this little brown column on the right, we have about 121 substances that are on the old List 4(b) that are the ones that we are, kind of, at this point we are trying to figure out what to do with.

So, this is where we are, where we are currently at with the Working Group. We have got, sort of, two schools of thought here, two main options that we are looking at and then trying to figure out how to move forward. But the first option is that NOSB should review all individual inerts that are currently in use, and by just starting with the ones that are known in use, and that are not on EPA's 25(b), so we would presume that we would allow the ones already classed as minimal risk by EPA and then review about 121 substances individually. So that is a lot of chemicals, synthetic chemicals, to review and consider for the National List. So, the group is trying to come up with a more streamlined proposal of grouping them in categories. And so we can maybe schedule TRs around certain groups. But, and then set up some sort of timetable for staggering the ones that are most of concern to get them reviewed and off the list first, if that was the case. And then have various, sort of, staggered implementation dates. But, this still means that all, these all have to be reviewed and all have to be on the National List and then each one of these things that appeared on the National List would have to be re-reviewed again in five years, in addition to the existing 220 substances. So we are talking about going up to 350. Although maybe, you know, the hope is that people would reformulate and we would not need all of these and it would be less, and it would be an incentive to have less. But, it did, does present certain resource problems for the NOP, because the technical reviews are running around \$10,000 apiece and this is a lot of materials to review. Plus, the time and the staff and, you know, it is just a lot, and then the NOSB's time.

So, second option is maybe coming at it from the other end. Allow all EPA approved inerts that have a tolerance exemption, but then go through and review those categories and specifically include on the list ones that should be prohibited and figure out a way to

identify the things that should be prohibited. In other words, identify certain chemical groupings that might be carcinogens, endocrine disrupters, you know, known problems, and then, and then go ahead and list them. And then have the option in future, as you find more information, to add more prohibited categories as times go on. This would require a lot of work, which is the problem, to like, kind of, look at the whole universe that EPA is allowing and trying to identify those bad actors. And then, we, it also has a problem of specific, you know, once you have prohibited say category, then identifying all the specific chemicals that would be part of that category. So there is a lot of problems there, too. So, but, it would have the up side of being more manageable in terms of Sunset review.

So I just wanted to just give you an idea of current thinking of the task force and we are hoping to resolve this and come up with a consensus opinion by the end of the summer and turn it over to the Board. So, that is basically what we are at. And, ...

Jay Feldman: We will discuss.

Emily Brown-Rosen: We can go forward.

Jay Feldman: Yeah. Thank you. We will discuss. You know, people will have time to ask questions about this. And, but, we wanted to give you an overall context of the whole inerts issue. Of course, today we are dealing with the List 3 inerts, which is a very narrow list of three or four materials. As we understand it, it is a very, it is a separate, it is a separate rule, it is a separate line in the rule from the List 4 inerts. And they have, for some reason, they have different dates for Sunsetting.

And just to, just to remind everybody, inert ingredients are ingredients in substances that can be active, biologically and chemically active. The reason they are not defined as active, however, is that the manufacturer does not include those ingredients in the product in an active capacity. They are not targeting an active or pest or whatever the target use of that product is. So for the most part, we are talking about crop materials here that are developed by manufacturers who list on the label all the ingredients. And if you, if you have ever picked up a material, a pesticide, you have noticed that the bulk of those materials, or the bulk of the ingredients, are listed as inert ingredients. They are the carrier, the surfactant, the mixing agent, the dust, the granule in which the active ingredient is put. And so, the purpose of reviewing this is to make a determination as to whether that particular ingredient in that product that we, as a Board, are allowing to be used, whether that ingredient has any properties, health, environmental, that we should be concerned about as a Board.

So, as Emily said, it starts out being a huge list. And then you realize you can cut that down, many non-synthetics, and also, many that are recognized to be not, not of concern. So, let us, let us move on then to, back to the recommendation for this particular listing. Okay.

So, this is what the Crop Committee recommendation proposes: That we phase out the List 3 inerts and passive pheromone dispensers from a general approval and move it to a National List review status. So, we would do that as part of our review process. It is understood that the former List 3 inerts require review, that are requiring review are limited to the, to these three substances, which I am not going to try to pronounce for you guys. It is also understood that there may be a fourth inert in this category that has been identified by the Washington State Department of Agriculture.

Okay, so the proposal acknowledges all that, and makes that change, and then establishes a deadline for action, an expiration date. Review and Board action is set for December 31, 2015, allowing two years to review the petitions and act, a year for the NOP to go to rulemaking. And I should note that we actually have petitions for these. But, they are old. They are very old, because if, you know, if you go back to the Board history, you can see that there was an attempt made by the Board to begin this review process years ago. And at that point, manufacturers started submitting petitions for these materials and we never acted on them at that point.

If for some reason the time frames are delayed, the backup Sunset provision, which we always adopt on Sunsets, allows the former List 3 uses to continue until Board action and rulemaking are complete. If the NOP adopts a policy by December 31, 2015, that covers former List 3 as well as other inerts – which is my hope – then that policy will prevail. So that hopefully by the time we actually get around to reviewing these, we will have a policy that we can bring back to you, the Board, and we can review everything at that time. But this, this really establishes this as a priority and indicates that given the history of Board policy on this, it is, we really cannot afford to move this in a five-year timeframe – that we really need to move this more quickly.

Comment [JMS12]: 03:00:00

So, here is how this translates into the actual language to the listing. List six, 205.601, synthetic substances allowed for use in organic crop production. So we strike out the word inert and add the other words in italicized here. As syn-, I will read the new language - as synthetic, other ingredients, not classified by the EPA as active ingredients for use with non-synthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substance. I am sorry. It is... That is... Let me read it again so that you can see it. Any synthetic other ingredients not classified by EPA as active ingredients for use with non-synthetic substances or synthetic substances used in this section and used as an active ingredient in accordance with any limitations on the use of such substances. That is the existing language. We are just changing a few words there.

Then, we are adding this language. Inert ingredients exempt from the requirement of tolerance under 40 CFR 180.1122 that were formerly on EPA list 3 in passive polymeric dispenser products may be used until December 31, 2015, after which point they are subject to individual review under 601, unless already covered by a policy adopted by the NOP for all other inert ingredients.

And then the Committee backup is obviously the existing language, the existing listing. So you can see it does not have the cross-throughs and all that.

And then we define passive polymeric dispenser products, which has not been really defined. And this is the definition: Solid matrix dispensers delivering pheromones through volatilization only at rates less than or equal to 150 grams active ingredient – active ingredient, AI – acre per year that is placed by hand in the field and is of such size and construction that it is readily recognized and retrievable – and this cites other Federal Register notices – to be removed as a definition when 601(m)2(a) and (b) expire. So in other words, we will not need this once we get to a generalized policy. This will be obsolete at that point.

So, this was our vote. We have a unanimous vote on this out of the Committee.

Just to give you a sense of the public comments. We received a lot of support from -- well, we received support from everybody for that, the actual language change. I think there are differences of opinion on the history and interpretation of the history. And, you know, what I have given you are quotes from the Board. So, you can take that, you know, as you will.

But, what we have are some individuals call for the elimination of List 3: Beyond Pesticides, CFS, NOC, Food and Water, Cornucopia are disappointed that former List 3 inerts have not yet been individually reviewed. The same organizations call for review of inerts formerly on Lists 4a and 4b.

And then, OMRI emphasizes the importance of having the appropriate plan for inert ingredients to pher-, in pheromone dispensers, and CCOF expresses a similar concern. WDA strongly disagrees with the Committee's conclusions about the duty of the NOSB to do individual reviews. OTA and CCOF view the recommendations as an acceptable interim measure while a comprehensive inerts policy is being developed.

That is the presentation. And, if any other members of the Committee would like to add to that or amend it or provide additional information, I would be happy to have you do that. And, if not, we can take any questions that you guys may have. I know this is sometimes a complicated subject. Yes?

Mac Stone: Looking at paragraph 2 of the recommendation, last line. Unless covered by policy adopted by the NOP for all other inert ingredients, shouldn't it just be for all inert ingredients? Because otherwise, it would...

Jay Feldman: Yeah.

Mac Stone: To include these. And I am reading that right?

Jay Feldman: Yeah. Let me see. Yeah, I guess we could remove. So, you are talking about the passive pheromone dispenser?

Mac Stone: Just take the word "other" out, because otherwise then, to include "these".

Zea Sonnabend: [Inaudible] It means the same thing either way. It is a little bit more cleaner the way Mac says it, but it means other, these – the ones we are talking about in this paragraph – as well as others.

Mac Stone: [Inaudible]

Jay Feldman: Okay. Any... Yeah, that is helpful. We can amend that. Any other questions or comments on this? Yes?

Harold Austin: Jay, have we gotten any further clarification from WSDA on that fourth potential ingredient?

Jay Feldman: Not that I know of. Do you know of anything?

Zea Sonnabend: The Inerts Working Group does know the identity of that. It was disclosed in the course of tabulating all the different inerts. So, Emily has that information. But, it is not released to the public, yet, and some procedure would need to be made to notify because, the Inerts Task Force knows the identity of the inert, but not what product it occurs in. So, a procedure would have to be made to solicit a petition on that one in order to review it.

Jay Feldman: Go ahead.

Harold Austin: Next question. Would this, more I think to the Program, would us passing this one, would it have any impact on the potential work of the Inerts Working Group and what you are looking to propose in the future?

Miles McEvoy: Yeah. We have a number of comments on this particular proposal, and one of those is about the Inerts Working Group. That the NOSB set up the, with the NOP, the Inerts Working Group to provide a proposal on Inerts – List 3 Inerts, List 4 inerts – because of the EPA getting rid of the List 3 and List 4 inerts. This is a very important issue that needs to be done through a comprehensive approach. So, the Inerts Working Group was formed to develop a proposal and come back to the Board with that particular proposal for the Board to then review. And so, this particular proposal is outside of that process that was established by the Board. And so, we are concerned that that would potentially conflict with the recommendation or the proposal that comes from the Inerts Working Group because this would set a precedent in terms of how we would be approaching inerts and it might conflict with the comprehensive approach that the Inerts Working Group, working with EPA and NOP, is working on developing. So, we see it as outside of the process that you already established, where you set up this Inerts Working Group to make recommendations back to your Board. So, it is outside of that process.

Jay Feldman: [Deep breath] Would you like my interpretation of this, Harold?

Well, first of all, this is Sunsetting, so the Board has to make a determination. It would be very problematic, I believe, for the Board to issue a five-year re-authorization of this, re-listing of this, given the history that I read to you and the history of this Board and its intent to review these List 3 inerts independently, and independent of whatever happens on List 4. I mean, if we are talking about dozens and dozens, you know, obviously that would be a different issue.

And, the other belief, given that, given the pace of the work of the Working Group, is that, you know, the expectation is it will be done and so we can come back to the Board with a comprehensive policy but that this has to be highest priority, given the nature of some of these reviews that are needed. And, that leaving it for five years would be inappropriate, given the history on this. I mean, the question of whether it is a precedent is really, you know, I respect that opinion. But, you know, this is List 3 and it has always been a distinct listing in this, in our rule from List 4. It has been treated distinctly. It has been reviewed distinctly. And so we have to, unfortunately, we have to make a decision on that, because of the expiration.

Mile McEvoy: Yeah, just to clarify on this particular listing. It was not part of the original, the final rule that was published in 2002, or was effective in 2002. That is why it is Sunsetting in 2013. It was added to the National List in 2003, so over a year after the final rule went into effect. And the reason for that is that it was thought that with passive pheromone dispensers, there is no application to the crop, so therefore, the inerts that were being used in these passive pheromone dispensers were kind of irrelevant. And therefore, were being used in organic agriculture, were being allowed by the Program and by certifiers and by the industry. And then, that was added as an afterthought in 2003. And that is why it is Sunsetting in 2013, rather than in 2012. So it really was not part of that original review that the NOSB did on, with the original recommendation that you referred to earlier. It was not under consideration. That recommendation was really about the List 4 inerts that are in active pesticide products that are actually applied to the crops. So there is a very, there is a distinction here on the passive pheromone dispensers.

Jay Feldman: Yeah, but to clarify, the Board has specifically taken up List 3 many times. And, you know, we talk about following policy. The Board has been very clear that it wanted to review these independently, as an independent specific...

Zea Sonnabend: I have a comment and a question for the Department. A clarification on the List 3's is that, just because something was on the old List 3 did not mean it was necessarily bad or toxic. It is just that the EPA had not classified it to one of the other lists yet, because enough studies had not been done. The fact that in their new exemption from tolerance schematic, they moved all the pheromone dispensers into their own section, with other semiochemicals, which is the 40 CFR 181.1122, implies that they have completed whatever studies they are planning to do, and that they have deemed those particular inerts to be not of concern – similar to the 4a Inerts, for the reasons that Miles stated.

My question, which is based on what Emily was saying, is: if the inerts policy is going to be put forward soon, but the rulemaking on the policy will not be completed until 2017, does that mean that the review of the individual inerts would not start until 2017? Or would be completed in 2017? Because that is a huge difference.

Emily Brown-Rosen: Well, we are not anticipating changing the current list, the current listing for List 4 until Sunset of... and that has to be changed by 2017. With... the process has to start three or more years before that in order to do that. But, it depends how that change happens. I mean and how much, what, you know, what it says.

Zea Sonnabend: So, if a policy is passed, yes, we want to review individual inerts, or even groups of inerts, but any review that we do, that review can start well before 2017, so that we can take List 4 off of the list in 2017?

Emily Brown-Rosen: I will let Melissa talk about this, because, you know, we could do separate rulemaking, you know, and have a whole separate thing going on there. But, let me let Melissa talk about that.

Melissa Baily: Yeah. I think what we would look for is to start that process many years before the 2017 deadline so that we could address it all in one streamlined regulatory action for list 4 inerts. So, I think that was the original discussion that the Program had with the Board when we talked about setting up the Inerts Working Group was that we would come up with some sort of policy and that that policy, if it does contain individual review of inerts, that we would address those all in one rulemaking for the Sunset 2017 for List 4. Does that answer your question? So in terms of timing, because this would be a change from current practice, I would certainly advocate for the more time that we can have to get the rulemaking done on this, the better. So, I would advocate that the Board start any kind of review quite early.

Comment [JMS13]: 03:15:00

Zea Sonnabend: Right, well that is exactly why we thought, we will start with these three, or maybe four, inerts and pheromone dispensers and try and complete that by 2015. So at least that can be done. And by then, we will have, be well underway on the overall policy with the overall other inerts. Because, three, compared to 121, you know, if we cannot do three by 2015, there is, like, we are not going to meet a 2017 deadline on the rest of them. Do you see what I mean?

Jay Feldman: Are there other questions? Okay. Go for it.

Zea Sonnabend: If, since we know that the Department doesn't like this 2015 date, but, since we feel that past, as Jay said, you know, past attempts to move inerts review forward have languished or failed in the five-year time period, is there any way that the date could be taken out, but, in the strongest possible of terms or language in the recommendation, it insists on moving the review of inerts forward?

Melissa Bailey: Is that a question for us?



Zea Sonnabend: Yes, I was asking the Department.

Melissa Bailey: So, you would be, to clarify, what you would be suggesting would be to remove just the date from the annotation you are proposing, and, but retained the reference to some sort of outside NOP policy that may be adopted?

Zea Sonnabend: Yes, possibly. I think I would like to retain the language about 40 CFR 181.1122, because I think that the EPA wants us to stop saying List 3, List 4, like that. So if it is in the regulation, I feel that reference should be maintained. And, I feel that the will of the Board, the past Boards, certainly, has really been to move this forward seriously. But, we do not want to make the Department mad at us, but we do definitely want to use the strongest possible efforts to move this forward.

Jay Feldman: Can the Program respond, or does the Program want to respond to it?

Emily Brown-Rosen: I would just like to say. I mean, I would have, well, what language are you proposing? I mean, maybe, if you... You are saying just take the date off and, and say exempt from requirements of tolerance under 181.1122, that were former List 3 may be used until 2017, or until next Sunset? Is that what you are saying? Or just end it there? And then, and then you could make a separate recommendation that is not a National List recommendation and recommend that the Program do, you know, something else that you want us to do? But, I mean if you, it is very hard for us to put in the National List an annotation that says, unless already covered by a policy adopted by the NOP. That... we cannot put that in the rule. You have to, you have to put the proposal up to there and stop. And you could make that as a separate recommendation. But that is not something that can go. You know something that goes in the register has, it is the rule, until you change it. So that would be the rule. It would not be something voided by another action. We would have to then make another rule to change it. So we cannot say this is the rule until we tell you something else. It does not work that way.

Mile McEvoy: Yeah, just to clarify, we cannot allow things that the Board has not approved. So, we cannot allow inert substances in passive pheromone dispensers unless the Board has recommended to do that. We cannot do that by policy. There is something that we can, but this is one area where we cannot. So, that part is definitely a problem.

Jay Feldman: That was intended to show the spirit of the committee's work, in terms of trying to coordinate with the List 4, but given the Sunset date that we have, the need to move forward on this and really make it clear that this is a priority, given the years of inaction on this matter. And by the way, just so that the Board members know, there is a high degree of frustration at EPA that we have not gotten our act together on this.

Zea Sonnabend: So, perhaps, would not it make more sense, in light of Emily's report, to put a date of October 2017 in it, so that it is at least in sync with the rest of the inerts and the rest of the proposed re-change of the inerts policy?

Miles McEvoy: We missed that, sorry.

Emily Brown-Rosen: Sorry.

Zea Sonnabend: Wouldn't it make more sense, in terms of what Emily presented, that instead of an automatic five-year renewal, we put a date of October 2017, which would be one year sooner than it would have Sunset normally, so that it is in sync with the rest of the inerts Sunset?

Miles McEvoy: You are making us, you are making us think a lot here. I think, okay, a couple of things. One is that, that Jay said that the EPA is frustrated. I think there might one person that has made some comments of that, but that certainly is not an official, official position from EPA that they are frustrated with us. So I think that needs to be clarified that there has been no communication from EPA that they are frustrated with the National Organic Program or have any problem with the National Organic Program's listing of List 3 and List 4. We are working together to solve this problem. And we have a very good working relationship and we will solve this problem.

Okay, so the other point was the 2017 versus 2018. That seems like that is a little, that gives us a little more flexibility. We could potentially work with that more easily than the 2015. We are just really, really concerned about the expiration dates, because it causes us a lot of extra work, and that means that we are not getting other work done. We know this is an important issue. Another concept would be to get the, to have a recommendation to get the correct annotation with the 40 CFR 180.1122, and then as a separate recommendation, say that the Board wants these List 3 inerts individually reviewed and evaluated by 2017. So, you take two separate actions. You direct the, well, your recommendation to the Program is, make this happen. And, that might be a way to split those two different issues, to make sure that we are accountable, to make sure that happens.

Jay Feldman: Would that be an annotation change? Make this happen?

Miles McEvoy: No, it would not be, it would not go into the rulemaking process. That would be separate from the rulemaking process.

Jay Feldman: Miles, I just, you know, we have had side conversations on this and, just so the Board knows, what is happening here is so detrimental to organic, in my view. This is an issue that could be easily resolved, should not have taken the Working Group two years to get to a conclusion. We should have been prepared at this Board meeting to present an overall policy, in my view. That did not happen.

We are in this situation we are in. We have to show the public we are moving forward, not with a make this happen resolution, but with a clear, extremely clear set of guidelines and actions that we can point to. And I can point to my constituents and say, the NOSB is serious about this. This has got to be resolved. We have too many other issues that have been hanging out there, and many people were told this was going to be resolved two years ago. We thought we would have resolved this by now.

I know we did not have specific deadlines in stone, and that is part of what is driving this approach with the deadline. Because when we do not get those numbers and dates in stone, other priorities do overtake us. I understand that frustration. But, I really want, you know, the Board to understand, at least in my view, that I cannot support delaying this beyond what is necessary to get the job done. And we can get this job. We could have gotten it done for this Board meaning, quite frankly.

This proposal was in deference to the work of the Working Group. It was in deference to the Program to not rush things with a deliberative process. And, and for me, and for the people that I am sitting here representing, even what we are proposing here is too long and has been, unfortunately, allowed to go on, after all of these Board votes. So we make a big deal around here of honoring previous Boards and the decisions they have made. And this is one where it is so clear. And I would like to honor what the previous Boards have said on this, and I respect what they have, their deliberations. And I would like, I do not think this is too much to ask. And, I know we can get it done and it will get us in a position where we can point to resolving a nagging issue that we, that we are... I know the Crops Committee is committed to working on. So thank you.

Any others? Go ahead.

Melissa Bailey: Just one other point. Or, I guess a question for you, Jay. How critical is the definition that you are proposing to this, to moving this recommendation forward? The addition of passive definition for...?

Zea Sonnabend: We look at it as fairly important until the individual materials are reviewed. Because, there are new pheromone technologies out there that groups such as OMRI and other mat- MROs have not been able to determine whether that technology is actually passive pheromone dispenser, as in the old language. And so, by adding the word polymeric, and defining passive, you know that passive polymeric is part of a thing, is fairly important to the MROs, if this language continues because the 40 CFR 181.-22 is much broader interpretation of semiochemicals rather, outside of passive polymeric pheromone dispensers.

Melissa Bailey: Okay. Thanks for that, that information. Just for your consideration, I guess, we have, to my knowledge, and somebody can correct me if I am wrong, we have never added a definition during a Sunset rulemaking. So, I am not sure what that would mean in, mean in terms of our process, and generally, the scrutiny that we come under trying to get these things out the door. So, I just wanted to make you aware that this is something new, unless somebody has other examples that we have not done before.

Zea Sonnabend: The definition language, however, is cited in another CFR section that we put in the definition there. And so, it is not like we made up the definition. We took, just took it from a different federal regulation.

Melissa Bailey: Sure, yep, yeah, I understand that. I am saying that if we are adding it to the NOP regulations, you are adding it to terms defined? 205.2? That we, that we have not done that kind of exercise, and generally Sunset has been about the materials and not adding new things to the regulations outside of the scope of the substances being reviewed under Sunset.

Zea Sonnabend: Can it be done through guidance instead of in the rule?

Melissa Bailey: Potentially.

Nick Maravell: Could it be done in the text of the amendment, just as a reference to another federal definition? We already have the reference to 40 CFR 180.1122, and then we could add the reference after passive polymeric [*polymeric*] dispenser products, and just put in the citation to the CFR.

Comment [JMS14]: 03:30:00

Unknown Male: Yeah.

Melissa Bailey: Yeah, I mean, I guess my answer would also again be potentially. What I am trying to do is explain to the Board, you know, we are in the middle of the Sunset 2012 rulemaking where we had a number of annotation changes that has really taken a lot of heavy lifting to get those out the door. And so my expectation would be, again, if we are, the more we are doing in Sunset on some of these substances, the more it is going to take for us to figure out how to actually execute them. And I do not know exactly what that looks like until we get it kind of in the queue and in the process.

Jay Feldman: That sounds like a good suggestion, since it is a CFR cite, and we have in, I believe, in other annotations, cited CFRs or other... So, it would not, it would not...

Emily Brown-Rosen: Jay, I think we have to check on that. I think that was a proposed rule but, from EPA, I do not think it is a CFR. It is just a Federal Register. So I am not sure if it is an official cite.

Jay Feldman: Okay.

Nick Maravell: Emily, are you saying that that is not a final rule? That citation?

Emily Brown-Rosen: I do not believe so, yeah.

Nick Maravell: Okay, well, then that is a problem.

Jay Feldman: Okay, we will, we will regroup and see if we can cite a, if there is a citation that is in the CFR. Yeah.

But, but otherwise, this, you are saying an edit, or amendment to 205.2 under definitions is a separate process or cannot be done in coordination with this process? Or would be a,

would it create an additional burden that you are saying would, might delay the process or something?

Melissa Bailey: Correct. Yeah, we, again, anything that we have not done before takes a lot of explaining on our part to get it out the door. And so I just want the Board with sort of clear eyes to understand that we have not done this before, so in terms of the rulemaking, I do not know what that ends up looking like. And, just want you to be aware of that potential unknown.

Jay Feldman: Okay. You know, just so the Board understands, we were trying to create clarity for the product manufacturers because this has not been defined. We were trying to provide some closure on this issue so that people were not asking questions about what we were talking about when we said poly, these passive polymetric [*polymeric*] dispensers. We could take that out and just leave the manufacturers in continuing limbo, and let folks figure it out for themselves. Harold, you may have something to say about this? I do not know whether you feel a definition is necessary, or you are happy with the way things are.

Harold Austin: Jay, I think a definition probably should be in there because all of these inerts really pertain to that specific process that is being used by the, the you know, the growers. I mean, so, I think, you know, these are not individual inerts that are used for separate, separate issues. They are all being used for one, one pointed application. So, I think having that definition in there, I think there is value to that. But, I would defer to the rest of the Board's thoughts as well.

Jay Feldman: Any other comments or questions or thoughts? Anybody? Board? Program? John?

John Foster: Thanks. As we were talking about the other night, Jay, in the Crops meeting, I guess I am not convinced yet, that the net benefit of a shortened timeline outweighs the, the potential problems. I am just not, not convinced, yet, that, that in total it is that way. And I would be interested to hear other Board members' thoughts on that because we have talked about it in committee and I would like a wider discussion, if we could have, on that. Because that really is a, it is an important feature of this, and there is a lot riding on it, I think, for industry, there's a lot riding on it from perception, and a number of angles. And my, I will just wrap it up with that invitation. But, my experience, when we have put accelerated expiration dates on things, my recollection is there is, that has caused a lot of problem in the past. And I am not looking forward to doing more of that unless it is just absolutely necessary. And I do not know if that kind of measurement has been met yet. So I would be interested in other, other Board members' thoughts on that.

Nick Maravell: John, have you heard specifically from the industry on this deadline issue on inerts?

John Foster: Yeah, anecdotally. I mean, like, I hear from a lot of, you know, community members on a lot of things. Just that particularly in the Northwest, I have a fair number of contacts there, and their... I do not think it is a well-organized, you know, set of

comments. But, the hope is to have as many tools as available as possible, especially on an essential tool for, and this is just Pacific Northwest, so I do not know as much about other production areas on these crops. But, it is, it is a critical tool, and to mess with a critical tool in anyone's toolbox is, that is, that is kind of threatening. So, that has been mostly the message is worry over a, an accelerated timeline, and the system's ability to actually process, to actually process what we do pass in a timely fashion, and, then also, concern over the ability of any one inert ingredient to get the okay that they would feel it needs particularly under, under that accelerated timeline. There's concern about that, also.

Nick Maravell: Jay, have you heard public comment with regard to the timeline issue here? Are we at risk of producers not having the tools that they would need to continue production?

Jay Feldman: Well, as you know, this does not take anything off the market. This creates, this subjects these materials to review, that is all. There is always a possibility when you review something that it gets annotated or removed, of course. But that is not what this is about. This is about bringing ourselves into review in accordance with what we are supposed to, what at least the Crops Committee, felt we are supposed to do and the previous Board, as I stated.

You know, I was pleased to see that the community came together around this, John. I, you know, I... We are always going to have different interpretations of intent and spirit and all that. But, it was great to see that people realize that even if they did not like this a little bit, that this was one of those issues that we, we as a community, had to come together on. And everybody did support. And to answer your question, Nick, the comments we got came through the Federal Register and they were all supportive of this language.

Whether people did that reluctantly, not with a lot of enthusiasm, I am not characterizing it. But, I am saying that people recognize that we have to put this behind us. We have got to get this, our house in order on these issues of inerts and, and we put them, we run them through the National List process. And then we move on. But, I have not heard anything, in terms of economic impact associated with the review process. I have heard, clearly, we all have heard, that pheromones are an essential tool in organic crop production or at least sectors of crop production. We have heard that many times and we have already discussed that as a Board. So we understand that part of it. This is a separate issue of whether we are going to move these inerts through the review process.

Okay, sorry.

Mac Stone: Just from listening, I would suggest that with the long history of the conversation here, and the lack of uniformity between the position of the Program and the Board on this recommendation, 2017 is still a hard, fast number. But, it gives everybody more time to align with the other inerts proposal, or policy. But it still is a hard, fast deadline, versus forcing the hand of a system that has not communicated real well, apparently.

Jay Feldman: Go ahead, Miles.

Miles McEvoy: Yeah, that would be good. Can I add a couple of other ...

Jay Feldman: Yes, go ahead.

Miles McEvoy: ... points? Yeah, I first want the Board to recognize that there is current standards on inerts, that the restrictions on inerts under the USDA organic regulations are part of the reasons why the USDA organic regulations are the, the highest standards in the world. No other organic standards, well, Canada has some restrictions on inerts, but the, the major organic markets, the EU, for instance, there are no restrictions on inert ingredients in approved, allowable organic pesticides. So the current standard is, part of the reason why the USDA organic regulations are very strict, and why, to a large extent, the USDA organic standard is the gold standard around the world. So I just want to make sure that people understand that, that this is a much more thorough review process than what is going on in other organic standards.

And the other point is that this, the approach of reviewing each inert ingredient, that that would set a precedent, or potentially set a precedent for the List 4 inerts, and we just do not have the resources, the financial resources to do the technical reports, or you do not have the time to do all the reviews for those 200 materials that are currently on List 4. So, you really have to think this through of how, how this particular proposal interfaces with those other 200 materials for inerts that are not even contacting the crop. It just seems like the, the inerts that are contacting the crops should be a higher priority from my perspective.

Unknown Male: [Inaudible]

Zea Sonnabend: Okay, I just, to respond to one thing that you say frequently, Miles, that, the, in Europe, they do not review inerts. The reality is that in Europe, their EPA-equivalent does not allow quite so many inerts as we do. And so what goes into products in Europe even though they may not review inerts, they are working with a much narrower group of things that they can put into those products. And so I just do not think that argument means all that much, in terms of our reality here in the US, where the EPA has put, you know, 900 or so ingredients that can be used for inerts, many of which would not be allowed in Europe.

Jay Feldman: The other thing I was, I am not sure I heard you correctly, but, these are, these are substances that come into direct contact with food, that, you know, this is not... Did I miss-hear you on that? I mean, these are, these are ingredients in products that we allow. And, we are trying to figure out a way given, and it is really, the motivation for this is hopefully you, you all recognize, and the recent inerts get separated out from the other ingredients that we look at, is because they are proprietary information. So when someone comes to us and says, I want to register, I want you to allow a particular substance, and they are, they are basically, we are allowing a product, per se. That product is a formulation that has a lot of different ingredients. Many of which we are not

privity to, because they are considered proprietary business information, confidential business information.

So, we, we have always had to deal with inerts in a separate track. We... That is why EPA deals with them separately, too. So, but, that does not mean they are not in products that we allow that are applied directly to crops, that are... Did, were you saying something different than that? I did not, I missed that, I guess.

Miles McEvoy: With passive pheromone, ...

Jay Feldman: Oh, I see.

Miles McEvoy: ... passive pheromone products, those are not being applied to the crop. They are being put into the ...

Jay Feldman: Right.

Miles McEvoy: ... the orchard or the field, and those pheromones passively are dispensed. And, but they are not applied. They are not ...

Comment [JMS15]: 03:45:00

Jay Feldman: Right.

Miles McEvoy: ... put in a spray tank and applied directly to ...

Jay Feldman: Right.

Miles McEvoy: ... the crop. So that is the distinction. [Inaudible]

Jay Feldman: Well. Okay. Obviously, it is a material. It is something that is subject to our review. I mean, that is, you are getting into the substance of whether we would allow it or not, which is not... You know, the presumption here is that pheromones are important materials. We are having a discussion on whether we, as a Board, have a responsibility to review those materials. You know? And to....

Miles McEvoy: Yeah. No argument there. But what I am just saying is that in terms of the, the application of the substance, those other inert or other ingredients in pesticide formulations that are directly applied – which are the List 4 inert substances – are things that are directly applied to the crop, versus the List 3 inerts – that are allowed in passive pheromone dispensers – are not directly applied to the crop. To me, it is a higher bar or a higher priority to look at things that are directly applied to the crop, than things that are not directly applied to the crop. That is the only point I am trying to make there.

And then in terms of, Zea, what you were saying about the EU review. The EU review is done member state by member state. And there are, there are substances that are allowed within those various member state reviews that are, go beyond the, the List 4 other ingredients, inert ingredients that are allowed. So there is no review process in terms of



their organic system. There are substances that are further restricted in the US system that are allowed under, in the EU system.

Jay Feldman: Again, Miles, I think why it is really hard to ask the NOSB to put aside a responsibility, based on a presumption that the use pattern is not of importance, vis-a-vis our, our checklist, our review in accordance with all the things we do as a Board, as a Crops Committee, as whatever committee we are on. We are, we are looking at food. We are looking at environment. We are looking at all kinds of issues related to the use of products. And, you know, we, again, we are not saying anything different here than has been said by previous Boards. We have just got to get, we have got to get moving on this. And, we will just have to decide whether that it seems like the timeframe is reasonable or not. But, that is what it is coming down to, it seems like. Thanks.

John Foster: So, I do not know if, I do not know if it was just a lot of thoughts in, in everyone's heads, but you were referring to these for a second it while ago as ingredients. And I think it might have just gotten caught up, because ...

Jay Feldman: Substances...

John Foster: I heard, I heard you say ingredients a few times. I think it was probably just momentum. But anyway, I wanted to call attention to that. But...

Jay Feldman: Well, they are ingredients in pesticide products so, you know, pheromones are a pesticide registered by EPA, it is a, I mean I guess technically, it is an, it is an ingredient in the product. So that is...

John Foster: Right. In the context of the sentence structure you were using, that was not necessarily clear, though, because we were talking about food also. So, enough about that.

But the other thing is, I do not, I do not get at all that the Program is asking us to set aside anything. I do not, I do not feel that that is the way. I do not feel pressure that way. I have not heard anything along those lines. So, I do not, I do not approach it that way. And I, I feel like this has been a very good collaborative process, on this issue particularly. And so, I wanted to get that out there, too. I do not, I do not feel like I have been asked to put aside anything. That is it.

Jay Feldman: But, five years, in my, I, I was saying that in reference to five years. Because to me, that just is, does not seem reasonable, given what the history is on this. It is a contextual.

John Foster: Right. Yeah.

Jay Feldman: Yeah.

Harold Austin: Jay, I rep-, for the stakeholders and stuff that I represent, I think the additional time to get some consolidation of the inerts I think probably makes better sense. I also think that by giving that extension that the Program has suggested, that if there was a problem with one of the three inerts or possibly four inerts that are in the, the dispensers, then it would give the stakeholders, that I sit here and represent, the opportunity to find alternative measures if needed because we cannot ensure that all of these are going to get passed.

Jay Feldman: Right.

Harold Austin: So I think that two year, I think you are still living up to the previous Boards' intent. I think also you can go back to the stakeholders that you are representing and giving them a definitive that there is a timeframe that has now been established that has not been in the past. And I think we can all do that. And I think it is a collaborative effort here that I think we can move this process forward and I think we can all take and come to a mutual agreement. But, I do not think what the Program is, is asking us to do – by extending it by two years and getting everything consolidated – I do not think that is an irrational approach at all. So I, you know, my, I agree with John. I think that moving it to two years down the road is not the end of the world. Actually, I think it, there is, it solves a lot of other issues that potentially could arise from that decision, if we move this forward as it sits right now.

Jay Feldman: Thank you.

Zea Sonnabend: I agree with Harold, and as such, I think I will, if this is called for a vote right now, I will vote against this and recommend that the Crops Committee [sigh] meet before Friday to [laugh] separate this in... Well, either that or I can propose language and we can put it off until Friday, to separate this into two separate motions. One would be the motion that exists now for the 40 CFR 180.-122, in- with a date, instead of December 31st a date of October 2017, and then a second motion urging review of these specific inerts sooner than that, if at all feasible, in the strongest language but not being a National List motion, that we could talk about in the Crops Committee further to develop that.

Tracy has a question.

Jay Feldman: Yeah. Tracy.

Tracy Favre: Miles, I have a quick question for you. If, if we do adjust the deadline language to 2017, I, I just need to get some clarification. It seems to me, as big of a concern is the potential setting a precedent for review of the individual materials. Can you give me some feedback on that?

Miles McEvoy: Yeah. We had those concerns about the individual, our capacity, the Board's capacity to review all individual inert or other ingredients in pesticide formulations. So, we have already invested, the Board has invested a lot of time and resources into the Inerts Working Group. Jay, yes, they have not reported back with a proposal but they,

they have reported back on a lot of information and they have a couple of things that they are mulling over to come back to the Board. The Board, the previous Board invested into that, the Program has invested into that Inerts Working Group. So, the main point is that we would suggest waiting for that group to come back with a comprehensive proposal around all inert ingredients, including the List 3 and List 4. So this particular discussion about going to 2017 to line up the List 3 and List 4 together, that seems, that does seem more feasible. But, we still have those concerns about the capacity, both of the Board, your time and energy, and the Program, in terms of resources for technical reports of individually reviewing all, all of these substances on an individual basis. On the other hand, you know, maybe this is a trial run, that you could see what it is like. And, if it is, becomes completely unworkable, then we get creative and find another way to, to move down the road.

Jay Feldman: We should... You know what? Can.. . We can pick this up because we should take the public comments. I feel bad that we missed them. I apologize to the public commenter who is hopefully still here. I realize I overlooked asking Jonathan Ashe, if he is still here, to make his presentation.

Michelle Arsenault: Actually, Jay, he rescheduled, and it should be Sarah Wintzel-Fisher.

Jay Feldman: Oh, okay. Well, at least you have the benefit of hearing what all of the issues are. So...

Sarah Wintzel-Fisher: Hi, I am Sarah Wintzel-Fisher. I am a small scale agricultural producer and I also manage Growers Markets here in the city. I live here in Albuquerque, just a few blocks away. I am a member of the Cornucopia Institute and I am here today as a citizen lobbyist.

The Cornucopia Institute supports the Crops Committee's proposal to review List 3 inerts. These chemicals should never have been listed without the proper review that is [background noise] required by the Organic Foods Products Act. And NOSB should move forward with the review. As outlined in the proposal, List 3 inerts should have been reviewed by January 1st 2002. Previous Boards have repeatedly stated that these inerts need to be individually reviewed. Given that there are only four List 3 inerts that require review and that the Crops Committee had no other work on its agenda for this meeting, it is inexplicable why the Crops Committee again delayed the required review of these materials.

Consumers expect organic food to be produced without the use of potentially dangerous chemicals, and they especially expect any synthetics used in organics to have been thoroughly reviewed and approved. This expectation is legally grounded in OFPA. These chemicals should not be given a free pass from the legally required review process simply because they have been given, they have been referred to as inerts.

The terms "inerts" is misleading, and even the EPA encourages manufacturers to use the term other ingredients instead of inerts. Inerts cannot be considered benign or harmless,

especially since they often act to increase the effectiveness of the active ingredients. Inert ingredients can have toxic, toxicological effects on human health or the environment. We believe that all inert ingredients, including those formerly categorized as List 4a and List 4b by the EPA should be reviewed.

While it may seem a daunting task given the number of chemicals on the list, it is absolutely necessary for the integrity of organics that all chemicals used in organic production be reviewed. Organic consumers expect nothing less. If strategies exist to facilitate and expedite the review of these chemicals, such as grouping certain chemicals in classes and reviewing classes, rather than individual chemicals, we would support any strategy recommended by Beyond Pesticides, which is a leader in the field of protecting human health and the environment from toxic effects of agri-chemicals. Thanks for listening.

Jay Feldman: Thank you, are there any questions? Okay.

Calvin Walker: You are suggesting, with the large list of inerts, the possibility of grouping them by certain classification to speed up the process?

Sarah Wintzel-Fisher: Yes, I think that that would be helpful.

Jay Feldman: Thank you. Oh, is there another question? Sorry, go ahead.

Harold Austin: Are you a farmer or a grower as well?

Sarah Wintzel-Fisher: Yes.

Harold Austin: Just a quick question. Are any of the crops that you deal with here locally, do they use maybe disruption or the pheromone dispensers on those crops?

Sarah Wintzel-Fisher: We do not at our farm, and I am not sure about other farms.

Harold Austin: Okay, thank you.

Jay Feldman: Go ahead. Do you have a question? No. Thank you very much.

Sarah Wintzel-Fisher: Thank you.

Jay Feldman: Okay, so this actually is the time period in which we designated discussion and modification proposal. Do people feel ready to vote on this? I mean, you had suggested, maybe, Zea, that we needed time to reconstruct something or construct something, but how are other people feeling? So, Zea, if we were to vote now, would you be able to propose an amendment to this? Or how would you want to proceed?

Zea Sonnabend: I feel that, in light of what the Department said, it needs to be divided into two motions to separate out the timeline issue from the individual review of the inerts issue.

Because, putting the individual review into the same motion is not really a National List Sunset subject at the moment. You know? According to what they say. So, I would like to have one line, one thing for the first part of the motion, with a deadline of October 2017. And then the second motion [sigh], you know, urging them to move forward with individual review as quickly as possible. And, I do not think I can quite get a good wording on the spot. I am wondering if anyone else agrees with me, but...

Harold Austin: Jay, I... is it possible to take like a five or a ten minute recess? Which may actually end up saving us time here, and to, to confer on this briefly? Would that, would that be a good idea from your point of view, Zea?

Comment [JMS16]: 04:00:00

Zea Sonnabend: Yes, perhaps if maybe the Crops Committee could get together in that recess and talk about revising...

Nick Maravell: Mr. Chair, Barry, can... we would request that you call a 15 minute break and then we could reconvene for 15 minutes to vote?

Barry Flamm: I have a couple of thoughts there. One, we have a gentleman that wants to, needs to catch a airplane. He has a, a comments that he would like to make, but it is on Livestock. I wonder if we could take that and then break for lunch. And that would give you extra, extra time to get your committee together.

Jay Feldman: Enough time to ruin our lunch?

Crowd: [Laughter]

Barry Flamm: Ruin your lunch.

Zea Sonnabend: And eat into the Livestock time after lunch so we can discuss the new proposal?

Barry Flamm: No, no.

Jay Feldman: No, no. We come back.

Barry Flamm: We will come back.

Jay Feldman: Oh, yeah. Would... Yeah, would we come back early? Is that what you are suggesting?

Barry Flamm: Yeah, come back early. And then you, and then you proceed with the voting. Just taking the lunch now, rather than taking it later, except, giving this gentleman a chance to make his three-minute comment. Is that okay with you, Jay?

Jay Feldman: Yes.

Barry Flamm: Is that alright? If we... Alright. John Bruinquett. Is that correct?

John Brunnquell: It is close.

Barry Flamm: Close, huh?

John Brunnquell: No, thank you. I appreciate the courtesy extended. I have to jump onto an airplane a little bit. I am John Brunnquell. I am president of Egg Innovations. Wanted to address some issues to the Livestock Committee. In response to several years of NOSB topics as they related to the organic egg industry, we wanted to share with you that our industry has begun to coalesce under the Organic Egg Farmers of America. And you will see several of those people out here today. I am coming to you also is a director of that group and as their secretary.

We, we presented to you through written comments our, our feelings on the methionine issues and we, we urge you to take a look at those. We want to share with you that, as a membership base, we currently represent about 10% of all organic egg certificate holders in the nation, but about 60% of all organic egg production in the United States.

The thing we wanted to chat a little bit about today was the vaccine issue and GM, GMOs and their use of that. As of July 7th this year, all flocks over 3000 birds in the United States, including organic birds, are going to be obligated to follow an SE prevention program. As part of that SE prevention program, it is strongly recommended by the FDA that vaccination for SE will be part of that program.

And so, that is our real world, where we come here, we agree in spirit about removing GMOs from organic. But, we have real practical issues where the next meeting we all attend, proverbially, is with an FDA person who is saying, tell us your SE prevention program, we really do not care that you are organic. We have food safety issues, and where that vaccination program is a little unique is that we are not vaccinating as specifically for a disease for the bird although as he is, we are really trying to do a preventative food safety issue, that we cannot wait and react to after it occurs to come back and deal with the source issue.

And so we share with you that these are issues that are out there. We support in concept the removal of GMOs from organic, but we ask you to move very patiently as it is the discussion of GMOs and vaccines in organic egg production. Thank you.

Mick Maravell: I do not know who is calling for questions.

Barry Flamm: I am going to let Wendy do it since it is her committee.

Wendy Fulwider: Nick.

Nick Maravell: Thank you for your comments. I have several questions, and I am glad you are here and we were able to get you before you had to leave. Are there a variety of SE, this is salmo-, salmonella and then...

John Brunnquell: enteritidis.

Nick Maravell: ...enteritidis. Are there a variety of vaccines available or are there only one or two?

John Brunnquell: The latter. There is, there is a very small bucket. There is I want to say two or three manufacturers, and there is about two or three choices of what you can use.

Nick Maravell: And do you, currently now, have any knowledge as to whether or not those vaccines might be impacted by our proposed, what was our proposal?

John Brunnquell: I do not have specific knowledge. I have a general awareness of how vaccines are developed. I wouldn't be surprised that they would be in conflict.

Nick Maravell: Okay. Because I, I do have some anecdotal information that goes both ways on that. Okay. So, so you are saying it is, it is open for discussion as to what, what your options really would be, to satisfy both an FDA program and an NOP type program.

John Brunnquell: Well, what we are saying is, we are going to vaccinate with whatever is commercially available with SE. We do not present ourselves as an expert on does that currently use GMOs, or are there non-GMO forms available. We are subject to, there is two or three choices. That is all we have to use independent of the organic discussion.

Nick Maravell: Right. And, if you were to try to find out that information, where, what would you do now? What are your options for finding out?

John Brunnquell: We would approach our technical service people that support our various companies.

Nick Maravell: And, and do you think that they have adequate guidance now to make that determination for you?

John Brunnquell: I could not speak to that without talking to them.

Nick Maravell: Alright. [Inaudible] So, would you say that most of your producers are going to fall under the FDA guidance of flocks of 3000? Or when I say your producers of, of the group that is forming the Organic Egg Producers, do you feel that most of them would fall under the FDA guidance rule of flocks of over 3000?

John Brunnquell: Currently, we have approximately 60 members, of which approximately 55 of them would be over 3000 birds.

Nick Maravell: Okay. Thank you. Are there any other?

Barry Flamm: Thank you.

Wendy Fulwider: Joe has a question.

Barry Flamm: Oh, Joe.

Joe Dickson: You said that the, the FDA, I think the language you used was strongly suggests the use of the virus, or the vaccine rather, but it stops sort of short of saying requires. Can you give a little more color to the extent to which that advice is being given out?

John Brunnquell: Certainly. We are, all flocks over 3000 birds beginning July 7th this year – all flocks over 50,000 are already subject to that rule – have to have some type of salmonella enteritidis prevention program. The FDA outlines several key characteristics of strong recommendations. They include harborage, which is preventing mice and rodents, cooler temperatures, and keeping eggs cool. And so there is a series of best practices. And of that, the vaccination with salmonella, you know, preventative vaccines is a strong recommendation. The other thing we have to bring visibility to, although we are not proud of it, the last egg recall of the United States was an organic farm. So, while we, we want to say, everything is great in the organic world, statistically, the last egg recall in the nation was organic. The vaccines are very effective. FDA does not mandate, at this point, that it is the law you use them. But, they do mandate that you have an SE prevention program. And best practice of science is that you would use that tool.

Wendy Fulwider: Mac.

Mac Stone: John, we met at the poultry meeting in Minneapolis. But, part of that is keep them indoors, right? Or, access to outdoors is part of this formula, if you will.

John Brunnquell: There is, the, that is an area obviously of a lot of debate. The FDA and the organic community, quite frankly, are going to have to figure that out beginning October of this year. October of this year is when we have been informed on-farm audits will begin. And, in our discussions with Jerry Ramirez who was there, it was very clear they do not have that figured all out, yet. They understand that organic says you must be outside. And they equally understand that that is not their issue. Their issue is prevention of salmonella. And so, there is not a clear path, at this point.

Wendy Fulwider: Nick.

Nick Maravell: What have you been able to determine in your management programs of, have been the most effective in preventing salmonella? In other words, there are, the FDA guidance has got a variety of things. You know, give us an idea of the types of things that you are currently doing, and how a vaccination program fits into that and your overall priority on vaccinations.

John Brunnquell: Sure. And, and I would encourage you, as other people during the course of the day speak to the Livestock Committee, they might have slightly different variations from ours. We start with baby chicks that are purchased from clean hatcheries. In our pullet



facilities, we monitor the fly levels. We monitor the rodent levels, and we swab the facilities during the lifetime of they are in the pullet facility to ensure that they are SE negative. In our world, we also vaccinate for SE twice during their pullet life. When we get to the layer level, again, we follow a very comprehensive program where we are monitoring on a weekly basis fly counts, rodent counts. We have people that audit the facilities as far as is the lawn mowed, are cooler temperatures maintained? So it is a very comprehensive approach which I think nears probably a lot of our colleagues in the industry. Vaccines, in of themselves, are not the answer. They fit in an overall program. Would we be extremely nervous without them? Yes.

Nick Maravell: At what ages are you vaccinating and do you vaccinate once you, or do you also have to vaccinate once they reach maturity?

John Brunnquell: We vaccinate twice: once in the window of time between 6 and 10 weeks old, and once in the window of time between 12 and 16 weeks old. There are two different types of vaccine so that you can provide a broad protection level for the bird.

Nick Maravell: So, there is no, no vaccination once they reach maturity?

John Brunnquell: Once they are in the layer barn, there is no supplemental vaccination.

Wendy Fulwider: Thank you.

John Brunnquell: Thank you all for your time.

Barry Flamm: We will now recess for lunch and be back here at 1:15.

Comment [JMS17]: 04:12:30

[BREAK]

Barry Flamm: ... back in session. Jay, would you continue with the Crops business? And...

Comment [JMS18]: 05:26:25

Jay Feldman: Thank you, Barry. Welcome back, everybody. Hope you had a good lunch. I have asked Michelle to put up language that we discussed over lunch. And I will give you the background on this.

The Crops Committee met over lunch and discussed, continued the conversation and tried to reach resolution on moving forward. And so, I think what we have is, is really a three-part proposal. And again, I am going to ask for clarification on this and concurrence. So, I, I am not meaning to have a perfect report at this point. But, I just want to make sure that we discuss these three elements. And that is the issue of the Sunset of List 3 and how that will be handled; the issue of defining passive polymetric [*polymeric*] dispensers and how that will be handled; and then, a motion adopted by the Board that would ensure that we, as expeditiously as possible, move forward with an inerts plan and incorporate those activities into the work plan of the Crops Committee. So that we might address the issue of inerts well before the deadline that is in the current Sunset for List 4 inerts. The goal in all of this being to get to a point where we can bring everything in sync, you know, have

List 3 and List 4 reviewed as, as one, one group of materials and prioritize, based on hazard or concern or whatever the prioritization system is. But, not slow down the process of review, and not delay this sense of urgency that many of us have, or at least sense of concern that we have, that we are not moving forward at the pace that we could be or ought to be.

So, the, the proposal, then... Let me see if I can get this up here. I will read it into the record. Is, Barry, is that sufficient in terms of having a written document? Or do you need anything more than that? I am going to read it now. Okay. So, starting at the beginning.

List 205.601, Synthetic Substances Allowed For Use in Organic Crop Production. (m) As synthetic other ingredients, not classified by EPA as active ingredients for use with non-synthetic substances, or synthetic substances listed in this section, listed as an active pesticide ingredient in accordance with any limitations on the use of such substances. (2) Inert ingredients exempt from the requirement or tolerances under 40 CFR 180.1122, that were formerly on EPA List 3 of passive polymeric dispenser products may be used until December, I am sorry, October 31st, 2017. Twenty-first. Oh, 21st? Yeah. Good. 2017. And then, that period and that would be the end of that part of the motion.

Comment [JMS19]: 05:30:00

Barry Flamm: Okay, would, Jay, would you restate that in the form of a motion? What will be precisely voted on?

Jay Feldman: Okay. The committee moves to... I am going to have a three-part motion because I think these all have to work together.

Barry Flamm: Do you want a separate vote on each one?

Jay Feldman: No, I... what I would like to do is put the motions out there and have discussion. I guess that we could discuss them separately. But, I would like, since we had, did this on the fly over lunch, what I would like to do is present them, have the discussion, and then go back and have individual. Because we may need to amend, amend the language, if that is okay.

Barry Flamm: It would be better if you just would state the motion and we vote on each one of them as we proceed.

Jay Feldman: Yeah. Okay, I... Then at this point, then, I would like to start with the, with the last part of this effort to reach consensus. And that is with the broader motion on our overall intent. And then I'll work backwards to this, if that is okay with you. And the intent being that, and I will just read what I have drafted so far. Motion: It is our understanding, or is the understanding of the NOSB, that the NOP is committed to expediting the review of all inert ingredients as soon as possible and will support the NOSB in creating a plan for inerts review and an accompanying work plan for the Crops Committee to complete this work.

Barry Flamm: Is there a second?

Unknown Male: Second.

Barry Flamm: The motion has been moved and seconded. I will not try to repeat without, I do not have that in front of me. Discussion?

Unknown Female: Could you repeat it?

Jay Feldman: It is the understanding of the NOSB that the NOP is committed to expediting the review of all inert ingredients as soon as possible and will support the NOSB in creating a plan for inerts review and work plan, accompanying work plan for the Crops Committee to complete its work.

Barry Flamm: Okay. And you have that in writing on your...

Jay Feldman: Yeah.

Barry Flamm: ... computer? Alright. Do we have any comments from the Board? Okay, Zea?

Zea Sonnabend: Okay, I guess, Jay, because we are taking this one motion at a time did not fully explain the reasoning behind this in the context of us extending the deadline. Because, we acknowledged, as a committee, that extending the deadline was a good idea and that in the overall inerts proposal that we hope to have before the Board at the fall meeting, there may or may not be an individual review of these particular List 3 inerts at the beginning of the process. And, because they are really further down the list in the scale of inerts of concern. And so that we will put them in the timeline somewhere, or categorize them somewhere when they come in in the full proposal in the fall. But, we did not necessarily, and the Department especially, did not think it should be locked into individual review of those three inerts sooner than the rest of the inerts proposal. So, in the context of that, the people concerned about inerts review among us, which is most of us, of course, said we can extend the deadline, but we want to only extend the deadline if we get a real commitment. If we let the Department know that we really have a commitment to get this done and we want them to facilitate that as best as possible. So, that is where this is coming from.

Barry Flamm: Thank you for that ...

Jay Feldman: Thank you.

Barry Flamm: ... excellent explanation.

Jay Feldman: Very good.

Barry Flamm: Are there any...

Jay Feldman: Can... May we ask the Department to just express its concurrence with this? I mean, I, I hope this reflects the agreement, or the sense, anyway, of our discussion.

Miles McEvoy: Okay, you said a lot of things and there is a lot of different proposals here. But, what we concur with is moving forward with the petitions that have been received for the, the List 3 inerts.

Melissa Bailey: [Inaudible]

Miles McEvoy: Okay, I am going to turn it over to Melissa since I am not paying attention here.

Melissa Bailey: Okay, so I think what we, our understanding, if I could restate it back, is that the, the Program agrees to support the, the Inerts Working Group process to move forward on inerts review. That may, depending on what kind of proposal the Working Group comes out with, the individual, any individual review of List 3 inerts may not actually occur first. It could occur later on in the process because of prioritizing inerts in however those may be reviewed, according to the Working Group for List 4. So, that we certainly support and would provide the, the resources and support to get there. That is my understanding. Emily, did, do you want to, is that your understanding? Is that, Jay, is that satisfactory? Or... Were you listening? [Laughing]

Jay Feldman: Yeah, I mean, clearly, the intent here is that we, we are not, it is not our preference, I should say, to delay this beyond what is necessary. And so, we do not want to just wait, as we typically do in a Sunset review process, for the date to approach, and then begin the development of a proposal, so as to meet a deadline at the end date. We want, we would like to see a process that begins as expeditiously as possible, and begins a process of review, hopefully, in, in hopes of, of resolving these issues well in advance of the, of the deadline.

Barry Flamm: Okay, thank you, Jay.

Mile McEvoy: Yeah. Just to clarify, we definitely can commit that, that this is important and we will move that forward. In context of all of the other things that we are moving forward as well. So, is a lot on our work plan, a lot on your work plan, you know what is important, we will move it forward.

Jay Feldman: Thank you. I really appreciate that.

Barry Flamm: [Inaudible]

Jay Feldman: So, moving back then, Mr. Chairman, to the first motion.

Barry Flamm: No...

Jay Feldman: Or, the second motion now. Sorry.

Barry Flamm: No, Jay.

Jay Feldman: Oh, we need to vote.

Barry Flamm: No, we have got to complete the discussion if there is any more comment.

Jay Feldman: Oh, sorry.

Barry Flamm: Since there is no more discussion or questions from the Board, we will begin the voting with Tracy.

Tracy Favre: Yes.

The Entire NOSB Board : Yes. Yes. Yes. Yes. Yes. Yes, sir. Yes. Yes. Yes. Yes. Yes. Yes. Yes.

Barry Flamm: And the chair votes yes, and I am sorry, I should have asked the conflict of interest question. Does anybody have a conflict of interest? And that would require withdrawing your vote. Hearing none, there is no indication there is a conflict of interest. So, the vote stands. It is 15 to zero. 15 yes, zero no. Proceed, Jay.

Jay Feldman: Okay, so the second motion is an amendment to what you received in your Board packet. Again, I will read it as I read it earlier. List 206.601. This is, this will be committee recommendation to adopt, as 205.601. Synthetic substances allowed for use in organic crop production, and as synthetic inert, other ingredients not classified by the Environmental Protection Agency, EPA, as active ingredients for use with non-synthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances. (2) Inert ingredients exempt from the requirement of a tolerance under 40 CFR 180.1122 that were formerly on List 3 in passive polymeric dispenser products may be used until December 21, 2017.

Zea Sonnabend: I second that.

Barry Flamm: Jay, we seem to have something different on the screen than what you...

Jay Feldman: Really?

Barry Flamm: ... you read. Is it? Or maybe I cannot see.

Miles McEvoy: That is it.

Barry Flamm: Was it okay? Okay.

Unknown Male: You cannot see the cross-out.

Miles McEvoy: Yeah, you cannot see the [inaudible].

Jay Feldman: It is hard to see the cross-outs.

Barry Flamm: Okay, that, that was your motion? Or you want to restate...

Jay Feldman: Yes, sir.

Barry Flamm: ... re-read it and form a motion?

Jay Feldman: Oh, I am sorry. I move that... Do I have to re-read the whole thing?

Crowd: [Laughing]

Zea Sonnabend: I second it.

Barry Flamm: I will ask later. Is there a second?

Zea Sonnabend: Yes.

Barry Flamm: Zea seconds. Discussion, and if anybody wants a clarification of what the motion is, Jay can provide that. Any questions, discussion from the Board? Hearing none, we will proceed with the, with the vote, beginning with Carmella.

Carmella Beck: Yes.

The Entire NOSB Board : Yes. Yes. Yes. Yes. Yes, sir. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes.

Barry Flamm: Again, I do not know if this required a request of, of any conflict of interest. Please state it. If not, ... Oh, Zea?

Zea Sonnabend: I put out pheromone twist ties on my apple orchard just last week, and by using them, I will get more apples and more money from selling the apples. Is that a conflict of interest?

Crowd: [Laughing]

Barry Flamm: There is ...

Miles McEvoy: Well, that is a disclosure of your interest. It is not a conflict that you would need to recuse yourself.

Zea Sonnabend: Thank you.

Barry Flamm: Okay, the vote stands, 15 yes, zero no.

Melissa Bailey: Barry?

Miles McEvoy: Barry?

Melissa Bailey: Excuse me, Barry? Did you actually say yes to the vote? Did you actually cast your vote?

Barry Flamm: Oh, I didn't. I say yes. Thank you.

Melissa Bailey: [Laughing]

Jay Feldman: And because of our process, I move, I move the committee recommendation for a backup vote to relist, which is list 205.601, synthetic substances allowed for use in organic crop production, (m) as synthetic inert ingredients as classified by the Environmental Protection Agency, EPA, for use with non-synthetic substances or synthetic substances listed in the, listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances, and (2) EPA List 3 inerts of unknown toxicity for use only in passive pheromone dispensers. I move that.

Barry Flamm: Okay. Second?

Harold Austin: I will second.

Barry Flamm: Harold seconds. Sort of redundant, but any conflict of interest on this?

Zea Sonnabend: Same disclosure as last vote.

Barry Flamm: Okay, I think the decision would be the same. Any discussion on this backup vote? Do you, any new member have any question on what the backup vote is for? Okay, hearing none... Oh, you have got a question?

Unknown Male: Just a comment. I know it is really hard for Jay to make that motion. [Laughing]

Jay Feldman: Thanks for feeling my pain.

Barry Flamm: Okay, hearing no more requests for discussion, I think John, you are up to begin the voting.

John Foster: Yes.

The Entire NOSB Board : Yes. Yes. Yes. Yes, sir. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes.

Comment [JMS20]: 05:45:00

Barry Flamm: And the chair votes yes.

Jay Feldman: And then, I move the Committee motion to add a definition to 205.2, terms defined. Passive polymeric dispenser products, solid matrix dispensers delivering

pheromones through volatilization only at rates less than or equal to 150 grams active ingredient, AI, acre per year, that is placed by hand in the field and is of both size and construction that is readily recognized and retrievable. 50 FR 7368, March 30, 1994.

Unknown Male: Do we still need to [inaudible]

Zea Sonnabend: I second.

Jay Feldman: Well, I, I guess we need to still include, to be removed, as a definition when 205.601(m)2(a) and (b) expire.

Zea Sonnabend: Okay.

Barry Flamm: Is there a second to the...?

Zea Sonnabend: Yes, I second it.

Barry Flamm: Okay, we have a motion on the floor which has been seconded. Is here any discussion? Yes, John?

John Foster: Can I ask about the, the necessity of the applied by hand portion? Is that, and I do not know, maybe Harold, you can, you have a better sense of how important that part is. But, and exactly, I mean, I hate to do this, but what, what do we mean by that? I can imagine, for example, using a tool to put something in place of one's hand, you know, to not necessarily twist it on with your fingers, but with something else. I do not know. My...

Unknown Male: A robot?

Jay Feldman: The, the majority of the, of the growers use application tools to physically put the pheromones up to the tree or to the trellis wires. They, they do not use their hands. There is a tool involved.

Zea Sonnabend: But, you are still doing it by hand because you are using a tool. It is not a machine that goes into the rows and does it.

Unknown Speakers: [Inaudible] Yeah, that is true. In the row. Yeah.

John Foster: I apologize for that question.

Crowd: [Laughter]

John Foster: But, I mean, it sounds silly to ask: what do we mean by applied by hand. But actually, I can imagine a world where someone would want, you know, could have issue with that. If we mean it is put on with a tool, then maybe that is not... If we do not want to be that specific, that is all I am saying.



Zea Sonnabend: We copied... The definition was copied out of a Federal Register definition, elsewhere. And they said by hand. So, that is what we are saying.

Jay Feldman: Any other? Carol, do you have a problem with that wording?

Barry Flamm: Any other questions, discussion? If not, we will proceed with the voting. With the... Joe is next.

Joe Dickson: Yes.

The Entire NOSB Board : Yes. Yes. Yes, sir. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes.

Barry Flamm: 15 yeses and zero noes, and myself. I always forget myself. The chair votes yes, and that makes it 15 yes, zero no. Thank you. That completes the Crops session. Next up is a Livestock Subcommittee with Wendy Fulwider, as chairperson.

Wendy Fulwider: Thank you, Barry, and Michelle has some slides that we are going to bring up. And I just want to let everybody know that we are going to take things slightly out of order because we have people that want to give public comment, and they have planes to catch. So we are going to take one kind of in the middle of our presentation.

I will start here while the slides are coming up. But, our agenda today, I am going to start out with animal welfare guidance, and the, the pieces that I am going to talk about are: why do we need animal welfare guidance? Who is generating the pieces for each species, and how will they be used? And after that, we will take off with the GMO vaccine discussion, and Nick Maravell and Jean Richardson will lead to that.

So, why do we need animal welfare guidance? First, we need it for consumers. Consumers expect good animal welfare, and they want assurance that the food producing animals are treated well. The majority of consumers do not have access to farms or no farmers at this point, with so many suburban folks. Less than 1% of our population is engaged in farming in this country. And, many consumers are not aware of the fact that there are animal welfare requirements within OFPA. One more. Okay.

Certifiers, inspectors, certified operations and animal care: When the NOSB passed the animal welfare recommendation, it was with the understanding that we would have strong outcome-based measures that would be a part of this Program. This is to be a tool for use by certifiers when they need it. It is not for use on every farm, or for every certification. It offers different ways to assess the compliance with the animal welfare recommendations.

The species-specific guidance pieces should be helpful for producers, because this should help them avoid doing multiple animal care audits by different certification agencies. It should all be covered within the organic certification. It is, will also be helpful to farmers that are transitioning to organic. I go out and do animal care checks with our Organic

Valley producers, and I use similar scorecards and tally sheets to what I have proposed here for use by the organic community. And, it is, it is very helpful when you are talking with a new producer that is new to organic, and they are not accustomed to the, the different ways that we manage, because it is different than when they were conventional. It is also helpful to producers that are expanding or renovating, you know, their facilities. Because they are going to do something different than they did when they were a conventional operation. It should also be helpful to farmers that are having issues, whether it is with hygiene or body condition or, or locomotion. Because, that is all part of management and management issues should be a part of the guidance pieces.

Who wrote the guidance drafts? The bison piece was written by Dave Carter, who is a former Board member. The poultry section was started by Holly Born when she was at MOSA and Sarah Shields, who is an HSUS consultant, and studied with Temple Grandin and Barry, Bert Rollin at Colorado State, did the academic portion of the poultry piece. The sheep guidance was written by Bonnie Wideman from MOSA, and we have, as a Board have already, or as the Livestock Subcommittee, have already started making refinements to that piece. The dairy outcome scores and tally sheet were written by me, and it is very similar to similar, very similar to score sheets that I have used in the past and the one that is also used at Organic Valley. So, I think with these pieces, you know, they are, they need a lot of refinement, and we need to do a lot of editing before they are ready to go. But, I think we are off to a really good start.

This is an example of the piece that we have prepared for the guidance. And, this piece shows the loco, locomotion scoring. And these are standard industry scores, the same with the body condition scoring, all standard industry pieces and similar to what the National Milk Program is using when they go out and do voluntary audits. There is the hock lesion. This piece has the hock lesions and the cow hygiene, and also similar to what is used in the National Milk Program Federation audit.

So, this would help you to determine if animals are thin on a farm, if they are not clean enough, how many lame animals are they, how lame are they? Is it actually issue? It is normal to have animals on a farm that are challenged. You know, if you have animals, they are going to find ways to get in trouble. They get sick. They get dirty. They get hurt. And so, it is just a tool to deter, determine whether or not there is an issue. So, the scorecards can be helped, can be used to help make decisions when you are out on a farm. And, the guidance pieces can also be used to educate and inform, whether it is consumers or producers or anyone else that is involved in, in checking welfare. So.

Future guidance will be developed for beef and swine and Tracy Favre has volunteered to do the beef piece. And I have two ladies working on the swine guidance, Marlene Halverson, a farm animal welfare consultant at Farm Forward and producer at Field Productions LLC. Tracy Harper is a reproductive swine physiologist and agribusiness and science technology instructor at Western Technical College in La Crosse, Wisconsin. And they are both familiar and have worked with organic hog producers.

Written public comments, we have received 626 pages in pdf form. So, we have not been able to go through all of them. Previously, Calvin has sorted and analyzed all of them for us, so that we can sift through and use part of it and make decisions on, on our refinements.

And so, I just want to let everybody know, if you are not going to be here for our, our closing, at the fall meeting, this is the list of things that we are going to be addressing, and of course, the things at the top of the list will be addressed first.

And with that, if there are a few questions, on the species-specific guidance, animal welfare pieces, I would like to take those from the Board and then we will move on to the GMO vaccines.

Okay. So, Jean, I believe that you are up next.

Jean Richardson: Okay, well the Livestock Committee worked for several months on the coming to this meeting with the recommendation that GMO vaccines should be used only during an emergency or they can be petitioned as individual substances. However, we received a considerable amount of public comment, suggesting that we needed more information and providing additional information, indeed, and also we got further information from the NOP staff themselves. So, it made it obvious that we would need to table this recommendation for this meeting.

However, what we are hoping that will happen today is that all of your expertise here will clearly help us and inform us with factual information and data that can allow us to come back to hopefully the spring meeting with a better recommendation or a clear recommendation, or perhaps it will be the same one. I mean I really do not know. Obviously, I am not going to second-guess the experts.

So, what my goal here just briefly, as briefly as I can with a complex subject, is to try to outline how we got to where we are right now. And then after I have spoken, Nick is going to look at some of the questions that have been raised during our work, and also from those that came in from public comment.

So, basically, the NOSB is seeking to clarify if in fact GMO vaccines as a class of substances is allowed or prohibited under requirements stipulated in 205.105(e) and 205.600(a). At the moment, livestock producers use all vaccines, as they are allowed to do, under the, under the standards including 205.603(a)4. But, the National, the NOP has received advice from General Counsel that GMO vaccines should only be allowed if specifically added to the National List. GMO vaccines are not on the National List. Obviously, vaccines are used nationwide in most farms, not all. There are closed herds and there are small farms that do not use vaccines on a routine, routine basis. We know from experience, our boots on the ground, that typically, producers do not go and ask their veterinarian or the producer or where ever they buy the vaccines from, if they are GMO or non-GMO at the present time. Producers... Let us see what else.

Comment [JMS21]: 06:00:00

Since its implementation in 2002, certifiers have routinely been allowed, routinely been allowing all vaccines. So that in 2009, the NOSB recommended that if non-GMO vaccines were not commercially available, then a GMO vaccine could be allowed because that was the practice of the time. So the status quo essentially was officially left in place. Nonetheless, what is very important is that all consumers out there are still assuming that all organic products, both in the processing and in the handling, are in fact non-GMO. And we have already had the Zea's vote on that yesterday, as I recall, that non-GMO is still as popular as ever.

So if we look at the relevant areas of the rule, if you look at 205.238(a)6, it states that livestock health care practice standard requires that producers must establish and maintain preventive livestock healthcare practices, including the administration of vaccines and other veterinary biologics. And then if you look at 205.603(a)4, in 2002, the NOP simply lists without annotation, synthetic substances allowed in livestock production, they allow biologics, vaccines, without annotation. Then, if you look at 205.105(e), the allowed and prohibited substances in organic production and handling, the product must be produced and handled without the use of excluded methods, except vaccines, provided – and this proviso is very important – provided that the vaccines are approved, according to 205.600(a). And, the relevant section of 205.600(a) requires, sets up evaluation criteria for allowed and prohibited substances requiring that we look at a whole group of criteria use, that the NOSB has to look at the whole range of criteria as specified in the, in the Act. And the reference is provided there.

Now, obviously, the NOSB has not reviewed GMO vaccines under 205.600. That has not happened. We have received a technical report, as you know, and we have used that as we began to go through the rule and look at the reality of what was happening out in the country. We also looked at the, the history of, of what the NOSB has previously done. In 2009, the NOSB added the phrase in their recommendations for excluded methods except vaccines, provided that vaccines made from non-excluded methods are used, if commercially available. And it was at this time that they essentially accepted status quo.

They said at the 2009 meeting, the rationale of the Livestock Committee at that time, it says: Previously, vaccines made by excluded methods were to be individually petitioned to the Board, for allowance or prohibit, prohibition of use. In reality, since – still quoting – in reality since implementation of the rule, certifiers have routinely allowed all vaccines, since they are used to prevent disease and needless suffering of animals. This recommendation will more closely align with what has been occurring in the field since 2002, however, it will actually make it incumbent upon the producers and certifiers that vaccines made by non-excluded methods are located and used before those made by excluded methods. End of quote from 2009.

The NOP responded to this in 2010, and let me read from, from their document, which includes reference to the, to the final rule as well. The Act allows use of animal vaccines in organic livestock production. Given the general prohibition on the use of excluded methods, however, we believe that animal vaccines produced using excluded methods should not be allowed without an explicit consideration of such materials by the NOSB,

and without an affirmative determination from the NOSB that they meet the criteria for inclusion on the National List. It is for this reason that we have not granted this request of commenters, but rather, provided an opportunity for a review of a narrow range of materials produced using excluded methods through the National List process.

So, the NOP's understanding is that excluded methods are prohibited under section 205.105(e), except for vaccines. And further, that this exception applies to vaccines that are produced only if the GMO vaccines are approved according to 205.600(a), again. So we still have that to keep in mind. The NOP requested a legal review from USDA's Counsel of, Office of General Counsel, the OGC, to determine whether vaccines produced through excluded methods are currently allowed under 205.603(a)4. The OGC opinion supports the position that GMO vaccines are allowed only if they are approved according to 205.600(a).

So, there we are. So, what do we have in, to work with, then, at the present time? The Livestock Subcommittee looked at a wide range of questions and attempted to get answers, both from the technical report by having people on phone calls from, from industry, from, from labs, producers of vaccines, to try to answer some of the questions that we posed. I am not going to go through those in detail right now. But, I will say the one thing that we, we were able to determine is that there is, in fact, a list: it is the APHIS list.

The Animal and Plant Health Inspection Service's APHIS List maintains a periodically updated list of all registered vaccines with code alpha-numeric annotations that could allow a certifier to determine if a vaccine being used is GMO or non-GMO. However, I should tell you, having looked at this list, it is certainly not easy to really be sure what it is you are looking at. Especially because the, the products on the list are typically listed by generic names and, and, and the code is not clearly able to be used.

And furthermore, what is important is what we have found is that obviously, most of the producers using vaccines are actually using combination vaccines. They are not just giving one at a time, they are using a group of six. So maybe one of those is GMO, one is, and all of the rest are not. We did get some information that allowed us to believe that it would be possible to have all of, basically all vaccines available in a, in a non-GMO format. And I am hoping that as we get into the discussion section that we will get some clarity on that.

So, if I just synthesize the findings. Section 205.238 requires producers to maintain preventive healthcare practices, including the use of vaccines. You cannot deny treatment to an animal in order to re-, maintain organic status. That is not permitted under the rule. Livestock vaccines are commonly used. The list is not easy to understand, and at the moment, there is no requirement that a producer be asked to tell their inspector or the certifier whether they are using GMO or non-GMO vaccines.

I should add also that Canada does not allow GMO vaccines, as far as I am aware, or we are aware. Europe does allow GMO vaccines, with the typical exception, as we presently

are using. An interesting sidebar in the World Health Organization and the Food and Agricultural Organization in Europe differentiates between GMOs in, in food, and GMO vaccines, saying that with engineered foods, the intention is to introduce a new trait into a food, and this trait is present in the food eaten by the consumer. On the other hand, genetically modified vaccines are used to, to provide a protective, protective immune response by means of an immune, immunogen that is often no longer itself present at the time the animal is slaughtered.

So we have a large amount of data and information with which to continue to proceed on this. So, public comment makes it clear that we need further information from all of you here today. And, and we are particularly concerned, of course, with the poultry industry issue, and the need for a greater understanding overall.

So, that is my general, sort of, introduction and I will turn it over to Nick at this point.

Nick Maravell: Wendy, do you want to [inaudible]

Wendy Fulwider: Yes, we would like Don Blake to come up and give public comment before Nick begins his presentation.

Don Blake: Is this where you need me? Okay, hello. I am Don Blake. I am the Director of National Accounts with Newport Laboratories. I work primarily with the production systems of the large food companies in the US and all of Latin America.

The comments that I want to make: Newport is the largest producer and manufacturer of autogenous vaccines in the US. And, we are also, we have the largest diagnostic lab, private lab, in the United States as well. And it basically supports our vaccine business.

What autogenous vaccines are, very straightforward, we get isolates in from the farm level. These would be primarily viruses and bacterias. We produce a vaccine. We can do combinations of viruses and bacterials. And, these vaccines are constructed under our USDA license, the protocols that we have registered with the USDA. But, unlike a commercially produced and licensed vaccine, our protocols are very broad.

And unlike commercial products, we can fully disclose to the customer, the veterinarian, a lot of information about the antigen that is in there, the adjuvant that is used, preservatives. Basically, you can direct the product. It is your vaccine. You can customize it. And that is what the large food companies really look to me and to our company to do. Food safety is what they are all about. So they want to control their inputs. They want to know everything that goes into it and they want to understand that.

So, on the GMO issue, we do not produce vaccines that way. We certainly can, we have the technology to do it. We can do it if we are asked to, but the autogenous is an alternative. Again, anything that we find on a farm, we can make a vaccine out of. And, it doesn't have to be done under GMO standards.

Recently, we were purchased, March 28th, by Merial. They are one of the world largest animal health companies. They bought us specifically for our autogenous production. Merial is a, has... Merial Select is the largest poultry vaccine company in the world. So, I heard from the Board that this is an area of concern.

So if you look at our capacities, I mentioned we are the largest. In 2011, we produced approximately 86 million doses of vaccines. That is about 63% of our internal capacity. We can expand our capacity very rapidly. With being owned by Merial domestically, Merial has three large animal health vaccine plants in Georgia. We can contract actual antigens to have them made there, if we need added capacity. We can finish them off in Worthington, where we are located. So, we, capacity I do not see as ever really being an issue in the arena that we play in. We are primarily pigs and cattle. But, we can also -- okay, I am done. Questions?

Nick Maravell: Yes, could you please continue? [Laughing]

Don Blake: Okay. Well, I am pretty much wrapped up from what I said.

Nick Maravell: Okay.

Don Blake: Timelines, though, I will be real quick on the timeline. When we get an organism in, if it is a bacterial, it takes us 4 to 5 weeks to make a vaccine on the first time. Viruses are about 6 to 8 weeks. We have two years that we can use that particular isolate organism we got in. So, you do not have to do the process every time. Every two years, we have to re-isolate or just renew it. So, that is kind of a timeline. So, end of my comment.

Wendy Fulwider: Zea.

Zea Sonnabend: Thank you for actually being a vaccine producer to come talk to us. For some of us who are not on the Livestock Committee and are trying to grapple with the issues, you explained that you could make non-GMO vaccines and you could scale up fairly easily.

Don Blake: Yes.

Zea Sonnabend: But, I am assuming you do not really want to make it for like 50 cows. And so, what, how, what is your minimum amount that you feel that it is worthwhile to make a vaccine? Is it feasible to do it on as small a scale as organic currently represents in the industry?

Don Blake: On an individual basis, it would not be. But, what we can do is regionalize it. The USDA lets us do what is called a, it is a non-specific herd of origin. Where, we can get isolates in from a region. A region can be the US. It can be a state. It can be a county. Where we could get together multiple producers in an area, qualify their isolates, so that they all have basically the same problem and make a common vaccine for the whole group. Now, economically, that works very well. We do that all the time right now with current customers. It is just called a non-adjacent forms that have to be filled out.

Comment [JMS22]: 06:15:00

Zea Sonnabend: Do you have a minimum, though?

Don Blake: Usually, for... yeah, 2000 doses would be a minimum.

Zea Sonnabend: Thank you.

Don Blake: You are welcome.

Wendy Fulwider: Mac.

Don Blake: Yes.

Mac Stone: [Inaudible]

Wendy Fulwider: Colehour.

Colehour Bondera: Yeah. Thank you, Don, for your, for your testimony. I appreciate it. And I have a, a question that I will admit I think I already know the answer to. But, I want you to verify. So, from what I heard you present and what I understand, you know, the situation that we are going to be dealing with and listening to the other testifiers, where if you leave, you will not necessarily be able to do, is that we are going to have some level of emphasis on this salmonella and poultry question. And my question to you is, from what you said, it sounded like you could readily produce a non-GMO poultry salmonella vaccine.

Don Blake: Yes.

Colehour Bondera: And that is my question, if that is a viable option to commercially produce such a thing...

Don Blake: Yes.

Colehour Bondera: ...at this point in time.

Don Blake: We, we currently make a lot of salmonella vaccine. Primarily, it is sold in the dairy calves, but to do poultry, I mean, it, it is just another strain of Salmonella. We have all the cell cultures we need to grow it in. It is really not an issue. You know, I do know how widespread it is in poultry. But, again, we have Merial Select in Georgia that produces, I do not know, 600 million doses of poultry vaccine a year. They are the world's largest. I do not see an issue there. I really do not.

Colehour Bondera: Thank you.

Wendy Fulwider: Tracy.



Tracy Favre: It is my understanding that there is two different types of salmonella vaccines: a live vaccine and a killed vaccine.

Don Blake: Mmm-hum.

Tracy Favre: Can you explain any limitations in the ability to generate a non-GMO live vaccine?

Don Blake: The autogenous outlines do not allow any modified live vaccines to be made as an autogenous. It is not allowed, we cannot do it. We know how to do it. The reason we modify modified lives, is if we do not, they will cause the disease. They will kill your animals. They have to be modified. That is why they call them a modified live.

Wendy Fulwider: Jean.

Jean Richardson: Don, when we read the technical report, we were given the impression from that that there are about 73 or so registered livestock animal vaccines. And, from all the other things we have read, we now understand that as far as we know, we could get those in non-GMO format.

Don Blake: Yes.

Jean Richardson: And yet, the APHIS list seems, has an inordinate number of vaccines listed, which makes it all very difficult, really, to understand. So can you help us to understand the, sort of, the interface between the fact that there is about 73, which really is not a lot of vaccines to be working with, and that list so that we can begin to understand how we can assess [inaudible]?

Don Blake: Jean, the document that you are talking about, you know, there is multiple manufacturers of the same antigen. Let us, we are talking about salmonella, let us stay on salmonella, but maybe not just in poultry. There might be several companies that manufacture and sell a salmonella vaccine. And in that document, it lists their, their license that they have at their facility. It lists the license they have for that vaccine, and then all the other licenses. So, if you sort through that, you are right, there might be, let us say instead of 73 vaccines, let us say there is 73 organisms, disease entities for which there are vaccines. And there might be multiple vaccines for those disease entities. Autogenous vaccines, what we do, do not appear on any list and they are not in any document. They do not have to be.

Wendy Fulwider: Nick.

Nick Maravell: Can you explain what the licensing procedures are for a company that makes autogenous vaccines? And whether or not autogenous vaccines are reviewed by APHIS for efficacy, and dosage?

Don Blake: We, with an autogenous vaccine, the only criteria we have with the USDA is we have to be a licensed vaccine facility. That is the same license. We also make commercial

vaccine. We have to have that. All of our autogenous products have to be safety tested. Every serial we make has to go into CDB and it is safety tested. All that really says is it is not contaminated. On potency testing, we do not, we are not required to do potency testing. But, a lot of our customers require it. So, when we make new serials, we do in-house potency testing. We have what I call non-target animal models that we have, we have developed to do this. We do not have to submit this to any regulatory agency. It is between us and the customer. We do report our potency results to the customer. We do not have to, but we do.

Nick Maravell: Can you explain the difference between potency and efficacy?

Don Blake: Potency means you, you make a vaccine, you inject it into an animal, let us say it is salmonella. And then the USDA has guidelines that you have to challenge with salmonella, and you have to record the level of protection in that animal. Potency and efficacy is fairly interchangeable.

Nick Maravell: So, you are saying your customers could require that, and you can perform that, but it is not required as a re-, as part of an APHIS review?

Don Blake: It is not required.

Nick Maravell: What about dosage [inaudible]?

Don Blake: Dosage, again, we have a lot of flexibility. We can concentrate. Our minimum dose is 0.2 ml, and we can go all the way up to 5 mls. The customer determines what dosage level. It also is determined by how many antigens we put in a vaccine. If we have eight different things in there, we probably need two or more mls as an actual dosing.

Nick Maravell: Okay. You said you can combine viral and bacterial...

Don Blake: Yes.

Nick Maravell: ...in the same vaccine?

Don Blake: Yes.

Nick Maravell: So, you can stack a variety of vaccinates and virals...

Don Blake: Yes.

Nick Maravell: ... in there? Can you explain what the disadvantage is of only being able to use inactivated or killed vaccine, organisms for use in vaccine as opposed to what would be considered in layman's term, a live vaccine?

Don Blake: A modified live is, is going to be used if you have an active disease outbreak going on in a herd. You come in with a modified live, and generally, especially with viruses,

because you cannot treat a virus with the antimicrobial or pharmaceutical. But, if you use a modified live, if there is one available for that particular virus that is breaking, it will pretty much stop the loss, the economic loss. It is not going to make it go away. But, it is going to have a real impact on your death loss with your animals. That is really the biggest difference. There is a difference in antibodies that are produced. Modified lives produce a CMA, where we do an IGM and a IGA. I do not think we want to have that kind of broad based immunology discussion. But, for layman's purposes, let us just focus on if there is a disease outbreak in a viral, modified live will stop your economic loss.

Nick Maravell: You are saying that for the viral. Is that also true if it is a bacterial?

Don Blake: Not really. The other advantage is it is a single dose. From a, from an immune response standpoint, a modified live is a single dose product. Where bacterials, autogenous, anything killed, you really have to use two doses to get your best immune response. There is really no way around it.

Wendy Fulwider: John.

John Foster: So, one of my concerns is about the capacity to serve, you know, and hopefully an ever expanding industry. And, I mean, I am pretty sure everyone in the room wants that. We want it to grow as much as it can responsibly and fairly and all that. So how, what kind of, my question is more about, I was unaware, I guess, of the new parent company. So what kind of capacity does that give you? And, are you able to [inaudible]

Don Blake: Well, it gives us access, it gives us access to two more very large commercial plants. Now, I cannot say we can, you know, they are not maxed out, either. But we could in emergencies, have them produce some of our antigens. At this point, I do not know how much that would be. You know, we have only been part of Merial since the very end of March. But, they have offered this to us. So, we have it available. But, I have never really had an issue with a large customer where we could not meet the demand. And as I said, you know, some of the, I deal with some of the largest food companies in the country right now. Not with poultry, but with pigs and some of them have huge demands for vaccine. But, I mean millions of doses at a time.

John Foster: Well, what I am hearing is that that scale is kind of giving you comfort to make sure that you are, you are going to be able to accommodate that. That is all.

Don Blake: Autogenous, scaling up on autogenous is so much different than scaling up commercial. It could be done so quickly and for a lot less money.

John Foster: Thank you.

Don Blake: Mmm-hum.

Wendy Fulwider: Tracy.

Tracy Favre: Just a point of clarity. You made a comment that a live or modified live vaccination is used for an outbreak. Is there any reason to use a modified live as a preventative in, for instance, the case of salmonella?

Don Blake: Yes. It, you will get a strong immune response, and you only have to give one dose. So that there is a convenience factor there.

Tracy Favre: So, could you accomplish the same results with a killed virus with two doses?

Don Blake: Yes. If, if we are talking about, from an immune perspective, yes.

Tracy Favre: Thank you.

Wendy Fulwider: Jean.

Jean Richardson: How easy would it be to generate a list of non-GMO vaccines so that the individual farmer and the certifying agency would be able to have, ask the right questions so to speak at the time they are deciding what vaccines to use and that would include of course listing, being able to get access to autogenous vaccines?

Don Blake: Mmm-hum. Jean, it, it is hard to, to say because commercial companies, you, you are getting into their intellectual property. There is a lot of things they do not have to disclose to the public, and they will not. However, part of their marketing materials will have that information in it. And what you really want to look for, in a GMO product, you want to look for vectors. There is a lot of the commercial vaccine that is put into a vector. And by your definition, it has been genetically modified. Because, they will take some, you know, amino acid sequences out of the disease organism, and they will put it into a benign vector that does not cause disease. And that is your vaccine.

Marketing materials have a lot of this information in it. But, the manufacturer does not have to disclose that to the public, on what they have done or why they do it. So, I do not know if I answered your question, but I would start with practicing veterinarians, they have access to the commercial vaccine companies that give them marketing materials. And, you will have to, I do not know of any other way to do that. I do not think you can look at the license itself. I do not think the general public is going to get, like, you cannot look at my licensed vaccines. I would not show it to you.

Wendy Fulwider: Nick.

Nick Maravell: We heard in earlier testimony that autogenous vaccines have a more narrow spectrum as to the strains of, let us say, salmonella, that they might protect against. And do you feel that that is a limitation? You were describing the ability to come up with regionalized autogenous vaccines.

Don Blake: Well.

Nick Maravaell: Is, is an autogenous vaccine going to be seen as less able to cover a broad, broader spectrum? And, I do not know how essential that is to production at this point, but [inaudible].

Don Blake: Well, of course. That is the reason for our existence.

Nick Maravell: Right, by definition.

Don Blake: Again, we go into the, the herd, and even to an area, and we identify all the strains of salmonella that are there. We do not make a broad-spectrum product. We put in it what we found. So, it, it is targeting exactly what we found. You are getting the disease that you had in your herd, that you had in a region, that you had in non-adjacents. So, the argument is not about if it is broad. If I made a commercial salmonella, I would have to make it broad. But, I, I am limited there because I cannot cover everything. But autogenous, I can.

Nick Maravell: Right, right. I understand. We have also heard about the difference, in terms of how quickly or how strong of a take or a reaction, if you will, you get from an autogenous vaccine that may have to be administered, or, or a vaccine that is using inactivated organisms versus a live vaccine may have to be administered at a later stage of development of the animal or may have to be administered twice, which is what you have said. So, do you see some disadvantages then to the autogenous vaccine, in terms of how strong of a reaction, how well it takes composed, as opposed to a live vaccine?

Comment [JMS23]: 06:30:00

Don Blake: I, I think that is a convenience factor. You know if you are going to deal with a... In the livestock industry, you know if you have parent animals that are producing offspring, and you need to vaccinate the offspring, then you want to rely on maternal antibodies. You have got to let them do their job. You cannot vaccinate with a killed product in the face of maternal antibody, a high level. Now modified live can come in and, you know, reformat that whole immune system, if you want to, want to do that. But, you have to wait for your maternals to drag out, then you can effectively immunize with the killed. So it might be a convenience thing. Somebody might say, look I will vaccinate young animals because I can do it. I do not want to wait until they are this old.

Wendy Fulwider: Thank you, we need to move on now.

Don Blake: Okay, thank you.

Wendy Fulwider: Nick, if you would like to continue your presentation.

Nick Maravell: Sure, Wendy. Was there a slide or two I should be talking to?

Wendy Fulwider: Michelle, if you could [inaudible].

Nick Maravell: Okay. What the Livestock Committee found was that we kept getting more information, which generated more questions. And, we went through a process and, in

reviewing the technical report, we came up with some key questions as we went through our, that were not answered by the technical reports. They were not necessarily posed to the contractor.

Then, as we went through our deliberation to come up with a recommendation, there were obvious questions that also emerged. Such as, why do not we make a list so everybody knows and is playing off of the same sheet of music? This is a vaccine. This is its name. This is the disease it treats. It is either produced with excluded methods, or without excluded methods. That we, we would really love to see such a, a document. Then, we came up with questions that we wanted to hear more information from the field. What would be the impact on the industry? What were the different types of species that were particularly in need of vaccines produced from excluded methods, etc.? And then, we went back to the Program and said, this is what we are thinking about, but, do you have questions that you want answered or think that would be valuable in proceeding with this issue? So, we sort of have four sets of questions. And, some of them will flash up on the screen. I am not going to go through all of them, maybe one or two.

One obvious question is: what specific disease problems can only be addressed with a GMO vaccine? And, we are not 100% on the answer to that question. We have got a lot of good information. Wendy has gone out and gotten us additional resources to consult. And, we are getting closer. But, we are not there yet.

Another question that we have, and I am going to put this off to the side, we did make a recommendation, with regard to emergency use. And, I should put a little bit of a preface on this. Vaccines generally should be used as a preventative 99.9% of the time. That is where vaccines are effective and should, desirable. There are instances beyond the control of normal events, and I, you know, I hesitate to mention these, but there are the realistic possibility of bioterrorism, and there is the realistic possibility of what are called foreign animal diseases, such as hoof and mouth disease coming onto these shores. In those instances, it is not always possible to have the tool in your box to meet the emergency. It is, though, a very hopefully rare occurrence, and so, the committee made a recommendation that in that instance where a federal or state official declared a state of emergency and mandated, required, all producers, not just organic producers, to administer certain treatments under that circumstance, we were making a recommendation that the Secretary change current policy and not exclude the organic products that would be affected: livestock and livestock products, such as milk, eggs, slaughter stock, young stock still in the last third of gestation in mammalian species, etc.

And our reasoning on that did not fall directly from the statute. So, we are going out a little bit on a limb on this. It would create multiple years of recovery for the organic livestock industry. And, you can debate how long that recovery would take. But, it would be a, a financial issue. It would be a major impact. We felt that if it was explicitly described to the consumers that they would understand, the entire country, the entire state was pulling together to meet a public health need. So, we felt it was justifiable. But, there is not an explicit criteria there in the statute. So, I just want to make that clear.

So, what we would like to do with, hopefully, with the remainder of our time, is we really want to hear from the public. We want the ability to have some back and forth, like we just did with that witness that had to catch a plane. So, we can truly understand the needs, and we are looking for your ideas as to what the next steps should be, as we move towards a policy on vaccines, GMO vaccines. What are the next steps that you would like to see take place, and who should be involved in those steps? Second, if this – these list of questions are up on the website – if there are specific areas that you would like to address, related to these or other questions, or you think there are questions we should add to our list – we are not sure exactly how these questions are going to get answered right now – we would like to hear that as well. So, we are looking for the next steps and we are looking to gain more information.

Wendy Fulwider: So, we are ready to start public comment. Bob Beauregard, if you are here. And, Mohammed Mousa on deck.

Bob Beauregard: Good afternoon. To the new members, welcome. Good luck.

Unknown Male: [Laughing]

Bob Beauregard: My name is Bob Beauregard and I am the general manager at the Country Hen. We are a small organic egg farm located in central Massachusetts and have been in the egg production business for, since 1988.

The Country Hen does not support the use of excluded methods in the production of organic seeds, crops, ingredients or other production methods. We have signed petitions endorsing the fight against GMO Round-Up Ready alfalfa and the mandatory labeling of GMO foods, ingredients produced by the means of excluded methods. We also support the proposed letter – [cough] excuse me – to the Agriculture Secretary Vilsack from the Ad Hoc Committee as well as support the national, the GMO vaccine comment submitted by the Organic Trade Association.

The National List identifies all vaccines as a group as synthetic substances allowed for use in organic livestock production, 7 CFR 205.603(4)(a), Biologics, vaccines. Although we clearly understand why GMO vaccines are being questioned, we do not understand the Livestock Committee's rationale to use these vaccines for emergency cases only.

Vaccines are essential in livestock production, and are specifically listed as preventative health care practice in the NOP regulations. The proposed LC document is inaccurate, lacks information with regards to the use of GMO vaccines in organic livestock production. There are many unanswered questions. Furthermore, the recently signed equivalency agreement between the United States and the European Union allows the EU organic livestock producers to market their products, potential, potentially produced with GMO vaccines, in the United States, which puts the US organic producers at a disadvantage if some of the vaccines are only produced as GMO and are thereby not allowed to be used in the United States.

We respectfully request that this proposal be withdrawn, which you have already done. And, we thank you for that. But, this comment was prepared, obviously, flying in on the plane. We know that more work is necessary. Difficult to answer questions for endovaginal vaccines must be addressed. We support the idea of specific lists that can be created and determine non-GMO and GMO vaccines as guidance for producers and vaccine manufacturers. Thank you for your time, your service and your consideration to the issue.

Wendy Fulwider: Thank you.

Nick Maravell: I have a question.

Wendy Fulwider: Oh.

Nick Maravell: I have questions. I have questions. Could you describe your vaccination protocol...

Bob Beauregard: Schedule...

Nick Maravell: Schedule, yeah and, also, how you are responding to salmonella as a, as a total management program of which vaccination is a part?

Bob Beauregard: Okay, so earlier, John basically described his.

Nick Maravell: Mmm-hum.

Bob Beauregard: And, ours is pretty much the same.

Nick Maravell: Okay.

Bob Beauregard: We are using, you know, the, the 4 to 6 week, and then the, you know, the 10 to 14 week vaccination program. One is a live version, one is a killed version. It is all done in the pullet Stage. It is being done. We, we have always used a salmonella vaccine. The egg prevention, FDA egg prevention, salmonella prevention plan that came out, obviously, that is suggested by the FDA that you use that as a prevention method. It is not required. It is not mandated, same thing that John said. And that is pretty much the program that we are using. Obviously, we, we are keeping our farms clean. We have different areas of production. We have got one farm that has 50,000 birds on it, but, they are all in small flocks, between 65 hundred and 7 thousand birds in each flock. But, then we have farms that are not on that address that you have to have separate prevention plans for. We have those plans set in place for this coming July. So, you know, the smaller areas will be inspected come this October. The bigger areas have already been inspected. So, as a prevention plan, you want to put everything in that plan that is going to prevent salmonella from, from entering.

Nick Maravell: So, you are administering twice now.



Bob Beauregard: Yes.

Nick Maravell: And, if those vaccines do not contain excluded methods, that would, that would be just fine with you?

Bob Beauregard: That is the ultimate.

Nick Maravell: That is the ultimate.

Bob Beauregard: That is our goal.

Nick Maravell: That is your goal, alright. So, if, if you can get that, that will satisfy your production needs.

Bob Beauregard: Exactly. We just need to know which ones they are because, our certifier, since day one, has requested that we get statements from our vaccine producers that a non-GMO statement. So we have done that since the day we were certified. And that statement, I think, may be what is more in conflict than the vaccine. I mean, so that is where the producers and certifiers are as confused as to what vaccines are actually GMO and non-GMO. So, that is where we need the clarity, as producers.

Comment [JMS24]: 06:45:00

Wendy Fulwider: Joe.

Joe Dickson: I think, actually, I think Bobby just answered the question that I was going to ask. So you, you do not feel that you have sufficient information from your vaccine manufacturers to determine...?

Bob Beauregard: Well, I mean as the gentleman, as the gentleman just spoke, I mean, some manufacturers are not going to disclose the methods of the production of their vaccines. So, I mean, they can tell you that it is non-GMO and that is what you have to go by. But, do you really, really know that? You know, so that, there is the question in my mind as to that.

Wendy Fulwider: Mac.

Mac Stone: So, what does that non-GMO statement say? What do you get from [inaudible]?

Bob Beauregard: It says that the vaccines are not produced using excluded methods. So, that puts it in the non-GMO category. And that has satisfied the certifier. But, it has always left the question.

Wendy Fulwider: Tracy.

Tracy Favre: Did I understand you to say that in your two rounds of vaccination, one is a killed, and one is modified live?

Bob Beauregard: That is correct.

Tracy Favre: Can you explain why you do both?

Bob Beauregard: Well, we do one in the beginning which is the live version, and then we use the killed version as a booster, which was suggested from our vet, our veterinarian, poultry science specialist Mike Dairy, from the University of Connecticut. So when we, when we built our vaccination program, this is how it was built. And this is what we have done all over these years, you know.

Tracy Favre: We heard in the previous comments that it is possible to get a similar immune response with two applications of the killed virus. Would it be possible, or would you consider doing two rounds with killed virus versus one live versus...?

Bob Beauregard: I would certainly discuss that with the veterinarian. If he feels good about it, then I would feel real good about it.

Tracy Favre: Okay.

Wendy Fulwider: Thank you. Harriet, you are up next. Yeah.

Mohamed Mousa: My name is Mohammed Mousa. Thanks for the Board and thanks for the Program and the team. Issue with the vaccine: the question is why we vaccinate. Much money was spent for the vaccine, and what we vaccinate for. We vaccinate to protect the birds from very fatal diseases. There are several of them. There is viral. There is bacterial. There is protozoa and there is mycoplasma.

For the viral diseases, I made some information, because I have only three minutes. So, you can read it on, on that. The viral diseases have more advanced vaccine than any other disease because, it has been implemented and there are so many research has been done on that. There is about 12 viruses can kill the chicken from day one. There is some of them have very short an incubation period, there is like IBD and Newcastle, and LT, and there is some of them have very long, like Marek's Disease and Laryngotracheitis, Lymphoid Leukosis, and others.

The issue was, was GMO vaccine or non-excluded methods, we are not educated enough in the field to know exactly how that vaccine produced. There rather some vaccine which it has a donor and a vector and you, they take part of the donor, and put it, and they call that, it say HVT, IPD, and so on. Those five of them and they are very known. Most of those vaccines can be done in a day one. But also, I do not know too much about exactly how they do it. They do not tell us. The other vaccines, which is normal vaccines, we call them, we do not also know how they do that. How they stop the virus from growing, and become attenuated virus. The method of attenuating that virus, if they use chemical in it, is this considered GMO? I do not know that.

The other issue is bacteria. The bacterial infection, if it is E. coli, or if it is salmonella, and there is Clostridium, and there is others. I will just specify those. E. coli can kill approximately 25% of the floor raised birds if it is very, very vicious bacteria. When I open birds, the septicemia which happened to the organs and the damage to the liver and the, the gizzard and the spleen and the ovary and all that, when you open the bird, you feel very sad for that bird. E. coli, it must be vaccinated for the floor birds. In a cage facility, we do not vaccinate for E. coli at all, because we separate the birds from their feces. If the birds are in the floor, they are raised with their feces. There is recycle in here in the bacteria and the bacteria gets stronger and stronger as it cycles.

The other issue, issue of salmonella and the food safety: Salmonella will not cause very disturbance to the chicken too much, unless the bird is weak. If the bird is weak, E. coli comes on beside it and cause a lot of damage. Salmonella is a human health issue. The gentleman who was before, before Bob talked about the autogenous, autogenous vaccines: they do not work. We have prevention, like what Nick said. You cannot wait until you have a disease and you kill the chicken then you make a vaccine. And it is narrow targeted. It is more suitable for larger animals like cattle, sheep, goats, bison, other large animals.

Wendy Fulwider: Questions?

Nick Maravell: [Inaudible]

Wendy Fulwider: Nick.

Nick Maravell: Could you amplify a little bit or explain some more? You are saying that the autogenous vaccines do not work. Is that what you said?

Mohamed Mousa: Yes, that is what I said.

Nick Maravell: Okay. Now, one way to produce an autogenous, well, the only way to produce an autogenous vaccine is, is to have lesions of some sort that you can then culture out and use a killed bacteria to create a vaccine. Can you explain from your experience how autogenous vaccines fail to work effectively?

Mohamed Mousa: The birds – the chicken, general poultry – is the only creature we raise have another wild reservoir in the air. There is birds, if you step outside now, you are going to see birds, you are not going to see cattle or sheep or others. The recycling from the wild reservoir always a change, and when you isolate that virus or that bacteria from the environment, it is specifically for that virus. If there is any mutation, it does not work. I used it with mycoplasma. It did not work. I tried it to see if, if is here that I talk to him, it did not work. Because it was mycoplasma, I had to get an F strain and Microvac L from commercial vaccine to use it, because the local one which I had, they changed it and it specific for that organism.

Nick Maravell: So, you, you are not seeing the possibility to control salmonella with an autogenous vaccine because of the reservoir in the wild flocks...

Mohamed Mouse: It have...

Nick Maravell: ... you always introduce additional strains?

Mohamed Mouse: In, in the situation of salmonella, it would have to be targeted, a special strain. We have about 200 and some strains of salmonella. You have to have that target. And when you change the flock, then what do you do if you have another one? Plus, the autogenous vaccine is very expensive.

Nick Maravell: Okay, so it is more expensive than commercially available?

Mohamed Mousa: About 10 times the cost. And, the small producers will have a hard time to get into that, unless they have resources, you know, somebody to help them with grant or so that they can get that vaccine if that is the way it goes.

Nick Maravell: Okay.

Wendy Fulwider: Will you still be here for a while if we have additional questions?

Mohamed Mousa: I will be, but I want to say I support taking all GMO out from the organic production, but, we need to reserve for the life of the bird and the health of the bird. Thank you.

Wendy Fulwider: And Aaron Brin is on deck.

Harriet Behar: Hello, everyone. I am Harriet Behar with MOSES, and I am also a, MOSES is also a member of the National Organic Coalition whose diverse stakeholder group of farmer, consumer, environmental, retailer and handler organization strives to aid your work in maintaining organic integrity and trust in the organic label. First, I would just like to give a statement about animal welfare.

While there are some useful suggestions in the animal welfare recommendations, since many of these came directly from animal welfare standards that were developed in reaction to conventional confinement and industrial style agricultural systems, many of these suggestions do not quite fit with organic systems. I have concern that the numerical guidance will be used literally by certifiers, which would result in stifling innovation in the development of systems that recognize the symbiotic relationship of livestock with their ecosystem. When there are numbers applied to an assessment, assessment, certifiers and inspectors tend to use them to evaluate a farm in a snapshot type fashion, rather than an evaluation that assesses the organic system that is in place over the full year.

Now, on GMO vaccines: And I just want to refer you to the NOC and my own written comments because we do not have much time up here.

So, the first issue with GMO vaccines is we are really dealing with two issues here. We are dealing with GMO vaccines that may be used currently in organic production, and those are being used illegally. The Office of Inspector General has said that, and we need to use the system that we currently have in place to deal with those vaccines. Those vaccines need to be petitioned and put before the Board. However, your current review criteria is, probably is not going to be able to deal adequately with this novel technology, and you may look to increasing the questions that you put to those materials. So, I, I refer you to the NOC questions that we have in our written comments.

The second is the emergency issue. And I believe this is an animal welfare issue, as well as one that could affect the livelihoods of many organic livestock producers, as well as the health of the organic marketplace. We believe that if you are going to be looking at this emergency exemption, it should be moved over to the temporary variants section, 205.90, and make a new 4(a) through (d), which is what we recommended in our NOC recommendations. But, we among NOC are not 100% sure that we really want to support GMO at all in organic, but we are concerned about this emergency need. If the vaccine is allowed, one thing that was not included in your recommendation was that it would be eventually reviewed. So, we feel like it is very important that if there is an emergency exemption, that that immediately triggers a technical review and that within 18 months, you guys are at least talking about it. And then, maybe there would be an annotation that it would be for emergency only. Any questions?

Wendy Fulwider: Nick.

Nick Maravell: Could you explain what you think the current impact would be on producers, were they to administer a GMO vaccine in an emergency or otherwise? Well, let us say in an emergency. What would be the economic impact? What, what would be affected? How, how deeply would this run in the organic livestock community?

Harriet Behar: Well, if it, if it was being enforced as the rule is written, those animals would be taken out, the, well, their products would be out of organic production. So, a dairy producer would have to, would stop selling organic milk, would have to find a market for their conventional milk. And I am not sure how we would deal with it. They would probably have to be transitioned or, our rule does not allow for a dairy herd to be re-transitioned into organic production. So they would either have to start out with young stock and raise those up organically. So, a dairy producer, – if they were raising all of their own animals and not bringing in new animals – it could be two years. Obviously, for a poultry operation, they could bring in day old chicks and start out new and fresh. But, they would have an investment in organic feed in those animals that would be lost, because since they could not sell them on the organic marketplace anymore. And a lot of times, the conventional marketplace is not necessarily open to the organic producer [snap] like that. You know, a dairy producer might not find a conventional buyer for their milk, you know, the day after they have given a GMO vaccine.

Wendy Fulwider: Tracy.

Tracy Favre: Hi.

Harriet Behar: Hi.

Tracy Favre: I am intrigued by your comment about the animal welfare standards not being prescriptive with numbers. And, I would like your input or your thought on how you create an outcome based program without relying on prescriptive numbers.

Comment [JMS25]: 07:00:00

Harriet Behar: Okay, well as an example, we have a rule right now about buffer zones, which have to be of sufficient size to prevent unintended application of prohibited substances. And that is then reviewed on a site-specific basis. And that is a discussion between the certifier, the inspector, and the farmer. If someone has got a row of arbor vitae trees that are 10 feet wide next to a conventional field, their buffer maybe 10 feet. If someone is next to an operation that is aerial spraying, they may have to have 100 feet or more of buffer zone. So what we have given in the regulation in many places in our regulation is a vision of what we want for organic agriculture. And we have been allowed the producer to put forward a way to meet that regulation through a systems-based approach.

So, there are things. I mean, there is a thing about prevention of abuse and having perhaps a minimum number of things, of numbers. But, as far as having, you know, cleanliness scoring, that sort of thing, when you are there in a snapshot... I was an organic inspector for many years. I could show up after a 4 inch rain. Those animals could be having difficulty walking. They could be filthy. You can have an inspector who does not understand, who just flew in from somewhere else. And then that farmer, whose system throughout the year could be very good, but had, just had an extreme climactic event, would be penalized. And, and their report, even if they maybe would not have lost organic certification, it would be a permit record of their farm, you know, looking poorly.

And a lot of these animal welfare standards are based on really confining the animal, having them in much more controlled environment than we in organic see as the beneficial system between the livestock and the ecosystem. So, when they are outside, they are going to, you know, get cut. They are going to be dirty, you know, there is, there is things that happen when they are interacting with their environment. When you have them in a more controlled, you know, you have them in a freestyle barn, all on clean sand, where they, you know, walking on concrete, they do not get as dirty. And there is just, we, we know we have less control in the natural environment, but we also know that is where the animals should be.

Wendy Fulwider: Tracy.

Tracy Favre: As you might imagine, in my regular job, I am very much about systems based methodologies and processes. So, how do you balance the need for objectivity in standardizing evaluations with a systems approach that is on a case-by-case basis?

Harriet Behar: Well, as an inspector, you should be sticking to the facts and talking about what you saw. And a good inspector will ask the farmer, why are the cows so dirty? What happened yesterday? Why is this area causing an injury? Or, or whatever it might be. And so, that is then given to the certifier, who is actually the one supposed to be making the decision anyway. And so, in a descriptive sort of way, you are discussing the whole organic system. You are discussing what you see there that day. But, the inspector should also be discussing overall what the farmer should do. And rather than kind of writing down just a score, that really the farmer does not have much input into, there is a discussion with the farmer which the inspector then puts in the report about what the farmer had described as their challenges, and how they were meeting those challenges on the farm.

Tracy Favre: Thank you.

Wendy Fulwider: Zea.

Zea Sonnabend: Thank you. Apologies if this is a naive question, Harriet. But, the gentleman earlier who said he could make any vaccine as a non-GMO, which appears like it could solve the whole GMO vaccine problem, and I am curious what you thought about that and what challenges there might be in believing that.

Harriet Behar: Good question. And, I was myself was thinking about it, and I am mostly speaking now for myself and for MOSES than I am for NOC. Well, I, I really think that there is an issue with an emergency. There could be a time when the Secretary or a state official might declare a mandatory vaccination for animals or, or a destruction. That is your choice. Of course, most farmers would choose to vaccinate. And, we would not want those farmers to then lose their livelihoods in the organic industry. So, so I think that the development of vaccines, anywhere from 4 to 8 weeks, could be too late for the type of outbreak that we are looking at for this type of emergency. But again, if it is then reviewed by the NOSB, going through a technical review, if any GMO vaccine is approved for that emergency use, it immediately must trigger a, a review. No petition necessary, just get it here. So then, there can be further deep thought about, is there another way to do this, because, an emergency is basically to avoid a catas-, catastrophic situation.

Wendy Fulwider: Nick.

Nick Maravell: Harriet, could you give us your thoughts on what would help to administer a policy with regard to vaccines, which could, could potentially include excluded methods? What would it, what would be necessary, what would be necessary for you certifiers, producers, inspectors. What would it be necessary for them to, to have available in order to do this?

Harriet Behar: Well, the, the comments that both NOC and myself made by putting it into the temporary variants, where we mandated that the Secretary and the National Organic Program both discuss this emergency. Is it truly an emergency? And, like I said, that

there is a mandated review, that there is, hopefully the NOP will be able to help us figure out in a short timeframe. Is there truly no non-GMO alternative? Those are the, the items. That is a beginning. I do not say that what we proposed is a final, but, but I think that our written comments were quite well vetted, at least amongst the National Organic Program members of, of trying to make it so the emergency would not be abused. That there would be a limit to the emergency and it would not go on for five, six, seven, 10 years with no review. And that, but, but at the same time that we were providing to those organic livestock producers the safety net that they need to remain in organic farming and to take care of their animals.

Wendy Fulwider: Thank you. Nancy Coonridge on deck.

Aaron Brin: [Inaudible] You ready for me? Hi, Wendy. Thank you. My name is Aaron Brin, I am the new inspection manager at MOSA, Midwest Organic Services. We certify over 550 dairy farms in the, in the Midwest, over about 15 states. And, we have over 700 livestock operations that we certify. I am also working with about 42 contract and staff inspectors. And, I was looking at your discussion document, again, about methods of verifying animal welfare and that you believe outcome based scoring is the best measure of farm animal welfare, and that made me feel like I should comment on that some.

We are glad, Wendy, for your clarification that your, you do not expect inspectors to do body condition scoring, cleanliness scoring and all that on every form in every situation. That would be really a burden. It would be very expensive. And it, it really would not get us any further along than we are now.

What, what I think about this, and, and some of this is similar to what Harriet was talking about, is we have to look at it in terms of a broader context of, of certification, where there is inspector and reviewer. And the inspection report, I feel, basically is an appropriate document for communication between the inspector and the reviewer who makes that certification decision about animal welfare issues.

I can see that numerical scoring can be an adjunct to that report. But, it is, it is limited. It is oriented towards the animals' condition. It does not describe the organic system plan, or the situations in the organic system plan that have given rise to those problems in the, in the animal or the animal group.

We have used, in place of that, we use photographs extensively, so that again, the reviewer is getting information from the inspector, which is an observation, a verification of the organic system plan, but it does not look like a judgment or an attempt by the inspector to make a certification decision. And, I think that is an important distinction. I think, actually, numerical scoring can be well used by certification reviewers when they are making decisions about animal livestock issues. I also think unannounced inspections are something that would be a really valuable tool to look at, besides scoring. Thank you.

Mac Stone: [Inaudible]



Wendy Fulwider: Yeah. Mac.

Mac Stone: If you get an inspection report and it indicates that they are too thin or their poultry are too crowded, or outdoor access, how do you educate or help that customer fix the situation?

Aaron Brin: Right, you know, in most cases of animal welfare issues, I think that the final reviewer is going to issue a minor non-compliance with a need for correction. There may be situations where the system is so badly broken that, that it cannot be certified. But, mostly, it is going to be a minor non-compliance with a clear description of what the, what we expect our correction to be. And, that would be a situation where if you are seeing a very thin animal, and you have a picture of that animal and it looks like it is malnourished, you can say to that farmer, we will expect within x number of days that a veterinarian or some other professional will come back and score your animal and your animal will be up to the next highest level, or, you will not have corrected the problem.

Wendy Fulwider: Thank you. Nicole Dehne on deck.

Nancy Cooridge: Hi. My name is Nancy Nathania Coonridge, and I am an organic dairy goat farmer in the wilds of New Mexico. I have been up there for 30 years now, producing wonderful cheese. And, since many, you know, citizen - I am here as a citizen lobbyist. And, I am a member of Cornucopia Institute. And, groups like that really cannot afford to get paid lobbyists and paid lawyers and paid, you know, witnesses. So, you got me.

If the goal of developing animal welfare standards and guidances is to satisfy the concerns of our organic consumers, and the animal welfare community, this goal is not being met. And, if the goal is also to create a viable marketplace alternative to inhumane and unhealthy conventional livestock production, then the NOSB must reconsider the direction that it is taking. As it stands right now, the recommendations do not meet the expectations of my organic consumers, and the, and the animal welfare community. And it places ethical, family farmers, like myself, at a, [sigh] at a disadvantage, because we want to follow the spirit of the, of the organic standards, and if other people are just skimming along, where does that leave us?

The most important thing, I think, is why is the Livestock Committee so focused on spending time and resources on guidance recommendations? The purpose of certification systems are to assure consumers that certain standards are being met, and that all farmers are following those same standards. And listen, I have been living out in the wilds of New Mexico for 30 years, it is hard for me to say, give us more standards. But, I want everyone to be on a level playing field with this. So, there is guidance documents right now in place that certain standards need to be met, but it is just recommendations. Let us make them rules, okay? Let us have everybody following the same rules. Thank you very much.

Comment [JMS26]: 07:15:00

Wendy Fulwider: Questions? Calvin.

Calvin Walker: What type of livestock you raise?

Nancy Coonridge: Dairy goats.

Calvin Walker: Dairy goats.

Nancy Coonridge: Absolutely, they are the best. And they get no respect. Okay, I agree. I agree.

Crowd: [Laughter]

Wendy Fulwider: Thank you. Christopher Ely on deck.

Nicole Dehne: Hi. My name is Nicole Dehne. I coordinate the certification program for Vermont Organic Farmers. I want to thank the Board for the opportunity to speak today and for all the hard work you all have put into these documents.

VOF appreciates the Livestock Committee's commitment to continue their work to refine animal welfare recommendations. It is very important. We believe that the NOSB should try to create standards that invest the concerns of consumers and assure animal comfort and care while remaining practical for farmers, both in assessment and application. So, we do believe though that strong animal welfare recommendations, recommendations should include tools, like the NOSB scorecards from making a quantitative assessment regarding animal welfare. We have provided body condition scoring training for inspectors, not to make them fluent in body condition scoring, but to give them language and foundation to describe their concerns. So, we ask our inspectors right now to report back on basic animal welfare assessments, and I have include it in my written comments examples from our inspection report.

But, in addition, it should be understood that VOF inspectors are trained to involve the farmers in their assessment of animal welfare. So the inspection report should include not only a description of what the problem is, but how the farmer is addressing that problem or whether they even believe that they have a problem. So, if... We feel that if ACAs are going to continue to improve our assessment of animal welfare, we are going to need to make judgments about the condition of care on the farm. And we are going to need tools like the scorecards presented by the NOSB to make these judgments fair and consistent. So, without specific guidelines that are quantifiable, we are, we are afraid that the recommendations will be too vague, and it will be difficult for ACAs to cite farmers for animal welfare non-compliances.

So in regards to vaccines, we support the withdrawal of the recommendation. It was said yesterday, we live in a polluted world and I would also contend that we live in a bit of an imperfect world where in a small number of cases, and I think they are small, GMO vaccines may be the only vaccines available to farmers who strive to prevent disease in their herds and flocks. So we currently have a list of all the vaccines that are used by our producers. What we do not yet have, I will stress yet, is the criteria or process by which to evaluate whether or not those vaccines are GMO. And, we are, we would like to better

understand what criteria APHIS uses to determine whether a vaccine is GMO, and how that lines up with our NOP definition of excluded methods.

So we support the Committee's efforts in developing a compromise to ensure that farmers have the vaccines that they need to prevent diseases, be it in an emergency or routine. If the NOSB recommends allowing limited GMO vaccines, based on the fact that there are no alternatives, then our job as an industry would be to educate the organic consumer about why this is necessary and important for the viability of our organic livestock producers. So, we would contend that organic consumers are vital to the success of the organic industry, but so are our organic farmers.

Wendy Fulwider: Okay, thank you. Any questions? [Inaudible] Christopher? We will be taking a break after Christopher's comments.

Christopher Ely: Hi. I am Christopher Ely, co-founder of Applegate. We have been in business for over 25 years. I am also a PAACO certified animal welfare auditor. And I am third-generation farmer, having grown up on a Angus farm, turkey farm in the state of New Jersey. And yes, there are nice place, parts of New Jersey.

Applegate would like to thank NOSB for its hard work in establishing the animal welfare recommendation and guideline for organic livestock and poultry. At least 95% of the organic livestock and poultry raised for Applegate today are by farmers, who have transitioned from conventional farming to organic. These converted farms are not the CAFOs that we all read about, but rather small, family farms that have invested in one or two barns purposely built to raise either their chickens, their turkeys, their pigs, whatever they were raising.

The number one reason for their switch: with the total disillusion, with the conventional livestock industry, from the practices of over-crowding, and lousy elusive returns on their investments. Most of these farms are on properties where they practiced diversified farming. Most of them are still paying off the loans not only for the initial investment to build these barns, but also for the consistent pressure put on by the conventional contractors to upgrade their barns. If organic is truly going to compete with conventional farming, contribute to the overall food supply in the world, then we have to design standards that are realistic and allow farmers to easily come over to the organic way of life without creating a financial strain in the process. We need to continue to grow the organic agricultural model in order to satisfy the ever growing consumer base that demands organic products.

On average, the size of our turkey organic flocks are in housing designed specifically to hold an average of about 6500 birds. You know, this is based on the recommendation of 7.5 pounds per square foot. They are also given outdoor access. Since these growers grow in space requirements to achieve the best... Excuse me, I am losing my place here.  
[Laugh]

Our concerns, though, are about the outdoor standards. As written in the, in the guideline proposal, they are saying 2 pounds per square foot. If we use these calculations, this means that they would have to get over two and half acres per barn for outdoor access. Unfortunately, the majority of these barns were not designed to accommodate this requirement, due the proximity to other agricultural structures, rip, riparitory [*property?*] boundaries, roads, houses etc. I have already been notified by most of our farmers that they will no longer be able to grow organic turkeys if they are required to use these space requirements. The industry indicates, the industry estimates indicate that we have already lost about 30% of our organic grain growers in the United States. All have said the same thing. The configuration of their barns and properties would not allow them to increase to this area. So our recommendations, if we could have the indoor standards match the outdoor standards, that would be applicable and work for all of them. Thank you.

Wendy Fulwider: Questions? John.

Johan Foster: Amongst your grower base, ...

Christopher Ely: Yeah.

John Foster: ... how old are some of these? How long have these operations been in [inaudible]?

Christopher Ely: Most of our base are older farms. Most are Amish and Mennonite farmers. So, their, they are, they are always have been practicing diversified farming. They are older buildings. And, so they struggle to keep up, and had struggled to keep up with the conventional business, because of this. To build a new barn today would cost close to half a million dollars.

Wendy Fulwider: Calvin.

Calvin Walker: You mentioned that approximately 30% of organic grain growers have went out of business. [Inaudible]

Christopher Ely: No, I did not say go out of business. They have left the organic...

Calvin Walker: What time frame?

Christopher Ely: Within the last two or three years is the estimates when we asked, you know, where is the supply? If you know where, over two years ago or no, less than two years ago, for example, organic corn was about five dollars a bushel. It is now over \$16 a bushel. Part of that is, is supply. They all went because it is easier to grow ethanol, you know, corn for ethanol. Make a lot more money.

Wendy Fulwider: Alright, thank you.

Christopher Ely: Good, thanks.

Barry Flamm: We will take a break now and returned at 3:45.

Comment [JMS27]: 07:25:02

[BREAK]

Barry Flamm: Wendy, you can continue with the public comment part of your committee work.

Comment [JMS28]: 07:51:40

Wendy Fulwider: Michelle, could we have that slide back up? Okay, Michelle has the url here where you can go and see the question list that we have for the GMO vaccines. So that is available. It is on the website, on the NOP website. Okay, and Mel Gehman, you are up for public comment, and Dena Jones is on deck.

Melvin Gehman: Good afternoon, members of the NOSB and the National Organic Program. I am Mel Gehman, represent, Mel Gehman of Heritage Poultry Management Services. Since 1997, we manage organic egg production, produced in Pennsylvania farms, and certified by PCO, packed for high-quality brands in the Northeast markets. I also serve on my second term on the Animal Health and Diagnostic Commission of Pennsylvania Department of Agriculture, as Chairman of Poultry Health Committee. PDA is a certified, a certifier of the PCAP Program for 21 years, which includes SE environmental testing, and inspection.

I want to address the Livestock Committee's agenda item, vaccine for excluded methods. Thanks for the Livestock Subcommittee for the delay. Thanks for your diligent efforts to understand these complicated issues. I think we need some scientific input on different types of gene, gene changes and vaccines and so on. So, I commend your efforts, and wish you the best in coming up with some ideas on how to handle this.

We recommend that the decision on vaccines for excluded methods be postponed until there is clear, acceptable choices of live salmonella and E. coli vaccines available for our food safety commitment. Salmonella vaccination is a proactive, preventative program that is considered essential in well-regarded food safety programs, to name a few, the PCAP Program in Pennsylvania, FDA egg safety law and the Line Code Egg in Britain. And that is some potential export market, because they are very short on organic eggs in, in Europe at this time.

Salmonella vaccination is a very vital component of an integrated management food safety program. Many egg farms may not experience or know of their experience of salmonella, unless they have a testing program. Salmonella can come into an organic egg flock by underground water supply or insects besides other well-known vectors. We need a good option for salmonella vaccination, and today, are, there are national and regional supermarkets that require vaccination, vaccinations.

I am sorry, I ran out of time. I had a few pictures of organic farms in Pennsylvania that have been on the Pennsylvania quality assurance program and tested since the late 90s, if there is any interest.

Wendy Fulwider: Questions? Okay, thank you. Melissa Liszewski is on deck.

Dena Jones: What do you think, am I tall enough? Oh, now I feel really tall. I think I will go back down. [Laughing] Thank you, though.

I am Dena Jones with the Animal Welfare Institute and thank you for allowing me to comment on the guidance documents and the scorecards. Wendy, your introduction was very helpful. It did answer my, some of my questions.

Before I talk about the guidance documents, though, I wanted to mention quickly the US-EU equivalency agreement. As you know, the two partners have, trade partners have entered into an agreement on organic and animal welfare is one of the areas, it is where they differ quite a bit. There is no exception, as there is in the Canadian equivalency agreement for animal welfare, for stocking densities, or anything like that. So we feel that this is a disadvantage to the producers in the EU and some of the US producers that produce to a higher standard. So, we are not happy about the equivalency agreement on the basis of animal welfare.

As to the guidance documents and the scorecards, we still believe that the guidance should not replace regulations, and that some of what is in the guidance belongs in regulation. If a practice is to be prohibited, then that pro-, prohibition should be spelled out in regulation, not in guidance.

The three guidances for sheep, bison and poultry are quite different and it is clear that they have been written by different people. And I know that you are aware of that. They cover different things. They address different kinds of issues. They are organized differently. The poultry guidances cover transport and slaughter, for example, while bison and sheep do not. The scientific justification for the guidances vary significantly. The bison, bison guidance appears to be some sort of producer's handbook with very few references, while the poultry contains 175 scientific references – that must be Sarah Shield's influence – and the sheep has no scientific references at all.

We support the use of scorecards, but not in isolation. So, in this case, we have guidances for poultry, bison and sheep, with no scorecards. And then we have scorecards for dairy with no guidance. We think that they should be done together and not in isolation.

We thank the Livestock Committee for your work over the last few years. Know it has been difficult. You spent a lot of time on animal welfare. I think it does show but we feel that a lot more does need to be done and that you are off to a good start but we want you to continue on and eventually reach your goal of being the gold standard for animal welfare and also closing the gap of the differences between the EU and the US. Thank you.

Wendy Fulwider: Questions? Colehour.

Colehour Bondera: Thank you for your, for your testimony and I apologize if you are going to be repeating yourself a little bit. But, could you comment either a little further or start out by

repeating what you said about the animal welfare issues as they relate to the agreement with the EU?

Dena Jones: Right.

Colehour Bondera: [Inaudible]

Dena Jones: Well, the Animal Welfare Institute did a side-by-side comparison of the US and the EU on animal welfare and there is dozens of major differences between the two. So, they are not close. When we entered into an agreement with Canada, Canada made an exception for stocking densities. That was an animal welfare issue. There is no exception here, and we feel that that puts some of the producers that produce animals, raise them to a higher welfare standard, puts them at a disadvantage. So there is many differences. We, and we, like I said, we have a side-by-side comparison if you are interested.

Comment [JMS29]: 08:00:00

Wendy Fulwider: Colehour.

Colehour Bondera: Sorry, just as a, as a follow-up to ask, maybe that is where I wanted you to give more information is you do feel like producers in, in both the United States and the European Union are, some of them are going be, some of the ones that are doing things at higher animal welfare standards are going to lose out by this agreement? Or could you be more specific?

Dena Jones: Yeah, we believe that it puts the EU producers and some US producers at a disadvantage. So I am saying that basically all the EU producers are producing at more of a consistent standard than the US is. And that it is generally higher on animal welfare. So, it is a disadvantage to EU producers and some US producers that produce to a higher level.

Wendy Fulwider: Did you submit the document you are referring to in your written [inaudible]?

Dena Jones: No, but I have it with me and I can. I can... Can I hand it to you right now?

Wendy Fulwider: That would be fine, thank you. And, Hanna Whitehead would be on deck.

Unknown Male: Thank you.

Melissa Liszewski: I am Melissa Liszewski with the Animal Welfare Institute. And first of all, I would like to thank the NOSB for allowing me to comment on the proposed species specific guidance documents today. Oh, thank you.

While AWI appreciates the NOSB's continued efforts to address the lack of animal welfare standards under the NOP, these guidance documents must be strengthened in order to better assure that animals are well cared for and that the organic community maintains focus on making truly continuous improvement. A few of the areas in need of strengthening are as follows.

First of all, with the ammonia level: If USDA organic wishes to have higher animal welfare standards than the conventional industry, then guidance should state that ammonia levels in poultry housing be less than 10 ppm and action must be taken if the level is more than 15 ppm. The current proposal that ammonia levels should be less than 10 ppm and must be at or below 25 ppm is too weak.

For space allowances for poultry: Minimum indoor and outdoor space allowances should be increased for chickens, turkeys, geese and ducks. Although the space allowances were increased during the last NOSB, NOSB meeting, they are still too low.

For catching and carrying: Standards should be set requiring that all birds be carried by both legs and not by the neck, wing or a single leg. Also, birds should be caught in low light situations and no more than three birds should be carried per hand.

For method of stunning and killing: Guidance should discourage killing poultry without stunning, and recommend gas stunning over electric to avoid removal from transport crates, shackling and inverting of live birds.

For euthanasia: Acceptable methods of euthanasia for both sheep and bison should be specified or reference made to the international OIE guidelines.

AWI encourages the Livestock Committee to strengthen these guidance documents for poultry, sheep and bison to increase animal welfare and to help bring the care of animals under the organic program closer to what consumers expect of the label. Thank you very much for your time and consideration.

Wendy Fulwider: Okay. We have a comment, question, here. Mac.

Mac Stone: I see on your list, you are talking about force-feeding in foie gras.

Melissa Liszewski: Mmm-hum.

Mac Stone: There are several public comments that came to Livestock Committee, and I guess in consultation with other Board members, we felt that, you know, it would not be allowed in organic if it is not a natural situation and do not know of any certifiers that certify that.

Melissa Liszewski: Mmm-hum.

Mac Stone: But in general, it would not be allowed in organic just [inaudible].

Melissa Liszewski: Mmm-hum. Okay, thank you. Yes, we, we did look into this issue, and we just felt that it might be something that would be clarified, it would be helpful to be clarified in the guidance document or in the standards, because we did many searches for organic foie gras products. And although we were not able to find any with the USDA organic seal, there was a lot of misleading products for sale on different organic food websites,



gourmet food websites, that made it appear that it was an organic product. Although, when I look at the packaging an actual picture, I did not see the USDA organic seal. So as further clarification to help consumers, it might be helpful to just have this stated outright.

Wendy Fulwider: Okay, thank you.

Melissa Liszewski: Thank you.

Wendy Fulwider: Suzanne McMillan is on deck.

Hannah Whitehead: Hello, my name is Hannah Whitehead. I worked on an organic urban farm in Chicago. I have worked on organic farms through Worldwide Workers of Organic Farms in Europe, and right now I am volunteering at Nancy's organic goat dairy, Nancy Coonridge's organic goat dairy here in New Mexico. I am here today as a citizen lobbyist, testifying on behalf of the Cornucopia Institute.

I want to reiterate what Nancy said about how the recommendations do not meet the expectations of organic consumers and place ethical family farmers who adhere to the spirit of organic standards at a competitive disadvantage. I want to talk a little bit more about the chickens and the outdoor space allotted which is an embarrassment, compared with European standards, which require 43 square feet, with no more than 3,000 birds per building. In the US, the organic brand with the largest number of farmer suppliers, Organic Valley, has proven that five square feet outdoors is commercially viable for egg production. Two square feet outdoors also deprives chickens of the ability to exhibit their natural behaviors in an outdoor environment, which is part of the organic regulations. Chickens like to sort of run around and flap and forage everywhere, like you know and like we see all over at Nancy's farm. And chickens with only two square feet clearly do not have the ability to do any of that.

Also I want to reiterate what she was saying about the limits on ammonia levels in poultry houses which should be lowered and the confusion about 20 ppm and 25 ppm should be clarified.

There must also be a minimum age of slaughter for chickens to make sure that the practice of choosing unhealthy breeds that grow too quickly, which happens in conventional poultry in the conventional poultry industry, does not happen in organics.

The only way to ensure that animal welfare standards are met is to create... to ensure that animal welfare standards are met is to create standards that are meaningful and, and enforceable, as others have said. So, we urge the Livestock Committee to focus its energy and resources on strengthening these standards. Thank you.

Wendy Fulwider: Questions? Calvin.

Calvin Walker: You mentioned you had some experience in Europe?

Hannah Whitehead: Yeah.

Calvin Walker: Can you share with us maybe one or two differences that you see as it relates to animal welfare?

Hannah Whitehead: I guess it is hard for me to say because here I am working also on an organic farm that adheres not only to the regulations, but very much to the spirit of, of organic. So I see a lot more similarities than differences. So, unfortunately, I do not know. Yeah.

Wendy Fulwider: Thank you. Trey Reish is on deck.

Suzanne McMillan: Hi. My name is Suzanne McMillan. I am director of Farm Animal Welfare for the ASPCA. By virtue of being alive and sentient, farm animals pose unique challenges for the organic sector, which crop and other inanimate commodities do not. The recent US-EU equivalency agreement makes it all the more timely and urgent that we address animal welfare concerns. Our written comments address five areas, and I, I will touch on each briefly.

First, the topic of space: Stocking densities should allow for animals' natural movements and behaviors. All too often, this is not the case. Frequently, birds are unable to engage in even the most basic comforts, which they desperately crave, such as spreading their wings, foraging, and dust bathing. Providing adequate space also supports physical health, such as leg health and undisturbed sleep. NOSB's recommendations are a strong first step in the right direction, but fall short in certain key areas which we have outlined in our submissions to you all.

Secondly, the topic of ammonia: Birds who are housed predominantly indoors, such as organic rules currently do allow, generally live with their own droppings. Which in turn, generate ammonia, which has the effect of irritating eyes and respiratory tracts. And so, we are asking you for please lower the allowable level of ammonia to 10 ppm.

On the topic of beak trimming: Thank you for recognizing that the perceived need to beak trim is in fact tied to numerous industry created underlying factors, such as using breeds prone to pecking, providing inadequate space for birds, lack of enrichment for these birds, offering an improper diet, and other factors. As a result, birds experience stress and exhibit misdirected pecking behavior. Therefore, farms should be made to address these underlying factors, rather than allow it to simply mask the real problem by perpetuating its underlying causes.

On the topic of forced feeding: Forced feeding is not covered, currently, by NOSB recommendations or proposed guidance, expressly covered. But, is it, we feel it is an important topic to address because there is an active foie gras industry in the US in which ducks and potentially geese are or will be force-fed and this is particularly a cruel and controversial practice. The EU does expressly bar force-feeding in organics, and the reality is that the current poultry industry rules here argue, arguably would allow it.

And, on the last topic, slow-growing breeds: Thank you so much for recognizing that this is a key issue of bird welfare. The broiler and turkey industries have for some time now relied on fast-growing breeds, decreasing the time that it takes to get them up to slaughter weight. The combination of fast growth and excessive growth creates physical complications when their skeletons simply cannot match with the excessive breast musculature, resulting in horrendous and frankly avoidable suffering for these birds, including leg abnormalities, severe problems with locomotion, often chronic pain, bone, joint, and tendon problems. Thank you very much.

Wendy Fulwider: Questions? Okay, thank you.

Suzanne McMillan: Thank you.

Wendy Fulwider: Leah Garces on deck.

Trey Reish: My name is Trey Reish and I want to thank you for letting me speak. I work for Veterinary Service Inc. in, in the West Coast and we distribute animal health products. My job mainly is poultry vaccine.

I was going to say a lot of other things, but I think I want to try and clarify what the salmonella vaccines are. There are two types of vaccines, there is live and there is killed. The killed is not what you guys are talking about. The live is the GMO. There are three companies that produce them, Lohmann Animal Health, Pfizer, and CEVA. Their, the names of those vaccines are MEGANEG or MEGAVAC, Poulvac ST, and SALMUNE.

On the West Coast, and I believe here I think there is something, the recommended application of these vaccines are two lives and one killed. The first one is given around in the first week of age, then six weeks, and then somewhere between 11 and 14 weeks. And the purpose to do it in that manner is, the live vaccines are not a booster, or not a primer for the killed. What the live vaccines do is they protect the bird during that grow period up to 11 to 13, 14 weeks. And then you give them the killed, which gives them protection that carries them out for the rest of their lives. So, it is real important that you do that.

The application of the two vaccines, the live vaccine, which is the GMO – let us get that clear, live is GMO, there is no company out there, there is no company out there making a vaccine that is not a GMO that is not a live. He is making the same vaccine as the killed that all the companies have. The application of the live is done through the water or spray. And again, it is done at an, at an early age, somewhere around six, one day, one week of age, some out to six weeks we do the second one. Then you come in with the killed, and that is an injection. And that is the only way it can be given.

Thank you. I am, I got it. Any questions?

Wendy Fulwider: Questions? Thank you.

Nick Maravell: I, I...

Wendy Fulwider: Nick. [Laugh]

Unknown Male: Jay [inaudible].

Barry Flamm: Jay has a question.

Nick Maravaell: Is there a, is there a reason that the inactivated or killed bacteria cannot be used in the earlier stages of development, in terms of the health and the growth of the animal?

Trey Reish: I cannot give you a specific reason, except one: that the chicken is probably too small to accept that injection. A vet could answer that question very clearly. But, I used to, I have been in poultry industry for 35 years, and the chicken is probably just too small to take that volume of a... There is an adjuvant that is put into, and it is an oil, that is put into the chicken with the vaccine and it spreads out there and it stays there for a long time and continues to give protection. And the, the salmonella vaccine that they are giving at, at 14 weeks, it is usually a combination with the Newcastle, which is a virus, and a bronchitis, which is a virus, and the salmonella, which is a bacteria.

Comment [JMS30]: 08:15:00

Nick Maravell: You say you have been in the industry about 35 years?

Trey Reish: Yeah.

Nick Maravell: What happened 35 years ago? That was about, well, roughly the time that GMO vaccines were first developed. Not for, not for birds but. What, what occurred back 35 years ago?

Trey Reish: The GMOs really, in my experience, have probably been in the last 10 years.

Nick Maravaell: Mmm-hum.

Trey Reish: And, other than salmonella, there is a, a gene inserted vaccine, where they take the Marek's vaccine, which every chicken gets a day of age, and they insert a gene from Newcastle, bronchitis – something else [inaudible] – oh, IBD, infectious bursal disease, and they insert it into the, the cell, or the, the cell of the Marek's Disease. The chicken sees that without the actual virus being present, and if there is an attack of that disease on that bird, the bird has protection to fight off that. And, the, why this technology is, is so needs to really be looked at is because there are a lot of diseases out there. And I am from Southern California, and we have a bunch. And all the farms are close around. Is that if you use this vaccine, and it is successful, the virus is not there. If you continue to use a live virus to treat your diseases, which is what we are doing now, you continue to keep the virus going. You keep it at a low level. But it continues to, it continues there. If you were to use the gene inserted, and it is successful, and this is new technology, you may be able to eliminate the disease or you might not have to vaccinate.

Nick Maravell: The gene inserted, I assume, would be considered a biotechnology method or an excluded method or a GMO method.

Trey Reish: Yes. Yes. It is GMO.

Nick Maravell: But, but are you saying that you would not have any virulence in that, from that gene?

Trey Reish: No.

Nick Maravell: Right. So, you have attenuated, you have deactivated that?

Trey Reish: You put it there, and it only seems to appear when it is needed, because it is being attacked. The body has some memory there, like, hey, I have seen this one before. I can go after it.

Nick Maravell: But what occurred before you have this technology in the poultry industry?

Trey Reish: Live vaccines.

Nick Maravell: Live. So, so live vaccines, live vaccines prior to using GM, GMO methods to inactivate them?

Trey Reish: In my experience, the GMOs have only been out for about the last eight years, 10 years.

Nick Maravell: Right.

Trey Reish: Okay. So what is your question?

Nick Maravell: Well, what did, what did, what happened in the poultry industry 30 years ago with regard to vaccination before there was the GMO technology and the current live vaccines?

Trey Reish: We just, we dealt with each vaccine, the man who did the autogenous, there was a number of people who made their own vaccines. They would take their own bug and they would make their own in the bathtub and try it. And that is how technology has grown. The vaccine companies came in and they have made theirs, you know, there is four major ones. That man mentioned the Merial, and I did not mention that one earlier. And they just kind of kept up with technology, or the needs of the farmer, as the disease became a problem. Probably, I am going to guess 20 years ago, we did not have any vaccine for MG, *Mycoplasma gallisepticum*. And that is one that plagues us now, and we have a vaccine for it and it, it works very well. So, as these disease, diseases appear, the companies make their vaccines for them. But, generally, most vaccines over

the last 35 years have been live, and this, this technology is, it is, it is an attempt to try and get rid of the diseases themselves.

Nick Maravell: But, in, in the past eight to 10 years, have you seen that actually occurring with salmonella, for example? [Inaudible]

Trey Reish: Salmonella is not the gene inserted, it is gene deleted. And the reason, the reason for that is, you are not, you want, you do not want to take salmonella and put it out there, even though Europe has a vaccine that does that. They put it out there, and it is salmonella typharium [*typhimurium*], they gene delete it so it cannot become active. And that is the purpose of the gene deleted. Lohmann and Pfizer have gene deleted and CEVA Biomune has a chemical deleted. Any other questions?

Wendy Fulwider: Jay.

Jay Feldman: Thank you. Of your vaccine suppliers, can you determine which materials are GMO?

Trey Reish: Yeah.

Jay Feldman: Is that through labeling? Or how do, how do you make that determination? Just based on this formula of live versus killed?

Trey Reish: No. In the sales of the vaccine, I am around the vets all the time. And it is a topic that we bring up all the time. Is this one a GMO? And generally, most of the HVT, the herpes virus vaccines, that have the insert, so when you see the HVT vaccine on a vaccination schedule and then you see a secondary disease there, like HVT-IBD, which is Infectious Bursal Disease, HVT-ND, which is Newcastle, HVT-LT, which is Laryngotracheitis. That one is inserted, and those are all GMO. And then, the salmonella, the ST, salmonella typharium [*typhimurium*?], is a gene deleted, not gene inserted.

Jay Feldman: Are you dealing with the universe of vaccines? Or, you are West, West Coast-based, right? [Inaudible]

Trey Reish: I deal with all the major manufacturers. I sell whatever the customers are looking for.

Jay Feldman: So, you know, in your view, would it be difficult to transfer the information you have to the, to the farm community or to the certifier community?

Trey Reish: That, that is what I do. Oh, to the certifying community? Yes, I can get that done. And I can, I can put you in touch with people who can explain, like the question I said you need to ask a vet that, of how it is actually done.

Jay Feldman: Thank you.

Trey Reish: Because all of my information comes from sitting on the sidelines and listening to vets explain, ...

Jay Feldman: Right.

Trey Reish: ... explain how their, their vaccine works. And, and when they have difficulties, you know. We do not only, only vaccinate for, to prevent. Sometimes we vaccinate to put down a, an outbreak.

Jay Feldman: Thank you.

Trey Reish: Thank you very much.

Wendy Fulwider: Thank you. David Will on deck.

Leah Garces: Hello, and thank you for this opportunity, and also for your very hard work to date on these standards. I know it has been a difficult process. By way of background, Compassion in World Farming is headquartered in the UK, but we have a US presence in Atlanta. And throughout our 50 year history, we have been integral to banning some of the cruelest confinement systems throughout the EU. And we have also provided comments and guidance to the EU organic standards and continue to provide those comments. And we work to end factory farming globally.

We appreciate the efforts that have been done to date, and of you, as you have heard with some of the other comments, we are deeply concerned with regard to the recent equivalency agreement between the EU and the USA regarding the organic standards. And there are some very significant differences between the EU and the US organic standards, with regard to farm animal welfare. And, I would like to talk about some of those today and answer any of your questions that you might have.

We have been working in the EU with the organic community to raise our concerns with the commission to this regard, because we strongly disagree that these are equivalent standards at this stage. We have had press and consumer interest in the EU. But, we also have been emphasizing the wonderful opportunity we have here, to have the US organic standards rise to the potential of meeting, to be truly equivalent to the EU. I have submitted lengthy comments, some of which outline the differences between the EU and the US, which you have received. But, I would like to talk, highlight a few of them that have concerned consumers in the EU and, of course, will be highlighted when this equivalency agreement comes into effect on the first of June.

One of them is on water for swimming for ducks and geese. This has been mentioned already. But, the EU organic standards says as follows: water fowl shall have access to stream, pond, lake, or a pool whenever the weather and hygienic conditions permit, permit in order to respect their species specific needs and animal welfare requirements; where the US organic standards just require dipping their heads or splashing their feathers, which could be accomplished through a small trough.

The other big one for us is the minimum space allowance. Now, I know that we discussed this at the last meeting, but they are still too low. We have discussed that the EU have, has an outdoor requirement of 43 feet squared per bird, and we are talking about two here. That is not equivalent.

And there were other issues which are not addressed to date, which are, for example, there is no minimum space allowance for pigs, and there is extensively written space allowances for pigs in the EU, and for all species for that matter.

So, electric prods are also expressly prohibited in the EU and they are not in US standards.

So we respectfully urge you to incorporate the standards that have already submitted and continue your hard work to have the US organic standards rise to the potential of what consumers expect in the spirit of organic. Thank you.

Wendy Fulwider: Questions? Thank you. David Bruce on deck.

David Will: Ready, set, I have this timed. Go.

Hi. My name is David Will. I am with Chino Valley Ranchers. I also sit on the California State Organic Program Board. And I am the newly appointed Chairman of the brand-new United Egg Producers Organic Group. My comments are based solely on our, my position as general manager of Chino Valley Ranchers. We are organic egg producers in California.

I wanted to thank the Board very much for the work that they have done so far on the standards, and just wanted to bring up one minor concern that we have as being one of the few organic producers that molt our organic laying hens. We found that the standard does not match what already is in existence by Animal Certified Humane, the United Egg Producers program, or the Humane Animal Certified program. You do not take into account the fact that when a bird goes into molt, that its nutritional needs have changed and that comparing the ration consumed during the life of a bird during its egg laying phase versus in molt, there is definitely a different nutritional requirement and therefore, the feed requirement would be different.

Second, we support the change proposed by the Methionine Task Force. I know that is not up for this Board meeting, but we did want to let you know that we do support the change to the 2 pound cap over the life average of the bird, not a 2 pound cap per ton of feed. Because as different age of birds, they do have a different nutritional requirement, and capping us does not allow us to adjust for that specific need. Also, there is many times at the end of a bird's life that the 2 pounds is woefully over feeding, and we would like to be able to have it based on science.



Also, I have one concern with the, the language in the GMO vaccine about requesting that a state organization, perhaps, be the one to declare an emergency for the use of GMO vaccines. I would like you to please look at the written comment that was submitted by the California Farm Bureau Federation where they do address the fact that they do not think a state organization or a federal government would be as not in the practice or practical for them to declare a state of emergency, and that states would be reluctant to declare states of emergency.

Also, I wanted to point out that we do use two live and one killed SE vaccine. We do that solely due to the demand of customers. Also, the, our vets have required it. After the outbreak of 2010, I cannot tell you the number of phone calls from retail chains that we got, including one of the largest natural food chains that has 300 locations worldwide, making sure that we are using live and killed vaccine because at the time, it was a very hot button with the introduction of the FDA egg safety rule, at the same time as that 2010 outbreak.

Also, just know that of the last three salmonella outbreaks that have occurred, two were on organic farms. Coming from California, we are proud members of the California Egg Quality Assurance Program, and that program has been in existence since the early 90s and strongly supports the use of the two live and the one killed vaccine for our state.  
[Sigh]

Wendy Fulwider: Questions? Thank you.

David Will: Thank you.

Wendy Fulwider: David Bruce? Woodie Williams on deck.

David Bruce: Okay. Good afternoon, everybody. My name is David Bruce. I work for Crop Cooperative, which markets under the Organic Valley and the Organic Prairie label. I direct the juice, eggs, meat, produce, and soy pools. I am also President of the Organic Egg Farmers of America, which is a affiliation of about 40 farmers from small to large and industry affiliates and certifiers that have come together to have educational events, to do research, to talk about issues that we hold in common that we all need to learn about. And all, obviously, this is one of those, too. And then I am also on the Methionine Task Force as well.

First off, in terms of the GMO vaccine issue, I would say clearly and loudly that I am not a, a GMO, or a vaccine expert by any means. But, I hear from my producers all the time about how important this is in their toolbox for organic layer hens. There are not very many options in terms of treating diseases and so clearly this is something that needs to be very, very well understood before we move forward on recommendation for organic producers, particularly in terms of the, as other people have said, in terms of the FDA salmonella rule. It is just a really hard time to be looking at taking that tool away from the producers. We also follow the two live and one killed vaccine regime, both from customer standpoint and just because our veterinarians are, are advising that. And so,

Comment [JMS31]: 08:30:00

until we truly understand, I mean, obviously there is a lot of expertise in this room, and what I had heard was that we could not necessarily gather the true information. So I think if we come together, I think OTA has done a tremendous job in their comments and, and in terms of the research that was done there, and so I would really endorse that recommendation, that we form a task force working with USDA and the industry to try to address those things. So we are happy to be involved, if we can.

In terms of the animal welfare for organic layers, I personally feel like we really are on a slippery slope here with having such long detailed analytical documents to work off of. I understand that this is a discussion document, but, you know, it seems like it had not been well reviewed by the committee or the NOSB as a whole since the density requirements were not the same as what had just been put forward. It seems like it is one particular view, one author's view of these issues and that it ought to be vetted through the community so that it represents all sorts of different production models. And so, I, I just feel like, obviously the step from discussion documents to guidance to proposals. And we all know that we are dealing with livestock inspectors on the ground that are not necessarily well-trained for the current things they are doing. And so to add this layer of expectation that they are going to be suddenly able to score hens, which is not, you know, it is difficult for anybody, really depends on the breed and the stage of life and the conditions that they are in. So, I think that while I agree that we need to incorporate these kind of things, we need to get down to a bullet points and something that is really, truly something that can be used in the field and is applicable.

In terms of the Methionine Task Force, I would just echo too what has been said already. You know we really appreciate that the rule came out and has been put into place. We are all talk, tired of talking about methionine. But, we know that the, the levels that were put forward came from the step down rates which were not responded to by the last NOSB or two NOSBs ago, or I forget how long ago. So, we would really request that the petition on the table be picked up and dealt with. We put it in in terms, we put it in in time to be dealt with at the fall meeting, and while I believe that perhaps we might be able to get away with 2 pounds average for layers, I am really concerned about broilers and turkeys, in particular, because of ammonia issues, health issues in regard to that. So thank you.

Wendy Fulwider; Questions? Thank you. Please come up.

Woodie Williams: I am going to make a few comments, which I hope I can deduct from my real comments. This is my first time at a NOSB meeting, and I will have to say, it is rather illuminating. I come from an academic background, a professor of nutrition department head, and really have been in the consulting business, international consulting in poultry, etc. for some 30, 40 years. And I have followed the organic situation quite well from a nutrition standpoint. And, I just want to make a few comments today, basically pertaining to methionine.

Most of us look at methionine as being an amino acid, just an amino acid. But, it is unique among the amino acids. And we need to, need to remember that, because, the methionine issue is not only a nutritional issue, it is an animal welfare issue. Because,

methionine is one of the amino acids, that if it is deficit for any period of time, the birds may begin to loose feathers, they begin to become cannibalistic, and you can have a real mortality issue. Now I say that in preference to, to saying, well, it is a, it is a critical issue. And, understand it is from a nutritional issue, and it is a animal welfare issue. If you have never seen a group of birds which have been deficit from methionine for a period of time, you have not seen a real animal welfare issue. So my comments today relate to how do we prevent this, and how we make it possible for producers to, to enhance their performance.

Now, in the issue which I have put forth in the pamphlet, most of us in my case, we recommend multiple phases of feeding. We fix, we feed six phases to laying hens, organic or non-organic. Which means that in the case of methionine supplementation, as you will see in the handout, then initially, for example, that if you assume a bird is eating a given amount of feed, we put a given amount of methionine in, or amino acids like lysine or arginine or tryptophan, or any the others.

So what I urge you to do, basically, is to look at it from the standpoint that in phase one, we need about 3 pounds. In the phase six, we only need about less than 0.9 pounds. So, you see if you will average this – excuse me – if you will average this over the life of the bird, we can live with two, two and a half pounds. But, if you do not give us some help, the growers on the front end when we need maybe two, three pounds, we will have a problem. We will have a serious problem on our hands, and it is, it will be caused by a nutritional issue becoming a animal welfare unit. Thank you. If you read the documents, I think you will see a little more of what I am, what I am saying and it will be passed around to you. Any questions?

Wendy Fulwider: Jay.

Jay Feldman: Can you tell us what the natural forms of methionine are in the diet, or could be in the diet?

Woodie Williams: Natural forms would come in from any ingredient. You see, in the US, and I have had experience in Europe for organic feed, we rely upon soybean meal as our principal source of protein. It happens to be very good in lysine but very low in methionine.

So in Europe, though, they do not have the same problem. I have formulated some feeds for Europe for organics. It is a, it is a different problem, where we do not have a lot of ingredients that are high in methionine, except for maybe, say, fish meal, and some others that are not very abundant. And I certainly would, would not have liked to have been dependent upon fish meal when we had the oil spill in the Gulf of Mexico. That would have been a disaster for the organic people relying upon fish meal or something of this nature and have such a, such a dependency.

So, we get it from corn. We can get it from wheat. We can get it from alfalfa. We can get some from soybean meal. But basically, other than that, from a distributor's standpoint,

you do not have much alternative. Lysine is not a problem. Why? Because soybean meal has a lot of lysine in it, so we do not worry about that. Europe has to worry about lysine, you know, because the difference in ingredients.

This is what, sometimes I think, we forget that we talk about what Europe is doing and what we are doing. We do it different because we have different things to work with.

Jay Feldman: Thank you.

Jennifer Taylor: [Indiscernible-low volume] through pasture, pasture management?

Woodie Williams: Minimal. Grasses are very, very low in methionine as such. It is very minimal. So you cannot do much to correct that from a natural grazing standpoint. So, we, we have some products, like, that may be high in methionine, or high-er. Meat meal, but we cannot use it in organic, see. So we are limited what ingredients are produced in the US that are organic certified that have any cornmeal methionine in them. So I do not know, I would be real honest with you. Down a few years from now what is going to happen if we take methionine out. I just do not know. Unless we have an abundance of other ingredients coming along, it is going to pose a real problem. Let us just face it. It is not going to be an easy, easy thing to settle in the US. Much easier settled in Europe, because we have done most of it in Europe. But, the US is quite different in feed ingredients. They do not want soy. Why do not they want soy? They have to bring it in. They do not want to import it. So, they go another way. So, it is, it is really interesting to watch it worldwide. That is what I am saying.

Wendy Fulwider: What about all the research that is being done on other alternative sources of methionine?

Woodie Williams: Well, I, I have to say this. I do not give it much, much hope. A lot of work went on with corn, for example, breeding more corn. Well, they could breed a little bit more protein, but methionine in relation to protein did not change. So, that really was not much of a fruitful effort. And it is a long-term thing. Plant genetics is a very, very long-term thing, unless we can get some soybean meal, which has a lot of methionine.

Wendy Fulwider: Any other alternatives?

Woodie Williams: I do not see it. And I have worked with this thing for 10 years, and unless we can do some importing from Europe.

Wendy Fulwider: All right, thank you. Based on all the public comments we have received today, we, the Livestock Subcommittee has come up with a proposal that Nick would like to share.

Nick Maravell: Well, I just, whoop, I just sent it to the Livestock Committee. I do not know how quickly the..., oh, it just went, how quickly. And Miles, you have a copy of it, too. This is a draft.

Let me explain a little bit about what, what the Livestock Committee would like to do on the GMO vaccine issue. We would like to work cooperatively with the Department to come up with what we have heard from the public are some vital first steps before we can move forward with the final formulation of policy. And the first step is clearly identifying the list of current vaccines as to their GMO content and then the second part, that we are proposing is that as we speak, any new registered vaccines either be labeled or there would be a tracking system that is publicly available. So, the list would automatically update. We need to know what are we talking about first.

So, I would like to propose a, a resolution in draft form that can be considered by the public, if, if we have an opportunity for additional comment, and by the Program, that the Board could vote on as its sense of, of the Board, as to what we need to do in order to go forward. And, we vitally need better information. There is no question about it.

So, I can, let me see if I can find it now, I can. Would you like me to read that even though...? Or, or I do not know that it can be, if it could be put up on the screen. Can you...

Unknown Male: [Inaudible]

Unknown Female: You can send it to Michelle.

Nick Maravell: All right. I can cut through the introduction and the conclusion and just read two or three key sentences in the middle. What we are requesting is that USDA require livestock vaccines be labeled when they contain GMOs or were developed using GMO techniques, or, USDA have a real-time, publicly accessible tracking system to identify GMO vaccines as they are registered. And, (2) APHIS or other appropriate USDA agencies identify which currently available livestock vaccines are GMO, so that the NOSB, organic livestock producers, and organic certifiers can make informed decisions.

That is the essence of what we, we are requesting. We are requesting the information that we do not feel we have solid ground on right now. And so, I guess -- oh, is it up on...? Okay, it is up on, on the board.

We are further asking that at our October and our spring 2013 meeting, that any information that can be shared on this issue continue to be shared on this issue if we are making progress towards answering, for example, those two items.

And we have also attached a list of, and I do not know if I, I do not have the attachment on this particular one. We have also attached a list of questions that we have collected from the public, from the Program, and from our review of the TR and our deliberation. If there is a way to also address those questions, we would love to work with the Department in discussing what the possibilities are for answering those questions.

But, the two essential ones we have outlined in the body of the text. And, we feel it is, it is responsible and fair to collect this information, make it publicly available, and have everybody able to then weigh in on the subject, based upon what we actually know.

Comment [JMS32]: 08:45:00

Melissa Bailey: Zea? We are, the, we are wondering, you know, how you feel about this or what you think about this proposal.

Zea Sonnabend: I think it would be good to work in conjunction with Livestock to look at these issues. But, [sigh] the GMO aspects of it are not necessarily the same as like an em-, if you decide to go towards an emergency declaration language, like some people suggested or whatever. So, I did not receive it in writing, so I, and I was sort of half involved in paying attention when you were talking, Nick.

Nick Maravell: I did not send it to, I was, I thought we were... I thought first to consult with the Livestock Committee before we but, but we can go ahead and do it with, and send it to everybody.

Zea Sonnabend: You know, the GMO task force would be happy to take a look at anything, you know, new coming up.

Nick Maravell: Right. What we are, what we are proposing here, and this does not cut across committee areas, what we are looking here is to get a sense of the Board resolution.

Zea Sonnabend: Oh.

Nick Maravell: That this is where we want to go. And, we would, would appreciate if the Program would like to respond now to any comments that the Program have. We are looking to work together and, and get the information we feel is necessary to respond to the issue raised by the Program.

Miles McEvoy: Yeah, thanks, thanks a lot for this. We just got it, so it is going to take us a little while to look at it and see what the meaning is. And the Board as well is just getting this proposal. We can take another, we can look at it and get back to you on Friday with any particular comments.

A lot of really good information was shared here today, we have also had a lot of assistance from APHIS in terms of them providing information over the last few weeks. They are very willing to engage and help out as much as they can with information. So, it seems like there is a, a lot of really good information that just needs to be assembled.

What is the best mechanism to make that happen? I think we can work very closely with the Livestock Committee to see how we can move this issue forward, if that is just a matter of working with our, our sister agencies to get that information, getting the Livestock Committee more closely connected with APHIS in providing their, their expertise on this, with, you know, other industry experts on this particular issue, we have just got to assemble this information.

The concept of the task force, potentially, to address this, to take some of the burden off of the Livestock Committee's to assemble some of this information might be a way to go as well. So we look forward to working with the Livestock Committee on resolving this issue.

Barry Flamm: Wendy, I suggest that the Livestock Committee distribute the written form of this and we will, I suggest we add this to the agenda. We have two, two different opportunities to put this on the agenda on Friday, and we will see if we have a resolution then. And, and I, either under new business, or under the area of differed voting. Either one of those, depending on the, if we have enough time under deferred voting, we can put it there. Otherwise, put it under new business. This is a proposed change to the agenda. And without objection, we will, we will change the agenda. Please, please distribute that to all the members of the Board.

Nick Maravell: Wendy, I am going to try to do that right now. We will see if I [inaudible]. If I could type, it would help.

Barry Flamm: This completes the agenda for today. We are in recess until tomorrow morning at 8:00. Have a good evening.

Comment [JMS33]: 08:50:19

[Event Concluded] (End)

Meeting Of The National Organic Standards Board  
May 24, 2012

**United States Department of Agriculture  
Agriculture Marketing Service (AMS)  
National Organic Program (NOP)**

**Meeting Of The National Organic Standards Board (NOSB)**

**May 24, 2012**

Hotel Albuquerque Old Town  
800 Rio Grande Boulevard NW  
Albuquerque, NM 87104

The National Organic Standards Board convened at 8:00 a.m. with Barry Flamm, Chairperson, presiding.

**Members Present**

Barry Flamm, Chairperson  
Harold Austin  
Carmela Beck  
Colehour Bondera  
Joe Dickson  
Tracy Favre  
Jay Feldman  
John Foster  
Wendy Fulwider  
Nick Maravell  
Jean Richardson  
Zea Sonnabend  
Robert "Mac" Stone  
Jennifer Taylor  
Calvin Reuben Walker

**National Organic Program Staff**

Miles McEvoy, Deputy Administrator  
Melissa Bailey, Director, Standards Division  
Dr. Lisa Brines, National List Manager  
Emily Brown-Rosen, Agricultural Marketing Specialist, Standards Division  
Michelle Arsenaault, NOS Advisory Board Specialist

\*\*Please note that this transcript may contain errors or omissions and does not represent an official record of all proceedings that took place on May 24. Please refer to the live webcast for a more accurate representation of the meeting.



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Barry Flamm: Take their seats. Board members, please take your seats. The NOSB Board meeting is back in session. The first order of business this, this morning is the Policy Development Committee report and the proposals and recommendations plus public comments. Chair Colehour Bondera, please proceed.

Colehour Bondera: Thank you, Mr. Chair. Yeah, I would like to go ahead and start with – Michelle, can you put up the first slide, please? – with the, the Policy Development Committee. I will briefly introduce it. And I have not used what I am holding in my hand before so hopefully it works. I am using a remote modifier to that machine, but it seems to work fine.

So the Policy Development Committee, briefly, what we, what we, who we are, what we do: provide guidance, clarification or proposed standards of Board operations, policies and procedures; maintain the content and updates to the NOSB Policy and Procedures Manual and New Member Guide; work with other committees to develop joint recommendations where policy issues are involved. And as was introduced, I am the Chair of the Committee, C. Ruben Walker is my vice chair. Other members include Jay Feldman, Jennifer Taylor, Barry Flamm, Jean Richardson, Joe Dickson, and Mac Stone. And I must thank, like he told us before, Barry Flamm served in the role that I am in for four years so he is not the easiest act to follow, but try, I will.

Well, it worked up to... Okay. Sorry. I apologize.

So then, we have, our Committee has three recommendations that we are here to talk about and in the order that they are going to be presented in: conflict of interest, public comment, and public communications. And like it says, these topics were prioritized for a variety of, from a variety of sources: the, the NOP, the public, an internal NOSB request for review and updates of Policy and Procedure Manual. The honest truth is, in several of the cases, it was, it was, you know, more than one, but not in all. The conflict of interest recommendation was actually put forth at the Savanna meeting in November. And it was tabled and has now been substantially revised, the recommendation we are looking at. The public comment was presented at that same meeting as a discussion document so we have seen it before and it has also been substantially revised. If I fail to say in the future the fact is, that I was the person that was the lead and am still on the lead on that but I must formally thank Jean Richardson for the role that she has played since she joined the Board on that particular recommendation. Like I said, in case I forget to do so in the future, she well deserves it. So thank you, Jean. And public communications recommendation is to establish a policy on public communications.

And so my intent is, and I have not said all of it, but is to just go through the three recommendations. C. Ruben Walker will be presenting the first one in a few moments on conflict of interest. And then I will take back because I am the lead person and present about public comment. And then it will go to Jennifer and Jennifer will present about public communications. And then it will come back to me and we can have what we need as discussion and the public comment that we have at that time. So, with that, I would like to – and like I said electronically I am not sure if I can figure out how – but I am going to put this down and turn it over to Calvin. Thank you.

Calvin Walker: Good morning.

Crowd: Good morning.

Calvin Walker: Good morning. That is good. Again, I would like to thank the PDC for giving me the opportunity to take the lead on this particular important issue. While everyone is half-sleep, I suggest that you strap on your seatbelts and we can get through this real fast and we can move on to other topics on the agenda.

I am ready. Next slide.

As Colehour mentioned, the chair of PDC, stakeholders at the Savanna meeting was overwhelmingly in support of our conflict of interest documents but I am a person that likes to try to bring about a consensus, even with those who might be in the minority to try to craft together something that could be of benefit to everyone. And some, someone once said that a consensus is something that both sides are still pissed off in the end.

Crowd: [Laughs].

Calvin Walker: So I think at the end of this, we will see that both sides will still be ticked. Maybe that is the better word since it is being... Could you scratch that from the transcript?

Crowd: [Laughs].

Calvin Walker: Okay. [Inaudible] Okay. The next slide here, Colehour suggested that I get through these real fast and I definitely will do that. The, first I would like to mention that conflict of interest probably had its beginning during the Biblical days when Adam, Abel and Cain had a issue. You know, Cain killed Abel because God accepted the offering of Abel so maybe that is where conflict of interest began, or maybe with Eve and Satan.

Crowd: [Laughs].

Calvin Walker: As, as it relates to a broad view of conflict of interest, there are over 1000 advisory committees. They provide advice to over at least 50 departments. The cost per year is \$390 million each year and they are projected to go up at least another 20 million

each year. The public is definitely concerned about the advice that these advisory committees are giving to these agencies that make policy. And our Board is no different.

Overview: NOSB is seeking to enhance its conflict of interest policy by providing additional definitions and outlining some general procedures for declaring, evaluating, and acting upon a conflict of interest. How did this come about? Not by the Policy Committee, but it came about by several stakeholder groups: National Organic Coalition, Cornucopia, Center for Food Safety, Food and Water Watch, and there was several that was just individual citizens just saying that we need to enhance our conflict of interest policy. At the Savannah meeting, we was intent on bringing this forward. But we withdrew it because a couple of stakeholders group, that, that their comments are very valuable and of value to the organic industry, trying to get a consensus, we tabled it to make some substantial changes. So Board member, Joe Dickerson [*Dickson*] and I worked on this to try to improve it from where it was. Okay, next page.

Purpose: I think I have already said that. We will go to the next slide. I know everyone is happy on that if we move along.

Background: The original proposal that we was intending on sending forward, we had a definition for several types, types of conflict of interest. We outlined the steps and we outlined the steps for conflict of interest in TRs and a declaration of interest form.

So what we did was and try to get a consensus and move this to the Board, because we know that the Board will ultimately, NOSB will ultimately make that determination. Because I remember in June of last year, I called the Office of the Inspector General. I talked to the Deputy, I think her last name was Diaz, I have forgotten the name. The question she asked me was, after 20 min-, we had a 20 minute conversation, and she essentially said it was left up to the Agency. And I tried to, when you are dealing with lawyers, you have to kind of tune in on all the words that they say. But in essence, she said it was left up to the agency. If that was a problem, the agency will contact them and not our Board. So she was very polite in telling me that and we began to talk about Cajun and Creole foods in south Louisiana.

Crowd: [Laughs].

Calvin Walker: So she was very diplomatic in saying that if the agency have a problem, then they would get with them to, to get that rectified. Upon that, I did, I think I approached someone at NOP and they just encouraged us to go ahead with all the policy until they could get some firm and definitive answers. So the PDC Committee on Conflict of Interest are trotting along. Okay, as it relates to stakeholders written comments, 91% of the stakeholders that responded to what was put out on the website, 100% agreed with recommendation number one. Recommendation number one was to keep the current policy on page 8, I believe. And recommendation three, to outline a procedure for the Board in dealing with the conflict of interest, there was a 100% agreement. As I said before, the majority, the 91%, they still wanted some form of conflict of interest for those

who testify, expert testimony, conflict of interest surrounding TRs to also be looked at another time. So to try and get this moved this along, we removed the...

Oh, ahead of myself. That slide was alright. We have, we have, the PDC COI Committee have three recommendations. Recommendation one, everyone that submitted published, written testimony had no problem with recommendation one. They had no problem with recommendation number three. And three groups had a problem with recommendation two. So we was in the process of trying to work that one to satisfy those who had a issue with some of the definitions. But by the time the PDC Committee could act on that, the Program, like CNN breaking news, had came up with recommendations that came from the, the Ethics Office as well as their Program. So we did not have a chance to address some of the comments of some of the stakeholders that wanted to see a different definition of some of the words, of some of the language we was using.

Okay, Recommendation number one essentially is already in the policy. Nothing was changed. No one had a issue with this recommendation.

Recommendation number two dealt with definitions. The Program has weighed in and we appreciate them weighing in because it would have saved us a lot of sweat, but, such is life. Recommendation one is the definition of a conflict of interest. That came from NOP upon consultation with the Office of, I believe, Ethics which give a, a definition of conflict of interest similar to what we had initially. And it also dealt with immediate family members. Some of the concerns of some of the groups that did not like the definition of conflict of interest, it was broad because I had parents, grandparents, biological stepchildren, you know all that kind of stuff. You know you may have to have a family reunion and try to get all these financial interests. But the Program I thought on consultation with the, with the Ethics Office came up with something that was very nice. So immediate family member is now limited to parent and the spouse or partner, as well as your children that are in the household, as opposed to your uncle, you may have a problem with your uncle anyway. So you, you may not want to try to deal with that. So I was really pleased to see the definition of immediate family member shortened because we did have one that was quite broad. Of the last definition, direct financial gain, nothing was changed. It is already in the policy.

Comment [JMS1]: 00:15:00

Recommendation three essentially says that if you have a conflict, if you disclose, if you have a conflict of interest and if it is financial, you should surface that at the committee level as well as at our biannual meetings before you discuss and as well as vote. But going forward, the Program, upon consultation with legal, our Chair Mr. Barry Flamm, the process you used yesterday was the one that will be going forward is that the Board will not decide if there is a conflict... If Calvin – I guess I called my own name – disclosed that I have a conflict of interest, the Board will not determine if that is a conflict. It will be determined by the Program. Like yesterday, when Zea disclosed that she had a conflict and the Program, upon hearing the nature of it, made a determination whether it was a conflict of interest or not.

Moving along. We are almost finished here. Summary: The revised conflict of interest policy and procedures are an attempt to address several stakeholders' requests for updating the Board's conflict of interest policy providing a greater level of transparency in the deliberation, discussion and voting on matters pertaining to the Board for the benefit of the organic community. The second item, every stakeholder that wanted a tough, leaner, meaner, clear conflict of interest policy we did not address the issue that is related to public testimony, expert, I mean, expert testimony, consultants, and technical reviews. These groups that was in favor from the beginning believe that conflict of interest need to also be dealt with individuals that come before us to, to give their expert advice on a matter.

And I think at some point, if not next, our next meeting, but in the near future, that we would if the Board, if the Board and Program concur, that we need to look, at least put this out in the form of a discussion document. May not be in term of a technical reviews but I think the Board, NOP have a policy all, already for technical reviews. Well they use the term covered relationship. But if we are to listen to our stakeholders, and maybe it would provide a better collaboration, cooperation with the different groups if at some point soon, that we would look at seeing what our stakeholders as a whole think about conflict of interest as it relates to that for experts who come before us and consultants. So, the PDC Committee is saying that we would like to see this particular proposal go forward. We know that what this Board do is not to make rules or regulations but to advise, at the next level changes and corrections will be further modified.

The Board met on Monday evening with these revisions. Actually, the Board, NOP had some additional changes but it would have been so much so we decided that we would make some changes to our policy and at their level, they would along with the, the Ethics Office, for the refining.

Barry Flamm... You can see we have a good cross-section of support. Barry Flamm, yes. Jay Feldman, yes. Joe Dickerson [*Dickson*], retailer, yes. Mac Stone, certifier, no. Jean Richards [*Richardson*], public interest, yes. Jennifer Taylor, yes. Colehour Ben-, I should know as much as I talk to him [laugh], Mr. Hawaii, Colehour Bondera, organic producer, yes, and yours truly said, yes.

Ten more slides. Just kidding. And the last slide is c'est tout. That is it.

Colehour Bondera: Michelle, can you put that slide back up? Thank you, Mr. – yeah that guy over there, the Louisiana guy. Thank you very much. I appreciate it.

Crowd: [Laughs].

Barry Flamm: A little pay back.

Colehour Bondera: Do what we got to do, you know. So, yeah, I hope that that was useful and helpful for him to, to do that. And I am just going to move us on to the next

recommendation at this point in time. So now that we are, we are all slowed down and we have done the big thing, now we get to go on to the easy things. Hum. Very good.

So the next one is our, let us see, I am going to have to give you some background before I go into this, I think.

What we are going to do is we are going to look at the policy for public comments at our meetings. And the truth is that the recommendation that was publicized is what I am going to present to you right now and read through. However it is worth noting that our Committee has discussed changes. However, since our Committee has not agreed upon any, our, our whole Committee has not agreed upon changes and in fact, I have Committee members including something that you just heard from Mr. Walker, of ideas of additional things or different ways that, since I am under, under occupied as the Committee Chair, that our Committee should be putting a little bit more energy into and putting into the work plans and things like that. My point is that there, there are even some proposed modifications to the modifications that have already been circulated within the Committee but not concluded upon. And so I will be referencing some of those but what is going to be presented right now is the recommendation as it has been put forth.

And this one is not as, I think, easily separate-able into categories as what we just saw in terms of distinct recommendations. However, several of the items that you are going to see already exist in the Policy and Procedure Manual and there has been no suggestions for changes. And that is... Actually, when you look at this, that is the first two paragraphs already exist in the PPM and there are no suggested changes from public and/or from the National Organic Program and/or internally.

And so I can still read through those. All persons wishing to comment at NOSB meetings during public comment periods must sign up in advance per instructions in the Federal Register Notice for the meeting. So you will be happy to hear, if we call that Recommendation number one, that there is no contest.

Anyway, item number two: All presenters are encouraged to submit public comment in writing according to the Federal Register Notice. Advanced submissions allow NOSB members the opportunity to read comments in advance electronically, and – [sigh] God, I mean I, I have to interrupt myself just to say that electronically has been last night and this morning, quite a interesting issue for me, so I do not know if it is always a viable option to be saying it is going to be a possibility, but – and decrease the need for paper copies to be distributed during the meeting. So that item also has not received any discussion or suggested changes and that will change henceforth.

Number three: 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. And in the revision that we will be discussing in a few minutes as a Commit, as a Committee probably, then as the NOSB, before we vote on this, this one has several changes, notably, the fact that people will be called upon if they sign up but

we cannot guarantee it will be in the order that they sign up. Because we are not necessarily,... People may have signed up but then they are talking on a topic that is in a different order than where they wanted to be. So the concept is that people will be called upon if they sign up. And we cannot also focus on, you know, there are time, potential time constraints of the meeting which could be an issue as well and the word potentially will be eliminated so there is a couple of details.

Number four: Excuse me. Time allotment for public comment per person will be three minutes with the option of extending to a maximum of five minutes at the discretion of the Chair during the meeting. And we – actually when I get, in a moment, to public comment on this issue, you know – have received quite a bit of response to that particular item and I think that there is, you know, we can still discuss that further, but I think it is standing at this point in time with the variation going to be that it is at the discretion of the Chair in collaboration, association, or connection with the NOP and/or FACA rules. So I think that that is an issue we are going to have to straighten out in a few minutes.

Number five: Persons must give 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 the Board by major topics under consideration. On that item, our, we have discussed but again, like I said, have not finalized eliminating the “by the Board” clause in that part of it.

Number eight: Individuals providing public comment will refrain from any personal attacks and from remarks that otherwise impugn the character of any individual.

So I am going to carry on to the next one. Excuse me. The next part of that, which is also in the Policy and Procedure Manual. Two paragraphs that are in there. 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 NOSB Chair depending on the availability of time. And, that one has pretty much in discussion remained where it is with elimination of the NOSB at the beginning, with the replacement of the word “we”, we will attempt is what I have put forth as a internal discussion and at the end, where it says the NOSB Chair, that is going to get some additional descriptor referencing the NOP and/or FACA rules.

So finally, members of the public are asked to define clearly and succinctly the issues they wish to present before the Board. This will give NOSB members a comprehensible understanding of the speaker’s concerns. And I am going to, I am sorry to say, move on and we will come back to those things.

In terms of written public comment on this public comment recommendation, 93% of the comment received were supportive. Most of those, 84% of those, though do, did present



conditions to their support. And it is worth noting that comments came from both individuals and groups, from consumers, farmers, interested citizens, farmers, like I said, farmers associations, trade associations, advocacy, non-profits, the whole range were, were represented in public comment. Here is a few quotes from my presentation that I did on the, on the letter to Vilsack I used the same process. So nothing new here. Right? In, in other words, here is a, there are subsets of, of quotations from comments we received. Nothing I think really new but it is worth noting.

“Allow more time for public commentary.” Like I said, that is a notable subset of the comments and that is the item number four that I presented in reference to that. Several, sev-, a few of the comments were: “The ability to comment by proxy is especially helpful for public interest organizations.” And it is worth noting that that was part of, of what we received as well. Another one was: “Be flexible according to the circumstances.” And I think that that is very important. I think that Barry has done a, a very good job of doing that during this meeting in my opinion but I think that, you know, that is where, where things are ideally is be flexible as much as we can, like that person said. And again a, a repeated kind of comment, but in quotes like it says: “Prefer, prefer to see a stand, standard five-minute comment period that is adjusted downward.” And that is instead of a three-minute that would be increased upward as the recommendation reads.

Comment [JMS2]: 00:30:00

I think on this public comment recommendation, you know, the N, the NOP comments to us internally have indicated that the DFO, the Designated Federal Officer, is responsible for how these details are scheduled. And so I think that that was worth noting. And, you know, we are going to receive a little bit of live testimony and if, if some of it is specifically on, on this recommendation, then, you know, we will be dealing with that before we vote on the recommendation. So that is going to bring my public comment recommendation presentation to a close. And I just want to say “mahalo” for listening to that. And I am going to, at this point in time, request that our third recommendation be presented. And Jennifer Taylor is going to present about public communication and, so I will pass the mike to her.

Nick Maravell: [Whispering]

Colehour Bondera: [Whispering] Yes. Thank you.

Jennifer Taylor: Thank you. Good morning. The National Organic Standards Board Policy Development Committee has put before the public a proposal for public communications. And I am going to read it to you.

An introduction: A primary role of the National Organic Standards Board is to advise and counsel the Secretary – thank you, [whispering], okay – 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; coming from the Policy and Procedures Manual page four through eight. The Federal Advisory Committee Act meeting obligations to, to the public suggest 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.

Background: The Organic Foods Production Act, enacted under title 21 of the 1990 Farm Bill serves to establish uniform national standards for the production and handling of foods labeled as organic. The Act authorized a new USDA National Organic Program to set national standards for the production, handling, and processing of organically grown agricultural products. In addition, the Program oversees mandatory certification of organic production. The Act also established the National Organic Standards Board which, which advises the Secretary of Agriculture in setting the standards upon which the Program, the NOP, is based. Section 2119 of US, 7 USC 6518 states that the NOSB consist of four individuals who own or operate an organic farming operation, two individuals who own or operate an organic handling operation, one individual who owns or operates a retail establishment with significant trade in organic products, three individuals with expertise in areas of environmental protection and resource conservation, three individuals who represent public interest or consumer interest groups, one individual with expertise in the fields of toxicology, ecology or biochemistry, and one individual who is a certifying agent.

The statutory mission of OFPA states: 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; OFPA Section 2119(a). As stated in the NOSB Policy and Procedures Manual, page five, 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.

In carrying out the mission, key activities of the Board include: assist in the development and maintenance of organic standards and regulations, review petition materials for inclusion on or deletion from the National List of approved and prohibited substances, National List, recommended changes to the National List, communicate with the organic community including conducting public meetings, soliciting and taking public comments, provide timely information and education on the NOP, making reasonable use of a variety of communication channels, communicate, support and coordinate with the NOP staff.

The Policy manual, page eight, states that the NOSB members shall act impartial, impartiality [*impartially*] and not give preferential treatment to any organization or individual. The PPM indicates that to fulfill their responsibilities, Board members agree to adhere to three duties, duty of care, duty of loyalty, and duty of obedience. The PPM continues.

The duty of care calls upon a member to participate in the decisions of the Board, to be informed as to the data relevant to such decisions. In essence, the duty of care requires that a member be reasonably informed. It is the duty of all Board members to seek and

study the information needed to make a reasonable, a reasoned decision and/or recommendation on all business brought before the Board. The NOP will provide some of that information, but other information must be developed from independent sources. The National Organic Standards Board members study and evaluate all public communications, written and verbal communications, as a function of the NOSB role and duties in order to benefit the organic community. In so doing, National Organic Standards Board members are able to provide effective and constructive advice, clarification and guidance to the Secretary of Agriculture and to the NOP.

The NOP said in the National Organic Program newsletter, December 11th 2011: The members of the National Organic Standards Board and the National Organic Program often receive letters and requests from people interested in our upcoming regulatory activities and meetings. In this note, we summarize the best way to direct your letters and requests. As a federal advisory committee, the NOSB has a well-defined scope of activity. If you have opinions and requests to share with the Board, please use the public comment period that is open before each NOSB meeting to submit your thoughts, or submit a formal National List petition for consideration using the guidelines provided in the link below.

The NOP is the best place to send your letters outside of the NOSB public comment and petition process. In addition to formal public comment periods on specific regulatory actions, we are always open to comments on a variety of topics related to organic agriculture. While we cannot guarantee that every letter we receive a direct response, your letters do get an audience and help us identify and prioritize needs. We look forward to hearing from you.

This explanation by NOP describes the current official means of communication outlined, outlined in the PPM which does not prohibit other forms of communication between the public and the NOSB members. The NOP statement, however, suggests a need to clarify the ability of the public to communicate with NOSB members outside of the Board meetings and the public comment period to inform the un-, ongoing deliberations of the Committee work.

In summary, the National Organic Standards Board, through its Policy and Procedures Manual, establishes procedures for its activities. The manual is designated, is designed to assist the Board in its responsibilities, on page four. And establish procedures for carrying out its responsibilities in accordance with its advisory mission. Because of 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 OFPA. 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's, Board meetings. Additionally, and as a part of its responsibility to communicate with the organic community pertaining to the implementation of OFPA, the Board may 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 deli-, in the deliberations of the Board and the community decision-making process. The procedures of the Board should facilitate public communication with Board members in the course of those deliberations.

Recommendations: PPM section six, miscellaneous policies, page 26, is amended by adding a new subcategory, which is provided in italics. NOSB policy on its Advisory Board and communication with the Secretary of Agriculture: Based on the communications and input it receives from the public, the National Organic Standard 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's, 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 Production Act.

PPM section six, miscellaneous policies, page 27, is amended by adding a new subcategory, which is provided in italics. NOSB policy for public communications between NOSB meetings: The NOSB accepts public communications to NOSB members outside of Board meetings and public comment periods to inform the on-going deliberations of Committee work. The Board requests that communications on specific subject matters be sent to the entire Board membership of the relevant Committee or, on matters relating to the full Board, be sent to all Board members.

PPM section two, page 13, role, role of the Executive Director, is amended to include the following language: Receive and maintain an archive, archival record of all communications submitted by the public to the National Organic Standards Board and make communications available to the Board members. Maintain a public listing posted on the NOP website of contact information for NOSB members including an e-mail address or other points of contact.

Comment [JMS3]: 00:45:00

We had a Committee vote and five of the Committee members, I am sorry, six of the Committee members voted in favor of the proposal. Two members were absent.

Colehour Bondera: [Inaudible]

Jennifer Taylor: We are going to be leading to the, no, I am going to PowerPoint. I have a, yes.

Michelle? Could, okay, control it where, here? Here. [Laugh] Oh, here. Okay. Okay, thanks. Okay. Okay.

Michelle Arsenault: Press here, that should go forward. [Inaudible]

Jennifer Taylor: Okay. I will now provide a review of the written comments. And I needed to ask Michelle or someone from Program, did we receive any comments through the mail?

Michelle Arsenault: [Inaudible]

Jennifer Taylor: They were, they are included. Okay, thank you.

This is a review of the public written comments that have been provided by the organic public, consumers and stakeholders. A written review of the comments: A review of the written comments indicated that the majority of commenters supported the proposed recommendations. One commenter stated that the National Organic Standards Board, in carrying out, that the National Organic Standards Board, in carrying out its statutory responsibilities, plays an important role in bringing to the USDA information, experiences, and perspectives directly from the organic community.

We support both elements of the proposed public communications policy. It is very important that the NOSB be able to express to the Secretary of Agriculture the views of the organic community that it receives. This is particularly true of views that may be at odds with current or proposed US pop, USDA policy such as the views of the organic community concerning so-called coexistence with farming you, farming utilizing genetically modified organisms.

The transparency policy, this is another comment, the transparency policy passed at the last Board meeting will, when implemented by the NOP, allow for the public to follow NOSB deliberations more closely. This policy will allow for those who have information useful to the Board to provide that information in a more timely fashion. As a follow-up to these comments, we applaud the Policy Development Committee for bringing this public communications policy recommendation forward.

The policy as written provides the proper balance between inch, ensuring an open and collaborative process with the organic community while giving the NOP the ability to establish the most cost effective means of achieving this policy goal.

Another comment: We urge approval of the recommendation that has been proposed. The NOSB is intended to represent the organic community as a whole. This would be more easily accomplished if the community were able to provide input throughout the NOSB decision-making process.

Another comment: We har-, we heartily endorse the Board's clarification as to their role in communication with the Secretary of Agriculture, and the ability of the public to communicate at any time with the Board.

It is the statutory responsibility of the NOSB to communicate to the Secretary on any and all issues relating to the organic, relating to organic that the Board deems important. Additionally, it is necessary that NOSB communicates, communicate issues of concern

directly to the Secretary regarding organic, that they have heard from the public, whether or not it is the subject of proposed regulations, standards, or recommendations.

Another comment: The NOSB not only has the statutory authority, but also the responsibility to directly communicate issues of critical concern from the greater organic community directly to the Secretary of Agriculture.

Another comment: These issues include those of the NOSB bi-annual agenda and those outside of the Board's agenda which members of the public are compelled to raise in their written and/or verbal comments.

We also strongly believe that the NOSB's work is greatly improved when experienced stakeholders are consulted during a Committee development, a Committee's development of a discussion document, proposed guidance and/or recommendation.

We also had comments in relation to the concept of a public docket. These comments included: To facilitate communication between NOSB Committees and the public to receive comments, this would be a valuable mechanism for stakeholders to engage individual Committees on critical issues of concern to their constituents.

Another comment: We fully support the following addition to the policy manual as proposed by the pop, PDC. The NOSB policy on its advisory role in communication with the Secretary of Agriculture and it goes on to include the, the paragraph that we proposed.

We support of the following addition to the PD manual, the NOSB policy for poba-, for public communications between NOSB meetings. Opportunity for public comment should not be limited to the official public comment period.

We received a comment from the Program on May 10th as a result of a, a meeting that they held with the USDA Committee Management Officer. The Program's comments follow.

They suggested to add to the third line – are you able to go there Michelle? In the recommendation? They suggested to add in the third line of the, of the proposal, NOSB policy on communications with the Secretary: We request that the phrase “directly to the Secretary of Agriculture” be modified to read “to the Secretary of Agriculture, through the NOP's Designated Federal Officer”. We request that the phrase “directly to the Secretary of Agriculture” be modified to read “to the Secretary of Agriculture through the NOP's Designated Federal Officer”. The USDA Secretary delegates authority and responsibility for the NOSB to the NOP and the DFO. It is specifically required to be the point of contact for Board communications. The NOP will ensure transmission of any letter to the Secretary through the appropriate chain of command. To ensure both appropriate delivery and consideration, we ask that the letter not be sent directly to the Secretary by the Board.

Okay, oh, okay. Yeah. I am back to the private one. Anyway. Okay. Thank you, yeah.

The comments continued. For public communications between NOSB meetings, in the section on receive, and maintain, and archive, archival record, the NOP will be happy to research and propose a year-round mechanism and archival record by which public feedback can be received and posted for public viewing by both the NOP and NOSB. This general communication mechanism needs to be set up outside of the FACA driven meeting public comment process so it will need to be established as a forum by which people can provide feedback to the NOP and the NOSB, not just the NOSB. The solution also needs to be selected with an eye to staffing resource demands, as NOP would need to administer and monitor this kind of mechanism.

That is right. That is written down.

The comment from the Program continues. For public listing of NOSB members, this is not a proposal the NOP will be able to accept. We are not permitted to post Board members' info, personal information on our site. The public feedback mechanism that is established, that is established, previous bullet, is the best way for people to share their thoughts with the NOSB outside the meeting-driven public comment process.

Okay. That completes the com-, the comments from the Program, as well as those, a summary of some of the comments that we received from the public. And I just added a note that the National Organic Standards Board members' contact information is currently avail, available on the NOP website. And it is currently available for, for the public. That concludes my presentation. Thank you.

Colehour Bondera: Thank you, Jennifer. At this point in time, I would like to turn the mike over to the people that have signed up to make public comment to our Committee on these recommendations, etc. And so we have two people that are signed up. Is that correct, Michelle? So Will Fantle from the Cornucopia Institute, if you could step forth. And I have David Rogers in queue. Thank you.

Will Fantle: Yes. Good morning everyone, my name is Will Fantle. I am the co-director at The Cornucopia Institute. We are a research and farm policy organization, national organization. Most of our members are organic farmers scattered across the country. Want to welcome the new Board members. You signed on for quite a ride here.

A policy issue is, is something too that is becoming and has become aware to us of the increasing importance of it. We had not followed this as closely, but the need for robust discussion, not stifled, transparency, and a vibrant and full exchange of information is something that has become more and more apparent and obvious to us. So I think the Board is well served by the policy recommendations, many of them which are brought before you today. Some that we would propose some tweaks to. But your Board chair who served for four years on this Committee has a pretty good perspective and he has been able to observe and watch and monitor the proceedings of this Board and I, I think that has contributed to the breadth and wisdom of some of these recommendations.

Three minutes: You have heard many commenters up here in the last few days that have said it is just too short. Not only does it stifle the breadth and fullness of a presentation, but it also has a tendency to degrade it as people start talking really fast and trying to get all their words in. It becomes difficult to understand and comprehend the nature of what they are trying to convey to you when that occurs. People are anxious. They have been lots of things that they want to share with you. And we think that some tweaking of that is worth doing, going to five minutes. We think that proxies are something that are worth bringing back. Proxies have afforded us in the past, to bring other voices before the Board to populate this discussion with former NOSB members, who are advisers or Board members of our organization, farmers. In one case, we turned even over a proxy to a retailer to allow that person to present their information to the Board.

Conflict of interest: I want to add some remarks to something that I know you are going to be considering in the future and that deals with TRs. You need to know who the authors of the TRs are. You need to know if there are conflicts of interest there. Those individuals that come before this Board and, and testify as well as from the public, I think it is wise for you to know who they are representing and what conflicts they may have. Consultants that come before you rarely are hired to advocate for the public good. It is principally for an economic interest of a client. You should know that. You should weigh that in your decision.

Comment [JMS4]: 01:00:00

Board communications: You need to be able to hear from people during the entire year, the whole process. This is particularly important when proposals are being analyzed and assessed during Committee proceedings when you can get full information. Thank you.

Colehour Bondera: Yeah, I would like to see if there is any questions. Jay, you have a question?

Jay Feldman: Yeah. Thank you, Will. You among some other organizations take advantage of the opportunity, or exercise what you believe is a right I take it, to communicate directly with Board members, correct?

Will Fantle: That is correct. It is something that has not been something that we have done real often during our history, but it has become more frequent in the last year and a half or so as we try to share views and information with Board members.

Jay Feldman: How the heck did you find their personal information?

Will Fantle: [Laugh] That is why we are researchers.

Jay Feldman: Was it difficult?

Will Fantle: In some cases, very difficult, yes, that is not easy to find, but certainly, mailing addresses have been much easier to find. Electronic can be quite difficult but we take a pretty good look and dig and dig and dig.



Jay Feldman: How would you feel about a public docket system as opposed to communicating directly with Board members who, by the way, sometimes feel overwhelmed by having direct communications with the public. You are aware of that, right?

Will Fantle: Totally understand that, that you can be overwhelmed by the volume of communication. Unfortunately, I think that is one of the things you signed up for, as, as part of the job. Public docket I think would be helpful. That would be another venue that I think people would take advantage of and to try to provide information that comprehensively could be collected and aggregated.

Jay Feldman: My final question: would, would you use that instead of direct communication, or would that be sufficient? Would you feel that? Because what I am hearing on our end, is that that might help to organize the flow of information in a way that would be less disruptive, you now, to all the other work people are trying to do as part of their, their, the jobs that put food on the plates.

Will Fantle: Right.

Jay Feldman: So would you, would you utilize that system feeling it was adequate, an adequate form of communication with the Board?

Will Fantle: We would utilize it. I am sure of that. I cannot make a firm commitment that that would be the only path of information that we would use.

Jay Feldman: Thank you.

Colehour Bonder: Other questions, Board members? Yeah, I, I have one myself. Will, thank you for your presentation. I, you said something in reference to the number of minutes in the public comment part, that I would like to hear your response to something else that I have heard regarding that, which is, a reference, or reflect upon or respond to whether or not it is the number of minutes that a testifier is given to testify or how does that relate to or is associated with the amount of time that that person can receive questions from Board members of their testimony. Can you associate those things?

Will Fantle: Yes. What has been proposed for Board questioning of commenters I think is an improvement to over what we have recently seen. So I think that is good. The amount of time, many of us come with multiple issues to talk about and discuss and the three minutes is just a very difficult perimeter to fit all that information into and try to convey it to you in a meaningful fashion. We do take advantage of written testimony. We provide that in advance. Others do as well. But we know you are overwhelmed and we also know that many Board members, reflecting upon their experience on the NOSB have highlighted this particular aspect of the NOSB hearing public comments in public testimony is one of the things that they enjoy and take a lot out of. So I think it is important for you to allow that expression, if the Board members also are benefiting from this type of discussion. So I, I think it enhances the level of discussion and the conveyance of information.

Colehour Bondera: Thank you. Other questions? Mac, you had a question.

Mac Stone: Will, do you all feel that public testimony has any more gravity than written, submitting written comments?

Will Fantle: It is hard for us to know that without being in the decision-making aspect of the room. I, I do know from having been an elected official myself, and participating in numerous public hearings, the value of, of public testimony and the impact that I have seen that that has upon my fellow Board members, when I was on the County Board, in the decisions that they made, some people process information differently. Verbal has more impact for some people than written. I, I just notice that in my participation in the public arena.

Colehour Bondera: I am going to go Nick and ...

Barry Flamm: Colehour, [inaudible]

Colehour Bondera: ... yeah, and then Harold.

Nick Maravell: Will, you, you sort of addressed the question I am about to ask, but many of us have had the, the experience of presenting public testimony and being on many sides of the table. Do you have any models in mind of other bodies that you might suggest that could inform how this body would work?

Will Fantle: Well, I do not know that I have anything that, I have witnessed anything that is uniquely different. I will say that what we had in the past, and historically have had before the National Organic Standards Board, I think was an improvement over what we have gone to the last few meetings with a fuller discussion and the ability to bring in other voices to populate that discussion with proxies. That worked pretty good.

Colehour Bondera: Harold?

Harold Austin: Will, thank you for your testimony. You made a comment about the consultants' expert witnesses being allowed to testify. I, I know that can be a kind of a two-way dynamic that takes place, but is not there also value to that testimony, from those types of peoples, if used in the right context to take and help enlighten and enrich the knowledge of the Board and the, and the people that are here? I mean, would not you think so?

Will Fantle: Please do not misconstrue what I am saying about prohibiting their testimony. I am not advocating that at all. I merely advocating, and we are advocating, that they disclose who they are representing and what that brings to the table so that you can factor that into your decision-making. I know it makes a difference. The Planning and Development Committee hearings that I have sat on when the advocate comes and wants to add something or develop a property in a certain way, you know what his interest is. And you

are able to factor that into your decision-making as it pertains to other interests when they present testimony. So.

Harold Austin: Thank you for that clarification.

Will Fantle: Yes.

Colehour Bondera: Very good. Thank you very much, Will. I appreciate your testimony. Do we have David Rogers? Thank you.

David Rogers: Good morning everyone, I am Dave, I am David Rogers, a policy adviser with the Northeast Organic Farming Association of Vermont. NOFA Vermont is one of the oldest organic farming associations in the country. We are a member NOC, and I am presenting NOC's comments this morning on the Policy Development Committee's recommendations.

NOC fully supports the rec, these recommendations to amend the Policy Manual to clarify conflict of interest definitions and procedures. It increases transparency, and, and therefore, increases the quality of the, the Board's work and the integrity, and protects the integrity of organic products and is consistent with the core principle of continuous improvement, which should include procedures of the, of the Board. So these recommendations send us down the road and, and are improvements, go some way in improving transparency but they do not go far enough. There is a missing piece and that has to do with, that has to do with the experts, expert consultants and folks involved with technical reviews.

The rep, technical reports directly affect the quality, completeness, and integrity of the Board's deliberations and decision-making, particularly those pertaining to the addition and removal of substances to the National List. I think we all know that we are way beyond the time when the work of scientists and the judgments of scientists can be naively assumed to be somehow removed from personal interests and affiliations. These, these interests may be financial. They may be direct. They may be indirect. But they may affect the objectivity of, of experts' judgments. This is why codes of professional content, conduct routinely requires the disclosure of such interests. This is why professional scientific journals, at least the better ones, require authors to declare financial interests and sources of funding. So for these reasons, for the, in the interest of integrity, in the interest of continuous improvement, in the interest of transparency, it is clear that conflict of interest policy should include those who provide the Board with technical information. This information should be, the disclosure should include direct and indirect financial interests that may constitute a conflict of interest. They should declare sources of funding, business associations that have the potential to affect the objectivity of their work and without this, the Board simply cannot have full confidence in its deliberations and decisions and be, be assured that its work will depend on reliable and objective information. The Center for Food Safety, which is also a NOC member, has proposed draft language for conclusion in conflict of interest.

What do we have? Oh. [Sigh] Okay. Ask me a question.

Crowd: [Laughs]

Colehour Bondera: Very good, thank you. Do I, do we have any questions for David? Yeah, go ahead, Jean.

Jean Richardson: Could you continue and give me some clarification? I am not really quite following what you have in mind.

David Rogers: Well, I will, I will read this draft language from the, from the Center for Food Safety. This is the recommended language for inclusion in the, in the conflict of interest policy.

Consistent with its conflict of interest policy, the NOSB seeks to ensure that contractors and consultants who provide research services to the NOSB do not stand to financially gain from any recommendations it makes with respect to the addition or removal of substances from the National List. Therefore purveyors of such services will be requested to sign a conflict of interest statement prior to the commencement of their work which explicitly states that there is no actual or perceived direct financial interest to be gained from the outcome of their research that could prejudice the tone, scope, or conclusion of the report in question or impair the individual or Agency's objectivity. If a given contractor or consultant is unable to or unwilling to sign the statement, then another individual or agency will be sought out to do the work.

Colehour Bondera: Go ahead, Jean.

Jean Richardson: Dave, have you already, has NOC already submitted this to us in writing? Because, I, I know I have heard the general concept of what it is you are talking about, but the specific language, do you know if that has been already submitted [inaudible]?

David Rogers: The specific language was submitted as part of Center for Food Safety's written testimonial, testimony, comments and NOC supported those in their comments.

Colehour Bondera: There was another person with question? Sorry.

Barry Flamm: Calvin had...

Colehour Bondera: Sorry?

Barry Flamm: Calvin had...

Colehour Bondera: Calvin, did you have a question?

Calvin Walker: We did get information back from the Program. I do believe that something needs to be done that relate to expert testimony as far as a conflict of interest. At the university,

when we write grants, we have to sign conflict of interest statements. One of the comments I got back from the Program, maybe the Program can add more, they use the term "Federal Acquisition Regulation" dealing with a covered relationship where contractors are asked to declare a conflict of interest. But I, I definitely agree that as a person on the Board, to know who is the author of TRs. In one instance, we do know that one of the references apparently did not concur with what was said, what they said in a personal communication and it can sometimes present a problem. So we hope at some point that we can look at that.

Comment [JMS5]: 01:15:00

David Rogers: I think such disclosure and transparency should extend to public commenters as well.

Calvin Walker: I agree.

David Rogers: I, I think it is a, I think the Board should perhaps make clear to presenters that this is what their expectations are. That, if you have financial interests, direct associations, that you would urge presenters to divulge those. You expect them to. I think most people do a good job of that. But there is plenty of opportunity for non-trans-, non-transparency up here.

Colehour Bondera: Jay.

Jean Richardson: Dave, is there a, you have been in this business for a long time. Is there a, a broad spectrum of perception that the technical reports are done by a limited stable of expert witnesses, so to speak, that do not necessarily represent the interest of a broader range of stakeholders or that they have biases, that are not... I understand you do not think they are always fully disclosed, but are they sufficiently biased that you feel the NOSB, in their technical reports that they receive, are not getting the best range of information and data?

David Rogers: I, you know, have been in the business for a while, yes, but not particularly paying close attention to this aspect. I am not, I am not sure what the quality of the disclosures are with respect to those doing, conducting technical reviews and because of that, I think the policy needs to make it, to ensure that becomes more apparent, becomes more public and, but I do not, I do not have any personal information would indicate whether or not there have been problems in the past or what the, whether associations have caused conflicts of interest. We just need to get this out, make transparent. It is consistent with protecting the integrity of organic products. It is consistent with the notion of continuous improvement.

Jean Richardson: Thank you.

David Rogers: I would also sup-, NOC, NOC also supports the idea of improved and continuous communications. This was discussed earlier. And the, the concept of a public docket is one that is of interest to us.

Colehour Bondera: Yes, Jay?

Jay Feldman: Thank you, David, for your testimony and the work you do. I want to switch gears here a little bit to an issue that came up pretty recently and Jennifer referenced and read from the Department or from the Program on the issue of communication directly with the Secretary of Agriculture. And given your long work on policy issues, I am, I am really interested in your viewpoint on this. I am, I, I ask you this in the context of policy because many of the things that I am hearing from the Program feel to me as an erosion of authority of the Board, the NOSB. And having been again, having been at the table when the law was written, this was, this Board was really established to have a, a large degree of independence, as you know, you were around at the time as well. And, and to create a, both a collaborative relationship but a check and balance on, on that relationship and so there was some degree of independence including convening, convening technical advisory panels and communicating with the Secretary of Agriculture. Now while on a bureaucratic level, I do not feel like it is a big deal that we send our letter to what, someone who happens to be a really nice person, who I trust will send the letter on to the Secretary. From a policy standpoint, do you feel that is an inappropriate or appropriate position for the Program to have?

David Rogers: Well, I think, I think OFPA provides for direct communication from this Board to the Secretary. So I, I would say, I would say any requirement that it pass through the Program first is, as you characterized it, an erosion. So and I think it is important again for the, in the interest of protecting the integrity, the perceived integrity of organic out there, that this, this Board, which is represents the public and the organic community, the organic world as a whole, has the power to direct, to communicate their positions and concerns directly to the Secretary.

Colehour Bondera: Thank you. Nick has a question.

Nick Maravell: You referred to the way that OFPA is constructed. I noticed in the Program comments that Secretary has delegated the authority to the DFO, the Designated Federal Officer. Do you feel that the Secretary has the ability to delegate the Board's authority that is statutorily given?

David Rogers: [Sigh] I think that is above pay grade.

Crowd: [Laughs]

Nick Maravell: Okay.

David Rogers: You know, I, there are so many pressing issues; the question of genetic engineering, of course, highest on the list, at least in terms of my thinking. Efforts to communicate concerns and express suggestions and such, I think it is tremendously important at this time with respect to that issue to have communication as open and as direct as possible and so I, I would say to the Board that it should work to restore the

power that they have under OFPA and to insist, if they can, to, to maintain that, the prerogative to, to communicate with the Secretary directly.

Colehour Bondera: Very good. Thank you very much for your test-. Sorry, go ahead, Calvin.  
Excuse me.

Calvin Walker: What is your view on time? I notice, this is my third meeting, expert testimony, stakeholders make comments. As a researcher, sometime it takes a while to digest things and sometime we make changes in 30 minutes, one hour. And we notice that local school boards, City Council, Supreme Court, you know, they hear sides and at some point later on they make decisions after digesting all the information coming before them. What is your view, or the NOC's? Do you think we have, we make enough, allowing enough time to kind of deliberate on such important information that come before us ...

David Rogers: So you are, you are ...

Calvin Walker: ... in such a short time?

David Rogers: ... you are talking about time for the Board to consider ...

Calvin Walker: Yes. On certain issues. Yeah.

David Rogers: ... its decisions on some issues? I think it is, you know, I have, I have been out there for a few years witnessing what you all go through and I think sometimes it is akin to drinking from a fire hose. And to, to expect on very complex issues, issues where new information comes to light in this exchange, this kind of exchange, and then to have you, sort of, later that day or 36 hours later or something, to expect you to have digested all of that, discussed it, and come to the most, you know, the best decision, I think that is unrealistic. I think the Board, I think you all should feel free to say, look, we know we were going to vote on it but now we really need more time. And then through an open docket process between this meeting, for example, and the next one, you could continue to get information, continue to think about it, and then come back right off the bat at the next meeting vote. Other issues, less, less difficult, you just stick to your plan and, and have a vote. But, you know, whatever is best I would say, whatever leads to the best decision, whatever is, you know, going to in the end help us protect the integrity of organic agriculture and, and continuously improve the, the work of the Board.

Colehour Bondera: David, thank you very much for your testimony. I appreciate it.

David Rogers: Thank you.

Colehour Bondera: At this point in time, I would like to request that we, as the NOSB, discuss the recommendations that have been put forth. From my perspective, it would be most appropriate if we could go through them in the order they were presented, and have a discussion first about the conflict of interest, and then move to the public comment, and then move to the public communications since that is how they were presented. And, if

people are willing, then if people have questions or discussion or about the recommendations put forth so far, that will be fine, or... Yes, go ahead, Mac.

Mac Stone: Can you, Michelle, can you put the conflict of interest back up please, the recommendation section?

Michelle Arsenault: [Inaudible]

Nick Maravell: [Whispering]

Colehour Bondera: Me too.

Nick Maravell: [Whispering]

Colehour Bondera: Yeah. Sorry. Yes? Yeah, go ahead.

Mac Stone: While she is getting that up, I know we were discussing this the other evening: is the word "potential" or "perceived", we were having that conversation. What was that final draft I guess is my question?

Colehour Bondera: Calvin, can you address that?

Calvin Walker: Oh, okay. I am sorry. As I mentioned earlier, trying to get a consensus and based on some of the information given to PDC by the Program after discussing with the Ethics Office, they essentially seem to have left it up to the Agency. And the definition of "conflict of interest" that we are putting forward was derived from that. Because the Ethics Office seemed to say that that is left up to the Program as a Board, as opposed to this Board. So, the definition that we have seen there is, it came from the Program. So, they may want to give us a little bit more than this. But we tried to capsulize it in this short form.

Colehour Bondera: Yes, Miles.

Miles McEvoy: Yeah, we have, we have learned a lot about the FACA over the last few months. We shared a lot of that information in our, my opening, opening remarks on Tuesday morning. And we have committed to work with the Policy Development Subcommittee on, on revising the Policy and Procedures Manual in, in alignment with the, what we are learning from the FACA rules. So we are very engaged in working very collaboratively with the, with the Policy Development Subcommittee to, to make that happen so that we are aligned both with OFPA and the FACA requirements. So that is going to be an ongoing project. We will be working on that over the summer. We really look, look forward to collaboration on that.

So we have learned a lot about conflict of interest over the last few months and specifically, it is important that Board members research any actual and potential conflicts of interest. So the Ethics Office and the, and the Community Management



Officer do use the term “potential conflicts of interest” in, in their definition of conflicts of interest. So it is a little bit broader than the, the conflict of interest definition that is in the current NOSB Policy and Procedures Manual. So it is important that Board members research any actual and potential conflicts of interest because of their organizational affiliation or relationships before they came, they come to the Board meeting. This is as much about the appearance of conflict and loss of impartiality as it is about actual direct financial interests. So again that is broader than the past definition of conflict of interest.

Members need to self-assess for self, proposals. Are there any areas where there could be any, an actual or potential conflict of interest? Do your homework before the meeting. We will be providing, you know, more specific information on this as we move forward. If a Board member discloses having a conflict of interest and offers to recuse him- or her-self, NOP will accept that, no questions asked. You do not need to give the details of the conflict, just state that a conflict exists. Because there may be times when you just want to recuse yourself, you do not need to necessarily tell people why. If a Board member discloses a potential conflict of interest and uncertain as, as to whether he or she should recuse him- or her-self, then the NOP will make the determination, the Agency makes that determination about whether a conflict exists and will instruct the member accordingly as to whether or not to vote. We are committed to doing that in a fair and consistent way. We are learning about this as we, as we go along and we will, we will do our best to, to do that as, in a fair and consistent manner.

In regards to the actual proposal, we do encourage you to, to move forward with, with your proposals on conflict of in, interest and those other proposals. That will be very good for our guidance as we move forward.

Comment [JMS6]: 01:30:00

Specifically, proposal one: let us see. Okay, there are three elements of the PDC proposal related to conflict of interest. The key point is, under FACA, the NOP is responsible for Board operations. The NOP will, will be working closely with the Board, the USDA Committee Management Officer, and the USDA Office of Ethics to review the Policy Procedures Manual over the summer to help definitively guide the Board's work in the future. The NOP, working closely with our USDA Committee Management Officer and the USDA Ethics Office, will review what the NOSB sends forward.

Proposal one relates to keeping standing conflict of interest language in the PPM. The NOP will review this existing language with our USDA Committee Management Officer and the USDA Ethics Office to determine what changes may be appropriate in the PPM moving forward. We will work closely with the Board through this process.

Proposal two relates to definitions. The NOP provided feedback to the PD, PD Subcommittee from our Ethics Office on definitions related to “conflict of interest” and “potential conflict of interest”. We will again review these recommendations with the Committee Management Officer to determine what changes may be appropriate.

And then, in terms of procedural steps, we will need to make adjustments to recommendation three. I think this has already been addressed. To, so that the, it is the agency that makes the decision on conflict of interest, not the Board. So, thank you.

Colehour Bondera: Yes, Mac.

Mac Stone: I am going to vote to move this forward. But thinking as a certifier, and as an inspector, we sign a conflict of interest ahead of time. And maybe pragmatically, if, as Miles just stated, if a Board member is evaluating the agenda ahead of time, I mean, this might be played back into Committee deliberations, not just sitting at the Board table. But, so maybe we should think about preparing this ahead of time so Zea is not wondering if she should recuse herself at the table and disclose all that. That, if we could do that ahead of time, would be greatly consistent with the way we accredited certifiers operate for that matter. And it can be pre-vetted before we get here. I would also just like to suggest maybe if Calvin is leading this, if you could kind of give us some case studies and hear some examples of where you would or would not so that we can sort of evaluate our own position with the various topics.

Colehour Bondera: Calvin, did you want to respond? Or Zea, you have?

Calvin Walker: I agree. What Mac had mentioned. And Miles also, the Program also mentioned that we have what? Two calls per month. At any point in time, a, a conflict, a disclosure may be necessary. And so the Program has committed to quickly, shortly coming up with a path of how do we deal with that. Because in the course of a call, you know, something may arise. And one may have to disclose if they have a conflict. So that issue, you know, still need to be worked out. And we think that the Program can get that done in short order. Because we should disclose it, not just at the bi-annual meetings, but it should be if it occurs, Mac, you know, when we are on a Livestock call, or GMO call, we need to be able to, to get clearance to continue to participate in that discussion on those. But I agree with Mac, as I said.

Colehour: Yes, Zea.

Zea Sonnabend: I agree with that advanced one. And for those of us who are in a position where, you know, it appears from this new policy that, for each vote, I would have to say something like: I work for a certifier who may certify products containing any of the ingredients that we are about to be voting on. Likewise, Joe works for a retailer that might carry any ingredient. And it, it does not make sense to say that before every single vote. So maybe we could do those kind at the beginning of a meeting or advance, and you say, okay, you cannot vote on anything, or, we can.

Miles McEvoy: Yeah, that seems very reasonable to, that this before the meeting, to know what those interests are and determine whether or not anyone needs to recuse themselves on any particular issue. It, it would be a much more thorough and consistent process to do it that way rather than to do it on the fly at the meeting.

Zea Sonnabend: And because, is the new policy going to make us recuse ourselves on everything because of that? Even if we work for an hourly rage, wage but our company certifies everything?

Miles McEvoy: No.

Colehour Bondera: Yes, Jean.

Jean Richardson: Yeah, this is a really question to Miles. So we seem, we appear to be different from the other FACA committees in, in this issue of conflict of interest because obviously each of us are appointed to represent something or somebody, some entity. So are there other, any equivalent situations that, that you have come across on FACA because now obviously we have to really pay close attention to the FACA, make sure that what we do is in accord with all of that, and yet we have this unique nature and construction.

Miles McEvoy: No. The point is, is that you are a FACA committee and you need to follow the, the procedures that other FACA committees are following regarding conflict of interest and ethics. And so that is where we are working closely with the commit, Committee Management Officer and the Office of Ethics to ensure that, that there is that consistency from this Board to the other FACA committees that are within USDA.

Jean Richardson: Yes, I understand the need for consistency and it is a good idea. But again, are there other FACA committees which are with people who are similarly appointed specifically to represent entities where obviously there, there is a bias in the background, because that is why they are appointed. So if you are a retailer, or a handler, et cetera, you are specifically appointed to represent that perspective. Are there similar situations on FACA committees that you are aware of?

Miles McEvoy: I, I believe that most FACA committees are going to have people that are representing specific interests, because you want to have those interests to be represented to have good decision-making and good input. So this is a, a normal process is to have a FACA committee with a diversity of interests that are stakeholders in the topics that are being discussed, so that, that is not different than other FACA committees. There are some unique natures about the NOSB. You have some statutory authority that is relatively unique and maybe, maybe completely unique in terms of FACA committees. Yeah.

Colehour Bondera: Yes, Calvin.

Calvin Walker: Since given this task, I have noticed that the NOSB conflict of interest seem to, to be probably, to me, the most advanced. I have looked at a few and our policy on conflict of interest seem to be much more advanced than some of the others. Some refer to have immediate family member in their... There is one from the Department of Interior that was recently formed, I think, two years ago. They mention immediate conflict of interest should not be allowed by Board members and "immediate family

member” but they did not define what was “immediate family member”. So in our regard, seem like our policy is kind of far ahead of the game.

Colehour Bondera: Very good. In an attempt to move us forward, if there is no more discussion about conflict of interest. Oh, there is more. Let us wrap it up with John, I hope. John.

John Foster: Just a comment I mentioned at the Develop, the PDC meeting the other night, was that, just a, a comment and a, a hope that, that we use our language really carefully. That most of the dialogue I hear, we are using the word “conflict” when we really mean “disclosure”. And I think we should be very careful about the language we use, particularly on those two words. That is a very, that is a big distinction, and as, as we have seen, a small word can move a lot of people. So I just would urge us to use “disclosure” when we mean disclosure, “conflict” when we mean conflict. Be very deliberate about that.

Colehour Bondera: Yeah, I mean that makes a lot of sense to me, but I think that my understanding of that reality is that you need to disclose things in order to verify if there is or is not a conflict often. So I think that they are directly associated even though they are not, not synonyms is I think worth, worth noting. Jay, Jay, you had a comment.

Jay Feldman: Yeah. I mean a lot of this information is new to us. We, you know, we deliberated on this for many months and these issues were just brought to us at this Board meeting in terms of the implications of FACA. I mean it was always my understanding that this Board was exceeding, to some degree, the FACA requirements, was putting in, was putting in standards that were tweaking FACA, maybe creating more onerous restrictions because of the, the sensitive nature of the relationships that we all have with our stakeholders and the community generally. But there is nothing in the training that we all have received as part of, as part of our ethics training that would indicate the degree of detail that is now being, was presented to us during this meeting for the first time.

And I, having looked at it and, and consulted with people, believe that some of these interpretations are incorrect. So what do I do with that at this meeting? What I would suggest we do as a Board, just to protect ourselves, to not institutionalize things that may be an incorrect interpretation into our own PPM, is that we just refer to our policies in addition to whatever we think is correct, whether it is potential or not potential, if we want to use that word or not use that word. That we should not be instructed by any interpretation at this meeting as, as to FACA rules, but we should just put a qualifier in what we do that would say subject to FACA rules. So that way we are acknowledging FACA plays an important part in what we do, but we are not advancing an interpretation of FACA that may be incorrect. And I believe, in many cases, is incorrect and we will find out after the fact is incorrect but we will have institutionalized those misinterpretations into our PPM. So if we just put the clause “subject to FACA rules” into our PPM in addition to whatever we believe is correct governance for the Board, then we will have both met the Program’s need to be in alignment with FACA and meet our own needs to govern the NOSB in a manner that we were statutorily approved to do.

And that is just a compromise, hopefully, that we could reach pending more deliberations on the subject of interpreting FACA and how it applies to a Board that we were told, during our ethics training, makes us all representatives, not government employees, not special government employees. And if you remember the slides, there were three slides on the ethics presentation. One was on government employees. One was on special government employees. And one was on representative. And we were told that we were representative. And the distinction on ethics application of ethics law was different on our slide than it was on the other slides. So there obviously is a distinction there. And I would like to see it in writing, similar to what you just des-, your discussion, Calvin, with David. You know, it, this does require some deliberations. I would hate put something in our PPM that is, that ends up being a misinterpretation.

Colehour Bondera: Yes, Nick.

Nick Maravell: Yes. Jay, just to add to your comments, I read from the statute: The Secretary shall establish a National Organic Standards Board in accordance with the Federal Advisory Committee Act. So is that basically what you are trying to accomplish here?

Colehour Bondera: Go ahead, Calvin.

Calvin Walker: So, Jay, you are essentially saying to the motion add the phrase “as subject to the FACA rules”?

Jay Feldman: Yeah, I am just, I am just saying, if we are being asked by the Program in this meeting to put in something that we are told is a FACA responsibility, that we do not really need to do that at this meeting. It just is my position, that we can simp-, if the Program believes that we are doing something out of line with FACA, we can just add the phrase in “subject to FACA rules”. And this goes for the next proposal as well regarding, you know, the, the issue of public comment and how the Board is run by the, by the, the Board Chair that we, as the NOSB, elect. I think that too and, and when the NOP steps in and does not step in. I think we should just establish what we believe is correct process for the NOSB and then add the line “subject to FACA rules” and at, at that point, we can get an, an inter-, or at a later point we can get an interpretation as to what that really means.

Comment [JMS7]: 01:45:00

Colehour Bondera: Yes.

Jean Richardson: I have listened to these comments over the last few minutes and, like Jay, a lot of what we heard at this meeting was news with regards FACA and we are aware of the fact the NOP is going, going to continue to clarify what language is the most appropriate over the summer. Are we foolish to go ahead and vote on this in a sort of a semi-complete way today? Should we wait and hold the voting until the fall?

Colehour Bondera: Yeah, I do not. Mac, do you want to comment on that?

Mac Stone: Just, just glancing at the Policy Manual on page nine, it looks like that the, there is a header or initial says that kind of states we have an inherent conflict of interest and it is a way to protect ourself from ourself. But you could just add at the end of that Jay's statement. The sentence reads, prevent – excuse me – prevent overt advocacy, direct financial gain, appearance of self-interest, appearance of wrongful activity, NOSB has adopted the following conflict of interest policy subject to FACA rules and then there is these definitives that we have come up with to kind of clarify that specific to us. But it would be easy to insert in my opinion.

Colehour Bondera: I, I do not know if you are comfortable with me doing this or not, Miles, but do you have any response based on the fact that when you were talking, you, you mentioned that you thought that the NOSB should move forward with these recommendations at this point in time? Related to this conversation, do you have anything to add?

Miles McEvoy: Well, I would say that what we have learned is that we need, we need to make the Policy and Procedures Manual align with the FACA requirements. And there will be some changes that are necessary. So if the Board did move forward with these recommendations as you would with any recommendation, the Program then reviews them and responds. So we would be able to provide that clarification to the, the recommendation from the Board to clarify anything that we need to under the FACA rules. So having a recommendation on these topics does not stop the process of us reviewing those recommendations and getting back to you with any clarifications or changes that would be needed.

Colehour Bondera: Very good. I would like to move us on to a as-brief-as possible discussion on the public comment recommendation at this point in time. I do not know, Michelle, if we can put up those pages on, from what I gave you. I did converse with the Committee and did, via difficult electronic communication processes, try to make some modifications in various ways this week. But now I just want to propose some modifications to the recommendation as it stands at this time before people respond further to it.

In item number three: I do not know if you all can see it there because of the cross-out parts, but instead of, yeah, I mean, you can read it, it, I am getting rid of "in the order they sign up" of like I said when I presented this and adding "subject to the time constraints of the meeting" and eliminating the word "potentially". So I think that those are the critical components of that modification there.

And I am going to go down to number four, where we are going to start to enter into what was just raised because what the, what the, what it says right there and I think that Michelle should be able to change it right now. Jay is suggesting that we change that wording to read, the red words would read "the discretion of the NOSB chair, subject to FACA rules". So it would eliminate the, it would eliminate "the NOP working closely with" from this suggestion. And that is repeated one more time further down.

I guess before I get further down, going to number seven, “by the Board” has already been eliminated in the previous slide. And then finally further down, in the, the second to last paragraph, the NOSB was eliminated and it says we – there is a little typo issue there where “however” is made into a separate sentence – and then the final sentence the suggestion was, for change was “in consultation with NOP”. And Jay is suggesting putting in that parentheses instead, where it says the NOSB Chair putting “subject to FACA rules” to leave it “not already decided”. So that is where... Michelle, did you get that?

Michelle Arsenault: No, please repeat it. [Laugh]

Colehour Bondera: Where the second to last paragraph reads “in consultation with NOP” in parentheses, the suggestion right now was “subject to FACA rules” instead of those words.

So I would, I would like to hear any discussion that people have on this recommendation at this point in time. I, I will mention again, on, at some level I am repeating it, but just to make it clear, I did try to work with the Committee to get people's agreement on these changes before I presented them, however, because of electronic difficulties, I do not have everybody's vote on, on the changes that are in red on this document so these are coming from, essentially they are coming from me, even though I did end up with a second and some votes, it was not concluded. So. Go ahead, Mac.

Mac Stone: I, I guess I missed something, where we jumped to public comment and that, that is in conjunction with the staff of the Program because they received the request and all that. So I was thinking Jay's comment was just on the conflict of interest because we do need to work with the Program on the timing of public comment.

Colehour Bondera: Yes, Miles.

Miles McEvoy: Yeah, just a, a point of clarification from what Jay was saying about the, the Ethics Office and the training. Jay, have you shared the information that you got from the Ethics Office from last week? That you asked a series of questions of the Ethics Office concerning the training, have you shared that with the rest of the PD, PD Subcommittee?

Jay Feldman: No, I have not had time to do that.

Miles McEvoy: Okay. So [inaudible].

Jay Feldman: You see, Miles, I did not know it was relevant to this meeting because the presentation that you provided us at the beginning came as a total surprise. So I was trying to be preemptive just to understand it for myself and so I had not had a chance, did not think it was necessary.

Miles McEvoy: Right, okay. So there is, there is a lot of additional information that Jay received from Mary Royster from the Office of Ethics around this particular question of training

and, and who is a government representative versus a special government representative. And we will get that out to the rest of the PD Subcommittee. So it, Jay, your characterization of the training, you have gotten additional information and that needs to get shared with the rest of the...

Jay Feldman: I do not believe the information I got clarified. The, the information I got simply referred to the authority of the NOP to apply applicable laws. That I believe the response I got from Mary Royster was inc-, inadequate and confusing.

Miles McEvoy: Right, but you failed to share that with the rest of the, with the Subcommittee and mischaracterized ...

Jay Feldman: Well, I did ...

Miles McEvoy: ... the, the training that was offered by ...

Jay Feldman: I did to share it with the Chair

Miles McEvoy: ...Ethics Office so ...

Jay Feldman: ... of the PDC. Miles, I did share with the chair

Miles McEvoy: That is great.

Jay Feldman: ... of the PDC.

Miles McEvoy: So we will get that out to the rest of the PD Subcommittee so that everybody has access.

Jay Feldman: And we did not think it was relevant to this meeting. It became relevant when you brought it up, on your own, without notification to me. At least, I was not aware of any notification to the Board that this was a topic of discussion for this Board meeting. So.

Miles McEvoy: It has, it has been shared with the Chair and the, of the PDC and with Barry. So.

Jay Feldman: Right, so, but you are, you are, [sigh], you are suggesting that I withheld something from the Board on a relevant matter and I am suggesting back to you that I was not aware this was a relevant matter for this Board meeting. I take my responsibility here and, and with my colleagues very seriously to be open and collaborative and for, I, I really I am taken aback by the suggestion that I did not share information that I should have. I gave it to the Chair of this commit, of the PDC, not knowing that this would be a ma-, a, a issue of discussion at this meeting and I believe, I am not sure he knew as well the extent to which we would be, be told that there were new interpretations of FACA. So, just so the other Board members understand, this was information that I was collecting because of communications that were going on in the PDC. That I did not realize that this would be a topic of discussion.



Miles McEvoy: Yeah, the point, Jay did get additional information about your specific question that is relevant and it is important that the rest of the, the Committee members see that. So I, I am just saying, when you presented that information, you only presented the part about the original training and not the additional information that you received and at this point, that is relevant and so now we can share that with everyone so that everyone has the same information.

Jay Feldman: I will be happy to send it around.

Miles McEvoy: Thank you.

Colehour Bondera: Yes, very good. I, I apologize as the Chair for not having interpreted to make sure that we all received that additional information. I am sure we all would have reviewed it carefully. And I acknowledge that I may have made an erroneous judgment in that regard. You have a comment, Nick?

Nick Maravell: [Inaudible].

Unknown Female: We cannot hear.

Nick Maravell: Yeah, I have a additional comment, not to follow up on this specific. Are we finished on this specific discussion? Okay.

My comment and, is that I would prefer to see our comment period remain as it historically has been. So I would propose that we set it at a five-minute comment period at the discretion of the Chair, in consultation with the Program. I think that has worked. I think we have responsibly used our time at the last meetings that I have been at. And I think perhaps we may be trying to solve a problem that may have occurred at one meeting and maybe we do not need to solve it at every meeting. And, and Barry has done a wonderful job here, you know, at this meeting. We have not had a problem. I think, if we had counted the minutes, we probably could have had each commenter, because we finished early on both days. We could have had the commenters extend their minutes by two minutes. So, I am old school. I want as much public comment as possible.

Colehour Bondera: Zea.

Zea Sonnabend: Thank you. I agree somewhat with Nick. As a person who has stood on the other side of that podium as much as anyone else in the room, I do not feel that legislating three minutes is appropriate. It is way too prescriptive.

I did count up the public commenters we had. And we had 22 on Tuesday, and giving them each two more minutes would have added 44 minutes to our agenda. And that is assuming the same amount of questions, where the two more minutes may have been able to reduce the amount of questions, if anything. Yesterday, we had 25 commenters; that would have added 50 minutes. It makes so much difference to the public, those two extra

minutes or even one extra minute, that I am perfectly willing to sit for an extra hour to hear them all.

However, I do not feel that waiting until we are at the meeting to decide is fair to the commenters, because they prepare ahead of time. And you have to rehearse to try and get it into three or even five minutes. And so, therefore, I feel like the decision of how many minutes should be made between the time the sign-ups close with public comment, you know, with the comment deadline and the meeting, and there is a few week period where it is totally possible for the Chair with the NOP to look at how many sign-ups there are, decide 3, 4, or 5 minutes, and let all the com-, all the people who signed up know before they get here. And so I cannot vote for this as-is but I do really strongly recommend the advance notice of how many minutes.

Colehour Bondera: Thank you. Do I have any comments on that topic or on the public communications recommendation at this time? Yes, sorry, go ahead, John. Sorry.

John Foster: I, I, so before I was on the Board, I, I spoke a few times and I found whatever the time limit was, it always seemed too short. So then, when I was on the Board the previous meetings, when we went to a three minute time period, I found myself much more engaged as a Board, as a Board member. It is much easier for me to keep up. It may seem a little chaotic to some but I found it to be just the opposite. I was able to track things and pay better attention for a longer period of time and that just worked better for me. I know that not everyone works that way but I just want to throw it out there, for those of us that do, that worked really well for me. I felt like I was more engaged, more on, on topic, and maybe my mind works a little bit differently but, than everybody else's, but it worked great for me. Having said that, if it were five minutes and we kept cadence going, kept it moving, that might have the same effect. It, for me, it is more about keeping things moving and hearing new ideas, new speakers, new voices, new perspectives. That is what keeps me engaged and the time period is not that big a consideration for me. I will leave it there.

Comment [JMS8]: 02:00:00

Colehour Bondera: Yes. Jean.

Jean Richardson: I like the three minutes. And I actually drafted this with, with Colehour. And the, on the PDC conference calls, we had considerable discussion on this point covering the issues, the very issues that Zea was raising, is that if we say it is going to be five minutes, I mean I know I have presented in three minutes, five minutes, ten minutes many times on other parts of other Boards, so that the first of the NOSB Board meetings that I have attended. And I, I think that to, once people are prepared for something, three minutes or five minutes is always going to feel too short. But if you are concise, you have thought it through, what are the main points you are going to present, and you can clearly present them. You will have left enough of a window open for the questions. And I think that I have learned much more by the question and answers that we have been able to have at this meeting. And I think that all the presenters really did an outstanding job in clearly presenting what they have to present in a concise and clear manner. And I particularly appreciated the ones that came with an extra piece of paper for us also to read

and consider, which we certainly do. So I, I would much rather see us stay with the three minutes, which could be expanded to five, as we did for some of the speakers by saying “go on talking” when there is time available for us to do that. So I, I would, I can support the three minutes and will do so.

Colehour Bondera: Very good. At this point in time, I would suggest that we bring this discussion to a conclusion and take a break. I don't know, Barry, how you feel about that and come back for the vote after a break.

Barry Flamm: I agree with the Chair, that, that we will take a break right now and come back in 15 minutes and the Policy Committee will then hopefully be able to vote on these recommendations.

[BREAK]

Comment [JMS9]: 02:03:05

Comment [JMS10]: 02:29:03

Barry Flamm: Board members, please take your seat. Colehour, you can proceed.

Colehour Bondera: Very good, thank you. Aloha, folks. Based on the, the conversations, discussion that we had on the Policy Development Committee's recommendations up until this point, I would like to request that we postpone the final discussion and final, and the voting on these until, until tomorrow, Mr. Chair, if that is possible for you to put that in the agenda that way so we can move on with what is scheduled as scheduled.

Comment [JMS11]: 02:30:00

Barry Flamm: Without objection, the proposal is accepted and the Policy Committee, its three recommendations will be dealt with tomorrow morning.

Colehour Bondera: Thank you.

Barry Flamm: Next on the agenda is the Handling Subcommittee, John Foster, Chairperson.

John Foster: So I was actually expecting to have a little bit of time, [laugh], not knowing this was happening. So I, so I beg even more indulgence than I would anyway. So, that, that would be, that would be a good heads-up to me to know actually. So let me, in a flurry, get things up on my computer. Sorry about this. And now I guess I know what, what we are going to do tomorrow. That is good. We were just talking about that. Okay. Alright.

Thank you, Barry. We have got a long list of materials today, a result of actually hundreds of person-hours, work on the part of the Handling Committee. It, it still remains a mystery to me, a wonderful mystery, that what could possibly motivate six people to, who are all busy, all over committed, all tired, and all talented. It is still a mystery to me about what, what could possibly drive them all to spend this much time on things. And I, it is a lovely mystery. I thank each, each of them. It is all the more striking that we, we really have a, a very long list of materials on Handling and the fewest number of Committee members. We may be asking to amend that in the not-too-distant future, seeing as our, our future work plan is pretty heavy also. But I would like to especially

thank Vice Chair Harold Austin, Joe Dickson, Nick Maravell, Tracy Favre, and Zea for all of the dedication, many, many hundreds of hours all together. So, thank you for that.

I, I am going to go off, off target for just a second here. Because I have been, I, I was awake for a long time last night. I was thinking about, what I ended up with, about the time the sun was coming up, was that I was wondering why I was here actually. Not an existential why are we here, which I am also prone to ask about, but, but mostly why am I here right now, today and why is my blood pressure so high. Very interesting. Because as I said in my intro, I am, this is my favorite thing in life to do. Like I am, I do not want to be with any other community I have ever, I have ever been around. So this is my choice to be here. So, but I was up last night worrying quite a bit and the question I got back to was why I was here. And once I started asking that question, I felt like, hmm, I wonder how many other people have stopped to ask that question. So I am going to take a minute, a very short minute and, and give you my, my little piece of it and I am hoping that each of you take that and ask yourselves that question. Think, think for yourselves on that. I think it will help the dialogue. I think it will help, it will make the discourse very healthy. And I think we will find that the ties that, that bind us are much stronger than we might have supposed.

So, my, my grandparents, my dad's parents, grew up on farms in northwest Missouri – yes, I said Missouri – outside of Union Star and Savannah, for that, those of you familiar with that lovely part of the country. I was real small. My, my grandfather would tell a lot of stories, as people from that part of the country are wont to do. And I listened. And mostly what I remember is excruciating detail about his time on a plow behind two mules. That was his life for many, many years. And he was not worldly, but he was pretty wise and no one knew the world better than he did, for, you know, his world, not worldly, but he knew his world. Over the Depression, things did not work out so well on the farm and we had a little scattering of family all over the place. Prior to that, I am really lucky to have a book that my grandmother put together that goes back about 400 years of, of family. And they were all farmers up to that point that the records disappear, and I, I think that there were not records before that in the part of England and Scotland they came from. But what is cool to me is that I can look back and see in that record 400 years of farming families and where they were and where we, where I came from. That is, it is, and so I come from a long line of that and I think that makes me a much better person actually. So it has been very, is has been very heartening to hear the, the farmers speak here and talk about how many generations they have been on, on the land. That is, that is something that is very meaningful to me and I, I really appreciate. I think it is a privilege that we get to hear, hear stories like that.

So, fast forward a bit and I guess back to the, the present here. So I am really privileged to, to kind of, to work for a company who has got a mission I really believe in, that is provide benefits of organic food to as many people as possible, serve as a catalyst for positive change. And I'm guessing that maybe while that is not a mission for everybody, that is, maybe it is not written down anywhere but that's probably what most of it is, of us in this room, that is what makes us get up every morning. That is what I want to get to. That is the tie that binds I think. So, that is, that is really why I am here. That is my intent.

That is my hope. And I think that a lot of us share that whether it is written or not. I think it is, obviously it is really important. My job, why I am here, is to represent handling and processing communities, that is my, that is the seat that I occupy in the position, so the seat that demands that. Obviously respect for OFPA, respect for the Program, respect for the standards, we need to act as all consistent with that. But if there is, if I am kind of conflicted, the last tiebreaker for me is: does this vote help to put more ground in organic production or not? And that for me, I am not saying that is for everybody, that is just for me, that is the tiebreaker for me. And so that is why I am here is to get more ground in organic production. I just want to be very upfront about that. Thank you all for your indulgence. And, for those of you that know me, that was a remarkably short period of time for me to, to go on about something.

Crowd: [Laughs]

John Foster: So thank you again. So we have, we are, as a group, reluctantly pleased, to be something of a guinea pig in this revised format in that we have a lot of material, materials to go through, a lot of discussion, a lot of voting to go through. We are going to need to move fairly quickly I think but we want to do a complete job so we may need to put one or two votes out to tomorrow. I, I would not be surprised if that was the case.

The materials we are dealing with today are choline, curry leaf, gibberellic acid, inositol, citrus hystrix. At then on Sunset – those were all petitions – then on Sunset, determinations for agar-agar, calcium sulfate, carra-, carrageenan/carrageenan, glucono delta-lactone, and cellulose. And then, lastly, we will have a brief update on our discussions around ancillary or other ingredients.

So in this format, I check in with the Program yesterday, so we will ask the National List manager to provide a brief introduction to a material, I, I believe in the order of the agenda, and then – and by the way, I am really grateful for that, I think this is a positive thing, I appreciate that about this format. Then the person on the Handling Committee who is the primary reviewer will address that, that material with respect to the discussion we had, a brief, brief summary of, of public comment. And then we will move to public comment in one big chunk.

I will, I, just forewarning, I would like to ask that after public comment is done, that we have a break in mind, because I, one way or another, I think we are going to need it. And then lastly, I just ask the public for a little leeway as we work through this new, new process. It is going to be a lot of toggling between screens for me and documents for, for everybody else. So there may be a little more quiet than people are comfortable with and we just need to work to work through that process. So please bear with us.

With that, I would ask Lisa to start out with choline.

Lisa Brines: Okay. Thank you, John. So the first petition material on the agenda today is choline, which there is actually two different petitions. The first petition was submitted in April 2011 by Nestle Infant Nutrition, Gerber Products Company and it requests the inclusion

of choline at Section 205.60(b) of the National List as a synthetic substance for use as an ingredient in infant formula and toddler foods. Second petition was submitted by Ballchem Corporation on June 29th 2011 and it requests addition of the same substance to the same section of the National List but with a broader allowance. There, choline does not appear anywhere on the National List at this time. To assist in its review, the Handling Subcommittee had requested the development of a third-party technical report. That report was drafted and provided to the Committee and was available to the public in advance of the opening of the public comment period. The Committee did, the Subcommittee did complete its review of the substance according to the criteria in OFPA and the NOP regulations and has a proposal which was posted on the NOP website also for public comment. Public comment was received on this substance, and I believe both petitioners are signed up for in-person public comment during this session. And as a petitioned substance, the Board will be taking presumably two votes on this substance, first for classification and second for the listing motion. And with that I will turn it over to the Subcommittee for a discussion of the proposal.

John Foster: Alright. Thank you, Lisa. Zea, you were point on this. If you would, go forward.

Zea Sonnabend: Thank you. Michelle, could I have the choline summary, public summary?

Okay. First I am just going to read a little bit from our recommendation and then I will get into the public comment. Choline is a synthetically made nutrient that also occurs naturally in food. It is considered by most regulatory bodies to be essential in non-milk based infant formula and is required by the FDA for this purpose. It is permitted but not required to be added to milk-based infant formulas. All the organic infant formula brands that we could find through an Internet search contain added choline, both milk-based and non-milk based. Allowing it in adult foods that are in the “made with organic” category would allow such foods to highlight the fact that they are fortified while at the same time limiting the number of non-essential synthetics in organic processing.

Now we realize that the “made with” category has not been utilized much by the NOSB in recent years, but we saw that it might be better than nothing for those companies who emphasize fortified food. We, the Handling Committee, felt that synthetic, the consumers do not expect synthetics in their food any more than are necessary to produce the food. And so fortification is not necessary to produce the food and should not necessarily be allowed in the full organic label. However, for infant formula, because human milk is very high in choline, but even though it is not regulated in milk-based infant formulas, the cow's milk and sheep's milk is lower in choline than human milk.

So, choline public comments: We received 13 specific comments about choline and a bunch of general comments about synthetics in handling. Of the specific comments, nine were in favor, three were against and one was mostly raising a point about international trade in the “made with organic” claim. All of the ones in favor did not like the proposed listing for “made with organic” only and wanted full allowance for choline in all organic food. So, I want to specifically address a few of the points made in the public comments.

One was “choline is essential”. Some people seem to have missed the part in the TR and in our recommendation that said that: yes, we acknowledge choline is essential but choline can be obtained from food and synthetic choline is not necessarily essential. Humans who can choose what foods that they eat can select foods that are high in choline and the body can extract choline easily from the highest foods and an, an Internet search on foods high in choline brings you lots and lots of information beyond what was in the TR, the highest sources of choline include eggs, many types of meat, peanuts, caviar, beans, shiitake mushrooms, dried, which have as much as a poached egg for instance, milk, and even meatless bacon bits. In fact, choline is a component of lecithin and the body can break down lecithin although not necessarily in infants. Choline can be also acquired by synthesis in the body where the body can make it from smaller food molecules.

Comment [JMS12]: 02:45:00

So our recommendation was that choline supplementation was not essential, not that choline was not essential. Many commenters gave us a lot of detail about the ADI, average daily intake, and the AI, adequate intake, for choline in people. These have been well established and it is well established that the average American diet is deficient in choline. We recognize that humans need choline but ADIs alone are not relevant to our decision. Look at what the average American eats that that recommendation is based on. We did not see data from people eating a balanced organic nutritional diet as being deficient in choline. Humans who make food choices can get a balanced diet and can choose foods that are suff-, sufficient in choline.

Now, infant formula: Infants do not have the ability to choose what they eat. Human breast milk is by far the best source of choline for babies and breast-feeding is by far the best alternative. However, the Committee felt that not all mothers are able or willing to breast-feed their babies and that is just a reality in life. But it is important for infants to get off on the right track when they cannot make their own food choices. And so that we felt that allowing synthetic choline in infant formula is the right choice for those who must choose formula. By the time baby is able to eat solid foods, a mother can choose a varied diet and include foods that are high in choline in, in the diversified baby's diet.

Okay. Commenters raised the point about GRAS status of choline. We heard input on both sides that it was not GRAS and that it was GRAS but there were some C-, CFR citations given for its GRAS status so we do not believe this to be relevant to the discussion further.

The argument was given that choline should be allowed as a flavor modifier because – and I am quoting from a public comment – choline chloride’s unique non-nutritive functionality augments the taste impact of sodium chloride which has important implications for acceptance and palatability of reduced sodium food. We do not find this suggestion palatable or important to organic deliberations because this is not even fortifications, this is just some food modification function.

Several commenters pointed out: if organic food manufacturers are not allowed to fortify their products, they will not be able to compete fairly with conventional products and this

will harm the industry. We did not see a criteria in the Rule or in OFPA that competing fairly is a, a criteria that we use to evaluate materials. We would entertain data in the future to determine how many consumers would choose conventional just because a fortification over organic food but such data was not presented to us.

Conclusion on the public comment: One commenter said “choline should not be a compromise”. They may not have meant that the way we might be meaning it but we agree. And although the “made with organic” idea did not get very much traction and that was probably the comp, compromise they were referring to, we are keeping that on the table for the Board to vote on.

Now, with that in mind, we are proposing an amendment because I realize that in preparing for this, that we had not been very specific about what forms of choline we were adding to the National List and so first, I e-mailed this all to the Handling Committee a little while ago and Michelle, if you can put the amendment. I am requesting changing the motions to refer to the CAST numbers for choline chloride and choline bitartrate so we are all clear what forms of synthetic choline. The old language said choline as petitioned but that is not really on the National List entry. And so, is that okay with everyone on the Handling Committee? I am assuming it is; moving forward. Okay. So, thank you. Any questions about choline? Okay, well we will hear public comment and then we will come back to it.

John Foster: Okay. That also caught me by surprise actually. So let me, so we will move to the next item on the list, curry leaf. And, Lisa?

Lisa Brines: Okay. Thanks, John. The next petition is for the substance curry leaf. The petition was submitted in August of 2011 by the company Curry Love, Incorporated, who is a certified organic handler. This petition for inclusion at section 205.606 of the National List as an agricultural product, as a non-organically produced agricultural product allowed as an ingredient in or on processed products labeled as organic and would be subject to commercial availability requirements. In evaluating the substance, the Handling Subcommittee did not request a technical report in support of its review but was able to complete a proposal based against the OFPA criteria and the NOP regulations. So the Committee proposal and the petition have been available to the public in advance of the opening of the public comment period for this meeting. Public comment was received on the substance and the Board will need to take two votes: the first is a classification decision and the second as a listing motion. And I will turn it back to the Handling Committee for discussion.

John Foster: Thank you. This is one that I, I was point person on. Let us see. Too many screens open, I apologize. Here we go.

So, we did receive the petition. We talked about the curry leaves being natural, not reported, as far as we could find, to be toxic or dangerous, a pretty common condiment, an ingredient in human diets and that is the rationale why the Handling Committee did not request a TR. Also in light of the, the other TRs already in, in queue, there was a lot



of demand for precious time there so those of the two reasons together, mostly focusing on the commonality of it though, and lack of any documented concerns. So we did some searches on the NOP database, two major organic certifiers' databases and few suppliers coming up on US supply of, of organic curry leaves and then there was, there are, there are more organic pretty high volume outside of the US. Unfortunately, it is one of, one of several crops that are under quarantine because of a, a pretty dangerous horticultural pest. So getting them into the country is next to impossible. In fact, it is as organic because they require fumigation, as far as our research could find. So obviously, that fumigation would prohibit the materials, would make the products no longer organic. So the, the availability of quantity was, is just not there on the US market.

The petitioner indicated that a, yeah, pest species is the Asian Citrus Psyllid, so we did a little research on how troublesome that was. It turns out to be quite troublesome for a variety of crops and is under a, a pretty tight lid so that is not likely to change anytime soon in terms of quarantines or, or mandatory treatments. We did look at volumes of the available supply in the US. They are reported to be quite a bit less than what the petitioner is looking for, and so based on quantity. Now this, now this is going to reveal a little interesting feature on the lack of commonly available or easily available market data. TRs do not generally get into that anyway but we did our best to, to call around to companies that, that would be interested in creating products that might need this and they felt like it was their suppliers that they knew would not be able to supply even a little bit of it. It has a pretty, a pretty narrow, a pretty specific flavor profile and adds a specific kind of flavor complex to food so there is not a lot of substitutes. Also part of our feeling was that we would much rather have helped, you know, push a, a market for organic ingredients than to push companies into natural flavors, that is one of our considerations. Any question or discussion on that? Yes, Jean.

Jean Richardson: There are a number of other species of this genus. Was there only the one that was under consideration and is it adequate to list only one species in the genus?

John Foster: This is the, the species that, that has the culinary value. So, yes, a lot of other citrus crops out there, I am sorry, *Murraya* crops out there but this is the one, this is the one that was under the petition. So and, and to the best of my knowledge it was the one that is in common use in, in these kinds of entrees, conventional or organic. Other, other questions? Alright. Moving on to gibberellic acid. Lisa.

Lisa Brines: Thanks you, John. The next petition substance is gibberellic acid. The original petition was submitted in September of 2010 by Valent BioSciences Corporation, is a petition for inclusion in section 205.605 of the National List. There was an amendment to the petition that was submitted by the same organization in August of 2011 that would expand the use. So the original submission was for post-harvest use, post-harvest handling on bananas and the expanded use that was submitted later also included post-harvest use on citrus and pineapples. Gibberellic acid does not appear elsewhere on the National List but it was reviewed by the NOSB previously in consideration of its use on, in crop production. To assist this review, the Handling Subcommittee did request the development of a new technical report. That technical report was developed and provided

to the Handling Committee. So there is actually two hand, two pieces of technical information available: the new technical report, which addresses the handling criteria, and there was an old Technical Advisory Panel report that was completed in 1996 during the NOSB's initial review of the substance for crop use. The Handling Subcommittee was able to evaluate the substance according to the criteria under OFPA and the NOP regulations and come up with a proposal. So the proposal, the technical reports, and the petition and petition amendment were all available and posted on the NOP website in advance of the opening of the public comment period for this meeting. For public comment, written public comment was received on this substance. The petitioner, I believe, is also signed up for in-person public comment. For the vote on this substance, generally, for Handling Committee, for handling materials, the Committee would vote on the classification of the substance, that... This substance has been previously classified as non-synthetic during the initial review. I do not know that is needed, but the listing motion will be needed to determine whether it will be included on the National List. That is all I have. Thanks.

John Foster: Thank you, Lisa. Zea, you were point person in this. Would you take it from here?

Zea Sonnabend: Yes. A material I am quite familiar with. So gibberellic acid is pretty well accepted in crops and is non-synthetic. It is derived from a micro-organism fungus and the review of this posed some, a few interesting issues. First of all, it is for post-harvest use which is not a specific section of the National List. And then second of all, it is a, because it is proposed to harvest use, the not, the criteria in the Handling Checklist were not all exactly relevant to the same thing as an ingredient that appears in final food.

So we had some concern on the Handling Committee that while the TR was as complete as it could be, we were not getting all the information that we needed to make a decision on this. So, reading from [our recommendation: Two issues of concern to the Handling Committee](#) that we are seeking public comment on. The first is whether there are cultural practices that would serve the same function in bananas to reduce the disease pressure after harvest; and the second is the effect of post-harvest treatment on the nutritional content of the fruit. For this reason, it is being recommended for bananas, where the nutritional profile is, remains the same, and not recommended for other uses. There was information in the TR that pointed to a decline in nutrition from its use on citrus but not from use on bananas and we were hoping that other information would come in on that subject, which it did not. However, some information did come on cultural practices.

We recognize in doing this review that there is a flaw in the Handling Checklist and also therefore the TR points that the, the contractor has to address because there is no question addressing whether growing practices could reduce or eliminate the need for this material. So we would like whoever deals with a checklist in the future on these issues to take a look at that subject.

So as far as the public comments go, we received relatively little public comment, especially from growers. We received only eight comments and since they are so few and they raise all valid points, I am going to address them indi-, each of them. The comments

Comment [JMS13]: 03:00:00

were from Valent BioSciences, Organically Grown Company, OTA, Wolf, DiMatteo and Associates, OMRI, Beyond Pesticides, Cornucopia, and NOC. Both OTA and OMRI pointed out an oversight on my part which is that inerts were not on the Handling list either, and gibberellic acid is already form, always formulated with inerts. And therefore, they each gave suggested wording for inerts. And we concur with this and when we go to make the motion a little later, we will add, we liked OMRI's inerts wording better, which is up there on the board. Gibberellic acid for post-harvest, for post-harvest banana use only may only be formulated with 2004 EPA list 4 inert ingredients. Much as I hate to put List 4 on the list another time, but it is inevitable for this.

Okay. So, OTA, OMRI, and Wolf, DiMatteo and Associates asked the NOSB and NOP to consider the ramifications of adding post-harvest materials to 205.605 and whether that would mean that all other post-harvest materials have to be petitioned. We do share this concern and would like the department to comment on their view on this subject. Miles: your view on the subject of petitioning for all post-harvest materials?

Miles McEvoy: I am sorry. I was talking to Lisa. Can you repeat the question?

Zea Sonnabend: Okay. The concern from the commenters about whether all post-harvest materials, especially non-synthetics, would have to be petitioned for inclusion on to 6, 205.605.

Miles McEvoy: Yeah, the Program is looking at guidance for post-harvest materials. If you look at the National List, there are post-harvest materials that are on 601 and others that are on 605. So it is somewhat of a confusing area that is ripe for clarification. I would say that the article in the Organic Processing Magazine, from I think it was January issue, it kind of explains a lot of the dilemmas around post-harvest materials. That article characterizes the current situation very well and we are in the process of writing that draft guidance and will have that out for public comment later, later.

Crowd: [Laughs].

Miles McEvoy: I would say later this year, but Melissa will kill me.

Melissa Bailey: Yeah.

Crowd: [Laughs].

Zea Sonnabend: Okay. Thank you. Okay. Back to public comments.

Cornucopia urges rejecting this because it is a preservative. We reject this argument because it is not a preservative. Beyond Pesticides wants it rejected because of the purification methods of the gibb with solvents. And also they do not see it as necessary for production. We reject the solvent issue until a full classification policy is adopted. We will talk more about necessary in a minute. Valent provided testimony that post-harvest pitting is a citrus peel disorder that is characterized by the physiological breakdown of oil

glands and is caused by high temperature storage waxed fruit. This is for citrus now. Pitting can be controlled by low temperature storage, less than 10 degrees centigrade, or application of waxes with high gas permeability. However, refrigeration is costly and often difficult to implement, while wax with higher gas permeabilities have gloss values that are considered to be insufficient for consumer acceptance. Adding gibb to approved waxes has been seen to be beneficial to post-harvest storage. We find that argument a little odd because suggesting that refrigeration is a good alternative, means refrigeration is a good alternative, and so why would we need the material then?

OGC and NOC both supported the cultural practices idea and OGC was the only one who gave direct information about this. They actually did a survey of their banana growers and they distribute 6 million pounds of bananas, primarily grown in Mexico with some grown by Ecuador and Peru, they also handled 725,000 pounds of pineapples from Mexico, Costa Rica, and Hawaii, and 8.5 million pounds of citrus fruit from the US and Mexico. When they surveyed their growers of all of these fruits, they found none of them had the need or desire to use post-harvest applications of gibberellic acid to support post-harvest. They learned from the field managers that the on farm use of cultural practices, such as attention to soil fertility and removal of infected plant material, combined is the best approach for controlling Black Sigatoka disease, which is a prevalent disease in bananas. They found that using cultural practices reduced the pressure of the disease on the fruit and the trees and therefore provided acceptable control of the disease later during shipping. They stated that the careful attention to soil fertility and field sanitation also improves the long-term health and rigor of their production systems.

We would like to commend OGC for providing public comment on what we asked for. It is compelling to us that cultural practices can be effective in controlling the disease that would cause bananas to break down in shipping. We wish we had received more input from other areas of the world where bananas are grown so that we can be sure these practices are used everywhere. Thank you.

John Foster: Thank you, Zea. Questions from the group? Colehour.

Colehour Bondera: Thank you, Zea, for what you presented. And I, I, yeah, I have, I guess I have a clarification question and I will put my cards on the table. I do grow bananas and I do not export them and I do not try to figure out how to preserve them either. But nonetheless, I think that this final part of your presentation sort of struck a chord with me and maps with my question which is: The concept here is essentially to seek uniform ripening, it seems like. And my question is, up until now, what have the bana-, the organic banana producers, and I will admit it you know all of the imported bananas, I grew-up on a farm in Oregon, people eat bananas all the time in temperate climates, they are exported all over the world, there has been organic bananas, not just for a few days or weeks or months or years, but forever and they have been exporting them successfully and functionally without this being included in the organic list so I guess that is my question, have not we successfully been transporting organic bananas for many decades without the use of this partic-, I understand there is a petition on this question so we have to answer it. But I just, it seem like we are already doing it successfully without this and I

think you gave some exam-, or the, the commenter gave some methodologies that people manage that it is unnecessary so I am wondering about the conclusion of recommending that we, you know, want to support it is confusing to me.

Zea Sonnabend: Well, keep in mind, we made the recommendation before we received the public comment so the recommendation is on the floor, but we have received public comment now. The question that you asked is the key question, but we do not have an answer, I do not think all of us, but we might want to direct that question to people who do give public comments on that topic.

John Foster: Calvin.

Calvin Walker: What was, what was the sample size from OGC? And what areas did they take that from?

Unknown Female: Six million pounds.

Calvin Walker: Six million pounds?

Zea Sonnabend: Okay. They had 6 million, six million pounds of bananas primarily grown in Mexico supplemented by fruit grown in Ecuador and Peru. And someone from the, will be giving public comment on behalf of that organization. Question?

John Foster: Jay.

Jay Feldman: Thanks, Zea. I am glad we are going to listen and hear from those who have experience on the essentiality of this because I appreciate your question, Colehour. I think it gets to the root of obviously a key issue that, that goes to our review process. So, here is where I think we need to come at this from and that is where we have data that shows the lack of essentiality. I would think it was the burden of the petitioner to show us essentiality. In other words, we would always like to have more information. Obviously, that is a challenge. But in a situation like this where a producer/distributor has information for us and we do not have any countervailing information, I think the burden is on the petitioner to show that, in fact, there is essentiality and, you know, – [cough] excuse me – and this does [cough], this does raise the issue of how do we get this essentiality information at the front-end of our review process. I know it is a difficult thing to get, but I would hope we would have a bet, a mechanism to do that.

Zea Sonnabend: Yes, it is lacking in many technical reviews. You do have to keep in mind, six million pounds is probably less than Whole Foods alone sells in a year. I mean that is a drop in the bucket of the amount of bananas that happens. So we have only heard from a small segment of the industry and maybe there are some other commenters here today. We will see.

Jay Feldman: Yeah. The other question I had is around the alternatives. Could you, I did not quite catch your comment on refrigeration. Is, are you saying that is not a – and then I

have one other question about the solvents – but are you, are you saying refrigeration is not practical or...?

Zea Sonnabend: Well, bananas cannot be refrigerated, no.

Jay Feldman: Oh, that is true.

Zea Sonnabend: But for citrus, that was for citrus and citrus can be refrigerated.

Jay Feldman: Okay. Thank you. On the solvent issue, the way I understand things stand now, we have the authorities aboard to address the solvent issue when we are reviewing a material. We have done that, obviously we did that with the annotation on hexane. Do you know what the solvents are and could we annotate around solvents that we find to be problematic?

Zea Sonnabend: I suppose theoretically you could, but I do not doubt if you have enough votes to do that right now when the classification of materials policy is yet to come out to clarify the solvent issue.

Jay Feldman: Okay. Well my point is we have been doing solvent annotation. Not just us, but previous Boards. So I think it is appropriate for the Committee in doing its review to ask the question about solvents and at least bring that forward as a possibility for annotation. The other issue I think you know inerts, no one is surprised to hear me raise the issue of inerts, right? You know the Crops Committee has put on hold a lot of proposals for inerts in List 4, pending the completion of the policy. I, it is, I feel a little uncomfortable having kept those petitions on hold and allowing something like this to, to move through. So, yeah, those petitions were for individual inerts, I understand that. But you know in this case, where we have a policy pending analogous to the issue on solvents, which I am not sure I buy, but where we have a policy pending like this we, we need some consistency and the Crops Committee has chosen not to add List 4 inerts pending a policy and I would hope we could do that across the Board. But is the problem here that this simply cannot be used without the inerts, is that correct?

Comment [JMS14]: 03:15:00

Zea Sonnabend: Yes, all formulations of gibb on the market contain inerts. We already have an inerts policy for crops and this is consistent with that inerts policy that we currently have. It will be switched when we have a different inerts policy if this passes.

John Foster: Thank you. Other questions? Other voices? Alright, thank you. Moving on to inositol. So I started on that. So two things here. One, the public comment for inositol mirrored pretty closely that for choline. And Zea did such a great job of encapsulating that and I conveniently noted that choline was ahead of inositol.

Sorry. Question? Oh! I am sorry, I went out of order. Lisa, would you please introduce inositol?

Lisa Brines: Absolutely. Yes, the next substance under consideration is inositol. There was a petition submitted in July of 2011 by the International Formula Council and it is requesting inclusion of inositol at Section 205.605 of the National List as an ingredient to be used for nutrient fortification of infant formula. In support of its review, the Handling Subcommittee received a third-party technical report which addresses the criteria under OFPA. In their consideration of the petition and the technical report, the Handling Subcommittee was able to evaluate the substance and come up with a proposal. Both the proposal, the petition, and the technical report were posted on the NOP website and available to the public in advance of the opening of the public comment period for this meeting. Written public comment, as John said, was received on this substance. And the petitioner is signed up for in-person public comment. And for this petition, the Committee will need to take two votes, first for the classification of the substance and a second vote for listing. Thanks.

John Foster: Thank you, Lisa. My, again, my apologies for going out of order. I was just so excited. So, yes, fortunately for me, Zea did a, a great job of, of covering public comment and, and almost word for word, the comments for inositol were, were the same as choline. A slight difference in, in that for choline there is some, some documented deficiencies in some population subgroups that has not been documented for inositol as far as we could find. In general, I, in public comment we were roughly four to one in favor, although that was a, a qualified in favor similar to choline that infant formula was, was fairly well uniform, there was some dissent but, but for the most part pretty good consensus from comment that it should go into organic, should be allowed in organic infant formula but also the same concern over the "made with organic" claim as Zea described with choline. Actually that is, that is, it is very similar that all the comment, all of the discussion was almost mirrored, like I said, word for word on, on this. So I am going to, in the interest of saving a little time, we are going to [inaudible]. Yeah.

Zea Sonnabend: One, one teeny difference, though. I think, I did not do a literature or an Internet search of which foods are high in choline on their own. It may not be the same list of foods, I mean high in inositol, same foods might not be high in inositol as are high in choline.

John Foster: The, some of the same foods are. Not, it is not exactly a mirror but it is close, including that of breast milk and all the things you spoke to in that, in that case. The other little significant difference I forgot to mention was that choline is considered essential by, by groups and, and inositol is not. So, Jay, did I see you had your hand up?

Jay Feldman: Yeah, I guess this pertains to inositol and the one you were talking about, choline. Are there non-synthetic? Well, you mentioned that, that choline was not, did you say it was non-synthetic?

Zea Sonnabend: When, when it occurs in food, it is non-synthetic.

Jay Feldman: Right.

Zea Sonnabend: But the petition things are synthetic.

Jay Feldman: Okay. So were there no non-synthetic forms of choline that could be added to...?

Zea Sonnabend: There are foods. [inaudible]

Jay Feldman: No, I know, but are there, was there a finding of ...

Zea Sonnabend: To my knowledge, there is no choline extracted from food that is used as a supplement.

Jay Feldman: Right. And in terms of the FDA requirement is, does that pertain? My understanding was that pertained to non-milk products as opposed to milk products in terms of the, you know, the FDA allowances and the FDA finding. Do I have that right or is there...?

Unknown Female: Yes, [inaudible].

Jay Feldman: So we are talking about allowing this in milk products, right? Why the distinction there? What...?

Zea Sonnabend: I did not say that, but ...

Jay Feldman: Oh, I am sorry.

Zea Sonnabend: Although it is not required in milk-based products, cow and sheep and whatever milk is still lower than human breast milk in choline and we felt that it would be worthwhile to fortify for people who cannot choose their own foods and also to make, it is much easier to understand if all infant formula is allowed to have it in it than only...

Jay Feldman: Right, I mean, I heard that. I am just, my question, maybe I was not clear enough. Why would you, why would we distinguish ourselves from what FDA requires? What, what is the basis for that?

Zea Sonnabend: What I just said is the, our reasoning for [inaudible].

Jay Feldman: So just because we believe in sup, supplementation or...? That goes beyond what the FDA thinks is necessary.

Zea Sonnabend: For that case, particular case.

Jay Feldman: And is there science to support that? I mean, where, what are we citing?

Zea Sonnabend: There is, there is science to support that there is not enough choline in milk compared to human milk and that you cannot, there was one suggestion that you just put more lecithin in.



Jay Feldman: Right.

Zea Sonnabend: There is well-established research that you cannot put enough lecithin in to make up the difference. Just technically you cannot.

Jay Feldman: See this, you know, this is the road that people were worried about when we heard testimony on DHA that we are, we are going down this road of supplementation in organic that goes well beyond what the FDA has deemed is required and necessary. And I understand people may want these things in their diets but I think as a organic community we have to, we have to have a little more before we just putting, just start putting all these things in as supplementation. I realize that is a personal opinion but I think at least we should have clear documentation on the science that really says to our Board, this is why we disagree or believe that the FDA standard is not sufficient and therefore we are allowing this additional supplementation that the, the agency itself does not deem necessary.

Zea Sonnabend: What would you like beyond the research paper that says you cannot add lecithin and the amount of choline in milk? I can provide you with those figures.

Jay Feldman: I, I get a lot of good information when I shop at Whole Foods or other, you know, Safeway or my local Co-op about things I can do with cooking and diet and so forth, where I can get other sources of these nutrients and that is where I think all lot of people, you know, what I am hearing is a lot of people in the organic community believe we should be at as a community. We should not be putting all these synthetics into our food to supplement what we can get through other means in this very same store which we shop.

Zea Sonnabend: But that, that is our whole point. You can choose what you eat. A baby cannot choose what it eats.

Jay Feldman: Yep. The, hopefully, the parents can be educated. I mean that is the whole point here.

Zea Sonnabend: A parent cannot go to Whole Foods and choose like different foods for an infant. It is either breast milk or formula.

Jay Feldman: Well, then I will ask the same question Colehour asked in a different context. Is there an identified deficiency that the FDA has identified that would put this on a list of required supplementation for meeting nutrient needs of, of infant development? And I just do not see that anywhere. I just, I need to see that to be able to support something like this.

John Foster: Alright. I have got Colehour, then Jean.

Colehour Bondera: I, I guess my question, and I apologize I that did not do it when we were talking about choline, I, I was not thinking fast enough. But it, it applies to these, them both and it is actually more of a logistical question of layout. And I think that Zea might have just alluded to the response but it is still a little bit unclear to me. The way that these are presented as two separate listing motions and one of them is specifically the infant formula component and says “labeled organic” or “made with organic”. And then that, that is the first listing motion in both cases. And then the second listing motion – and now I have to go back and forth – but in both cases is agricultural products other than infant formulas and then just labeled “made with organics”. And I get concerned and confused that we are going to, and I am not saying this is your goal or point, but mislead the parents of infants, that those things are organic because they are for infants but the same exact thing, if it is for an adult, we are not going to call it organic, we are going to say “made with organic”. And I just do not get the, the exact rationale as to why, when we are talking about the same exact things, but all we are differentiating is adult versus infant, and it is required for the infants therefore we are going to call it organic but it is not required for the adults therefore we will just say “made with organic”. That is how I am reading these differentials and it is confusing to me and I would like to hear a little bit more as to the rationale I think.

Zea Sonnabend: The rationale was there in our summary of, of our recommendation. It is so you have a choice to vote for one motion and not the other if you feel that you would like to comply with the FDA requirements for infant formula but you do not think it belongs in adult food at all. You can vote yes on one and no on the other. If the motion for infant formula fails, you could put in a substitute motion for just non-milk-based infant formula, for instance, to separate it out even more. But we believe to put, we decided to put forward the choice of the “made with” for adult food in case it, people on the Board thought it was a good idea that such foods could highlight the fact they are fortified but at the same time, and contain some organic ingredients, but at the same time limit the number of non-essential synthetics in organic processing. So, you know, vote yes for one and no for the other, or vote no for both of them, but we, we thought it, they were different enough issues, they should be two different motions.

John Foster: Thank you. Jean?

Jean Richardson: When I look at the inositol, it, it appears that there is a non-synthetic form that could be used in place of a synthetic form when I read the, your, the, the wording in the, in the document. Should I address this to John or Zea? Sorry, but this is on inositol. But the, where going... We would be voting to support synthetic addition, synthetic version of inositol into the infant formula because it is more commercially available than the non-synthetic. And so I would like some clarification on that, you know, because I sort of hate to see us putting in a synthetic into a, you know, into infant formula with, when we could, in fact, be encouraging the use of a non-synthetic. I understand the commercial issue but I wonder if you would address that on your Committee?

John Foster: We did. And if the phrasing in the, in the proposal is confusing, I apologize. That was my fault. The, the idea, what I was trying to convey, was that while inositol is a non-

synthetic originally in all of the sources we were talking about ahead of time, the sources that are available for this kind of supplementation are synthetic.

Jean Richardson: And are there no non-synthetic versions of it that could be used in infant formula?

John Foster: Similar to choline – Zea, correct me if I am wrong – well, “none” is, I do not know. I, I try to stay away from “always” and “never”, but they were, they were not in a, they did not appear to be commercially available such that they would be useful to the, to manufacturers. That was my, that is what I could find anyway. Zea, was that the same for choline?

Zea Sonnabend: [inaudible] I do not remember what the inositol TR said. I am looking for it now, but a lot has come and gone since I looked at that TR.

John Foster: Okay. While Zea is looking at that, are there other questions?

Unknown Male: [Inaudible]

John Foster: Jay?

Jay Feldman: Did you guys look at the extraction issues again here? Did that come up at all?

John Foster: For both, both you mean?

Jay Feldman: Both are the same extractant?

Zea Sonnabend: They are not extracted. They are just totally chemically synthesized.

Jay Feldman: Okay.

Zea Sonnabend: Well, I do not know about inositol once again I [inaudible]. Choline is just totally chemically synthesized.

John Foster: Tracy.

Tracy Favre: Yeah, according to the TR it says inositol is not available; non-synthetic production methods are not available for use on commercial scale.

John Foster: Thank you, Tracy.

Comment [JMS15]: 03:30:00

Zea Sonnabend: And we will look at the extraction method too while we are at it.

John Foster: Alright, I am feeling like I want to kind of wrap up inositol. Is it alright if we get back on the extraction after? Is that alright, Jay? Okay. Alright, moving along to citrus

hystrix. Here is another one where, oh, I am sorry. God dang it. Lisa, would you be so kind?

Lisa Brines: We will get his down by the end I think.

John Foster: Thank you.

Lisa Brines: So the next substance under consideration is citrus hystrix, also known by its common name Kaffir Lime leaves and fruit. Petition was submitted in August of 2011 for inclusion of citrus hystrix into section 205.606 of the National List as a non-organically produced agricultural product allowed as an ingredient in or on processed products labeled as organic. The petition was submitted by the company Curry Love Incorporated, which is the same petitioner that submitted the petition cur, for curry leaf which is under consideration at the meeting as well. The Handling Subcommittee did not request a technical report for this petitioned substance, but using the petition they were able to complete its evaluation according to the criteria under OFPA and the NOP regulations, and have issued a proposal. Both the proposal and the petition were posted on the NOP website and available to the public in advance of the public comment period opening for this meeting. Public comment has been received on this substance and the Board will need to take two votes, the first a classification decision and second a listing motion. Thanks.

John Foster: Thank you, Lisa. So you, you will notice on the, the prior 606 addition, I did not talk about public comment because I will do that all one, all as one now. The comments for curry leaves and the comments for citrus his-, hystrix are, are lock-step together. Petitions, petitioner was the same. The lack of at least readily available market data was the same, the essentiality, leading to the essentiality question. The importation had similar concerns. The, in general, public comment was in favor of it. There was an, an articulate question I think in, in one public comment about the essentiality, which I, I imagine we will get to it in discussion when, when that time comes, same as, same as for the curry leaves. Again, we did not ask for the TR based on its at least apparent non-synthetic status to us. And I, actually everything else is the same. We had a handful, not many, not many comments. We did the same kind of literature review on, on availability, found the similar findings. Questions? Jay.

Jay Feldman: I just want to raise an issue that came up while we were looking at this which, which I had not thought about before but, because of the importation issue here and quarantines that are in effect by APHIS and the use of materials that we would not like in terms of fumigation and that, that sort of thing. I just raise it because it raises an issue of production and it raises an issue outside the scope of the Program but gets to more sensitivity on the part of APHIS to identify alternative fumigation or quarantine procedures that are more in alignment with organic. And we have seen this historically happen with mangoes, for instance. I mentioned this previous Board meeting where they went from, you know, ethylene dibromide fumigation to hot water dip. And to the extent that we as a Board can encourage quarantine practices that are not heavily relying on

toxic chemicals, especially when we are allowing those crops to be used as ingredients. You know what I am saying? That would be really helpful down the road.

John Foster: That is a good thought. I, I do not know if it is going to make it to the, the top of the list of research priorities but that certainly, it sounds like that would be an appropriate way to look at it. It also sounds like a good maybe master's thesis for somebody out there. Colehour, question?

Colehour Bondera: Yeah, I, I guess I am not intending to add to what Jay said, but you know both of these items, Kaffir Lime leaves and curry leaves, grow quite prolifically and easily in Hawaii. I am not aware of anyone who is producing them commercially. I do at my farmer's market sell Kaffir Lime leaves all of the time to customers. So I, I think that, you know, I am not familiar with the, you know, USDA rules and processes on importation and transportation of those within the United States and Hawaii, to, you know, I am not familiar with those. But I think that the issues that Jay raised are the critical issues because it is not as if these things could not be readily produced at an organic scale without any difficulty.

John Foster: Sounds like you need to get planting. Jennifer?

Jennifer Taylor: [Inaudible] I would like to add that the Kaffir Lime is, the farmers grow it in Florida and it is grown and they sell it in the market as an organically grown citrus. So there, there is a possible market for it.

John Foster: So, those did not come up on, if – I do not know how to say this – so if they are being represented as organic, they are not readily coming up on any of the searches I could find. So, may want to look into that. But also, this, you know, this, prior Boards before us have, have noted that 606, I think Joe Smiley was probably the, the biggest, the speaker to this most often, was that this should be the list of, of products that growers ought to get involved with and that, that was part of the intent behind having a list and I think it, it still could be a very positive way to, to get more ground in organic production. Zea, you had a question?

Zea Sonnabend: Yeah, I wanted to supplement what you just said last by saying that all of the commercial availability clauses are aimed at handlers trying to source commercially available organic ingredients but there is no backward line of communication for a grower to know what to plant that there might be a market for without putting something on this list. And this list would give notice that these are things that are being looked for in the industry. And while I have very ambivalent feelings and do not really feel qualified to assess the market on any 606 items, but I do feel that that is one real reason to consider some of these additions and keeping that in mind that this is a way for growers to know what there might be demand for.

John Foster: Other questions or discussion? Alright, I believe that is the last petition item on this time around. Moving on to Sunset determinations. Lisa, would you be so kind?

Lisa Brines: Yes, thanks, John. So the first Sunset material under consideration is agar-agar. It was originally reviewed by the NOSB in April of 1995 and added to the National List with an effective date November 3rd, 2003. We, it was renewed under a Sunset process in 2008 as well. So the current listing reads as follows, it is included at section 205.605 as a non-agricultural, non-organic substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic” specified ingredients or food groups. It is under (a) non-synthetics allowed as agar-agar without annotation. Its current Sunset date is November 3rd, 2013. In support of its review, the Handling Subcommittee did request additional technical information to assist in its review. So there is two pieces of technical information available. There was a new technical report that was developed in support of this Sunset review which is posted on the NOP website. And there was an also an old Technical Advisory Panel that was conducted in 1995. And both of those reports are available on the NOP website and were available in advance of the opening of the public comment period for this meeting. So the Committee was able to conclude its review against the criteria under OFPA and NOP regulations and issue a proposal. And that proposal was also available on the NOP website in advance of this meeting. In terms of public comment, public did have the opportunity to comment in advance of this meeting and in an addition to that, the Program had published an advance notice of proposed rulemaking in June of last year to announce the Sunset 2013 materials. And that NPR had a 60 day comment period as well. Thanks.

John Foster: Thank you, Lisa. Harold, I believe this was in your court. Would you be so kind?

Harold Austin: Thank you, John. The Handling Committee at this time would like to modify our recommendation based off of public comment. And that would be, the, our recommendation would be to relist it as previously stated without the modifications that we had submitted in February. So that we would be recommending to relist it under 205.605 non-agricultural, non-organic substances allowed as ingredients in or processed products labeled as “organic” or “made with organic” speci-, specified ingredients or food groups (a) non-synthetics allowed. Originally, why we had recommended making some changes and we were going to ask that it be listed based off of the TR and the, the extraction processes – we did look at those, Jay – and it, we looked at the TR information. It does, it did have a tendency to make us think that there was some modifications taking place to the product itself. But based off of the public comment, a lot of public comment was giving us some pretty good feedback that at this juncture, we should not recommend making a change until the draft guidance that was submitted to the NOP in 2009 becomes final and then we can use that. They felt that we would be setting precedents and the Committee agrees with that. So we are going to list, we, we are going to, we move to as a Committee or recommend it that we go ahead relist it as it originally was.

This is a, a seaweed-derived polysaccharide. It has been classified GRAS by the FDA since 1972. It is world, it is recognized around the world, originated, originally used in Japan in the 19-, 1650s, recognized by the FDA, CODEX, a commission of the European Union, the Canadian General Standards Board, IFOAM, as food safe. Its primary use is as a, a stabilizing agent, a gel, a gelling compound, used in bakery goods, used in

products such as yogurt, some dairy, some dairy goods. There are alternatives to this but based off of public comment, there are some unique characteristics with the product that is derived from agar that has a, a very high loop between cooling and heating so that especially in bakery goods, it makes it a, a very unique material that is not have another alternative to replace it with.

On the TR, well okay on public comment, on the ANPR, the advanced notice of proposed rulemaking that ended August 1st, 2011 there were several comments that were in favor of relisting it. There were none that were opposed. On our just recently ended public comment, there were a handful of comments that were in favor of relist, relisting, one opposed, primarily based off of the fact that there were other alternative materials out there that could be substituted. But based off of the additional public comment that we saw, that although there are alternatives, there are not alternatives that meet this specific need especially in the bakery goods and in, in some of the products like yogurt and stuff. So that is why I think we have looked at it and we have gone into our proposal of support to move it to relist it.

John Foster: Thank you, Harold. Question from the Board? Jay.

Jay Feldman: Thanks, Harold. I am wondering if you could just repeat, because I, I am not sure I followed what changes you were making to the original [inaudible].

Harold Austin: Okay, our original amendment, or our original recommendation, Jay, was to, we were going to propose, I will just read it to you. At this time, we would, we recommend that the relisting of agar-agar as it currently is listed on 205.605(a) as a non-synthetic allowed but based off of the information from the TR then we also recommended an additional listing of agar under (b) synthetics allowed. We have since retracted that and we are going to go back to the original recommendation of listing. So that we are going, we are going to strictly list it under 205.605(a) non-synthetic allowed. The one comment that I will put in there though is that we would also recommend that the listing be revise, revisited once the NOP has finalized a draft guidance for materials classifications. This would help to ensure that the materials have been properly classified and thus remove any further confusion from their status and help with future reviews.

Comment [JMS16]: 03:45:00

John Foster: [Inaudible] Oh, question?

Jay Feldman: Okay, can I follow-up to that?

John Foster: Follow-up.

Jay Feldman: Thank you. Okay. So basically the Handling Committee has decided that we are not going to follow the material classification policy as it was adopted by the Board, which we have been doing since the materials classification policy was adopt, excuse me, adopted. I guess that is how I am interpreting this because we have used and struggled with the definition of class, chemical change on a whole bunch of listings and what we are still going to have to do that under new petitions, and the way we have operated, as I

understand it, is to apply the policy that the Board adopts rather than waiting for the guidance to come out. We, we have done that on a whole series of material. So you are now, you are, you decided as a Committee I guess that we are going to wait on a policy. Is this just for Sunsets? Or it is...? How are we going to apply that thinking to petitions? What policy are we going to use for that?

John Foster: The other Committee members, please chime in if you want, but the thought was stick with the existing classification as it has been. And it has been what it is for a while and if I am remembering it wrong, please correct me, but and knowing we had clarification coming, it seemed to be consistent with wanting to keep things moving forward. There were not a whole lot of other concerns that, that told us this had to be changed right now.

Jay Feldman: Okay, so in terms...

John Foster: Hold on. Hold on.

Jay Feldman: This is Sunset.

John Foster: So that, so that we, we have faith that we are going to get that clarity. That is also why we added the portion of revisiting once that clarification comes, comes through. Other Committee members, am I, am I on or no?

Harold Austin: No, I think you are on, John. I think, Jay, one of the reasons why we opted to take and go back to the original recommendation of listing as it existed was that we, because we knew that the draft guidance was coming, we did not want to take and because I think you have, you have made the comment of the extraction process. And it is a very confusing, very complex scenario that takes place and it is up to indiv-, a lot of it is up to individual interpretation. And we did not want to set a precedence by stepping out of something that has already been reviewed, already been listed in a, in a specific position, and then all of a sudden in the twelfth hour we are changing it. We felt that we would wait until the draft guidance became, it became a rule and then look, look to that clarification if we needed to make any, any changes in the future. And that is why we added that last statement that in the future, once we had an official rule that was in place, then we would revisit, then possibly revisit it at that time.

Jay Feldman: Just one clarification. I, I will finish on this. So are we, does that mean we are going, you expect the Board would take this up at the point because we are issuing a five-year relisting. Would we take it up prior to that five-year relisting, or we would take it up again at the end of the five years' Sunset?

Harold Austin: You know I think that is really up to the Board to decide but I think it is, it is really when we see that, that final rule back to us, how that looks, and the verbiage that is in it, then we can to make that determination on it on a, at that time.



John Foster: That was our thinking. Also to not just, you know, look at this but all the other similar products, some of which are 605(a), some are 605(b), some are 606 and using that clarification to hopefully align all of those at the same time would be, would be the hope. And I think that, that serves, I think that serves everybody actually. Yeah, Zea did you want to, did you want to add anything? Okay. Jean, and then Mac.

Jean Richardson: Generally I do not have an issue with approving the agar-agar going forward. However, I, I would like to know if the Committee, since this is going to be for another five years, I would like to have some reassurances that the Committee looked at the extent to which this red seaweed is in anyway being over harvested. Because we know with other species, like in the Brown Laminaric Group, there is considerable overharvesting for other reasons. So did you look at that issue?

Harold Austin: We did look at that issue. From what we could see at this point that does not seem to be an issue but it is definitely something that needs to be, you know, for future needs to continue to be monitored. But there was nothing in the TR report or anything else that we, we researched to show that there was any negative effect on the biodiversity of, of the surrounding areas and beaches.

John Foster: Then I had Mac.

Mac Stone: When you all are evaluating this, investigating this, did it ever come up why is it “agar-agar” and not just “agar”?

Crowd: [Laughs].

Harold Austin: That one I cannot answer.

Jean Richardson: Actually it is agar-agar.

Crowd: [Laughs].

John Foster: Po-tay-to, po-tah-to.

Crowd: [Laughs].

John Foster: Any last questions, anybody? Alright. Thank you. Next on our list though is calcium sulfate, is another Sunset item. Lisa, would you be so kind?

Lisa Brines: Thanks, John. Yes, the next material under consideration is the Sunset listing for calcium sulfate. It was originally reviewed by the NOSB in September of 2000, I am sorry, September 1996 and there was a petition for this substance in November of 2000 as well. The substance was originally added to the National List effective November 4th, 2003 and was renewed under the Sunset process in 2008. The current listing is on section 205.605 as a non-agricultural, non-organic substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic” specified ingredients or

food groups. It is under (a) non-synthetics allowed and reads calcium sulfate, mined. The current Sunset date is November 3rd, 2013. In support of its review, there was not a new technical report developed for this review. The most recent technical report was from 2001, and that was available on the NOP website in advance of the opening of the public comment period. So in addition to the public comment period for this meeting, the substance was also included in the advanced notice of proposed rulemaking that was published in June of last year with a 60 day comment period. And as a, I guess, for this particular substance and for all Sunset substance, the Committee really just needs to make the one vote, the listing vote, since these materials have been previously classified unless changes are being considered. Thanks.

John Foster: Thank you, Lisa. Joe, I believe this was yours. Would you be so kind?

Joe Dickson: Thank you John. Calcium sulfate – let me just get my ducks in a row here – is currently listed on 605(a) as calcium sulfide, mined, which restricts the, the use to the mined form instead of the synthesized form. It is used primarily as a coagulant in tofu production and it has a long, well-documented history of use in that function. There are a few other documented uses in beer brewing and various baked goods for a couple of different reasons. From the commenters we heard from for this meeting, three organizations, Quality Assurance International, Wolf and DiMatteo, and the Soy Foods Association of North America, supported relisting noting its extensive use in tofu production. Beyond Pesticides proposed or they supported relisting with an additional restrictive annotation to read “for use only as a coagulant in bean curd, tofu and similar products”, basically, you know, restricting the use to tofu production only. The Handling Committee has not had an opportunity to consider that proposal but will before the vote is taken. My concern there, of course, would be that it, it may currently be in other uses that we did not hear about because the annotation was not in the published proposal. Those were the only public comments we received about this material. Any questions or discussion on that substance?

John Foster: Alright. Thank you, Joe. Next on the list, another po-tay-to/po-tah-to: carrageenan or carrageenan. I hesitate to say, let's call the whole thing off. But, but Lisa, would you be so kind.

Lisa Brines: Yeah. Thanks, John. I will use the hard “g”. Thanks.

John Foster: Alright.

Lisa Brines: So the next substance under consideration is carrageenan which was originally reviewed by the NOSB in April of 1995. It was added to the National List effective November 3rd, 2003 and renewed under the Sunset process in 2008. The current listing reads as follows. It is included at section 205.605 on the National List. It is a non-agricultural, non-organic substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic” specified ingredients or food groups. It is under (a) non-synthetics allowed and listed just as carrageenan without annotation. Current Sunset date is November 3rd, 2013. In terms of the technical information

available, the NOSB Subcommittee, Handling Subcommittee, had requested a new technical report in support of their review of this Sunset substance. So that technical report was developed and was posted on the NOP website in advance of the opening pot, opening of the public comment period for this meeting. In addition to this new report, there was an old Technical Advisory Panel report from 1995 which was also posted on the NOP website. So the Committee did it, was able to complete its evaluation of this Sunset substance and the proposal was again posted for public comment in advance of this meeting. There was a lot of public comment received on this substance in advance of this meeting. In addition to this public comment period, this substance was included in the advanced notice of proposed rulemaking that the Program published in June of 2011 and that had a 60 day comment period. Thanks.

John Foster: Thank you, Lisa. And Harold, I believe this was your material. And let me just preface this by saying, sometimes you eat the bear and sometimes, well, the bear eats you.

Harold Austin: You know and when John gave me this one, he told me this was really a simple deal.

Crowd: [Laughs]

Harold Austin: You know, it is a review, it is up for Sunset. You know, no problem. Yeah, right. Okay. Yeah, it is, we got a lot of comments, alright, to go with it though. Our original proposal, again, we have chosen, the Handling Committee has chosen to modify, partially because of the same rationale behind what we use in agar-agar waiting for the final draft, the draft guidance to become a guidance document to give us an idea of definition, definite how to handle some of the compounds and some of these issues when we are dealing especially with the areas of extraction. So our modifications would be, first, we would like to go back and recommend that we relist it under 205.605(a) non-synthetic allowed. Our posted recommendation was going to break that down into 605(a) non-synthetic allowed and (b) synthetic allowed. And we are going to retract that part of it.

The additions that we will make to try to take and help deal with some of the public comment, which was a lot, would be the verbiage that we have implemented into the original recommendation would be: after further review of public comment and committee discussion, the Handling Committee during its the May 9th, 2012 Handling Committee call has voted to make the following changes to the recommendation on carrageenan: To relist it as currently listed under 205.605 non-agricultural, non-organic substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic" specified ingredients or food groups, (a) non-synthetic allowed. We would recommend including the follow annotations because there has been some concerns raised as to the possible health risk from the use of carrageenan we feel that these risks can be addressed by allowing only the carrageenan with the following cast numbers to be permitted for use as food processing ingredients or additives. These cast numbers would be 9000-07-1 General, 9062-07-1 Iota, 1114-20-8 Kappa and 9064-57-7 Lambda.

To further address concerns that have been raised, we would also like to add the additional annotation that carrageenan not be allowed for use in infant formulas. Its use in foods for older infants older than six months and weaning foods for young children would be allowed.

Comment [JMS17]: 04:00:00

The rationale and reasoning behind the two annotations are as follows. While there are concerns raised regarding adverse health effects caused by the use of carrageenan in some studies, most scientific reports tend to agree that the cast numbers that we have mentioned are for, for use as food ingredients and have been approved as such by the FDA, while carrageenan listed under other cast numbers are not recommended for use in food production as ingredients or otherwise.

The reason for the second annotation regarding infants is based on concerns that have been raised by the EU Scientific Committee on, on Food, specifically that with the use of carrageenan in infant formulas for newborns. The SF, the SCF's concern is based on facts that the Pediatric Nutrition Handbook that, that explains that in newborn infants, the neonatal intestine is uniquely capable of ab-, absorbing macromolecules via endocytosis. This is the reason why it is recommended by pediatric-, pediatricians not to feed infants solid foods until they are four to six months old to help prevent food allergies, as printed in the Pediatric Nutrition Handbook. The SCF had no objections for the use for older infants or in weaning foods for young children. We feel that there are enough scientific discussions on this subject that by add, adding these two annotations to our recommendation that we address concerns, or at least the majority of the concerns raised during public comment.

Public comment was substantial, a lot of comments. You on the Board, the one thing that I would, I would make mention of, and I am sure that it is always there, is that there were a lot of percentage of those public comments that were kind of a canned response, looked like they were probably originated from one or two sources and, you know, sometimes people just do not have the ability to say the words that they think or what they mean, so they, I mean I, I think it is standard practice. But there were a lot that, that were a just simply a canned response. And then there were a lot of others that were from the heart that were individuals that making comments. A lot of the responses were raising health concerns, regarding this material, as a possible carcinogen, as material that has, would maybe cause some intestinal internal irritations and concerns. And I am going to let Zea address some the scientific stuff here in just a minute.

The one thing that I would mention that during the public, a lot of the public comments referred back to publications that have been done over the years that I believe the individual that drafted those documents is going to be one of our public speakers later on. So she will be able to enlighten us a little bit on that. Others have responded to point out that there are different forms of carrageenan that in a scientific community that have where there have been concerns raised. And I am going to let, I am going to fall back. There are two specific types of carrageenan. And I am going to let Zea go into the specifics on, on the differences between carra-, carrageenan and polygeenan.

Probably the other area that we had significant input from stakeholders from trade associations was that our propose to reclassify. And that was one of the main reasons why we chose not to do that at this time until we can wait until the draft guidance comes through. Public comment also, from stakeholders also, states that there is definite still a need within the industry for the continued use of carrageenan, beer production, whipping cream, chocolate pudding, chocolate milk, some characteristics that some of the other materials that are available as an alter-, alternative or a substitute, some of the properties that they do not have as a replacement or as an alt-, a substitute. This product has been deemed as food safe by the FDA, by Canada, by the Joint Evaluation Committee for Food Additives.

One of the things that we did see was raised a little bit also in public comment and it was mentioned a little bit in the TR was some concerns with the environmental impact, the harvesting. There are concerns as the uses continues to grow, that the extraction from the sea of the red seaweeds and algae may have some negative impact on the bi-, on the biodiversity of the, the existing area. But that is a complicated issue because there is other things being harvested at the same time that also impact that environment, that biodiversity. So, looking at the information we have, it is a concern that is out there but it is not one that we feel has been substantiated to a level that we would deem it has an impact at this juncture. But it is definitely worth noting and it is definitely continuing to monitor and look at in the future. That is all I have. Zea, you want to kick in on this one?

Zea Sonnabend: Yes, thank you, Harold. All right I want everyone to put their scientist hat on because in order to understand this material we really have to delve into the science. And I am sure we are going to have a lively discuss-, discussion on these issues this afternoon after we hear public comment. But in the way of framing that discussion, I am just going to read from a few scientific papers that address some of the basic points of carrageenan and then after we hear public comment, we can come back and discuss the merits of, of various points of view. Okay. These, these are the discussion topics that I am going to address somewhat in this, in this discussion. I am leaving alone the issues of alternatives and what happens in the marketplace and just focusing on the parts that are justifiable in the scientific literature at the moment.

And you know I do, while I have my virtual science hat on, I left my real science hat at home. I had a sci-, sci-, a hat made that said, Miss Information.

Crowd: [Laughs]

Zea Sonnabend: But I am not wearing it today so I hope to give you accurate information from the literature. Now one thing I found, I delved into the original literature beyond the public comment, the citations that were given and some citations that were not given, to look at what has been done on carrageenan. These, to boil this down for non-scientists, these are the basic questions that we should be asking ourselves as we hear the following discussion. What is the difference between un-degraded carrageenan and degraded carrageenan? What type of carrageenan is in food? Are there environmental issues from

the production of carrageenan? Does – and I started abbreviating after this, but – does it degrade in the human digestive tract? Does any form of it cause colitis or inflammation in humans? Does it cause cancer or tumors in humans? And whose research is believable and which research method, methods might be flawed? Can I have the next page?

These are the literature sources that I am using for the purpose of this particular discussion although I have read many, many, many more than this but I thought that these were good for starting off the discussion. The first three I will be reading from rather than stating my interpretation of them. And I apologize for those of you not scientists that this might be overwhelming and you might get sick of hearing about rat colons by the end of this, but that is what science is all about so.

Okay, from the first reference, which is JECFA, an FAO organization that reviews data on food ingredients. This is a review of toxicology literature pertaining to carrageenan and processed eu-, eu-, – I do not know how to say that – seaweed published from 1997 to 2006 by Doctor Samuel Cohen from Nebraska and Doctor Nobuki Ito from Japan. And these are excerpts. If I read the whole 69 page thing, I think everyone would be asleep by then end but these are excerpts.

Carrageenan has often been confused with polygeenan. Polygeenan involves a different manufacturing process. It utilizes carrageenan as the starting material which is exposed to intentional extensive acid hydrolysis at high temperatures over 80 degrees centigrade resulting in significantly smaller sulfated galactose polymers with an average molecular weight of approximately 15,000 daltons. Though of, of no toxicological significance, carrageenan contains a negligible amount of low molecular weight polymers. Depending on the analytical method used, the low molecular weight forms are less than 12% of the total composition of the commercial carrageenan used in foods. Because carrageenan is extracted from seaweed under alkaline conditions, degradation to smaller polymerized pal-, polysaccharides is avoided. As long as the pH is maintained above six, carrageenan is stable to heat processing. Once carrageenan is in the gel configuration as in the case for its use in food systems, the carrageenan becomes highly resistant to degradation even under more acidic conditions such as occur in the stomach. Carrageenan ingested in the gel form either as homogenous carrageenan gel or one consisting of a carrageenan protein gel from meat or dairy is also stable to the conditions of passage through the digestive tract – and a lot of citations are given. Based on these broad, basic properties of carrageenan, there are several obs-, observations which must be followed in any evaluation of literature regarding the pet-, potential safety of carrageenan from food. – And I might add these are basic properties I am about to read as what you also should pay attention to in listening to public comments. –

1. Carrageenan is a high molecular weight substance with well-defined specifications, a.k.a. purity criteria.
2. In its commercially utilized form, carrageenan is not degraded in the intestinal tract.
3. Carrageenan administered in food and beverages is not absorbed from the gastrointestinal tract.

4. Studies involving polygeenan, a low molecular weight substance historically referred to as degraded carrageenan, and which is produced by the acid hydrolysis of carrageenan, are not relevant to the biological or toxicological evaluation of carrageenan.

5. Experiments using systemic administration, subcutaneous, intra-peritoneal and intravenous, this means injection in general, are not relevant to biological or toxicological evaluation of orally administered calla-, carrageenan such as food.

In vitro studies evaluating carrageenan are not relevant to the biological or toxicological properties of orally administering carrageenan. The relationship between the molecular weight and concentration of the test material needs to be considered. The concentration in diet, especially in drinking water, can greatly affect the acceptability of the administered substance by the test animal as well as affecting availability of water and nutrition. In publishing a study of the scientific literature, it is essential to fully disclose the characteristics of each carrageenan being administered including the type and viscosity, the dose and form in which it is being administered, the route of administration, and evaluation of the specific bioassays being utilized to utilize, assess the biological or toxicological properties of carrageenan. A comparison to commercially utilize carrageenan and polygeenan should be provided. – And that is by each, in each study that you are looking or each commenter.

Okay, from the second reference, The European Commission. Opinion of the Scientific Committee on Food on Carrageenan. A recent publication from Uno *et al.* in 2001 re-examined 29 samples of food-grade carrageenan, showed that the average molecular weight of these samples ranged from 453,000 to 652,000 daltons. Polygeenan, which range from 20,000 to 30,000 dalton, was not detectable in any sample. While this study indicates that should any lower, lower molecular weight fraction be present in food-grade carrageenan, it would represent only a small proportion of the material. The Committee noted that the specification for carrageenan does not exclude the possible presence of lower molecular weight material.

Two studies in rats with known colon tumor initiators, either azoxymethane or N-methyl-N-nitrosourea or 1,2-dimethylhydrazine, showed that co-administration of carrageenan at 15% or 6% in the diet increased the incidence of colon tumors compared to animals treated with initiator alone – citation given. Study conducted to a classical design for detection of tumor promotion in which four weekly injections of the initiator dimethylhydrazine were followed by 32 weeks of feeding carrageenan at concentrations of zero, 1.25, 2.5, and 5.0 in the diet, did not find any increase in the incidence of tumors compared to animals treated with the initiator alone – citation given. The nominal 5% dietary level gave a calculated mean intake of carrageenan during the study period of 3230 milligrams per kilogram of body weight a day.

The Committee noted that this negative study was not included in the review by Tobacman – citation given. JECFA – which is the publisher of this monograph – review, an earlier review in 2002 pointed out that the two positive studies using higher dietary levels of carrageenan, while negative studies used lower dietary levels of carrageenan. The review further noted that since the carrageenan in the positive studies was fed, fed

Comment [JMS18]: 04:15:00

before, during, and after the administration of the tumor initiator, the enhanced carcinogenesis may have resulted from promotion but could not, also have resulted from altered toxico-kinetics or biotransformation of the carcinogen used as the initiator.

In the absence of any further information on the possible absorption of carrageenan by the immature gut of the very young infant, the Committee reaffirms its earlier view that it remains inadvisable to use carrageenan in infant formulas that are fed from birth, including in those categories of food for special medical purposes. The Committee has no objection to the use of carrageenan in foods for older adults, older infants, such as follow-on milks and weaning foods.

Okay, that is all from that reference. But you may be asking yourself if you paid attention, what the heck is the comparison between 5% dietary level, 1.25, 3.2 milligrams per kilogram? So, I could not find a concise place, although the document discusses this, I could not quote a concise thing so I have tabulated that for you from the document. Typical human intake is 30 to 50 milligrams per person per day. Studies are often done on 5 percent of body weight which gives a mean intake of 3230 milligrams per kilogram per day. For a 220-pound person, which is the easiest to calculate because a kilogram is 2.2 pounds, ...

Crowd: [Laughs]

Zea Sonnabend: ... this would be-, equivalent to 323 milligrams per person per day, which is in contrast to 30 to 50 average milligrams per kilogram today. These levels did not show adverse effects in these studies. However, these levels are well, well above average daily intake. The levels that did show adverse effects in the other studies were two to three times as much as this 323 milligrams per kilogram.

Okay, next, next reference and this is the last one I will read from. The Durham Research Online paper from Burges Watson in 2008. Public health and carrageenan regulations: a review and analysis. It is concluded that current assessment of risk associated with carrageenan have, in some contexts, failed to take into account the full spectrum of safety assessments that have been carried out and the maturing of food additive regulations thereby allowing a myth of risk to continue. The Scientific Committee of Food from the SCF recently endorsed a mess, a molecular weight distribution limit on carrageenan that is more restrictive than is the case in the US – citation given. At the same time, the SCF acknowledges there is no evidence that exposure to low molecular weight carrageenan from the use of food-grade carrageenan is occurring. Since 1969 scientific assessments of carrageenan included short-term and long-term generational studies, involved different dosages of degraded and non-degraded forms, and various animal studies including rabbits, rats, mice, rabbits, rhesus monkeys, squirrel monkeys, pigs, gerbils, baboons, hamsters, ferrets, chick embryos and dogs – citation given. All of these studies support the safety of carrageenan for use in foods. Regulatory authorities saw no reason to question the safety of carrageenan as long as the average molecular weight was 100,000 daltons or higher.



There is also the increased recognition of the potential value of carrageenan for antiviral, hypocholesterolaemic and hypoglycemic properties – citation given. If current rounds of research prove successful, carrageenan will play an important role, part in sexual health applications, such as microbicides for HIV, AIDS and use, and can reduce the risk of cervical cancers by inhibiting the human papilloma virus – citations given. This diversity of possible new uses for carrageenan across different regulatory settings provides a complex context for assessing health risks and benefits, but the positive nature of these applications will help the public and regulators to understand the potential health effects of different products.

Okay, I will have more to add on the other discussion points after the public comment period but I am sure we will get some divergent opinions from public commenters and I would like to hear them before we proceed. But are there any questions on what I have said so far? *[Inaudible]*

Calvin Walker: How would you summarize all you have said in scientific jargon? What would be your message from research *[inaudible]*?

Zea Sonnabend: My, I would rather wait for a complete summary until after we hear the public comment, but in general, what the researchers say, seem to be squabbling about the most, is that the research methods that find tumors and lesions and problems, the research methods with those are flawed and the research conducted with what the reviewers consider to be good scientific methods are the ones that are the more believable.

Jean.

Jean Richardson: My question does not directly relate to this, the technical science of it right now; relates more to the impact on the marine ecosystems and is this the right time to ask the question or not?

Zea Sonnabend: I think we should wait until after public comment on that, if you do not mind. Because I think some of our testifiers will have more information that we could get from them.

Harold Austin: Calvin, I think one point to, to follow up on what Zea had just said though, to, to clarify what her presentation was, that there has been a lot of, in the scientific community, there has been a lot of banter back and forth about, about what is, what was working, what you know as far as the scientific approach to it, because there are two very distinct materials that we are talking about, carrageenan and polygeenan, with very distinct, very specific molecular weights that are involved. Based off of what she had just said, this is, this was the scientific rationale why, why most of the international bodies have deemed this product as food safe. And so, and I think we will find more and hear more of this as the public comments begin.

Unknown Male: *[Whispering]* Barry, *[inaudible]* break for lunch and then do these two.

John Foster: Yeah.

Nick Maravell: Yes, this is not, not to follow up on your comments, but to Harold's. I will do this as delicately as possible here. I read many of the comments on carrageenan and many of them were coming off of a standard type of formula. But I did not find them any less heartfelt and I think you may have meant to say more that they were, they did not provide additional insight and further, further evidence. But I, I do want to see the comments that come from the field and people have different levels of expertise and, and knowledge and so I think we should characterize them all and assume them all as equal in their intent and heartfelt-ness. And I know that is not what you meant. But I just want to clarify that for the public that we, we do want to see all comments, big and small.

Harold Austin: Nick, thanks. And, and yeah, that was, if I came across that I was giving those any less credence, that was not my intent at all, I was just, just trying to make it, I guess to categorize that there were a, a couple of very distinct groups of comments and that, and that there were a lot of others. So that, yeah, it was I took nothing away from those comments. I just, I am new and that was my observation and I was just trying to put that forward.

John Foster: Nick. Okay, Jay.

Jay Feldman: Than you. Thanks, Zea, really appreciate that reading. I am going to send you studies to read to me and you can tape them and send them to my office.

Crowd: [Laughs].

Jay Feldman: So, I mean it is, it is a little difficult to absorb obviously as you are sitting here listening to it. But what I got out of some of the public comments was that distinct, distinction between high molecular and low molecular weight is somewhat of a false distinction because in effect, the, the food-grade, which I pres-, I understand to be the high molecular, is typically contaminated by the low-grade, which is the low molecular. I am sorry, the degraded, degraded carrageenan, which is a low molecular. And so, I guess my question is, did the studies that you are citing acknowledge that a high molecular was, was contaminated with low molecular, or food-grade was contaminated with degraded carrageenan? Did that come up in the studies?

Zea Sonnabend: Contaminated is the wrong word.

Jay Feldman: Okay.

Zea Sonnabend: But, yes, in some of what I read said it contains a certain percentage of lower molecular weight. But there is a big difference between 100,000 daltons and 10,000 daltons which are the typical weights. And one of the things I read that said, well, a hundred thousand daltons is the minimum for food-grade, it can go up between 400,000 and 600,000. So, they have no, they are arguing a lot and I did not even want to get into it because in the end it is not totally relevant. But they are fighting over the scientific

methods to measure how much degradation is occurred extensively. But there is a whole range of different degradation, say it is a hundred thousand and it degrades and it goes down to 80,000. That, they call that degraded because it is degrading somewhat but it is still 80,000. It, you know, there is no conclusive evidence that shows that it degrades all the way to 10,000, and that, therefore, it is in there at a level, that the extremely highly extracted polygeenan is in there. They cannot tell, you know, they just say it is degraded somewhat, well the degradation could be anywhere between any, you know, that whole range in between. So it is degraded, the adjective, how much does it degrade and degraded the noun, degraded carrageenan.

Jay Feldman: Thanks, Zea. Follow-up: Did the, did the studies look at the metab-, the metabolizing of the material in, in the test organism, or in?

Zea Sonnabend: Yeah.

Jay Feldman: Okay. So it is looking at another issue that I understand to be, to come into play here is that once this substance is ingested into the body it takes on a different form as well. So it is not just a question of what percentage of the food-grade contains a degraded form, but it is also a question of what happens to that material when it is metabolized in the body. And did these studies look at, look at that mechanism?

Zea Sonnabend: Carrageenan is extremely well studied. There are thousands of studies. So, yes, of course they have looked at it. But whether you, you know, what conclusions can be drawn from any individual study compared a whole group of studies, is somewhat subjective.

Jay Feldman: And then finally, John, this is it, in terms of tracking what, you know, sort of epidemiology on this, did you guys, you guys did not see, at least in the documents I saw, did not seem to recognize that there is a proportion of the population that is experiencing adverse effects. In fact, one of the, one of the submissions from a respected scientist indicated that he himself experienced reactions but was not aware of anything in the scientific literature that identified his problem to be widespread and yet I have seen other references to the, to the or I have seen other citations that indicate that there is a proportion of the public that suffers from an adverse reaction to this.

Comment [JMS19]: 04:30:00

Zea Sonnabend: I would like to get back to that point after lunch and after the public comment, because I do have something to add but it really was not part of the introductory material.

Harold Austin: Zea, and that I think there was another, actually another written submitted public comment that was from one of our original Board members that, that was part of the TAP that has an allerg-, an allergic reaction to carrageenan but he also recommended continuing forth in listing this material.

John Foster: Thanks, Harold. Last questions? Calvin.

Calvin Walker: How would you characterize the public comments? You mentioned that it was substantial. Would you say it was substantial for or against?

Harold Austin: I think from the individual comments coming in, it was definitely against listing. Quantifying that, part of it I think was based off of documentation that was presented that I think Zea is wanting to address maybe at a little bit later date, little later point in time after we have had some public testimony. There was a, a lot of stuff that was submitted also, Calvin, that was basing, and, and it goes back to this commentary that I made earlier about the, the back-and-forth within the scientific community about some of the studies that are being used to substantiate the, the negative impact of the carrageenan. And so I, I think as we go into public comments this afternoon, a lot of these types of questions, I hope for all of us will get clarified and cleaned up so we can, we can make a, a good honest vote on, on a true, a true feeling.

John Foster: Alright, thank you. I think, I have been, through an intermediary, communicating with the Barry on wanting to stick to our lunch schedule which I believe is right about now that would mean that we would come back to cover glucono delta-lactone and cellulose after lunch and then go straight into public comment. Barry, is that, is that alright with you?

Barry Flamm: Yes, I, I think we should take a break for lunch now, a one-hour lunch break, that would put us back here about 1:30.

[BREAK]

Barry Flamm: Take your chairs.

Unknown Male: Want some water, Barry?

Barry Flamm: Yeah. I got a glass. Thank you.

Unknown Male: This is a far cry from [inaudible].

Unknown Female: It sure is. But it is good.

Unknown Male: This is my next group here.

Barry Flamm: Do I still need to make your announcement?

Unknown Male: You can make it too, or I caught up with everybody so do not worry about it.

Barry Flamm: Okay, I will not worry about it if you caught everybody.

Unknown Male: Hey, Dave. David. [Inaudible]. So one thing we are noticing as people are discussing topics in between each other, they are facing away from the mikes. That makes it really hard [inaudible] to hear. Their words disappear. [Inaudible] So as you are

Comment [JMS20]: 04:32:30

Comment [JMS21]: 05:42:27

answering questions just try to be a little more [inaudible] somewhat in that direction and we will pick it up. Okay.

Barry Flamm: [Inaudible]. We are back in session. John, please continue a Handling Subcommittee comments.

John Foster: Thank you, Barry.

Barry Flamm: Sorry.

John Foster: Zea just handed me a, an announcement to make to make sure everyone realizes there is a reception tonight to join the New Mexico Department of Agriculture's Organic Program for a reception following a day of good work. Today, 5:30 to 7:00 o'clock in the courtyard of this here hotel. Is that? You need any more? Good. Good. I am going to write myself a note now to make sure to always call on Lisa first.

Moving back into the agenda, we have two, two more remaining materials then we will hopefully have a quick update on, on ancillary and other ingredients, then we will move to public comment. First of the remaining two materials are Sunset determinations for first one is glucono delta-lactone. Lisa, would you be so kind?

Comment [JMS22]: 05:45:00

Lisa Brines: Sure. Thanks, John. So, yes, the next Sunset material on the agenda is glucono delta-lactone. It was originally petitioned to the National List in March of 2002, reviewed by the Board in September of 2002, and added to the National List with an effective date of November 4th, 2003. It was previously renewed under the Sunset process in 2008. And it is currently listed on the National List with annotation under 205.605 non-agricultural, non-organic substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic" specified ingredients or food groups under (a) non-synthetics allowed. And the listing and annotation reads: Glucono delta-lactone production by the oxidation of d-glucose with bromine water is prohibited. Current Sunset date is November 3rd, 2013. There is not a new technical report that was developed for this round of Sunset. The most recent technical report was developed in 2002. The NOSB Handling Subcommittee was able to conduct its review according to the criteria in OFPA and NOP regulations. And both the petition, the 2002 Technical Report, and the NOS, the Handling Subcommittee's proposal were available to the public on the NOP website in advance of the opening of the public comment period for this meeting. In addition to the written public comment that was received in advance of this meeting, this substance was included within the advanced notice of proposed rulemaking that the NOP published in June of 2011, which had a 60 day comment period. Thanks.

John Foster: Thank you, Lisa. Joe, I believe you were point on this. Would you be so kind?

Joe Dickson: Thank you, John. Moving back into the world of tofu coagulants, GDL, as we call glucono delta-lactone, is also like calcium sulfate used as a coagulant in tofu production. It can be produced via two different methods, one of which renders it a synthetic material and is not allowed based on the current annotation, that would be the, its production using

oxidation by bromine water. The other, only other method of GDL production is the oxidation of gluconic acid with microorganisms or enzymes derived from microorganisms, and that does result in what the original NOSB and the, the TAP review determined to be a non-synthetic form of GDL. That is the form that is currently allowed under the listing on 605(a), which reads: glucono delta-lactone production by the oxidation of d-glucose with bromine water is prohibited. We received a number of public comments on this material. Three commenters, the Soy Foods Association of North America, QAI, and Wolf and DiMatteo, supported the relisting of this material. Beyond Pesticides also supported the relisting of this material but proposed a restrictive annotation that, rather than prohibiting the bromine water method, would positively require use of the other enzymatic method, and additionally read, and I will here, I will just read their proposed annotation: for use only as a coagulant in bean curd, tofu and similar products when produced by oxidation of the d-glucose by non-genetically modified, non-pathogenic, or non-pathogenic and non-toxicogenic microorganisms or by enzymes derived from these organisms; no volatile synthetic solvents may be used in the crystallization process. Those were the only public comments we received on that Sunset recommendation. There any questions or discussion from the Board? Alright. John.

John Foster: Alright then. Last of the materials for today are, is cellulose, also a Sunset determination. Lisa?

Lisa Brines: Thanks, John. Yeah, the National List addition for glucose was a result of a petition that was submitted in December of 2000. Cellulose was added to the National List effective November 4th, 2003 and renewed under the Sunset process in 2008. It is included in section 205.605 of the National List as a non-ag-, non-agricultural, non-organic substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic" specified ingredients or food groups. It appears under (b) synthetics allowed and is listed with the following annotation: cellulose for use in regenerative casings as an anti-caking agent, then in parentheses, non-chlorine bleached, and filter aid. The current Sunset date is November 3rd, 2013. There was not a new technical report that was commissioned for this Sunset review, but there is a, a Technical Advisory Panel report available from 2001. The Handling Subcommittee was able to review the substance according to the criteria under OFPA and the NOP regulations. And the commit, the Subcommittee's proposal, the 2001 Technical Report, and the original petition had been posted on the NOP website and were available to the public in advance of the opening of the public comment period for this meeting. In addition to the public comment received for this meeting notice, the substance was also included within the advanced notice of proposed rulemaking published in June of last year with a 60 day comment period. Thanks.

John Foster: Thank you, Lisa. And Joe, you lucky devil, I think this was your, your material also.

Joe Dickson: Why, yes it was. So, cellulose, as Lisa just said, is listed on 205.605(b) synthetics allowed with the listing: cellulose for use in regenerative casings as an anti-caking agent, non-chlorine bleached, and a filtering aid. Five commenters, Smuckers, QAI,

International Flavor Additives Council, White Wave Foods, and Wolf and DiMatteo, supported the relisting of this material, noting that there are no alternatives in several different applications. I in fact noted that, while the production of non-synthetic cellulose is theoretically possible, there are no commercially available products on the market at this time. Two commenters, and this got a little confusing, so Beyond Pesticides and Cornucopia both expressed very significant concerns about the use of microcrystalline cellulose, which is a highly processed form of cellulose that it is our understanding is not allowed under the current listing. It is also OMRI's position that microcrystalline cellulose is not allowed under the current listing and had some conversations with the Program about that. And I am wondering if Emily or Lisa, could you just give us a quick overview of your thinking on that question?

Emily Brown-Rosen: Okay. Sure on, cellulose was originally reviewed in 2001 by the NOSB and at that time, there, there was a TAP review, actually the same TAP review you, you are using this time and which went into detail about three different forms of cellulose and the three forms that were described were powdered cellulose, microcrystalline cellulose and cellulose used in regenerative casings. The TAP reviewers that were polled in that TAP, in the TAP review, none of them were in favor of the microcrystalline form and the NOSB discussed, it is in the transcripts, that there was no need for the microcrystalline form in inorganic production. There was some debate, but for whatever reason it did not specifically annotate cellulose as the powdered form but that was the form that they were, they discussed and they felt that the annotation of for only anti-caking agent, agents or filtering agent would limit that, that would not allow. Microcrystalline is not used for that purpose generally, or was not at the time, so they did not feel a need to specify at that time.

Joe Dickson: Great. Thank you. Yeah, so given that we think it is extremely unlikely that certifiers are allowing microcrystalline cellulose for that use but we will discuss the possibility of adding a clarifying annotation to, to double-check and ensure that that is the case. And that is really the summary of comments on that issue. The only, you know, complicated one was the sort of question of microcrystalline and whether it is, it is out there. Any questions or discussion? Jay.

Jay Feldman: Thanks. Just on the alternative side, you know we heard from a, the rice producer, the ribus product. Is, is there, does that have a similar function? Or do you know if there is an alternative that is possible to use as an anti-caking agent?

Joe Dickson: My understanding from the commenters is that there, there are applications where this is the only functional ingredient.

Jay Feldman: Yeah. Thanks.

John Foster: More questions? Alright. Ah, let us see. So could we, well I was going to have Zea to do a quick little description. Is she there and I just cannot see her? Well. Well, this is a predicament.

Unknown Male: Here she is.

John Foster: Right on cue, she is entering the, the room. No pressure, no pressure. Zea, we just wrapped up discussion on the cellulose and I was hoping you might give us the update on ancillary and/or other ingredients. Sorry to catch you off guard.

Zea Sonnabend: Okay. We realize that some people may be impatient because they were hoping to see a proposal already on the agenda for this meeting after it came out right before the last meeting. However, because there were many new Board members, a big workload and a complicated subject that we had to work with, we could not complete work on a proposal at this time and so we are putting it on the work plan for the next meeting. We have, I have decided to enlist the support of the Materials Working Group who has historically helped on issues of classification of materials. This Ad Hoc group is open to anybody who would like to join it. And we will be developing a proposal to help me inform my NOSB colleagues as we work on it in the Committee and we will have a proposal for the next meeting.

Oh, I should add, if anyone is, is interested in joining the Materials Working Group, you can talk to Kim Dietz in the back. Kim, wave. Okay, thank you.

John Foster: Thank you, Zea.

Jay Feldman: John, can I ask a question now?

John Foster: Sure, Jay.

Jay Feldman: Can you tell me, historically, what collaboration goes on between a working group and, the Materials Working Group and say the Committee that has jurisdiction over that issue? And, and how does that, how do you interface with, with the Board Committee?

Zea Sonnabend: In the past iteration of the group, there was at least one NOSB member and maybe two or three on the calls. And they hashed through the details, you know, of the very complicated subjects of what could hap, how do you make a materials decision, what are classification. And we, there tries to be a, a pretty broad base between, you know, certifiers, OMRI representatives, industry people, trade groups and public interest sector, who wish to join. But we are real wonky in talking about materials. And so then during the public comment periods at NOSB meetings, someone reports on the work of the group. In the past has been showing the decision tree for classification of materials, or sometimes it has been not just public comment but a scheduled presentation within the meeting. And then the NOSB Committee takes that under advisement and brings it forward like any other NOSB proposal. It is toe...

Jay Feldman: So is the process to bring that to the material of jurisdiction and then to the Board, or to the Board and then the Committee?



Zea Sonnabend: No, the commit. The Committee will work with the Materials Working Group. John and I will be, are on the Committee and I am the point person. So I will bring forward the Committee's work and we may call on them for a presentation at the next meeting or it may be public comment. And we will develop a recommendation from their work.

Jay Feldman: Okay but, but I am just trying to get the process down here. So that would have to go to, that would have to be on the work plan somewhere.

Zea Sonnabend: It is on the work plan.

Jay Feldman: Okay, of the Materials Committee? Okay.

Zea Sonnabend: No, of the Handling Committee.

Jay Feldman: Of the Handling Committee.

Zea Sonnabend: It was assigned to the Handling Committee. Mmm-hmm.

Jay Feldman: Okay. Okay. Thanks.

Mile McEvoy: Yeah, we need to think this through in terms of how that works with the Subcommittees and the public process and the FACA. Because you, you are basically forming a group, a voluntary group. So we, we need to talk about this process and how that works and aligns with the, the requirements under FACA.

Zea Sonnabend: Is it any different than me asking for advice from anyone at any point in time?

Miles McEvoy: Well, you are forming...

Zea Sonnabend: Including my job?

Miles McEvoy: You are forming a, it sounds like you are forming a group. Now we have some informal groups that have formed, as the Methionine Task Force and the, the Fire Blight Task Force, and there are independent groups that have assembled people together independently and are providing information on given topics. So now you are sort of trying to form a subcommittee of the Handling Committee.

Comment [JMS23]: 06:00:00

Zea Sonnabend: No. It is just a group of, that already existed and we are resurrecting it, of colleagues to give me input in developing a proposal.

Miles McEvoy: Okay.

Zea Sonnabend: It has no standing at all within the NOSB or NOP scheme of things. They are just helping me bring a proposal to the table.

Unknown Male: [Inaudible]

Miles McEvoy: So how does that relate to the NOSB?

Zea Sonnabend: What?

Miles McEvoy: How does that relay, how does that interface [inaudible]?

Zea Sonnabend: I will bring a proposal to the Material, to the Handling Committee and we will put it through the regular process. You know, the how a, how a Committee develops a proposal.

Miles McEvoy: I guess the question is how do you make this an open opportunity for folks that want to be involved to be involved?

Zea Sonnabend: It is open. Anyone can talk to Kim.

Miles McEvoy: Well, it is open in an announcement that you are making here at this meeting. There is a lot of people who are not on, at this meeting that might not hear you make that announcement. Who do they contact? So we have got to figure this out in terms of a procedural way so we make it open and transparent to everyone that has an interest in this particular topic. Because otherwise it is just that your, you are, you would be creating a select group of people that would, would be able to provide input.

Zea Sonnabend: There was no problem with Katrina doing it before. Has that changed?

Miles McEvoy: Yeah. It, the, the, it may have. Yeah.

Zea Sonnabend: Okay, well then you have to explain to me, you know, I, I thought I could ask anyone I wanted for advice in doing my job as an NOSB member.

Miles McEvoy: Yes, you can do that.

Zea Sonnabend: Okay.

Miles McEvoy: But what you are talking about is forming a group that is, if you are forming a group that is associated with the NOSB, then it has got to go through some kind of [inaudible].

Zea Sonnabend: The group is not associated with the NOSB.

Miles McEvoy: Okay. So then it is not part of this process then. You are just [inaudible].

Zea Sonnabend: Okay. Just forget I just said all that, and I will determine appropriate advice and ...

Crowd: [Laughs]

Miles McEvoy: But how about we work together to, to make sure that it is an open process that people can participate in and provide information to as they collaborate on this.

Zea Sonnabend: Okay. It is an open process, and this is very weirdly confusing to me, so we will have to talk off-line.

Miles McEvoy: Sounds good.

John Foster: I am, I am certain we can figure out how to make it work the way it needs to work. How about that? How is that?

Miles McEvoy: Yahoo.

John Foster: So, at this point, I would like to move into taking up public comment. I apologize, we are about an hour behind. So I am going to, I am going to guess that there is going to be a couple of subjects in here that are going to bring up a little more discussion, so in light of that, I will, I will, you know, try and divvy up the, the question time, post-comment, you know appropriately. I will do my best. But if there is any chance we can get back on, on track, I, I will try to do that. So with that, I have, I have the most recent, hot-off-the-presses list of public comment. I understand it is changing periodically but, I have got, I got one that is ten minutes old.

So, first up will be Luis Mon-, Mon-jay, Mon-gay, hard gee, soft gee. And then up on deck would be Maria Herrero.

Nice.

Luis Monge: Excuse me. It is okay. Hi. Wow. Good afternoon. My name is Luis Monge. A, I am the manager of Dole Fresh Fruit International, Organic Program. We grow and source organic bananas and pineapples in five different countries in Latin America since 1996. The organic program supplies more than 90,000 tons of fresh organic bananas to the US market every year. Our organic bananas are currently grown in Ecuador, Colombia, and Peru by more than 2000 micro, small, medium and large farmers. And I came here today to speak on their behalf.

Organic banana growers from South America fully support the Handling Committee recommendation to include the use of gibberellic acid on 205.605 for postharvest use of bananas. Gibberellic acid represents a very helpful tool for organic banana growers in order to reduce the volume of rejected fruit, especially during rainy season. I do not think, I think I do not need to tell you how difficult it is, it is to grow organic bananas, especially with extreme weather conditions the planet has been facing during the last years. And I need to say that I have changed the approach of this comment several times during the meeting. But at the end I realize that the more, the most important argument I can present to you at this time is the people. Yes, the people we handed delicious bananas

some of you, hopefully most of you have tasted in your life, and especially during the last two days. Organic, organic banana growers of Peru, Colombia, Ecuador are fighting against many different factors, including the most aggressive variation of *Mycosphaerella fijiensis*, which is the, the scientific name for Black Sigatoka. And the only way that they have to survive as organic growers is by maintaining their ability to sell the fruit into the organic market. Years of research have shown that the use of gibberellic acid postharvest on bananas allows farms to ship their fruit to the market with a much lower risk of early ripening and subsequent rejection of the fruit and the huge economical losses. On behalf of the more of 2000 organic banana farmers, their families, and their workers, I ask you to approve the petition to include gibberellic acid on 205.605. Thank you. That is it.

And then the footnotes, okay? Regarding the comment from Zea on the public comments, Dole organic banana growers have sent letters to the Handling Committee on this regards on March 2011, August 2011 to the NOP, and September 2011. Regarding the comment from the six million pounds of bananas produced in Mexico, I have to say is that this is equivalent to three containers a week and according to my numbers, it would be no higher than the 2 percent of the US market demand. Producers in Mexico are in a privileged situation since their transportation time to the US market is just 30 hours by truck compared to the 15 to 21 days by parcel that the organic bananas produced in South America require to arrive the US market. And I will be more than glad if you ask me the question on the Sigatoka thing. I can answer that.

John Foster: Thank you, Luis. Any questions? Colehour.

Colehour Bondera: Yes, thank you. Thank you, Luis. I guess I am going to ask my question pretty generally. But I, I understand the difference that you were mentioning related to transportation in terms of where the bananas are coming from but my question is, what were organic banana producers in these countries, if we are talking about Ecuador and Peru, or whatever specific countries, doing in the past in terms of controlling for Black Sigatoka in their bananas?

Luis Monge: Okay. First of all, we have not faced the extreme weather conditions that we are facing today. It has no precedent. For example, in La Guajira, Colombia, northern Colombia, in 2005 we opened a, a 450-hectares organic banana farm. At that time, with the recollection of the statistics and rainfall, we knew it for sure that that region receive less than 100 inches of rain a year. 2011, the same region receive 1000 inches of rain. That means that there is a big change in weather conditions. That, that is number one. But addressing directly your question, what have we done in the past? And this is the first claim that I received in my website, doleorganic.com. If you want to check it out, you can. A, the consumers are just yelling at me because it is not a, it is not fair, it is not on the same concept of organic that we grab organic bananas with plastic. We have done that because it is the only available alternative and it is very expensive by the way. That we can simulate a anaerobic condition to the crown of the fruit so we can in a, in a very ineffective, but it is only resource we have, to delay the early ripenings of the fruit. Just as a, as a comment I, I feel that this is important. Gibberellic acid is not intended to control Black Sigatoka. In fact it is very ineffective by controlling Black Sigatoka. What

we really need is to delay the natural message that, that the plant sends to the fruit, that it is something like, hey, I am dying, you have to ripe right away, we have to preserve the species, something like that. But we want to delay that message to the fruit so the fruit will survive that transportation time.

John Foster: Thank you, Luis. Another question? Zea.

Zea Sonnabend: The, the question that I do not think we have had answered, that I keep coming back to is there seem to be a lot of bananas in the store now. There does not seem to be a shortage of bananas and this is not approved yet. So what would you say about that point of view?

Luis Monge: Okay. I, I would have to disagree with that comment. I mean I have to go to four different supermarkets in Albuquerque to find the, the bananas that I brought to the meeting. And it is something that is just happening. And it is not only the US market that is growing, because it is growing, but we also have, I mean, the US market has the competition from Europe and the increasing demand in Asia. So this is, this is about to happen. What, why, what has or what is the reason why there is not a, a, or what is the reason why the markets still have enough bananas here is because we have been growing more land and we have been moving from the regions where the Sigatoka is a, is a major disease to a semi-deserted regions in, in the tropics. But that portion of land is limited. We cannot keep moving to an, another place. And the problem is not about the importers and the exporters because if I see this situation from the importers point of view or, or the exporters, we can change the suppliers. But the point is what happened with the growers? The growers have only their land they have. They cannot move their farm to another place. They have to live with it. And if they get without resources to face this situation, they will move into conventional production once again.

John Foster: Alright, thank you, Luis. We appreciate it. Carmella.

Carmella Beck: So, Luis, you said that there was 90,000 tons of, of bananas that you export to the US, is that correct?

Luis Monge: Yes, yes.

Carmella Beck: And so in pounds, what is that?

Luis Monge: Well, times 2.2 times 1000. Something like 90 million, something like that.

John Foster: One hundred and 80 million.

Luis Monge: Well it is like, I, I put it in, in containers, so you can make the compare with the, the value from the commenter, from the volume coming from Mexico. The volume coming from Mexico is only three containers a week and the volume that Dole is supplying the US market is 50 containers a week.

John Foster: Thanks. Jay, did you have something? I saw your hand up?

Jay Feldman: Yeah. We received a statement from Organically Grown Company. Do you know them?

Luis Monge: Yeah.

Jay Feldman: Yeah. And ...

Luis Monge: I read their comment, at least [inaudible].

Jay Feldman: You read their comment. So do you have a comment on their comment?

Luis Monge: Well, yes. All I can say is that they have a ground approach to the question because they, as their, their managers, the people in the fields, if they find a gibberellic acid as a useful tool to fight against Sigatoka and there is not why, that is not the question. I mean, even I do not use, or I cannot use a gibberellic acid to fight against Sigatoka because there is no control. There is no control. And Sigatoka does not affect the fruit after harvest. The problem is, and this is, this is something that needs to be explained is a banana plant produces one leaf a week. Alright, right? There is one new leaf on the plant every week. Once the fruit appears, the, a, the leaves, the production of leaf stops and all the energy of the plant goes to the development of the fruit. It means that if at the time of, of the appear of the fruit, you have eight, eleven or three leaves, that is all you have to develop and grow that fruit. If there are not enough leaves on the plant, the fruit is going to receive the natural message from the plant to the fruit saying, you have to ripe because we have to preserve the species. I mean, I am, I am dying. I, I do not have enough resources to make you grow. You have to ripe right away. And this is, this, this situation can be caused because of drought, floods, winds, but the, the main reason is the attack of fungus and the main fungus that attack the, the banana plantations in Latin America is Black Sigatoka. So answering your question, they did not ask the right question to the farmers.

Comment [JMS24]: 06:15:00

John Foster: Thanks, Luis. Tracy, and then we are going to have to wrap this up.

Tracy Favre: Hi, Luis.

Luis Monge: Hi.

Tracy Favre: I, I am a little confused. I hear that the, the gibb is not used for control of the disease. It is to delay ripening of the fruit for transport. Is that correct?

Luis Monge: Well, while the plant is attached to the plant, the fruit is receiving natural gibberellic acid from the plant so the fruit stays green. Right? Once you take the, the fruit out of the plant, that supply is no longer there. It is not a problem if, if there is enough leaves to make that fruit develop and grow, but when you do not have enough leaves, that fruit is in a high risk to early ripening.

Tracy Favre: Okay. So that, that kind of maybe answers the second part of my question. Because you had made a reference to the fact that some, some growers could not move to new land but that purchasers could go to other growers and other land. And so do I understand you to say that the existing growers that are having problems with the disease would, would benefit from application of the gibb, gibberellic acid to be able to continue to stay and produce there, but it is not specifically because of the control of the disease. It is because that they cannot afford to move to another location and start another farm where they would be away from the disease. Am I making myself clear?

Luis Monge: Yes, yes. And, and I think your appreciation is correct.

Tracy Favre: Okay.

Luis Monge: Thank you.

Tracy Favre: Thank you.

John Foster: Thank you very much, Luis.

Luis Monge: Welcome.

John Foster: Right up here now we have Maria Herrero and then Lynn Coody is up after this.

Maria Herrero: Hi. I have, yes, a presentation so I am not a very good public speaker unless I have something to follow. So the next, okay, thank you. Okay, first of all, USDA has come out indicating that for organic practices, one of the major problems is postharvest decay to maintain food safety and also competitiveness. I also want to mention that gibberellic acid, while not GRAS because it is not specifically added to food, is found in food because it is a natural component of vegetation. The FDA has reviewed it, because there were some people who were concerned about the toxicology of it, and it is used actually be for malting of beer because the barley grains actually all contain gibberellic acid. For malting, you need to germinate that grain, but different grains have different amounts of gibberellic acid in them. So there is a natural indication already from FDA that they, they are okay to be used in this compound. As has been indicated, bananas are usually harvest mature green stage but they are green and they stay green because the gibberellic acid maintains the chlorophyll content that they have. GA3, as has been indicated, has nothing to do with controlling Black Sigatoka. It is just the way for farmers to be able to get to the market. There were indications as to what alternate methods are available and, as been indicated, those are polyethylene bags, controlled atmospheres in terms of changing the atmosphere that they are shipped in from a oxy-, from a CO2 component to an oxygen is also available. Those are extremely expensive and really not used very much. Those methods are much more expensive and less sustainable and less effective than the gibberellic acid. This is the picture of actually how the gibberellic acid is done and it, you can see they are simply brushing it to the crown of the banana. And the substance is not used as the preservative, although that has already been indicated. It

is simply to maintain the natural healthy activity of the banana. The GA3 is metabolized within the banana and then the fruit ripens normally. And then for citrus, basically what I want to indicate is, and I did not explain myself very well in the comments that we sent out, citrus is treated postharvest with all kinds of fungicides. Organic citrus does not have that ability. The only thing they have are hot water treatments. What happens, they are trying to reduce the number of spores of fungi on them. Stop there.

John Foster: Thank you. Are there questions? Calvin?

Calvin Walker: Could you explain a little bit more on your slide dealing with alternative methods instead of the GA?

Marie Herrero: The alternative methods that are available right now, if you wrap the bananas in plastic so you try and create an, an atmosphere, sort of reducing the atmosphere so they are not available com-, they are not exposed to any air. That reduces the amount of harvesting. Not very effectively, but it does work to some degree.

John Foster: Calvin. Follow-up comment.

Calvin Walker: Could you, oh. Could you give me a percentage of level of effectiveness for some of these alternative methods?

Marie Herrero: That would have to come more from my colleague, Luis, than from myself.

Zea Sonnabend: Will you call on me?

John Foster: I [sigh], I am not really, I am not comfortable. We are taking a lot of time on these. Is there a way we can follow up with that at a, at a break perhaps? Luis, will you be around during, for the rest of the day?

Luis Monge: Yes.

John Foster: Maybe we could follow that, that follow-up question. Could we do at a break, is that all right, Calvin? To follow-up on that at a break, is that okay?

Calvin Walker: That would be good.

John Foster: Okay, thanks. Then, Zea, then we should wrap up.

Zea Sonnabend: Could you comment on waxes as an alternative because we do have some organically approved waxes for citrus, for the use on citrus.

Marie Herrero: That is correct but those waxes are put on warm, the same way that the hot water treatments are and what happens is it causes pitting in the citrus and that pitting actually permits the fungi to enter in. The gibberellic acid again has no control on the fungi



themselves, it simply maintains the health of the peel so that the pitting does not occur and fungi do not enter.

Zea Sonnabend: Thank you.

John Foster: Thank you. Lynn Coody is next and then on deck is Rob M., no Rob Moore I believe.

Lynn Coody: Thanks, I am afraid I will fall off it. Okay. Now for the other side of the issue. My name is Lynn Coody and I am commenting on behalf of the National Organic Coalition, a national alliance of org-, organizations representing farmers, environmentalists, industry members and consumers concerned about the integrity of the national organic standards. As an overview, I would like to point out that the NOP regulations do not clearly address postharvest handling issues creating a kind of no-man's land for the regulation of activities that occur between farming and processing or packing. NOC asserts in general that control of postharvest diseases on organic produce must begin in the field. The NOP regulation lays out a stepwise approach for disease control in 205.206 which specifically requires the use of soil and crop nutrient practices, sanitation measures to remove disease divec-, vectors, and management practices which suppress the spread of disease organisms. Careful attention to such practices can reduce or even eliminate the need for the use of materials in postharvest handling. According to our research, this principle is relevant to the petition for gibberellic acid. The reason that we, we got started on this topic was the note from the Handling Committee asking the question about the possibilities to reduce disease incidence of Black Sigatoka. That was a specific request from the Handling Committee and that is what we responded to. So NOC urges the NOSB to wholly reject the petition for a listing gibberellic acid for postharvest use because it fails the evaluation criteria 2.10 that the material should be necessary to production. In general, we agree that the commit, with the Committee's findings that the gibb should not be allowed for postharvest use on citrus based on the inf-, information in the technical evaluation report that the material reduces the nutritional content of citrus fruit. We agree with the Committee that the petition does not make an adequate case for use on pineapples. However, NOC does not agree with the recommendation that supports the use of gibberellic acid for postharvest handling of bananas. As Zea mentioned, we are basing our opinion on this on information detailed in the comments of a NOC member, Organically Grown Co-, Company, the largest distributor of organic fruits and vegetables in the Pacific Northwest. Zea gave some background on the poll that OGC did. They learned that farmers currently employ cultural practices in order to control diseases that affect bananas during shipment. These agricultural management practices coupled with good sanitation dur-, during at harvest and practice were sufficient to control postharvest diseases including Black Sigatoka, which is specifically mentioned in the technical report. So that as far as I can get and so I will stop there.

John Foster: Thank you, Lynn.

Lynn Coody: Thanks.

John Foster: Is there a question? Colehour.

Colehour Bondera: Yes. Thank you. Thank you, Lynn, for, for what you were able to present and I would appreciate it if you would at least in brief talk about some of the farm management or farm system approaches that you just stopped on because I would be curious as to understanding those alternatives a little bit better. Thank you.

Lynn Coody: Thanks, I would be happy to do that. The reason that I, I feel that there is at least some relevance of Black Sigatoka to the need for gibberellic acid is as one of the previous commenters noted, when the leaves fall off the, a plant, it does not have enough energy really to, to keep the, the fruits from ripening. Well, as he explained, the, the gibberellic acid is a, is being supplied to the plant, to the fruits and then when, when the leaves fall off, the plant is ready to just give up on it and the, and that creates the, the difficulties in shipping. But why are the leaves falling off? That is from fungal spores. So that, so we go back to trying, if you can control Black Sigatoka, you may have a better chance at having healthier fruit come off the plants. So on behalf of NOC, after we got the information from a NOC member Organically Grown Company, I did some research in plant pathology literature that reinforced the growers' experiences that, that were reported to OGC. So the, the research that I did found that there were other things that growers could do and do indeed do, especially growers who are more, I do not know, you might say subsistence farmers or smaller growers. They use, they use the following things were reported in plant pathology literature as things that might, might help as a systemic in a, like in a farm plan situation to, to create a good enough amount of control. So field sanitation, good drainage, increased plant spacing, inter-planting with non-susceptible crops, planting in partial shade, and also back up with two materials that are already listed on the National List, Bordeaux Mix and Horticultural Oils, are currently used to help control Black Sigatoka as a system, systematic approach, not a one-on thing, everything used together in order to create a farm plan that is viable for an organic grower. And in addition there are breeding, breeding programs in multiple countries that are focusing on ver-, banana varieties that are resistant to Black Sigatoka. So thanks.

John Foster: Thanks, Lynn. Okay, we got, we need to, we can, we can go if it is important, let us do it. Alright, we are, I am going to try and focus on newer voices if that is alright. So, Harold, go for it and then we are going to have to wrap it up.

Harold Austin: Okay. In the scope of the, of the growers that you are getting the information from, the climatic conditions that Luis was talking about versus the growers, as far as the annual rainfall, do, do you have any of that, that comparison?

Lynn Coody: No, I am sorry I do not. The, the growers that they, that they polled were mostly in Mexico and Peru and some in Equador I believe. But that is, that was the, the range of growers, that they, they, these are just the growers who supply them, that is all they have information from.

Comment [JMS25]: 06:30:00

Harold Austin: Because I think, I think, you know, when we are, when we are looking at the disease vectors and stuff, I think, you know ...

Lynn Coody: Oh, yeah.

Harold Austin: ... the amount, the amount of humidity and moisture ...

Lynn Coody: Absolutely.

Harold Austin: ... is still going to have a significant impact.

Lynn Coody: Yeah, no, no doubt about it, I agree with you completely.

Harold Austin: Thank you, Lynn.

Lynn Coody: Yeah. Okay.

John Foster: Thank you very much, Lynn.

Lynn Coody: Thanks, guys.

John Foster: Thank you. Next up we have Rob Moore and then Cheryl Van Dyne is on deck.

Rob Moore: Hello, my name is Rob Moore and I live here in Albuquerque, New Mexico. I am here as a consumer and as a retailer through my work with La Montanita Co-op to urge you to protect those of us who choose to eat organic foods. I am here to ask you to remove carrageenan from organic foods. Carrageenan can be classified as low molecular weight degraded carrageenan, or high molecular weight, or un-degraded carrageenan. Processors tend to portray the difference between degraded and un-degraded carrageenan as a simple black-and-white distinction. They claim that food grade carrageenan sold to processors falls entirely in the un-degraded category and is therefore safe. However, studies including industry funded studies have shown that food grade carrageenan is linked to colon inflammation and colon cancer in animals. Humph. Studies have reported that high molecular weight carrageenan can degrade in the gastro-intestinal tract to low molecular weight carrageenan. In 1975, a study with Rhesus monkeys found adverse effects in the intestinal tract when the animals were given low levels of un-degraded carrageenan in their drinking water. In 1978, a study published in Cancer Research found that rats fed a diet containing un-degraded carrageenan had higher rates of cancer than rats fed a controlled diet without carrageenan at all. The authors concluded, quote, the un-degraded carrageenan in the diet had an enhancing effect in colorectal carcinogenesis in rats. In 1980 and 81, leading carrageenan researchers Marcus and Watt published two letters in The Lancet titled "Danger of carrageenan in foods" and "Potential hazards of carrageenan" respectively pointing out health concerns with the consumption of carrageenan including un-degraded carrageenan. They noted that they harmful effects of un-degraded carrageenan in animals, quote, are almost certainly associated with its degradation during passage through the gastrointestinal tract, unquote. In 1983, the World Health Organization classified degraded carrageenan as a group to be possibly carcinogenic in humans. In March 2003, the European Commission Scientific Committee

on Food reviewed safety data on carrageenan. The Committee suggested that the amount of degraded carrageenan should be kept to levels below 5%. Your decision should be based on the law as a Committee and the law states that ingredients with adverse human health effects should not be in organic foods. Please reject the relisting of carrageenan. It is clear from the preponderance of scientific studies conducted using food grade carrageenan that there are reasonable questions about its safety in any food, much less organic foods. As an organic consumer and a father, I want you to rely on the organic, I want to rely on the organic label as an assurance that there are no potentially dangerous ingredients in our food. If I have to choose between a chocolate milk that I have to shake before serving it to my children or chocolate milk that I do not have to shake but contains an ingredient that is a potential carcinogen, I do not think I have to tell you which one I will choose. If I do, it would be the one without. Thank you.

John Foster: Thank you. Do you have a question? Thank you, sir. Next, we have Cheryl Van Dyne and Troy Aykan on deck.

Cheryl Van Dyne: Thank you for the opportunity to speak. My name is Cheryl Van Dyne. I am the Director for Regulatory Affairs for CP Kelco. To address the Sunset: CP Kelco is a carrageenan producer and a member of Marinalg, the seaweed producers industry group, and we respectfully request that the NOSB accept the recommendations of the Material Handling Committee to relist carrageenan with no annotations. My objective is to provide information to the Board if there are questions for which we as CP Kelco carrageenan producers would have science or safety knowledge that you would need to, regarding carrageenan. In regard to safety of carrageenan, carrageenan safety has been reviewed by leading world health organizations and deemed safe as a food additive. These include JECFA, the Joint Evaluation Committee for Food Additives of the World Health Organization, the European Union, and the US FDA, and many other countries globally. These safety reviews were based on validated safety and toxicology studies. The food additive carrageenan is not polygeenan and carrageenan is a soluble fiber. The uniqueness or essential functionality of carrageenan, when carrageenan is used, it can be used alone or it can be used with other materials to impart properties to organic consumer foods, beverages and other uses that are unique and essential to the producers' product. For organic status, carrageenan is approved in global organic production standards and regulation without concern. In regard to synthetic, it is requested that any evaluation of synthetic be done after the NOSB has well established the criteria for synthetic and non-synthetic and at that time it is recommended that all materials be reviewed at the same time and that we request that the Sunset review of carrageenan or any other material not be used for the evaluation of synthetic or non-synthetic. Thank you.

John Foster: Thank you very much. Do we have a question? I see Harold and Mac.

Harold Austin: Thank you.

Cheryl Van Dyne: Okay.

Harold Austin: Oh, no, I have got a question for you. Could you explain to us, during the harvesting of the material, you know, there is, there is some environmental concerns, you know, that there may be some negative effects on, on biodiversity the, on, on the environmental impact. Could you explain to us that process and what safety pol-, procedures you have in place to make sure that that does not happen if there is such a, if you do have such a policy in place?

Cheryl Van Dyne: The, the farming of carrageenan, it is farming and I am going to let Bill from FMC speak to that. He has prepared some slides on the farming for you. And I think it would be helpful. But as far as environmental impact, these are family owned farms. It is well documented that there is no environmental impact in the way of carrageenan is farmed and I will let him speak to that. He is, he is well prepared to speak to that. Any other questions?

John Foster: Thank you. I had Mac and then Jean if we have got time. We are going to keep it quick. Oh, Jean is going to hold off, so Mac.

Mac Stone: If, if someone were averse to carrageenan, does it always show up on the label of the product?

Cheryl Van Dyne: Depending upon the food regulations for labeling, I would assume that it would. Food additives are required to be labeled in most regulations so if you, and it depends on the order of precedence and sometimes they are put together but yes, carrageenan would show up as carrageenan as a rule. You would have to check with each individual country regulations. But in the US, for certain.

John Foster: Fine. Thank you very much for your time. Next up we have Troy Aykan and Harris Bixler on deck.

Troy Aykan: Can I have the remote control please? Fine. Which one? This? Okay. Thank you. Sorry. [Laugh] I was too close. My name is Troy Aykan. I am a lawyer with a background in food science and nutrition. I work for The Hain Celestial Group. I also teach part-time food laws and regulations at two different universities in Southern California. We support the Handling Committee's recommendation to allow both choline and inositol in National List for use in infant formula labeled "organic" or "made with organic". Choline and inositol are added to infant formula because they are essential for the proper growth and development of infants. These two nutrients are also classified as GRAS, which means generally recognized as safe, and permitted by the FDA for addition to both milk and non-milk infant formulas. Furthermore, FDA mandates choline and inositol to be added to non-milk-based infant formulas. But they are, they have always been added to milk-based formulas because cows' milk do not contain as much inositol and choline and, and when they do, they are, the values vary. So manufacturers cannot get a stable nutrition profile without adding it. When it comes to choline and products other than infant formula, the Handling Committee recommended that it, choline would be allowed in only "made with organic" category. However, toddlers and young children are not infants, but they are vulnerable to inadequate intakes of nutrients because their

brain and other organ systems are still developing. In national health and nutrition examination survey found that all segments of the US population have inadequate intakes of chol-, choline. Foods fortified with choline will help ensure that these young children and adults receive proper nutrition that they need. According to an OTA survey, 78 percent of the organic food consumers stated that they would prefer buying fortified organic foods was either very important or somewhat important. Consumers should be able to purchase an organic product with fortification if they choose to do so. We urge the Board to vote yes to adding choline and inositol to infant formulas. In addition, we urge the Board to allow choline to be added to “organic” and “made with organic”. Additionally, we strongly support the relisting of cellulose, calcium sulfate and glucono delta-lactone as these substances are GRAS and do not pose any risk to the environment. Thank you. Any questions?

John Foster: Thank you. Is there a question? Jay.

Jay Feldman: Thank you. So maybe I, you can help me understand the law since you teach it. What better person to ask, right?

Troy Aykan: Yes.

Jay Feldman: Are there foods, or there are foods, how many are there, that require, are required by FDA to be fortified or to, to contain a certain level of essential ingredient? Can you give me a couple examples of that?

Troy Aykan: Yes, sir. The FDA, as, as a general rule, if you look at the spirit of the laws, we do not like to mandate people add stuff to foods unless we think that, you know, it is, like, targeted for certain populations or special dietary use. To make the long story short, that FDA decides, decides that certain categories of food should be fortified with given things. Examples, fruit juices that, although it is not mandatory, okay, they say you may, but you, I am sorry, you said when it is manda-, mandatory.

Jay Feldman: Mandatory, yeah, required.

Troy Aykan: Yeah, okay. Let me rephrase that because I was talking about prescribed nutrition but not necessarily mandatory. When it comes to man-, mandatory nutrition, I could think of the infant formula obviously.

Jay Feldman: Yeah.

Troy Aykan: And other than the infant formula, what else would be mandatory by the FDA is that, yeah, I cannot think of any examples that very specific fortification [inaudible].

Jay Feldman: I am thinking vitamins as well, sort of like milk, vitamin D.

Troy Aykan: Again, vitamin A and D to milk and margarines, they are, they are codified regulations but they are not mandated. You may purchase milk without vitamin A and D.

Jay Feldman: Okay, so now switching to this particular proposal, what category would this be in, this, this, you know, choline and inositol, or choline? Would this be in a category of mandate [inaudible]?

Troy Aykan: Mandate.

Jay Feldman: Mandated. In what? In, in soy-based or in milk-based?

Troy Aykan: Choline it, it, this is a, by I understand enough to regulations, choline and inositol must be present in the infant formula, whether it is milk or, or non-milk. At the time the Infant Formula Act passed in 1990, the legislature or the FDA thought that for non-milk-based formula this must be mandated because they would not be getting any. For the milk formula, they did not mandate it, thinking that this would be coming from milk. But in, in practice, that assumption by the FDA did not seem to have worked out. The manufacturers over the course of 32 years determined that the only way, because let me back up and tell you this too. The, the choline and inositol must be reported on nutrition facts label on an infant formula. Okay? If you are using non-milk, then you have the mandatory addition and list it. If you are using milk formula and, and not adding any inf-, inositol and choline, then you may be reporting two to three, which is like it should be four to seven and it may be falling short of what is deemed as proper in a infant formula by the FDA. So to make up the difference, the manufacturers are adding with the FDA's permission and approval to match those levels.

Comment [JMS26]: 06:45:00

Jay Feldman: Thank you. Thanks.

Troy Aykan: You are welcome.

John Foster: Thank you, sir.

Troy Aykan: You are welcome. One more question?

John Foster: Yes, sir.

Troy Aykan: Great.

John Foster: Got to go quick.

Calvin Walker: What would be an alternative to choline? Choline is a vitamin, right?

Troy Aykan: Yes, it is.

Calvin Walker: So what would be an alternative to choline? Would breast-feeding resolve that?

Troy Aykan: Oh, how do we get choline in our diet? Yah, the breast milk is, you would get it in breast milk obviously if you are breast-feeding. And infant formulas, as we always say,

even, even though on our packaging, that the best way to feed a baby is by breast-feeding. But if for one reason or another reason, you are unavailable, available to, or unable to do so, we offer you this, to, to you know closest match that we could offer as permitted by regulations.

John Foster: Thanks. We do need to move along. Thank you, sir.

Troy Aykan: Thank you.

John Foster: Next up Harris Bixler and following him is Beth Unger.

Harris Bixler: I am Harris Pete Bixler, an MIT graduate in colloid chemistry with a Ph.D. I am been in the carrageenan industry for 43 years so I hope I speak with some authority. I am here as a member or a director of Marinalg International. It represents the producers of agar agar and carrageenan. Probably the most useful comments I can make is to fortify the health, safety of carrageenan when used in foods. First of all, we start with a premise that the major international regulatory agencies have all approved carrageenan for use in foods when used at GMP. The, these conclusions by these organizations have been based on the study of in recognized animal species and at, at recognized protocols. A lot of the information in the literature on carrageenan is based on faulty protocols or in inappropriate animal species. And I, I think that the report made to you this morning made it clear the distinction between the two. The other thing we are seeing a lot of these days are in vitro studies, lab bench studies, if you will, on carrageenan and while those studies are very interesting, I think it is going to be a while before we, they can support their claims of carrageenan being unsafe as a result of the in vitro studies. There were several questions that came up from Committee members earlier and one in particular was about the metabolism of carrageenan in the human gut. And care, the human gut contains no bacteria that may naturally make carrageenan, carrageenase, the enzyme necessary to, to metabolize the carrageenan. And this is, you can demonstrate this principle on, on the laboratory bench by showing that the apparent VOD of carrageenan is very high, but in fact it is not. And the reason for that is that to generate, there is a long lead time needed to generate the per-, the bacteria that can metabolize the, the carrageenan itself. So that, the, the human gut just does not have the ability to metabolize carrageenan. The, there are few experiments in the literature, they are very difficult to perform, but clearly show that at least 95% of the carrageenan that goes through the gut is, is excreted in the feces or excreted in the urine. And with that, I will thank you.

John Foster: Thank you very much. Is there a question? Zea.

Zea Sonnabend: Thank you. Could you comment on the anecdotal reports that we receive about incidences of colitis from consuming carrageenan?

Harris Bixler: I, I know of no studies that are done under a reputable protocol and where the fault is, usually is the way in which the carrageenan is introduced into the body. For instance, in drinking water, the problem there is carrageenan is a great water absorber and in many cases the animals are dehydrated as a result of the way in which they are



receiving carrageenan. So I know of none that, and I know of none myself and certainly the regulatory agencies have not found any in their examination that are reliable and upon which you can make conclusions.

John Foster: Thank you very much. We, a quick follow-up maybe? Alright, we have to keep, yep, quick.

Zea Sonnabend: [Inaudible]

John Foster: Yep, I know. I know.

Zea Sonnabend: Could you state your opinion on the amount of degradation of the high molecular weight carrageenan that occurs in the handling and extraction of it before it gets into a person's body?

Harris Bixler: Yes. You know, the, the European Commission has placed a limit on the amount of degraded or low molecular weight carrageenan that can be in food-grade carrageenan, that is less than 5% less than 50,000 molecular weight. The problem is, that is a very difficult analytical job, even with today's most modern spectroscopic equipment. The amount is so small that the analyst is virtually having to count the, the molecules of carrageenan present. What we can say with assurance is that there is probably less than 5% and definitely less than 10% of that material less than 50,000 molecular weight in food-grade carrageenan.

John Foster: Thank you, sir. Appreciate your time.

Harris Bixler: All done?

John Foster: Yep. Thank you. Oh, oo. Beth Unger is up at the moment followed by Joanne, Joanne Tobacman please.

Beth Unger: Good afternoon. I am Beth Unger. I work with CROPP Cooperative. It is a farmer owned cooperative with over 1700 farmer members marketing products under the Organic Valley and Organic Prairie brand names. I have two topics I wanted to cover today, carrageenan and cellulose. I want to express a great deal of appreciation to the depth of the work that the Handling Committee has done in looking at carrageenan. I was really impressed with the, all of the dialogue that was going on earlier when you were presenting the substance. Harold, I think that your first meeting on the National Organic Standards Board and I was very impressed in the way you dialed right in on the fact that although the comments were substantially against the relisting of carrageenan, that you were able to see that a lot of these comments were what I would call a cut-and-paste variety, even to the extent where the same punctuation error existed in many of the comments. Yes, I read all of the comments as I am sure every one of you did. So and, Zea, you know, the work that you did in your research, you know, it, it totally changed what I was going to say to you all today be I wanted to caution you about, you know, the varying types of studies and, you know, I think that is true in anything that you want to

look at, you can find stuff to, you know, studies that are funded by somebody to express the results that you want to see. And you can see that in the public comment that had some substance to them. So I really appreciate that. But I did want you to know that we do use carrageenan in some of our products. We are also working to not have carrageenan in our products but there are certain functional effects that we cannot do without. Oh, my gosh, I got to get to cellulose. Heavy, you know, the UHG heavy cream, there is no substitute. And the chocolate milk as a stabilizer, there is no substitute. And I am going to move right into cellulose. I was shocked. I did not include it in my written comment, because I had no idea that this was an evil synthetic. It is not. It is a ubiquitous thing. We use it in our shredded cheese and in our Parmesan and there, rice cells will not do it. We need it. Please, relist it. I am, I am fully in support of the recommendations the Handling Committee put on the table.

John Foster: Thank you, Beth. Is there a question? Colehour.

Colehour Bondera: Yeah, thank you for your testimony. And I, could you expand very briefly on, I, I guess I wrote it down, sorry but you said that you are working to have no carrageenan in your products ...

Beth Unger: Yes.

Colehour Bondera: ... when you gave that, and I was curious, why?

Beth Unger: Thank you, that was going to be in there in the five-minute version.

Crowd: [Laughs]

Beth Unger: I cannot remember how many years ago, but there was some concern brought forward about carrageenan and we have a, well I want to backup for just a moment, Colehour, because at CROPP we really want to formulate our products to be as clean as they possibly can. This has always been the case and we worked very hard to ensure that, that the formulations are, you know, filled with certified organic ingredients to the extent possible. So there is constantly product development work going on to improve our product formulations. And, you know, I have a number of examples of that. But two products, it is out of the eggnog. It was used in the eggnog as a, yeah, to ...

Unknown Female: [Inaudible].

Beth Unger: ... keep the little nutmeg things all floating around nice.

Crowd: [Laughs].

Beth Unger: And then we also have it in our soy beverages, not our soy creamers, but our soy beverages. Our product development team has been working on getting that out of the soy beverages for a long time now. This is not, this is a challenge. It is a huge challenge. I think that they are getting close. I believe that we are going to be going to plant trials and

that, for that, some new formulations. But the, the terrifying thing about that is, and I am not sure what material they are trying to replace the carrageenan with, but it is something else on 605. And it, you know, is like, it is like rolling the dice when you cannot take a material that is on 605 out of a formulation and use another one because that will be, it, it is expensive to keep reformulating, you know, and trying to do the best, cleanest products possible and wondering, you know, what is the next thing to go.

John Foster: Thank you. Jay, then we have got to wrap it up.

Jay Feldman: Yeah, just quickly. Thank you, Beth. Try to go back to the nasty cellulose [inaudible].

Beth Unger: Yeah, yeah. [Laugh].

Jay Feldman: You know, a lot of this stuff is a surprise to a lot of us. I am just wondering if you would feel okay with an, an annotation that is specifically focused on the, the microcrystalline material.

Beth Unger: No problem, yeah. We use the powdered.

Jay Feldman: Thank you.

John Foster: Thank you, Beth, very much. Alright, let me... We have Joanne Tobacman, followed by Britt Lundgren.

Joanne Tobacman: Okay. Good afternoon members of the National Organic Standards Board and other meeting attendees. I am a physician/scientist at the University of Illinois College of Medicine who has been studying the effects of carrageenan in human cells and in animal models for almost two decades. I am a graduate of Harvard University Case Western Reserve University School of Medicine trained at the NIH and the CI, and I am Board Certified in internal medicine. With collaborators, I have published 19 peer-reviewed papers that address the biological effects of carrageenan. Most of this work has been funded by the NIH and the Veterans Administration. I will address three major points. First, exposure to carrageenan causes inflammation which is harmful. Second, the amount of carrageenan consumed in the human diet is sufficient to cause inflammation. And third, both un-degraded and degraded carrageenan cause inflammation. Carrageenan is used in food due to its potent chemical effects that improve the texture of food products. But carrageenan has no nutritional value. The same potent chemical effects that change the texture of processed foods can lead to harmful biological effects in human cells and in animals exposed to carrageenan. Carrageenan has been used in thousands of biological experiments over several decades because it predictably causes inflammation. Inflammation is well known to be the basis for many human diseases and is associated with over a, a hundred human diseases, including inflammatory bowel disease, rheumatoid arthritis, arteriosclerosis and inflammation is also linked to cancer. In experiments with human colonic cells in my laboratory, we do small amounts of high molecular weight carrageenan and yet determine the specific molecular mechanisms by

Comment [JMS27]: 07:00:00

which carrageenan causes inflammation. There are three major pathways by which carrageenan causes inflammation including stimulation of an innate immune pathway. This pathway is also activated by pathogenic bacteria such as salmonella and is stimulated due to the unusual chemical structure of carrageenan. Stimulation of this pathway is no accident. It is a direct result of the unusual chemical structure of carrageenan including an alpha-1, 3 galactosidic [*glycosidic*] linkage. And stimulation of this pathway has features that can lead to prolonged inflammatory effects in human cells. The effects of carragan [*carrageenan*] induced inflammation are not limited to the intestine. And when laboratory mice were exposed to low concentrations of carrageenan in their food for eighteen days, they developed profound glucose intolerance and impaired insulin action. These responses are precursors of diabetes which is associated with activation of the innate immune pathway. In the past many investigators used carrageenan to cause inflammation to study how specific drugs could reduce inflammation and to study the cells and cell products involved in the inflammatory response. Our recent work has looked instead within cells to study the signaling processes caused by carrageenan exposure and we have found convincing evidence that carrageenan activates biologically significant pathways. Some of these effects are related to activation of reactive oxygen species, reduction activity of sulfatase enzymes, and activation of genes involved in carcinogenesis. Quantitative assessment of these is included in your written materials. I guess I am supposed to stop. I would like to go on. Does someone want to ask me a question?

Crowd: [Laughs],

John Foster: Alright. As [inaudible].

Joanne Tobacman: See maybe you would ask me a question? I was very upset by the comments this morning that were based on literature from industry. Two out of three of the papers that you referred to were industry based. That was very disappointing.

John Foster: So I, my inclination is to have our scientist member go, go first.

Zea Sonnabend: Okay. I actually have two questions ...

Joanne Tobacman: Yes?

Zea Sonnabend: ... for you. And I would like you to continue but address why the other scientists in those papers, of which there were considerable number of citations, of, thought, criticize your work so much.

Joanne Tobacman: Well, I think you have to look at the date of things. My work is originally a review. In 2001, I wrote a review of carrageenan. That is rather hard to, it seems to me, to criticize. I think industry was very upset about the review because it showed that un-degraded carrageenan also had profound effects. And in general, the feeling has been to try and separate the effects of degraded and un-degraded carrageenan. And that has been a decoy argument for years within the industry because the, in our experiments we used

un-degraded carrageenan. The structure of un-degraded carrageenan contains this biologically active component in each of the disaccharide molecules and this is an inflammatory inducing chemical composition. You cannot get away from that. And that is present in the un-degraded and the degraded. There is a lot of reluctance to accept this. People have been using carrageenan successfully in food products for decades. But that does not mean it is safe. We have a lot of unexplained human disease.

John Foster: Uh, but, ...

Joanne Tobacman: And our only hope is to be able to find ways of getting, of understanding it better. And I think the inflammation caused by carrageenan is a real factor in human disease and I think that you as the Organic Standards Board have a wonderful opportunity to improve the safety of organic foods in this country.

John Foster: Uh, okay. I got a, hold on a second. Zea, I am going to finish with you.

Zea Sonnabend: I did have a second question.

John Foster: Is it, it is follow-up or is it new?

Zea Sonnabend: It is a different question.

John Foster: Alright, is it okay if I wrap up with you?

Zea Sonnabend: Alright.

John Foster: Okay, thanks. So I had out of the corner of my eye, Calvin. I saw some hands down here to my left.

Unknown Male: Jennifer.

John Foster: Jennifer and Mac.

Unknown Male: No, Nick.

John Foster: We are obviously going to go a little bit longer on this particular commenter, so. I am sorry, Nick after Jennifer.

Calvin Walker: I am, I am impressed as an M.D. you have 19 refereed publications. That is, that is very good. You mentioned grants from NIH, which is a big name organization. Were those grants that you received peer-reviewed as relates to ...?

Joanne Tobacman: All, all of the grants that we have had to be, that fund carrageenan work have been peer-reviewed. Some of it has been to fund inflammation. I do not want to make it sound that all of those were specifically for carrageenan. It was to fund infla-, work on inflammation as well.

John Foster: Alright. Jennifer.

Jennifer Taylor: [Inaudible] Were you able within the questions as they asked to complete your presentation of information today?

Joanne Tobacman: I had wanted to be able to – thank you for asking that – I wanted to be able to make a specific comment about why the Board is uniquely positioned at this time to make a determination when previous evidence could not have been as convincing. And I think the Marinalg work in 2006 with the round-robin analysis of food-grade carrageenan in which they showed a lot of variability among the food manufacturers in determination of the molecular weight of the low molecular weight component of the food-grade carrageenan ranging up to 25 percent in food-grade carrageenan that was being put into the processed food that would then be used into the final food product. Up to 25%. This is low molecular weight, under 50,000 is what they were using as the cut off in response to the European Union. So that is a lot. If, if you are still going to go by the argument that the degraded polygeenan is carcinogenic and that this is what we should be avoiding, which was the argument brought to the FDA in 1972, when they were ready to say, no more than 10 percent of molecular weight less than 100,000 as a regulation. But, so, that is a unique change that that was, that material became available in 2006 in response to the European Union recommendation. So we have from industry itself that they cannot supply a food-grade carrageenan that is free of low-weight molecular carrageenan [inaudible]. And that is a new finding that you have the opportunity to act upon. Okay, that was mainly what I want to say.

John Foster: And then I believe Jay and we will finish up with Zea.

Jay Feldman: I, yes, I am going to ask a question about your views on, on carrageenan with relationship to what the FDA has found and what the charge of this Board is – and this may or may not make sense to you as a question, so if, if it does not, then I will understand. We, we are charged with looking at the impact on human health and the environment. FDA is charged with looking at food safety. In your, if you were to evaluate this product for us, versus if FDA asked for an evaluation, would you be evaluating it by the same standard or do you feel that we, we see, we are held to a, a different standard?

Joanne Tobacman: I am not sure that I have enough experience with the underlying annotations and regulations that you are dealing with to be able to answer that as well as I would like to. I, I would say that there is an environmental aspect of the carrageenan farming that has not really been dealt with substantively now that there has been a consideration in the past and we wrote a letter to Science about this about a year or so ago in response to damage to coral reefs occurring in the Bay of Bengal and someplace else, Pacific Atolls, Pacific Islands. There was significant damage to coral reefs and that was thought to be related to overgrowth of carrageenan-producing algae or red algae that would make carrageenan. So there is potentially an environmental impact. In terms of health versus safety, I, I do not know that I see those as all that much different. I think that the criteria for inflammation is a, a significant one since inflammation is a precursor for so much

human disease and I think that can be taken into consideration both in terms of organic foods and from the FDA's point of view.

John Foster: Thank you. We have got Jay and then Zea.

Jay Feldman: [Inaudible] Have you, thank you. Have you fully explained the mechanism for inflammation in your recent work? Is that, do you need more explanation of that in terms of bringing new information to this Board that, that needs to be considered? And then, do you feel that levels, because I understand FDA has set a level, a level for degraded carrageenan. How did they get to that level and what are the deficiencies in that process in light of the kind of research that you are doing?

Joanne Tobacman: FDA proposed a level in 72 of, as I said, less than, no more than 10% of molecular weight less than a hundred thousand based on concerns about the harmful effects associated with the polygeenan, the low molecular weight. But they rescinded that in 79 anticipating, actually not saying that carrageenan was safe, they never said carrageenan was safe. They anticipated a more comprehensive regulation. But I think it became a very much a, a deregulatory environment and perhaps more and more food conglomerates with political power, speculation there. But they, they have not acted on carrageenan in this intervening period of time except with regard to the Philippine drive variation but that, that is not a significant issue at this point in time. Terms of inflammation, I think we have very well defined the activation of an innate immune pathway by carrageenan. This was unexpected. People had, as I said, had used carrageenan for, since experiments dating back to at least the 50's to, because it predictably causes inflammation. This is no surprise. This is well known. The same time, it has been used increasingly in food products. It is also sort of in a parallel way been used increasingly in scientific experiments, but with a, the idea mainly of identifying treatments for inflam-, of inflammatory diseases, looking at the medications that would be effective to reduce the carrageenan-induced inflammation. So back in our pathways looking at the innate immune response were completely unexpected because that puts it in a somewhat even more provocative and worrisome light than if it were causing inflammation by other means.

John Foster: Excuse, excuse me. My, my thought was about literature, more information, was that, I lost track.

Joanne Tobacman: It [inaudible].

John Foster: See I, I am trying, boy, it is a tough crowd to wrangle. I got to tell you. This, Jay, as I understand it you wanted to know more about what more information was needed, right?

Jay Feldman: Yeah, I, I was thinking that she had, her more recent research on inflammation ...

John Foster: Got it. Okay.

Jay Feldman: ... was, would be helpful to the Board.

John Foster: Okay. Thanks.

Joanne Tobacman: Were there other questions?

John Foster: And then Zea. You are going to bat clean-up.

Zea Sonnabend: Okay and my question is complicated so bear with me. Your review contained, your 2001 review contained a variety of studies, some of which involved feeding, some of which involved water administering the carrageenan, and some of which involved injection and other methods. And the testi-, what I read this morning indicated concerns that injection and especially of higher doses was not necessarily a valid way to do research on this and water studies, where it was administered in water were not necessarily accurate for doing research because when the carrageenan enters your body, when you consume it in a product, it has already formed a gel and the gel colloid is more stable once it reaches the human digestive system than a in vitro cell study or a water study or an injection type of study and could you comment on, first of all, the range of types of studies in your review? If that, if I characterized that accurately and what proportion of studies were what and that perception that once it is in a stable gel, it is not so easily degraded.

Joanne Tobacman: Alright, I passed out I think the first page from that review which might provide some overall sense of ...

Zea Sonnabend: We have, we have the whole thing in public comment.

Joanne Tobacman: Oh, I, okay, good. There were studies in a wide variety of animals. This was just the, the studies were selected, they were not in, inclusive of all the studies but they were selected because they were well controlled and the amount of carrageenan given and the route, everything was clear. So these were highly selected studies that showed significant harmful effects on the gastrointestinal, development of gastrointestinal lesions. I, I am not sure that this needs to be taken as the last word. There are on-going studies of the harmful effects of carrageenan. Now, whether or not you look at the gel product that is included in food, well, when you drink chocolate milk that has carrageenan, there is no noticeable gel obviously and there is also this presence of a fair amount, up to 25 percent we have said, of degraded carrageenan. So some of the carrageenan that is incorporated into that final product is not in gel form, since the low molecular weight form is not going to form gel. But lambda is non-gel forming. It is also used very commonly in the, in food and, and considered in the annotation now as a separate product. So, lambda is non-gel forming so that does not partake of the issues with regard to the kappa and the iota.

Comment [JMS28]: 07:15:00

Zea Sonnabend: And studies with lambda were in your, part of your review?

Joanne Tobacman: Oh, yes, yes. I am not sure what other specific question you might have.



Zea Sonnabend: It was: what proportion of the studies that you did review were in vitro versus feeding studies versus the tumor injection kind of studies?

Joanne Tobacman: Well, the study in the, in the review were all animal studies. I did not use any, there were no in vitro studies in the, in the review. And in terms of the injection studies, I, I avoided much analysis of those because those are more alarming. They include development of mammary cancers from injectable carrageenan. I do not really want to get into that until we have better information. But I think this is a very harmful substance and there is just no reason for it to be there. The, the products can be made with different formulae. Shaking probably does work for some of the chocolate milk and it would be wonderful to get this out of our human exposure. So.

John Foster: Alright, we are going to wrap it up. Thanks.

Joanne Tobacman: Thank you for the opportunity to speak.

John Foster: Next up we have Britt Lundgren, followed by Robert Rankin on deck.

Britt Lundgren: Thank you for the opportunity to comment today and thank you to the Board for all of your diligent work. Are we on? There we go. Alright, so anyway, thank you for this opportunity. My name is Britt Lundgren. I am the Director of Organic and Sustainable Agriculture at Stonyfield. I am going to be commenting today on behalf of Stonyfield on the Handling Committee's proposal for carrageenan. And we wish to express support for the Handling Committee's recommendation of relisting carrageenan and also like to note our support for the comments heard earlier from Beth Unger of Organic Valley and for the comments that were submitted by White Wave and by OTA. Stonyfield was founded in 1983 with seven cows and the goal of helping family farmers survive and protecting the environment. Today we are the world's largest, largest leading, world's largest organic yogurt producer. Our volume of production allows us to support enough family farms to keep over 200,000 acres of farmland in organic production. And this avoids the use of 210,000 pounds of toxic persistent pesticides and nearly half a million animal drug and hormone treatments annually. We are committed to meeting consumer expectations for a pure organic product that is free from unnecessary artificial ingredients, flavors, and fillers. We are also fully committed to the concept of continual improvement in the organic standard. We believe that the Sunset process is a valuable tool for facilitating this continual improvement. As we well know by this point in the day, concerns have recently been raised about whether carrageenan has negative impacts on human health. We take these concerns very seriously because we want to be sure that we are provided the healthiest possible product. We engaged a scientist to conduct a thorough review of the literature with regard to these health impacts and, based on this review, we feel the evidence shows that carrageenan is in fact safe to eat. However, I am not an expert on this topic and in my comments today I want to stick to Stonyfield's area of expertise which is the process of making yogurt. Stonyfield uses carrageenan in our YoKid squeezers and in the caramel in our Oikos caramel yogurt. Carrageenan provides a critical function in each of these products, creating a unique combination of stability, texture, and

mouth feel. To our knowledge, there are no commercially available organic ingredients that could replace the functionality of carrageenan in these products. The ingredients suggested as alternatives in the technical report do not provide both the structural and sensory properties that we are seeking. Some of the alternate ingredients suggested in the technical report may provide some of the properties that we are looking for but, as far as we have been able to determine, none of them can provide all of these properties, either alone or in combination. We also do not know if these alternative materials suggested in the technical report are available in sufficient quantity in organic form to meet our need and if it turned out that we could use a combination of them as, if we could use a combination of them as a substitute. So we are very concerned that if this ingredient is removed from the National List, that we will no longer be able to offer the products that contain carrageenan to our customers and this will have a substantial negative impact our business. I urge you not to remove carrageenan from the National List at this point in time. Thanks. I will take questions.

John Foster: Thank you, Britt. Is there a question? Mac.

Mac Stone: Does carrageenan show up on the label of your yogurt?

Britt Lundgren: Yes.

Mac Stone: Okay.

John Foster: Joe.

Joe Dickson: So, if carrageenan were to go off the List, what would happen? Would you reformulate the products with something else? Would they become conventional products? Would they disappear from the market? Like what, assuming it went off the List at this meeting, would the impact on your business be?

Britt Lundgren: Well, we are investigating whether we could reformulate. We do want to be responsive to consumer concern and so we are, we are looking to see whether we could take carrageenan out of our product, but as I said, we really have not been able to find anything else that we could use in place of it. So we may just have to pull the squeezers and the caramel Oikos from the market.

John Foster: Okay, I have Jennifer, Nick [laugh]. Jennifer and Nick for sure.

Jennifer Taylor: Hi. I like for you to tell me as a representative from your company, an organic company, how and where do you place the health of the community that you are serving with the new knowledge that you now have maybe about carrageenan?

Britt Lundgren: As I said, we prioritize the health of our consumers very highly. Stonyfield's mission is healthy planet, healthy business, healthy food, and healthy people and we take all four of those "healthy"s very seriously. We do not put one of them, any one of them above the other. That is why we conducted the literature review that we did and that is

why we continue to investigate this issue. But as I said, we feel confident that the literature does conclude that carrageenan is safe to eat.

John Foster: Thanks. Nick.

Nick Maravell: Yes. This is a follow-up to some of Joe's questions. What would, you have two products that use the carrageenan now?

Britt Lundgren: Yep.

Nick Maravell: Roughly, what percentage of, of your business do those two products represent? You know, I mean, ballpark figure. We are not going to hold you to it. 5%? 50%? 1%?

Britt Lundgren: I was afraid someone was going to ask that. I do not know. It is, they are very popular products. The, the squeezers represent a growing product line for us. And the caramel Oikos is a, is a very popular flavor of our Greek yogurt. But of course, we have probably over 60 products on the market right now and that is two of those products.

Nick Maravell: That is what, okay. And then could you just give us a, sort of a rough idea, if you, if you were, you seem to be constantly coming up with new products and you are consid-, you would consider reformulation if that were, if carrageenan were not available. How long does that process take, you know, to develop the reformulation of market tested, and things like that? Are we talking weeks, months, years, in order to, to accomplish that?

Britt Lundgren: Well, the reformulation process is, varies depending on what it is that you are trying to do. And in a situation like this one, where the ingredient is, is important for the fundamental constitution of the product, it, we are concerned that it could actually take years. And in my written comments, you will see that I, I do request that if the Committee does choose to de-list carrageenan, that we ask that you recommend extending the Sunset date past November 2013 to November 2015 to give us adequate time to reformulate because we really have no idea what, what else we would use in those products.

John Foster: Alright, I believe that is it. Thank you very much.

Britt Lundgren: Thanks.

Unknown Male: We probably ought to take a break at some time.

John Foster: Okay. We have Robert Rankin and then followed by Zareb Herman.

Robert Rankin: Thank you very much. Good afternoon. My name is Robert Rankin. I am Associate Director at the International Formula Council. The IFC is an association of manufacturers and marketers of formulated nutrition products including infant formula. These comments are on behalf of IFC members who manufacture organic infant formula as well as the Hain Celestial Group which is not an IFC member but is in the organic

infant formula market. The IFC supports the continued use of all substances currently allowed as ingredients in infant formula products labeled as “organic” or “made with organic”, including choline, inositol, and carrageenan. These substances have been reviewed by the US Food and Drug Administration for their safety and suitability for infants. The IFC strongly supports the Handling Committee's recommendations to add choline and inositol to the National List at 205.605(b) for use in organic infant formula. Manufacturers, they follow US law and the law that was talked about a little bit earlier, the US Infant Formula Act, requires that choline and inositol are present in infant formula. I have here a copy of the Infant Formula Act which was codified in 1980 and which I am happy to share with the NOSB and the NOP following my comments. It includes a table which lists all of the nutrients that are considered essential and that must be present in infant formula. Choline and inositol are both listed on here as required nutrients. There is a footnote which specifies that this is for non-dairy infant formulas, so all non-dairy formulas must contain these levels. So those products must be fortified. In regards to milk-based infant formulas, at the time that this law was codified in 1980, the general consensus was, or the thinking was that cows' milk provided that level of choline and inositol such that those products do not need to be fortified, so it is not mentioned in the Infant Formula Act. However subsequent regulations, which I believe were I guess codified in 1984, reflected research and development from the manufactures which showed that the levels of choline and inositol in milk-based infant formulas is variable. So in order to make that level that is required for soy-based or non-milk-based infant formulas, those products are fortified by the manufacturer. And if a product is fortified, a milk-based product is fortified or soy-based, that must be shown on the label. And of course that goes back to the law so that if a, if a government or whoever is looking at the fortification of that product and it does not contain those levels, it would be considered misbranded, adulterated, and it would have to be pulled off the market. I also wanted to speak to the support for carrageenan. Carrageenan again is a, is a substance that US manufacturers look towards US regulations for and, as has been said before today, the US Food and Drug Administration which governs the safety of, of foods in the US has said that carrageenan is safe for consumption by infants. And there is also a very long history of safe use of carrageenan in liquid infant formulas. Excuse, me, I am just skipping around a little bit here. In the event that, well, thanks.

John Foster: Ah, yes, Jay and then Calvin.

Jay Feldman: Thank you for that. It is very helpful. I, I am trying to understand the process. You, you, it starts with, you did explain it to some degree that, you know, the Acts passed and then a decade later, whatever, new information comes along, there is a proposed rulemaking to change the levels or in, include additional nutrients on the mandated, or required list. What is the process by which you would seek to get a nutrient or fortification on the list, on the mandated, required list as it is in that Infant Formula. Does, I, I do not imagine it takes an Act of Congress to do that. What would, what would the process be and why has not, why has not that process been completed with regard to, you know, inositol, choline in infant formula?

Robert Rankin: Well, I, I do not think I could speak to why it has not happened, but to your first question, **one** would have to approach the FDA, which, which implements that law and through a conversation I guess with FDA and Education or what have you, they potentially could agree to reopen that and discuss the essentiality of nutrients. In terms of the, the levels and, and what is in the products, the law requires that it is in the non-milk-based infant formulas. And as I said before, after 1980 through continuous research and development it was determined that the levels in the milk-based products are variable. So some are below that level; some are above that level. And in order to ensure that those levels are what they should be, those manufacturers fortify. And if those manufacturers fortify, they have to label it. And if it is labeled, then you have to be able to guarantee that it is in the product and to cover yourself against the law.

Comment [JMS29]: 07:30:00

John Foster: Alright. Calvin.

Calvin Walker: I did not hear the last part of your statement. You said something about in the event, and you was cut off.

Robert Rankin. Yes. Thank you. I appreciate that. What I was going to say is that if choline and inositol were, were not allowed to be present in organic infant formulas, we believe those products would have a nutritional disadvantage as well as a competitive disadvantage against non-organic products which do not have, they are allowed to formulate with those nutrients. And in the event that organic infant formulas cannot compete with non-conventional or conventional infant formulas, then that would, I think the manufacturers would, would have to evaluate their presence in the market. I think it would also affect consumers who as the gentleman, the local gentleman earlier said, he wants to be able to provide organic formulas, organic, excuse me, organic products. And, you know, I think that consumers want the most nutritionally adequate product they can get. And knowing that these nutrients are required by law for certain products, I would think that they would want to have that option for the organic products as well. So it is a, it is a consumer preference issue and it is a, a competitive issue or I guess it is a presence in the market issue from the manufacturers' point of view. Also with regards to carrageenan, I did want to also say that if that is no longer allowed in organic liquid infant formulas, that would also result in potentially a disruption in the market for those particular products and it would also I think force the manufacturers to re-evaluate their presence the market as well just because of the process that would have to be undergone to, to replace carrageenan.

John Foster: Alright. Thank you very much. Short. Real short, Nick.

Nick Maravell: You said choline and inositol were in milk-based formulations where it was very variable. It could be high. It could be low. And it could be below recommended rates. Is there any information on what that variability is caused by? What are the factors that contribute to it?

Robert Rankin: It is, it is just the naturally occurring presence of those nutrients in cows' milk and again in 1980 the assumption was that milk delivered that amount. Subsequent

research showed that it varies. Some were low. Some were high. I mean I think it depends on the animal. And then, so then to, to address that, the products were fortified at a level to make sure they were at the, the level.

John Foster: Thanks very much for your time.

Richard Rankin: Thank you.

John Foster: Zareb Herman and then we had a request to take a break which sounds like a pretty good idea to me.

Zareb Herman: My name is Zareb Herman. I am a nutritionist and food scientist with the Hain Celestial Group. We have been producing natural and organic foods for over 40 years. We wish to strongly support the Handling Committee's recommendation to re-list carrageenan on 205.605(a). Carrageenan is an essential ingredient derived from seaweed and it is used in thousands of organic products. Carrageenan is unique. Its unique characteristics are not matched by any other substance. And in many applications, it cannot be replaced by any other substance. Carrageenan is often used in combination with gums, starches, and emulsifiers. It has taken years of research to develop these combinations for specific applications in organic products and carrageenan is essential in these applications. On safety, the FDA has determined that carrageenan is GRAS or generally recognized as safe for direct addition to food for human consumption. And has already been stated, carrageenan [*carrageenan*] is all, is also been determined to be, be safe by Health Canada and the FAO-WHO Joint Evaluation Committee for Food Additives. Arguments questioning the safety of carrageenan are based primarily on animal studies that do not reflect the way that humans consume food-grade carrageenan. Also, in vitro studies of human cells that have been taken out of the body and soaked in carrageenan solutions have little relevance to how cells operate inside the body. It is a huge stretch to take these selected studies and then claim that food-grade carrageenan is harmful to live human beings. Such a stretch [*strategy*] ignores the most important studies in which food-grade carrageenan was fed to animals with no adverse health effects. There are also no studies whatsoever showing adverse effects on, on live humans who have consumed foods that contain food-grade carrageenan. Today you are hearing a lot of arguments for and against the safety of carrageenan. If you are not a scientist, and maybe even if you are, you may have difficulty deciding. The good thing is, you do not have to. The FDA has already determined that carrageenan is safe. The FDA has the legal authority to determine the safety of food ingredients in the United States. It is amazing that some people think that they know better than the scientific experts at the FDA, Health Canada and other international authorities. Carrageenan is safe. And it is essential for organic handling. I urge the Board to not react to unfounded claims about the safety of carrageenan. A "no" vote is totally unwarranted and would have a devastating impact on the organic industry. Thank you.

John Foster: Thank you. Do we have questions? We must have got it, must have answered them all already. Okay. Thank you very much. We are going to take a, Barry, I will hand it over for taking the break.

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May 24, 2012

Barry Flamm: We will take a 15 minute break. Be back here at, what, three, four, 3:55.

Comment [JMS30]: 07:37:07

[BREAK]

Comment [JMS31]: 07:52:58

Barry Flamm: It is still turned off. They got me turned off. [Laugh] Hey, Ben? Hey, Mac, get Ben to turn me on.

Unknown Male: You are on. You are on.

Barry Flamm: Am I on? I was not. Board members, please take your seat. I did not, I did not hear myself.

Unknown Male: Yeah, I, I was right by the speakers.

Barry Flamm: You heard it?

Unknown Male: Yeah.

Barry Flamm: Oh, I thought you turned me off. [Laugh]

Unknown Male: [Laugh]

Barry Flamm: I thought maybe you turned me off, Ben, because all of a [inaudible].

Unknown Male: We do during the break. We turned you back on.

Barry Flamm: Oh, okay. Thanks, man.

Unknown Male: Can you go ahead and make that announcement again about what we were discussing? They are doing great but just to reiterate.

Barry Flamm: Oh, okay, I will do it right now. Where is everybody? They are not paying much attention to my...

Unknown Male: We are almost at quorum, sir.

Barry Flamm: Huh?

Unknown Male: We are almost at quorum.

Barry Flamm: Hey, Nick. Jay. Calvin.

Unknown Male: Sit down so we will be at quorum.

Barry Flamm: I would like to remind the Board members that when you are having discussions, particularly with, or questions with, with your neighbor, or close by, to speak in at all times, speak into your microphone please. It is, this is just a reminder. John, would you proceed?

John Foster: Yep, thank you, Barry. Coming back from the break, next in sequence is Cheryl Callen. Thank, and thank you for being on spot on time. Thank you. And on deck is Steve Freeman. Steve, you in the room? Excellent. Thank you.

Cheryl Callen: [Inaudible] Thank you. Good afternoon. Is this on? Is that better? Okay. My name is Cheryl Callen. I am representing Nestlé Infant Nutrition. We currently market organic baby foods and toddler foods and infant cereal under the Gerber brand. And many of these organic foods currently have added choline. As one of the petitioners to add choline to the National List, we are here today to lend our support to the Handling Committee's recommendation to allow for the addition of choline to organic infant formulas. We are also here to encourage the Board to reconsider the recommendation to only allow choline addition to adult food made with organic ingredients. We are asking the Board to specifically consider the addition of choline for foods positioned specifically for infants and toddlers, including infant cereal which is commonly fortified with vitamins and minerals. I would like to briefly review for the Committee some of the points we made in our written comments. Choline is important for cell function and there is substantial evidence indicating that choline plays a role in brain development and function. Adequate choline is important in periods of rapid growth and development including infancy and early childhood and is important for optimal fetal development during pregnancy. In 1998, the Food and Nutrition Board of the Institute of Medicine recognized choline as an essential nutrient and established adequate intake levels, or AIs, for population groups including infants, young children, and pregnant women. Prior to 2005, little data were available on choline intakes in the US population. Starting in 2005, the INHANE surveys estimated choline intakes. Mean intakes for men and women are below the recommended AIs established by the Institute of Medicine. And especially concerning, is that the mean intake for women is 40% below the AI. The Nestlé Feeding Infants and Toddler Study, or FITS, is the most comprehensive dietary intake survey of infants and young children in the United States with a sample size of over 3000 children between the ages of zero and 48 months. Data from FITS shows choline intakes for infants are below the AI with over 75% of children ages seven to 12 months below the adequate intake levels. For toddlers, 12 to 24 months, 66% have intakes below the AI. The Handling Committee recommendation states that the addition of choline is not harmful and that there are no adverse effects on the environment from the use or manufacture of choline. The limitation of choline addition to foods made with organic ingredients seems largely based on the availability of food sources for choline. Clearly based on the surveys done by both USDA and Nestlé, a significant portion of the population, both adults and children, are not getting choline from available food sources. I am not aware of any data to indicate that organic consumers are faring any better, or even are aware that they need to modify their diets to achieve adequate intakes of choline for themselves and their children. Given the low levels of intake, especially concerning for pregnancy and for infants and children during development, we urge the Board to consider allowing the addition of choline to



organic foods and specifically for foods intended for infants, such as infant cereal. Consumers of organic food should have the option to choose foods with this important nutrient. Thank you. I will take any questions.

John Foster: We the, do you have a question?

Cheryl Callen: Any questions?

John Foster: Alright. Thank you very much.

Cheryl Callen: Okay. Thank you.

Jay Feldman: I had a question.

John Foster: Oh.

Jay Feldman: Just a quick question. I am sorry. I was waiting to see if there were any others. Thank you. I have a whole lot of questions. I am going to cut back to one. Do you guys measure, I am assuming in the milk-based infant formula, liquid formula, do you measure levels of choline and inositol before you add?

Cheryl Callen: Actually, I am not, we do not make an organic infant formula. We only make organic baby foods and toddler foods. Mean in our, we do...

Jay Feldman: In your conventional line.

Cheryl Callen: We do make a conventional infant formula, yes.

Jay Feldman: Right. And do you, do you test for levels before you add?

Cheryl Callen: Yes, we do. We test our incoming ingredients for naturally occurring nutrients and then our formulations are developed to assure, as was said earlier, to assure adequate intakes of choline in the final formulation.

Jay Feldman: Thank you.

John Foster: Thank you very much. Appreciate it.

Cheryl Callen: Yes, thank you.

John Foster: We have Steve Freeman and then Kelly Shea is on deck.

Comment [JMS32]: 08:00:00

Steve Freeman: I do not need the box. Good afternoon and thank you for having this opportunity to express. I am here today on behalf of Jackson Farms, a tree fruit producer in central California of organic cling peaches and, and thank the Board for its passage of the ability to peel peaches with potassium hydroxide at the December 2011 meeting. It is frustrating to Mr. Jackson and, and his processors that it is taking so long for this minor amendment.

The material is used currently and approved to use for individually quick frozen peaches and this would be used for canning peaches and it is taking a very inordinate long time for this minor amendment, minor change in the regulations to take place and with harvest imminent in the, in the next month or so and him not being able to market his fruit as organic canned peaches, he is here to, to implore the Board to ask the, the USDA to get this change adopted in a posthaste manner, and I would, I would help get you guys back on schedule by that would be the terms of my comments. So, thank you.

John Foster: Thank you. Could, actually we, do we have one question?

Joe Dickson: Sure.

John Foster: Alright, we have got one question.

Joe Dickson: This is more of a clarification, maybe a question for the Program. My recollection is that in Savanna we did approve the annotation to allow the additional use of potassium hydroxide and it is now with the Program, correct?

Melissa Bailey: Yeah, that is correct, Joe. So I, I have actually spoken also directly with Mr. Jackson before. Appreciate your coming to represent him. We are, what I have expressed to him, is that the Board made the recommendation in December. That was transmitted to the Program I believe in January. We have it as part of the drafting for a Handling docket that we are working on now for a proposed rule that we are trying to get to our General Counsel, you know, sometime in June. So, but I did express to him that in terms of rule-making, these National List amendments do still take our process to get through after the Board has done its work. So we will continue to, to make progress as, as we can on that.

Joe Dickson: Thank you.

John Foster: Thanks very much. Next up we have Kelly Shea followed by Steve Warshower, I believe.

Kelly Shea: Hello, welcome to our new NOSB members. My name is Kelly Shea with White Wave Foods. We make Horizon Organic and Silk Organic products. Horizon has been making organic dairy products since 1991. We are the largest organic dairy brand in the US, sourcing organic milk from over 600 farmers across the US. And Silk has been making organic soy milk since 1996. It is the largest organic soy brand in North America. We purchase all our organic soy from US farmers. In transparency, I serve on the Board of Directors of the Organic Trade Association. I have in the past served on the Board of Directors of OMRI as well as other organic organizations. I have made my living and supported my family by working in organic food and farming for almost 25 years. White Wave submitted written comments and I am here to reiterate those and to support the comments of my colleagues at Organic Valley and Stonyfield as well as the many other organic food manufacturers, input suppliers and trade associations who are asking that this Board renew on the National List carrageenan and cellulose, specifically powdered cellulose in our case. These have been used by organic food processors for almost 20

years. I mean we are actually awaiting organic aquaculture standards so we can have organic carrageenan. We have heard and read consumer comments asking that you maintain the integrity of the organic standards. Well, relisting these items is maintaining that integrity because they are not new to organic. Carrageenan and cellulose have been used in organic soy products and other organic products since before the USDA, NOP even existed. We have millions of consumer that every day see these ingredients on our package labels and choose to purchase them and have for decades. The Federal Register notice on Sunset materials published in August of 2011 solicited nothing but positive comments to re-list these materials. So I do not know where these concerns were at, at that time. The Handling Subcommittee also unanimously voted to re-list handling materials during the Sunset review. So if this Board is contemplating action other than re-listing these materials, I really want you to consider something important. Based on the positive Federal Register process, the unanimous Handling Subcommittee vote, there are many participants in organic agriculture as this is a global program that have not traveled to this meeting as they had no idea there was going to be any issue at all with the re-listing because all of these things just sort of happened at the 11th hour. And I would just like to keep that, you to keep that in mind and I thank you for the time to address you today.

John Foster: Thank you. Do you have any questions? Jean.

Jean Richardson: When you source your carrageenan, what percentage of it comes from wild source seaweed as opposed to farmed?

Kelly Shea: I believe, with speaking from our manufacturers, that it is all wild sourced seaweed.

John Foster: Thank you. Joe?

Joe Dickson: On the sort of necessity angle, can you speak a bit to what would happen within your business and your product line if carrageenan were to go off of the list? Would there be, where would there be opportunities for reformulation and where would products disappear from the marketplace?

Kelly Shea: Sure, we have a really robust R&D department and they are little research monkeys that love to do nothing more than discover new ways to make really cool, awesome food. And we are constantly trying to not use things that are on 605(a) and (b) and 606 because it is really like Russian roulette. It takes a couple of years to formulate a product and then you have really only got two years left of it on the National List before it is up for Sunset again. So our R&D department really likes it when they are not using things on the National List. But, for many products, for example for our soy milks as Britt from Stonyfield said, in our Tuberz Yogurts, as Beth had commented in our chocolate milks, carrageenan is just very uniquely positioned to work in those products and that is why it is so ubiquitous in so many food products and I have never before heard these types of concerns that we are hearing today. It has been boldly labeled our packages since about 1993 in the case of Horizon.

John Foster: Thank you. Yep. Joe.

Joe Dickson: Totally different question, on the cellulose issue, would you support an annotation that excludes microcrystalline cellulose?

Kelly Shea: Absolutely. It has been the understanding of the organic community that that has always been prohibited. We use a powdered cellulose in our cheese shreds.

Joe Dickson: Thank you. Jay.

Jay Feldman: Thanks, Kelly and thanks for your support on the GMO letter. Appreciate that.

Kelly Shea: Always.

Jay Feldman: I was curious in terms of the product lines that would be affected by ...

Kelly Shea: Mm-hum.

Jay Feldman: ... carrageenan and so far I have heard about chocolate milk and ultra-pasteurized whipping cream and I am wondering is there something unique to the ultra-pasteurized whipping cream that requires it in that, but not in the, on the pasteurized line?

Kelly Shea: I do not know the answer to that. I am not a food scientist. Maybe somebody else in the room can speak to that.

Jay Feldman: Okay, thank you.

Kelly Shea: Sorry, Jay.

Jay Feldman: That is okay.

Kelly Shea: I am a theater major.

Crowd: [Laughs].

Unknown Male: Perform very well.

Crowd: [Laughs]

Kelly Shea: It is because it is what I believe in, much like yourself, I am sure.

John Foster: I think we have a question from Jennifer.

Jennifer Taylor: [Inaudible]. I am sorry. Hi. Is it possible to use, is it called comm-bu, k-o-m-b-u seaweed instead of the carrageenan that you are using?

Kelly Shea: I am only familiar with kombu from eating it in Japanese food.

Jennifer Taylor: Yes.

Kelly Shea: And it is, I love kombu salad.

Jennifer Taylor: Yes.

Kelly Shea: But I have never known it to my knowledge to be a thickener for use in food products.

Jennifer Taylor: Okay.

Kelly Shea: Much like wakame is the one around ...

Jennifer Taylor: Right.

Kelly Shea: ... the sushi, I have never known that to be a thickener for use in food products either.

John Foster: Alright. Thank you very much.

Kelly Shea: Thank you.

John Foster: I believe we have Steve Warshower followed by Diane Wilson.

Steve Warshower: Good afternoon. I do not know how well I can follow a theater major. But, Handling Committee, my name is Steve Warshower. I am a farmer here in New Mexico and I also work with a number of farmers helping prepare their products for the supply chain and encouraging them to choose the organic label as a assure, an, an assurance of integrity and value to the consumers who will be choosing their products. I am also a member of the Cornucopia Institute and I am here today as a citizen lobbyist. In 1943, Sir Albert Howard, one of the founders of the organic movement wrote that the approach to the problems of farming must be made from the field, not the laboratory. When soil fertility suffers, organic farmers turn to natural sources of nutrients rather than to synthetic fertilizers. Should not the same principle apply to organic food? Chemical and pharmaceutical companies and their customers are now petitioning the NOSB to allow synthetic nutrients to be added directly to organic human foods. For every one of these synthetic nutrients there is an organic alternative, naturally nutrient-dense organic food. Just as synthetic fertilizers, which are synthetic soil nutrients, are prohibited in organic farming, synthetic nutrients should be prohibited from being added directly to organic foods. Synthetic choline and inositol are essen-, are not essential for organic handling since these nutrients occur naturally in food. There has never been a documented case of inositol deficiency since it is so common in everyday foods. Good sources of choline include peanuts, tofu, chicken, beef, eggs, broccoli, spinach, navy beans, fish, et cetera. In infant formula, organic soy lecithin would be a good source of choline. The technical review for synthetic choline points out concerns with the use of ethylene oxide and

synthetic solvents, resulting in the possible presence of carcinogenic 1,4-dioxane and other toxic contaminants. The technical review, technical review also points out that people suffering from depression should avoid choline supplementation. Organic foods should be a healthy and safe option for all Americans including the 21 million suffering from depression. For infant formula, with the proposed NOP rule change clarifying the annotation for nutrient vitamins and minerals, any nutrients required by FDA would be permitted. Therefore there would, there would not be a need to add these nutrients to the, or vitamins to the National List. Please reject the inositol and choline petitions in their entirety. There is no need to allow these synthetic nutrients in organic food. Please also reject re-listing of carrageenan. It is clear from the preponderance of scientific studies conducted using food-grade carrageenan that it is not a safe ingredient for any food and we should be able to rely on organic food as a safe alternative to conventional foods. Thank you.

John Foster: Thank you. Nick.

Nick Maravell: See you were not a theater major, Steve.

Steve Warshower: Working on it.

Nick Maravell: You were obstructing your stage presence with your computer. I, I want to ask a question. I do not know if you can answer or have any knowledge of. I, I know that you are knowledgeable about cattle, but I do not know if you are knowledgeable about dairy. Is there any indication that the, your production system in dairy would change the levels of inositol and choline in milk?

Steve Warshower: I do not have any direct experience at a scale which would allow me to report on that from, you know, from data, but it stands to reason that it would.

Nick Maravell: And, and it stands to reason because?

Steve Warshower: Well, the, the feed composition affects the product of, of a lactating mammal.

Nick Maravell: And what would be in the feed that, that might increase the inositol or choline levels in, in dairy cattle?

Steve Warshower: Yeah, that one I could not answer.

Nick Maravell: Okay.

Steve Warshower: Have not addressed it at that level.

Nick Maravell: Okay. Thank you.

John Foster: Alright. Thank you very much. Next up Diane Wilson followed by John Ashby.

Diane Wilson: Good afternoon. My name is Diane Wilson. I am a registered dietitian and I am also the Nutrition Director for Nature's One, the manufacturers of organic pediatric nutritional products. Thank you for this opportunity. I did have a formal presentation. I am going to go to the very end of it in the summary in the event that I run out of my three minutes. And basically, what we are asking the National Organic Standards Board and the NOP is to really take into consideration a group of, of medically challenged and medically vulnerable people who have not been addressed yet regarding the choline and the inositol issue. And this is a group of children, especially, from at least my perspective, where inositol and choline are absolutely essential. These are children who are enterally fed. And let me give you a definition of enteral as defined by both Medicaid and also by FDA in the Orphan Nutrition Act, I should say the Orphan Medical Act. But the Centers for Medicare and Medicaid Service recognize the importance of enteral nutrition products and have reviewed and approved our products, Nature's One products, for use in eligible patients. They have assigned what is called a Healthcare Common Procedural Coding System Number, often referred to as a "hick-pick" [HCPC] number to be used by themselves and private insurance carriers for coverage of enteral nutrition products. Now, the, they define it as organic pediatric has been assigned the code, for example, our product PediaSmart as code B4160 specific for enteral formula for pediatrics. What this means is a child is unable to consume a normal diet of foods. The child must obtain their nutrition either orally from a liquid complete nutrition product or by tube. This tube would be inserted through the nose into the stomach or be placed into the stomach directly, a gastrostomy tube. These are children that absolutely require this nutrition. We are not talking about nice-to-have supplements, we are talking about complete nutrition that is often life-sustaining and often times needed for life. Okay. Let me also give you the definition by FDA. Under the FDA, Orphan Drug Act, Act, this is a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition. Again, we are not talking about a normal child or teenager who can eat foods and get these two nutrients. Now, I am running out of time, but what we are asking, is that you expand the definition of infant nutrition to include enteral nutrition products that medically... Thank you very much and I would be happy to address any issue pertaining to choline deficiency or organic inositol.

Comment [JMS33]: 08:15:00

John Foster: Thank you. Question from Zea.

Zea Sonnabend: Do those children and their caregivers, or their caregivers, understand what "made with organic ingredients" means?

Diane Wilson: I am not sure I understand your question. I mean, the, we have... The people who are using our products are seeking organic products compared to the standard non-organic that are on the market.

Zea Sonnabend: So, we are proposing to allow these nutrients in the category "made with organic", which would mean that it contains at least 70% of organic ingredients and could be higher, but then is also fortified with synthetic ingredients.

Diane Wilson: Our consumers are hard-core organic consumers and they would appreciate having us listed as organic, over 95%.

John Foster: Thank you. I wonder, I, I have a clarifying question. I could not do this and write at the same time. You said the, your preferred listing would be entero- and then I lost it.

Diane Wilson: It is called enteral medical nutritional products, e-n-t-e-r-a-l.

John Foster: Got it. Thank you. Jay.

Jay Feldman: Thank you and I want to thank you for your creativity in finding an alternative source of DHA that is ...

Diane Wilson: Thank you.

Jay Feldman: ... not synthetic. That is a testimony to the creativity and, I think, the future of organic. So in that respect, I, I wonder how deeply you have looked at the production of choline and the, I think one of our presenters earlier said, mentioned the 1,4-dioxane used in the production process, you know, to, to produce the choline and whether that, given your other efforts, would be of concern to you or were you aware of that or anything on that subject?

Diane Wilson: Of course, we are aware of it. As you mentioned, we have taken great pains over the years to use a source of DHA and ARA that is not from algal and fungal sources. And we eventually, as of last year, we were able to introduce products with an egg phospholipid organic compliant product. Regarding the choline, it would be wonderful if soy lecithin had adequate amounts of choline in it in order to support the needs of a child. We are certainly looking into options for organic choline. When organic choline and organic inositol are available, and we continue searching worldwide for such ingredients, you can bet your booty that we will certainly use it.

Jay Feldman: Thank you.

John Foster: Alright. Thank you very much.

Diane Wilson: Thank you.

John Foster: And thank you for bringing the "bet your booty" phrase back into style.

Crowd: [Laughs]

John Foster: It was one of my favorites. So thank you. [Laugh] We have John Ashby up and following him is Bill Matakas.

John Ashby: Hi. I am John Ashby with California Natural Products. We have been, we have been making organic products actually since 1985. I just retired after serving several



years as the Chair of the State of California's Organic Products Advisory Committee. I am currently the Chair of the Board of OMRI. I understand a little bit about volunteer work in a contentious situation and one of the things I want to do is reassure you that in my experience, no good deed ever goes unpunished. So just be prepared. But, in our family phrase, what we use is we talk about being a duck. And what being a duck means is the duck would freeze to death if the duck let the water get down to its skin but it does not because he just lets it roll off. So just be a duck. I am getting a little more concerned about organics in general. I feel like we are moving beyond the circular firing squad into a game of Russian roulette with a six-gun with seven chambers full. There is, there is too much focus on too much negativity on too much trivial stuff. And I would like to see us think about this and I am just mentioning a few generic thoughts here about how we can approach things a little differently, have a few thoughts out in front of us. We need to be a lot more focused on what the values of organics are and a lot, worried a lot less about, about trivial little things. One thought that I do want to put in front of everybody here is you should always be thinking about avoiding policy or material decisions that are likely to conflict with FDA safety policies because if we fall into that trap, we are going to lose and FDA is going to win. That is not saying that you have to think "what would FDA want me to do", but be really careful about that. I am thinking about specifically about the vaccines for the salmonella. When, you know, they say, well we kind of recommend this as a procedure, they are saying a little bit more than, saying a little bit more than recommend. So, be careful about that. If we get too anxious about not allowing some nutrients into organic foods, we leave ourselves wide open to other people saying look they are not nutritious enough. Okay. I see in the comments, often, I see comments like, well there is a substitute, there is a substitute, there is a substitute. People who are saying that are usually not food product developers. I caution you to be careful with that statement. I have got decades, plural, of food product development behind me. Things are a lot more complicated in the real world, real world than you think. The last comment I do want to make, is that be really, really, really cautious about ever eliminating anything off of the National List. And I want to remind us that we do have a 100% category for people that want this. We ought to be thinking not as the only driver of our thoughts, but we need to be thinking balancing this versus more agricultural land under organic management.

John Foster: Thank you, John. Maybe I missed it but could you, I know your affiliation, but could you give your title and ...?

John Ashby: General Manager for California Natural Products.

John Foster: Thanks. Thank you. Questions?

John Ashby: Thank you.

John Foster: Alright, we are good. Thank you. We have Bill Ma-, Matakas – sorry for mispronouncing that.

Bill Matakas: It is alright. It is Matakas.

John Foster: Matakas. Thank you. And Jonathan Ashe deck.

Bill Matakas: So good afternoon. My name is Bill Matakas. I represent FMC Corporation. I am the Carrageenan Product Manager, so we obviously make the carrageenan. We support the continued listing of carrageenan as a allowed for use in organic non- synthetic. We also support the use of carrageenan in all applications. I was going to talk about, and I still will make comments on, the environmental nature and sustainability of seaweed farming but I do want to correct a, a comment I heard earlier. And the comment was based on the fact that the manufacturers have 25% low molecular weight product in there. The study that is out in the public on the website actually talks about five or six different ways that the industry and analytical chemists have tried to evaluate and measure low molecular weight carrageenan. That 25 percent was in one study and really showed the fact that that analytical method did not work, and it just crashed and burned. So it got a spurious result. I am not a analytical chemist, but I did read the study on the website while we were sitting here. And you can go to the Marinalg website if you want to read about that study. So I would really like to talk now about seaweed farming and its importance and also how seaweed goes from a sustainable farm product to a product that is used. Carrageenan is a safe product that not only is a good hydrocolloid but also helps the organic industry. I have one minute to talk about farming. Seaweed farming has happened since the 1970s. Sustain, it is sustainably grown on mo-, on family farms, small family farms in Southeast Asia and East Africa. FMC makes a priority of having people in the field to teach best farming practices, where to grow seaweed, how to grow seaweed, where not to put seaweed farms, how to harvest sustainable raw materials for the use in, in farming. On, also on the Marinalg website, there is a discussion paper on introducing species and control of that. That was discussed earlier about invasive species in a couple of areas that were done by people who did not do things properly. So the industry has taken a position and written a paper on that. You can look at that on the Marinalg website also. Finally, seaweed farms really help people who are at the fringes of the world economy. They are small family farms. They are people in East Africa, mostly women who have taken entrepreneurial spirit and, I have to stop. Do you have any questions?

Thank you. Jean, I think this is the speaker you have been waiting for.

Jean Richardson: You are the speaker I have been waiting for.

Bill Matakas: Okay.

Jean Richardson: So I am one of those environmental types really struggling to understand the impact of seaweed harvesting on the marine ecosystems.

Bill Matakas: Sure.

Jean Richardson: So what I am looking for is some understanding of the percentage of carrageenan that is today sourced from wild as opposed to farmed and for you to see if

you can provide me with some of the cons-, the data which would suggest that there is still wild a lot of wild carrageenan harvesting taking place which is having a negative impact both on coral reefs and also on the, the over harvest, excessive over-harvesting such as off the coast, coast of Nova Scotia.

Bill Matakas: The, the, so there is two types of seaweed. There is the wild harvest seaweed that primarily occurs in cold waters. So the coral reefs do not come into play with those. Where coral reefs are, and, and let me give you an analogy. If you look at the three largest countries that provide seaweed to the industry, Indonesia, Philippines, and, and Tanzania. If you took a look at the total area of their coral reefs and you equated that to a football field and you said, if you were to put all of the seaweed farms over top of that football field, how much area would that take up? You would put the football on the one foot line and basically have that little strip. It is about three tenths of a percent. Most seaweed farming is actually done on a floating line system, where seaweed is tied to a nylon rope. And they really recycle most of the drink bottles and use those as floating devices. And so then they are, then that material is brought in by these family farmers and then sold through co-ops in these villages to people who then sell it into the processing industry. The over-harvesting, there are normally management plans, I think Canada has a management plan and most of the cold water countries have management plans to manage their own marine environments.

Jean Richardson: May I have a follow-up question? What about the, the seaweed harvesting in the areas which are basically, need, need the, those species to protect the coral reefs?

Bill Matakas: The, the seaweed is done floating above the coral reefs so it is done in pretty deep water when I have been out there on the, their little plywood boats the, the seaweed farmers tend to use. So they are not touching the coral to destroy it. The coral destruction primarily happens due to dynamite fishing in these regions, where people either are fishing to for sustainability of food or the tropical fish trade can happen. So they, they throw dynamite in and then that destroys the coral. There was a good article on a marine park at Indonesia that was a protected area and the coral has been completely destroyed by dynamite fishermen.

Jean Richardson: Did you give a percentage of how much of the sea-, carrageenan is coming from wild as opposed to [inaudible] farmed?

Bill Matakas: Wild harvest is probably about 20 percent of the total seaweed harvested for the carrageenan industry. It is a pretty small amount.

John Foster: Great. Thank you very much.

Bill Matakas: Okay.

Comment [JMS34]: 08:30:00

John Foster: We have Jonathan Ashe and then Charlotte Vallaeys is up on deck.

Jonathan Ashe: Hello. My name is Jonathan Ashe and I am owner and farmer of Thunderhead Farms in Bosque Farms, New Mexico. I am also a conscientious consumer seeking the best quality foods when I am unable to produce them myself. To me, that means the organic label. It also means I put my trust in you, the NOSB, to maintain the integrity of that label. I am also a Cornucopia Institute member and here today as a citizen lobbyist. Cornucopia supports the re-listing of agar agar as a non-synthetic with the annotation of "from *Gelidium* species only, processed without alkaline treatment." According to the technical review, two different species of red seaweed are generally used to produce agar agar: *Gelidium* and *Gracilaria*. *Gelidium* was the original species to use to make agar agar. *Gracilaria* is only suitable as an alternative to *Gelidium* if it is treated with alkali, which cause a chemical change that leads to increased gel strength. The technical review misleadingly states that *Gracilaria* species are usually, usually subjected to alkali pre-treatment, when in fact, commercially viable agar agar from *Gracilaria* must be treated with alkali before extraction. This is an important distinction which bears repeating because it is crucial to understand the reason for our proposed annotation. Agar agar from *Gelidium* is not treated with alkali and therefore does not undergo chemical change while agar agar from *Gracilaria* requires alkaline pre-treatment and the chemical change to be useful for commercial applications. We therefore urge the NOSB to adopt the following annotation for agar agar: "from *Gelidium* species only, processed without alkaline treatment." Next I will briefly address the Sunset material cellulose. Cornucopia cannot support the re-listing of cellulose without a new TR that bridges the eleven-year gap from 2001 when a, the TR was performed, until today. The original TR found microcrystalline cellulose to be highly processed material, and not compatible with organic handling systems. And reviewers unanimously suggest that microcrystalline cellulose be prohibited in organic foods. The 2001 TR pointed out environmental concerns with the production of microcrystalline cellulose as well, quote, acid waste due to the hydro-, hydrochloric and other acids. For cellulose, please add the annotation. From DHA to carrageenan, it is true that we cannot always rely on the work of past reviews. Please request a new technical review for every Sunset material. Thank you.

John Foster: Thank you. Question? Alright. Thank you very much.

Jonathan Ashe: Thank you.

John Foster: Next up, we have Charlotte Vallaey's and last commenter will be Kim Dietz after this.

Charlotte Vallaey's: Thank you. My name is Charlotte Vallaey's. I am Director of Farm and Food Policy at the Cornucopia Institute. Thank you, Board members. Welcome to the new Board members. Thanks for your hard work on these very important issues. The Cornucopia Institute has approximately 7500 members, with certified organic farmers as our primary constituency. We feel very fortunate that a number of our members including organic farmers living in or near Albuquerque were able to be at this meeting to present testimony. I would like to speak about carrageenan. I wish I also had time to comment on inositol and choline, agar agar but I will focus my three minutes on carrageenan. The human health concerns in foods from car-, from carrageenan are so serious, according to

the preponderance of scientific evidence, that I urge you to make your decision based on the law, and on the scientific evidence presented to you in written and oral testimony. The law states that the National List may provide for the use of substances in an organic handling operation that are otherwise prohibited only if the use of such substance, substances would not be harmful to human health. The International Agency for Research on Cancer has classified degraded or low molecular weight carrageenan a List 2B, as a possible human carcinogen based on the fact that it is a carcinogen in animal studies. The European Union determined in 2003 that no more than 5 percent of food grade carrageenan should contain the low molecular weight, less than 50,000 daltons. The industry then tested their own product, products to determine if they could meet that standard. They found that first of all, and I have copies, which the previous presenter mentioned as well, I have copies of the study he mentioned for, for everybody. They found first of all that they were not able to reliably test. Second, they found levels ranging from a very low percentage, but ranging all the way up to 25%. I repeat, the industry's own data show that degraded carrageenan, a classified possible human carcinogen was found in every sample that they tested. We are also very grateful that Doctor Tobacman travelled here at our invitation, but at her own personal expense to present her research to you. As the leading physician scientist who has devoted the last two decades of her professional career to studying the effects of food grade carrageenan, we urge you to consider her testimony and expertise when you make your decision as to whether carrageenan, any carrageenan, fits the law's criteria and is safe for human health. And I will end right there.

John Foster: Thank you. Do we have a question? Nick.

Nick Maravell: And, John, I may very likely have one follow-up question as well.

John Foster: Thanks for the heads up.

Nick Maravell: Charlotte, what, in your opinion, based on your investigation, what information would satisfy you that carrageenan was indeed safe to use and, and I will just make up an example. If independent studies showed that the use of, of food grade carrageenan was essentially of the high molecular weight, a very low percentage of the low molecular weight carrageenan – I am just making that as an example; I am not trying to put that into your lexicon – but I am just saying, could you, could you give us an example of what information you think that we should have available to us before we would allow carrageenan on the National, continue to be on the National List?

Charlotte Vallaeys: Right, well I personally, I, I buy organic food because I am looking for a safe alternative. I, I, I also really believe in the precautionary principle and I would... When I look at the science, even if the science is mixed, so Doctor Tobacman's research, independently funded, shows she has determined the pathways by which this causes inflammation so you have that, that research. If there is research showing that, coming to conclusion that there are no human health impacts, that, that is a mixed research and I would hope that the precautionary principle would be guiding the decision in determining

whether something would be safe in, in organic, in food, and all food. Does that answer your question?

Nick Maravell: Well, yes. Let me follow-up with the, the precautionary principle, which is something that is, is more predominant in Europe, than in the United States with regard to how we evaluate environmental and food safety issues. What is the status of carrageenan in, in Europe and I know we have, we have heard some of the European studies and, and limitations on infant formula, etc.? What is the general condition of the allowance of, of carrageenan in, in Europe where there is more acceptance, I do not know total acceptance, but more acceptance of the precautionary principle?

Charlotte Vallaeys: I, I do not know the current status. All I know is that when the European Commission's Scientific Committee on Food reviewed the scientific data on carrageenan, that they did say no more than 5% of degraded, less than 50,000 daltons molecular weight carrageenan in the food and that is what prompted this industry testing of which I have copies of in which the, they were trying to figure out if they could meet that standard and, and that is where they found that they were not even able to really reliably measure. So, I, I, but I do not know where they are right now in the European Union.

John Foster: Thank you. Okay. Did you want to [inaudible]?

Nick Maravell: But if we, if that standard were met, would that satisfy the concerns of Cornucopia here in the United States?

Charlotte Vallaeys: Oh, no, I mean I, I believe in the Delaney Clause. Zero percent carcinogens should be the acceptable limit in our food. I, I do not think 5 percent. When you are talking about a possible human carcinogen, I do not think 5 percent is, is an adequate limit. I think it, it should be zero percent.

John Foster: Thank you. Mac.

Mac Stone: As an organic food buyer, what foods do you wish you could buy organically that have carrageenan in them and you cannot buy or you choose not to?

Charlotte Vallaeys: It is interesting that you should ask that. I actually have to avoid carrageenan in my diet. I am, I am one of those people who unfortunately experiences very serious gastrointestinal symptoms to carrageenan and it took me years to figure it out. And, and I am actually grateful for the organic program because it is, it is only now that I have really been able to confirm that it is carrageenan that has caused these symptoms. So, yes, I have been avoiding carrageenan. And, and it, it appears that from previous comments, that ultra-pasteurized whipping cream, chocolate milk, are, are some foods but again, it is not just me, because I actually experience the symptoms, I am aware of them very much but also, for my children, if I had to choose between a chocolate milk that I had to shake in order to get the cocoa particles to be evenly distributed again or, or knowing that I was giving them something that has perfect texture and good mouth feel but was causing them

potential harm, I, I personally would I mean obviously choose the kind without the carrageenan.

Mac Stone: Thank you.

John Foster: Colehour.

Colehour Bondera: Yes, thank you and thank you for your testimony, Charlotte. You just said something that I, I am not quite sure, I made myself some notes and I am not quite sure I have this straight, but that whole, like it is not health, the dietary issue of reacting, and adverse reactions, and I am just wondering through what sounded like you have done at the beginning, you, you made it sound like you have researched this and I am just wondering if there are outside of your own personal experience, if you have documented cases of adverse reactions to carrageenan that it sounds like you, you made it sound like you are an example in experience but, can you take that any further in terms of, you know, is there science, literature and cases a-, around that?

Charlotte Vallaeys: Yes, well interestingly, there was one comment, written comment, which is from another individual who also, like me and many others, exp-, actually notices the gastrointestinal inflammation from eating carrageenan and, and he made it sound as if he was a unique individual and in experiencing those symptoms. And he actually cited a study and I went and I looked up that study and it was a 26-year-old woman and – this is in a peer-reviewed published journal – I actually do not remember the exact journal name – but it was the case of a 26-year-old woman who experienced serious gastrointestinal symptoms that led to invasive procedures. And, and the study noted that her symptoms went away after she eliminated carrageenan from her diet. So there is a document, I mean, that is a documented case but, you know, I will document my case right here. I will say it on the record. And I, I am also very aware of online forums. If you Google carrageenan and gastroin-, gastrointestinal symptoms, you will find many online forums of people who have noticed that if they remove carrageenan from their diets, symptoms that sometimes they have been living with for years, disappear. So ...

John Foster: Thank you. We have one more question. Tracy.

Tracy Favre: Would you advocate removing products from the marketplace that provoke inflammatory response in other types of foods and other types of ingredients?

Comment [JMS35]: 08:45:00

Charlotte Vallaeys: I, I think that with carrageenan, the inflammation, some people notice it. I do. I asked Doctor Tobacman, you know, why, why do I experience it and, and not others and she has an explanation for that. But what she has shown in her research is that everybody experiences the inflammation. It is just a matter of whether you are aware of it and it has to do with maybe the gut flora, but that, so her research has shown that it, it does cause the inflammation. You may just not know about it and therefore, it is, it is different from being an allergic reaction. Because I understand the argument, well we are not removing organic peanuts from the marketplace because some people are allergic to peanuts. I think this is a very different, a different situation.

John Foster: Alright. Zea, drop dead last question.

Zea Sonnabend: Thank you. You and your team of lobbyists keep referring to a preponderance of data. The three reviews that I cited had 157 citations by 100 different authors approximately of which you cited some of the same ones in yours, about maybe 20 and selected different parts of them to put in your review, but I, with about 40 citations. I just do not see how you can say a preponderance of data when the vast majority of those studies in the reviews I cited had opinions that disagreed with your opinion. What is your response to that?

Charlotte Vallaeys: Yes, well I think it is interesting to look at who fund, who funded those review studies.

Zea Sonnabend: A hundred of them?

Charlotte Vallaeys: The review studies.

Zea Sonnabend: But they cited other studies. That, those are the citations I am referring to.

Charlotte Vallaeys: Right, so I, I mean I can give you one example. When the Marinalg Working Group put their findings, their position paper on the safety of carrageenan on their website, for example, they cited a study which was their way of saying look, the, it is safe. And they cited the study. When you actually went to the study, they did find higher rates of cancer. They just had a different conclusion. If you, so there are different ways of, of taking the data and, and I am sorry to say, but sometimes twisting it. And that is why I do think it is important to look at who cites, who funds the studies that you are looking at and also to look at, at, well I will end it right there.

Zea Sonnabend: Thank you.

John Foster: Thanks. That is it. Thank you. Last speaker, Kim Dietz.

Kim Dietz: Last but not least. I am the least. I think I am the last of the whole session, right? Okay. Good afternoon. My name is Kim Dietz and I served on the NOSB from 2000 to 2005 as handler representative. I am the founder and co-chair of Materials Working Group. My employer is James Smucker Company and I have worked for them for 28 years. I have been an active stakeholder in this industry for about 25 of those. Today I am here to provide comments, personally, as a materials expert and secondly, on behalf of my employer. Smuckers would like to support the continued use of cellulose and carrageenan. I was on the NOSB when of cellulose was reviewed and agree with the Program's interpretation that the intent was for powdered cellulose. Therefore I support an annotation change for the powdered form for use as a filtering aid. Excuse my laptop but I did not plan on giving public comment. But I felt that was necessary today. Carrageenan: Smuckers uses carrageenan in a blend, a blend of four gums. One gum is organic and the other three are on the National List. Carrageenan provides a specific



functional effect and there are no organic or conventional alternatives. The percentage of gums including carrageenan in our finished product is 0.073. Yes, it is labeled on the product. The criteria for removal of a substance, of a material during Sunset is that it must be demonstrated that a substance is harmful to health. I am not convinced that approximately 0.0025 percent of carrageenan in a bottle of organic juice is harmful to health. Most likely, we would not be able to purchase that blend of gums without carrageenan. As Board members, it is your job to use the facts presented to you. At the end of the day, if there is not absolute evidence that you should discontinue, that you should not disrupt this industry and remove a material during the Sunset process. Personal comment: Lastly, I want to remind this Board and the public that, as consumers, we have a choice in purchasing organic products. We have three labels, 100% organic, organic, and made with. If the consumer wants to purchase products without any substances on the National List, then they should purchase the 100% organic label. If you would like to ask me about my role with the Materials Working Group, I would be happy to answer that.

John Foster: Thank you. Nick, Jay and then Joe.

Nick Maravell: Do you have any products under the 100% label, that you market under the 100% label?

Kim Dietz: We had two products, 100% lemon and lime but with the processing aid change, we took those off. We, no, we do not. It is, it is pretty much impossible.

John Foster: Jay.

Jay Feldman: Thanks, Kim, for testifying. I know you did not have stage fright.

Kim Dietz: I know, well I do, actually. I hate to do this but that is okay.

Jay Feldman: Well, thank you. I, I am struggling with a couple of things. One thing I am struggling with is, eating ice cream one day, I looked at the container after having read all the great work of the Handling Committee, and I noticed that my favorite ice cream had carrageenan in it. And then I went to one of my favorite grocery stores and I looked in the fresh, in the freezer and I picked out another one of my favorite ice creams and it did not have any carrageenan. So I said to myself, is this necessary? And then I had the opportunity to read the public statements and a couple of companies indicated the necessity, the essentiality of this material in certain products. And I am trying to still get a handle on what those are because certainly I do not, I, I hope everyone in this room would agree that we can take the non-essential stuff off the table right at the get-go. And then we move to how we move away from something that has uncertainty. I may differ with you here, and I, this is where I wanted to see if we could get your help. Both on the issue of, you know, uncertainty when there is uncertain science, is organic not a place where people can go until certainty is found? Certainty on the side of safety and health, is that not a valid, given that you were on the Board, and is that not a valid position to take on this Board? And can we come up with a list of where, you know, there really are no

other alternatives to this, to this material? And then tell us about the Materials Working Group.

Kim Dietz: Okay, thank you. Well, first of all, when you review materials, you know, you have to go through the list of all of the different criteria. And it is not that you must meet one or two or three, you have to look at all the criteria in a whole and decide whether or not that is something that is the best choice. So you have to make that choice. That is how I did it as a Board member. The essentiality of it, Jay, you know, yes, you, you could probably make ice cream – we do not make ice cream – but for us, for juice, if we did not have that specific gum in our products, they would totally separate and float. And it, it is, just the consumer would not buy it and at least that is my opinion, and we would probably most likely not market that juice. So that, that is my response to that. Material, was there another question or you want me to ...?

John Foster: Continue. Continue.

Kim Dietz: Oh, okay. So the Material Working Group: I know that there was some discussion about what our specific role was with the NOSB, so I want to just provide you with that. We, I founded the Materials Working Group after my role on the Board, so that the history of materials would not be lost, so that we could give, provide to you, as current Board members, the history of how things, how things were reviewed and so that we had consistency, year to year to year to year. So we were not a formal NOSB task force. What we were was a separate group, independent, anybody could join as Zea had said and we were given special time on the agenda as presenters. So you have a policy in your handbook, I believe it is still there, that, where you could invite presenters. So we were invited as presenters during the materials review process and we gave you our technical information. We would be happy to serve in any function, whatever you see fit. Thank you.

John Foster: Thank you. I had Joe next. I actually had Joe next in line.

Joe Dickson: Going back to cellulose, you said you would support an annotation restricting it to the powdered form?

Kim Dietz: Yeah, I kind of, kind of took what you had, but yeah I think we, I would definitely support it. That was the intent when I was on the Board and I also downloaded our spec sheet this morning just to try to make sure that I could craft something correctly. I think really all you need to do is add the word powdered right before non-chlorine bleached and as a filtering agent and that would work.

Joe Dickson: So, if it read, and let me try like this on here, if it said cellulose for use in regenerative casings, powdered cellulose as an anti-caking agent non-chlorine bleached et cetera?

Kim Dietz: Well we, we actually use cellulose as a filtering aid so ...

Joe Dickson: Right.

Kim Dietz: ... yeah,

Joe Dickson: Well, yeah, that is ...

Kim Dietz: ... either, either, yeah, so if it was before, it would be fine.

Joe Dickson: Okay. Thank you.

John Foster: And, Zea, I saw your hand up at the last minute. Did you get what you needed?

Kim Dietz: Okay. Good luck, thank you.

Crowd: [Laughs]

John Foster: Thank you. [Laughs] Thank you. Do not quite know how to take that. So, we are considerably behind schedule. Barry and I conferred and we are going to try and get a few of the Handling materials through the next step, recognizing they are not all going to get done. He and I kind of took a barometer and we feel like the Board has probably got a half an hour left in it, gas in the tank, today and so we are going to try to get done what we can in the next half hour. Be, because of that, I do not think, we are not going to be able to cover the materials in sequence. My suggestion, Barry concurred, was to try and move through, huh-huh-huh, hopefully the less contentious things today, right now, see what we can get through and the rest will, of course, be need to be moved to tomorrow. So, Miles, your question earlier of what we are going to do tomorrow, I, I think we have it figured out now.

So, my, my suggestion is that we try and get curry leaf and citrus hystrix worked on right now. They seem to be less contentious, anyway I can only hope and we will get as far as we can on those. Now, this is the part where we are moving into a new, a new kind of a phase in the, in the format where it comes to, that I am going to need help with. And, and actually, this is why I wanted a break before this too but we will do the best we can. I need help knowing now if, how, what the process needs to be. Is Barry going to call on me to present materials or do I do that myself? And I do not think we worked that out ahead of time.

Barry Flamm: You want to go directly to motions on these, on, on the ones that are easy? And then have discussion afterwards?

John Foster: We can, we can. Yeah. Okay. Program okay with that? Oh, okay.

Barry Flamm: So you, you need to tell me which, which are the easy ones you want.

John Foster: Well, I thought we would, curry leaf first. Cur, curry leaf first and then citrus hystrix.

Barry Flamm: Okay. Do we, do we have a motion on, on curry leaf?

John Foster: Yes we do. Let me find it. We, we would be making two motions here and actually there, there needs to be a correction on here that the motion to determine the substance is agricultural. This was an error that we had. So the first motion, the, I, I would move that we determine curry leaf as petitioned to be agricultural. Is there a second?

Tracy Favre: I will second.

Barry Flamm: Is there a second to the motion?

Barry Flamm: Tracy seconds.

John Foster: And Tracy seconded. Discussion?

Barry Flamm: Discussion on the motion to, to consider curry leaf an agricultural product. There being no, no questions, no discussion, we will begin the, the voting.

Comment [JMS36]: 09:00:00

Zea Sonnabend: Conflict of interest.

Barry Flamm: Conflict of interest. Thank you. My note, right in front of my nose but... Anybody have a con- ... I would like to just, can, is it possible to group these? Or do you think each one has an individual potential conflict of interest? I do not want to take too much time. I, I will just proceed with this one and ... Conflict of interest, Zea?

Zea Sonnabend: I work for a certifier which has growers who grow this product as well as every other product, or have, use it as an ingredient in every other product in the Handling Committee agenda today.

Barry Flamm: Okay. So you are either [inaudible]...

Zea Sonnabend: Should I recuse myself? I do not feel the need to recuse myself.

Barry Flamm: I am sorry?

Zea Sonnabend: I do not feel the need to recuse myself but Miles has to say.

Miles McEvoy: No, you do not need to recuse yourself.

Zea Sonnabend: Thank you.

Barry Flamm: Alright. Anybody else have a con-, concern over conflict of interest? I will look down. Jennifer, I do not want to forget you.

Unknown Male: He cannot see you.

Jennifer Taylor: I beg your pardon? No. I am, I am fine.

Barry Flamm: Do you have a conflict of interest?

Jennifer Taylor: Oh, no.

Barry Flamm: Okay, we will proceed with the, with the voting with Jean.

Jean Richardson: Yes.

The Entire NOSB Board: Yes. Yes, sir. Yes. Yes. Yes.

Jennifer Taylor: It is me? Oh. I am already on. No.

Barry Flamm: Remember the, the motion is on whether this is an agriculture, this is agriculture or not agriculture.

Jennifer Taylor: Oh, okay.

Barry Flamm: So you, you voted that it is not agriculture.

Jennifer Taylor: Oh, okay.

Unknown Male: [Inaudible]

Jennifer Taylor: I will change my vote to yes, please.

Barry Flamm: Jay.

Jay Feldman: Yes.

The Entire NOSB Board: Yes. Yes. Yes. Yes. Yes. Yes.

Barry Flamm: Oh, you already voted, did not you? And me, yes. Chair votes, yes.

Unknown Female: Okay.

Barry Flamm: Lost track of vote. Okay, do we, do we have a motion on, on listing?

John Foster: Yes, we have a listing motion. I move that to add *Murraya koenigii*, parenthetically curry leaves, to section 205.606 not organically produced agricultural products allowed as ingredients in or on processed product labeled as organic.

Barry Flamm: Very good, John. Do we have a second?

Unknown Male: I will second.

Barry Flamm: We have a, a motion and it has been seconded to list curry leaf, and I will not even try to say what John said. I will ask again is there conflict of interest? But have we cleared ...

Zea Sonnabend: Should I repeat mine for each vote we take?

Miles McEvoy: You do not need to do that again for the same substance.

Zea Sonnabend: Okay.

Barry Flamm: Okay. That is what I was hoping the answer was. Any, any other conflict of interest? Hearing none, start with Harold.

Harold Austin: Yes.

The Entire NOSB Board: Yes, sir. Yes. No. Yes. No. Yes. Abstain. Yes. Yes. Yes. Yes. Yes. Yes. Yes.

Barry Flamm: And the Chair votes yes. Let us see the count.

Unknown Female: Two no, one abstain.

Unknown Males: Yeah. Yeah. Twelve yeses. Twelve yeses. Twelve yes, two no.

Barry Flamm: The motion carries. I want to make sure of the vote count. What is it again?

Unknown Male: 12, and 2, and 1.

Barry Flamm: Twelve yeses; two noes; one abstention. It was, John, which is the next one you want to bring up?

John Foster: Next one would be on the petition for citrus hystrix leaves and fruit.

Barry Flamm: You want to make a motion?

John Foster: Do as a classification motion. I move to determine the substance is agricultural.

Barry Flamm: Do we have a second?

Jean Richardson: I second.

Barry Flamm: Jean seconds. We have the, the motion and the motion has been seconded to, to classify citrus hystrix as a, as agriculture product. Any discussion? Okay. We will begin, begin the voting.

Zea Sonnabend: Conflict of interest again. Do we, did it cover it for every item or do I have to repeat it again?

Unknown Persons: No. No. You are already covered. No.

Zea Sonnabend: Yes?

Barry Flamm: We are not going to repeat for you again.

Zea Sonnabend: You have to have the requirement, though.

Barry Flamm: You are covered. But does anybody else have a conflict of interest?

Miles McEvoy: You, you are doing it for each substance, so you are doing it each time, so you disclose that you have the conflict?

Zea Sonnabend: Every single time.

Miles McEvoy: Or you have to, [inaudible]

Zea Sonnabend: I cannot do it once for all the handling Committee items on our agenda that I ...

Miles McEvoy: So for every single one.

Barry Flamm: Yeah, I thought we...

Miles McEvoy: Yeah, you can disclosure interest and it is the same interest, correct? So you do not need to recuse yourself.

Zea Sonnabend: Thank you.

Barry Flamm: So you are clear. And that was my understanding before, that that was your decision. But, but that does not apply to the others. So I should ask the question. Hearing none, I think we can proceed with voting.

The Entire NOSB Board: Yes, sir. Yes. Yes. Yes.

Unknown Male: This is to classify.

Jennifer Taylor: Yes.

The Entire NOSB Board: Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes.

Barry Flamm: Yes.

Unknown Male: Fifteen-oh.

Barry Flamm: Fifteen yes. Zero no. The motion passes. What is the next, John? Oh, no, we are still on this one.

Unknown Male: We need a listing...

Barry Flamm: We need a motion now to list.

John Foster: So I will move to add citrus hystrix leaves and fruit to section 205.606 not organically produced agricultural products allowed as ingredients in or on processed products labeled as organic.

Barry Flamm: Do we have a second?

Harold Austin: Second.

Unknown Male: Second.

Barry Flamm: Harold second. And we, we have a motion and it has been seconded to list citrus hystrix on the, on the List. Okay. This is somewhat redundant to ask on the same product twice, but I will ask if there is any conflict again.

Zea Sonnabend: I think Miles said you only have to do it once per product.

Barry Flamm: Yeah, I would think so. I will not do it again on the next one.

Unknown Male: [Inaudible]

Barry Flamm: Okay. I think, is there any discussion? Any discuss, any discussion on the motion? Hearing, hearing none, we will move to the vote beginning with Wendy.

Wendy Fulwider: Yes.

The Entire NOSB Board: No. Yes. No. Yes. Abstain. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes, sir.

Barry Flamm: Yes. Have, I believe...

Unknown Male: 12, 2 and 1 abstention.

Barry Flamm: Twelve, 12 yes; two noes; one abstained, one abstention. The motion passes. What next, John?

John Foster: Alright, I think we probably have room for a couple more. We are going, we are going to move to Sunset item calcium sulfate. Joe?



Joe Dickson: I move to accept the Sunset recommendation to re-list calcium sulfite, sulfate rather, mined on 205.605(a) non-synthetics allowed. Is there a second?

Jean Richardson: Second.

Unknown Female: That was Jean.

Barry Flamm: Motion, let us see, are we, no, we do not have to do the classification on that. That is right. We have a motion to re-list calcium sulfate? The motion has been seconded. Is there discussion?

Unknown Male: Jay.

Jay Feldman: I would like to move to amend the motion to include an annotation that says for use only as a coagulant in bean curd in parentheses tofu and similar products.

Barry Flamm: You are proposing an amendment to the motion?

Jay Feldman: Yes. I would need a second, I think.

Barry Flamm: Yeah, you will need a second.

Colehour Bondera: I will second that.

Barry Flamm: So we will have discussion on this amendment and the vote on it separate from the, from the, the main motion. We will, we will take care of that first. Discussion on the amend, amendment which, which has been seconded? Yes.

Joe Dickson: [Inaudible] On the proposed amendment, I just want to argue against it because the ...

Barry Flamm: Okay. No, I was going to open it for the discussion right now. Go ahead.

Joe Dickson: I am, I am okay to discuss the amendment right now. Okay, good. Just figuring this out. The version of the Sunset proposal that was posted did not include that annotation language and my fear is that there are beer brewers in particular and potentially other stakeholders who are using the ingredient and do not know that it is about to no longer be available to them if this annotation passes. So for that reason, and that group of stakeholders, I would not support that amendment.

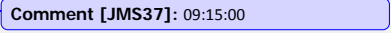
Zea Sonnabend: [Inaudible]

Barry Flamm: Zea, please.

Zea Sonnabend: Thank you. I would like to ask Jay why, like you think it will be abused in some way if it is allowed for everything?

Jay Feldman: [Sigh] Well, we, we, I thought we had an understanding that we knew the uses but this is a process issue for me. I think we do need to know uses to make a judgment on essentiality and I would hate to be in the situation, Joe, every time that we are evaluating these things where we have not involved the whole community of users on these things. We, we need to have a process that brings everybody in and they know that the material they depend on is being discussed and, and should be aware of our process enough to know that anything can happen at these meetings so, unfortunately. And that is, by the way, that is my plug for the communications policy.

Zea Sonnabend: But is there something that leads you to believe that there is concern in some uses and not others? That you would like arbitrarily pick some uses when you do not know all the uses?

Jay Feldman: Well, I, no. I mean, I ex-, we ex-, in this whole system, there, there were uses that, you know, in terms of skin irritation and I mean there are issues we could run through all the hazard issues and then there are questions of alternative management strategies or alternative materials that can be used as a coagulant for other products. So the whole goal of this program I think is to reduce to the extent possible, reliance on these things and identify where the uses are truly necessary or truly needed and then, you know, ratchet it down to the extent possible. So yeah, I mean, when I looked at this, it seemed pretty convincing to me that there are other, other uses, other coagulants that could be used in this situation. And so the one that rose to the top is the one that was both most widely used and most necessary. But I would turn that around to the com-, was this use that is being defined is tofu, but what I would do is turn around to the Committee and tell me what you found relative to the use and why we need to leave this open ended and not evaluate each of the uses that, for which this is being used. That, that is my question.  you know, I am not saying you should take me at my word on, you know, on this particular use but this is what I proposed, you know, was proposed by Beyond Pesticides early on in the process, it went to the Committee, the Committee had it, we had an opportunity to discuss whether this issue of necessity was, was not, you know, was a bogus issue or not and then my hope was that we would have had that discussion and then we would come to this meeting and everybody would have been able to, to make a decision based on the criteria that, that we are supposed to be evaluating. So, again, I, I view this as somewhat of a process issue but yeah I am concerned that when we have these open-ended use, uses, that stuff happens, use happens, and expansion and goes on.

Barry Flamm: Nick?

Nick Maravell: Yes, Jay, I think you raise an important question. It, it is a broad, much broader question than this material. And I can also say that I do not think that there is a broad consensus that, you know, we are trying to move in a direction that would reduce reliance on materials on the National List. If that were true, I think we would see the National List

getting shorter and shorter. So, you know, I do not think, I think it is a good discussion to have, but I am not sure we, if, if this is the appropriate place and time to have it.

Barry Flamm: John, you want ...

John Foster: I think this is, I think this is one place where if we, if we had an unlimited time to work on things, we could have gotten to this, but I think for all the right reasons, it was not at the top of the priority list for the Handling Committee to try and deal with. There were other things that the public certainly felt were a higher priority. And, I mean, I hate to say that we, we do not have the time to deal with this, with, with everything but the truth of the matter is, we do not. None of the Committees do. So I think it, if anything, it was a little more priorities and I do not want to speak for the rest of the Handling Committee but I think we prioritized the best we could.

Unknown Male: [Inaudible] table coagulants was presented in the testimony [inaudible]

Barry Flamm: Zea and then I will since I will give the proposer of the movement, motion the last word and then will, I will call for a, and we will have a vote.

Zea Sonnabend: I just want to say that while I somewhat agree with you on synthetics in processing, this is a non-synthetics in processing and everything in the Rule does not lead us to a great deal of concern about non-synthetics in processing.

Jay Feldman: [Sigh] I just, I just hope ...

Barry Flamm: Last word.

Jay Feldman: In, in the spirit of what you said, Nick, I, I really hope we can get a process that enables us to say to our community, we have evaluated these things, the uses, and we made a determination that these things are acceptable. I, I also do not like blind siding users of materials that people have come to depend on and in that spirit, I will vote for the motion but I, I really think we need a process that clearly evaluates these things, on use basis-es. That is only basis on which we can make a determination.

Unknown Male: Thank you.

Barry Flamm: Did I, I am sorry, Jay, did you make ...

Jay Feldman: I withdraw my motion if Colehour agrees to that.

Colehour Bondera: I agree.

Barry Flamm: Okay, I guess we are... Are we ready to vote on the ...? We have a, a motion that has been seconded to, to list calcium sulfate. Is there any further, is there discussion on

the motion on the, on the floor? Question on the floor? Hearing none, we will begin the vote with, with Colehour.

Colehour Bondera: Yes.

The Entire NOSB Board: Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes, sir. Yes.

Barry Flamm: Chair votes yes. Fifteen yes; zero no.

Miles McEvoy: Conflict of interest was missed.

Barry Flamm: Sorry?

Unknown Males: Conflict of interest [inaudible]

Barry Flamm: We did it way back.

Unknown Persons: No.

Barry Flamm: Did not we?

Miles McEvoy: No. You did it for the two other substances. You did not have disclosure of interest for this particular substance.

Barry Flamm: I thought we, so much time passed, I thought we already did it. Is there a conflict of interest? You are excluded I think, Zea, by...

Zea Sonnabend: I have actually no idea if this is in anything from CCUF. The other things I knew, but I work for a certifier that may or may not certify products with this in it.

Miles McEvoy: Is that it? Okay.

Barry Flamm: Yeah, that is it. So it is ...

Miles McEvoy: No recusal necessary.

Nick Maravell: Barry, I have a question.

Barry Flamm: Yes.

Nick Maravell: Just, just out of curiosity, I thought our Policy and Procedures Manual, or maybe it does not say this, says it is the responsibility of Board members to bring forth their potential conflict of interest, does, does that mean we cannot rely upon the good faith of the Board members but we do have to seek it every single time?

Miles McEvoy: Yeah, the, the process has been that before every substance is voted on, that the, the Chair ask that question, are there any interests that need to be disclosed, any conflicts, anybody want to recuse themselves? So that has just been the normal process for each substance, so, you know, we are just getting started here, so get into the swing of things so we will be fine.

Barry Flamm: Okay, bec-, I do not know if I gave the results yet, but it is, I will repeat it in any case, it is 15 yes. Zero no. The motion passes to list calcium sulfate. John, we going to try one more?

John Foster: We are going to try for one more.

Barry Flamm: Pick an easy one.

John Foster: We are going to try for glucono delta-lactone, another Sunset proposal. This is glucono delta-lactone on 205.605(a). Joe.

Joe Dickson: I move to accept the Handling Committee's Sunset proposal to re-list glucono delta-lactone production by the oxidation of d-glucose with bromine water is prohibited to 205.605(a) non-synthetics allowed. Is there a second?

Unknown Male: I will second.

Barry Flamm: We have got a motion and, and it has been seconded to re-list, I will just say GDL. Is there a conflict of interest?

Zea Sonnabend: I have no idea but maybe. I work for a certifier that may or may not certify this.

Barry Flamm: I think you are home free.

Unknown Male: It is getting redundant.

Barry Flamm: Oh, John.

John Foster: Earthbound is getting into beverage, beverage manufacturing and we may, in the future, in the near future, use a co-packer who might use this as a, as a material.

Miles McEvoy: Okay, is that it? That is ...

John Foster: That is it.

Miles McEvoy: ...that is good.

Unknown Female: Joe, is fun party?

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Joe Dickson: For the sake of transparency, I will get on this conflict wagon. I work for a retail organization that sells products made with every single item on this agenda, if you consider that a conflict of interest.

Miles McEvoy: Thanks, Joe. In these situations, you do not, none, none of the folks that disclosed their interests need to recuse themselves.

Joe Dickson: Thank you.

Zea Sonnabend: But we still have to do this every single vote?

Miles McEvoy: That is the process that has been the standard process for materials for, for all motions is that there is that question before the final discussion and vote.

Barry Flamm: Discussion? Any discussion on this material to be re-listed? Hearing none, we will start the voting with, with Nick.

Nick Maravell: Yes.

The Entire NOSB Board: No. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes, sir. Yes. Yes.

Barry Flamm: Yes. Fourteen yeses; one no. The motion carries.

John Foster: Mr. Chairman, in light of the time and the kind of the sense of, of the Handling Committee, I think that we are going to wrap that up for today. We are going to need to carry over the next votes to tomorrow. This, and I would like to request that the Handling Committee have a quick, a quick meeting in preparation for that to my right after this. That is all we are ready to do.

Barry Flamm: I have an announcement to make. The New Mexico Department of Agriculture Organic Program reception has been moved to Salon E.

Unknown Male: To what?

Barry Flamm: Salon E. I guess that is a room or a conference room.

Unknown Male: Yeah, thank you.

Barry Flamm: And the time is the same as the invitation, 5:30 to 7:30.

Unknown Male: 5:30. That is in three minutes.

Barry Flamm: We will recess until tomorrow morning at 8:00.

[Event concluded] (End )

Meeting Of The National Organic Standards Board  
May 25, 2012

**United States Department of Agriculture  
Agriculture Marketing Service (AMS)  
National Organic Program (NOP)**

**Meeting Of The National Organic Standards Board (NOSB)**

**May 25, 2012**

Hotel Albuquerque Old Town  
800 Rio Grande Boulevard NW  
Albuquerque, NM 87104

The National Organic Standards Board convened at 8:00 a.m. with Barry Flamm, Chairperson, presiding.

**Members Present**

Barry Flamm, Chairperson  
Harold Austin  
Carmela Beck  
Colehour Bondera  
Joe Dickson  
Tracy Favre  
Jay Feldman  
John Foster  
Wendy Fulwider  
Nick Maravell  
Jean Richardson  
Zea Sonnabend  
Robert "Mac" Stone  
Jennifer Taylor  
Calvin Reuben Walker

**National Organic Program Staff**

Miles McEvoy, Deputy Administrator  
Melissa Bailey, Director, Standards Division  
Dr. Lisa Brines, National List Manager  
Emily Brown-Rosen, Agricultural Marketing Specialist, Standards Division  
Michelle Arsenaault, NOS Advisory Board Specialist

\*\*Please note that this transcript may contain errors or omissions and does not represent an official record of all proceedings that took place on May 25. Please refer to the live webcast for a more accurate representation of the meeting.

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Comment [JMS1]: 00:41:10

Barry Flamm: Board members, please take your seat. The NOSB Board meeting is back in session. Good morning.

The Entire NOSB and Crowd: Good morning.

Barry Flamm: We have an incredibly busy morning this morning. And I am going to give you the agenda for this morning. From 8 o'clock to 8:15, Livestock will present a proposal which will require voting. From 8:15 to 8:30, the Policy Development Committee will make their report. From 8:30, 8:45, the Handling Committee has requested a, a brief period where they can huddle and get together for, for their presentations this morning. It will be, then, the Handling Committee for the rest of the morning until 11:30, with the, with their Sunset and petition items. At 11:30 to 12 o'clock, is work plans will be presented. Each Committee will be allowed three minutes to present their work plans for, for the next fall and spring. And, and this meeting will end at 12 o'clock according to the official agenda. So, if the Livestock Committee will proceed? Wendy, please?

Wendy Fulwider: Thank you, Barry. I would like to refresh everyone's memory as to the Livestock [inaudible]

Unknown Female: Mic.

Wendy Fulwider: Sorry. Thank you, Barry. I would like to refresh everyone's memory as to the Livestock Committee's discussions on Wednesday. And as a result of public comment, the Livestock Commit-, Subcommittee would like to, more information to move forward with our work on the GMO vaccines. We would like to make a request to the Program and Secretary to get the information that we need. Nick, would you please present the document?

Nick Maravell: Well, I will, I will present what I have. But, my, I cannot seem to connect to the Internet, so I do not have the document, so bear with me. Given the full way of public comment, we felt we had a very constructive discussion here about the use of GMO vaccines in livestock production. And, we feel that we need more solid information in going, in order to go forward. And, we are proposing a resolution of this Board to send our request to the Program, to basically do three things.

The first thing is to establish a list that would be specific to pathogens by strain, and that list would make reference to the known registered vaccines. And, that list would include an indication of which of those vaccines are produced by the definition of excluded methods, and those which do not.

We, the second thing is, we would request that there is a regular procedure to update that list. We are suggesting real-time, as it happens, as new registrations come in. So that producers, certifiers would all be able to look at one list.

Comment [JMS2]: 00:45:00

The third thing that we are requesting is to in, use the auspices of the National Organic Program to encourage vac-, vaccine manufacturers to voluntarily identify the absence of GMO technology on their vaccines. So, in other words, if you were to buy one at a livestock supply store, it might say, produced without GMO technology or without excluded methods or something. But, this would be encouragement and it would be voluntary and it would not be anything that would be required. But, it would be verifiable, because certifiers could verify, indeed, this is a truthful label claim, because I can go to the accessible list.

And, the fi-, last thing, that we, what we have said, is that we are going to continue to work on a list of questions, some of which have already been posted on the NOP website, that would better inform the policy making on the use of GMO vaccines in livestock production. And, we, we are going to refine that list, accept additional comment on that list of questions. And work with the Program to see how it might be possible to get that information that might be useful for the community, and, and for the NOSB to make policy in this one area of GMO vaccines.

So, that is the essence, and it, it looks like -- oh, and we are requesting ... Thank you. Wendy, it is up on the screen. Okay. We are also requesting that at the next meeting in Providence, and the next spring meeting, that we revisit this issue, and get a, basically, an update. And, and we may also put out something in the Federal Register during the meeting agenda to, to indicate that we might want additional input on specific questions as we move forward on this. Do I? Okay.

So, I would make a motion that we pass a resolution of the Board, addressed to the National Organic Standards, National Organic Program as outlined in the document that is on the screen which was approved unanimously after taking into account all concerns that we were able to, legitimate concerns we were able to identify, so approved unanimously by the Livestock Committee. So, I move that we adopt that and forward that resolution to the National Organic Program.

Barry Flamm: Do we have a second?

Wendy Fulwider: I second that.

Barry Flamm: It has been moved and seconded, the, the Livestock Committee resolution, which you see shown on the Board, be adopted. Is there any conflict of interest? Hearing none, we will proceed with voting, Jennifer leading off. Jennifer.

Jennifer Taylor: Yes.

The Entire NOSB Board: Yes. Abstain. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes, sir. Yes. Yes. Yes.

Barry Flamm: The chair votes yes. Four, 14 yes, zero noes, and one abstention. Thank you, Livestock Committee. We will proceed to Policy Development Committee report.

Unknown Female: Barry.

Barry Flamm: The Program has a comment to make.

Miles McEvoy: Yes, the NOP welcomes the resolution. We will evaluate the resolution and respond back to the Board with a full response. We will explore the concept of developing a GMO Vaccine Working Group consisting of NOSB Board members, NOP, APHIS, and other relevant technical experts. So thank you very much for this work and we look forward to continuing to work on this issue with the Board.

Barry Flamm: Thank you for those comments. Colehour, would you proceed?

Colehour Bondera: Very good. Thank you. Speaking to you as the Chair of the Policy Development Committee, and I have two things I would like to do in a short amount of time. And actually, it will only take a very short amount of time, to be frank. The first one I want to do is to withdraw the three proposed recommendations that were put forth at this point in time, given the fact that, to be frank, we are out of time. So, that said ...

Barry Flamm: Before you move on to the next point, without objection, the Policy Committee's request to withdraw their prop-, three proposals is accepted. Continue, Colehour.

Colehour Bondera: Thank you, Mr. Chair. I, I, after meeting with the Policy Development Committee and discussing with other Board members, I am prepared to, and would like to make a statement from the Policy Development Committee to enable our efforts to move forward more smoothly and functionally in the future. And, the statement is on the screen. Our Committee hereby requests complete written communication from the National Organic Program regarding how FACA informs our policy efforts.

And, we have kept that fairly simple and straightforward. And, we are not, you know, thinking or wanting there to be any difficulty in this. Instead, we would just like something written in our hands that we can reference, so we know what process is going to be occurring. Because, several people, at least, have felt that the un-clarity of what things are going to be happening at what stages has led to the, the place we are at where we have resulted in withdrawing the recommendations that we have worked on this session. So, that is the request we have made. I do not know if the National Organic Program needs to or would like to respond right now. And I understand either way, but, but that is what I would like to put the table. Thank you.

Miles McEvoy: Yeah, that is fine by us. And we look forward to providing more specific information and collaborating with the Policy Development Subcommittee.

Barry Flamm: Thank you. With that, we will... Oh, Zea, you have a question?

Zea Sonnabend: My question is just of concern over the portion of the recommendations about having a public docket open between meetings. And I am wondering if maybe, since I do not think that is the convert-, controversial part of the recommendation, if the Department could explore that in between this meeting and the next meeting without having a motion on it?

Miles McEvoy: Yeah, we are already exploring that option and looking at ways that we can make that happen.

Zea Sonnabend: Thank you.

Barry Flamm: Okay, at the request of the, the Handling Committee, we will, we will break for 15 minutes while they huddle, have a word, and then, we will get, we will return and, and proceed with the formal presentations of the Sunset items.

BREAK

Comment [JMS3]: 00:54:05

Comment [JMS4]: 01:16:47

Barry Flamm: Board meeting is back in session. The Handling Committee will continue, please. John.

John Foster: Thank you, Barry. We will continue – [cough] sorry – we will continue with handling materials, picking up from yesterday. We have six materials to, to vote on today. We have a hard stop at 11:30. The Committee work has a hard stop at 11:30, so we are going to correct, re-prioritize, make sure that we can get to Sunset first. And then we will do petitioned items. We will start off the motions with carrageenan. Carrageenan.

Barry Flamm: Is there a motion on Carrageenan?

Joe Dickson: I move, I move that we accept the Handling Committee's recommendation. I will read it as it has been modified. At this time, we would recommend the re-listing of carrageenan on the National List 205.605, non-agricultural non-organic substances

allowed as ingredients in or on processed products labeled as organic or made with organic specified ingredients or food group or groups. We recommend re-listing under 605(a), non-synthetics allowed.

We would also include the following two annotations. The first annotation, only carrageenan that is in one of the following four CAS numbers will be allowed for use as a food additive: 9000-07-1 (general), 9062-07-1 (Iota), 11114-20-8 (Kappa), and finally 9064-57-7 (Lambda). All other CAS numbers would not be recommended for use in food production as an ingredient or otherwise.

The second annotation, carrageenan would not be allowed for use in infant formulas. We would also recommend that the listing be revisited once the NOP has finalized the draft guidance submitted by the NOSB on November 5, 2009. Re-evaluation of the materials classification, agricultural, non-agricultural, synthetic, non-synthetic should be considered to ensure that the listed material has been properly classified and thus remove any further confusion from its status thus helping to, to, during future reviews.

Barry Flamm: Is there a second?

Unknown Female: Second.

Barry Flamm: The motion to re-list carrageenan has, has been seconded, and we will have discussion now. John and the Chair, Subcommittee Chair will lead the discussion.

John Foster: Alright. Other questions or discussion items? I have got Zea, then Jean. I am sorry, Zea, then Tracy.

Zea Sonnabend: Thank you. We realize that concerns have come to us about this material in the last month. And yet, we have also heard from a number of companies that these concerns are news to them, too. And, even the most highly rep-, high integrity and conscientious companies have stated that they are going to need some time to try and remove this from their products. And so, we would like to proceed with the re-listing of this, but, to put an accompanying statement somehow that says, the Board intends to explore these concerns further, and put the community on notice that we would like it to be off the List by the next Sunset period, if possible.

John Foster: Thank you, Zea. Tracy?

Tracy Favre: In an effort to make sure I understand the process for Sunset review, I have done a little exploration, including looking at the Policy and Procedures Manual on Sunset review. There is sort of a decision tree that helps us understand that process. In particular, there is three criteria for evaluating whether or not a material should come off the List. And that is, there is three. The first is whether or not it is harmful to human health and the, or the environment. Number two, it is unnecessary because of avail-, availability of alternatives. And number three, it is inconsistent with organic farming or handling. So I, I

urge all of us on the Board to keep those three criteria in mind as we are looking at evaluating whether or not to re-list this substance.

John Foster: Thank you, Tracy. Further discussion items, questions? Jay?

Jay Feldman: Thank you. And, I appreciate your comment, Zea, on, on this. In a perfect world that approach would probably work. That is, we put, to quote you, the industry on notice or manufacturers on notice. Unfortunately, having studied the history of the Board and actions on, on materials and processes that have been identified as problematic by this Board, that kind of operationalization of a, of a view, that does not seem to result, to ensure results unfortunately.

So, I believe, and that is why I have been an advocate for expiration dates, because I think it offers industry an opportunity to adjust. It creates a date certain. It establishes a decision that the industry can be sure about. There is, there is no equivocation in that. And, it allows us to meet our statutory responsibilities to take action on the material. I think the Committee made a lot of progress in, in moving this issue and being responsive to the public, and I appreciate that, in terms of amending the, the proposal that first came out of the Committee.

You know, one of the things that we have to do as a Board when we evaluate science is recognize that what decisions were based on before us may not have been, may need updating, may need to be re-evaluated, I think along the lines of what Tracy just said. It is our responsibility to re-evaluate the science and obviously that is why we get these technical evaluation reports. If you look back to the original decision and the science that supported the listing of this material, I think and we did not have a full discussion of this, but I think you will find it very unsatisfactory.

You know, one example of that is the reference to GRAS. And GRAS, we can have a day-long seminar on GRAS and issues around generally recognized as safe, and how FDA arrives at that. But the, and, and I would be happy to read to you a recent GAO report that came out last year that identifies the deficiencies in GRAS in reading, in reaching scientific determinations, in general. But, when you look at it relative to what our responsibilities are to look at adverse impacts on health and the environment, the, the process is, is wholly deficient. And, and so, you know, if you view the G, the US Government Accountability Office, an arm of Congress, as something that is useful, I think that, you know, we have to take that into account.

So, what we do with this TER, is we, we look back and we identify implicitly that the, the original scientific basis for the listing was in some way limit, limited. And, we are updating it through this TER, right? So, the TER then identifies a range of scientific opinions on these things. And this is classic. You have seen it before in your work, right? We get different opinions, scientific opinions on where, where things are at, on different opinions on what the science says, what it means, what its implications are, in terms of use.

I mean I have been dealing with this personally, professionally, on materials regarding pesticides for, for years. And I can tell you, we debated chlordane, we debated chlorpyrifos, dursban, and in every one of those situations over decades, we debated with EPA the, the science. You know, what is the science on this side? What is the science on that side? And we came to the conclusion as an organization at Beyond Pesticides that uncertainty was not in the public interest because in most of those, in virtually all of those situations where we had the science, like you know of, of independent scientists, we had industry scientists, we had academics who were supported with industry money, et cetera, et cetera. We have government money supporting other scientists, whatever it is. We have seen these wrenching debates on dis-, and discordance among in the scientific community. So what do you do with that?

Well, we turned to organic for that. That is why we got involved with organic. Because we said that, you know, this is a place, as I said yesterday, where we can eliminate uncertainty to the highest degree possible. This is not a place like the conventional food system, we believe, this is our opinion, Beyond Pesticides, where we can and should accept the degree of uncertainty on hazards.

Now where does the uncertainty come in with carrageenan? Okay, we have got, we have got the International Agency for Research on Cancer that has identified de-graded carrageenan as a carcin-, as a carcinogen. Okay, that is, in our organization, we use the International Agency for Research on Cancer historically for determinations. It is a respected international body. And, and so, the, the carcinogenicity issue seems to be a real one. I had not heard anyone during our proceedings dispute the cancer issue. Did I?

Zea Sonnabend: [Inaudible]

Jay Feldman: Okay, then you will do it in a few minutes. Okay, so anyway, you have got this, you have got this cancer finding. Now, does that apply to the, to the high molecular formula or weight formula? Or, does it only apply to the food, the food grade material? Or, does it only apply to the de-graded, and to what degree is de-graded is showing up in food grade? So in that respect, my, my sense is we have a, we have some degraded. We do not know how much that is in it, in the... We have de-graded carrageenan in the food grade. We do not know how much of the de-graded is in there. And, we do not have a proposal on the table that limits it in any way.

John Foster: Hey, Jay, can we...

Jay Feldman: Yeah.

John Foster: I want to make sure that we get a lot of other voices, too. [Inaudible]

Jay Feldman: Okay. So, so the bottom line is that if we have a carcinogen, even in percentages in five, the 5 to 10 range, we are exposing the public to a carcinogen. And, when you have a material that has a no threshold dose, no one has brought to this proceeding, because we cannot, an identification of an exposure to a carcinogen that in, that does not result in

initiating or promoting carcinogenesis. This is the, the safe place of organic. We do not bring carcinogens to the table. We do not do that. It is not a part of our ethic or our fabric.

And so, we are not even getting into the, the debate of whether somebody believes there is a, a weight of evidence that you can bring to this argument of carcinogenicity. We have elim-, we have traditionally tried to eliminate carcinogens. So then you get to the issue of necessity and, and on and on. And, and so, I think, I think we, we have a duty to reject this.

Comment [JMS5]: 01:30:00

I would like to see some sort of phase out that recognizes this caught everybody by surprise, that this was not something on the table even a year ago. And so, in good faith, I, I am, this is why I am a proponent and have been since I got on the Board, of, and in my work with EPA as well, for expiration dates. I know the Program does not like them. But, I think it, it allows us to affect a transition in an orderly way and give the industry an opportunity to retool so that we can meet the standards and feel we are doing it ex-, expeditiously in the quickest time possible.

I am looking for a compromise here, John, and I just want to, I apologize the amount of time I took. But I wanted you to understand that this is based on what I believe the history of our involvement in issues that involve carcinogens is, carcinogenesis and, and other health impacts that we heard about in terms of, of the research that was presented to us. Thank you.

John Foster: Thanks. Other comments? Harold?

Harold Austin: I think to further clarify a little bit for the comments that Jay just made.

Regarding the scientific information and re-evaluation, the data is the same flo-, the same data that has been out there since this product was originally listed. It is, the argument is still the same, being made by the same science, by the same studies, by the same author that have been continually rejected by fellow scientists and that the majority of the World Health Organizations repetitively over the last 18 years. There was nothing new that has been presented that has not already existed.

What we have done is we have researched, looked through the different testimonies, looked through the data during the review of this material. The things that have been brought to light, is that there is a distinct difference between the high molecular carrageenan, the low molecular polygeenan. There has also been reference made to the fact that there is some concerns about newborn infants up to the age of four months. We have included that. I do not think we have the expertise to take on every world health organization that is out there and **defute** [refute] what they are saying and what they are accepting. I think that is a travesty to our stakeholders.

Comment [JMS6]: Defute in the Urban Dictionary means to refute a comment in an argument in a dirty way. I do not think Harold meant to use this word.

I think we have put the consumers on notice. I think we have put the stakeholders on notice that there is an issue, a potential issue, with this material. I think we are putting in place the safeguards that are necessary to continue to allow, to allow this material to go out to our stakeholders, while at the same time, serving ner-, notice that they need to do



more in-depth research in order to make sure that we do have a material that truly is safe for the consumer. And I think if that research has not been provided to the Board by the time this comes back up for review in five years, then I think the outcomes could possibly be a totally different outcome. I really do.

But, I think, I think to allow this to go through the, the Sunset review process to, to re-list it, I think is the right move for the right reasons, knowing that we have, we have really bought a lot of materials, a lot of things out to the forefront on this issue on both sides of it. And I, I think, that is a fair evaluation as this Board, representing all stakeholders in the organic arena.

John Foster: Thank you, Harold. More discussion? Oh, Zea.

Zea Sonnabend: Okay. I just have to refute the cancer claim. What is on the AR, AI – right, okay – it is polygeenan, ten to thirty dal-, [cough] thousand daltons. I am going to read brief, I, I think there are valid concerns raised about inflammatory properties of carrageenan. The cancer studies of which there are three, on food grade carrageenan, involved injecting rats with tumor provoking chemicals and then injecting them with carrageenan, to see if they actually got to, can-, tumors from the injections. And in two of the studies, they did get tumors, and in one of the studies, they did not. But, they were injecting like 10 to 20 times the average human daily dose into rats.

So, I can read you these paragraphs from the research. But, it is absolutely unsubstantiated that eating food causes carrageenan, eating food carrageenan causes cancer. And, while I still have the mike, because you did not call on him, I am going to from the British report, which is the most recent review of literature, it says, there is one issue upon which the Committee felt further research should be undertaken. The possibility that native carrageenan could cause significant amounts of polygeenan, either by processing techniques or by acids during digestion. This is the val-, to me, this is the valid concern. The Committee suggested, if feasible, a molecular weight limit of below 5%, less than five percent below 50,000 daltons should be introduced into the specifications to ensure the presence of low molecular weight carrageenan in food is kept to a minimum. So, I, further research, that is the key point; the inflammation, the cancer, forget it.

Crowd: [Laughing]

John Foster: Yes, Jay?

Jay Feldman: Sorry, John.

John Foster: [Laugh]

Jay Feldman: I just have to say, I mean this, obviously we, again, me, we, the organization I work for, have been through these cancer debates for decades now. We do not test on humans in this country, or in most of the world. And certainly, EPA does not even accept

canc-, human studies. They will accept studies, occupational studies, from the workplace that are basically epidemiologic studies that look at exposure in different settings. They have done farmer studies. That has helped us to remove a lot of pesticides in agriculture.

But, they do not rely on those studies. They rely on animal studies. This is how we test in our modern world for adverse outcomes. And in, in the area of cancer, we test at maximum tolerated doses. Right? I mean, a lot, I am telling a lot, a lot of you know this already, and I apologize. But, I have to, I have to dispute what you are saying, Zea, because these are the protocols we utilize for classification of materials. We, we are not, not, not the classification of materials we talk about on this Board, but in terms of pointing to other institutions that identify cancer-causing chemicals, you cannot find any, with the rare exceptions, and those are the ones that we have found through epidemiologic studies, after they have been out in the market, like arsenic or arsenical materials. You cannot find any other studies except laboratory animal studies that identify carcinogen-, carcinogenesis. That is what we use in our, in our st-, in our world today.

So, when the International Agency for Research on Cancer describes its study protocol, which involves the injection of a material into the organism, that is then extrapolated and they come up with their classification, possible carcinogen, probable carcinogen, you know, the, the different classifications, based on the strength of the, of the reaction. And, that is the methodology that is used. It is used worldwide. It is accepted as a methodology. So to pull out the study design and protocol and to, to say to lay people, how could you accept a high-dose animal experiment as indication that low-dose exposure in the food supply is going to cause an effect, is, is quite outrageous, I, I must say, given that these are the protocols that are utilized worldwide in our own government to make determinations on cancer outcomes, and on other outcomes, as well.

In fact, years ago, there was an attempt to try to do low dose experimentation in laboratory animals, because again, we do not test on humans, where they set up a million control group, and a million so they could get their levels for 1 million. We look at cancer in levels of excess levels of cancer per million population. And, it was a dramatic failure. We realized we could not do that. So, we went to, we tried, gov-, you know, science tried to do that. And, it, it went to this maximum tolerated dose, high-dose exposures, low numbers of animal population, extrapolated to humans. And that is all we have got to go on. So, to dispute the science and the finding and classification of the International Agency for Research on Cancer, IR ...

Zea Sonnabend: [inaudible]

Jay Feldman: This is, this is part of the degraded, part of the degraded material that is showing up in food grade carrageenan. Unfortunately, this is a common problem where we have contaminants or we have materials, as you all know, in our ingredients that are not intended to be there. They are not purposefully added, you know, but, they show up. And unfortunately, you cannot ignore them. If we are going to do our job as a Board and we

are going to provide the public with clean food met, that is meeting a standard, this is what..., this is the rigor with which we have to look at these things.

John Foster: [Inaudible] interrupt.

Jay Feldman: Please do not dismiss findings of, of agencies that determine classification of materials.

John Foster: More voices? Alright. As they say, last call. Oh, Colehour.

Colehour Bondera: Yes, thank you, John. I, yeah, I admittedly am hesitating because I am not sure that I have something to add. But, when you said more voices, I can go ahead and add more voice. Because, I think that in my opinion, based upon what I have read and heard and as Tracy said, attempting to follow the policy that we are subject to be utilizing, my personal conclusion is, I guess along the lines of what, I think, correct me if I am wrong, but I think Zea brought up is that, you know, we need to try to address this topic by recognizing its current, it, its reality, what, where it is used and how it is used at present. But, then to try to look at, you know, maybe we should be raising the flag to this for the, from my perspective, for the various health reasons are, are a big emphasis, and, and I think that one of the other big issues is related to this, the, the science that is quote unquote, proving different things seems all over the map. But, I, and that is up to interpretation for better or worse.

But, I think that I could support, if there were a something to this recommendation that specifically said a date that was well before the five-year time frame. Then I could see that being something that I understand that the current industry cannot change overnight. And so, you know, if we put in a two or three-year time and said this is as long as it goes to and then it goes and, you know, it has to get re-reviewed at that process or whatever, then, then I think, and, and you know, looking, you know, have more, put some pressure on getting some more research done as, as necessary, et cetera, I, I could see wavering on my, my conclusion, which is, you know, not in support of, of the recommendation as it stands. And I hope that that makes sense. Thank you.

John Foster: Thank you, Colehour. Tracy?

Tracy Favre: You know, as someone new on the Board and going through this process, it has, it has been interesting to me to try to tease out where I stand on things, based on the fact that the science reports are coming in on both sides. I think, probably the only thing I would want to remark on is I am, I am a little bit troubled by this sort of piling on mentality that we have seen on some of the public comments, and my own personal nature is to be very cautious if there seems to be sort of a momentum that springs up out of nowhere and comes on board. Everybody is going to pile on board against something. That, that raises a red flag for me for a lot of reasons. Particularly when the science has been so ambiguous, and when some of the material that was presented as science has been sort of debunked by other scientists.

I think it is really incumbent upon us to not let sort of that momentum of, I will not call it hysteria, that is a perjorative, I do not mean it that way, but, the momentum of negative feeling to kind of swell at the last minute and sort of stampede us into making a decision. And is, and as someone who is grappling with this for the first time, it seems to me that it would be wiser for us to proceed cautiously, and to get more updated information before we let sort of that tide of momentum sway us because this does have far-reaching consequences, not only for the individuals that depend on this for their livelihood, but also for the industry that manufactures products for it and with a long time to reformulate.

Comment [JMS7]: 01:45:00

So, I do not really have a question. It, it just seems to me that anytime there is this swell and this momentum, rushing towards judgment, my personal inclination is to actually slow down, rather than speed up because there is usually a reason for that rush.

John Foster: Thank you. We are going to, in the, knowing we have got a lot of materials, we, we are about a half an hour into this material, so I am going to wrap up that. I did ask for last call, which I think everyone recognizes. So, a good discussion. I think a lot, I think all, all kind of different opinions were, were voiced there. Yeah, well, the motion has been made. It has already been seconded, so we had the discussion. We can move on to voting.

Barry Flamm: John, I, I heard some, it sounded like interest in, by a couple of members, of perhaps of amending the motion. And I just want to see if that was something on, on the table. I think that, I think Zea sort of hinted at, at something, Jay and Colehour. And before moving on with the vote, I just want to see if there is, if there is a desire to propose an amendment.

Zea Sonnabend: I did not suggest an amendment, just a statement to go along with it that we intend to take it off after the five-year Sunset period.

Barry Flamm: Jay?

Jay Feldman: May I respond to that? You know, normally, I am inclined to put, put forward a compromise. But, it seems like that strategy does not work too good. [Laugh] So, I am, I am just going to vote it down. I, I do not want to do that, but I am not, we are not getting support from the Program, typically, regarding expiration dates, despite the fact that most of the peop-, the manufacture, or many of the folks that provided statements suggested they were looking, moving in this direction, and were looking for alternatives or open to looking to alternatives.

This is not my preferred position, but, the compromise thing does not seem to work too well. So, I am, I am just going to vote against it, Barry, unfortunately. I would, I would love to see support for a compromise on this. That is where I would want to go. That is where I want to go. But, I do not see, I do not see that happening. And so, if I cannot get a decisive vote on the compromise, I lose my opportunity. I just, I just would like to go forward with the compromise and feel there was support before putting a motion forth.

Barry Flamm: Colehour.

Colehour Bondera: Yes, thank you. And, Barry, maybe you can clarify for me. I am not sure but my understanding of the process, that, that, and Zea, I appreciate your, your clarification and thoughts. I think I understood fine. But, my understanding is, you know, if ... We would have to vote to reject a product and then it would have to be re-petitioned for it to be, you know, we cannot, at this point in time, decide that something would come off. It is just a hypothetical that in five years, at another Sunset, the NOSB could vote to, to not support it. And so, if we made a statement, that would not have any impact. So that is my understanding of the process anyway.

Barry Flamm: You, you could propose an amendment to the, the motion that, with an alternative date. But, Jay has explained the, you know, the problems with that. But I just wanted to give, you know, anybody who suggested something to that effect, so I just wanted to give that opportunity before taking a vote on the motion.

Zea Sonnabend: Barry, can I ask a question? This is a point of procedure but if this motion fails, could not somebody bring back a motion for a, a alternative date for expiration? That would be the compromise.

Barry Flamm: I do not know if we have ever done that. I, I suppose we could.

Zea Sonnabend: We have in, the NOSB has in the past.

Barry Flamm: Have we? Okay. I would, I would be open to that. Nick.

Nick Maravell: Is, is there some way to get a sense of the Board whether a compromise position would indeed be likely to get a decisive vote? I, I personally think a compromise position would be acceptable and I think this could very well be a decisive vote for that.

Barry Flamm: So, what, what are you suggesting, Nick?

Nick Maravell: Well, in the past, and I am a newbie here, still, I consider myself in terms of parliamentary precision, procedures, we, the previous chair would do something called like a straw vote. Can people help me out here? Is there... We used to do sort of a sense or a straw vote, where people were leaning, or am I making that up? I seem to remember having...

Barry Flamm: That has been discussed, but I am not, I am not enamored by that approach.

Nick Maravell: Okay, then I withdraw the suggestion.

Barry Flamm: Okay. John, please.

John Foster: I just want to point out we have a, we have a motion and a second, we have had discussions, so I think there is a lot of options in front of us, but I, I feel like it is going to

get much more confusing if we, if we get in the middle with something else. Past experience is telling me that.

Barry Flamm: Yeah, I will, I will proceed with the vote, then. Is there a con-, anybody have a conflict of interest?

Zea Sonnabend: Barry?

Barry Flamm: Wendy, Wendy you want to ...

Wendy Fulwider: ... work for Organic Valley, and they do use carrageenan.

Zea Sonnabend: I work for a certifier that may or may not certify products with carrageenan.

Barry Flamm: Where, are you making the, the NOP decision?

Melissa Bailey: Yeah. Do you want me to make it after each person?

Barry Flamm: Yeah, I think we ought to do it after each person.

Melissa Bailey: Okay.

Barry Flamm: So let us back up just a moment to, to Wendy.

Melissa Bailey: Okay, Wendy, you do not have to recuse yourself because you, along with many food producers, all use carrageenan. You do not have a particular specific sole sort of agreement to... You are not the only one who has access to use that particular ingredient, so you do not have to recuse yourself.

Barry Flamm: Okay.

Zea Sonnabend: I have to say it again?

Barry Flamm: Zea.

Melissa Bailey: Sure.

Zea Sonnabend: I work for a certifier that may or may not certify products with carrageenan.

Melissa Bailey: You do not have to recuse yourself.

Barry Flamm: Jay, you had your hand up.

Jay Feldman: I work for an organization that receives support from Organic Valley and Stonyfield for our national conference and scholarship fund.

Melissa Bailey: You do not have to recuse yourself.

Barry Flamm: Tracy?

Tracy Favre: My organization has provided educational and training to Horizon Organic at their corporate owned dairies on pasture management.

Melissa Bailey: You do not have to recuse yourself.

Barry Flamm: John?

John Foster: One of Earthbound's product lines has a minor ingredient in which a minor ingredient is likely to, it could be carrageenan, I just do not remember. But, it could be.

Melissa Bailey: You do not have to recuse yourself for the reasons I specified for Wendy. Joe?

Barry Flamm: Joe?

Joe Dickson: I work for a chain of retail stores that sells products which contain the ingredient.

Melissa Bailey: You do not have to recuse yourself, Joe.

Barry Flamm: Anybody else? Okay, we will proceed with the vote, beginning with Jay.

Jay Feldman: No.

The Entire NOSB Board: Yes. No. Yes. Yes. Yes. Yes. Yes. Yes. Yes, sir. Yes. No. Yes. No.

Barry Flamm: I know I have to vote.

Crowd: [Laughing]

Barry Flamm: This is a vote I do not want to make. It is probably the hardest vote I have had to make since I have been on the Board, and I have heard such incredible testimony on both sides of the issue. However, sitting in the environmental seat and believing in the precautionary principle, I have to vote no.

Mac Stone: [Inaudible]

Barry Flamm: What is the count? The vote is ten, 10 yes. Where is the, the other person? The vote is 10 yes, five noes. I believe I am correct, the motion carries. John, would you proceed with the next item?

John Foster: So traditionally we have done, when we have made changes, we have done a, a backup vote on Sunset items. Am I remembering correctly? Excellent. So, Harold, you ...

Barry Flamm: That is correct.

John Foster: ... take that forward.

Harold Austin: I would move at this time that we move forward the backup vote to, to re-list carrageenan.

Barry Flamm: And, and for clarification, that is a, the difference is that the annotation, it would not be there, is that right?

Harold Austin: Correct.

Barry Flamm: Do we have a second?

Unknown Female: I will second.

Barry Flamm: It has been moved and seconded. Is there discussion? Hearing none, we will proceed with the, the vote. I do not think a, a question conflict of interest needs to be taken again on this. Zea?

Zea Sonnabend: Yes.

The Entire NOSB Board: No. Yes. Yes. Yes. Yes. Yes. Yes. Yes, sir. Yes. No. Yes.

Jennifer Taylor: My role is to represent the public and the consumers. No.

Jay Feldman: No.

Barry Flamm: I will vote yes. What is the count? 11 yeses, 4, noes. The motion passes. John, next item.

John Foster: Thank you. We will move on to agar agar. Harold, I believe you are the fortunate individual to carry that, also.

Harold Austin: You are just bound and determined to continue to throw the new kid under the bus, aren't you?

John Foster: [Laugh]

Harold Austin: Okay, our motion, as it has been modified on agar agar, at this time, we would recommend the re-listing of agar agar as it is currently listed on the National List, 205.605, non-agricultural, non-organic substances allowed as ingredients in or on processed products labeled as organic or made with organic, specified ingredients or food groups non, (a) non-synthetic allowed. We would also recommend that this listing be revisited once the NOP has finalized the draft guidance for materials' classifications. This



would help to ensure that the material has been properly classified and thus remove any further confusion from their status and help during future reviews.

Zea Sonnabend: Second.

John Foster: Thank you. Is there a second?

Zea Sonnabend: I will second.

Barry Flamm: It has been moved and seconded. Is there discussion on the motion? Zea. Oh, no, John, take over please.

John Foster: Alrighty. You got it. Zea?

Zea Sonnabend: Okay. I just would like to put in the public record that we received some very good testimony from a gentleman who, with a lot of experience in colloid technology who indicated the flaws in the National List structure in regard to colloids, and once the classification of materials docket or guidance comes out, I do think we have to take another look at all the colloid materials and things like seaweed derivatives.

Comment [JMS8]: 02:00:00

John Foster: Jay.

Jay Feldman: You know I was hoping that the discussion would yield a more precise classification of this to the non-synthetic 605(a) listing. But, I do not think, it does not sound we are headed in that direction. So, I will be voting against this.

John Foster: Thank you, Jay. More comments, discussion? All right, seeing none, Barry, I think we can, Mr. Chair, we can proceed to vote.

Barry Flamm: Okay, where are we at? Is there a conflict of interest? Zea.

Zea Sonnabend: I work for a certifier which may or may not certify products with this material.

Melissa Bailey: You do not need to recuse yourself. John.

Barry Flamm: John.

John Foster: One of our co-packers has a minor ingredient in a minor ingredient that might have agar agar in it.

Melissa Bailey: You do not need to recuse yourself.

Barry Flamm: Any other?

Melissa Bailey: Joe.

Barry Flamm: Joe.

Joe Dickson: My company sells many products which contain agar agar.

Melissa Bailey: You do not need to recuse yourself.

Barry Flamm: Any others? All right, I, we can proceed with the voting beginning with Calvin.

Calvin Walker: No.

The Entire NOSB Board: Yes. Yes. Yes. Yes. Yes. Yes. Yes, sir. Yes. No. Yes. No. No. Yes.

Barry Flamm: Okay, yeah. Yes. [Inaudible] The vote is 11 yeses, 4 noes. What is next, John?

John Foster: Thank you. Next on the list is last, this is the last of the Sunset determinations, and this is for cellulose. Joe?

Joe Dickson: Thank you, John. I would like to move that the Board accept the recommendation on the re-listing of cellulose to 205.605(b) synthetics allowed with the following modified annotation. Cellulose for use in regenerative casings, powdered cellulose as an anti-caking agent, non-chlorine bleached, and filtering aide. Is there a second?

Unknown Female: Second.

Barry Flamm: It has been moved and seconded. Is there discussion? John. I will turn it over to John.

John Foster: Okay. Any discussion items on cellulose? [Inaudible] Thank you.

Joe Dickson: I just want to clarify that what that annotation does is clarify the, it strengthens the exclusion of microcrystalline cellulose by making it very clear that only the powdered form is acceptable under this annotation. It appears that that is what practice has allowed, but, you know, there is an opportunity to, to make it a little clearer so that is what that does.

John Foster: Is, is that what you ...?

Jay Feldman: Just, thank you. I want to thank you for that.

John Foster: Okay. More questions, discussion? Okay, seeing none, I think we can proceed to vote. Oh, okay, I will ask conflict of interest on this one?

Barry Flamm: Declare... Jay.

Jay Feldman: I work for a company that has received support for our national conference and scholarship fund from a manufacturer that uses, from Organic Valley that apparently uses it, according to the testimony.

Melissa Bailey: You do not need to recuse yourself, Jay.

Barry Flamm: Zea.

Zea Sonnabend: I work for a certifier that may or may not certify products with this in it.

Melissa Bailey: You do not need to recuse yourself.

Joe Dickson: I work for a chain of retail stores that sells many products which contain this ingredient in different forms.

Melissa Bailey: You do not need to recuse yourself.

Joe Dickson: Thank you.

Barry Flamm: Wendy.

Wendy Fulwider: We, at Organic Valley, may use cellulose.

Melissa Bailey: You do not need to recuse yourself, Wendy.

Barry Flamm: I believe that we can proceed with the voting starting with, starting with Tracy.

Tracy Favre: Yes.

The Entire NOSB Board: Yes. Yes. Yes. Yes. Yes. Yes, sir. Yes. Yes. Yes. No. Yes. Yes. Yes.

Barry Flamm: Chair votes yes. What is the count? 14 yes, 1 no, the motion passes.

Joe Dickson: Now, we need to do a backup vote to re-list the material as is. So I would move that we re-list cellulose to 205.605(b) with the annotation as it currently reads for use in regenerative casings as an anti-caking agent, non-chlorine bleached, and filtering aide.

Unknown Male: Second.

Unknown Male: Second.

Barry Flamm: It has been moved and seconded.

John Foster: Discussion?

Barry Flamm: Would you restate the, the motion for me on the annotation?

Joe Dickson: Yeah. The motion is just to re-list the material as it currently appears on the National List which is with the annotation: cellulose for use in regenerative casings as an anti-caking agent, non-chlorine bleached, and filtering aide.

Barry Flamm: Okay, it is... I will turn it over to John for a discussion.

John Foster: We have got a motion and a second. Is there discussion on this item? Jean.

Jean Richardson: So that would mean that the crystallized version could indeed be used?

John Foster: In theory, although, I, I think, Joe, you were saying it is, and my understanding is that that particular kind is not in, is not used in commercial production. Joe?

Joe Dickson: Yeah, I mean we have heard that the current thinking of both the Program and the Organic Materials Review Institute is that microcrystalline cellulose is a distinct substance that is not covered under the existing listing. But the, the modification to the annotation is simply to shore that up after some stakeholder comments expressing concerns. And this motion on the table is just the backup motion which is a procedural measure that basically ensures in the event that the changed annotation cannot go through the, the rulemaking process expediently, that the, the substance does not inadvertently come off of the List.

John Foster: Additional questions or discussion? Okay, seeing none, I think we can proceed to vote.

Barry Flamm: And I believe we are covered on the ... We are starting. Okay. The voting is starting with Carmella.

Carmella Beck: Yes.

The Entire NOSB Board: Yes. Yes. Abstain. Yes. Yes, sir. Yes. No. Yes. No. Yes. Yes. No. Yes.

Barry Flamm: The chair votes yes. 11 yes, 3 noes, and one abstention. The motion carries. Does that complete the Sunset items?

John Foster: That does complete the Sunset items.

Barry Flamm: You wish to move on to the petitions?

John Foster: All right, we will do that. And I just want to double check here. We have a break scheduled for about, in about half an hour, is that correct?

Barry Flamm: That is correct. Would you like to take the break now or ...?

John Foster: No, I think this is, I think, I think we are, I think we are in a good groove. We can keep on. I, I would like to take a break around 10 though, if that is alright.

Barry Flamm: We will do that.

John Foster: Alright. Alright, next up is going to be the first of the petitioned items of the day. The first one up is choline. And, Zea, I believe you are point on that.

Zea Sonnabend: Thank you. Oh, that is not, oh yeah, it is the new version I gave you. It is just very big. Okay. Yesterday, or whenever that was that we presented the motion, we presented the amendment just to provide CAS numbers and be specific about what compounds we were talking about.

Based on the testimony we received yesterday, we decided to put in an additional amendment to include, in addition to infant formula, to include the products for medical, nutritional enteral use. And these are products that are fed to sick children, primarily through a tube, and are a sole source of nutrition. And we felt this was compatible with our thinking about the infant formula because the person cannot choose what food they get to eat. And, these are, there is no chance that these materials would be abused by anyone else, because they have medical labels on them, and therefore can only be used under care of a physician and for medical use. And we feel that those people should have the opportunity to have access to organic food with a complete nutritional profile. So, we have added that to the motions for both choline and inositol.

Now I do want to clarify one other point that came up yesterday, and that was why the FDA would mandate it for non-milk based infant formula, but not for milk-based infant formula. And the people from the formula group that spoke yesterday clarified this for me after the meeting was over. The FDA has a number of things that, for them to review to put on their approved list or mandated list for infant formula. And, they are a little bit behind in their regulation writing. Much as the Department sometimes gets behind, they have to go through similar types of loophole or, you know, stuff, red tape, I guess you would call it. And so, they see this as something that is widely in use and since 1988 or, and again in 1998 or 2000, people have urged them to put this, as well as selenium and some other nutrients onto the list. And they have every intention to, but they have not gotten to it, yet.

So, I think that we are on very safe ground here in recommending it for all infant formula, which is also much clearer to consumers than trying to distinguish between milk-based and non-milk-based. So, I put the motion on the table. We do them one at a time?

John Foster: Yes, please.

Zea Sonnabend: Okay. The motion on the table to classify that choline chloride, CAS number 67-48-1, and choline bitartrate, CAS number 87-67-2 are synthetic.

John Foster: Is there, is there a second?

Unknown Female: Second.

Barry Flamm: It has been moved and seconded, to classify choline, both, both the CAS numbers, as synthetic. Is there discussion on the motion?

John Foster: Nick. Nick?

Barry Flamm: John, do you want to take over?

John Foster: You bet. Go for it, Nick.

Nick Maravell: Zea, two points. Do we, in the annotation there, normally put C-A-S and a hash mark before the numbers or do we just leave that out? That is just a minor point. And... Go on.

Zea Sonnabend: We have not started really using CAS numbers in the actual listings until very recently, but, this was definitely a cause for concern, that things were not precise enough in their listing. So, I do not know what the exact precise format is.

Nick Maravell: Well, to the, to the layperson, it might be helpful to have a CAS number, at least C-A-S.

Zea Sonnabend: To say C-A-S?

Nick Maravell: It might be helpful.

Zea Sonnabend: Okay.

Nick Maravell: Because, other, yeah, it might be.

Zea Sonnabend: Okay. Does the Department think it makes a difference? Yes? Okay.

Lisa Brines: For consistency, with the way it is represented for other substances on the National List, yeah, we would in-, we suggest including the acronym CAS and then the number sign.

Comment [JMS9]: 02:15:00

Zea Sonnabend: So then we will add C-A-S before the numbers in all the motions.

Nick Maravell: And then, Zea, my, my second question is concerning the clarification on the milk-based infant formula and the action, if we can call that, from FDA. You are indicating that there is a high likelihood that this will be listed in the future as a required supplement in milk-based infant formula, the addition of the choline. Is that correct?

Zea Sonnabend: Yes, absolutely.

Nick Maravell: If, has, you, has FDA gone through any part of its process towards that? In other words, how do we know that indeed, yes, that is likely to happen? I, I understand the industry is prepared to do it and is doing it now, to some extent, et cetera, et cetera. But, is it, is there something that FDA has done to date or indicated?

Zea Sonnabend: The FDA is not very transparent in their working, so I cannot answer that question.

Nick Maravell: You cannot. Okay. Thank you.

John Foster: More questions, discussion? Jay.

Jay Feldman: Are we talking about the synthetic/non-synthetic motion, is that what we are on?

John Foster: That is correct.

Jay Feldman: I believe the motion should be structured as a motion, move that choline as a non-synthetic, and that we vote on it being non-synthetic, and we can then determine it, we can vote that down. I believe it is...

Zea Sonnabend: [Inaudible]

Jay Feldman: I know. But, I believe our motions, I mean, I would like to check with the Program on this, but I believe our motions are on synthetic/non-synthetic questions are written to the non-synthetic perspective.

John Foster: Would the Program like to clarify? Or help us understand?

Melissa Bailey: Just give us a minute here to double check.

John Foster: You bet, you bet.

Lisa Brines: Thank you for your patience.

John Foster: That is fine, that is fine, take, take what you need.

Lisa Brines: It does not appear to be directly stated in the Policy Manual that classification motions for handling materials would always be structured in the affirmative in the same way that listing motions are. Based on, I mean, the classify, taking a classification vote first is a fairly new practice that was reinstated by the Board after a break of some period of time. But, our current recollection and understanding is that it would be appropriate to make this particular motion to classify this material as synthetic and take the vote on that basis.

John Foster: Just, just for clarification. Leave it the way it is. Leave it the way it was presented just now.

Lisa Brines: That is under, our understanding, the way it would work.

John Foster: Okay, excellent. Thank you. And thanks for checking that out in short under, in short order under public scrutiny, I appreciate that. Okay.

Jay Feldman: I would just like to get something on the record.

John Foster: Yes, Jay, go ahead.

Jay Feldman: I would just wanted to get something on the record regarding this. I had, I had advocated that we have a discussion document on synthetic/non-synthetic to resolve these sorts of issues. What we are doing by voting on a synthetic motion is recruit, we are creating a higher standard, a higher burden on the Board to deem things synthetic, whereas the, the Act and Law is structured in just the reverse. That is, the higher burden, the higher burden should be to those who are seeking to find that a material... Well, the, the idea is that we re-, we, the default should be that we review materials, and put them on the National List, unless there is a finding of synthetic. And, it should not be difficult. The burden should not be high to reach that finding of synthetic.

And, as, as we put out in the discussion document, that did not make it to this meeting, what we are doing here is creating a higher burden on the Board to review things for the National List, by structuring motions in this manner. It should not be difficult to review, to put things on the National List, because that provides a fail-safe for us to be able to evaluate them fully, according to our checklist and the criteria that is in the statute. What we want to do is, is err on the side of caution, and therefore make it less difficult to review things under the standards of the statute.

In this situation, although this is not a controversial one, I recognize that, but, as a matter of process, I think the burden should be shifted here, and I hope we can work this out down, down the road with the Program. I, I assume we can. But, that we have some clarity on, on these points. Because, at the end of the day, if this is controversial, then it is much more difficult to subject this chemical to review under the National List process when we establish the motion in this fashion. That is all.

John Foster: Duly noted. Alright. Any other additional discussions? Seeing none, I think we can proceed.

Barry Flamm: Is there any conflict of interest on this material? Jay and Zea, I do not know if you heard the request or not. Is there a con-, do you have a conflict of interest?

Zea Sonnabend: I work for a certifier that may or may not make things with this ingredient, certified.



Melissa Bailey: You do not need to recuse yourself.

Barry Flamm: Anyone else wants to declare a conflict of interest or ...? Joe.

Joe Dickson: I work for a retail chain of stores that sells many products which contain this and other supplementary ingredients.

Barry Flamm: Thanks you.

Melissa Bailey: You do not need to recuse yourself, Joe.

Joe Dickson: Thank you, Melissa.

Barry Flamm: Anyone else would like to make a declaration? Hearing none, we can proceed with the voting. John, would you begin the voting?

John Foster: Yes.

The Entire NOSB Board: Yes. Yes. Yes. Yes, sir. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes.

Barry Flamm: Does that complete? The chair votes yes.

Zea Sonnabend: I am waiting for the ...

Barry Flamm: 15, 15 yeses, zero noes. The motion passes.

Zea Sonnabend: Thank you, Barry. Our next motion is to add choline, choline chloride, with a CAS number 67-48-1, and choline bitar-, bitartrate, CAS number 87-67-2 to the National List 205.605(b) for use in infant formula and medical nutritional enteral products labeled organic or made with organic specified ingredients or food groups.

Barry Flamm: Is there a second?

Unknown Female: Second.

Barry Flamm: It has been moved and seconded. John, would you lead the discussion?

John Foster: You bet. Is there any discussion on this? I have Jean.

Jean Richardson: I will be voting in favor of this motion but with considerable reluctance to see anything, any synthetic things being added to infant formula, the only reason being is that it is going to be, it is required by the FDA for soy right, infant formula right now and will be for the milk-based ones in the not too distant future.

John Foster: Thank you. Additional? Colehour.

Colehour Bondera: Yes, thank you. Based upon my understanding and review and in addition, even the revisions to the motions as was presented previously by Zea, I just wanted to let people know that I will be voting against this motion unless the words organic or are struck from the motion. Thank you.

John Foster: Thank you. Other ...? Jay.

Jay Feldman: Thank you. Thank the, I would like to thank the Committee for its work on this. I know these are difficult petitions. I, you know, the law was written in such a way as to allow those requirements from FDA to be allowed under the organic statute. And that made, that makes sense to me. Unfortunately, FDA has been slow on updating its standards over the years. We heard testimony on that. And, we know from other discussions, previous discussions, that that has been the case.

At the same time, I think there has been some degree of acceptance of certain nutrients and vitamins that are deemed recommended. Even though FDA has not mandated them or required them. And so, I would like to put into the record a citation here on this point, which comes out of the Pediatric Nutrition Handbook second edition by the American Academy of Pediatrics. The second edition, I do not have a date, unfortunately. Appendix 1, recommended ranges of nutrients in formulas. And, this is, this is something that I think we need to consider as a Board when we look at these things. And, it includes on the list, choline at seven milligrams per 100 kilogram or cuh-, what is k, k-c-a-l, nutrient and inositol at four. Okay, and the date of the publication is 1985, American Academy of Pediatrics. 1985?

Unknown Female: 85? [Laugh]

Jay Feldman: Okay. Okay, so just to put that on the record, I am, obviously, I am concerned about fortification in organic, especially with synthetics. I, well, with synthetics, that is, I should say. So, fortification of, of synthetics, I think I, I really want us to consider as a problem area that we should not take lightly, and we should, we should look at this very carefully when we are talking about recommended nutrients and accepted nutrients that are advanced by the American Academy of Pediatrics and others. I think we need, that is a different, different discussion. Okay.

Now, having said that, of course, we come at, we, we have to face this discussion a little bit differently than I think the conventional industry does, in the sense that we, we should be looking at both whether there are non-synthetic versions of these things, number one, and we should be, be aware of whether there are hazards associated with the production of these, these nutrients that we view as recommended and necessary or essential to some degree.

Comment [JMS10]: 02:30:00

And, your TR, the guys, the one you guys looked at in the Handling Committee, on the first point, on the issue of non-synthetic or natural sources did not do, I do not know how you felt about this, I wanted to hear from you guys. I, I found it very unsatisfactory and I want to read this to you. This is a question: provide a list of non-synthetic or natural

sources of the petition substance, which is a checklist question for review. Choline can be supplemented through diet by addition of organic liver, eggs, wheat germ and other foods high in natural choline. Breast milk is another natural form of choline for infants whose mothers are not able to breast-feed. While choline is a natural non-synthetic substance found in many foods, some people do not synthesize or consume enough choline in their diet. That line is choline 2008.

It does not appear that there are natural or non-synthetic sources of the petition substances, choline chloride and choline bitartrate. One natural source of choline that may be used as a food additive in place of synthetic choline salts is unbleached lecithin which contains – can you pronounce that for me? – phosphatidylcholine. Yeah, that one. Lecithin is defined by FDA as a naturally occurring mixture of phospholipids [*phosphatides*] of choline, etha-, whatever these are, and inositol, with smaller amounts of other lipids. It is isolated as a gum following hydration of solvent-extracted soy, safflower, or corn oil.

So, my focus here, John, is this issue of whether there actually is a non-synthetic alternative. And I, for one, I know we have had this discussion and I, I know you are in agreement, that we really get a good fix on whether we have a non-synthetic alternative. And, this, this equivocal language is really, I just want to raise this as a, as a problem. I, I really feel, especially on petition substances, we are not, you know, when we have this discussion on Sunset, I know people's reluctance to move something off with some shaky discussion as to whether there really is a non-synthetic alternative. I understand that. But, here we are adding something to the List. And so, I think we need to really have, and you may have an answer to this. We really have a good fix on the, the non-syn-, non-synthetic. So, I, I hope Zea will address that.

The, the other point on extractants is, and this speaks to the issue that the Committee, I think, wisely identified. And that is this made, using this made with category. This issue of the extractant, and again, it is ironic how these conversations sort of blend together. But, the TI, the TER said the organic component 1,4-dioxane has been classified as possibly carcinogenic to humans by the World Health Organization's International Agency for Research on Cancer. It may be present in choline salts, due to the use of ethylene oxide in the manufacturing process. And then recognize that 1,4-dioxane not only is there a huge consumer movement on the toxics, on the industrial toxic sites to remove 1,4-dioxane from cleaning products and detergents, but here, even this chemical is on the Proposition 65 list at, in California.

So, I do not think there is any real question that this is a hazardous carcinogenic extractant or ingredient or mix, mixed, I do not know what the technical term would be, but it is used in the manufacture of this material. And so, that puts it into a totally different class, in my view, I mean, as allowed in organic. So, I just put those two issues on the table and I appreciate again the Committee's work on this.

John Foster: Discussion? Zea.

Zea Sonnabend: Okay, the part of the TAP review about alternatives, we did look into. And, I am not sure if I can find it that easily, but, found at least one research paper from the 70s about how it was not technically feasible to get enough lecithin into a formula that would provide a substan-, enough choline. And not only that, but since the lecithin is derived from soy and there is considerable controversy about whether soy is a good thing to feed your baby or not, it just really seemed to leave that alone and it was not a viable alternative. And, in the desire for precaution, this is why we only recommended it for infant formulas, where it was mandated by law and for these medical products, where they don't have alternative nutritional sources.

John Foster: Thank you. Let, Nick and then Harold I believe.

Nick Maravell: Yes, I would, I would like some clarification. Maybe the Program can provide this just on the record. Let us just suppose we take no action, whatsoever, with regard to choline, and it is required by FDA under certain circumstances. Would those products be permitted to be used by default or some other mechanism in products labeled as organic that are infant formula?

John Foster: We will wait to see if the Program wants to weigh in on this.

Crowd: [Whispering]

Melissa Bailey: Okay. Oh, John has walked away from the table. [Laughing]

Crowd: [Laughing]

John Foster: I just had, I just had to stretch my legs for a minute. Thank you. Thank you for the, your indulgence on that. Yes?

Melissa Bailey: Okay, so as the Board knows, we are, the Program is currently engaged in a rule making, specific to the listing for nutrient, vitamins and minerals on the National List at 605(b). The proposed annotation in that rule making would cover the use of choline in non-milk-based infant formulas, should it be finalized. But, it would not cover the use of choline in milk-based infant formula, hence why you have this petition on the table.

John Foster: Thank you. Alright, Harold.

Harold Austin: Yeah, this, either to, back to Jay or to Zea, either one. On the appendix that Jay, Jay was quoting from and the numbers there, how does that match up with what the FDA mandate is on that?

Zea Sonnabend: Actually, address that to Emily, because I believe those numbers are in the docket that you just referred to, in the rule making, the numbers.

John Foster: Em-, Emily? Thank you.

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Emily Brown-Rosen: If you give me a minute, I can pull that up. But, you are talking about the, the requirements, guarantees for infant formula? Yeah, I will, I will get that.

Zea Sonnabend: The required levels for infant formula. I think there was a chart in the docket.

Emily Brown-Rosen: We did, yeah, we did. It is from the, the FDA rule on infant formula requirements, but I will, I will get that to you in a second.

John Foster: Thank you. Additional questions? Looks like last call. Alright. Seeing no more, we can move to voting.

Barry Flamm: Would the, would you restate the motion for clarity of the, the Board?

Zea Sonnabend: The first listing motion is to add choline chloride, CAS number 67-48-1, and choline bitartrate, CAS number 87-67-2 to the National List 205.605(b) for use in infant formula and medical nutritional enteral products labeled organic or made with organic, specified ingredients or food groups.

Barry Flamm: And there was a second, so conflict of interest?

Jay Feldman: Point of order. What, did we, maybe I misunderstood what Colehour was suggesting. Were you, was he suggesting a, an amendment to this or, or not? I, I was not clear on that.

Colehour Bondera: Yes, I, I am requesting the removal of the words "organic or" from this motion.

Jay Feldman: Okay.

Unknown Male: Are you [inaudible].

Unknown Male: So it, it just, excuse me, so it just reads "labeled made with organic".

Zea Sonnabend: The maker of the motion rejects that request. You will have to propose it as a second motion if this fails.

Barry Flamm: Colehour, do you...?

John Foster: So...

Colehour Bondera: [Inaudible]. Thank you.

Barry Flamm: Okay, we will proceed with the voting. Who is next? Joe, would you begin the voting?

Joe Dickson: Yes.

The Entire NOSB Board: Yes. Yes. Yes, sir. Yes. No. Yes. No. No. Yes. No. Yes. Yes. Yes.

Barry Flamm: Yes. The chair votes yes. The vote is 11 yeases, 4 noes, the motion passes.

Zea Sonnabend: Thank you, the second listing motion is to add choline chloride, CAS number 67-48-1, and choline bitartrate, CAS number 87-67-2 to the National List 205.605(b), for use only in agricultural products other than infant formula and medical nutritional enteral products labeled made with organic, specific, specified ingredients or food groups, and prohibited in agricultural products labeled organic. Now I, oh, I guess we need a second before discussion.

Unknown Female: Second.

Zea Sonnabend: Okay.

Barry Flamm: Moving [inaudible].

Zea Sonnabend: I did not know if we needed the last part or not, to clearly state prohibited for the other. But, I put it in. And then I would also like to ask the Department for clarification on what happens to, this is a unusual one, but a precedent for a lot of other ones coming up. There are products already out there in the marketplace using an organic label with choline fortification. And, if this, if they are not added to the National List, will they get a grace period to use up, to re-label and reformulate? Or, do we have to put that in the motion?

John Foster: From the Program?

Miles McEvoy: Yeah, you are asking a general question about an existing rule making action that we are conducting on nutrient, vitamins and minerals in terms of the phase out. And, and in the proposed rule, we asked for comments, specifically about that, and we will, we will be able to address that in the final rule on, on nutrient, vitamins and minerals, in terms of the phase out.

Zea Sonnabend: Except, the specific part of that question is, do we need to put something in the motion right now, or it would not happen?

Miles McEvoy: What you are working on is a petition to add something to the National List, so there is no phase out involved in adding something to the National List.

Zea Sonnabend: Okay, thank you.

John Foster: Additional ...

Barry Flamm: I will turn it over to John for guide discussion.

John Foster: Additional discussion? Jay.

Jay Feldman: Thank you. Okay, so now we are talking about allowing a substance for which there are other sources of choline, right? To a made with labeled product. Not, well, made with product. And, what, why do you think we need to do that, if there are other sources that, that are not, I mean, in the case of infants, certainly we are talking about a, as I understood it, an essential ingredient at a certain level in a product. That seems to have some degree of agreement around, although, I guess there is some, still some question as to whether the recommended ranges of nutritive-, nutrients in infant formulas is, is a appropriate citation. But, regardless of that, now we are, we are moving off of something that is in this gray area of recommended, required, to something that clearly does not have essentiality but manufacturers would like to have. Could you just explain a little bit more of the thinking of the Committee on that point?

Zea Sonnabend: The thinking of the Committee on this was allowing it in adult foods in the “made with organic” category would allow such foods to highlight the fact they are fortified, while at the same time limiting the number of non-essential synthetics in organic processing. It was felt that a large number of consumers buy fortified foods, and a large number of manufacturers make them. And therefore, that would highlight the fact that these materials were synthetics in the foods that they were buying by putting it in the “made with organic” category. Now, personally, I would much rather, I would allow it in the “made with organic” category if it could have on the ingredient panel “synthetic choline”, but I do not think that is within our purview to mandate. And I personally will not be voting for this motion. But, we put it forward from a Committee for people who wish to have that choice.

Comment [JMS11]: 02:45:00

John Foster: Okay, Jay and...

Jay Feldman: Yeah, I am...

John Foster: Hold on just a second, I am going to, I have got a response to your question. But, I am going to wait until everyone else is done, so.

Jay Feldman: Again, just to reiterate, quickly, I am worried about this fortification issue as it, as it relates to synthetics. So, I, I almost feel like we, as a Board, need a more lengthy and detailed conversation on, on this, and how it fits within the structure of the statute. And, the intent associated with the allowance of essential materials, essential synthetic materials in organic production, handling, processing. So, I think until we have that discussion and get clarity around the issue of synthetic fortification, I do not feel comfortable. I think it is outside the category of allowance in our statute. And, and we should really look for natural forms of these materials, if they are available. And, and encourage manufacturers to, to go down that road. Thank you.

John Foster: Any other discussion, thoughts? Alright, hearing none, I told you that I would save mine for the last. So one of the schools of thought was that, this relatively small amount of materials like this, encourage a broader use of a, a wide variety of organic ingredients

from a handler's standpoint. Where customers need to be, you know, attracted to products, that is a, that is a worthwhile consideration. So, I just wanted to get that out there. That is part of the thought is that it, it encourages the use of additional organic ingredients in the marketplace. Alright, now we will do last call.

Barry Flamm: I believe that is, complete the discussion.

John Foster: Completes the discussion, ready to vote.

Barry Flamm: We are ready to vote. I believe, believe we did the conflict of interest earlier. So, proceed with Jean please.

Jean Richardson: No.

The Entire NOSB Board: Yes. No, sir. Yes. No. No. No. No. No. No. No. Yes. No.

Barry Flamm: The chair votes no. Three yes, 12 no, the motion fails. We will take a 15 minute break at this time.

[BREAK]

Comment [JMS12]: 02:49:10

Comment [JMS13]: 03:10:28

Barry Flamm: Board members, please take your chair.

Nick Maravell: Barry, I think that there is, there is, I am wondering if we can reintroduce the [inaudible] so maybe we can talk about that after [inaudible].

Barry Flamm: I do not think we can [inaudible] the vote was taken.

Nick Maravell: Well, I voted for it [inaudible] in fact I thought, thought we were going to [inaudible].

Barry Flamm: But I, we have got to proceed.

Unknown Male: Are you unplugging yourself, sir?

Barry Flamm: The Board is back in session. John, would you like to proceed?

John Foster: Yes, Barry, thank you. I would like to proceed with the petition for gibberellic acid. And if I am not mistaken, I believe Zea was point person on that. Zea, would you be so kind? Thank you.

Zea Sonnabend: Okay. Thank you. Before we put forward a motion on this one, what we decided to do but did not actually pass in Committee was to adopt the language suggested by OMRI. Our original motion was "gibberellic acid for postharvest banana use only" and the addition by OMRI suggested was "may only be formulated with 2004 EPA List 4 inert ingredients". And that is the motion, although Miles is not here, but here he comes.



But maybe Emily can answer this whether this is actually an appropriate form or whether, like in 205.601, inerts needs to be a separate listing. So inerts used with the products in there. Is this an appropriate listing?

John Foster: Program?

Emily Brown-Rosen: Yes, sorry for the delay there, but, yes, we think that you should put it in the annotation if you want to include a reference to inerts. We do not think it is necessary to say 2004. It should just say EPA List 4 to be consistent with the rest of the National List.

Zea Sonnabend: Okay. So, would anyone on the Committee like to make that motion, or anyone for that matter? To put gibberellic acid on the National List, 205.605(a), for postharvest banana use only, may only be formulated with EPA List 4 inert ingredients.

Jean Richardson: For the motion. So moved.

Barry Flamm: Is there a second to the motion?

Zea Sonnabend: Okay.

Harold Austin: Second.

Zea Sonnabend: Okay, Jean moved and Harold seconded.

Barry Flamm: Is, call for point of order.

Unknown Male: Does it need to be classified first?

Zea Sonnabend: Well, it has previously been classified for crops as non-synthetic, so my understanding is it does not need to be reclassified. Is there discussion? Should I call for discussion or you?

Comment [JMS14]: 03:15:00

Barry Flamm: No. John, I will pass the discussion to you.

John Foster: You bet. Thank you, Barry. Yeah, any discussion on the motion? Yes, Jay.

Jay Feldman: Having worked on inerts and as you all know, we are moving ahead with an inerts policy. It is wholly, I believe, inappropriate to add inerts to products at this stage that are not evaluated independently. That would also be, I believe, unfair to other manufacturers that have, have been waiting in the queue for a review of their inerts which are also on these lists, List 4, a or b. So I, in an interest, in the interest of fairness, and given the fact that we do not have a good hazard evaluation of the full, full formulation that we are talking about here, I cannot support this. Sorry, Louise.

John Foster: Thank you. Thank you, Jay. Conditional comments, please. Zea.

Zea Sonnabend: Okay. In response to Jay, this is not adding new products to the list because it is the same formulation of gibb, formulations multiple that are already in use for crops.

Jay Feldman: Adding new, new uses. I misspoke.

Zea Sonnabend: New uses. Yes. Okay. And, where do I want to go? Oh. This is, at this point, not the Committee opinion, but is my personal opinion. As a scientist, I like to make the distinction of what is opinion from fact. I struggled with this one a great deal, because I do not think there is really harm in the product itself, gibb, in gibberellic acid as formulated for uses. However, the mandate of putting things on the list in handling has, you know, a different set of criteria. And, we ask, you know, we asked for input on one aspect of it, which was the call on whether cultural practices could control the disease Black Sigatoka. We did get some input that that was, that could happen. But, we also got some input that, and this was true from the original petition, that the concern over Black Sigatoka was only one of the concerns.

And the additional concern was being able to ship bananas for long distances without have them, having them ripen prematurely. The distances that, and the length of time that was presented to us in public comment yesterday was, I believe, 22 to 30 days. This, to me, was, is not one of the criteria that we evaluate things for handling. And, much as I hate to do it because I have total sympathy for small farmers, I believe I have decided to vote against this material because it has, its use has not proven to be essential to me. I cannot get beyond the fact that yes, we have plenty of bananas, not yes we have no bananas. [Laughing]

Crowd: [Laughing]

Zea Sonnabend: I am corny, that is why I am called Zea.

John Foster: That was awesome twice over. Wow. Well done. Well done. Additional, additional comment? I will save mine for after everyone else is done. Additional comments? Alright, maybe we are done.

I, I will be voting for this. I think, I think the arguments around quantities are I do not know, I know there is a lot of organic bananas, but I would like to see more and it seems to me that this will help that. So after particularly seeing the photograph of delicately putting paint, applying this material with a paint brush to the tops of the bunches, I cannot imagine a more precise and strategic use of a material than that. In fact, I cannot think of an, anyone in agriculture or postharvest handling that is that precise and that controlled. So, from that point of view, you really, you, a, a producer would not be doing that unless they felt it was absolutely necessary. So, I am, that is, that is all I wanted to say. Oh, sorry, Harold.

Harold Austin: Sorry, I know you wanted to go last, but...

John Foster: No. I just did not want to crowd anyone out. That is all.

Harold Austin: Well, I think the other thing too to take a look at is that gibberellic acid is also a natural, naturally occurring substance within the plant itself. So they are just augmenting that process once the, once the bunches have been removed to stabilize the, the plant from over ripening. I think the other thing to point out is that it, it does, it would help those small growers to be able to deliver a better quality product with less rejections, thus giving them a more sustainable presence in the market. So, I think when we look at that part of it, I think there is value in, in at least considering this as an option to, to include for them as a, as another tool to put in their toolbox.

John Foster: Thank you, Harold. Additional comments? Okay. Seeing none, we can proceed with vote.

Barry Flamm: Is there a conflict of interest? Zea.

Zea Sonnabend: I work for a certifier who I do not think certifies bananas, but I am not sure. So, I guess I need the ruling.

Miles McEvoy: You do not need to recuse yourself.

Barry Flamm: Any other? All right, we can proceed to the voting, beginning with Harold.

Harold Austin: Yes.

The Entire NOSB Board: Yes, sir. Yes. No. No. No. No. No. No. No. Yes. Yes. No. No.

Barry Flamm: The chair votes no. What is the count? Five yes, 10 noes, the motion fails. What is next, John?

John Foster: The next material is the last material on the Handling Committee's agenda. And that is inositol. Michelle, I believe, could you pull up the most recent version, please? Alright, and if we could scroll to the last, there we go, right where the red ink is there. Just before a motion, very quickly, we did, you will see on the next page in a second, we made a, a slight amendment, similar to choline. The discussions around this were similar to discussions we had around choline. So I will not go into that. We did add CAS numbers, and we did made another similar amendment that you will see in a second here. And this is paragraph that is just speaking to that point. So if we could go one more page. I guess one more page. There, thank you. So, I, with that, I would like to move that inositol as petitioned, CAS numbers 87-89-8, myo-inositol, and 6917-35-7, nonspecific isomer, is synthetic. Do I have a second?

Unknown Male: Second.

Unknown Male: Second.

Barry Flamm: It has been moved and seconded to add inositol to the, to the List. John, you want to lead the discussion?

John Foster: Sure. Is there any discussion? Yes, sir, Colehour.

Colehour Bondera: I am sorry. I am sorry, we are just talking synthetic/non-synthetic, is that accurate?

John Foster: That is correct. This is for classification.

Colehour Bondera: I apologize. I do not, I do not, yes, I apologize, I withdrawal.

John Foster: Okay. No problem. Alright. Additional discussion? Seeing none, Barry, we can proceed to vote.

Barry Flamm: Okay. We are voting on synthetic/non-synthetic...

John Foster: This is classification.

Barry Flamm: The motion is of this material. We are voting on declaring this a synthetic, correct?

John Foster: Correct.

Barry Flamm: Okay. Zea? Is there a con, a conflict of interest on this, this material? Zea are you...?

Zea Sonnabend: I work for a certifier that way or may not certify products with this in it.

Miles McEvoy: No recusal necessary. [Laugh]

Barry Flamm: Joe.

Zea Sonnabend: Gets old, huh?

Joe Dickson: I, I work for a chain of retail stores that sells many products that contain this ingredient.

Miles McEvoy: You do not need to recuse yourself.

Barry Flamm: Anyone else? Alright, we will proceed with the voting, starting with Mac.

Mac Stone: Yes, sir.

The Entire NOSB Board: Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes. Yes.

Barry Flamm: Chair votes yes. 15 yeses, zero noes, the motion passes to classify this as a synthetic substance. We will proceed.

John Foster: Yes.

Barry Flamm: John, do you have a motion?

John Foster: Yes, sir. Michelle, I wonder if we could have that up on the screen again, please. Thank you. Next motion is a listing motion. I move to add inositol, CAS numbers 87-89-8, myo-inositol, and 6917-35-7, non-specific, non-specific isomer to the National List, 205.605(b) for use in infant formula and medical nutritional enteral products labeled organic or made with organic, parenthetically specified ingredients or food groups. Do I have a second?

Unknown Male: I will second.

John Foster: Discussion?

Barry Flamm: Do we have a second? Oh, okay. It has been moved and seconded to list inos-, inositol on the, on the List as described on the screen now. John, you want to take over the discussion?

John Foster: You bet. Do we have any discussions on this point? Colehour.

Colehour Bandera: Yes, thank you, John. I feel like I am going to be repeating to some degree what I said about choline, but more specifically as a father who has two children and understands the issue of infant formulas. But, also as a consumer who looks very carefully. And I will throw in the fact that we are all are consumers. And as a consumer who looks very carefully at products to know what I am getting and to look for accurate representation, I hereby request that the motion strike the words "organic or", and then it would have my support. Thank you.

John Foster: A point of order. Is this a friendly amendment? Well, I mean, well, proposed amendment.

Crowd: [Laughing]

Colehour Bondera: You, you suggest [inaudible] amendment?

John Foster: Depends on your point of view, I suppose. As with choline, I will, I will reject that.

Colehour Bondera: I hereby thank you for your friendly consideration.

Crowd: [Laughing]

John Foster: Jay.

Jay Feldman: But I would like to second the motion, in a very friendly way of course.

John Foster: Oh, I see you are smiling. Of course, that would be mean to be necessary. And then I would actually friendly reject that.

Jay Feldman: I do not think... I think we can vote.

John Foster: Oh, no, you are right, you are right. We have to, I am sorry, my, my mistake. We need to have discussion on that point.

Jay Feldman: Right.

John Foster: Yes. Thank you. Thank you for correcting me, Jay?

Comment [JMS15]: 03:30:00

Jay Feldman: Okay, so a lot of this is similar, as you pointed out, to choline. So just want to make sure again that we recognize the Pediatric Nutrition Handbook, and the apparent recognition of, of the essentiality of inositol [*inositol*] at a certain level. They, they have it here in milligrams per kilogram at 4.0. Which, for me, in terms of fortification, or I would view this more as nutrient addition, a very distinct discussion from fortification of, with synthetics outside of that context of required for, especially for infants.

Having said that, I, the reason I like Colehour's approach on this is, and I wish we had considered it more thoroughly with the choline, it because it, it is a good compromise. It, it allows for product differentiation in the market, which we are really trying to get at. And I really appreciate what you are const-, constantly reminding of us, of us here, John, that we do want to, you know, increase the demand for organic, and thereby increase acreage, et cetera, et cetera, and that consumers we know are, parents especially, are looking for certain things and products that their pediatricians tell them to look for, et cetera.

On the flipside, of course, I feel we in the organic community have an obligation to educate consumers with, with our, you know, with, with the best information we have at, have on the subject. So, the reason this is a good compromise is because, and I remember this as you all probably do from the early days, you know, a lot more products with the "made with" before we were putting all this stuff on the National List. "Made with" was a category that did differentiate, and still does. And there are many manufacturers out there that use it very successfully and profitably. And yet, it, it enables us to put a synthetic in that I would typically vote against.

But, because of these nutritional requirements, I feel compelled to support, but not in the, not under the label. See? That is a distinction. Because, here we are putting, we are adding a form, a synthetic form. Again, we talked about this in the past. Hopefully, part of what we are doing here as a Board is we are creating incentives for manufacturers develop natural, to develop natural forms of these synthetics. And so, I think by putting these synthetics on, just jumping in whole hog under the label that we are not, we are not

doing that. We are cutting off the incentive to develop the alternative. So, thank you, Colehour, for that amendment, and I hope others will support it.

John Foster: Sorry, is there more discussion on the, I do not even know what we call that, the amendment?

Barry Flamm: We have a... Who, who seconded the amendment? Jay?

John Foster: Jay seconded.

Barry Flamm: Okay.

John Foster: Hum-mmm. More discussion on the amendment? Okay, seeing none, I believe we can proceed to vote on the amendment.

Barry Flamm: So we are voting on amendment to the motion. And the amendment... If the maker of the motion would re-state his amendment for clar-, so that the Board is clear what we are voting on.

Colehour Bondera: Yes, thank you. The amendment is to strike the words, where it reads "infant formula labeled organic or made with organic" to strike the words "organic or". That is the amendment.

Barry Flamm: So, it would read just "made with organic"?

Colehour Bondera: That is correct.

Barry Flamm: Alright.

Unknown Male: Mr. Chair. [Inaudible] has a question.

Barry Flamm: Okay. There is the question.

Nick Maravell: Are we, are we, can we, can we, is there an opportunity for discussion on this?

John Foster: We, I, I asked for discussion I think.

Nick Maravell: Oh, yeah, I, I have a question. If this amendment passes, then we would have a little bit of lack of parallelism, if you will, between choline and inositol.

John Foster: That... Correct.

Nick Maravell: And, I would, I, I guess what I am asking is, if this were to pass, I voted for choline as it went through, would it be appropriate to reconsider that vote and give the, give the Board the opportunity to consider amending our previous action?

John Foster: I, I cannot really speak to that.

Nick Maravell: Okay. [Inaudible].

John Foster: It is above my pay grade.

Nick Maravell: Well, let me ask, would it, would it be in order, maybe appropriate is the wrong word, would it be in order to ask for a reconsideration of, of the choline vote to determine if any members wanted to re-do?

John Foster: I, I would need to give that over to the chair. That would be his discretion, or his decision.

Barry Flamm: Let us, we have a tight schedule, so let us proceed with the vote on this amendment, and we will, we will consider your ... after the outcome here.

Nick Maravell: Okay.

Barry Flamm: Wendy will lead off the vote on the amendment.

Wendy Fulwider: No.

The Entire NOSB Board: Yes. Yes. [Inaudible]. No. Yes. No. Yes. No. No. No. No. No. No. Yes, sir.

Barry Flamm: The chair votes yes. Five yes, 10 no, the amendment fails. We will proceed with the, the main motion.

Lisa Brines: Excuse me, Barry? We had a, we had a different count for that vote.

Barry Flamm: I am sorry.

Lisa Brines: We had six yes and nine no.

Barry Flamm: Okay. Alright. Thank you for the correction. Six yeses, nine noes. The motion still fails.

John Foster: All right, we will proceed with the main motion, then. Would you like me to restate?

Barry Flamm: Yes, would you restate the main motion?

John Foster: Michelle, could you put that up on the screen again or...? Oh, sorry. This is a listing motion. I move to, the motion was to, to add inositol, CAS numbers 87-89-8, myo-inositol, and 6917-35-7, non-specific isomer, to the National List, 205.605(b) for use in



infant formula and medical nutritional enteral products labeled organic or made with organic, parenthetically specified ingredients or food groups.

Barry Flamm: Thank you.

John Foster: We can proceed to vote.

Barry Flamm: We already have.

John Foster: Oh.

Barry Flamm: Was there any more discussion, John?

John Foster: Apparently, Jay. Yep.

Jay Feldman: I am sorry. Yeah, I was just trying to support the motion. I did not, I, I wanted to get on the record the concerns that were raised in the TR, just so that it is clear here, that according to the TR, gibberellic acid, at least that which is made by submerged fermentation techniques is quote purified using methanol, acetone, ammonia, ammonia salts, and/or ethyl acetate, specific details on recovery and purification processes are generally not published but rather kept...

Jean Richardson: Point of order.

John Foster: Were you talking about gibberellic acid?

Jay Feldman: Oh, I am sorry. Thank you. I am reading the wrong thing. Yeah. Apologize for that.

John Foster: In, in your favor, you had a lot of people like going with it for a second.

Jay Feldman: No. no.

John Foster: That was very convincing.

Jay Feldman: I do not know how that. Oh, I see what happened. I am sorry. No. You are right. Okay, well, let me, before I get back to, to the issue of synthetics used in its production, I wanted to, to address the issue of whether there was, you know, the manufacturing processes and what, what we, what we know and do not know about the manufacturing processes of, of this and how it is made. I guess my question is, maybe, Zea, you can help me with this, my understanding was that there was a process of dilution with water boiling and agitating that and whether this, whether in fact when you looked at the manufacturing process, that, that there were no ingredients or processes that were, that were identified as pot-, as potentially hazardous. I guess that is what I am getting at.

Zea Sonnabend: Can I respond to that?

John Foster: Zea.

Zea Sonnabend: Thank you. I was not the point person in this, so I did not delve into the research as much as I did on choline, but my understanding is that it, while it could be made non-synthetically, it is not in any form that anyone can buy. So, it is not commercially available. Although theoretically feasible to ex-, make it from a non-synthetic source.

Jay Feldman: Yeah. Okay. I do not want to belabor this point, but I wanted to make sure we had on the record, and I cannot find this now, the, the materials that are actually used in the process of making this, and whether in fact, you know, we are, have fully evaluated what those materials are. Again, because this is viewed as essential, obviously, this is not a, not as, as critical as in other situations. But, it still in my mind goes back to the point of whether we should be carrying this under the organic label. But, we have already voted on that so, apologies for reading from the wrong script here.

John Foster: That, that is all right. It has been a long week. Duly noted. Thank you. Additional discussion? Alright, seeing none, I believe we are ready to proceed to vote.

Barry Flamm: Thank you, John. Let us see who you got here. We will begin the voting with Colehour.

Colehour Bondera: No.

The Entire NOSB Board: Yes. No. No. Yes. No. Yes. Yes. Yes. Yes. No. Yes. Yes, sir. Yes.

Barry Flamm: Chair votes yes. 10 yes, five no, the motion passes. John, do we have any...?

John Foster: Yes, we have one more, what I believe is one more motion to put forward. Could we have that up on the screen again, please, the, the pages? Thank you. This is a second listing motion. I move to add inositol, CAS numbers 87-89-8, myo-inositol, and 6917-35-7, non-specific isomer, to the National List, 205.605(b) for use only in agricultural products other than infant formula, other than infant formula, and medical nutritional enteral products labeled "made with organic, specified ingredients or food groups" and prohibited in agricultural products labeled "organic". Second? Joe?

Barry Flamm: We have a second?

Joe Dickson: I second that.

John Foster: We have a second. Is there discussion?

Barry Flamm: For the...

John Foster: Alright. Seeing none, I believe we can proceed to vote.

Barry Flamm: Okay, we will start the voting with, with Nick. Nick, would you start the voting, please?

Nick Maravell: No.

Comment [JMS16]: 03:45:00

The Entire NOSB Board: No. No. Yes. No. No. No. Yes. No. No. Yes. No, sir. Yes. No.

Barry Flamm: Chair votes no.

Zea Sonnabend: Could I change my vote to no because I was, thought it was the previous vote.

Barry Flamm: Without objection. What was the count?

Unknown Female: 12 no.

Barry Flamm: The vote is three yes, 12 no, the motion fails.

John Foster: Mr. Chair, it is with some happiness I report that is the last of the voting items for the Handling Committee.

Barry Flamm: Whoopee.

John Foster: Oh, my God.

Barry Flamm: Next, next on the agenda is a presentation of Committee work plans. Maybe after this session with Handling, I think maybe we, we all need to stand up for a moment, but do not leave the room. Stretch your legs and then we will go to, then we will start with the work plans. Just a moment or two.

Comment [JMS17]: 03:46:50

[BREAK]

Comment [JMS18]: 03:53:40

Barry Flamm: What do I do? [Inaudible] The Board meeting is back in session. Please come to order. We are going to present the work plans, the Subcommittee work plans in the order of the way they, the Committees were listed in the beginning of the agenda. And that is the CACC will begin, followed by GMO ad hoc Committee.

Joe Dickson: Thank you, Mr. Chair. Michelle, do you have the work plan that was presented you know?

Michelle Arsenaault: [Inaudible].

Joe Dickson: Well, I will just use my words. [Laugh].

Michelle Arsenaault: Okay.

Joe Dickson: Thank you. The Compliance, Accreditation, and Certification Subcommittee's work plan for the fall of 2012. The first item is the discussion document on sanitizers and 100% organic products will most likely be turned into a recommendation, based on the feedback we received through public comment at this meeting. The Material Review Organization recommendation I believe is officially complete and off of our work plan. Also, for fall 2012, we will be covering monitoring practices and procedures for organic system plans, as described in 205.201(a). That is a discussion document for the fall that will be worked on by Mac and Barry. We also have on our work plan a recommendation or, or other communication related to calculating the percentage of organic ingredients and some of the issues surrounding the 95% organic category, and how those, those ingredients factor into the cert-, certified multi-ingredient products. Barry will be leading us through some reconsideration of the earlier 2009 joint Crops and CACC biodiversity recommendation and a few loose, loose ends that are trailing from that recommendation and may necessitate further work or consideration. That is the extent of our, our fall work plan, as it currently sits on our agenda. Thank you, Barry.

Barry Flamm: Thank you, Joe. Next up is Zea, present the...

Miles McEvoy: Barry, could, could the Program make some comments on this?

Barry Flamm: Yes, certainly.

Miles McEvoy: We had a few questions on a couple of these items. On the sanitizers and 100% organic products, we are going to, as agreed upon, we are going to provide an overview to the CACS of food contact substances, processing aids, et cetera. And, I think there needs to be a lot more work done in this area, and not sure if it is going to be ready for a proposal by the fall, so, but, certainly willing to work with the, with the CACSC on that. Okay. Review criteria, that is done. Let us see, monitoring practices. We just wanted to get a little more clarification on what that particular item is, monitoring practices and procedures for organic system plans, so that we can continue to work with the Subcommittee on clarifying that. Calculation of percentage of organic, we are, that is very exciting that you are going to work on that. That is a very important item. And biodiversity, we already have the 2009 joint Crops and CACC recommendation that we are working on implementation. So, look forward, I guess, to more information on that as we work towards implementation of that biodiversity recommendation.

Joe Dickson: Great. On the sanitizers and 100% organic products, yeah, depending on the timing of more clear information from the Program, we look forward to working with you guys over the summer and, you know, if it is right for something in the fall, it is. If not, it will stay on our work plan until such a time that it is appropriate. I am going to ask John to chime in a little on the 205.201(a) recommendation or issue rather.

John Foster: Yeah, 205.201(a)(3).

Joe Dickson: Yes. Sorry.

John Foster: So, the idea there, this has, this has been kind of something of a undiscovered country of the organic system plan for a while. It has, it has been the least, I do not want to say least monitored, but it is certainly the least articulated part of the organic system plan. There is a fair amount of cloudiness about what it means and how it should apply. This is coming from some certifiers from many inspectors having trouble with the, what that means. And so, there was some public comment, I believe, at the last, I cannot remember if it was the meeting or the meeting before now, but for clarification on this and suggested some pathways to, to help, well, suggested an interpretation, actually, of, of what that meant. Meaning, how are operators monitoring their own systems, such that they can ensure compliance with the Act, compli-, or consistency with their own OSPs over time, since the inspector is not there every day. It was, that was, that is my recollection of the gist of the need or the, or the ask. And so, this, this work plan item is designed to flesh that out, gather more information from those constituencies. And, and if there is a need for, for clarity that we can get, that would be helpful, then that is what we would work toward.

Barry Flamm: Thank you, John. We will, we will have to **move** on. We do have to close this meeting on time at 12 o'clock so there is limited time for each of the Committee's presentation and we have allocated three minutes per Committee to present the work plan.

Comment [JMS19]: 04:00:00

John Foster: Just I wonder if the Program wanted to respond to that.

Miles McEvoy: Yeah, that was some helpful clarification. We just have two quick things that we are going to ask for clar-, some help with. The residue testing response to the IOG audit, we will put that in writing to the Board and the CACS in particular. And also sanitizers and milk trucks: we are looking for the Board to help us and collaborate on those two projects as well.

Barry Flamm: Thank you. Zea, would you present the [inaudible] *[GMO ad hoc Committee work plan]*?

Zea Sonnabend: Okay. We have three particular things for our fall work plan. We are going to put forward I hope a seed purity discussion paper. This, you know it all starts with the seed and keeping things free of GMOs, and this may not advance further to a recommendation but it will be a call to the community to ask for input on this very important topic. We also will help give feedback to the NOP and their response to the IOG audit about testing feed products. And we will be discussing plant breeding issues such as cell fusion and mutagenesis. And there are some other plant breeding issues, and I am not sure, we will be doing this in conjunction with the Crops Committee. I am not sure if it will result in a discussion paper or a recommendation, but, we will see.

Barry Flamm: Okay.

Miles McEvoy: That sounds great.

Barry Flamm: Okay, we will move on to the Materials Committee.

Jennifer Taylor: Thank you, Barry. The Materials Committee draft work plan will include:

To develop and implement the framework for the NOSB research priorities that have come out of the implementation of the research priorities frame, framework recommendation.

To examine issues focusing on genetically modified organisms.

To examine and update petitions and technical review process jointly with the Policy Development Committee.

To examine confidential business information transparency, again, also jointly with the Policy Development Committee.

To examine ion exchange chromatography and impact.

Thank you.

Barry Flamm: Questions, comments, Program?

Miles McEvoy: So, from the Executive Committee, we have the ion exchange chromatography that, that is, that sounds great. And then we have the examine CBI and petitions, right? That was the second one?

Jennifer Taylor: Yes.

Miles McEvoy: That is great. And then, the, there was a third one on identifying substances made with GE materials. Was that the one?

Jennifer Taylor: Right, to examine issues focusing on that. Another one was to examine and update the petitions technical review process.

Miles McEvoy: What was the fourth one?

Barry Flamm: Jennifer, would you speak up? I cannot hear you.

Jennifer Taylor: [Inaudible] Oh, okay, I am sorry. Examine the, and update petitions, the technical review process.

Zea Sonnabend: Also, they are collecting the research priorities was the first thing she said, which is as per the recommendation that was passed this meeting.

Jennifer Taylor: Right. And then...

Miles McEvoy: Okay, thank you for the clarification.

Jennifer Taylor: Alright, okay.

Barry Flamm: Okay. Miles? You okay? Next is Crops. Jay, please.

Jay Feldman: Okay, we have a number of petition substances on the Crops Committee that we are dealing with, ferric phosphate, snail bate, PGML, oxidized lignite, biodegradable plastic mulch, polyoxin D zinc salt, vinasse, sulfuric acid, aquaculture materials for plants, CO<sub>2</sub>, is one I guess, micronutrients, perhaps. I am not sure. Some housekeeping on Rotenone.

And then we are not sure where things are at with streptomycin and tetracycline. But, those will have to be petitioned to the Board if there is a, a desire to maintain their uses.

In the inerts ingredients category, as you know, we have the List 4 inerts, or, or the sort of overall inerts policy, now. And then we have, as I have mentioned throughout this meeting, we have another individ-, a number of petitions for individual inert ingredients: Polyglyceryl Phthalate Ester Coconut Oil Fatty Acid, 1,1-Difluoroethane, Magnesium Sulfate, Monphhydrate, Ethylene DDSA or EDDS, as it is known, Turpenes. So those are the inert issues that we have got before either pending or sort of on the plate, as it were.

And then, other issues that have come up that have been on the work plan, so I guess we have to really decide whether we are going to do something with these things: Seed Purity, Plant Breeding, review public comments on GMO issues, Mushroom standards, food safety, Fire Blight, which obviously is under streptomycin and tetracycline, and Organic Seeds, so I guess that is part of seed purity, but one was GMO and the other was more general. Thank you.

Barry Flamm: Questions from the, from the Program?

Miles McEvoy: That is a long list, but it looks great. [Laugh].

Barry Flamm: Okay, thank you, Jay. Next is Livestock Committee.

Wendy Fulwider: Thank you, Barry. Michelle, you have our list?

Michelle Arsenault: [Inaudible].

Wendy Fulwider: Okay, I had sent a revised one, but that is fine. It is close. We will begin our work on petitions for Nonanoic Acid and Pet Food Amino Acids. And then we will be working on aquaculture. We will be working on Carbon Dioxide, Chlorine, Micronutrients, Vaccines and Biologics. We will have a GMO vaccines update. We will try to complete the rest of this list as it is rather lengthy. There is a Parasiticides for Fiber Bearing Animals discussion document, a Poultry-Omnivore Diets discussion document, and then, of course, the Beef Guidance, Dairy Guidance, and Swine Guidance.

Barry Flamm: Thank you, Wendy. Comments from the Program?

Melissa Bailey: Thank you, Wendy. In terms of the work plan for additional species-specific guidance, or I think you might have had up there a mention of the stocking density for other species that were not covered in the previous recommendation. The Program at this time would appreciate us taking the time to focus on looking at the Animal Welfare Recommendation that the Committee already passed. And, sort of allow us to figure out what we are going to do with that recommendation before we start getting more and more additional information and proposals from or recommendations from the Board on species-specific guidance and the stocking densities. You guys did a lot of great work before. We have not fully digested all of that work, yet. And so, we would like an opportunity to do that before having the Committee spend a lot of time on these additional items. So.

Barry Flamm: Wendy?

Wendy Fulwider: We were just considering working on refinements to the pieces that we have, if we have the time.

Barry Flamm: Any other comments? Okay, Colehour, Policy.

Colehour Bondera: Michelle, can you...?

Michelle Arsenault: [Inaudible].

Colehour Bondera: Yeah. Thank you. Yes, so, for the work plan of the Policy Development Committee – go to the next one, Michelle, please – for October 2012 and beyond. We may or may not be able to read it, sorry about the font size issue. I started adding too many things and frankly when I added back the Public Comment Policy, the Public Communications Policy, and the Conflict of Interest Policy back to this that were not on it up until this point in time, it did confuse it a little bit. But, those three items are appearing at the top of the list along with Policy Procedure Manual Updates, which does include, it was already on there before, the review of the Ethics Rules, our you know existing and updated components of that PPM.

We also need the New Member Guide Update to be, to be dealt with, and we are hoping from a time, time frame perspective all of those things will be dealt with in October 2012. But we will see. We have on there, and we will get the NOP's response, but, the Material Initiation Policy, and if necessary, Jay can speak further to that one. But, that is where, because we have with the NOP discussed this to some degree, in terms of where mate-, where the initiation comes from, in terms of having it in policy, if, if it is coming from the public, if it is coming from the NOP, or if it is coming from NOSB, and what the processes are for that.



The Confidential Business Information joint with the Materials Committee was mentioned by the Materials Committee, and that is on there as well. I think that the next one overlaps with that presentation, too, from Materials, which is technical review, policy review and, which includes a proposed threshold to stage technical review. The decisive/indecisive determination on the NOSB votes is on there. And, and I am not sure in what form that will take. But, I wanted to leave it on there, because we are working with the NOP on that issue, but just so that if we need to put it forth in its own way at one of these meetings, that we are avail-, able to do that.

And then I have added on there “Convening of Technical Advisory Boards and Working Groups Policy” so that that is clear within the Policy Procedures Manual, how we are dealing with that process of those things. So, we are all on the same page with that. And so, I, I welcome any comments. Thank you.

Barry Flamm: Comment from the Program?

Miles McEvoy: Yeah. I, I think we covered most of these things at the last Executive call. If you could put that back up there so that I could respond to it, that would be great. Thank you. The Policy Procedure Manual updates, we are certainly going to work very closely with the PDSC on that, including the Conflict of Interest, Public Comment Policy, Public Communication, New Member Guide, all very committed to, to working with the Subcommittee on that. Material Initiation Policy, we are, I, I think this is related to, Jay, what we talked about a few weeks ago, on how, clarifying the process for how substances are brought to the Board and, but we still need a little more clarification on, on what that is. And I guess we can work that out as we move, move down the road on that. But, we are, I am still not real clear on exactly what the parameters are, and. and further conversation I think will help to clarify that. So, I do not know if you want to add anything to try to help clarify that.

Jay Feldman: Yeah, I mean... Yes, thank you. Yeah, the, it is pretty clear what the, what the public needs to do to get a material before the Board, and that has been laid out for many years in the Policy Procedures Manual. It is not clear what the process should be for the Board. If the NOSB was to revisit in, a material prior to Sunset or in the absence of a petition, how that would happen and the hurdles that we would need to go through are not clear. So, that was just, maybe it just requires clarification.

Miles McEvoy: Okay.

Nick Maravell: Jay, would that include, I am, I am not sure, quite sure that I am following it completely. But, suppose we get some form of a, of a policy recommendation or clarification from the Program, requesting us to add something to the National List. Would that be part of that?

Jay Feldman: Right, yes. Yes, exactly.

Nick Maravell: Okay. Thank you.

Barry Flamm: Okay, Thank you for the comments. Miles, did you have anything?

Miles McEvoy: Yeah. The, the other part on the decisive/indecisive vote, that we are providing specific information to the Policy Development Committee, Subcommittee on that, and what will become of that, whether there will be something in the fall to, to either present or discuss, I guess we will, we will see how that process unfolds.

Barry Flamm: Okay, thank you.

Melissa Bailey: Barry, could I just add one thing? Could you put that up? Sorry. On the CBI information petitions and the technical reviews, including this two-stage concept that was presented: If the Committee could, I, I understand you will be working with Materials, but if you could make sure to keep Lisa Brines in the loop, because she does work quite a bit with those contracts for the TRs, and that will impact our process at the Program. So I would appreciate her being part of that.

Comment [JMS20]: 04:15:00

Colehour Bondera: Yes, thank you. And thank you NOP for your input, and we will work with you and I will make sure I am cc-ing every member and inclu-, make sure Lisa is included. Thank you.

Barry Flamm: Colehour, does that conclude your presentation?

Colehour Bondera: Yes. Thank you, Mr. Chair.

Barry Flamm: Thank you. John, Handling, will you present your work plan, please?

John Foster: Sure. Michelle, could you put that up, please? The, yeah, from the Excel sheet. If we cannot see it, does that mean that we do not have to do it?

Unknown Female: [Sigh]

John Foster: That was an old joke. Little joke.

Michelle Arsenault: We are just trying to get it big enough so people can see it.

John Foster: Thank you, including me.

Michelle Arsenault: That look okay?

John Foster: Thank you. Handling Committee has a, a fairly long list of petitioned materials. And, and I have already spoken with Melissa a little bit on, on knowing that we need to strategize a little bit to make sure that we are, we are going to get through all of these. They are, are all petitions. There is no Sunset items. The only exception is a, hopefully a proposal on, if not a discussion document on, other or ancillary ingredients. But, the remaining work plan items are all petitions. They are for L-carnitine, L-methionine, Beta-

carotene, Taurine, Nucleotides, Ascorbyl palmitate, Lutein, Lycopene, Barley Betafiber, Sugar beet fiber, Bergamot bitter orange powder, Sulfuric acid, and if we can get the TR for DBDMH prior to about August 20<sup>th</sup>, I am sorry about August 10<sup>th</sup>, we can probably get, fit that in, also. That is the work plan.

Miles McEvoy: Sounds great.

Barry Flamm: Thank you, everyone. Well we are coming down to the end right now. And, I want to thank all of you diehard participants that are still here, and for the record, all the people who presented comments during the week. I think we had a, had a extremely interesting and valuable interactions and participation and tremendous comments. And, I, I would like to thank the, the Board members for the, their great cooperation in, in dealing with a new format. And, I appreciate all what you have done, and thank, thanks to the NOP for their, for their partici-, participation and help and the advice that they have given. So, with that, I adjourn this meeting of the Board.

Nick Maravell: Mr. Chairman? Mr. Chair, could I introduce another item for the Board to engage in?

Barry Flamm: You want to introduce a ...

Nick Maravell: Basically, a discussion to ask. We have changed our formats a little bit here. And, we have got some new policies and procedures we are following. And, I am just sort of wondering. We want, we might want to go around and just sort of ask a minute or less what worked and what did not work about this meeting, and to include the NOP staff in that discussion. So, I, I, that, that is my suggestion.

Barry Flamm: We will definitely have a thorough discussion and evaluation and dialogue on considering talking about what worked and what did not work under the new format. And, that will be done subsequently. I have no, no objection with the time left, if you, if members want to just off the cuff, but I think we need some of this to soak in and think about and talk about later. But, I, I have no objection if, and since, Nick, you, this is not a motion or anything, but it, since you introduced it, do, would you like to make a few comments and keep them brief? We have, according to my, I do not know if my, my clock, how much time does other people have? We have got to be done.

Nick Maravell: You have got to watch me carefully.

Barry Flamm: I have two different clocks here, and they give me different times, so.

Miles McEvoy: You have got about 15 minutes.

Barry Flamm: Okay, we have, we have time. Go ahead, Nick.

Nick Maravell: I think the new public comment arrangement whereby we try to group comments of similar impact or, or topic is very good. I think we stumbled in how we arrange and get

the general comments and how we have enough time to get the full view of information from people in the field, and particularly national organizations that are commenting on multiple items. So, I think that that might be something we would want to work on, in terms of increasing the public comment. And I will st-, I will also comment that I think it has, it has taken a lo-, I am not sure I have gotten used to the rhythm of how the Committee decisions are made during the meeting, as opposed to how they were at previous meetings, when we seemed to have more time to readjust. So, I will just, those are my comments.

Barry Flamm: Anybody else want, would like to make a comment at this point in time? Mac, go ahead, please.

Mac Stone: I, I too like the format of grouping by Committee conversation. It does seem awkward of wordsmithing, sort of on the fly. So, how we can structure that, maybe around breaks or whatever. But, I like the clustering, but just not the wordsmithing on-the-fly.

Barry Flamm: Anybody else? Zea.

Zea Sonnabend: This is more of a question. But, how much longer today do we have to turn in our final forms for our motions that we made with the final votes, which I might have gotten all down right, and might not have.

Barry Flamm: As soon...

Zea Sonnabend: Because I, that seems to me to be a problem, because we are in the thick of the discussion and so now I have to fill out this form. And so I have to wait until we are done. So how much longer?

Barry Flamm: That is, I am going to be here until 2 o'clock. I thought that would allow everybody time ....

Zea Sonnabend: [Laugh] Is not it how long Miles is going to be here though or...?

Barry Flamm: I do not know. I have not ...

Zea Sonnabend: Do we turn them in to ...? We turn them in to you, Barry.

Barry Flamm: Yeah, you turn them into me. And are you going to be doing it electronically or hard copy?

Zea Sonnabend: Electronically, I do not have a printer.

Barry Flamm: Okay. Well, just copy me and copy Michelle, that is all.

Zea Sonnabend: Okay, and if the vote is wrong, you will double check it?

Barry Flamm: I will.

Zea Sonnabend: Okay, thank you. [Laugh].

Barry Flamm: Soon as I can open my computer.

Zea Sonnabend: I, because I just see that a flaw, like having to do this final thing right now and so maybe that could be thought about for the future.

Barry Flamm: Yes, I know, handling this is a particular problem. I think everybody else has, has got theirs done. John, John, please.

John Foster: I was just going to say that I, I as chair need to send that, I need to send that to Barry.

Zea Sonnabend: [Inaudible].

John Foster: I will be here as, as long as I need to be here. So, but, but, procedurally, it needs to go through the chairs, to Barry. And then ...

Barry Flamm: Yeah, right. Thanks, John.

John Foster: Okay. And then, my, I really enjoy, I really appreciated the, even though it took me a while to get into the groove of it, I really appreciated the introduction of each material. That was really helpful. And it, it got, once, once I got used to the idea, I think it really helped to set a good cadence. And, I, I think that has, that is only positive, so. That was my big, I liked that part of it.

Barry Flamm: Any other comments? Does the Program want to make a comment? Oh, oh, Jennifer.

Jennifer Taylor: Well, I, I actually did not have a comment myself. I was trying to get the attention of Calvin, because Calvin had been talking to many of us. And also I believe that he talked with you, Miles, about the introduction of a new kind of concept and a way to hear from the public. And then, think about it in a while. And then address some of the issues. Calvin? Can you talk about it?

Calvin Walker: I have closed that part of my brain.

Jennifer Taylor: Oh, okay.

Calvin Walker: I, I believe that was on Tuesday, mentioned sometime we are making quick decision, maybe the format that we have may need to be tweaked to allow more time to digest recommendations. Because, the Supreme Court, city councils, sometime do not decide things on the fly, on a short time, on a short time on it. So, maybe as we look at

this arrangement, as far as voting, discussing, particular issue, we may have to look at a different arrangement. That was the essence of it. Maybe some of these things could be brought back and voted on at another time at the next meeting, something of that nature. Not everything.

Barry Flamm: John, please?

John Foster: To, to add the, to what Calvin was saying, he and I spoke about it a little bit, and it seemed to us that if we, that part of the problem in trying to implement something like this in the past has been that in, at least since I have been on the Board, we have been in high season for Sunset, and we really did not have the, the time to get out ahead of things. And right now, we are in a bit of a low season of Sunset items. So if, if we are going to look into this, now is exactly the right time to do it, so that we can incorporate Sunset review in addition to petitions in that kind of more proactive way. So, so there is a little time-of-the-essence feature here. But I think it is a good opportunity and we should give it, give it some good thought. I, I thought it was a great idea.

Jennifer Taylor: Yeah.

Barry Flamm: Thank you.

Jennifer Taylor: Thank you.

Barry Flamm: Any other Board, Board members [inaudible]?

Unknown Male: Just the Program.

Barry Flamm: Any other Board member? Miles, would you like to make a [inaudible] comment?

Miles McEvoy: Yeah, I would just, just like to thank the Board for your public service, all the hard work that you did. You had a lot of really difficult discussions and, and fruitful discussions. Lot of really good work that was done. Really loved the process. We will continue to work together and provide the support we can. But I would like to give a round of applause to the Board members and their service.

Crowd: [Clapping]

Barry Flamm: Thank you, and I do not want to be too abrupt, but if there is no other new business, I adjourn this meeting, and thank you all.

Crowd: [Clapping]

Mac Stone: [Inaudible].

Barry Flamm: Huh? Oh, Mac says I got to hit it one more time.

[Event concluded] (End)