

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

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MEETING OF THE NATIONAL ORGANIC
STANDARDS BOARD (NOSB)

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TUESDAY
OCTOBER 26, 2010

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The National Organic Standards Board convened at 8:00 a.m. at the Best Western InnTowner, 2424 University Avenue, Madison, Wisconsin, Daniel G. Giacomini, Chairman, presiding.

MEMBERS PRESENT

- DANIEL G. GIACOMINI, Chairman
- STEVE DeMURI
- JOE DICKSON
- KRISTINE "TINA" ELLOR
- KEVIN K. ENGELBERT
- JAY FELDMAN
- BARRY R. FLAMM
- JOHN FOSTER
- WENDY FULWIDER
- JENNIFER M. HALL
- KATRINA HEINZE
- TRACY MIEDEMA
- JEFFREY W. MOYER
- JOSEPH SMILLIE

STAFF PRESENT

MILES McEVOY, Deputy Administrator, National
Organic Program
MELISSA BAILEY, Director, Standards Division,
National Organic Program
LISA BRINES, Standards Division, National
Organic Program
MARK LIPSON, Organic and Sustainable
Agriculture Policy Advisor, Office of
the Secretary
ARTHUR NEAL, Director of Program
Administration, National Organic Program
EMILY BROWN ROSEN, Agricultural Marketing
Specialist

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1 P-R-O-C-E-E-D-I-N-G-S

2 8:04 a.m.

3 MR. GIACOMINI: The Tuesday
4 session of this meeting, the National Organic
5 Standards Board is now in session where the
6 quorum of the board members are seated.

7 Audio crew, are we ready?

8 (No audible response.)

9 MR. GIACOMINI: Thumbs up from the
10 audio crew. And the programmer was telling
11 me we were late. So, I assume they're ready.
12 So, we're ready to proceed.

13 I just want to make one quick
14 statement before we move on this morning on
15 some of yesterday's public comment. We had
16 some new commenters that we don't always hear
17 from. We even had one, I believe his
18 statement was, "I don't talk too good." He
19 came up and talked to me afterwards and I told
20 him then and I'd like to put in the record now
21 that, you know, sometimes it's the stone with
22 the least amount of polish that has the most

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1 shine. So, we just want to express our
2 appreciation for all the people that have come
3 and all the people that will be giving public
4 comment tomorrow.

5 I hope you all had a nice evening
6 and that we're ready for business. The first
7 business this morning is our regular reminder
8 of the material process with a presentation
9 from the chairperson of the Materials
10 Committee on the material review process.

11 Katrina?

12 MS. HEINZE: Good morning. Thank
13 you. And I apologize that I used a dark
14 background on my presentation. So, we're all
15 sitting in the dark. So, the public see it.
16 I will bear that in mind for the next meeting.
17 So, I appreciate your indulgence.

18 So, this is our regular meeting
19 update on the material process, which we like
20 to schedule at 8:00 in the morning so that
21 everyone can wake up.

22 So, I'm going to remind everyone

1 about the National List, what our petition and
2 sunset review items are, how the process
3 works, the criteria for both the National List
4 and the sunset review and just end with some
5 final notes. And really this is to remind the
6 Board before we deliberate on materials today
7 and to aid the public if they're not familiar
8 with it.

9 Okay. So, just a reminder, the
10 National List has six sections; two for Crops,
11 two for Livestock, and two for Handling. For
12 Crops and Livestock there are synthetic
13 substances which are allowed which have been
14 reviewed for the Board and deemed allowed for
15 use in organic production. Those are section
16 601 for Crops; 603 for Livestock. Then there
17 are non-synthetic substances which are
18 prohibited for use in organic production,
19 again reviewed by the Board and recommended as
20 such. Those are sections 205.602 for Crops
21 and 604 for Livestock.

22 For handling things are a little

1 bit different. For a material to be allowed
2 it must be on the list.

3 I should go back and say for Crops
4 and Livestock if it's non-synthetic and not on
5 the list it is allowed. So, non-synthetics do
6 not need to be listed.

7 For handling everything has to be
8 listed. The list is divided between non-
9 agricultural materials; those are in section
10 605, and agricultural materials which are not
11 available in organic form, quantity or
12 quality. That is section 606. Section 605 is
13 divided between non-synthetics and synthetics.

14 And then we talked about this a
15 lot yesterday, but just a reminder that 606,
16 just because a material is on the list doesn't
17 mean that it automatically can be used.
18 There's a process that handlers have to go
19 through with their certifier to show that they
20 are looking for organic forms.

21 Okay. The material review
22 process, if a member of the public wants a

1 material to be reviewed, or if they want to
2 change an annotation, or if they want to
3 remove a material, they petition to the
4 Program for that, and guidelines on how to do
5 that petition process are available through a
6 Federal Register notice.

7 So, here we have that the material
8 review process has a minimum time frame of 145
9 days. I really, really want to emphasize this
10 is a absolute minimum if everything runs
11 incredibly smoothly and it does not include
12 time for rulemaking. So, this is the time
13 from when the petition is deemed sufficient to
14 the NOSB making a recommendation. And the
15 time frame will be affected by how complete
16 the petition is, and really the biggest impact
17 on the time frame is the manpower within a
18 specific reviewing committee. So, for
19 example, right now when committees have been
20 very busy with subset, which has to be a top
21 priority, petitions fall lower on the list.

22 Also, the timing of our public meetings

1 can affect this and the time to get a complete
2 technical review can affect this as well.

3 Okay. So, a brief overview of the
4 material review process. The NOP gets the
5 petition. They review it for completeness.
6 They'll do some communication back and forth
7 with the petitioner. Once they've deemed it
8 complete, they will forward it to the
9 Materials Committee and the appropriate
10 Material Review Committee, whether that's
11 Crops, Livestock, or Handling. Again, there
12 will be a second review for completeness,
13 determination of whether a technical review is
14 needed and there will also be a review of
15 other questions the Committee might have which
16 needs to be included in the technical review.

17 Once the technical review is back,
18 there will be work in committee to use that
19 technical information, gather independent
20 research if that's needed to review the
21 petition, and then a committee discussion will
22 happen. And based on that a committee

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1 recommendation will happen. That committee
2 recommendation gets posted for an NOSB meeting
3 with a 45-day required comment period. And
4 then at the meeting, which we'll be doing
5 later today, those committee recommendations
6 are presented and discussed. We have further
7 comments from the public on many of them. And
8 then the full Board will take a vote.

9 The thing I'd like to highlight
10 here is that all communication -- so this is
11 really for the public, and I'm sorry I'm not
12 looking at you. It's really important to
13 remember that all communication on petitions
14 needs to go between the petitioner and the
15 Program, and then from the Program to the
16 NOSB. And that's so that we have a full
17 record of that communication and that they get
18 to the right people and don't kind of get lost
19 in the process. It's also I think important
20 that folks on the Board can get buried in
21 email, and so this kind of helps manage that
22 a little bit for us. So, just a reminder,

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1 communication from petitioners to the NOP, not
2 to the Board.

3 Okay. So, some criteria for the
4 National List. So, generally any material is
5 going to get reviewed for detrimental chemical
6 interactions with other materials used in the
7 farming system, toxicity and mode of action,
8 impact on the environment, impact on human
9 health. And this is all in the rule. Effect
10 of the substance through interactions in the
11 agro-ecosystem and alternatives. So, we'll
12 look at alternatives to the material. And
13 then really it comes down to the compatibility
14 with the system of sustainable agriculture.

15 There are some different criteria
16 for processing aids or adjuvants. So, here
17 you're going to look at if it cannot be
18 produced from a natural source and there's no
19 organic substitute. Again, effect on the
20 environment, effect on human health, making
21 sure that quality of the food has its
22 nutritional quality maintained, that the

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1 substance's primary use is not as a
2 preservative or to kind of recreate the
3 qualities of the food that might have been
4 lost during processing, that the substance is
5 generally recognized as safe and that we will
6 look to determine its essentiality.

7 For items on 205.606 there's a
8 different list of criteria. Here we're really
9 looking for fragility of supply. So, there
10 may be things on the list that are available
11 but are not consistently available in the
12 form, quality or quantity. So, what the NOSB
13 considers is why the substance should be
14 permitted and then we're going to look at
15 current industry information to look at where
16 is it produced. We'll look at things like
17 climate, number of regions, the number of
18 suppliers, how much is produced, current and
19 historical supplies. So, you might look at
20 weather events; floods, droughts that can make
21 something that might be available in organic
22 form not consistently available. And then

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1 trade-related issues. You know, some things
2 are grown in regions of the world that have
3 unrest, and so getting them may be more
4 difficult. And then other issues which could
5 present a challenge. And often it's those
6 other issues that we spent quite a bit of time
7 talking about as well.

8 Okay. So, then just a reminder
9 about the sunset review criteria. All
10 materials on the list must be review every
11 five years to stay on the list. And the way
12 we've historically thought about this; and I
13 know we're talking about the sunset process at
14 the meeting, but our current process is that
15 these exemptions to the rule; so anything on
16 the National List is really an exemption, were
17 accepted because the evidence available showed
18 that the material was found not harmful to
19 human health or the environment, the material
20 was necessary because of the unavailability of
21 wholly non-synthetic alternatives and use of
22 the material was consistent and compatible

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1 with organic practices. So, in the review
2 we're going to look for whether there's any
3 new information available on those three
4 topics.

5 Any questions on that?

6 (No audible response.)

7 MS. HEINZE: Oh, let me do this
8 slide real quick. So, really sunset is the
9 opportunity to revisit the continued need for
10 the exemption. So, it's our time to determine
11 if conditions relevant to acceptance of the
12 exemption have changed. So, any of those
13 things I talked about on the last slide. If
14 a review finds that the initial conditions
15 still exist, the listing is renewed for an
16 additional period of time. So, this is our
17 current process.

18 So, our current process is this is
19 not a time to add new substances to the
20 National List, it's not time to change an
21 existing annotation and it's not time to
22 reinterpret unchanged information. So, if

1 there isn't new information and what we have
2 is the same information that a prior board
3 used to make their decision, sunset isn't the
4 time to do that. We have our normal process
5 where folks can petition and say they don't
6 think it's essential or any other things they
7 can petition.

8 Okay. So, if there aren't any
9 questions on that, I'm going to go through
10 materials that were currently in process.

11 So, I'll start with Crops. So, at
12 this meeting Crops has four petition materials
13 that they're looking at and their sunset 2012
14 material. Then they have a number of
15 petitions that are kind of in process. And I
16 will say that we had a number of petitions
17 this summer, much more than we'd had in my
18 previous time as Materials Chair. So, they
19 have one petition to remove, four to add a
20 substance and five additional inert ingredient
21 petitions that Crops has received. So, that's
22 just as committees work on their work plans.

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1 This is a nice summary for you.

2 Livestock has one material they're
3 looking at for this meeting and their sunset
4 2012 materials, and they have no other
5 petitions at this time.

6 Different story for Handling.
7 Handling got two slides. So, at this meeting
8 they have four petitions to consider and then
9 all their sunset 2012 materials. And then
10 they have received a number of petitions. So,
11 we have two petitions to remove that we've
12 received within the last month or two, so very
13 recently. We have three annotation change
14 petitions and quite a list of petitions to add
15 substances.

16 Any questions on that?

17 (No audible response.)

18 MS. HEINZE: And then I just
19 wanted to give a preview of sunset, so
20 hopefully we can continue to update this as we
21 look out.

22 So, at this meeting for sunset

1 2012 you can see the materials we're looking
2 at. Then we have at our spring meeting some
3 2012 cleanup to do. That will be I think our
4 last meeting to be able to get those done.
5 Then we do have sunset 2013 materials that are
6 coming. You'll see that Livestock is in
7 pretty good shape here, but Crops and Handling
8 have some work. We have nothing for 2014.
9 And then 2015 we'll have one. And then, you
10 know, we'll add, but 2017 will be the big
11 hitter again.

12 Okay. And then my last final
13 note, and we added this at the last meeting;
14 and this is really for the public to be aware
15 of, that it's our practice when a material is
16 being worked on in committee that the
17 petitioned or sunset material is going to get
18 assigned to a lead reviewer. So, someone
19 who's really responsible for shepherding that
20 material through the process, they're often
21 chosen due to their area of expertise. So,
22 that person is going to find all the relevant

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1 material. They'll develop an initial
2 perspective for the recommendation, provide
3 that perspective to the rest of the committee
4 and really lead the committee debate. So,
5 that person is responsible for making sure
6 that all sides of the topic are presented.
7 They'll write the committee recommendation
8 with input from the rest of the committee and
9 they will be the person presenting it
10 typically at the board meeting.

11 We want the public to know that
12 just because a person is presenting the
13 information, it may or may not be their
14 personal point of view. They are just the
15 person who is responsible for shepherding it
16 through. So, just a note there.

17 Okay. And then you can't see this
18 very well, but it will be available when this
19 is posted, but these are the three relevant
20 Web sites to be aware of. There's the NOP Web
21 site, the NOSB Web site and then public
22 comment.

1 And that is it. So, I hope
2 everyone had a chance for coffee so we can get
3 rolling. Any questions?

4 MR. GIACOMINI: Any questions or
5 comments for Katrina from the Board?

6 (No audible response.)

7 MR. GIACOMINI: Okay. Thank you,
8 Katrina.

9 If we could get a little more
10 lights here, Board would appreciate it.

11 The main items on the agenda this
12 morning and the remainder of the day are the
13 committee presentations and discussions. The
14 committees each have spent the last six months
15 working on a number of recommendations,
16 guidance documents. Put a tremendous amount
17 of work in a number of documents that we'll be
18 discussing today. Committees have also
19 reviewed public comments submitted on
20 regulations.gov and heard the comments
21 presented here yesterday.

22 So, starting with the report from

1 the committees, first up is the Crops
2 Committee and Chairperson Tina Ellor.

3 MS. ELLOR: Thank you, Mr.
4 Chairman. Uncharacteristically, I actually
5 have quite a lot to say this morning.

6 The Crops Committee met 16 or 17
7 times. I went through my minutes and we met
8 a lot between the last meeting and now and,
9 boy, accomplished quite a lot. And more
10 importantly perhaps, had tremendous
11 discussions on what directions we wanted to
12 go. There's a wide range of diverse opinions
13 and a huge range of knowledge and experience
14 represented on the Crops Committee and I have
15 to say I've learned so much from all of our
16 discussions and look forward to our continued
17 work together.

18 Also, a big improvement on the
19 Crops Committee has been the addition of Emily
20 Brown-Rosen as an NOP staff member who joins
21 our calls and gives us support. And those of
22 you who know Emily, know what a tremendous

1 resource that is. So, we really appreciate
2 that addition.

3 We had a lot of discussions, and
4 you will have noticed from Katrina's slides
5 that we carried a lot of 2012 sunset materials
6 over, and we did spend a lot of time talking
7 about that and the reasons for that on the
8 Crops Committee meetings. We have a lot of
9 requests out for additional technical
10 information. And although it wasn't a
11 complete consensus, the majority consensus on
12 the Crops Committee was that we would wait for
13 that additional material if we possibly could
14 before we do further deliberations on those
15 materials. So, we're expecting to have a lot
16 of work to do before the next meeting to
17 shepherd those materials to where they need to
18 go.

19 I want to apologize right up front
20 about the late addition to the corn steep
21 liquor recommendation, and I have to take all
22 of the hostile fire for that. I even heard

1 somebody say that it made us look like
2 bumbling idiots. And I just want to correct
3 that. There's only one bumbling idiot, and
4 that's me. But the way that happened -- and
5 believe it or not, this isn't all we do. You
6 know, we have other things that we do. And
7 when it came time to write the final
8 recommendations, I could have passed that one
9 off, but I did not pass that recommendation
10 off.

11 And I wrote that original majority
12 opinion, even though I'm on the minority
13 opinion. And let me say right off that that
14 did not affect how I wrote the opinion. I
15 wrote the opinion based on the minutes in
16 front of me. I was very short in time because
17 I had an unfortunate incident involving a new
18 puppy, a cat, a cup of coffee and my computer.
19 So, I was without my computer during that
20 critical time and therefore I did get the
21 recommendations out on time. I asked for
22 feedback from the Crops Committee, especially

1 on that recommendation, because I wasn't
2 completely comfortable that I had represented
3 the majority opinion adequately. They did not
4 have time to get back to me.

5 So, you know, it was my decision
6 as Crops chair that if members of the
7 Committee weren't feeling like their opinion
8 was fairly represented that they should have
9 the opportunity to do that. They did a great
10 job rewriting. And when we started to get
11 some negative feedback on that saying you guys
12 can't do that at the last minute, we got back
13 together as the Crops Committee and we decided
14 that we did do the right thing. We want
15 everyone's voice to be heard and to be heard
16 in a way that they feel fairly represents what
17 their intentions are.

18 So, any hostile fire on that
19 should be directed at me.

20 Moving along. We have four new
21 petition materials, and this gets to be a bit
22 of a complicated issue. And after I'm done

1 with this introduction, I'm going to hand it
2 off to Jeff. We talked a lot about how to
3 handle -- all four petition materials are List
4 3 inerts. And we found now that we're
5 beginning to review inerts based on criteria
6 that were written to review actives, that
7 there's some inconsistency and difficulty
8 using those criteria to look at inerts. And
9 I'm going to let Jeff address that in more
10 detail with a statement later one.

11 As Katrina said, we as a committee
12 appoint people or people take point on
13 particular materials, so for ethylene glycol
14 Jeff had point on that one and he'll be
15 introducing that. EDDS I believe was Jay's
16 material. He did a tremendous job with that
17 one. And we do have a complication about that
18 material which we'll bring up during that
19 discussion. I had point on tall oils, and
20 Kevin did some work on that one as well. And
21 tetramethyl decyne-diol, if I pronounced that
22 correction, is Barry's to introduce.

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1 I'll go through quickly the
2 reaffirmation for sunset and then we'll go
3 through our sunset 2012 EPA List 4, which
4 again I'll over to Jeff. For the majority
5 opinion we have a minority opinion which will
6 be presented by Jay. The corn steep liquor
7 recommendation, Jay will present the majority
8 opinion and John will present the minority
9 opinion.

10 All that said, I'm going to turn
11 it over to Jeff before we go to the individual
12 materials to talk about the inerts issue and
13 the complications surrounded by that.

14 I'll turn it over to you, Jeff.

15 MR. MOYER: Thank you, Tina. Yes,
16 what I'd like to do, if I could direct the
17 Board's attention to the screen.

18 Okay. I think Katrina did a very
19 good job of leading into this conversation and
20 it's really a follow up on the conversation we
21 had last April. Looking at inerts seems to be
22 a little bit different than looking at active

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1 ingredients, yet the only process we have is
2 the one, as Tina mentioned, for active
3 ingredients.

4 As you may recall, last April we
5 made a proposal to the Program to enter into
6 a Memorandum of Understanding of some sort
7 with the EPA. At this point in time that
8 process is moving forward. I know I've been
9 in many conversations with Arthur Neal and
10 with other folks at the Program to help guide
11 that and steer that process forward since Tina
12 had appointed me Inerts Tsar temporarily.

13 So, if you look back or go back in
14 a history a little bit to April, what we did
15 was we proposed to the Program, we requested
16 of them that they create a Memorandum of
17 Understanding with the EPA to assist in the
18 evaluation of the materials previously known
19 as EPA List 4 - Inerts of Minimal Concern and
20 EPA List 3 - Inerts of Unknown Toxicity
21 Allowed.

22 The MOU should serve as a platform

1 for an implementation strategy that may
2 include an official task force or some other
3 structure to achieve the following objectives.
4 And then we listed six objectives that we all
5 approved last April. And those were to create
6 a sub-list from what we call the current but
7 not supported by EPA List 3 and List 4 inerts
8 that might meet our criteria as non-synthetic
9 or natural materials.

10 Because it's my understanding from
11 talking with EPA that some of the materials
12 currently on that list probably are naturals.
13 Then from that list give pesticide formulators
14 an opportunity to reformulate to that
15 shortened list, if possible. If it wasn't
16 possible for them to do that, for them to
17 supply the information needed to the Program
18 or to EPA in terms of CAS numbers or CBI so
19 that we could begin a petition process of some
20 sort to go through those materials that they
21 would wish to defend. Based on all of that
22 criteria, what we did last April, we were for

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1 this meeting presented with some inert
2 materials to look at.

3 So, what we'd like to do at this
4 point in time -- can we make it so we can see
5 that, Lisa, because I think it's the only way.
6 People don't have this in front of them. It's
7 a relatively new document.

8 What we're doing is we created
9 some language with the help of Program to
10 present to the Program.

11 And we're in the dark and I
12 apologize for that. On my screen it's very
13 bright.

14 And I'll just read verbatim what
15 we wrote. And again, this is a statement to
16 the Program.

17 "The goal of this statement is to
18 manage the National List of materials
19 regarding inerts used in pesticide
20 formulations as found on 205.601(m) (1) and (2)
21 and to protect consumers' interests and
22 producers' needs. Since the April 2010

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1 meeting several petitioned materials were
2 reviewed by the Crops Committee under the
3 Review Evaluation Policy that fell under the
4 heading of inert materials used in pesticide
5 formulations that were previously listed under
6 EPA List 3 - Inerts of Unknown Toxicity.
7 Without a reviewed or newly developed
8 evaluation process as discussed in the
9 proposed guidelines to the NOP in April as
10 documented above," because there was a bunch
11 of preamble language that I'm not going to sit
12 and read, "targeted to inert materials, the
13 Crops Committee agreed the existing review
14 evaluation process may be flawed."

15 So, our guidance statement that
16 we'd like to propose here is that in an effort
17 to optimize the management of the Board, the
18 Committee's time and the Program resources,
19 the Crops Committee asks that the following be
20 considered until the NOP/EPA process
21 recommended at the April 2010 meeting is
22 resolved or completed:

1 (1) A suggested moratorium on
2 inert materials into the petition process.

3 (2) An allowance of any material
4 currently in the review process as an inert to
5 be temporarily withdrawn by the petitioner
6 without prejudice including petitioned
7 materials evaluated by the Crops Committee for
8 the fall 2010 meeting. Any material withdrawn
9 by a petitioner or material voted on at the
10 fall 2010 meeting is eligible for
11 repetition pending the outcome of the
12 NOP/EPA process.

13 (3) All former EPA List 3 and List
14 4 inerts currently allowed in the organic
15 production should continue to be acceptable
16 for use until the EPA/NOP evaluation process
17 is finalized subject to our current sunset
18 process. And we'll discuss that when we get
19 into the list of sunset materials.

20 So, in short what we're suggesting
21 is that -- I don't want to say it's a waste of
22 time, but it's a tremendous drain on the

1 resources of the Program and of the Crops
2 Committee and ultimately of the Board to
3 review these materials under our current
4 evaluation process. Because when you look at
5 them, many of them, at least the List 3,
6 they're almost all synthetics. So they're
7 going to fail that vote, they're going to be
8 called synthetic. And when we run them
9 through the evaluation process, they're almost
10 all going to fail the environmental criteria.

11 So, it's not that we want to tell
12 people don't bother petitioning them, but we'd
13 rather wait until we have the process in place
14 that we've already requested before we go
15 through this process and use up valuable time
16 and resources only to come to a conclusion
17 that we already know what that's going to be.

18 So, that's our statement that
19 we're going to make today to you folks and
20 would like you to think about that on the
21 Board as we evaluate our comments for
22 Thursday's vote.

1 We're going to get into some
2 materials that were petitioned and that we did
3 evaluate, and we'll discuss those. The
4 Committee is prepared to present those. But
5 again we are also prepared to entertain a
6 motion, which is atypical for me. I don't
7 like to go through the process that the
8 Committee went through only to have things
9 withdrawn at the last minute because somebody
10 didn't like the way the vote was going. But
11 in this particular case; and that's why we
12 mentioned they could be withdrawn without
13 prejudice, it's not their fault. It's not our
14 fault. It's just the situation we're in and
15 we don't have that resolved yet.

16 So, I guess I'd open it for
17 comments or discussion from the Board and the
18 Program.

19 MR. GIACOMINI: Any debate?
20 Arthur?

21 MR. NEAL: Good morning. Arthur
22 Neal. My comments I think will be brief.

1 We have met with EPA and their
2 leaders in various programs related to
3 biopesticides and some of the more
4 environmentally-friendly programs that they
5 have. And there is a lot of interest within
6 EPA to help us get this problem resolved and
7 establishing a working group, a Memorandum of
8 Understanding to help us address the whole
9 inert issue within organic agricultural
10 production.

11 We will be touching base with EPA
12 again probably sometime in November so that we
13 can continue working on the MOU. The Program
14 had drafted a Memorandum of Understanding. We
15 sent it to EPA. They have reviewed it. We
16 have to refine it some more and look at our
17 resources both personnel and financial
18 resources to see what we can do to collaborate
19 and effectively address this issue for the
20 organic industry.

21 But there's a lot of interest
22 around it, a lot of energy. So, we do believe

1 that we'll be able to have a process outlined
2 that will be effective in accomplishing this
3 goal.

4 MR. GIACOMINI: Thank you.

5 Kevin?

6 MR. ENGELBERT: Yes, I'd like
7 everyone to be sure or to be aware that there
8 was concern in the Crops Committee about the
9 steps we've taken. There's concern that even
10 though these materials are called inerts,
11 we've learned that in many cases they're not
12 truly inerts and it's simply just a label.
13 But given the situation that we're in, we all
14 agree that this was really the most prudent
15 approach to take. I think it's going to be
16 very important to see how this plays out.

17 But I just wanted to make sure
18 everybody knew we did talk about that and we
19 don't want to give the impression that these
20 are just going to be given a free ride or
21 lesser criteria. It's just going to take more
22 research and more work to be sure that we're

1 doing the right thing as we look at these List
2 4 and List 3 inerts.

3 MR. GIACOMINI: Jeff?

4 MR. MOYER: I think that's a very
5 good point, Kevin. The Crops Committee did
6 talk about this I believe at every one of the
7 17 phone calls that we were on. It is a very
8 important topic.

9 The bottom line is once the new
10 criteria is out and we do evaluate these
11 materials, they could very well all end in the
12 same fate as we're talking about now, but at
13 least this way we felt that we'd be more fair
14 and responsible to the petitioner, to the
15 consuming public and also to the farmers who
16 are requesting or need these materials. We
17 want to be fair to everybody and run it
18 through the proper process.

19 MR. GIACOMINI: Arthur?

20 MR. NEAL: One thing I do want to
21 say to the Board is that as we dialogue with
22 EPA the resounding issue that came up was the

1 fact of what criteria are we going to use to
2 evaluate these materials? We looked at some
3 of the criteria for the actives. And as you
4 stated, Jeff, many of them may not pass the
5 test. So, that was one of the resounding
6 issues that came up. If we did establish this
7 working group or this task force, what
8 criteria will be used to evaluate the
9 material?

10 MR. GIACOMINI: Tina?

11 MS. ELLOR: I could be mistaken
12 here, but I think that we were hoping that
13 would be a product of this collaboration.

14 MR. NEAL: And it will, but we
15 just wanted you to understand as well that EPA
16 recognizes it, too. One of the things that
17 they don't do is try to make the decisions
18 for our program, but they do want to assist us
19 in making the decisions that represent the
20 best interest of the organic industry and the
21 intent of the Organic Foods Production Act.
22 What they're trying to do is cross their

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1 regulatory authority.

2 So, we're going to be looking at
3 criteria that we could potentially use in
4 making these decisions. And as we begin to
5 set up the working group, we'll be
6 communicating with you, keeping you informed
7 every step of the way.

8 MR. GIACOMINI: So, where do we
9 stand now? That seemed to include a request
10 to the petitioners. Where do we stand with
11 the ones that we are looking at that were on
12 the agenda for this meeting?

13 MR. MOYER: As a committee we're
14 going to move forward on the materials that we
15 have in front of us unless there's a
16 representative in the room who formally
17 withdraws the petition at this time. That's
18 why we stated that if they did that they would
19 be withdrawing the petition without prejudice.
20 By the same token, if we move forward with it;
21 and the committee struggled with this sort of
22 language, because typically if a petition goes

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1 through the process and fails, it's a little
2 more difficult for them to just repetition it.

3 And so; it's not on the screen at
4 the moment, but in our language we did say
5 that any of these materials that we vote on
6 today, should we accept the recommendation of
7 the committee as a Board; they may fail, they
8 would be eligible for repetition pending
9 the outcome of the NOP/EPA process, which may
10 be the exact same set of criteria. We don't
11 know at this point. That's the point. As
12 Arthur just mentioned, we don't know what that
13 criteria is going to be, that evaluation
14 criteria. It may very well be the same
15 criteria we have today and the outcome could
16 very well be the same. But in all fairness to
17 the petitioner, to the public and to farmers
18 who use those products and materials, we'd
19 like to let the process run its course.

20 Now, we can't stop somebody from
21 petitioning this committee or this board with
22 a material. We're just suggesting to them

1 that they look at the outcome of these
2 particular materials. We just don't want to
3 use up all of our resources. You can see we
4 have five more materials coming up for the
5 next meeting. There could be hundreds.

6 MR. GIACOMINI: Okay. Anything
7 else on this topic? Any further debate?

8 (No audible response.)

9 MR. GIACOMINI: Okay. Tina?

10 MS. ELLOR: So, in keeping with
11 the agenda, we're going to stay with Jeff and
12 present ethylene glycol.

13 MR. MOYER: Thank you, Tina.

14 If I can direct the Board's
15 attention to the ethylene glycol evaluation
16 document that the Crops Committee went
17 through, you will notice that we followed our
18 procedure and took two votes on this material.
19 The first vote was to determine whether or not
20 ethylene glycol was in fact a synthetic or not
21 and we had determined by a vote of five to
22 zero with two absent that the material is

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1 indeed synthetic based on the TR review and
2 our own information.

3 You also notice then that we took
4 a vote on whether or not the material passed
5 or failed the criteria in the evaluation form,
6 and by a vote of -- I don't see that. Again,
7 the motion was made to list ethylene glycol on
8 the National List 205.601. So, the motion was
9 made in the affirmative and there were zero
10 yeses, six noes and one absent at the time of
11 that vote. So, in the Crops Committee's
12 opinion, based on the information we had in
13 front of us supplied by the petitioner and the
14 TR, this material failed to be listed on the
15 National List.

16 I would entertain any discussion
17 or questions. Again, this was one of those
18 inert materials that we had to run through our
19 process. So, this is just the first of four
20 materials that you're going to see today that
21 went through the same process. And, you know,
22 quite honestly there was a lot of information

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1 on this material that we struggled with in
2 terms of the global use of this product. On
3 one hand we're talking about minute amounts of
4 the material being allowed in pesticide
5 formulations and it's the same material that
6 they spray on airplanes to deice them on
7 runways. And so, they put millions of gallons
8 of it -- just dump it on the ground and it's
9 in the environment. So, there's this real
10 struggle that we had. But when we look at the
11 criteria that we had in front of us, this
12 material, you know, it strictly failed. And,
13 you know, again the Committee struggled with
14 that and said "Is this really the direction
15 that we want to go?" But based on the
16 criteria we had in front of us to evaluate
17 this on, it failed.

18 MR. GIACOMINI: Tina?

19 MS. ELLOR: We had only one
20 comment in support of listing this and it was
21 from the petitioner, and they referred us to
22 some comments. And this, by way of a little

1 bit of history, is part of the Cocide
2 formulation. But we weren't reviewing Cocide.
3 We were reviewing ethylene glycol as an inert
4 use in that formulation, which used to be
5 allowed. And there were two farmers that came
6 to the spring meeting and testified that they
7 would like to be able to use Cocide again. So
8 there was that in favor of it. But that's the
9 only comment that we received.

10 MR. GIACOMINI: Comments and
11 questions on this issue? Katrina?

12 MS. HEINZE: This is maybe more of
13 a process question. For synthetics that are
14 on the crops list already, do they have to
15 pass all the criteria or is it an evaluation
16 and a tradeoff between benefits and risks?

17 MR. GIACOMINI: Jeff?

18 MR. MOYER: Well, that's a very
19 philosophical question. It's a little bit of
20 both. You know, like all the committees we
21 try to balance that. But we have to find some
22 areas where it passes the criteria and then we

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1 can weight those. But in the case of these
2 types of materials, you know, List 3 inerts,
3 they're tough ones. I mean, they're not mild
4 materials. They're not, as Kevin said,
5 they're inert in the way they act on the
6 target pest, but they're not inert in the way
7 they act in the environment. And so, they are
8 relatively, in some cases, like this case,
9 fairly harsh materials. So, like every
10 committee we try to weight those things, but
11 this didn't pass anything. So, we have
12 nothing to weight in favor of it because of
13 the criteria we had to judge it by.

14 MR. GIACOMINI: Katrina?

15 MS. HEINZE: Thank you. That's
16 helpful.

17 MR. GIACOMINI: Other comments?
18 Steve?

19 MR. DeMURI: So what's the impact
20 if this is not listed?

21 MR. MOYER: My understanding is
22 that the petitioner would not be allowed to

1 use it in his or her Cocide formulation. If
2 they did continue to do that, Cocide would
3 stay out of the production practices the way
4 it is today. So, nothing changes as of today.
5 It's just that a material that had been used
6 in the past, is now disallowed, would not come
7 back on for use by farmers.

8 MR. DeMURI: And is it used in
9 anything else, any other formulations?

10 MR. MOYER: We don't know. As far
11 as we know it's not, but we had no information
12 to go on because we only had what the
13 petitioner supplied and then of course the
14 technical review information that reviews it
15 as a chemical or as a material that it is, not
16 in the terms of any other formulation. So, if
17 it's out there, we don't know of it. Was
18 Cocide the only one that was being honest and
19 said it was in there, I don't know. They're
20 inerts. The information is locked up at the
21 EPA and somewhere else. We don't have it.

22 MR. GIACOMINI: John?

1 MR. FOSTER: So, in the discussion
2 we had, a lot of talk about the difference
3 between an inert and the finished product;
4 Cocide in this case, and that there was I
5 think a reasonable amount of support or
6 recognition of a grower's need for Cocide and
7 that was a valuable tool no longer in the
8 quiver. For a lot of growers it was a very
9 valuable tool and my experience was that it
10 was used pretty judiciously. Point being that
11 if there is another material, a non-synthetic
12 material that this manufacturer could use,
13 they will find it now for sure because Cocide
14 is a material with a lot of market value.
15 Growers want to use this. If they can find
16 another material that's non-synthetic, they
17 will do it. Build it and, you know, they will
18 come. So, they will have a choice now.
19 Cocide won't happen unless they find something
20 non-synthetic. My point is if they don't find
21 a non-synthetic material, that's a very good
22 sign that there's no other choice here.

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1 And so the utility of this
2 particular synthetic associated material,
3 inert seems to have gotten this pejorative
4 connotation I'm not really in support of, but
5 this other material, they'll find something
6 non-synthetic or they won't have Cocide. The
7 market wants Cocide. So, I want to just point
8 out now that the manufacturer has never been
9 more motivated to find something non-
10 synthetic. If they can't find it, it's not
11 for lack of trying. And I'd like to suggest
12 that we build in to our future criteria that
13 kind of information. Because if I'm
14 manufacturing Cocide, I'll scour the earth for
15 something I can find. And if we don't have it
16 very soon, then we ought to be able to
17 consider that in our future considerations of
18 these kinds of materials. The utility of this
19 in the context it's going to be used, not
20 whether or not this material meets our
21 existing criteria for all materials for
22 review.

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1 MR. GIACOMINI: Yes?

2 MR. MOYER: Just as a quick follow
3 up to that comment, Joe.

4 I agree with what you're saying,
5 John, and the Committee did talk about that.
6 What we have to be careful of is that if we
7 list this on 205.601 just as a material, then
8 anybody can use it in any way, shape or form.
9 We can put an annotation on it, but I think
10 we'd be amiss if we annotated it strictly for
11 Cocide. So, we can't go that far, I don't
12 think. So, there's a balance. And we're
13 hoping again, as you indicated, that the new
14 process figures out a way to do that. At the
15 same time, yes, if we do follow through with
16 the vote that the Committee is suggesting or
17 recommending to the full Board, that will be
18 an indication to the manufacturers of Cocide
19 of the direction that things are heading.
20 And, yes, that would be the impetus they need
21 to scour the world to find a material that --
22 if on the other hand we have voted to allow

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1 this, they wouldn't have to do that. So, yes.

2 MR. GIACOMINI: Joe?

3 MR. SMILLIE: So, this material
4 could come back without prejudice and be
5 judged by the new criteria, is that correct?
6 So, by voting it down today we're not damaging
7 its ability to come back under the new
8 criteria that EPA is going to establish?

9 MR. MOYER: That's correct. If
10 the Board approves tomorrow the language that
11 we're suggesting to the Program, you are
12 absolutely correct. If we decide not to
13 accept that language and to move forward with
14 these materials as they currently are being
15 petitioned to us, then you would be incorrect.
16 So it's up to the Board.

17 MR. GIACOMINI: Katrina?

18 MS. HEINZE: So, what happens in
19 between? So, presumably for these inerts that
20 we're evaluating today and again at the spring
21 meeting they are currently in use in
22 formulations. No? None of them are? I'm

1 just trying to get an understanding of what
2 the impact on farmers is going to be.

3 MR. MOYER: They should not be in
4 use and as far as I know they are not, though
5 the materials that are currently on List 4
6 could be in use and probably are in use.

7 MS. HEINZE: So the ones before us
8 today are not on List 4?

9 MR. MOYER: That's correct. They
10 were formerly on List 3. It's just our
11 feeling that the petitioners in their
12 anxiousness to get their product to the market
13 have a little bit jumped the gun in terms of
14 our process. And I understand that that's a
15 little unfortunate for them and ultimately for
16 the farmers, but to try to protect consumers
17 and farmers who want to use the product we
18 want to go through this process that we
19 recommended in April. And again, I think it's
20 an important process. I was a little
21 disheartened to see that it was far down the
22 list of what Miles presented yesterday. It

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1 was on the list and they did discuss it. And
2 we'd like to see it move up the list because
3 I think it's very important to our committee.
4 They have a lot of work to do.

5 MR. GIACOMINI: Katrina?

6 MS. HEINZE: So, what I understand
7 is that the ones we're looking at, if an inert
8 is on List 4, it could be in use today and
9 would continue to be allowed. Things that are
10 not on List 4 may be the things that we're
11 starting to see petitions for and so they're
12 probably not in use today because List 3 isn't
13 on the list, isn't on the National List. Am
14 I understanding this properly?

15 MR. MOYER: You're absolutely
16 correct, assuming that this Board votes on
17 Thursday to relist under the sunset process
18 List 4 inerts. If the Board chooses to not do
19 that, then they would all be done. But if you
20 follow the recommendation of this Committee,
21 which we'll get into later on in the
22 discussion, what you said is absolutely

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1 correct.

2 MS. HEINZE: Thank you.

3 MR. GIACOMINI: Further debate?

4 Questions? Considerations?

5 (No audible response.)

6 MR. GIACOMINI: I think that's it.

7 Okay. Next item.

8 MS. ELLOR: The next item on our
9 agenda is ethylene DDS. And we had an
10 embarrassing wrinkle in this material which
11 Jay pointed out to me last night. We had a
12 comment from the petitioner that they would
13 like us to defer this vote so that they can
14 provide us with more material, and that will
15 be part of our discussion. But, boy, Jay did
16 some sterling work on this material. And this
17 one we as a committee unanimously decided
18 would not be good on the list. But again, in
19 view of the big picture and the whole story,
20 we're going to go ahead and present this
21 material.

22 MR. GIACOMINI: Jeff?

1 MR. MOYER: Before we present the
2 material I think the question that we need to
3 pose as a committee to the Program is is a
4 sentence in a comment, a public comment to
5 withdraw this material grounds to withdraw
6 this material from voting? To us it did not
7 seem like an official request to the Program
8 to defer the material to a later time. And
9 their request was not to defer it pending the
10 new process coming out of the joint effort
11 between the NOP and the EPA, but rather to
12 defer it so that they could give us more
13 information, and we saw that as a real
14 difference.

15 MR. McEVOY: Okay. Conferring
16 with my colleagues here, yes, it's up to the
17 Board to decide whether or not you would defer
18 the vote or table the vote until a later time.
19 So, it's your choice whether or not to accept
20 their request to defer the vote.

21 MR. GIACOMINI: Jeff?

22 MR. MOYER: Again, for the Board's

1 reference, if we accept the language tomorrow
2 that we just presented here regarding a
3 moratorium on petitions, then even if we
4 follow through and vote on that material, they
5 would be eligible to repetition immediately
6 upon that new process coming out. So, we're
7 trying to be as fair to the petitioner as is
8 possible.

9 MR. GIACOMINI: I think there's a
10 significant difference though from what we've
11 seen in other situations in the past where a
12 substance that was having a negative
13 recommendation and showing very little
14 support, the petitioner withdrawing it
15 seemingly for no other reason than to hope to
16 have a more favorable shuffle of the cards in
17 the future as the Board turns over. This
18 doesn't necessarily seem to be that kind of
19 request. This is more of an informational
20 request where they want to try and provide
21 more information. I'm not telling you to
22 agree with it or not as a committee, but I

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1 think there is a difference there.

2 Jay?

3 MR. FELDMAN: I'm inclined to
4 agree with that. I mean, I think the
5 petitioner responded to the Committee's work
6 and acknowledged that more information was
7 needed on a particular issue that we
8 identified and is now asking for it to be
9 deferred after having presented additional
10 information for our consideration. So, I
11 don't know what the Board has done in the past
12 on this, but it seems like a somewhat
13 reasonable request.

14 MR. GIACOMINI: In the past the
15 Board has shied away from allowing petitioners
16 to withdraw a petition at the very last stage
17 after we've done all our work and made all our
18 recommendations simply to avoid a negative
19 vote. But this is an entirely different
20 situation where we're already looking at the
21 fact of changing the process and acknowledging
22 that there would be no prejudice to reposition

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1 something.

2 Jeff?

3 MR. MOYER: I would come back to
4 the Program though and request some guidance
5 on whether or not a single line in a public
6 comment is a formal request to the Program or
7 to this Board to defer. Is that considered a
8 formal request, just one line in the --

9 MR. NEAL: I guess that the
10 Program has not put in the *Federal Register*
11 how to withdraw a petition, however, the
12 Committee did request or provide that
13 instruction to petitioners if they wanted to
14 withdraw that they could. And this seems like
15 a response to that request. So, the Board can
16 decide to accept that because it was the
17 substance in which this petitioner had
18 petitioned for review.

19 The additional comment that I have
20 is that although the Board is proposing or the
21 Committee's proposing a moratorium to review
22 inerts, the public still has the right to

1 petition the inerts. I think the thing would
2 be to communicate with those petitioners the
3 position which we are so that we can
4 facilitate a fair and adequate review of the
5 substance. Make sure that we let them know
6 this is where we are currently in the process
7 concerning these types of materials. You may
8 want to consider, you know, holding off until
9 we get a little further down the road in
10 establishing the criteria, the guidelines that
11 would help us give your material an adequate
12 review.

13 MR. GIACOMINI: Yes, from the
14 Board's perspective we're asking them if they
15 would consider withdrawing the petition. I
16 would think the ability to do that without
17 having to pay for a plane ticket and a hotel
18 room when you're asking them to take no
19 action, when that was what the request was, it
20 seems like a company would want to do that as
21 cheaply and as easily as possible.

22 Jeff?

1 MR. MOYER: I know we're spending
2 a lot of time on this, but it does seem to be
3 important. Just as a process question, the
4 Board has not approved the language that the
5 Committee is suggesting in terms of withdrawal
6 of petitions until Thursday. So, my
7 suggestion would be that we go forward at
8 least today with the presentation of the
9 information pending the Board's determination
10 on whether or not they do want that language
11 presented to the program, because we don't
12 have that officially done yet.

13 MR. GIACOMINI: That's up to the
14 Committee.

15 MR. NEAL: Would you mind
16 repeating that for me one more time just for
17 clarification?

18 MR. MOYER: Yes, Arthur. What I
19 was saying is that this Board has not accepted
20 the language that the Crops Committee has just
21 put forward regarding the moratorium or the
22 discussion on withdrawal of petitions without

1 prejudice or the repetitioning of those
2 materials. So until this Board votes to
3 accept that language and present it to the
4 Program, we don't have any grounds to act on
5 in terms of the material today. And my
6 suggestion is that we follow the agenda and
7 present the material as it is listed on the
8 agenda. The first vote we'll take on Thursday
9 is to accept this language. If we do that,
10 then we could withdraw and not have to go
11 forward with that vote. That's my suggestion.

12 MR. NEAL: In reading the
13 petitioner's public comment, it seems like
14 he's asking the Board to particularly defer on
15 the material because it appears that they've
16 submitted substantial new technical
17 information. So, with that information I
18 think they're asking the Board to defer so
19 that you would have time to review that
20 information before you make your final
21 decision. And that was in response to as well
22 the work that you all had done.

1 Now, I think that what we probably
2 need to do is just communicate to the
3 petitioner also the current position or the
4 place we are concerning inert materials so
5 that that petitioner can make an adequate
6 decision about next steps.

7 MR. GIACOMINI: I think we have a
8 problem here in that the Committee is going to
9 be asking the Board to take a vote on
10 essentially a document or a procedure that has
11 not been posted, has not been reviewed, has
12 not been seen even by any of us outside of the
13 Committee. I'm not sure according to our
14 procedures that that is going to be a proper
15 vote to take at this time, at this meeting.
16 I would like to possibly review that by the
17 Program. But everything we do, even within
18 the "Policy and Procedure Manual" and the "New
19 Member Guide" goes through that exact same
20 posting process.

21 If the Committee would like to
22 proceed with that action and they wish to deal

1 with these relevant petitions internally
2 within the Committee on deciding whether to
3 proceed or withdraw, that is up to the
4 Committee's decision. But as far as voting on
5 a Board policy on something that has not been
6 posted and not had an opportunity for anybody
7 to be reviewed I'm not sure is in order and
8 I'm not sure the Chair would be willing to
9 proceed with that vote.

10 MR. MOYER: Yes, the Committee
11 understands that and certainly discussed it.
12 And that's why we are prepared as a committee
13 to move forward with all the materials that
14 are petitioned and in front of the Board.
15 That's why I suggest that Jay go ahead and
16 make his presentation on this material. We
17 follow through with that on Thursday with a
18 vote. And why we have said that in that
19 document, if we do discuss presenting that to
20 the Program and posting it for public comment,
21 that those materials that went through the
22 process today should not be disadvantaged

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1 because of that but should be allowed to come
2 back into the process immediately. And that's
3 why we put that language in there.

4 So, I don't want to speak for
5 Tina, but the Committee, as Vice-Chair of the
6 Committee I know we're prepared to move
7 forward on these materials under our standard
8 procedure.

9 MR. GIACOMINI: Yes, I think the
10 decision to proceed or not is definitely up to
11 the Committee. I think both of those the
12 Chair would certainly find reasonable actions.
13 But voting on a document and a recommendation
14 that has not been posted and reviewed I don't
15 think would be in order.

16 MS. ELLOR: Yes, and I think our
17 original intent was just to read it into the
18 record so that we would have on the public
19 record what the issue was. So, you know, I
20 don't think that the document we presented
21 this morning was one up for voting anyway.

22 MR. GIACOMINI: It's not --

1 MS. ELLOR: Right. So, I think we
2 should proceed with the EDDS. Okay.

3 MR. FELDMAN: Thanks, everyone. I
4 want to thank the USDA NOP S&T for the review
5 that we received, the technical review. It
6 enabled I think a thorough review by the
7 Committee and it really shows -- when the
8 process works that way, it enables our work.

9 I think what we're discussing, and
10 that is this tabling issue, is a tribute to
11 that review because we identified some issues
12 that in fact the petitioner acknowledged were
13 perhaps not fully disclosed and evaluated, and
14 so they're submitting additional information
15 which they would like us to consider.

16 But having said that, we did vote,
17 we did evaluate this material, this substance,
18 which is an inert ingredient. To my knowledge
19 it is not used in the United States at this
20 time. The vote, I think has already been
21 said, was five -- I think five of us voting
22 against -- well, we voted in two stages.

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1 First we vote on whether the chemical is
2 synthetic, as you know. And that vote was I
3 believe five against and two absent. And then
4 voted against the material, or the listing of
5 the material, five to two. Two absent, I
6 should say. Zero voting for.

7 Just to put this in context and
8 just to show you how difficult the road is
9 ahead, the petitioner believes that this is a
10 safer alternative to inerts that are typically
11 used in formulations, which is called EDTA.
12 You're all familiar with that. So, they
13 believe they're doing something positive. And
14 I really want to put that into the discussion
15 here because it's the framework in which we
16 will be struggling with, what will be called
17 other ingredients down the road as opposed to
18 inert ingredients that are used in
19 formulations. So, from our perspective that's
20 an important piece of information in the
21 context of an EPA review of a chemical that
22 might subject the public to less risk. But in

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1 our world the question is does it meet the
2 standards in terms of impacts on the
3 environment and impacts on health and
4 compatibility with organic production systems?

5 The other interesting thing of
6 note here is that we received information from
7 the technical review that we did not receive
8 in the petition. So in other words, the
9 petitioner viewed some of this information as
10 proprietary I guess and did not include that
11 information, but the technical review somehow
12 has access to that and provided it to the
13 Committee. In the future of course through
14 this collaborative process it's our hope that
15 we will have all the information we need to
16 conduct a complete and comprehensive review
17 and then make a fully informed decision on
18 this.

19 So, walking through the evaluation
20 criteria you can see that the issue of the
21 components, the manufacturing process or the
22 components of this material are exceptionally

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1 troublesome because it is composed of a number
2 of materials including ethylene dibromide.
3 And dibromoethane, which is material we're
4 talking about, according to the Agency for
5 Toxic Disease Registry; and this is in the
6 technical review, is reasonably anticipated to
7 be a human carcinogen and has been banned by
8 EPA for most kinds of uses since 1984.

9 So, that of course right out of
10 the box raises a serious issue. And is that
11 issue which the petitioner is now providing
12 additional information, which you referenced,
13 Arthur, in its comments, feeling that the data
14 that we receive, the information we receive
15 from the technical review process I guess was
16 in some way inadequate. But we worked off
17 that technical review. We worked off of other
18 reviews that were cited in the document and
19 found that the constituent of this material,
20 being EDB, did not meet our criteria. I mean,
21 that's shorthand for this comment, this issue.

22 One of the things in the TAP

1 review that is really clear that I would like
2 to read here. This is quoting from it.
3 Although the labeled part -- they radio
4 labeled the different components to see if
5 they had impact on the environment over time.
6 And, although the labeled part of the EDSS
7 component to CO2 gas that did not necessarily
8 assure the unlabeled part also decomposed to
9 CO2 gas since that part was not directly
10 measured.

11 So, here you have, you know, an
12 issue where the Committee is aware of an
13 ingredient, EDB, banned by EPA in this
14 product. The manufacturer, according to the
15 technical review, the petitioner and
16 manufacturer conducted environmental impact
17 reviews on one component or one constituent of
18 this material but not the other, the other
19 being the more dangerous one that EPA has
20 banned. Because of the hazardous nature of
21 EDB and its regulatory history this of course
22 was of great concern to the Committee. We

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1 also do not know whether EDDS and its
2 components react differently in different
3 pesticide formulations.

4 So, as is the case with a lot of
5 the materials we review, and we'll be
6 discussing some of this under other chemicals
7 later, we're left with some unanswered
8 questions. And I think the Committee felt,
9 especially given the knowledge about the
10 classification of this constituent, EDB, in
11 this formulation that not having knowledge was
12 not a good thing and that the lack of
13 knowledge should not support the approval of
14 a material like this.

15 The question was raised earlier in
16 our earlier discussion this morning about how
17 this is used and in what products it is used.
18 And similar to the answer we heard earlier, we
19 don't know that. All we know is that this is
20 used in formulations that presumably would be
21 applied across agriculture. So, in that
22 context we can't even do essentiality review

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1 to determine whether its use pattern would be
2 compatible with organic production because we
3 don't know -- we can assume, but we don't know
4 specifically what formulations or what
5 materials this chemical will be used in.

6 So, we're left with a degree of
7 unknown or insufficient information, but given
8 again what we know about one of the major
9 constituents of this material, as you heard
10 earlier, we voted this down.

11 MS. MIEDEMA: Thank you. Is there
12 any further comment? Questions for Jay?

13 MR. FELDMAN: I guess for the
14 record I should say we didn't receive any
15 other comments. I didn't see any except for
16 the petitioner.

17 MR. SMILLIE: Totally got what you
18 said and agree. My only feeling about this is
19 that what is the petitioner going feel,
20 because they feel they've withdrawn it and
21 we're moving forward. If I could get a quick
22 answer to that.

1 MS. MIEDEMA: Tina?

2 MS. ELLOR: I think, as a point of
3 order, and I was hoping Dan would be here, but
4 maybe someone else can help us, is that we'll
5 get together quickly as a committee and take
6 a vote on whether we choose to defer that.
7 And then we'll present that to the full Board.

8 MR. FELDMAN: Thank you.

9 MS. MIEDEMA: Okay. So, Tina,
10 back over to you and what's up next?

11 MS. ELLOR: Next up is tall oil,
12 which was a very interesting material to look
13 at, and I took point on that one. I'll just,
14 you know, make it 150 percent so I can read
15 the tiny writing.

16 You know, at first blush when we
17 looked at it, we thought this is a fairly
18 benign material. It's extracted from trees.
19 It's a byproduct of the paper making process.
20 But when we discussed it further and looked at
21 it more closely, what we realized is that
22 although it's being petitioned as an inert, it

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1 also has uses as an active. So, it failed our
2 criteria based on that it would act in the
3 environment in ways for which its not being
4 petitioned, which is inadvertent but doesn't
5 prevent that from happening.

6 We voted six to zero with one
7 absent that this is synthetic and we voted to
8 reject the material, or to not allow it to be
9 listed six to zero with one absent.

10 We did get some comments from the
11 petitioner about that there are different
12 extracts and different -- I can't come up with
13 the right word -- forms of tall oil that
14 they're petitioning for that do not have some
15 insecticidal activity. But on the other hand
16 substances with the same CAS number that might
17 be called something else, but since they have
18 the same CAS number, they have the same
19 identity CAS number, that they do have
20 insecticidal properties.

21 And again, this would be listed,
22 if it makes it to the List, as a List 3 inert.

1 And the Crops Committee is recommending that
2 we do not allow that.

3 MR. GIACOMINI: Any debate on this
4 issue? Katrina?

5 MS. HEINZE: Not debate but a
6 question. Could you briefly summarize the
7 thought process on the classification? Not
8 that I disagree with it, I'm just trying to --
9 since it's an extract from trees, I'm sure
10 there's more to it than that.

11 MS. ELLOR: And that was an
12 unfortunate term for me to use. It's a
13 byproduct of the paper milling process so it
14 does not exist, you know, in nature without
15 that process happening. And it was petitioned
16 also as a synthetic. So, yes. I don't know
17 if you need more information than that, but I
18 will go through the TR which explained what
19 the process was and what the chemical changes
20 were that make it a synthetic.

21 MS. HEINZE: So it is not a
22 substance that exists naturally? It's a

1 different substance?

2 MS. ELLOR: It's a different
3 substance.

4 MS. HEINZE: Okay. Thank you.

5 MR. GIACOMINI: Any other
6 questions?

7 Moving on.

8 MS. ELLOR: Next up is Barry with
9 tetramethyl.

10 MR. FLAMM: Thank you.
11 Tetramethyl is a twin to our earlier
12 discussion with ethylene glycol. They're both
13 used in the formulation of Cocide, but we
14 shouldn't mention that because we're
15 evaluating this material as petitioned. And
16 tetramethyl was petitioned by Dupont on
17 January 18th, '08. We subsequently received
18 a technical report and we had a number of
19 questions and sent it back. And our questions
20 were answered and it was a very valuable TR,
21 what we got back. And the Crops Committee
22 received this technical review last May,

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1 actually after the -- at least I didn't see
2 until after the spring meeting.

3 Just a little background.
4 Tetramethyl is a wax used to enhance the
5 wetting of copper hydroxide, which is the
6 active ingredient, and to prevent excess foam.
7 It's a defoaming agent. And mentioned before,
8 just like ethylene glycol, it's a List 3 inert
9 of unknown toxicity.

10 The only comment we received this
11 time was from the petitioner, Dupont; at least
12 the only one I saw, and they primarily
13 referred back to the written comments at the
14 spring meeting, which were reviewed in looking
15 at this.

16 After running through the
17 checklists and everything we decided that it
18 was synthetic. It was petitioned as a
19 synthetic. And the Committee rejected the
20 petition. The vote was one yes, five no and
21 one absent.

22 The TR points out the

1 environmental risk in the material, the
2 incompatibility with organics, and
3 additionally the possibility for build up in
4 the soil and that.

5 So, I'm personally rather familiar
6 with Cocide. I used it when it was available
7 a number of years ago occasionally and
8 certainly was a tool. But it hasn't been
9 available for several years and obviously
10 during those years growers have found
11 alternatives. So, our choice is not whether
12 this is better than the alternatives on the
13 market. We're evaluating against the
14 checklist tetramethyl itself.

15 And all the comments that Jeff and
16 others have made regarding, you know, our
17 examination of inerts, that all applies to
18 this material. And the main things that were
19 discussed with ethylene glycol are relevant to
20 this one here, so I won't try to repeat it.

21 MR. GIACOMINI: Okay. First
22 question I'll ask. There was one affirmative

1 vote as opposed to all the rest of them being
2 zero-six. What was the consideration on that
3 from the member of the Committee?

4 MR. MOYER: I'm sorry. Could you
5 repeat that?

6 MR. GIACOMINI: The vote listed
7 here on this substance, as opposed to all the
8 rest of them having been zero-six, this is a
9 one-five vote. I was just wondering what the
10 consideration of the one member of the
11 Committee, that they didn't --

12 MR. FLAMM: You can ask that
13 member if you'd like.

14 MR. GIACOMINI: -- in support of
15 it. I don't know who it was.

16 MR. FLAMM: If John wants to speak
17 up, it was his vote.

18 MR. GIACOMINI: John, did you have
19 any comment on that vote on that? It may have
20 been merely a matter of time frame.

21 MR. FOSTER: What do you mean
22 matter of time frame? I don't understand.

1 MR. GIACOMINI: It may have just
2 been this was the first one you reviewed in
3 May and the perspective at that point in time
4 was that vote and as you got into more of them
5 and more of the inerts that may have evolved.

6 MR. FOSTER: Certainly my thoughts
7 about the process and where -- at that time I
8 had a lot more concerns about and kind of
9 weighing the unwieldiness of having
10 discussions about materials in a decision
11 making or a process that clearly was not
12 intended to address these kinds of materials
13 and was really uncertain about how to proceed
14 and how much sticky to put in the wicket right
15 then because it wasn't clear to me at that
16 time that we were going to go ahead and say,
17 you know what, this is too weird. We can't do
18 this anymore. It wasn't clear to me at that
19 time. So, I was kind of in the mind set of,
20 well, we push forward. We do, you know, what
21 we need to do. In that frame of mind I was --
22 in my head I can convert the context in which

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1 these materials were going to be used as
2 inerts. And at the time I was thinking, well,
3 we're going to have to kind of flex our
4 criteria to include inerts in that.

5 And so in my vote I'm thinking,
6 okay, well, we're going to have to figure out
7 a way to make this fit. This is how I'm
8 making it fit. It's used in small quantities.
9 Our discussions about the utility of Cocide
10 were hot and heavy at that point and there was
11 general agreement -- well, I shouldn't say
12 that. There was some agreement that Cocide
13 was a valuable material. That in my mind it
14 was valuable, much better than the
15 alternatives on the market, certainly in the
16 conventional world. So, I was thinking we
17 were going to go proceed and fit the other
18 ingredients into our process somehow.

19 And I'd still be open to that. I
20 know that's not where we're headed as a
21 committee now, but at the time that made sense
22 to me. So, I was still of the mind to --

1 what's the right word -- to build the context
2 into what we need of -- into the process.

3 MR. GIACOMINI: Okay.

4 MR. FOSTER: Thanks.

5 MR. GIACOMINI: Thank you. Any
6 other comments or questions?

7 (No audible response.)

8 MR. GIACOMINI: Seeing none, Madam
9 Chairman.

10 MS. ELLOR: Okay. Moving onto the
11 next item on the agenda is the reaffirmation
12 of the § 205.601 and 205.602 2012 sunset votes
13 that the Board took in April.

14 We did not receive any comment
15 after the last meeting or prior to this one
16 that would indicate any desire to change those
17 votes. We didn't receive any comments that
18 would indicate that people weren't happy with
19 that decision.

20 So, the Crops Committee is
21 recommending that we as a Board reaffirm those
22 votes as we took them in April. And I'll list

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1 them as individual materials when we go
2 through the vote on Thursday.

3 MR. GIACOMINI: Thank you. Any
4 discussion any on that item?

5 Next item, please?

6 MS. ELLOR: Okay. The one
7 material or bunch of materials that we did
8 decide to proceed with during this term was
9 the EPA List 4 listing and the Crops
10 Committee's -- actually, I'm going to turn
11 this over to Jeff because he's done the most
12 work with this.

13 MR. MOYER: Thank you, Tina.

14 You should see in front of you the
15 Committee's summary following the
16 recommendation to the Board in the spring 2010
17 meeting regarding these materials. It's
18 recommended that we relist EPA List 4 inerts
19 pending review by the Program of inerts
20 individually and as a class of materials. To
21 allow these materials to sunset at this point
22 would be disruptive to the industry.

1 So recognizing as we did in April
2 that even though the EPA does not currently
3 support anything called List 4 inerts, we are
4 suggesting that as a Board we maintain that
5 list as a static list, not dynamic. It's not
6 growing or shrinking. It is what it is. We
7 know what the materials are on that list and
8 so we're suggesting that we relist that -- at
9 least the Committee's recommendation is that
10 the Board relist that category of materials as
11 EPA List 4 inerts.

12 Now, there is a minority opinion,
13 and I'll read that minority opinion into the
14 record, but if those folks who supported that
15 minority opinion want to comment, I'm
16 certainly open to that. And I'll just read it
17 verbatim.

18 "Given the statutory
19 responsibility of the NOSB to evaluate
20 allowable substances on the National List
21 including inert ingredients in pesticides it
22 is critical that the now-defunct EPA inert

1 ingredients listing process on which the Board
2 relied be replaced as soon as possible by a
3 new system of review based on a collaboration
4 between the EPA, NOP and the NOSB.

5 Is the minority opinion of the
6 Crops Committee that a blanket five-year
7 relisting of List 4 inert ingredients under
8 the sunset review process is much too long
9 because of the widespread use of these
10 ingredients in product formulations and the
11 current reliance on the now-non-existent
12 review process.

13 As is recognized by EPA and the
14 guidance recommendation adopted by the NOSB at
15 its April 2010 meeting, so-called inert
16 ingredients including those in products for
17 use in organic systems are not biologically
18 and chemically inert. They may act as
19 solvents, emulsifiers, synergists or even
20 active pesticide ingredients as we have seen
21 from the EPA's previous de-listing of numerous
22 lists for inerts.

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1 The review of these chemical is
2 not a static process and listings are subject
3 to change based on updated reviews, new
4 science and better understanding. Therefore,
5 the NOSB must insist on an expeditious process
6 to implement the inert ingredient guidance
7 document adopted by the Board at its April
8 2010 meeting.

9 It is the strong minority view of
10 the Committee that the best way to express the
11 Board's sense of urgency in upholding the
12 legitimacy of its materials review process is
13 to limit the time frame for relisting on the
14 National List those chemicals previously on
15 List 4 to three years. It is our hope and
16 desire that setting a reasonable yet firm time
17 frame will help to elevate the importance of
18 this issue and move implementation ahead in a
19 most expeditious fashion."

20 So, the point of all of that was
21 that the minority opinion does not disagree
22 with the process but it's merely the time

1 frame of the sunset process that we're
2 suggesting the Board follow. In other words,
3 moving from a five-year sunset to a three-year
4 sunset to put pressure on the Program to
5 expedite this process.

6 The majority opinion, and we did
7 have a lot of discussion on that in Committee,
8 the majority opinion was more sympathetic to
9 the Program and to the idea that we're
10 striking out in new territory where we're
11 building cross-departmental bridges between
12 the USDA and the EPA, between the National
13 Organic Program and the EPA, which is going to
14 take some time, and we understand that. We
15 also as a committee are very sympathetic to
16 the minority opinion, recognizing that these
17 materials should be given their fair day in
18 the sunshine and be reviewed, but also
19 understanding that the Board has a lot on its
20 plate, a lot of pressure, and as Miles
21 mentioned yesterday in his opening comments,
22 things at the federal level move slower than

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1 we would all like. So, the majority opinion
2 recognizes that the minority opinion wants to
3 turn up the heat on the Program.

4 MS. ELLOR: Yes, and I did intend,
5 you know, for the minority -- and I think,
6 Jay, you were assigned that job to present
7 their side of the story, too.

8 MR. FELDMAN: Yes, thank you.
9 Yes, we're very unsympathetic, the minority.
10 We're just an unsympathetic duo here.

11 Just to remind everybody about
12 List 4, List 4 is divided into two parts; List
13 4 A, which is minimal risk inert ingredients,
14 and list 4 B which are other ingredients for
15 which EPA has sufficient information to
16 reasonably conclude that the current use
17 pattern in pesticide products will not
18 adversely affect the public health or the
19 environment.

20 So, in effect we have materials in
21 use right now that are presumably unacceptable
22 given our standards, but are in use because

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1 we're relying on an EPA evaluation system that
2 considered exposure patterns and risk
3 assessments that incorporated elements or a
4 definition that includes elements that go to
5 average body weight, average consumption,
6 occupation, different types of exposure
7 patterns. As you all know, that is not an
8 element of our review.

9 So having said that, I just wanted
10 to give you just a couple examples of why we
11 think this is so urgent and are troubled
12 actually by our inability to do our jobs in
13 the context of materials review without having
14 this information. I mean, I think the dilemma
15 you discussed, John, in terms of Cocide and
16 not being able to look at the full formulation
17 in the context of essentiality and all those
18 other questions, if I understood you
19 correctly. is part of the problem here. We
20 cannot do a complete review unless we know all
21 of the ingredients. And now that we have an
22 EPA process that has ingredient

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1 identification, we have the ability to get at
2 that information in a much more comprehensive
3 way.

4 We've got to bump this up,
5 otherwise we'll be facing the next sunset in
6 five years without this information, I would
7 bet, and that would be a real travesty I
8 think.

9 So, let me give you a couple of
10 examples of the List 4 inerts of concern, and
11 this sort of underlies why we're so concerned
12 about this. Urea --

13 MR. GIACOMINI: Jay, let's start
14 with one. Okay? We've got a lot of this
15 stuff to go on today.

16 MR. FELDMAN: Okay. EDTA is the
17 one I mentioned earlier. It's identified by
18 NIOSH as a mutagen, a reproductive affecter.
19 We've got titanium dioxide identified by NIOSH
20 as a carcinogen and a mutagen. I've got a
21 list here of about seven or eight materials
22 that are listed by federal agencies as having

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1 adverse effects.

2 We can quickly go through those
3 lists, get that information before us in a
4 step-wise process so that we don't let the
5 Government work its will on us. And I know
6 you're frustrated by this. I know that the
7 Program is often frustrated by the slow moving
8 bureaucracy. But in this case it really
9 impedes our ability to do our job.

10 So, I can provide more examples
11 for you if you'd like on this, but I really
12 think we need to bump up the time frame on
13 this and somehow get this to be very close to
14 top of the list of NOP priorities so that we
15 can do our job and meet the statutory
16 requirements. Thanks.

17 MR. GIACOMINI: Barry?

18 MR. FLAMM: Jay has done an
19 excellent job of presenting the minority
20 opinion and Jeff was very fair in the way he
21 presented it. And for the record, I'm a part
22 of that minority.

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1 MR. GIACOMINI: Miles?

2 MR. McEVOY: Yes, I just want to
3 clarify that this is a priority for the
4 Program to address the inerts that are allowed
5 in organic pesticides or organically-approved
6 pesticides. Very much one of, you know, a
7 couple dozen high-priority items that we're
8 working on and we're putting significant
9 resources into working this issue. We have
10 had a productive meeting with EPA. We plan to
11 have the NOSB part of that process of that
12 Memorandum of Understanding so we can develop
13 the criteria.

14 I would say in terms of what we've
15 heard from EPA in terms of the public
16 disclosure of ingredients that are in
17 pesticide formulations that the Federal
18 Government moves slowly. It's going to be
19 years before that occurs. They have the
20 intent to that, but you know, that's not going
21 to happen soon. It's going to be years.

22 So, I would say that hopefully in

1 three years we'll have this all figured out,
2 but it's a good chance that's going to take
3 longer than that, especially if there's any
4 rulemaking that we need to do as part of this
5 process. It's going to take some time.

6 But it is a high priority for the
7 Program to work with EPA. We have a lot of
8 ideas of how we can really leverage more
9 resources with EPA, switching details, getting
10 somebody from EPA working in the NOP, getting
11 somebody from NOP working at EPA. Lots of
12 different ideas of how we can move this issue
13 forward.

14 MR. GIACOMINI: Kevin?

15 MR. ENGELBERT: If we're going on
16 the record, then I also need to chime in and
17 say that I wanted to be part of the minority
18 opinion, but I realize what the Program is up
19 against and what the ramifications might be.
20 I guess it's because I'm in this year's
21 graduating class and have seen just how long
22 these processes take.

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1 MR. GIACOMINI: Also one of the
2 things that we're doing on the Material
3 Committee is to evaluate that entire petition
4 process, the petition to remove process, all
5 of those so that -- I'll say it again; I've
6 been saying it every meeting for the last five
7 years, the petition process is broken. And at
8 any point in time when the Program and EPA can
9 get this issue resolved, hopefully we'll be
10 through fixing the petition processes and all
11 those works and will come forth with a
12 petition to remove it. But I think trying to
13 force their hand on it at this point would not
14 be in our best interest and the potential of
15 getting to that three-year point of the
16 potential impact on the industry.

17 Any further?

18 (No audible response.)

19 MR. GIACOMINI: Seeing none, Madam
20 Chairman, next up? Somebody? Joe?

21 MR. SMILLIE: The other
22 consideration is if we do the three-year, then

1 all of a sudden we put that in their laps.
2 They go to OMB. OMB says you're going to take
3 all this business away from all of these
4 things. There's going to be another kerfuffle
5 with OMB. You know, I understand your intent,
6 Jay, but I just don't think it's worth it.

7 MR. GIACOMINI: Right now we can't
8 go three year. We do not have in our policy
9 and procedure to amend a sunset listing at
10 this time. The preference of the minority
11 opinion would be a petition to amend the
12 annotation for a three-year drop dead listing.
13 Right now we are looking at sunset where we're
14 not currently allowing those and it needs to
15 be a yes or no vote on whether we're relisting
16 this for at this point in time the next five
17 years. And a negative vote on that amendment
18 would be to take it off where it would sunset
19 on its sunset date, which is -- what is the
20 sunset date on this item? Do we know?
21 Sometime in 2012.

22 PARTICIPANT: October 2012.

1 MR. GIACOMINI: October 2012. It
2 would just come off the list and become
3 totally unavailable. So, that is the question
4 that we are faced with right now.

5 Any further on this item?

6 (No audible response.)

7 MR. GIACOMINI: Madam Chairman,
8 your next item.

9 MS. ELLOR: All right. The next
10 and last item on the Crops Committee business
11 docket here is corn steep liquor.

12 So, we have two very strong
13 opinions about this on opposite sides of the
14 tables, with absolute respect. Jay is going
15 to present the majority opinion and John is
16 going to present the minority opinion. I'm
17 just going to stand back.

18 MR. GIACOMINI: Before you begin,
19 Jay, this is one of a number of very
20 contentious issues we have before the Board.
21 The Chair will do its best to allow everyone
22 to state their case, but to use a phrase, you

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1 know, once the horse is dead, you don't need
2 to keep beating it. Everybody will be allowed
3 the opportunity to state their case, but I
4 think generally that case can be made in a
5 minute or two. It doesn't need to go on for
6 10 and it doesn't need to be done four or five
7 times. So, everyone will be allowed to state
8 their case, but we have a lot of business to
9 attend to and I'd just ask everybody to
10 consider everybody else on the Committee,
11 respectfully deal with all the other opinions
12 and recognize the fact that we do have a long
13 day.

14 MR. FELDMAN: Thank you, Mr.
15 Chairman. And, Tina, I think you're doing a
16 great job and did a great job on this. We had
17 a little glitch, but I really don't see it as
18 big a problem as you've suggested.

19 I looked through all the comments.
20 We received 12 comments on this. Nine of the
21 comments basically supported the listing of
22 this as a non-synthetic and three supported

1 the listing of corn steep liquor as a
2 synthetic.

3 Most of those supporting this as
4 non-synthetic -- well, let me not go there.
5 So, given that as the context, I wanted to
6 just give a framework for why this has become
7 so contentious and why I think people feel so
8 strongly about how we come down this as a
9 board. And I always start with the law, but
10 the reason I start with the law is because I
11 think we're talking about this issue in the
12 context of organic integrity, as we've heard
13 yesterday and as we know is a priority of the
14 USDA NOP and the NOSB, and that is consumer
15 trust in the process. So, this has become an
16 important issue because it is a linchpin issue
17 from which flows a lot of other decisions.

18 As you heard today on the
19 materials or the crop decisions, we start out
20 every review with a determination as to
21 whether something is deemed synthetic or not.
22 So, that is key to the integrity of our

1 evaluation process. And to have a format and
2 a framework that is not questioned, that is
3 understood by the public, that is uniformly
4 applied, that is not looking at outcomes per
5 se, what impact would that have on the market,
6 but is looking at the scientific processes
7 that go into the decision. That's where we
8 need to focus this discussion and this
9 decision.

10 So, as the document cites,
11 synthetic is defined as a substance that is
12 formulated or manufactured by a chemical
13 process or by a process that chemically
14 changes a substance extracted from a
15 naturally-occurring plant, animal or mineral
16 source except that such term shall not apply
17 to substances created by naturally-occurring
18 biological processes. I think we're going to
19 face in the discussion today all of those
20 issues and how corn steep liquor fits in or
21 doesn't fit in with that.

22 So, the focus is process and the

1 characteristics of that process. You know,
2 and it's interesting to note, as I was
3 thinking about this and how to put this in the
4 context of the larger work that we do as a
5 board, I was thinking about this question of
6 process as it's been used in the context of
7 our conversations and our decisions under the
8 Organic Certification Program. For us it's a
9 question of process and inputs. It's not a
10 question of the outcome of that process per
11 se. In other words, we're not determining
12 acceptable processes based on the outcome. In
13 organic agriculture we're not focused on the
14 residue. We use residues as a check, but
15 we're not focused on the residue of an end
16 product. We're focused on what goes into the
17 process that yields that end product. And
18 that is an analogy I think that we have to
19 keep coming back to when we consider corn
20 steep liquor.

21 We're dealing with a process here
22 and the question is not whether the outcome of

1 that process is compatible with organic
2 production. That's a decision we make another
3 day under another process. The question
4 before us is whether the process that is
5 producing this input is being done so in a way
6 that defines it as synthetic. The discussion
7 of compatibility with organic systems of that
8 synthetic is a different discussion and I
9 think is not the discussion we're having.

10 So, that brings us to the science
11 on this issue because obviously we're dealing
12 with a waste product of the corn wet milling
13 process that does not occur on its own. It
14 does not occur on its own. If it were to
15 occur on its own, we wouldn't need to add or
16 manufacturers would not need to add sulfur
17 dioxide to that process. So, we're adding a
18 synthetic material into a process, a wet
19 milling process of an agricultural product to
20 cause a specific chemical reaction, which we
21 heard yesterday. And that chemical reaction
22 causes a breaking of disulfide bonds.

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1 Disulfide bonds, as we heard yesterday, are
2 covalent bonds. And if you look that up in
3 medical dictionaries, numerous medical
4 dictionaries will define disulfide bonds as a
5 strong covalent bond important in linking
6 polypeptide chains in proteins.

7 So, that sort of puts us in a box.
8 Whether we want to be able to use this thing
9 or not and whether we do end up using corn
10 steep liquor or not is again not the question.
11 We have to decide whether this in effect is
12 chemical change.

13 Now, some will argue that the
14 intent of adding sulfur dioxide is not to
15 break bonds or break apart any materials or
16 cause insoluble proteins to become soluble.
17 The point is to effect fermentation, which is
18 a natural process. I think again what the
19 Board has to decide is whether the intent of
20 the introduction of this synthetic ingredient
21 or this synthetic substance is to break the
22 bonds, which I believe it is. But even if it

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1 isn't and even if something else is going on
2 in that process that expedites an otherwise
3 natural process, we still are breaking the
4 bonds in this process by intentionally adding
5 a substance. And I think this is where the
6 public comes down on this.

7 So, if we're adding a synthetic
8 substance and it just touches that product but
9 doesn't cause a chemical change, then we'd be
10 having a different conversation. We'd be
11 talking about an additive process that doesn't
12 affect change and we'd be talking about is
13 there a significant residue level in the end
14 product? We're not having that conversation.
15 We're having the conversation around an
16 intentionally added material that causes
17 chemical change.

18 Now, there's a lot of reference in
19 this discussion to again outcomes, which I
20 don't believe should be the focus, and the
21 safety of the outcomes. It's been cited in
22 some of the discussion that CSL has a long

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1 history of safe use as an added source of
2 nutrition in animal feed, in fermentation
3 processes and in antibiotic production. It is
4 not a significant source of water or air
5 pollution. These are outcomes. These are
6 outcomes that we can consider in the context
7 of a compatibility in organic systems. And if
8 we blur that distinction, I think we're not
9 doing our job and we're really creating a
10 slippery slope for future decisions, again the
11 first threshold decision we have to make in
12 every material that we make down the road.

13 But the reality is whenever you
14 talk about safety of a synthetic; my
15 experience, there's usually another side to
16 the safety question.

17 I just want to put this on the
18 table just to show you that it's never that
19 black and white on safety issues when you talk
20 about outcomes. Rich Theuer, who I'm sure
21 will be cited numerous times today in
22 different contexts, basically said that the

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1 draft technical document refers to the fact
2 that AFCO has listed corn steep liquor as a
3 livestock feed ingredient. Corn wet milling
4 byproducts historically have been used in
5 conventional ruminant production, however,
6 feeding newer corn wet milling byproducts
7 masquerading under the same generic feedstuff
8 names can have an adverse impact on the health
9 of ruminants due to too much sulfur. Too much
10 sulfur destroys thiamine in ruminants leading
11 to thiamine deficiency and PCM,
12 polioencephalomalacia.

13 So, again even when we talk about
14 the hazard about this material and its
15 outcome, you know, we face a tough road. It's
16 not an easy decision. I think it may be
17 easier than this discussion, but it's not an
18 easy decision.

19 So, just in closing here, because
20 I know we don't want to spend a lot more time
21 on this, we have to focus on what our task is,
22 I think. And our task is to determine whether

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1 there is some chemical process going on here
2 that constitutes a chemical change, whether
3 there's an intentional adding of an unnatural
4 or a synthetic ingredient into a process to
5 intentionally break bonds and to do that in a
6 way that has an outcome that results in a
7 chemical change. And I think that part is
8 clear. And I look forward hopefully to a
9 discussion on how we can incorporate this
10 product into use in a different context; that
11 is, under the National List process for
12 determining whether this is compatible with
13 organic production as a synthetic.

14 MR. GIACOMINI: Kevin?

15 MR. ENGELBERT: To briefly chime
16 in, everyone that has attended these meetings
17 and that have been here knows that I didn't
18 get a nickname as Mr. No for no reason.

19 Jay's position is not the farthest
20 in that direction. I personally believe that
21 it doesn't matter what the outcome or the
22 intent. If you use a synthetic with an

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1 agricultural product it's no longer
2 agricultural. I know there are implications
3 to other materials on the list, and as I've
4 said in the past it doesn't matter to me. One
5 or two, three, four wrongs don't make a right.
6 If other materials have to be looked at, then
7 so be it.

8 I liked the analogy yesterday with
9 Urvashi and Joe, whether Urvashi's here, and
10 the argument that her hair has remained the
11 same, but technically it's not. To me there
12 would be argument presented, well, her hair
13 could be rinsed and there may be insignificant
14 levels of that left on her hair. To me it
15 doesn't matter. To me you couldn't cut her
16 hair off and sell it as organic. It was a
17 synthetic. A synthetic was used and that
18 eliminates that. And I'll stop right there.
19 But I just want people to know that that's my
20 position.

21 MR. GIACOMINI: Other comments?

22 (No audible response.)

1 MR. GIACOMINI: Okay. I think as
2 an alternative view, when I look at this in
3 light of the material classification
4 documents, both parts of the document that I
5 agree with and where I disagree, I see this as
6 a non-synthetic in both cases. And I think
7 there's certainly a very reasonable view, I
8 think, with Kevin and the discussion. It is
9 still hair. And while we're not looking at
10 outcome, I think we do need to look at where
11 things are. A lot of other processes and
12 items come from these processes in the wet
13 milling and I think almost everyone here would
14 still consider them agricultural and that they
15 would need to be organic in livestock feed.
16 So, I just think that there's, you know,
17 reasonable alternatives and reasonable other
18 points of view. It is a good debate and we'll
19 have to see how the Board comes down on it.

20 Any other discussion? Joe?

21 MR. SMILLIE: I don't want to
22 disappoint Jay by not quoting Rich Theuer.

1 But again, Rich wrote a lot. You quoted parts
2 of it. It's like, you know, quoting the
3 Bible. You can just about quote anything you
4 want. The thing is Rich's overall view, and
5 I respect Rich's opinion. He was on the Board
6 in the beginning in 1995. He's followed it.

7 I listened to his comments really
8 carefully and he gave a very long detailed
9 reasoned approach to it. And it's one of
10 those judgment calls. You know, it's the
11 synthetic/non-synthetic. It's a slippery
12 slope. We live on a slippery slope. We're
13 not going to get there. We're there. We are
14 on a slippery slope at all times. And the
15 whole idea of the razor between synthetic and
16 non-synthetic I think is a great detriment to
17 this industry.

18 I think we need to look at
19 outcomes and not just so much, as you
20 stressed, the process. We need to look at the
21 overall good of something versus its
22 negatives. We have to weigh these things.

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1 That's what we continually are forced to do at
2 this Board. We have to weigh it all the time.
3 You could point out a lot of different things.
4 And whoever thought we'd be talking about corn
5 steep liquor so much? But it's not just about
6 corn steep liquor. It's about everything that
7 we look at, whether we judge it synthetic/non-
8 synthetic. And it's a huge very important
9 debate that has been going on since day one
10 and, you know, there's going to be two sides
11 to that. And I believe that you just look at
12 it in its totality, holistically and I believe
13 that Rich pointed out to us that you could
14 have both opinions. Just like we heard
15 yesterday, two chemists talking about covalent
16 bonds. There's two opinions on it. And it's
17 probably always going to be that way.

18 And I really think that overall
19 when you look at it, it's a non-synthetic.
20 It's an agricultural product. And, you know,
21 we don't want to go on about Urvashi's hair,
22 but it's still hair.

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1 MR. GIACOMINI: Katrina?

2 MS. HEINZE: It would be helpful
3 for me to hear John's perspective before we
4 have more debate. Is that possible?

5 MR. SMILLIE: I was waiting, but
6 then nothing happened.

7 MR. GIACOMINI: He will be on the
8 list if he raises his hand and lets me know.
9 John?

10 MR. FOSTER: Why thank you.

11 MR. GIACOMINI: It's the least I
12 can do.

13 MR. FOSTER: So, wanting to be
14 mindful of time, I was really heartened
15 actually -- well, first off, I never thought
16 I would ever, ever utter the word "disulfide"
17 as many hundreds of times as I have in the
18 last few months. It just wasn't on my radar
19 for my life plan at all.

20 MR. GIACOMINI: Welcome to the
21 NOSB.

22 MR. FOSTER: Yes. Yes. Yes,

1 really. But I was really heartened by, one,
2 the vigor of the debate and discussion on the
3 Crops Committee, that while frustrating for
4 all at some times, it was very inspiring to me
5 that so many people brought their A game all
6 the time week after week after week. And
7 that's how it should be. So, I appreciate
8 that process and the passion.

9 I don't generally think of myself
10 as simpleminded, but this is a topic where I
11 start thinking like that because I think I
12 maybe over thought it a little bit. I want to
13 be respectful of time. Like, I think I
14 appreciate Jay's focus on processes, but I
15 think it's not one or the other. I think it's
16 process and product in this case. We are
17 making a determination about a state of being.
18 That's how I see it. Like this mug is green
19 or not. What color is it? It's green. It
20 doesn't really matter to me how it became
21 green. It's green and that's our job. What
22 is it? Okay. It's green. Great. Next

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1 thing. I think of a synthetic state or non-
2 synthetic state of something as a state of
3 being. It exists irrespective of how we're
4 going to use it. And that's how I view this.

5 And those of you who know me for
6 awhile, and even back in April, I focused a
7 lot on consistency and our rationale that
8 leads to a decision should be consistent from
9 one decision to the next. And I just don't
10 understand how corn steep liquor -- I can't
11 get down in the weeds on the covalent bond
12 thing. I understand how it works, but that to
13 me is a part of a tree and I'm way more about
14 looking at the forest. So I get that there is
15 chemistry. I understand it in a theoretical
16 standpoint, but my grounding is broader than
17 that. And so that's the only way I can look
18 at this.

19 I don't see how corn steep liquor
20 can be synthetic and the corn starch is not.
21 And clearly corn starch is non-synthetic.
22 Clearly. I think it's important to draw a

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1 distinction between what's allowed in organic
2 production versus classification. And I think
3 very often in your discussions we're not
4 cognizant of that differentiation. We use
5 words that really are reflecting our
6 sensibilities around allowability, not about
7 classification. It's a very hard thing to
8 keep track of because they intermingle so
9 well, so intricately. But I know in our world
10 that we don't consider corn starch synthetic
11 and it's a product of the same process that
12 corn steep liquor is. I don't understand a
13 world where corn starch is synthetic. And
14 because of that I don't see a world where corn
15 steep liquor is synthetic. I can't justify
16 those two things.

17 I won't go into detail about the
18 minority opinion. I'm happy enough that it
19 inspired such vigorous following debate.

20 But again back to my starting
21 point, I'm confident that the process was
22 very, very good, very thorough, very fair.

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1 And on this subject I just admire, Jay, the
2 passion you bring. Really. Seriously, it's
3 challenged my intellectually and I need more
4 of that. I appreciate that and I look forward
5 to more years of that. But truly I do. I
6 don't mean to make light of it. It's exactly
7 how the process should be unfolding. And I'll
8 wrap up there. You know how it can go on, but
9 I won't --

10 MR. GIACOMINI: I think with all
11 your statements of the state of being and your
12 grounding we have found the philosophical
13 replacement for Dr. Hugh Karreman. He'd look
14 up in the sky and --

15 MR. FOSTER: Happy to be here.

16 MR. GIACOMINI: -- find his
17 philosophical base.

18 Tracy?

19 MS. MIEDEMA: I'm looking at this
20 as a material that's currently being used and
21 also in this broader context of Chilean
22 nitrate sort of being put on the table in the

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1 future and, you know, are we setting up
2 potential catastrophe at the farm level
3 rapidly removing these two inputs. You know,
4 in an ideal world we don't need them. We
5 don't want them. They go away. But can we
6 kind of yank the rug out from farmers?

7 MR. GIACOMINI: Tina?

8 MS. ELLOR: There's just a couple
9 points I'd like to make, and right up front
10 I'm part of the minority opinion on the Crops
11 Committee. I just can't see this as a
12 synthetic. I see it as a food processing
13 byproduct.

14 And if you'll indulge me, the
15 definitions of "processing," cooking, baking,
16 curing, heating, drying, mixing, grinding,
17 churning, separating, extracting,
18 slaughtering, cutting, fermenting, distilling,
19 eviscerating and on and on. To me the sulphur
20 dioxide is part of the fermentation process to
21 prevent putrefaction so that lactic acid
22 fermentation can take over. That's how I see

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1 it. I also think that it's an input to
2 compost, so it's an input into a liquid
3 fertilizer which goes through a liquid
4 composting process. Corn steep liquor, as
5 we've learned from the technical review,
6 doesn't go directly from corn -- you know, the
7 milling process onto the ground. It goes into
8 another product that's used in organic
9 farming.

10 So, you know, this process has
11 been amazing and I just harken back to
12 Katrina's chickens when we were looking at
13 what's indoor and what's outdoor. It just
14 seems intuitive. And it just intuitive to me
15 that this is one of many food processing
16 byproducts that are used after composting in
17 organic agriculture. So, I do see Jay's
18 argument very clearly.

19 And then we were talking about,
20 well, when are those bonds broken, you know?
21 And there was a lot of good discussion on the
22 OTA listserv about, you know, when are those

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1 bonds broken and by what? And I just think
2 why are we even going there? I see why we
3 have to go there, but to me instinctively and
4 intuitively this is an agricultural byproduct
5 and I just can't see it as synthetic.

6 MR. GIACOMINI: Kevin?

7 MR. ENGELBERT: I just wanted to
8 briefly respond to Tracy and say that we need
9 to be careful about arguing about whether or
10 not we're taking away inputs with the decision
11 that we've put forward because this material,
12 and sodium nitrate, I guess, aren't really in
13 my opinion compatible with organic
14 agriculture. They're more similar to
15 commercial fertilizers where you are just
16 simply applying something for a quick fix for
17 increase in production. There's no long term
18 building of the soil or organic matter or
19 improvement by using these. These are just a
20 temporary increase-our-production inputs.

21 MR. GIACOMINI: Tina?

22 MS. ELLOR: I'm not going to

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1 address sodium nitrate here because that's not
2 on the table, but this is a composted liquid
3 fertilizer product that's used by organic
4 farmers. You know, whether it builds soil or
5 not, I bet the bugs in the soil love it. But
6 anyway, I just want to say I don't want to
7 address sodium nitrate here because I don't
8 know much about that and, you know, that
9 wasn't on our crop discussion for this term.
10 We have discussed it a lot in the past, but I
11 just want to say that I think this liquid
12 fertilizer made from not just corn steep
13 liquor but other ingredients -- I can't say
14 that it doesn't build the soil. I think
15 possibly it might.

16 MR. GIACOMINI: Steve?

17 MR. DeMURI: I see a reference in
18 the recommendation to an OMRI decision on
19 this. I'm not familiar with what their
20 decision was. Does anybody on the Committee
21 know what the background of that is?

22 MR. FELDMAN: They identified it

1 as synthetic and they support the majority
2 opinion on the Crops Committee.

3 MR. GIACOMINI: Further
4 discussion? Katrina?

5 MS. HEINZE: I have some thoughts
6 on this as chair of the joint committee that
7 worked on classification. First I want to say
8 that I agree that compatibility is a question
9 for another day and I thank Jay and John for
10 highlighting that point.

11 I do feel I need to go on the
12 record to say that I am very disturbed by the
13 majority of the committee voting in conflict
14 with the classification document which passed
15 this Board in the fall of 2009. I understand
16 that folks may not have agreed with that
17 decision. I understand that that did not pass
18 with a unanimous vote. It did pass with a
19 majority of the Board. And I really feel that
20 the idea of not supporting the work of past
21 boards is a problem and perhaps sets us down
22 a troubling path.

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1 So, I wanted to highlight a key
2 outcome of the classification work, because I
3 think it's really relevant for this
4 discussion. And that outcome was that
5 classification is not about a chemistry
6 textbook. And I will tell you, when I started
7 work on classification as a chemist, I thought
8 it was about a chemistry textbook and I
9 thought that science could bring clarity to
10 the topic. And I will tell you I learned it
11 wasn't. It was really important going through
12 that process to learn that this wasn't about
13 being able to look in a chemistry textbook and
14 find the answer.

15 What I know and what we learned
16 was that chemistry is a dynamic process with
17 atoms attaching and reattaching all the time.
18 So, if we get two chemists in the room,
19 they're going to disagree on whether bonds
20 were broken or weren't broken. And we saw
21 that in the Material Working Group debates
22 time and time again, that we had the vigorous

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1 debate that happened here. We came to realize
2 that we could not focus on bonds breaking or
3 not, but had to focus on whether a new
4 substance was created, hence our
5 recommendation for the definition of "chemical
6 change." And I want to highlight that so the
7 Board can think about it as they think about
8 this classification. Chemical change as
9 defined by the classification document that
10 passed this Board was "an occurrence whereby
11 the identity of a substance is modified such
12 that the resulting substance possesses a
13 different distinct identity." And we had a
14 ton of discussion about what that was.

15 My understanding is that corn
16 steep liquor doesn't meet that definition, but
17 everyone needs to form their own opinion on
18 that.

19 So, finally, what I want to say is
20 I'm really concerned that we're rehashing
21 classification after the really, really hard
22 work that this Board and the Material Working

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1 Group did to reach consensus for that
2 document. The things we're talking about
3 today and that have been talked about on the
4 Crops Committee are the debate that we had on
5 the Material Working Group and in
6 classification. And so I am very grateful at
7 the end of the day for the debate because we
8 needed a real example to bring to life the
9 really hard discussions.

10 As a reminder, we agree on
11 classification on almost every material.
12 There are a few materials on which we needed
13 some help, and that was the classification
14 document. And CSL is a good example and will
15 help us formulate the work sheets that we work
16 through.

17 And then my final thought is
18 please remember that today is not the
19 beginning of classification decisions. This
20 Board and past boards have been deciding on
21 classification since the mid-1990s. And I
22 think it's very, very important that we rest

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1 our decision on the shoulders and hard work of
2 all those previous boards so we provide
3 consistency and aren't seen as swinging from
4 one side to the other. Thank you.

5 MR. GIACOMINI: Jeff?

6 MR. MOYER: Katrina, I tend to
7 agree with you about past board decisions,
8 however, it's my understanding that even
9 though we as a board approved that, the
10 Program has not acknowledged that into our
11 policy statement, in fact, has some serious
12 difficulties with the definition of chemical
13 change that we presented. So, as a committee
14 it was difficult for us. While we didn't
15 discount that totally, it's not in our
16 repertoire of things that we could base our
17 decisions on at this point in time.

18 MR. GIACOMINI: Katrina?

19 MS. HEINZE: You are right that
20 the Program did have a problem with our
21 definition of chemical change. It was not the
22 October 2009 portion of that definition.

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1 Their concern was with the second sentence
2 that we added last April which I did not
3 include in what I read. That was the part
4 where we talked about if you use something on
5 the National List it didn't count. And you'll
6 hear me say later when we talk about
7 classification that we agree with that. We
8 agree with their position, but that is not
9 this part of the definition.

10 MR. GIACOMINI: Miles?

11 MR. McEVOY: Yes, the other point
12 there is that we did not provide the response
13 to the NOSB until after the committee had made
14 their determination. So, you were really
15 working under the November 2009 work and April
16 2010 work that that committee had conducted.

17 MR. GIACOMINI: Okay. Jay?

18 MR. FELDMAN: Thank you. Katrina,
19 I'm as troubled by your reaction to our
20 deliberations as you are troubled by our
21 deliberations because I don't think that was
22 our intent and I believe we were following the

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1 understanding of the Board's policy. And I
2 guess I would like to get clarification on
3 that, because if we're having a discussion
4 about chemical change with a distinct identity
5 change that causes solubility -- and I don't
6 believe it's fermentation that is at issue
7 here, Tina. I believe if you read Biss and
8 Kogen, I believe as we cite, that we're really
9 talking about solubility and we're talking
10 about a process. Yes, fermentation can help
11 that process occur, but it doesn't do the job
12 and therefore the sulfur dioxide is needed.

13 But in terms of the actual policy,
14 if the Committee believed that there was a
15 chemical change occurring, honestly believed
16 that, why is that not an application of the
17 policy? How have we betrayed the Board's will
18 at that point?

19 MR. GIACOMINI: Katrina?

20 MS. HEINZE: I don't you to
21 misunderstand my comments. It's not a
22 betrayal or anything like that. You know,

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1 classification is very, very complicated and
2 in the classification documents and in all of
3 the debates that happened a lot of the points
4 that the Committee considered, or as I read
5 your recommendation and the minority opinion,
6 I think were considered during classification.
7 And I do recognize that since we haven't
8 completed the work sheets it was difficult for
9 the folks on the Crops Committee to fully
10 consider the classification work. So I do
11 recognize that.

12 With regard to the solubility,
13 that is a point specifically addressed in the
14 classification document, that the use of an
15 input in the process to make a material, when
16 that input is used to change the solubility
17 and then bring it back, if that input does not
18 remain at a significant level -- and I do
19 recognize that significant is problematic as
20 well -- but if that input does not remain,
21 that no chemical changed happened. Our real
22 focus was what is the material in the original

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1 source, and then what is the final material?
2 And that there's a lot of things that can
3 happen in between and inputs that will not
4 affect the classification. And there are some
5 specific examples in the classification
6 recommendation from the fall of 2009 that
7 address that.

8 MR. FELDMAN: And I guess the
9 understanding from the science that we've
10 looked at shows that there is a change, there
11 is a distinct identifiable identity change.
12 You know, it starts out in one form and ends
13 up in another.

14 And, you know, it's interesting.
15 One of the things that really caught my
16 attention on this because of dealing with the
17 world of unknowns applied to public policy
18 when it comes to science is a really
19 troubling, I think, challenge that we face as
20 a board. You know, somebody comes to us and
21 says we don't really know the mechanism. We
22 don't really understand what's going on here.

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1 And then you read a document that says and the
2 outcome of the process is very variable. The
3 sulfur content can be five times higher either
4 way depending on the particular process that's
5 used.

6 So, when you produce that green
7 mug, it could come out different shades of
8 green. It might even come out, you know,
9 pink. I don't know. I mean, but let's stick
10 with different shades of green. We just don't
11 know what's going to happen there according to
12 what the science and the TR is telling us.

13 So, I guess I am taking aback a
14 little bit by the charge. And, you know, it's
15 relatively serious, because I think I agree
16 with you wholeheartedly, Katrina, that it is
17 the job of the committee to carry out the
18 policies of the Board. That's our job whether
19 we agree with it or not. And the same is true
20 about the law, you know, the underlying
21 statute. It's our job, Joe. You know, the
22 synthetic thing is problematic as a defining

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1 threshold issue. But be that as it may,
2 that's our charge. And so we have to struggle
3 with that.

4 And so all I was trying to do in
5 sort of laying this out is to try to be honest
6 to the definition of a distinct chemical
7 identity and then move on from that to
8 determine compatibility later. But to meld
9 those two issues together because we believe
10 this is valuable to organic crop production is
11 not the charge we have as a board.

12 And so just in closing, I guess,
13 we did consider the distinct identity issue,
14 we did consider the process by which that
15 distinct identity occurred, we looked at the
16 TR, we looked at the science that was given to
17 us and, you know, on one level it seemed
18 pretty clear until the minority report popped
19 up. I mean, we did have a good discussion, I
20 agree with you. I mean, it was robust, as we
21 like to say. Everybody put what they had on
22 the table and, you know, I think people will

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1 disagree, yes, but again, where there is
2 disagreement and unknowns I think we have a
3 duty under the organic law especially to be
4 precautionary. That's a principle I think we
5 should embrace and that's another challenge
6 that we have. Thanks.

7 MR. GIACOMINI: Okay. Let's try
8 to wrap this up. Katrina, are you responding
9 to Jay? Okay. One last response.

10 MS. HEINZE: I do not disagree
11 with you. One of the reasons that our
12 classification recommendation had several NOSB
13 procedures that we wanted added and which the
14 Policy Committee graciously included in our
15 policy manual now is that we refocus on really
16 understanding our materials and classify them.
17 So, yea, we have done that on corn steep
18 liquor.

19 And second that we vote on
20 classification because there will be
21 differences of opinion. And so, I'm glad that
22 is happening as well. And there will be

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1 differences of opinion. And if you go back to
2 the early boards, they disagreed all the time
3 and I think that is good and it means we're
4 doing our job.

5 MR. GIACOMINI: John?

6 MR. FOSTER: ON the identity
7 thing, I looked and had a lot of discussions.
8 No one has been able to tell me what this new
9 chemical is that has rendered it a change in
10 identity. No one has brought that certainly
11 forward. I think the reason why is the same
12 reason that when you have wine in a cask and
13 you add sulfur dioxide, it's still wine. The
14 identity of the product is still wine. Wine
15 is wine before sulfur dioxide. Wine is wine
16 after. And again, this is maybe my looking at
17 the forest and not a tree, but I just don't
18 see that as an identity change. That's it.

19 MR. GIACOMINI: Okay. Thank you.
20 Unless there's any absolutely totally and
21 completely new on this, I believe we've
22 wrapped this one up and taken care of it

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1 almost as much as we possibly can for this
2 point in time.

3 And we're half an hour behind for
4 a break, I believe. So, 15 minutes. 10:45
5 please be back in your seat.

6 (Whereupon, at 10:31 a.m. the
7 above-entitled matter went off the record
8 until 10:48 a.m.)

9 MR. GIACOMINI: Please come to
10 order. Meeting's back in session. We move
11 onto the Livestock Committee. We have a few
12 more board members needing to take their
13 seats, but all the Livestock Committee is
14 present at this time and we have a quorum.

15 So, Kevin, please proceed with the
16 Livestock items on the agenda.

17 MR. ENGELBERT: Okay. I think
18 that given the fact that our animal welfare is
19 a discussion document for the first time since
20 I've been on the Board; the livestock
21 recommendations are probably the least
22 controversial of any that we're going to deal

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1 with, and I think we can make up some time
2 because of that.

3 PARTICIPANT: (Off mic comment.)

4 MR. ENGELBERT: Well, no, I
5 shouldn't make that assumption.

6 First I want to build a little bit
7 on what Dan said earlier about the speakers
8 that we had yesterday. I want to make sure
9 everybody that's here that doesn't have
10 contact or has never had contact with plain
11 folk that you don't mistake a lack of formal
12 education for training to be a poly-speaker
13 for a lack of intelligence. Those people are
14 very intelligent people and it's just against
15 their religion to have formal educations. And
16 for them to come forward and speak like they
17 did and interact with the English was just
18 taking an amazing amount of courage.

19 Before we get to our
20 recommendations, I just want to respond to a
21 couple of the NOP responses to the spring
22 recommendations. First, as we discussed

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1 yesterday, the Livestock Committee went back
2 and looked at our methionine recommendation
3 and at the present time we're going to stay
4 put. The only other option that the Committee
5 would consider was just simply letting it
6 sunset. And unless new information becomes
7 available or if it does become available we
8 are willing to readdress the recommendation.
9 But at the present time we're very comfortable
10 with what we recommended last spring and we're
11 going to stay with that.

12 On the issue of GMO vaccines, we
13 again believe that we made the right
14 recommendation last spring. We heard
15 testimony yesterday that 80 percent of
16 vaccines used by the poultry industry are GMO
17 with no other options and we remain very
18 concerned about the potential, as Hugh liked
19 to call it, train wrecks and we simply hope
20 they don't happen, but we have put vaccines
21 back on our work plan. We have requested a
22 thorough technical review of vaccines,

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1 including GMOs.

2 A couple of the questions that we
3 want to have specific answers to are
4 procedures that are used to make vaccines,
5 when a vaccine could become a GMO, if there's
6 anything used in the process that would
7 trigger that or when it's triggered, the
8 viability of vaccines being made strictly for
9 organic use, the economic implications of that
10 and what the realities are out in the world.

11 I'd also like to comment on two
12 quick sunset recommendation materials. The
13 Crops Committee has deferred their chlorine
14 materials and the copper sulfate. The
15 Livestock Committee is not doing so. We're
16 moving forward and including the
17 recommendations just simply because of the
18 completely different uses that they have in
19 livestock as opposed to crops. For example,
20 the chlorine materials, most milk marketing
21 ordinances, all milk marketing ordinances that
22 I'm aware of require chlorine as a

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1 disinfectant. It's simply has to be present
2 in a milk house to disinfect the pipelines and
3 equipment that's used to milk, and we just
4 didn't think we could take them off
5 separately.

6 Lastly, I'd also like to reiterate
7 that we very much appreciate having a liaison
8 from the NOP; ours is Mark Keating, on our
9 calls. It's been very helpful. Having the
10 direct contact has allowed us to get answers
11 to questions we have immediately without
12 having to go back to the Program and wait for
13 them. And we're very appreciative of the
14 newfound interaction that we have with the
15 Program, the increasing in the staff that's
16 allowed this to happen and we're very thankful
17 for that.

18 As we move into our
19 recommendations, it goes without saying that
20 the amount of work -- and I know everyone gets
21 tired of hearing about it, but the amount of
22 work that our committee has put into these is

1 tremendous. The people that will be
2 presenting each of these recommendations, that
3 have taken the lead have done an incredible
4 amount of work. The most detailed and
5 complicated of course is our animal health
6 recommendations. Wendy has jumped straight
7 into the fire coming on the Board and has
8 handled that just incredibly well.

9 The first recommendation that
10 we're going to deal with is the petition for
11 formic acid. Jennifer will talk about that,
12 get into the details. It has been fast
13 tracked but we wanted to alleviate any
14 concerns about that and she'll delve into the
15 reasons why.

16 The next thing we'll talk about is
17 the reaffirmation of the sunset
18 recommendations that were voted on in the
19 spring 2010 meeting. We also had no
20 additional public comments that came in after
21 the meeting, because if you remember the
22 comment period closed after the meeting was

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1 over. We had no additional comments come in
2 regarding that recommendation and none have
3 come in prior to this meeting as well.

4 Then we'll talk about the rest of
5 our sunset materials, the 12 items; aspirin,
6 the three chlorines, copper sulfate, the two
7 alcohols, furosemide, glucose, glycerine,
8 magnesium sulfate and EPA List 4 inerts of
9 minimal concern. They will be grouped
10 together as a recommendation. Again, we've
11 had no controversy on that and no dissenting
12 comments, no concerns from the public.

13 Then we'll move into the
14 apiculture recommendation that was originally
15 made in 2001. The Livestock Committee led by
16 Joe and Jennifer together have taken that
17 recommendation, updated it with new
18 information that was provided by the ACA
19 Apiculture Working Group and additional public
20 comments.

21 And then we will move into our
22 clarifying 205.238(c)(2) recommendation. As

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1 Dan spoke of earlier, a great deal of help was
2 obtained from CCOF and Dan will be handling
3 that recommendation.

4 And then lastly, we will move into
5 our animal welfare subjects, the stocking rate
6 discussions document and the animal handling,
7 transit and slaughter discussion document.
8 And Wendy will be leading that discussion.

9 So, if you're ready, Jennifer,
10 we'll move right into the formic acid
11 petition.

12 MS. HALL: Thank you, Kevin.

13 I want to make it clear at the
14 outset that the formic acid that is being
15 requested is synthetic, so there's no question
16 about that.

17 PARTICIPANT: (Off mic comment.)

18 MS. HALL: What? Yes, I'm
19 positive. At least this formulation, yes.

20 So, we received a petition to
21 include formic acid in its synthetic form on
22 205.603 for use specifically as a pesticide

1 with honeybee hives.

2 So as a committee we went through
3 and went through the evaluation criteria and
4 the formic acid did pass all of those
5 criteria.

6 First, I just want to go through
7 the petition itself and then I'll talk about
8 the history. Sorry, I should have said that
9 up front.

10 And so, as a committee we did
11 first, like I said, unanimously vote that
12 indeed the requested formic acid is synthetic
13 and that annotated for use only with honeybee
14 hives that it was also approved for that use
15 to be added to 205.603.

16 Now, part of the uniqueness of the
17 process with this is it is a little bit cart
18 before horse. As a part of our evaluation we
19 did also request the technical review. And so
20 typically that is received and examined prior
21 to a formal recommendation. But this petition
22 and the process that it has seen up unto this

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1 point with formic acid is a little bit unique,
2 so I ask you to indulge me for a little bit of
3 that explanation. I think it's pretty
4 important.

5 The history, as Kevin mentioned,
6 is there was a 2001 Apiculture Task Force that
7 took up apiculture as a full topic and
8 presented a recommendation. And as part of
9 that recommendation there was a list of
10 materials and that list was requested that the
11 NOSB evaluate those items expeditiously for
12 inclusion and recommendation to the NOP to be
13 included on the List. It sat for awhile.

14 And in that time, originally
15 Hawaii was not infested by the varroa mite.
16 That changed. And before that changed, the
17 beekeepers in Hawaii actually did come
18 together and approach the Department of
19 Agriculture in Hawaii and asked them to not
20 allow barges from New Zealand that typically
21 use Hawaii as a stopping point carrying bees
22 as cargo. Once New Zealand got infected, they

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1 did request that those be denied, that New
2 Zealand could no longer stop at their ports
3 with bees. That request was denied. And in
4 2007 varroa mites did indeed land in Hawaii.

5 And so, that's somewhat
6 accelerated the issue. And still this Board
7 has been pretty plagued with a lot of high-
8 priority issues and still the apiculture
9 document had not received any attention.

10 And for those who are not aware,
11 the varroa mite, once it infests, it works
12 pretty quickly and it's fairly devastating and
13 hives can be taken out of production really
14 fairly quickly.

15 So last spring at the spring
16 meeting some of you who were at that meeting
17 might remember that Dr. Lyle Wong from the
18 Department of Agriculture of Hawaii did
19 present in public testimony his petition and
20 a bit of the reasoning for his request that it
21 be expedited in the approval process.

22 And the reality is now that Oahu

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1 -- actually that island's hives are pretty
2 much 100 percent gone, including the feral
3 hives due to the varroa mite. The Island of
4 Hawaii is helping repopulate honeybee hives
5 over there, but due to the pollination needs
6 that agriculture requires, it's more than just
7 the honey, it's more than just the bees, it is
8 agriculture in general that is coming to great
9 threat there.

10 So, after Dr. Wong did his public
11 testimony, timing was kind, and my friends are
12 even kinder, and I actually had a trip planned
13 to Hawaii. And so I did meet with several,
14 four to five of the beekeepers and Dr. Wong
15 again while we were there and learned a little
16 bit more about what they're facing and why
17 other applications are not effective,
18 specifically in that climate and why this
19 request is so imminent.

20 And so, as part of that process
21 the formic acid that they're requesting,
22 they're actually specifically requesting a

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1 Mite Away II formulation because of the
2 temperature zone that their hives are in, that
3 there are other applications like thymol,
4 other kind of more oil-based and herbal
5 applications that only respond in a certain
6 temperature frame that Hawaii very rarely
7 hits. It's like a max of 85 degrees that
8 those applications can be used and the ambient
9 temperature in Hawaii really prevents that
10 from being useful.

11 So, though we have tried
12 everything and really done their best to find
13 other applications and work with their own
14 Department of Agriculture in the interim,
15 they've kind of hit this point where it's a
16 very threatening time. And though it may seem
17 like, well, if we lose, you know, organic
18 apiculture in Hawaii, is that a really big
19 deal? And there's two reasons that it is.
20 One is for North American they produced the
21 majority of organic honey. And if the answer
22 for agriculture in general there was to revert

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1 to convention just for the pollination needs,
2 it actually was a bit odd given the economic
3 incentives because imported honey is so much
4 cheaper than honey can be produced on Hawaii.
5 The margin that they get from organic is the
6 only way that apiculture is actually a viable
7 concern. And so it's more than risking just
8 organic, it's actually risking a lot of just
9 apiculture in general.

10 So for that reason I was willing
11 to kind of ask for my committee's ear and
12 willingness to consider fast tracking this,
13 and not in small part due to the fact that
14 formic acid for honeybee application is
15 already used in both the Canadian and the EU
16 organic standards. So there is also the
17 competitive playing field that is at stake in
18 this instance.

19 So, that gives a little bit I
20 think of the history and I would open it up to
21 questions from the Board.

22 MR. GIACOMINI: Kevin?

1 MR. ENGELBERT: Just to reiterate,
2 we did receive a lot of information on formic
3 acid. The petitioner provided what we thought
4 was a lot of viable information, but we did
5 request another technical review and it will
6 be readdressed in the future. But we were
7 very comfortable with what we received with
8 the annotation that we put on the material to
9 move forward with it. And also we haven't
10 received any negative public comments with
11 regard to this petition.

12 MR. GIACOMINI: Other comments?

13 (No audible response.)

14 MR. GIACOMINI: Seeing none.

15 Kevin, your next item.

16 MR. ENGELBERT: Okay. Next we
17 will move to Jeff to talk about the
18 reaffirmation of the prior sunset votes from
19 the April 2010 meeting.

20 MR. MOYER: Thank you, Kevin.

21 As everybody will recall and Kevin
22 had just stated in his opening comments, at

1 the spring 2010 meeting the Livestock
2 Committee did vote or did recommend votes to
3 the Board and the Board did pass on those
4 recommendations, and I'm going to list them
5 here.

6 And in the interim time we did
7 accept more public comment. We had received
8 actually two comments on materials for listing
9 on 205.603. One of the commenters stated that
10 Oxytocin and Ivermectin should be removed from
11 the National List. The other stated that all
12 materials should remain on the list. No
13 evidence was presented to justify the removal
14 of those two materials, therefore in
15 accordance with our current sunset rules the
16 Livestock Committee recommends now that those
17 votes stand.

18 So, the public period ended -- I
19 forget the exact dates when that ended.

20 PARTICIPANT: October 12th.

21 MR. MOYER: October 12th. We have
22 received no other comments. So, with regard

1 to 205.603 we're recommending that all 25 of
2 the sunset materials -- the vote stands on
3 those.

4 And then on items 205.604 we
5 received no additional comments and again the
6 Livestock Committee recommends that those
7 votes stand, Mr. Chairman.

8 MR. GIACOMINI: Jeff, mic, please.

9 Just so that we understand the mic
10 situation, we can have two mics on. If a
11 third mic tries to get in, it can't get on.
12 I'm taking the chair prerogative and trying to
13 control discussions. I'm keeping mine on. So
14 you guys will have to turn yours off.

15 So, any discussion on the
16 reaffirmation votes?

17 (No audible response.)

18 MR. GIACOMINI: Seeing none.
19 Kevin, next item?

20 MR. ENGELBERT: Okay. Now we'll
21 move into the sunset recommendation on the
22 remaining 12 materials that are on the

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1 Livestock Committee's sunset list.

2 These materials were deferred from
3 the spring meeting because the only
4 information that we had on them was what we
5 considered to be -- I don't want to say
6 outdated because it may still be relevant, but
7 it was older information and we at the time
8 wanted to give the chance to -- we requested
9 new technical reviews on these 12 materials
10 and we were hoping that we would get them in
11 time to look them over and make a
12 recommendation for this fall.

13 Those technical reviews were not
14 forthcoming, but the majority of the Committee
15 decided or felt that, thought that we should
16 move ahead and put them on the agenda for this
17 meeting. I don't believe we received any
18 public comments against relisting of these
19 materials. I will read them off.

20 First is disinfectants, sanitizer
21 and medical treatments as possible. Alcohols,
22 which are ethanol, as a disinfectant and

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1 sanitizer only, prohibited as a feed
2 annotation; isopropanol as a disinfectant
3 only. Two, aspirin, which is approved for
4 healthcare use to reduce inflammation.
5 Chlorine materials, which is for disinfecting
6 and sanitizing facilities and equipment.
7 Residual chlorine levels in the water shall
8 not exceed the maximum residual disinfectant
9 limit under the Safe Drinking Water Act.
10 Those include calcium hypochlorite, chlorine
11 dioxide, sodium hypochlorite. Furosemide, CAS
12 No. 54-31-9. In accordance with approved
13 labeling except that for use under 7 C.F.R.
14 Part 205 the NOP requires a withdrawal period
15 of at least two times that required by the
16 FDA. Glucose. Glycerine with the annotation
17 allowed as a life livestock teat dip must be
18 produced through the hydrolysis of fats or
19 oils. And magnesium sulfate.

20 The Livestock Committee did not
21 defer any votes any other materials under (a),
22 and we also recommends not renewing any other

1 materials.

2 Under (b) as a topical treatment,
3 external parasiticide or local anesthetic as
4 applicable, copper sulfate. We also did not
5 recommend deferral of any vote or not renewing
6 any substances in that category.

7 We recommend under (a) as
8 synthetic inert ingredients as classified by
9 the Environmental Protection Agency for use
10 with non-synthetic substances or synthetic
11 substances listed in this section and used as
12 an active pesticide ingredient in accordance
13 with any limitations on the use of such
14 substances EPA List 4 - Inerts of Minimal
15 Concern. There were not materials that were
16 deferred or that were recommended not renewing
17 in this category.

18 I'm not going to go into the List
19 4 inert situation. I think we're all familiar
20 with that. We have four members that are on
21 the Livestock Committee that are also on the
22 Crops Committee and we worked very well

1 together and kept each other informed of our
2 positions. And the Crops Committee has taken
3 the lead on that, but the Livestock Committee
4 was actively involved.

5 Our vote on that motion was six in
6 favor and one no. Again, the no was my vote.
7 I'm just uncomfortable with this current
8 sunset process and I didn't think we should
9 move forward with these materials until we had
10 new information, but I was obviously in the
11 minority and now open the floor up for
12 discussion.

13 MR. GIACOMINI: Just one
14 clarification, not that it disagrees with you,
15 but one of the reasons that we made that
16 original list of what we wanted new TRs with
17 was because we had not completed the public
18 comment period which is where we were
19 expecting people to come and say what
20 substances they had problems with. So, we had
21 to make a determination of what's easy to pass
22 through at the spring meeting and what's a

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1 little more difficult without knowing what the
2 full public comment was going to be. We
3 submitted all those as TRs. That got bogged
4 down. But one of the reasons that I think, at
5 least in my mind, that we agreed to go along
6 with this without the TRs was because once
7 that public process public comment period was
8 done, there had been no voice of concern. So,
9 that was the reason that, you know, we made
10 the original list without knowing what the
11 voice was going to be. Once we saw that there
12 was no voice of concern, we just decided that
13 we could proceed without needing all those new
14 TRs.

15 So, any other comments or
16 questions for the Livestock Committee? Kevin?

17 MR. ENGELBERT: Just to follow up,
18 those TRs are still in the pipeline though.
19 So, these materials will be looked at again
20 when we get those new technical reviews.

21 MR. GIACOMINI: Right. Nothing
22 further?

1 (No audible response.)

2 MR. GIACOMINI: Next item from
3 Livestock, please?

4 MR. ENGELBERT: Next we'll move
5 into the apiculture recommendation and Joe.

6 MR. DICKSON: Thank you, Kevin.

7 So the apiculture recommendation
8 is a committee recommendation for a practice
9 standard for the production of bees, or bees
10 used to produce organic honey as opposed to --
11 it's not a standard for bees used as
12 pollinators on organically-managed land, and
13 that's an important distinction to make. This
14 is a standard for bees that produce organic
15 honey or other bee products.

16 Bees are of course livestock, but
17 they're very unique among livestock in that
18 they cannot be contained and they go out every
19 morning and come back to the same hive in the
20 evening. And there's a consensus among
21 producers and certifiers that, you know, the
22 special nature of bees necessitates a practice

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1 standard specific to their unique behavior and
2 etcetera.

3 The NOSB made an initial
4 apiculture recommendation back in 2001. Due
5 to a lot of competing priorities at NOP, the
6 recommendation was never implemented. In the
7 intervening years a number of honey producers
8 have been certified by a number of certifiers
9 under the existing livestock standard. And at
10 the fall meeting in 2009 the Accredited
11 Certifiers Association submitted a comment
12 with a number of recommended changes to the
13 original NOSB recommendation.

14 The Livestock Committee has looked
15 at those recommendations. Jennifer and I, who
16 I think we were assigned the task because
17 we're the two beekeepers on the Livestock
18 Committee. Neither of us have organic bee
19 operations because we're in cities, but we at
20 least understand the lingo.

21 We worked directly with the ACA
22 with some representatives from their working

1 group, with networks of producers in our sort
2 of home areas and beyond. As Jennifer
3 mentioned she's worked with a number of
4 producers in Hawaii. And we, you know,
5 solicited as much feedback as we could and did
6 our best to integrate that into the revised
7 recommendation that we have posted.

8 The recommendation is
9 intentionally designed to be harmonious with
10 the expectations of organic consumers for
11 organic honey with current practice and
12 current certifier expectations and with the
13 existing apiculture standards and the Canadian
14 organic standards and the EU standards.

15 We've received five public
16 comments in support of the recommendation so
17 far with some specific feedback and requests
18 for changes. The Organic Trade Association
19 expressed that we should be sure to solicit
20 adequate feedback from impacted producers.
21 And to clarify, you know, we certainly have
22 worked with a number of producers on this

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1 recommendation. And the ACA's recommendation
2 I think encapsulates a lot of producer
3 feedback through the certifiers who worked on
4 that process and we'll continue to solicit any
5 and all producer feedback on the
6 recommendation.

7 Vermont organic farmers expressed
8 that the forage zone within our recommendation
9 should be allowed to include sort of lower-
10 risk non-organic land such as residences and
11 the minor commercial landscape without
12 additional inspection or affidavits. And
13 Harriet gave a good rebuttal to that yesterday
14 and we do need to discuss that feedback in
15 committee, and we'll be looking at that. But
16 as it stands the recommendation does not allow
17 for non-organically managed or wild land that
18 would be certifiable within the forage zone.

19 A commenter yesterday, an oral
20 commenter expressed that she does not use
21 plastic foundation in her hives and Jennifer
22 and I realized that we may have actually

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1 worded the standard to inadvertently require
2 the use of foundations, so we will revisit
3 that as a committee to make sure it
4 accommodate producers who are not using
5 foundation and they're using top bar systems
6 or other beekeeping methods that don't use
7 plastic or other forms of foundation.

8 And then Jennifer I believe has
9 heard from another individual who will deliver
10 oral comment on Wednesday with some other
11 concerns about the recommendation.

12 Jennifer, I don't know if you have
13 anything you want to add.

14 MS. HALL: Thanks. Just that it
15 has been a really great collaboration and I
16 also give thanks to the Apiculture Working
17 Group and ACA. And a special thanks -- I did
18 reach out to -- many of you are familiar with
19 Nancy Ostiguy who used to be on the Board and
20 is quite a bee specialist. So I have used her
21 extensively for feedback coming into this and
22 even with some of the feedback we've gotten

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1 recently, so I do want to give her great
2 credit for that.

3 The feedback that I understand
4 will be presented tomorrow and I think is good
5 is talking about not just excluding GMO crops
6 from our surveillance zone, but to actually be
7 more encompassing with all excluded methods,
8 which I think is a really, really great edit,
9 and talking about some other elements of
10 required records, which we will look at in
11 committee as well.

12 So, I definitely appreciate
13 everybody's feedback and willingness to
14 contribute to I think what is a really solid
15 recommendation.

16 MR. GIACOMINI: Okay. Kevin?

17 MR. ENGELBERT: Yes, I would like
18 to make sure everyone realizes that we will be
19 taking public comment into consideration. And
20 as is standard practice, the Livestock
21 Committee will be meeting tomorrow night to
22 fine tune this recommendation. We realize the

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1 importance of getting this finally across the
2 goal line and getting it into the NOP's hands
3 so they can begin with getting an ANPR out.
4 So, we will address the issues that we have
5 received and we will have what we believe will
6 be the best recommendation possible at the
7 present time for voting on Thursday.

8 MR. GIACOMINI: The Livestock
9 Committee also though was very aware that this
10 will be a major rulemaking process at the NOP
11 and that unless something really major comes
12 up, we're not going to let, as they say in
13 this case, the perfect be the enemy of the
14 good, that if there are still some minor
15 errors that may be needing to be corrected,
16 they will certainly be able to be corrected at
17 that level with the extensive public comment
18 that will be required there. So, we'll fix
19 what we can, but we're going to ready
20 hopefully to move ahead on this.

21 Jennifer?

22 MS. HALL: I'd also just like to

1 clarify that unlike the 2001 version that did
2 include a list of materials requesting kind of
3 carte blanche recommendation that we are not
4 doing that in this process and that like
5 formic acid if there are additional materials
6 that people want included in apiculture they
7 need to petition those separately.

8 MR. GIACOMINI: Miles from the
9 Program. I mean Arthur.

10 PARTICIPANT: Got a promotion.

11 MR. NEAL: Just a point of
12 clarification. Just wanted to ask whether or
13 not this recommendation replaces the earlier
14 recommendation or this in addition to the
15 2001-2002 recommendation?

16 MR. GIACOMINI: Kevin?

17 MR. ENGELBERT: Yes, this replaces
18 it, Arthur. We've updated that recommendation
19 and this will be the Board's current
20 recommendation.

21 MR. GIACOMINI: Joe?

22 MR. SMILLIE: I expressed it

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1 yesterday, but I share VOF's concerns about
2 the, you know, non-commercial residential
3 sites and the process by which the certifiers
4 will have to enforce this recommendation. I
5 think it's a good recommendation. I'm not
6 against it. I'm just worried about the
7 enforceability, especially in light of the new
8 wild crop guidance document from the NOP.

9 Did you guys have a chance to like
10 review that document while you were working on
11 this one?

12 MR. GIACOMINI: Not wild.

13 MR. SMILLIE: Yes. Well, you see
14 this cuts across a couple things. You know,
15 that big area that certifiers are going to be
16 forced to verify, the prohibition for three
17 years on chemicals is a tough enforceability
18 issue. You know, if you're in Northern
19 Saskatchewan or maybe Northern Dakota, yes,
20 it's not going to be that hard. Bureau of
21 Land Management, you go to one source, they
22 say no, there's been no, you know, power line

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1 spraying, there's been no this or no that.
2 But if we're going to have organic beekeeping
3 and organic honey, you know, I just hate to
4 see it pushed away from -- and I just hope
5 that you can just take a look at the wild crop
6 guidance from the NOP and look at it as how it
7 will interface with your document. Because
8 again, as a certifier having done wild crop,
9 to follow the letter of the law as far as
10 inspection of sites and the OSP is a major
11 league job. And, you know, you can't deny
12 anybody's application for certification, but
13 you can certainly say -- you know, you can
14 avoid it by other methodologies. But I just
15 want you to look at that as part of your
16 recommendation. That's all.

17 MR. GIACOMINI: Kevin?

18 MR. ENGELBERT: And I agree, Joe,
19 and two points. One is we all know organic is
20 based on trust. This isn't going to be any
21 different with producers and there's always a
22 trust factor involved. And two, I think it's

1 safe to say that there's probably going to
2 have to be some training involved with
3 inspectors and certifiers from the NOP, just
4 like they did possibly with the new pasture
5 standards, having training sessions to get
6 certifiers who are going to certify organic
7 apiaries up to speed on what they need to do
8 and how they need to do it.

9 MR. GIACOMINI: Other comments?
10 Questions? Katrina?

11 MS. HEINZE: We heard at the
12 beginning of this meeting that it's important
13 that we provide NOP with the support they need
14 to get recommendations through. In your work
15 with them were there any concerns or hurdles
16 that they saw in getting this through
17 rulemaking?

18 MR. DICKSON: Not that I'm aware
19 of. And, Jennifer, I don't know if you have
20 anything to add there. But from our work with
21 our NOP representative during the process we
22 didn't hear any feedback like that.

1 MS. HEINZE: Thank you. That's
2 good.

3 MR. GIACOMINI: Miles this time.

4 MR. McEVOY: Yes, this
5 recommendation looks pretty comprehensive and
6 I think we certainly can work with this. We
7 were moving apiculture into the rulemaking
8 plan with the prior recommendation. This
9 provides a lot more information that we'll be
10 able to utilize in that rulemaking process, so
11 I think this is going to be very, very helpful
12 for us.

13 MR. GIACOMINI: Thank you.
14 Further discussion?

15 (No audible response.)

16 MR. GIACOMINI: Seeing none.
17 Kevin, next item?

18 MR. ENGELBERT: Okay. Then we'll
19 move right back to you, Dan, with the
20 clarifying our 205.238(c)(2) recommendation.

21 MR. GIACOMINI: Okay. Thank you.
22 I just want to start by reading the official

1 name of what we called this document.

2 "Recommendation to Change § 205.238(c)(2) in
3 Conjunction With Scientifically Acceptable
4 Animal Welfare Practices Regarding the Care of
5 Organic Livestock." It's long, but I think
6 even that is fairly important.

7 This was a very difficult document
8 to prepare in that the time line and the
9 things that happened were very interweaving.
10 We discussed much of that yesterday. Again
11 like to recognize and thank the help done from
12 CCOF and Rob and Allen, not only in the way
13 that they helped us deal with this document,
14 but the way that they helped us deal with this
15 issue in coming to us and saying this is a
16 problem instead of it becoming a problem in
17 the field that then we had to react to
18 possibly in a way that may not necessarily
19 always be the best, the best we can in
20 reacting to it, but not the best way in
21 dealing with the issue. And we appreciate
22 them coming this way.

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1 If everyone remember the
2 discussion we had yesterday, the walk through,
3 the adding of the excipients and the changing
4 of the excipient annotation, the reason it's
5 still listed on the agenda with the animal
6 healthcare products; and to bring that up
7 without starting another debate right now, we
8 originally were hoping to deal with this issue
9 by adding the term "animal healthcare
10 products" into the excipient annotation. As
11 we tried to develop that definition and as I
12 will discuss in a minute hopefully, we felt
13 that that was not a way that was going to
14 resolve the problem. In dealing with the
15 program on that we requested comment on
16 whether we would just sort of have the Program
17 leave that aside and sort of ignore it or
18 whether -- well, that's not I'm sure the
19 proper term, or whether we needed to take
20 action to change that suggested annotation.
21 Their recommendation, what we heard back from
22 them was that we did not take formal action on

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1 that part of the recommendation for that
2 annotation change.

3 Arthur is looking at me very
4 concerned and I'm hoping that's --

5 MR. NEAL: (Off microphone.)

6 MR. GIACOMINI: Oh, okay. But the
7 reason I bring that up is because that was an
8 annotation change recommendation that was made
9 before the sunset review and it was very good
10 of us not to have reviewed that suggested
11 annotation change in the sunset recommendation
12 so that we would have to go back and
13 reconsider that one or re-review it. What we
14 reasserted for relisting on sunset at the last
15 meeting was the current existing annotation as
16 it is listed, and then there is a
17 recommendation for an annotation change that
18 is still pending.

19 But specifically then to the
20 details of this, when OFPA was written in the
21 1980s veterinary medicine was mainly a
22 proactive intervention of clinical and stand

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1 alone disease. It mainly involved infectious
2 disease and stand alone occurrences. During
3 that time of that era of veterinary medicine,
4 the pretreating in the absence of a disease
5 became a common practice and it was that
6 action that seems to have been the main
7 concern when OFPA was written.

8 OFPA, as it has stated, prohibits
9 medications except vaccines in the absence of
10 illness. The rule clarified that prohibition
11 to prohibit the administration of animal drugs
12 in the absence of illness and defined animal
13 drug with an FDA definition that essentially
14 included everything. It includes everything
15 that you deal with an animal, everything that
16 you look at animal with, everything that you
17 use in the evaluation of the health of that
18 animal and could include homeopathic, it could
19 include teat dips, it could be stretched in
20 the strictest sense of the term to include
21 absolutely everything including all of the
22 pain relief medication and other preventative

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1 practices which have over time since the late
2 '80s become more common use.

3 So in the 1980s scientific studies
4 began to be published that showed that disease
5 not a stand alone occurrence, but a cascading
6 series of disorders, illnesses and diseases.
7 Research of this type changed animal
8 healthcare from intervention to a systemic and
9 holistic management program to maintain
10 health. The scientific approach has become
11 much of the animal health and welfare
12 practices recommended and encouraged at this
13 time and required in many health welfare
14 certification programs today.

15 The reason we found that relevant
16 was in testimony before this Board regarding
17 animal welfare in 2007, now Deputy Secretary
18 Dr. Merrigan stated that at the time of the
19 passage of OFPA it was understood that organic
20 livestock production would eventually include
21 standards for animal health and welfare. She
22 acknowledged that rulemaking is a dynamic

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1 process and standards must be amended as
2 science emerges to suggest alternative
3 strategies.

4 So, while we were dealing with a
5 situation in -- if a strict enforcement of the
6 current language was enforced, there would
7 almost be nothing that would be allowed within
8 the preventative category of healthcare, pain
9 relief category of healthcare, and the science
10 of animal welfare has simply gone way beyond
11 that point.

12 So, the recommendation that we are
13 making from the Committee is for a rule change
14 to amend § 203.238(c)(2) to be stated as
15 administer any drug other than vaccinations,
16 preventatives and pain relief medications in
17 the absence of illness. We do not feel this
18 is a deviation from OFPA. We feel it is a
19 clarification of the new science of animal
20 welfare and we feel that it is a positive step
21 in the right direction. Because if you were
22 not allowed to use pain relief medication in

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1 dehorning, which is not an illness, if you
2 were not allowed to use pain relief medication
3 in surgeries that are not based on illness but
4 for some other reason, if we were not allowed
5 on the dairy side to use teat dip, which is
6 the major preventative against mastitis,
7 allowing the cow to get mastitis where we
8 would then need to take very -- use
9 potentially very prohibited and undesirable
10 treatments, it's just not sound animal welfare
11 at this time.

12 So, that's the recommendation of
13 Livestock Committee. I think I can say the
14 vast majority of the public comment was in
15 support of this document.

16 Kevin?

17 MR. ENGELBERT: And also to add in
18 that the Committee saw no potential for abuse
19 or any type of a loophole with this
20 recommendation. We think it's absolutely
21 sound and deals with a significant issue that
22 has come up.

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1 MR. GIACOMINI: Further comment?
2 Questions? John?

3 MR. FOSTER: I think this is great
4 example of getting ahead of problems before
5 they become problems, and I can see this being
6 very confusing three years from now. And
7 think it's really great work on the part of
8 the Livestock Committee to be ahead of the
9 curve like that. It's a great example of that
10 and I think the future livestock producers
11 will be thankful without even knowing what
12 they're thankful for because of this coming
13 in. Yes, I mean, assuming this comes through
14 this process.

15 MR. GIACOMINI: And that process.

16 MR. FOSTER: And this process.
17 It's a very good example of getting ahead of
18 problems and keeping something from becoming
19 a problem down the road.

20 MR. GIACOMINI: And again, we
21 appreciate CCOF's help and letting us do that.

22 Katrina?

1 MS. HEINZE: This is certainly not
2 my area of expertise, but in looking at the
3 public comment there were two public comments
4 received that asked some questions about how
5 the recommendation would be implemented. And
6 I was wondering if you could speak to those
7 either today or on Thursday so that we could
8 better understand.

9 MR. GIACOMINI: If you have that
10 in front of you, I would appreciate the
11 prompting. I remember one of those. I
12 believe those were from the OMRI comment. One
13 was whether it was to include the excipients.
14 Absolutely. We fully intended to. As we
15 discussed in the document, one of the problems
16 has been the active ingredient nature of the
17 National List as opposed to the products that
18 are developed that are available for the
19 treatment of the animal. That's why the
20 excipient language was inserted into the
21 National List. And we felt that it was a
22 stretch that that part of the regulation --

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1 that was not included in our recommendation.

2 And do you remember the other one,
3 Kevin?

4 Does OMRI remember what the other
5 -- the OMRI rep?

6 MS. HEINZE: You are correct, one
7 was from OMRI. One was I don't know from who.
8 I just have it in my notes that they had asked
9 some questions. I could find them, but I
10 could get them to you later today and perhaps
11 you could look at them and respond on
12 Thursday.

13 MR. GIACOMINI: Yes.

14 MS. HEINZE: Okay.

15 MR. GIACOMINI: Yes, we evaluated
16 those. We discussed them in committee. We
17 did not feel it justified to change in the
18 document.

19 MS. HEINZE: Perfect. That's what
20 I needed to know. Thank you.

21 MR. GIACOMINI: Yes. Further
22 comments or questions? Jay?

1 MR. FELDMAN: Just for
2 clarification. So, the result of this would
3 be more prophylactic drug use essentially?

4 MR. GIACOMINI: No.

5 MR. FELDMAN: No? You don't see
6 it that way?

7 MR. GIACOMINI: No. No.

8 MR. FELDMAN: Okay. Preventive.
9 A greater degree of preventive drug use. I
10 mean, how --

11 MR. GIACOMINI: No, this would
12 codify the status quo, which because the
13 status quo has not been in the majority of the
14 cases. In all the cases that I know there has
15 never been a full and complete enforcement of
16 this section of the statute to the letter.
17 It's the potential impact of in the age of
18 enforcement a full and complete to the letter
19 enforcement of this line, this item that would
20 cause the huge impact and change on the
21 industry. We do not believe that what we're
22 recommending would be any significant change

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1 at all. And if that change were made, the
2 firestorm that we would receive from animal
3 welfare where we were not allowing pain relief
4 in the case of dehorning and castration, we
5 were not allowing pain relief in the case of
6 surgery, where we were not allowing, to use
7 the same example, teat dip to prevent
8 mastitis, that is where the problems would
9 come from.

10 This is to reassert essentially
11 what is being done now. I have not heard from
12 any certifiers that say, well, we enforce this
13 to the letter and we don't allow any of the
14 things that were put on the National List.

15 You know, the majority of these
16 things are -- this includes both 603 and the
17 non-synthetic, you know, homeopathic type of
18 products. In most cases when they've been on
19 the list their use has actually been
20 encouraged when it's necessary. A full
21 enforcement of the way it stands right now
22 would be a huge disaster to animal welfare and

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1 to the industry we feel.

2 MR. FELDMAN: So I guess my
3 question is whether we're sufficiently
4 enumerating the situations in which use would
5 be allowed or --

6 MR. GIACOMINI: We're not telling
7 the producers how to be dairy farmers or
8 livestock producers, and to deal with that we
9 specifically say that we're not defining
10 illness. We decided that that would not be
11 the best route, because as Secretary Merrigan
12 stated, it the evolution based on science.
13 And if they had defined illness to the
14 definition of it at the time that OFPA was
15 written, it would not be a definition that was
16 applicable and current in its use today. And
17 we did not want to stand in the way of that
18 scientific progress, not that we were wanting
19 to allow more things to be used in the future,
20 but we did not want to tie the hands of
21 science on how the treatment of illness and
22 animal healthcare proceeded.

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1 MR. FOSTER: Thanks.

2 MR. GIACOMINI: Kevin?

3 MR. ENGELBERT: Yes, Jay, we're
4 not opening up the door for any type of abuse
5 whatsoever. I probably should have reiterated
6 that farther. We're referring to items that
7 are already on the National List for use in
8 livestock production that don't technically
9 deal with an illness, but are under the old
10 phrase an ounce of prevention is worth a pound
11 of cure. It's sometimes tough to determine
12 exactly when you move from a situation to
13 where an animal may have a health issue to one
14 that definitely does have an illness. That's
15 why we stay away from trying to define that.
16 But like Dan said, we want producers to be
17 able to use these materials that are on the
18 National List to do what's best for their
19 animals, to help them with the animal welfare
20 issues that have currently come to light.

21 MR. GIACOMINI: Any further
22 comments or questions?

1 (No audible response.)

2 MR. GIACOMINI: Seeing none.

3 Kevin, proceed please.

4 MR. ENGELBERT: Okay. With that,
5 we will move into our animal welfare
6 discussion documents and Wendy will guide us
7 across those coals and explain how we have
8 gotten to where we are today from where we
9 were last April.

10 MS. FULWIDER: Thank you. I
11 assume you've all had a chance to read the
12 documents, and I'll just hit the highlights
13 here, in the essence of time.

14 The document does not address free
15 stalls, tie stalls or stanchions. That's
16 really kind of a separate thing and would be
17 very prescriptive, and I think something
18 addressing that would belong in a guidance
19 type of document. But the document does
20 contain stocking density tables that include
21 bedded space requirements and space for an
22 outdoor run.

1 And when we put this together we
2 were looking at minimum space requirements for
3 winter or temporary confinement. So that's
4 why they would not be, you know, as a rule a
5 huge space requirement.

6 Some animals, you know, just don't
7 have standards put together in all of the
8 different standards that we reviewed, and that
9 would be why some of them seem really
10 different from what producers are currently
11 using, and we heard some public comment about
12 that yesterday.

13 I think the most important reason
14 for the standards that have been developed and
15 that are in use is because most animals are
16 confined. And so I think it's really
17 important that we kind of go down our own path
18 and I think the outcome-based standards are
19 probably in our best interest and the best
20 interest of our farmers.

21 Stocking density would best serve
22 as a guidance document I think for all of the

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1 different production models, because I know we
2 had one lady was talking about her lambing jug
3 area. And I know a lot of farmers that don't
4 use lambing jug areas. They just let the
5 lambs, you know, come out in the pasture. And
6 I don't use lambing jugs with my sheep.

7 Ventilation is something that we
8 put in there, and that's standard across
9 animal welfare documents from all the
10 different programs. And it's important
11 because when they do winter confinement,
12 animals and people can have burns to the eyes
13 and to the lungs. And so it's below 25 parts
14 per million is industry standard. And I think
15 it's important to realize that there are many
16 welfare programs and at some point all of
17 those are going to have to put together some
18 sort of a reciprocity agreement.

19 So with that, if you have some
20 questions?

21 MR. GIACOMINI: Questions or
22 comments for Wendy on the stocking document?

1 Jay?

2 MR. FELDMAN: So we heard a lot on
3 this yesterday in terms of the actual rates,
4 stocking rates. What is the process going to
5 be at this point to address those? Is the
6 Committee regrouping on the actual numbers?

7 MS. FULWIDER: Well, yes, that's
8 going to be foremost on our docket.

9 MR. GIACOMINI: Kevin?

10 MR. ENGELBERT: Yes, I don't think
11 we can say anything in this is solid yet, Jay.
12 It's still definitely a work in progress.

13 MR. GIACOMINI: Joe?

14 MR. SMILLIE: I remember in the
15 previous discussion that some of this was
16 built on the Canadian standard. And I'm just
17 wondering if you followed up on the Canadian
18 experience with that standard from CFIA or the
19 certifiers?

20 MS. FULWIDER: We didn't because
21 the Canadian standard is very different and
22 the producers have a very different program.

1 You know, they have quotas and the economics
2 are different, so we did not go down the
3 Canadian path.

4 MR. SMILLIE: But originally it
5 was cited, the first iteration. Oh, so that's
6 just gone? You've gone and revamped? Okay.

7 MR. GIACOMINI: Joe, the original
8 discussion document was based around
9 essentially sort of their set of numbers to
10 get the topic going. This document is based
11 much more on all of the U.S.-based animal
12 welfare certification programs and the public
13 comments that we've received. It's just we've
14 continued on the discussion without it being
15 the main point.

16 Jeff?

17 MR. MOYER: Yes, I was just going
18 to reiterate what I think you said, Dan, but
19 also to acknowledge the fact that we are sort
20 of focusing in with public comment from the
21 last meeting through the written comment, the
22 public comment we heard yesterday; we may hear

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1 more again tomorrow, as it helps us focus in
2 on what these stocking -- the square footage
3 of space that we're recommending for
4 allowance. And, yes, while we did start with
5 some Canadian standards and ideas, Wendy's
6 correct in that the economic situation is
7 different, and that was pointed out to us by
8 public comment. And so, that's helping us
9 focus in.

10 And what I heard yesterday was the
11 numbers we're talking about are no longer real
12 small indoors or real big. I mean, we started
13 to hear the same numbers repeated over and
14 over, what people can live with and can't live
15 with as minimums, and that's really the point
16 of this process. So, the continued feedback
17 from the producer side, the processor side of
18 the public comment is extremely important as
19 we begin to narrow this down and hopefully in
20 spring have a voting document that we can put
21 out.

22 MR. GIACOMINI: Further comment?

1 (No audible response.)

2 MR. GIACOMINI: Seeing none. Next
3 item?

4 MR. ENGELBERT: Okay. Next we'll
5 move into the animal handling, transit and
6 slaughter discussion document. And again,
7 Wendy will lead us through this document.

8 MS. FULWIDER: Thank you. And
9 this document addresses minimizing stress on
10 the animals due to the tremendous negative
11 effect that stress has on meat quality in
12 particular. And the information on beef, hogs
13 and sheep came from the newly released
14 American Meat Institute document that was
15 written by Temple Grandin, so that's industry
16 standard. And all of the others were
17 referenced from grandin.com or personal
18 communications I had with other folks within
19 industry or other experts in the field.

20 And slaughter is the current
21 industry standard with the exception of where
22 I banned prod use. And I know that there are

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1 organic slaughter plants that do not allow
2 prods, and so that would give us a leg up.

3 So, any comments?

4 MR. GIACOMINI: Comments on that
5 item? Joe?

6 MR. SMILLIE: I read some of the
7 comments. I was particularly interested in
8 the kosher and halal response to stunning and
9 I'm wondering -- it wasn't really clear from
10 your document really where you stood on their
11 comments, and they cited temple also on this
12 where that it would basically put those very
13 old certification organizations out of
14 business in a certain sense, and I'd hate to
15 see that happen. So I just wanted to hear
16 what your response would be to especially the
17 kosher one, which was, you know, a two-page
18 response.

19 MS. FULWIDER: Yes, the kosher and
20 halal, it's in there that that's allowed for
21 -- I had it for the beef and pigs. I didn't
22 reference it again in avian. But honestly I

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1 have not been in a kosher halal poultry. I
2 don't know what that involves, but kosher and
3 halal is certainly allowed.

4 MR. ENGELBERT: Yes, they're going
5 to be taken into account, Joe. We don't want
6 to exclude them from that. And if they have
7 special circumstances, we'll take that under
8 consideration. We, you know, obviously are
9 still soliciting input and that's important
10 input that we'll take into account.

11 MR. SMILLIE: Just to follow up
12 just to be sure that I'm on the right track
13 here, your document was requiring stunning
14 though, is that correct?

15 MS. FULWIDER: Yes, stunning is
16 required, but the kosher and halal lots of
17 times they, you know, have their own way to do
18 it and then you don't need to do the stunning.

19 MR. GIACOMINI: Jeff?

20 MR. MOYER: Yes, Joe, to answer
21 your question, I mean, I think that's the kind
22 of public comment just like Dave Carter said

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1 with buffalo or bison, we don't want to piss
2 them off.

3 MR. GIACOMINI: Officially on the
4 record.

5 MR. MOYER: Officially. Or Dave
6 Carter, we don't want to piss him off either.
7 You know, but taking all that into our public
8 comment. This is just a discussion document.
9 We're going to take that all back to
10 committee, reformulate that and I think what
11 you see next time will be supportive of those
12 other actions.

13 MR. GIACOMINI: Further items?
14 Kevin?

15 (No audible response.)

16 MR. GIACOMINI: I would just like
17 to go back. I found the issues that Katrina
18 addressed. If I could take a few minutes.
19 Regarding the 238(c)(2) document and OMRI's
20 comments, they questioned the need for a
21 definition for the word "preventative" and
22 "pain relief medication." We don't feel those

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1 are necessary at this time. They asked
2 whether this included excipients of 603(f).
3 We believe that it does without question.

4 And they stated here for
5 preventative products that are not typically
6 registered as drugs with APHIS, herbal tonics
7 and teat dips does the use of synthetic
8 excipients also apply? The definition that we
9 use for animal drugs is the FDA definition.
10 And I believe if you look at that definition,
11 which is included in the document which
12 includes all the various forms of homeopathic,
13 articles intended to use in the diagnosis,
14 cure, mitigation, treatment or prevention of
15 disease in man or in animals. Articles other
16 than food intended to affect the structure and
17 the function of the body of the man or the
18 animals would certainly include all of those
19 substances. So, I believe they're all
20 included in the definition that has been used
21 from FDA, or FDA CA official, and that they
22 are part of this recommendation.

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1 Kevin, wrap up livestock, please.

2 MR. ENGELBERT: Yes, I'd like to
3 wrap up livestock with just a couple quick
4 comments.

5 First, I didn't think individual
6 presenters as they finished and it wasn't
7 neglectful. I simply wanted to do it as a
8 group and make sure all of you realize my deep
9 gratitude and the amount of time and work that
10 each and every one of you has put into these
11 documents. And I'm just extremely
12 appreciative of the work that we did and the
13 contributions that were made.

14 Second, I'd like to recognize
15 Annette Riherd. Even though she's not here,
16 she did contribute to all of these documents
17 and we're very appreciative of the
18 contribution that she did make and we're sad
19 that she's no longer going to be on the Board.

20 Lastly, even though Tina didn't
21 make a presentation, she is by far the busiest
22 person that I know of and she contributed

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1 greatly to these as well. And even though
2 she's been silent, she was very, very much a
3 part of all our discussions and I'm very
4 grateful to all of her insights and
5 contributions along with all the other
6 presenters. And just overall thanks to
7 everybody for all the work that we've done.
8 I'm very, very appreciative.

9 MR. GIACOMINI: Thank you. We are
10 almost 12:00. We are half an hour behind
11 schedule, but let's take an hour for lunch.
12 Be back here at 1:00 and we will proceed with
13 the afternoon's set.

14 (Whereupon, then above-entitled
15 matter went off the record at 11:55 a.m. and
16 resumed at 1:00 p.m.)

17
18
19
20
21
22

1 thank both Lisa and Valerie. They both
2 participated in our calls. The transition
3 between Valerie and Lisa as the executive
4 director was seamless, in my opinion. And
5 Lisa picked right up where Valerie left off,
6 so that's been great. And then, having
7 Valerie on our calls every other week or more
8 has been a big help, as well. So, thanks to
9 both of you.

10 And to the Handling Committee, you
11 guys all stepped up this year, especially this
12 last six months, and we got a lot of work
13 done. And I really appreciate all your hard
14 work. So like has been mentioned a few times
15 by other folks here, we did split up the
16 activities and the duties, and being the
17 master of delegation that I am, passed off
18 most of these things everybody else on the
19 team.

20 So we'll start off with the
21 petition materials recommendations. We've got
22 yeast and pectin that Joe will handle, and

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1 then we had a petition to add glucosamine
2 hydrochloride that Tracy will discuss. Then,
3 back to Joe for the famous hops petition to
4 remove.

5 Once we get through those four,
6 we'll talk a little bit about reaffirmation of
7 some prior sunset recommendations for the
8 meeting in Woodland. We did separate out one
9 item out of that reaffirmation due to some
10 public comments we received. So I will talk
11 about the general list, and then John Foster
12 will briefly touch on the glycerides, mono-
13 and di-, that we broke out of that
14 reaffirmation and listed separately.

15 Following that, we have a colors
16 annotation recommendation that Katrina will
17 handle.

18 Then we go into our Sunset 2012
19 recommendations. There are three:
20 205.605(a), two that I will handle and one
21 that Joe will handle.

22 Then we have nine Sunset 2012

1 recommendations for 605(b).

2 Then we have a total of eight 2012
3 recommendations for 606 for sunset. One of
4 those is a large group of 18 colors, and we
5 have those split up. And then we've also
6 separated one of those out, as well. Under
7 the colors, we separated out the annatto, and
8 Katrina is handling all the colors and the
9 annatto. And then the other six or seven that
10 we have are split up amongst us. We'll go
11 through those.

12 And then, last but not least,
13 Tracy will talk with us about the Nutrient
14 Vitamins and Minerals Discussion Document that
15 we've had some brief discussions on already.

16 So, without further ado, let's get
17 started. Joe, you're up first with yeast. Go
18 ahead and take it away.

19 MR. SMILLIE: Paul, as a graduate
20 of the History Department, I'm pleased to
21 present, hopefully, the final chapter in the
22 Great Yeast Saga. It's been going on for a

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1 while and there's been a pretty good divide of
2 opinion on yeast and whether it's agricultural
3 or not. And the petition, which has been
4 deferred, tabled, resubmitted, has come and
5 gone a number of times, and we've looked at it
6 and we've always been sort of lurching towards
7 a solution. I think one of the more
8 interesting ones was regarding yeast as
9 livestock. But obviously, we didn't move
10 forward with it that way.

11 So there's a lot of history. You
12 can read all about it in the transcripts of
13 the NOSB meetings.

14 Where we are now is that we think
15 we've got a solution that hopefully will
16 please everyone, and hopefully we can move
17 forward and have organic yeast as a proud
18 member of the organic family.

19 So, we did two documents. The
20 document that you see above is the document in
21 a format by which petitions are presented.
22 I'm going to read from a different document,

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1 which is the mother document to that document,
2 from which we created it, because apparently
3 that's more proper formatting than the
4 document that we originally worked with. So
5 just bear with me. It's not that long.

6 "The petitioner requested that
7 yeast be moved to 606 so that organic
8 production methodology would be required.
9 There has been a long history to this
10 petition. Clearly, the petitioner has pointed
11 out the ecological differences between organic
12 and conventional production methodology.

13 "The issue of whether yeast
14 production is agricultural is controversial,
15 with vocal adherents on each side. This makes
16 its placement on 205.606 problematic. Organic
17 yeast is now available in many forms for human
18 consumption, so the committee wants the
19 industry to use these organic sources.

20 "The NOP has recently allowed
21 yeast to be certified after examining the
22 certification of the process and the product.

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1 In discussion with members of the Livestock
2 Committee, another concern became clear."

3 So again, in our process, we have
4 to understand the ramifications of our
5 decision for everyone. And as far as handling
6 goes, we were clear; we knew where we were
7 going. But Livestock was also involved. So,
8 we networked with the Livestock Committee, and
9 Dan gave more of his time to attend some of
10 our meetings and present the issues that our
11 decision would create for livestock.

12 Moving yeast to 606 would cause
13 hardship to livestock producers because they
14 are required to use only organic agricultural
15 materials with no commercial availability
16 option. Unlike 606, which requires commercial
17 availability -- I know you haven't heard that
18 before, but I just thought I'd mention it --
19 they don't have that option. You must use
20 organic. And there is a possibility, has Dan
21 told us, that organic yeast might even be
22 available for feed use. But the other uses of

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1 yeast in livestock health preparations could
2 not comply to this organic requirement.

3 So, in other words, from a
4 sympathetic point of view, we didn't want to
5 hurt the livestock producers, and from a vote
6 point of view, if we didn't solve their
7 problems, we wouldn't get enough votes to put
8 it on 606. So, basically, we looked at it
9 every way from Sunday and took everything into
10 consideration and came up with a compromise
11 that leaves yeast on 205.605, but adds an
12 annotation that requires "organic if available
13 for human consumption," and that seems to have
14 solved most of the issues. Not all, but most
15 of the issues.

16 The old annotation would be
17 changed to -- so we're changing the
18 annotation; we're leaving in on 605 and we're
19 moving, and we're changing the annotation --
20 the new annotation will be -- can you move to
21 that one, Lisa? -- "Yeast. When used as a
22 food fermentation agent or supplement, yeast

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1 must be organic if its end use is for human
2 consumption. Non-organic yeast may be used
3 when equivalent organic yeast is not
4 commercially available." And then, "Growth on
5 petrochemical substrate and sulfite waste
6 liquor is prohibited."

7 The committee, needless to say,
8 talked to the Livestock Committee and other
9 people in the industry and made this
10 recommendation. In response to that
11 recommendation, we had seven comments, which
12 I must say were glowing in their support, and
13 one comment that was opposed.

14 So basically, we think we've come
15 up with a compromise that hopefully will
16 satisfy most everyone.

17 MR. GIACOMINI: Comments and
18 questions? Jeff?

19 MR. MOYER: I just wanted to go on
20 the record for thanking you, Joe, for being so
21 masterful in your work to find some common
22 ground that the Livestock Committee and you

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1 could live with. I know that was a challenge,
2 and we've worked on this since I've been here
3 for five years and probably before that.

4 So, I think it's nice that it's
5 finally coming to some sort of a conclusion,
6 and I think you were masterful in shepherding
7 that through there. And the industry owes you
8 a debt of gratitude for that for sure.

9 I did have one question for you
10 though. In terms of the annotation change,
11 are you going to do anything with the part
12 that's in there now talking about nutritional
13 and smoked? Is that going to stay, or is that
14 disappearing?

15 MR. SMILLIE: No, we're dropping
16 out.

17 MR. MOYER: You're dropping that,
18 okay.

19 I'm sorry.

20 MR. GIACOMINI: Any other comments
21 or questions? Katrina?

22 MS. HEINZE: I know you said this,

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1 Joe, but I wanted to reiterate this. I'm very
2 happy with this recommendation because it
3 acknowledges that these, what I affectionately
4 call the microbiological thingies and the
5 products microbiological thingies were not
6 solved in the classification document because
7 there's still just a ton of information we
8 need learn about how they should be
9 classified, and I think this acknowledges that
10 and leaves room for us to continue that work.

11 And it's also in line with
12 feedback that we got from the NOP that, while
13 we can't do commercial availability
14 unilaterally for 605, that in cases where it
15 is appropriate, it might apply to unique
16 individual materials.

17 MR. SMILLIE: My understanding is
18 we did get the okay to move ahead with this
19 recommendation from the NOP.

20 MR. McEVOY: Uh, yeah --

21 (Laughter.)

22 MR. McEVOY: -- we haven't run

1 this through legal review in terms of having
2 commercial availability on 605. I have
3 expressed to the Board of being general
4 uncomfortable with the idea of having
5 commercial availability criteria throughout
6 605 because that was the question.

7 So, we will check that out, but we
8 will try to support this particular
9 recommendation. I think it's a very elegant
10 solution to a long-term problem that makes a
11 lot of sense from our perspective.

12 Just one question I have for Joe
13 is that you're proposing to delete the section
14 on the annotation, "autolysate, bakers,
15 brewers, nutritional and smoked." And do you
16 have any background of why you're proposing to
17 delete that part, and is that in the -- can
18 you put that into the public record?

19 MR. DeMURI: Microphone, please,
20 Miles.

21 MR. SMILLIE: That was, those were
22 examples. That wasn't an inclusive, those

1 weren't inclusive; there's other things. So
2 we thought our annotation really covers a much
3 broader array of possible materials. And our
4 annotation read -- I'm sorry; you'll have to
5 throw it up again -- "when used as a food
6 fermentation agent or supplement," and we feel
7 that that covers much more than listing
8 brewers, bakers, blah, blah, blah, smoked,
9 unsmoked, menthol, filter-tip, whatever.

10 MR. DeMURI: Jeff.

11 MR. MOYER: But at the end of that
12 part of the annotation, it all says that those
13 things must be documented. I guess the word
14 'documented' isn't included in your new
15 annotation?

16 MR. GIACOMINI: Well, I think if
17 we're, if they are eliminating the list of
18 what type of yeast it is, the type of yeast
19 that it is becomes less important to document.

20 MR. SMILLIE: Remember, it's got
21 to be organic if available, so the
22 documentation for the organic will be there,

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1 and that's why we left the prohibitions for
2 the conventional yeast, because if it isn't
3 available in organic form, we wanted to make
4 sure that the conventional yeast would not be
5 grown on a petrochemical substrate or sulfide.

6 I was going to withdraw that, and
7 Katrina caught that, I think, if I recall
8 correctly. She said, wait a second, what
9 about the conventional yeast that could
10 possibly be used? And I said, good, we'll
11 leave it.

12 I think that covers documentation
13 if that's what you meant.

14 MR. MOYER: It is. I think that
15 covers it. Thank you.

16 MR. GIACOMINI: And as I read
17 that, Jeff, it's only the smoke flavoring
18 process that is in this annotation that must
19 be documented.

20 MR. MOYER: Okay.

21 MR. GIACOMINI: Miles?

22 MR. McEVOY: Yes, I guess the

1 question would be, it appears from the current
2 annotation that if you're doing smoke
3 flavoring, it would have to be done through
4 non-synthetic methods with conventional yeast.
5 So if you remove that part of the annotation,
6 would that mean that if organic yeast is not
7 available and you were using non-organic
8 yeast, could you then use a synthetic smoke
9 flavoring process? You'd be removing that
10 from the annotation because, currently, it
11 restricts it to a non-synthetic flavoring
12 process for conventional yeast.

13 So, you just have to really think
14 through carefully of, if you're removing that
15 part of the annotation, what are the
16 implications of that? There must have been
17 some reasoning when this was originally put in
18 there. Was it from an original NOSB
19 recommendation from a long time ago? Why did
20 they put in that part, "Non-synthetic smoke
21 flavoring process must be documented"?

22 MR. GIACOMINI: I think the

1 Handling Committee will take that under
2 consideration.

3 MR. SMILLIE: The Handling
4 Committee's got a meeting, and we'll take that
5 under advisement. It's not going to be a
6 complicated fix to put it back in, so --

7 MR. GIACOMINI: Katrina.

8 MS. HEINZE: I do believe we did
9 discuss that, so we should start by looking
10 back at our Handling Committee minutes. I am
11 not recollecting what we concluded, but I do
12 believe we discussed it. So that might be our
13 first start.

14 The other thing is we did have
15 some discussion about the fact this is a
16 605(a) item, so it does need to be
17 non-synthetic. So we might want to consider
18 that in our discussion, as well.

19 But I would start with the
20 Handling Committee minutes because we covered
21 this topic.

22 MR. GIACOMINI: Yes, Kevin?

1 MR. ENGELBERT: Most of my
2 concerns have already been addressed, but two.
3 I think, if I remember right, Joe, the
4 negative comment -- there was an assumption in
5 there that it was going to be put on 605(a)
6 and 606. Was that the negative comment that
7 you recall?

8 MR. GIACOMINI: You're on, Joe.

9 MR. SMILLIE: No. No, there's no,
10 that is never come up.

11 The comment was very specific that
12 while they didn't -- the commenter was OMRI
13 and the comment was very specifically that,
14 while they didn't argue with the intent or the
15 meaning of our change and the fact it was a
16 solution to the problem, they found that they
17 didn't like the precedent of the logic of
18 having a non-organic -- I mean a
19 non-agricultural -- material.

20 But my response to that is that
21 had already been decided by the NOP when their
22 policy came out allowing for the certification

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1 of a non-agricultural material.

2 I'm not sure if that answers your
3 question, but that was the objection. I can
4 find it someplace.

5 Yes, go ahead please.

6 MR. FELDMAN: OMRI does not
7 support the recommendation for the following
8 reasons: As stated in 205.2, terms define the
9 term organic is, "a labeling term that refers
10 to an agricultural product produced in
11 accordance with the Act and the regulations in
12 this part."

13 And then back to OMRI -- "How can
14 yeast remain on 205.605(a) as a
15 non-agricultural, non-organic substance when
16 the NOSB is recommending that it be organic
17 when used in human consumption? How can a
18 substance be agricultural for one use and
19 non-agricultural for another? This
20 recommendation sets a precedent that is not
21 based in logic, and we ask the NOSB to
22 reconsider."

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1 MR. SMILLIE: As the quote was in
2 Shakespeare in Love, it's a miracle. It can
3 be both things.

4 (Laughter.)

5 MR. SMILLIE: The answer is, if it
6 can be certified under the NOP Program, then
7 we don't see a problem in that illogic.

8 I'd like to remind people that the
9 scientific community often accuses us of
10 non-logic, and I've become very comfortable
11 with other methods other than logic.

12 (Laughter.)

13 MR. SMILLIE: Logic's a wonderful,
14 wonderful scientific tool, and organic isn't
15 necessarily always logical, but that doesn't
16 mean it's wrong.

17 MR. GIACOMINO: Katrina?

18 MS. HEINZE: That's hard to follow
19 up.

20 (Laughter.)

21 MS. HEINZE: I have a slightly,
22 maybe an addition to that. I'm back to that

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1 classification document again, which is going
2 to dog me for another year.

3 We specifically addressed that
4 concern in the classification document, and
5 it's one of the reasons that those
6 'microbiological thingies' were not handled in
7 the document, classification of them wasn't
8 handled. That classification depends on the
9 process and the source of the material. And
10 for things like yeast, there's different
11 processes and different inputs and different
12 sources.

13 One of our principles in the
14 classification document was that, in fact, the
15 same material, if processed differently or
16 from different inputs, could be classified two
17 different ways. And I believe that that is
18 what is happening here with yeast.

19 MR. GIACOMINI: I think, to go
20 back to the question that Kevin had, of the
21 dual listing. The dual listing, if accepted
22 by the Program, could have been a solution now

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1 that would have handled both the human food
2 side and the livestock feed side. But with
3 the dual listing where the listings would not
4 be coupled, it would be very easy down the
5 road for a board to just say, it's on 605;
6 it's on 606; if it's on 606; we'll just
7 delete, we'll just drop the 605. And that
8 would have been, if the other issues are not
9 resolved, that would be very problematic.

10 This solution tries to do as close
11 as possible to the same thing but keeping it
12 all within one listing.

13 Yes, Kevin?

14 MR. ENGELBERT: One other quick
15 follow-up. What does the committee think the
16 implications are with other 605(a) items with
17 all of a sudden applying a commercial
18 availability clause to this, to yeast, for
19 example, dairy cultures or any other of those?

20 MR. SMILLIE: As usual, a very
21 good question. There are implications. We
22 see them. And I don't want to bring up another

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1 red herring or can of worms or whatever
2 appropriate analogy, but flavors are indeed in
3 the same position really. Some flavors should
4 be on 606, not 605.

5 So there are implications and we
6 hope that perhaps this is a precedent
7 "somewhat illogical" but not necessarily. It
8 could be a precedent to solve some other
9 problems, like flavors, and so, there are, you
10 know, it is a precedent-setting. But again,
11 we're not asking for commercial availability
12 on 605. We're asking for specific commercial
13 availability for this item only as part of the
14 annotation.

15 MR. GIACOMINI: And responding,
16 also, Kevin, on that, we have animal enzymes,
17 we have dairy cultures, enzymes. If whatever
18 means came before the Program and for whatever
19 reason, they came out with a similar type of
20 decision on any of those substances that they
21 have on yeast. It could be very good
22 situation.

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1 MR. ENGELBERT: Yes, I didn't mean
2 implying it would all be bad.

3 MR. GIACOMINI: Yes.

4 MR. ENGELBERT: I'm saying that
5 potentially maybe there's, it's a good
6 precedent-setting here as well.

7 MR. GIACOMINI: John.

8 MR. FOSTER: That's, that was the
9 point I wanted to make, was that it's driving,
10 the implication for me is that it's driving
11 things, it could start driving more things to
12 be produced agriculturally, and therefore
13 eligible for certification, which is, I think
14 we have pretty much 100-percent agreement.
15 One of the rare things I suspect all of us on
16 the board agree on is a good thing. And to
17 open that door, I think, is a very positive
18 direction.

19 But also, Joe, I think what you
20 meant was that there are some flavors on 605
21 that should be considered agricultural and
22 therefore certifiable; not necessarily on 606.

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1 MR. SMILLIE: Right.

2 MR. ENGELBERT: Okay. Okay.

3 MR. GIACOMINI: Further comment?

4 (No response.)

5 MR. GIACOMINI: Okay -- nothing
6 else for the Program on the one? Okay.

7 MR. SMILLIE: I would be remiss in
8 not again thanking you Dan for your excellent
9 help on getting us through that one.
10 Appreciate it.

11 MR. GIACOMINI: Thank you.

12 MR. DeMURI: One comment, Kevin.
13 If you pick up quite a few food packages in
14 the marketplace, you'll see that in the
15 organic food, there's quite a bit of
16 non-organic yeast being used, so this will
17 drive even a higher percentage of organic,
18 organic products.

19 All right, now that Joe's warmed
20 up, we're going to move right into pectin.

21 Go for it.

22 MR. SMILLIE: I've got to tell

1 you, I really love this one. This one's a lot
2 of fun.

3 (Laughter.)

4 MR. SMILLIE: Pectin's petition
5 was 2005. For those of you keeping track, and
6 I know Emily's one of them, this has been
7 sitting around for a long, long time. I'm not
8 sure why the process was so slow, but all I
9 know is when I got the job and I looked at it,
10 I went, oh, my gosh, this has been here for a
11 long time. It was like, brush off the dust
12 and dig in.

13 The first thing we did was we
14 asked for a TR on it. We got a TR, and the
15 honest truth is that the TR didn't answer the
16 question we asked it, so we sent it back. So
17 we were part of the delay. Again, I don't
18 have the dates of those TRs. I think it was
19 2007. And that TR just didn't do the job.

20 So we asked for another one. We
21 had to wait to get the next one, even though
22 we specifically said, just answer this

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1 specific question. It was just as specific as
2 you could possibly be. And we finally got
3 that TR, and other than the polygalacturonic
4 universe that I had to enter to read it, it
5 sort of indicated where it was supposed to go.

6 So, the first thing I did was go
7 back to 1995 when the decision on pectin --
8 now this, again, is a petition to move -- that
9 low-methoxy pectin be moved to, the original
10 petition was that low-methoxy pectin be moved
11 from 605 to 606. And as those of you policy
12 wonks that read the National List know,
13 there's high-methoxy and low-methoxy in
14 different columns.

15 Of course, being naïve and
16 innocent, I said, gee, there must be a reason
17 for that. I don't quite understand it from
18 reading the TRs and the scientific
19 information. So I went back to the '95
20 decision-making process, read all the
21 transcripts, looked through it all, and still
22 couldn't figure out why they had come to that

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1 conclusion. And then the word 'amidation'
2 entered my life, and they implied --

3 MR. DeMURI: You were never quite
4 the same.

5 MR. SMILLIE: -- no, I've never
6 been the same since.

7 (Laughter.)

8 MR. SMILLIE: But it's going to
9 gel. Trust me on that.

10 (Laughter.)

11 MR. SMILLIE: Stop.

12 So we looked at it.

13 Rather than spend more time on it,
14 I went to the source and started a long
15 dialogue with Richard Theuer, who was the
16 chair of the committee that made that
17 decision. And one of my favorite sets of
18 email back and forth was Richard and I talking
19 about science, of which he knew a lot and I
20 didn't know very much. But I was dogged in my
21 pursuit that I could not see a difference
22 between low-methoxy and high-methoxy.

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1 And we get back into the whole
2 idea of what is chemical change, and is
3 transesterification chemical change? And the
4 difference between the low-methoxy and the
5 high-methoxy pectin is the amount of time the
6 extraction process takes to pull the pectin
7 out. And to me, that wasn't a significant
8 enough difference to separate the two.

9 So Richard and I went back and
10 forth, and finally, the final comment was --
11 it's quite interesting because I think it
12 throws light on the subject we all love to
13 talk about. He said, I understand your
14 argument that the difference between
15 low-methoxy and high-methoxy is extraction
16 time and less molecular weight. The semantic
17 difference seems much greater 15 years ago
18 than the chemical difference does now.

19 (Laughter.)

20 MR. SMILLIE: This is one of those
21 materials where extraction and chemical change
22 are hard to separate, which makes me see the

1 argument to move both to 605 as
2 nonagricultural.

3 Your proposed annotation is a
4 significant improvement and clarification.
5 Basically, what that group at the time felt
6 was that low-methoxy and high-methoxy were
7 differentiated by the extraction time to pull
8 out, but then somehow, amidation got confused
9 with it. We've looked at it, and amidation is
10 a distinct, different process that happens
11 after the transesterification, and we have
12 made a series of recommendations guided by,
13 once again, Katrina.

14 My recommendation was a little
15 garbled, and we've straightened it out to make
16 a series of recommendations -- that pectin,
17 low-methoxy, be removed from listing on
18 605(b); that pectin, high-methoxy, be removed
19 from listing on 205.606; and that pectin,
20 non-amidated forms only, be added to 205.606,
21 which we feel is good science and supported by
22 both of the history and precedent and the

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1 classification document.

2 The nice thing about all of this
3 is it's not horribly controversial. At least,
4 it hasn't been up until this point. Again,
5 the TRs talked about this, and again, when
6 you're dealing in scientific terms, especially
7 those of us who are not scientists, you have
8 to try and simplify it.

9 The simplification is that it's an
10 extraction, that basically the pectin is
11 extracted from the pomace, in this extraction
12 time varies, and the product you get is
13 differentiated because of the molecular
14 weight. And I think, if I'm correct -- and I
15 can't seem to find it in my document -- but
16 the uses are different in that the difference
17 in pectins is the degree of esterification
18 that subsequently changes how the pectins
19 work.

20 High-methoxy pectin binds with
21 sugars at the bricks range of 60 to 65. Low-
22 methoxy pectins require a cation bridge,

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1 usually calcium, to bind with sugars and
2 function at lower sugar levels, particularly
3 40 to 45 bricks. So basically, your low-sugar
4 jams use the low-methoxy pectins, and your
5 higher-sugar jams use the high-methoxy.

6 But as far as our committee could
7 see, high-methoxy and low-methoxy are the same
8 process and product with different uses, and
9 our recommendation is to move them both to
10 606. They are agricultural. It's apple
11 pomace, extracted, and amidation is the
12 treatment with ammonia after, and that is
13 chemical modification to create an amidated
14 pectin.

15 I think it's possible, Richard
16 wasn't sure, but today it may have thought
17 that amidation was a part of the product of
18 low-methoxy, but that it is not. But Rich
19 isn't here and he can't defend himself.

20 MR. GIACOMINI: I have a question
21 for clarification. The current listing on
22 605(b), synthetic, is pectin, low-methoxy.

1 You're looking to -- so do I understand that
2 that's all forms of pectin, low-methoxy. And
3 by the recommendation you're doing here, are
4 we eliminating the low-methoxy -- granted,
5 you're saying it doesn't exist -- but is
6 low-methoxy, amidated, currently allowed in
7 the current listing?

8 MR. SMILLIE: It's not precluded.

9 MR. GIACOMINI: So you are
10 intentionally eliminating amidated from
11 605(b)?

12 MR. SMILLIE: Correct.

13 MR. GIACOMINI: Okay.

14 Any further questions?

15 MR. SMILLIE: Well, we didn't do
16 that in -- I mean, we looked at it and then we
17 talked to a number of industry people who use
18 pectin, and they confirmed that they thought
19 that that was the right thing, that they don't
20 use the amidated forms in organic, and they
21 thought there was no good reason why you would
22 need to.

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1 The comments -- there wasn't a lot
2 of comments, but we did have two comments from
3 the industry. There may have been more. I
4 only saw two; I'd love to be corrected if
5 that's not right. But we got comments from
6 Smuckers and White Wave saying that they
7 supported this move and that they didn't see
8 a reason for the use of amidated forms of
9 pectin because that is chemical change.

10 MR. GIACOMINI: What is amidated
11 pectin used for, as opposed to non-amidated?

12 MR. SMILLIE: It used for the same
13 -- well, my have to ask Kim --

14 MR. GIACOMINI: Kim?

15 MR. SMILLIE: -- to give us some
16 scientific -- but basically, it's used for the
17 same reasons; low-sugar jam production.

18 MS. DEITZ: Kim Deitz, Smucker
19 Natural Foods. I did talk to our supplier,
20 and the amidated means that there's an ammonia
21 process when they make the pectin and that
22 most -- pectins are not made that way anymore,

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1 so most pectins are non-amidated if that
2 answers your question.

3 MR. GIACOMINI: But is there any
4 use for that rarely-used, made, used form that
5 we might be eliminating here that we're
6 creating --

7 MS. DEITZ: Not to my knowledge.

8 MR. SMILLIE: The one thing I
9 didn't mention, of course, is the petitioner
10 is a jam maker, an organic jam maker. And you
11 know, the basis of that petition was that they
12 didn't think that amidated forms should be
13 used in organic production. They saw no need
14 for it. So there's the petitioner and two
15 supporting industry members on that.

16 MR. GIACOMINI: Steve?

17 MR. DeMURI: When we were going
18 through this, I looked up that amidation
19 process, and there were some literature
20 references that the amidation process possibly
21 produced a more pure form of pectin, but it's
22 also cheaper. So that's why it was used a

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1 little more often in the past.

2 MR. GIACOMINI: I love that, we're
3 going to add and make it pure.

4 Okay, Jay.

5 MR. FELDMAN: Thanks, committee
6 and Joe. I notice on the TR there's reference
7 to the demethylation. Did that come up as
8 this issue gelled for you?

9 MR. SMILLIE: That's part of the
10 polygalacturonic process.

11 MR. FELDMAN: But then there's a
12 reference to that being the process used in
13 the low, the LMP, the low-methyl.

14 MR. GIACOMINI: Mic, please, Jay
15 -- if you're done.

16 MR. FELDMAN: Sorry.

17 MR. SMILLIE: Yes, I found the TR
18 troublesome. I really did. I mean, I was
19 looking for a clear answer. What I asked very
20 specifically was, is there a difference in the
21 chemical process or in the extraction process,
22 the transesterification, between high-methoxy

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1 and low-methoxy? I just had one question. I
2 wanted the answer to that one question. And
3 a TR came back, and it really didn't answer
4 that question.

5 But in consultation with the
6 petitioner and other people, basically, the
7 answer came back the same every time, that
8 it's simply a matter of extraction time. And
9 I forgot the demethylation part, but I think
10 that's different -- again, there's chemists in
11 the room. I'm sure someone will leap to our
12 help -- but the transesterification process
13 has a lot of different processes within it,
14 and that may be one of the things you're
15 referring to.

16 I haven't got the TR right in
17 front of me, unfortunately.

18 MR. GIACOMINI: Katrina?

19 MS. HEINZE: Okay, so your chemist
20 is going to try to help here. I'm going to
21 start by saying, remember, it's not about the
22 chemistry.

1 When we talked about this -- so as
2 the extraction process proceeds, it's really
3 about time. The chemistry or the process to
4 make low-methoxy is the same as high-methoxy.
5 Low-methoxy is just a longer time for the
6 process.

7 As a result, there are different
8 bonds, but it is the same substance. It is
9 clearly the same substance. So, as a result
10 -- and I was going to bring this up -- the
11 committee voted to classify low-methoxy
12 non-amidated, and we voted that it was
13 non-synthetic agricultural.

14 What I'm trying to say, Jay, is we
15 evaluated that TR information. We had that
16 discussion, and our classification vote was
17 non-synthetic.

18 MR. GIACOMINI: Steve?

19 MR. DeMURI: And I know we
20 mentioned this a thousand times over the last
21 couple years, but don't forget, we're moving
22 this from 605 to 606, which now subjects it to

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1 commercial availability scrutiny. And the
2 forms that are being removed were on 605. So
3 anybody could use it anytime they wanted to,
4 in an organic product within the five percent
5 tolerance.

6 This was a petition to move, not
7 to remove, so we substantially cleaned this up
8 and made even tougher by doing what we're
9 doing.

10 MR. GIACOMINI: Question for the
11 Program. A lot of things are going on in this
12 recommendation, including the moving of
13 something from synthetic to agricultural,
14 going sort of the opposite of the last
15 problem.

16 Any problems the Program sees in
17 rulemaking on all of this manipulation?

18 MR. McEVOY: No, we don't see any
19 problems with this.

20 MR. GIACOMINI: Thank you.

21 Further comments, questions?

22 (No response.)

1 MR. GIACOMINI: Seeing none, next
2 item please.

3 MR. DeMURI: Thank you, Joe. Once
4 again, good job.

5 We'll give Joe a quick break and
6 move to Tracy for a petition to add
7 glucosamine hydrochloride.

8 MS. MIEDEMA: Thank you, Steve.
9 Hopefully this one will be short and sweet.

10 Glucosamine hydrochloride is a
11 dietary supplement. The material was
12 petitioned to 605(b) three years ago. After
13 some back and forth trying to help petitioner
14 understand some critical errors they had in
15 their petition, it was brought to us for
16 review about two years ago. We requested a
17 TR, and it did take two years to receive that
18 technical review.

19 There was only one comment
20 received during public comment period, and it
21 was from the petitioner asking us to withdraw
22 the petition. I reviewed our policy and

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1 procedures manual, and it is considered in
2 keeping with our policy and procedures to
3 allow the withdrawal of petitions right up
4 until the moment of voting if the petition is
5 for the purposes of improvement only.

6 Now there were some misgivings in
7 our committee because a TAP had been
8 performed. There was this notion that we had
9 put some work into it. As the lead reviewer,
10 I would not be opposed to it being withdrawn
11 personally. Just in respect to the
12 petitioner, three years is a long time to have
13 your petition sort of languish, and things can
14 change, and the petition actually needs a fair
15 amount of improvement.

16 We voted five no, one absent, zero
17 yes, to add the material to 605(b), and we did
18 so in large part because of unanswered
19 questions about impact to the environment and
20 the production of the material, which an
21 improved petition might clarify.

22 I'm not going to fall on my sword,

1 I guess, for this though. If my fellow
2 committee members really feel like we want to
3 go ahead and vote this through, I'm open to
4 that as well. But three years is a long time
5 to wait. There are new people that are
6 handling this material and weren't even aware
7 that it was still under consideration.

8 I can go into the technical
9 aspects of the material, but it's basically a
10 synthetic. This form of glucosamine is
11 derived from synthetic materials, as opposed
12 to sea shell, which is the main form of
13 glucosamine. It's typically used in dietary
14 supplements as a joint, for purported joint
15 benefits. They noted that a non-shellfish
16 form would be helpful for seafood allergies
17 and that sort of thing. That's not really one
18 of our bases for adding something to the
19 National List though.

20 That's about it.

21 MR. GIACOMINI: Just a
22 clarification on the document. That should be

1 marked as rejected from the committee,
2 correct, the recommendation to reject on the
3 box up on the screen? There should be a
4 checkmark on rejected; correct?

5 MR. DeMURI: That's correct.

6 MR. GIACOMINI: Okay. I just want
7 make sure.

8 So, further comments?

9 (No response.)

10 MR. GIACOMINI: Katrina.

11 MS. HEINZE: Tracy, I would
12 support having this withdrawn. I was taken by
13 the public comment where they concurred with
14 our assessment of the environmental impact of
15 their process and where the petitioners said
16 that they were under the impression that they
17 had withdrawn it, but due to some -- I liked
18 your word, Joe -- scarfuffle within their own
19 organization, they were not aware that they
20 had not withdrawn it until our recommendation
21 was posted. So I appreciated their
22 transparency on that.

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1 MR. GIACOMINI: Okay. I think
2 that's ultimately up to the committee. So,
3 you know, we've try to not allow someone, just
4 like we've talked before, to turn it over to
5 a different group of people on the board with
6 different ideas. But if the committee thinks
7 that it's a legitimate argument and not a new
8 creative way to do that same thing, then
9 that's up to you guys.

10 Next item, Mr. Chairperson.

11 MR. DeMURI: Thank you, Tracy.

12 Well, now we're going to turn it
13 back here to Joe in a second two discuss the
14 hops petition to remove.

15 I would like to preface his
16 comments by saying that we all appreciate
17 everybody's comments that were made, both here
18 and at the meeting. We'll probably hear some
19 more tomorrow. And written comments were
20 received as well. You did a good job of
21 flooding the NOP website with comments. I
22 commend you for that.

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1 One particular comment, I think,
2 kind of summed up what I heard, and that is:
3 Dude, organic beer should have organic hops.
4 No non-organic hops in the organic beer.
5 Otherwise, not so organic, you know. I mean,
6 hops is one of the most important ingredients.
7 That is all.

8 So that was the probably the most
9 succinct and to-the-point comment I saw in all
10 of them, but very good.

11 So, with that, I'll hand it over
12 to Joe for a discussion of the hops petition.

13 MR. SMILLIE: I think that's
14 another example of, sometimes the least
15 polished has the most shine.

16 We've had a lot of discussion
17 yesterday on this, so I won't go through it
18 all again.

19 A couple things to point out --
20 again, we talked about it a lot, but again,
21 I'm still of the belief that I could be the
22 only one left in the room that believes that

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1 actually putting on hops on 606 originally was
2 a really, really a good thing to do. It
3 brought attention to it, it gave the organic
4 beer industry a good start, and now it's time
5 to remove it.

6 That's the process that I want to
7 see 606 work. I believe that's the way it
8 should work. I believe putting something on
9 606 is setting up a target for entrepreneurs
10 to make it organic and bring it in. If you
11 don't put it on 606, maybe -- who knows? --
12 there wouldn't have been an organic beer
13 industry. They just would have said, well, I
14 can't get organic hops, so forget it; I'm not
15 going to make organic beer.

16 That's the purpose of 606. I
17 believe that's the driving reason, and
18 whatever we can do to make that work, we
19 should. And the first thing we need to do to
20 make it work is to get lecithin off 606
21 because we voted it off, and we will now get
22 hops off 606.

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1 Incidentally, also, I'd like to
2 point out that the petition was to remove hops
3 from 606. There was no date. It didn't say
4 remove immediately. It just said remove.
5 Thank you, Megan. That gave us a little
6 face-saving ability so that we can now remove
7 it, but on a date that allows for an orderly
8 transition.

9 And again, there was a lot of
10 emotion on this. We understand it. We
11 appreciate it. It's good emotion. But then
12 there was also some very good reasoning from
13 the hops growers themselves. They said, look,
14 you know, we understand it; we want to see an
15 orderly transition. We greatly appreciated
16 those comments also. It enabled us to move
17 forward. I think you showed a lot of mature
18 judgment, after the initial editorial
19 headlines were passed.

20 So bottom line, we think that
21 we're in agreement now. One of the problems
22 we had that was brought up in the NOSB and

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1 outside by the academics -- I think they were
2 both academics -- was the process, that the
3 process of our deliberations on the Handling
4 Committee were not clear, transparent and
5 democratic. We'll have to work on that.
6 Obviously, I was little emotional most of
7 yesterday in responding to that sort of
8 charge. We will work on it. We will work on
9 process. We will try and make it as open,
10 transparent and democratic as possible within
11 reason.

12 I think one of the mistakes we
13 made was -- it wasn't quite the, you know, the
14 pet dog killing the computer mistake -- but we
15 made a similar mistake, Tina, in that we had
16 two different forms we were working with at
17 the same time, and basically, we created this
18 long form, which is in front of you now, for
19 the hops.

20 We originally had shortened it and
21 put it into a form that you just saw for the
22 yeast, and a lot of words got clipped and

1 changed. And some of the errors that we may,
2 talking about significant public comments and
3 all that, I think part of the reason why was
4 shifting the old cut-and-paste. Some things
5 got cut and pasted that maybe shouldn't have.

6 So there were mistakes made in our
7 original thing about significant public
8 comment. We still believe the public comment
9 was significant, but we made it -- the
10 accusation was we made it look like there was
11 more than what was there, other than what we
12 have followed.

13 I think our revised document sort
14 of responded directly to that criticism as
15 quickly as we could possibly do it, and we
16 laid out who we talked to and when we talked
17 to them and all that sort of thing.

18 So, all that having been said, it
19 was a learning process and hopefully as new
20 boards, long they don't repeat the same
21 mistakes, because we all know what the
22 definition of insanity is: doing the same

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1 thing again and expecting a different result.
2 Let's hope that the process is as democratic
3 as it can possibly be and that everyone is
4 consulted to the best of our ability.

5 So that having been said, we'll
6 scroll quickly through it. Basically, there's
7 still, I think, a few issues. Petitioner
8 claims differences in quality of cultivars of
9 hops are not an issue. Some brewers still
10 feel, yes, this is still an issue.

11 We, in the second, in a comment
12 the petitioner made the follow-up comment
13 delineating the types of activity that hops
14 provide; not specific varieties, but floral --
15 I can't remember them all -- bitterness,
16 floral, aroma, piney, citrusy -- all of those
17 characteristics. That was very helpful in
18 helping us understand that maybe one cultivar
19 doesn't substitute directly for a cultivar,
20 but if they both contribute a floral note,
21 then they could substitute. So we learned
22 from that, and other people learned from it.

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1 Brewers are still out there making
2 marketing claims based on their exquisite
3 blend of hops, and that's still valid. And
4 the way that I think we're going to deal with
5 that is that as of January 1, 2013, our
6 recommendation is that organic beers must use
7 organic hops. I think everybody's happy with
8 that. I think the transition period is
9 adequate for brewers to forward contract or
10 find brokers that will supply the hops that
11 they need.

12 And if, indeed, there are brewers
13 it firmly believe that their particular
14 variety of hops, which their whole commercial
15 enterprise is based on, is not available, then
16 they can go to the wonderful process the hop
17 growers went through and they can petition
18 that particular hop variety for inclusion on
19 606. That's their injunctive relief as of
20 January 1, 2013.

21 Once again, it really illustrated
22 and brought to the fore that age-old

1 complicated -- Miles doesn't like it much, but
2 it's there -- the old idea of commercial
3 availability, that we certifiers have to apply
4 the screen of commercial availability for
5 material from 606 that's used.

6 And again, we did issue a guidance
7 document. I'm sorry; I can't follow the same
8 screen that you guys are following. We did
9 issue a guidance document in 2007 talking
10 about further guidance on the establishment of
11 commercial availability criteria, and I think
12 that that's important because the ACAs are
13 trying already. But again, there's more work
14 needed to make sure that we're all
15 consistently following the same commercial
16 availability rules.

17 So, the bottom line is that in the
18 words of Patrick Smith, we think we've laid
19 out a roadmap for both the brewers, the
20 malters, the barley growers and the hop
21 growers to all get together and have a joyful
22 celebration on January 1, 2013, the end of the

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1 Prohibition era on conventional hops.

2 Okay, so the recommendation is
3 that hops, *Humulus lupulus*, be removed from
4 205.606 on January 1, 2013, and the committee
5 was unanimous on the, except for one Committee
6 member who was lost in the Pacific someplace,
7 I think, as I recall.

8 MR. GIACOMINI: Questions?
9 Comments? John?

10 MR. FOSTER: So, I read each of
11 the comments that came in after the first
12 recommendation went out, and it was really
13 frustrating for me that none of those
14 commenters recognized the certifier's role in
15 commercial availability. I think it's, that
16 was a large oversight on those commenters'
17 part.

18 It's not necessarily a fault or
19 something like that, but it is a terribly
20 incomplete argument to talk about hops as
21 solely a decision of the NOSB. It's
22 incorrect, it's not consistent and it's

1 frustrating. And as challenging as it is for
2 certifiers, it's a very challenging thing to
3 deal with. But a lot of the dissent that was
4 expressed did not recognize that second door
5 that certifiers hold the key to.

6 So I think this recommendation we
7 have in front of us is a good one. It's the
8 right one. But I don't want the opportunity
9 pass without recognizing that any time we talk
10 about commercial availability, we as a Board,
11 we have to talk about it in conjunction with
12 the certifier's role with respect to
13 case-by-case, OSP-by-OSP determinations about
14 commercial availability, not to lose sight of
15 that.

16 MR. GIACOMINI: Further comments?
17 Program? Miles?

18 MR. McEVOY: Yes, I like what you
19 said there, John.

20 Commercial availability is
21 difficult for certifiers to implement
22 consistently, and that's my, I guess,

1 reluctance to have broad acceptance of
2 commercial availability for everything that
3 the NOP regulations includes, is because it's
4 really challenging.

5 It's really nice that is done on a
6 case-by-case basis, but we see in the comments
7 that were provided here that something's not
8 working in the system, because people should
9 know, the certifiers should be very diligent,
10 and I think they generally are. But something
11 was missing here because it doesn't seem like
12 they were consistently requiring a very
13 rigorous process for commercial availability
14 around hops.

15 So it's something that we're going
16 to look into, work with the certifiers, try to
17 understand how they're implementing commercial
18 availability for seeds for a 606 list, to
19 build consistency in this process, to build a
20 better process for commercial availability.
21 A very important part.

22 MR. GIACOMINI: Further comments?

1 (No response.)

2 MR. GIACOMINI: Joe, I would just
3 like to say that, based on your initial
4 comments on this, I, too, was there in spring
5 of '07. Of all the things that we had been
6 looking at for 606, I think hops was one of
7 the easiest votes I had in voting to put it on
8 the list.

9 I was quite dismayed and surprised
10 with the thrashing to within an inch of their
11 life that the Program went through after that
12 was posted. I think that was unfortunate
13 because in reviewing the information we had
14 and looking into it, and the difficulty,
15 certainly at the time, with the tools that
16 were available in providing a hops to the
17 brewer that was in a good, non-moldy form, was
18 difficult. So I certainly have no problem and
19 no question in my mind that we made the right
20 decision then.

21 At this point in time, I would
22 still like to hear from more brewers. We did

1 hear from one who uses all organic hops now.
2 I would certainly hope that tomorrow we can
3 hear from some that don't currently use all
4 organic hops, and they can address to us if
5 this will cause any problems.

6 The one thing that I have a
7 question with -- I'll be willing to support
8 this document and this recommendation. The
9 one thing that I have a question with that I
10 just have not had a satisfied response to, is
11 in my dealing with livestock and livestock
12 feed, I deal with crop years all the time, and
13 I don't understand cutting it off in the
14 middle of a crop-year usage.

15 If they're saying, well, we want
16 to be able to use conventional hops until
17 we're through the holiday beer season, but
18 then when we get into spring and summer beers,
19 we'll be ready to use all the organic forms,
20 I can understand that. But when it's not,
21 doesn't seem to be related to the dates of a
22 harvest season and a crop year, I don't

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1 understand where the date came from.

2 But other than that -- I'm willing
3 to go along with it. I just have, it just
4 doesn't make sense to me, and I haven't had
5 that understood.

6 MR. SMILLIE: We can take time to
7 discuss it and I can explain it, but if it's
8 not material to the vote or that -- it does
9 make sense.

10 MR. GIACOMINI: The only
11 materialness to the vote would be based on
12 what we hear from any brewers tomorrow, if
13 they're seeing --

14 MR. SMILLIE: Well, if we get some
15 up, we can follow up with questions.

16 But basically it is the end of the
17 crop year. It's the end of the 2012 crop
18 year. If you haven't got your hops in by
19 January 1st, you're in trouble.

20 MR. GIACOMINI: No, but a crop
21 year is based on harvest.

22 MR. SMILLIE: Yes, that's what I'm

1 saying. It's at the end of the 2012 crop
2 year. Harvest is in.

3 MR. GIACOMINI: The harvest, the
4 hops that are available on January 2nd are the
5 hops that were harvested in the previous
6 summer/early fall.

7 MR. SMILLIE: Well, or two years
8 ago. They keep -- pelletized hops can keep
9 for years.

10 MR. GIACOMINI: Right, so -- okay.
11 Katrina.

12 MS. HEINZE: I was just going to
13 suggest that perhaps we talk about it as a
14 committee. I think, Dan, your point is not
15 crop year but use of the crop year -- right?
16 -- so that the 2011 crop of hops needs to last
17 through the brewing year until the 2012 hops
18 crop is harvested.

19 MR. SMILLIE: Yes.

20 MS. HEINZE: And we put our date in
21 the middle of that. I'm not saying that's
22 right or wrong, but I just think that's Dan's

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1 point. So perhaps we'll just talk about it in
2 community and decide if we have any concerns,
3 to come back to address Dan's point.

4 MR. GIACOMINI: Further questions?
5 Comments?

6 (No response.)

7 MR. GIACOMINI: Seeing none, Mr.
8 Chairperson, next topic.

9 MR. DeMURI: Thank you again, Joe.

10 I'd also like to recognize that
11 Joe Dixon and John helped Joe a lot on this
12 recommendation, especially after we got the
13 flood of comments a month or so ago, six weeks
14 ago. They quickly crafted a response -- and
15 I appreciate you guys jumping in and helping
16 Joe out with that. All right, that's all for
17 petitions for this meeting.

18 Now we're going to move into the
19 reaffirmations of prior sunset, 2012
20 recommendations. These are the
21 recommendations that were made in Woodland,
22 California, in the spring.

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1 I won't read them all off, but
2 Lisa, if you can kind of scan through them
3 real quick, down at the bottom of each
4 recommendation is a list of what we are going
5 to reaffirm for 605(a). They're on separate
6 recommendations. Those are the 605(a) items.

7 There should be another
8 recommendation for 605(b). There you go.

9 And then the last one would be for
10 606.

11 The Committee is recommending, by
12 the votes that you see up there, that we
13 reaffirm all of these votes from the last
14 meeting.

15 We did receive one public comment,
16 maybe two -- I can't recall now -- for
17 glycerides, mono- and diglycerides. So we
18 pulled that one out, and I asked John Foster
19 to take a look at that to make sure that we
20 didn't need to go back and rethink that
21 decision.

22 So John, if you want to give us a

1 brief update on what you found there.

2 MR. GIACOMINI: John?

3 MR. FOSTER: I just want to do it
4 by the book here. That's all.

5 So, we did at the time, following
6 our April vote, we did have one comment
7 speaking to diglycerides. And consistent with
8 our decision in April to pull those out before
9 reaffirming at this meeting, that was enough
10 to pull glycerides out.

11 So in, so having that set aside
12 independent of the other votes, it kind of
13 gave us an opportunity to focus on that a
14 little bit more closely. This recommendation
15 went out -- obviously, we finished it in
16 August. And at the time, that Committee
17 summary reflected a true statement.

18 Since then, as a function of the
19 public comment we've gotten in this most
20 recent round that ended October 12, we got
21 several comments -- I'm recalling it's seven
22 or eight -- speaking to mono- and

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1 diglycerides. The majority of the comments
2 that have come in in this last, recent period
3 were very strongly in support of removal of
4 mono- and diglycerides. That, of course, is
5 very different than our vote in April.

6 I would say that all of those
7 comments are pretty compelling. There were a
8 couple who said that that they needed to keep
9 mono- and diglycerides on 605, not because
10 there wasn't any replacement for them but that
11 the replacement on the market was only useful
12 in partially replacing mono- and diglycerides
13 in various product formulations.

14 So the comments that asked to
15 retain it did note that agricultural, in fact,
16 organic alternatives were in place and
17 partially helpful. The majority of the
18 comments, like I said, said that it was the
19 agricultural and certified-organic
20 replacements were completely, would be able to
21 completely replace mono- and diglycerides in
22 product formulations.

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1 Among them, our friend Rich
2 Theuer, again, who has a fairly deep
3 experience with this, he was on the NOSB at
4 the time that this was first voted on and
5 wrote a very compelling and, I thought, very
6 insightful both history of the vote then and
7 what he's come to understand now about these
8 agricultural alternatives.

9 So I think as a committee, we need
10 to reconsider this recommendation that was
11 posted in light of the public comment. It's
12 substantial and compelling, I would say.

13 MR. GIACOMINI: Further comments
14 or questions?

15 Steve, there was one list, one
16 version of the reaffirmation that went around.
17 I don't remember whether it was in (a), (b),
18 or 606, where one substance didn't make the
19 cut-and-paste. That has been corrected,
20 right?

21 MR. DeMURI: I believe we
22 corrected that. Didn't we?

1 MR. GIACOMINI: Okay. I don't
2 remember what --

3 MR. DeMURI: We'll double-check.
4 I believe we got that corrected.

5 MR. GIACOMINI: I want to make
6 sure we get them all.

7 MR. DeMURI: Okay.

8 MR. GIACOMINI: Any further
9 comments?

10 MR. DeMURI: I have a question.
11 John, those comments that came in
12 that were opposed to relisting, did they come
13 in after the October 12th deadline for
14 comments for the first, for the Woodland
15 meeting, or after October 12th? Do you know?

16 MR. FOSTER: All of the comment,
17 the public comment I'm referring to, that is
18 compelling, came in within the time period of
19 public comment that closed October 12th. It's
20 on regulations.gov.

21 MR. GIACOMINI: Questions?
22 Comments?

1 All right. Mr. Chairman, next item.

2 MR. DeMURI: All right. So that
3 completes the reaffirmation work for this
4 meeting as a result of last meeting's votes.

5 Next we have a colors annotation
6 recommendation that Katrina will provide for
7 us now.

8 MS. HEINZE: Thank you. So I'm
9 going to give a bit of a history lesson as
10 well, following in Joe's footsteps. There are
11 currently 19 colors listed on 205.606. I'm
12 not going to read them to you, but they are in
13 the recommendation up there. You'll be
14 familiar with them by the end of our handling
15 discussions today.

16 These 19 colors were added 2606 as
17 a result of a 605(a) listing of colors,
18 non-synthetic, being allowed to sunset off the
19 list. So, originally on the National List,
20 colors was listed as a group, but there was
21 some debate about that. So, at the
22 appropriate time, five or six years ago, the

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1 Handling Committee recommended that those
2 sunset.

3 As a result of that, a number of
4 petitions were presented to the NOSB for
5 colors to be listed on 606. The Handling
6 Committee reviewed each of those petitions,
7 made recommendations to list those materials.
8 Some of those colors were not added by the
9 NOSB. These 19 colors were recommended for
10 listing, and that was done at the March 2007
11 NOSB meeting.

12 At that March 2007 meeting, there
13 was quite a bit of debate about annotations
14 for these colors, so I wanted to summarize
15 that a bit for you. For each of these, the
16 petitions talked about the extraction of the
17 color from the raw material happening either
18 through oil or water extraction plus some sort
19 of physical processing; so, for example, the
20 raw material being cut, ground or dried.

21 For 10 of the colors, the
22 petitioner very specifically identified that

1 process and in fact said that their process
2 was certified organic, but the raw material is
3 not. And obviously, that's not -- whether
4 they should be listed or not is not the point
5 of this recommendation.

6 The other nine petitions did not
7 indicate that solvents beyond water or oil
8 were used. And that point was strongly
9 supported by public comment during the meeting
10 because we were really trying to understand
11 how these were made and had discussion on it.

12 Further, actually, for two of the
13 colors, annatto and paprika, the Handling
14 Committee had originally recommended that the
15 oil extraction be restricted to using organic
16 oil. That March 2007 meeting was the first
17 time that the Handling Committee had reviewed
18 606 items, so it was a new process for us.
19 All that was heavily debated, and what
20 happened at the March 2007 meeting was quite
21 a bit of debate on how restrictive an
22 annotation could be on a material that was not

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1 organic.

2 The result of that discussion was
3 that we should not do annotations that were
4 restrictive beyond what was available in the
5 commercial marketplace. After all that
6 discussion, the result was that we did not
7 include any annotation for the colors with
8 regards to how they were extracted.

9 Since that March meeting, it's
10 come to our attention that folks may be
11 confused about that, so, since we didn't have
12 an annotation at all, we have gotten question
13 that said, does that mean that synthetic
14 solvents can be used? And that certainly was
15 not the intention of the Board at the time of
16 that recommendation.

17 After reviewing all the
18 transcripts, looking at the original
19 petitions, looking at the public comment that
20 we received at that meeting, as well as the
21 general TR on colors that was done originally,
22 the Handling Committee believes that none of

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1 the colors that were reviewed included
2 synthetic solvent extraction as a possible
3 manufacturing process. Well, it may be
4 possible. That isn't what we reviewed and
5 that's not what was available in the
6 marketplace.

7 Further, the Handling Committee
8 believes that use of synthetic solvents for
9 extraction of these colors isn't necessary
10 since each of the colors was petitioned as
11 available without synthetic solvent
12 extraction. Since there does seem to be some
13 confusion as to the original intent, what we
14 wanted to do was add a recommended annotation
15 for colors to kind of clarify this confusion.

16 We are recommending that the
17 listing for colors derived from agricultural
18 products on 205.606 be changed to, "Colors
19 derived from agricultural products must not be
20 produced using synthetic solvents and carrier
21 systems or any artificial preservative." We
22 picked that annotation because it matches the

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1 listing for flavors on 605(a), so we thought
2 the language was understandable by the folks
3 who needed to use the list, and addressed what
4 we wanted to address.

5 We don't feel that this is overly
6 restrictive, because we don't think anybody is
7 using colors extracted with synthetic
8 solvents. This is really perhaps a technical
9 correction to address some confusion that's
10 out there.

11 Finally, in response to the notice
12 for this meeting, we have received two public
13 comments, both of which supported this change.

14 And then, finally, our vote for
15 this was five yes; zero no; two absent.

16 Any questions?

17 MR. GIACOMINI: Any questions?

18 Jay?

19 MR. FELDMAN: Thank you. This
20 sounds good.

21 So my question goes to issues
22 around consistency. And again, I may be

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1 missing something here, but how does this jibe
2 with the classification materials policy,
3 given that some people take the position that
4 this simple addition or use of a synthetic in
5 the extraction process which doesn't result in
6 a chemical change does not make it a
7 synthetic, and therefore, wouldn't cause us to
8 restrict the substance?

9 MS. HEINZE: Thank you for the
10 question. This gets exactly to the point you
11 made earlier about the difference between
12 classification and compatibility. These are
13 agricultural products which would be
14 classified as agricultural even if they had
15 been extracted with the synthetic solvent.
16 However, we don't think that is compatible in
17 this case. So it's separate from
18 classification.

19 What we're saying is it's not
20 compatible and we want to be clear on that.

21 MR. FELDMAN: May I?

22 MR. GIACOMINI: Yes.

1 MR. FELDMAN: Again, I'm just
2 looking for consistency here. I mean, I agree
3 with you, but why is it not compatible? It's
4 not compatible because it produces -- I assume
5 the process by which these colors are being
6 produced is a synthetic process.

7 MR. GIACOMINI: No.

8 MR. FELDMAN: That's not why it's
9 incompatible? Why is it incompatible?

10 MR. GIACOMINI: It's incompatible
11 because of the synthetic substance that it
12 adds to the system. The extraction with
13 hexane of soybean oil from soybeans does not
14 constitute the soybean meal that is left over
15 as a synthetic substance. It's still an
16 agricultural substance that has been extracted
17 with a hexane solvent.

18 What we have said is that it's not
19 that it makes it synthetic; it is not
20 compatible with the organics.

21 Katrina.

22 MS. HEINZE: This would be one of

1 those gray areas. We have the luxury on
2 colors of taking this step because materials
3 exist that are not synthetic
4 solvent-extracted, and similar to our decision
5 on yeast, we in Handling feel that we should
6 continue to step things up on the continuum,
7 and this is one of those areas where, when
8 colors were originally listed on 605, there's
9 colors that very well may have been used that
10 were processed in less desirable ways. And so
11 then we were able to move them to 606, where
12 commercial availability applies, and you'll
13 hear about that later in our sunset
14 discussions.

15 At the same time, this allows us
16 to say, you know what? We don't want
17 synthetic solvents here. We don't think our
18 consumers want it and so we're going to do
19 that because in the marketplace there exists
20 both kinds of colors. And so we're able to
21 say "no synthetic solvents."

22 I guess the other thing that I

1 would say is, that was the original intent in
2 2007 when the Board debated these and listed
3 these. But we reviewed so many materials at
4 that meeting and so many of us were new, and
5 the whole annotation thing was so confusing --
6 that was my first public board meeting -- and,
7 speaking just for myself, it was overwhelming.

8 I think if we had had the time at
9 that meeting, the Board would have spent more
10 time on this and would have realized that this
11 is the annotation it wanted to include, but we
12 got buried in the confusion.

13 MR. FOSTER: Just to clarify, I
14 think I got it. These substances are deemed
15 synthetic?

16 MS. HEINZE: No.

17 MR. FOSTER: They're not deemed
18 synthetic? Okay, that's where I'm confused,
19 okay.

20 So, here, we have substances
21 deemed not synthetic that are not -- however,
22 they're extracted with a synthetic material?

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1 MS. HEINZE: No.

2 MR. FOSTER: Hexane?

3 MR. GIACOMINI: That's what we're
4 not allowing.

5 MR. FOSTER: Right, but they're
6 non-synthetic -- I'm sorry -- they're
7 non-synthetic materials that are deemed
8 nonessential to organic production
9 essentially, okay.

10 Thank you.

11 MR. GIACOMINI: Okay, anything
12 else?

13 (No response.)

14 MR. GIACOMINI: I have one
15 question for the Program, and I apologize to
16 Melissa that you're top dog here right now.

17 (Laughter.)

18 MR. GIACOMINI: Yes, I was almost
19 going to interrupt, "Miles, don't go."

20 I would like to address the
21 question to the Program of the necessity of
22 this recommendation. It is very clear when

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1 you look through the petitions and the
2 discussion that occurred in putting these
3 items on the National List, on 606 to begin
4 with, that we were only talking about water
5 extraction.

6 Would any hexane-extracted
7 materials in these, this category of colors
8 even be allowed? Is this simply a
9 clarification, or is this something that would
10 be needed?

11 MS. BROWN-ROSEN: This is Emily
12 Brown-Rosen, Standards Division. That's a big
13 question, and there's been a lot of requests
14 from certifiers ever since this has been
15 passed to clarify this, but we still have not
16 done that.

17 So I think in terms of our
18 synthetic carriers on, as specified, I think
19 it's 301, allowed in materials that are listed
20 on 606, and that's not really clear. We need
21 to work on a major policy to address that
22 coherently. So I think, in the meantime, it's

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1 a very good idea for you to recommend
2 clarifying your annotation now because it was
3 clear to the certifiers, after these things
4 suddenly were listed, that there are many,
5 many ways of making these colors, not just the
6 ones that you looked at.

7 So they did not have the guidance
8 that they needed to determine what, you know,
9 how to enforce that intent. So I think it's
10 fine.

11 Any questions?

12 MR. GIACOMINI: Well, that still
13 doesn't answer my question. Maybe Arthur
14 would like to put in his two cents.

15 We're discussing the annotation
16 change on colors on 606, adding the
17 restriction that hexane-extracted,
18 solvent-extracted and synthetic preservatives
19 are not allowed. Since the entire process of
20 this was, in 2007 -- and I don't remember if
21 you were still at that meeting or not -- was
22 obviously only representing the

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1 water-extracted, non-preserved forms, is this
2 petition even necessary, or would those forms
3 of hexane- and solvent-extracted even be
4 allowed?

5 MR. NEAL: Because I was not
6 involved in the initial discussion and it
7 appears that I can't remember if Kim had made
8 a comment on it yesterday about the CAS
9 numbers being wrong for, I don't know if it
10 was for flavors or colors -- okay.

11 So, if this recommendation with
12 changing annotation to specify non-hexane-
13 extracted -- if the petition is necessary,
14 that's the question, is the petition
15 necessary?

16 MR. GIACOMINI: No, is this
17 recommendation necessary --

18 MR. NEAL: Oh, you said --

19 MR. GIACOMINI: -- when the
20 consideration that was done in '07 was only to
21 discuss the discussion of water-extracted
22 forms?

1 MR. NEAL: It appears that there's
2 been confusion around the issue. People have
3 asked for clarification about that, whether or
4 not -- if we adequately captured the fact that
5 we were only looking at or allowing those
6 colors that were not extracted using hexane
7 and only water-based. So I think you could
8 add clarification.

9 MR. GIACOMINI: I didn't -- is it
10 necessary --

11 MR. NEAL: Who requested it?

12 MR. GIACOMINI: -- to prohibit --

13 MR. NEAL: Who requested it? I
14 know --

15 MR. GIACOMINI: I believe we could
16 say the Program requested it because it came
17 through communication with Valerie when she
18 was executive director.

19 MR. NEAL: Okay.

20 Let us touch base and get back to
21 you.

22 MR. GIACOMINI: Well, I'll put my

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1 cards on the table. I think this is a very
2 important question that I'm asking you
3 because, if you were to say that it is
4 required, that even though the only thing we
5 had been discussing was water but because of
6 the annotation listing, hexane was allowed, I
7 think that has -- one way or another, we have
8 a huge conflict with what you're saying the
9 Board is reviewing and what becomes allowed in
10 relation to your GMO vaccine comments.

11 These are both issues of how
12 something was claimed to have been reviewed by
13 the Board, how it's listed, and if you're
14 going to say one versus -- but in this case,
15 this is required because since we didn't
16 annotate specifically not allowing hexane when
17 it was specifically discussed as not even
18 existing, I would hope that your response to
19 the necessity of this would be consistent.

20 MR. NEAL: All right, and the
21 reason why I said I wanted to touch base with
22 you, one, is because, with the CAS number, I'm

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1 not sure if that CAS number is already taking
2 into consideration that hexane is not used. It
3 doesn't?

4 Okay, so then, that would dictate,
5 if it does not specify hexane is not used,
6 then that addition would be helpful in terms
7 of specifying that hexane is not allowed for
8 use and is water-based only. That would
9 clarify the original intent of the National
10 Organic Standards Board concerning the listing
11 of those colors.

12 MR. GIACOMINI: And I would
13 contend that that's in conflict with the
14 statement of the policy that you're making and
15 telling us regarding GMO vaccines.

16 Miles, do you want to get in the
17 middle of this?

18 (Laughter.)

19 MR. McEVOY: No thanks.

20 MR. GIACOMINI: Okay. Arthur is
21 looking at me like he doesn't understand the
22 connection. We can discuss it later, but I

1 wanted to get it on the record.

2 Steve?

3 MR. DeMURI: Where was I? Oh.
4 Katrina, were you complete? Or do you have
5 further questions for Katrina? I tried to
6 wait until we were done.

7 Jeff?

8 MR. MOYER: I just want to ask
9 you, Katrina, and I could easily have missed
10 it, were there any public comments out there
11 regarding this decision?

12 MS. HEINZE: We had two public
13 comments supporting it.

14 MR. MOYER: Supporting making that
15 annotation change?

16 MS. HEINZE: Correct.

17 MR. GIACOMINI: If there's no
18 further discussion and debate, Steve, next
19 item.

20 MR. DeMURI: Thank you, Dan.

21 After that, we move into Sunset
22 2012 recommendations, and let me preface this

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1 section by saying that there is a little bit
2 of complication in here because some of the
3 items that we're considering for sunset have
4 also already been considered for petitions, so
5 it made things a little bit complicated.

6 Generally, I think, in all cases,
7 the person that worked on the petition also
8 worked on the sunset so they could try to keep
9 everything straight on dates, what would
10 happen if this didn't happen, how we're going
11 to handle a sunset failure with a petition,
12 that kind of thing. So you'll see how that
13 plays out as we get through this list.

14 We'll be jumping around a little
15 bit. We're going to do the first three,
16 205.605(a) items. I've got the first two.
17 Joe's going to follow up with the yeast sunset
18 2012 recommendation.

19 The first one is flavors, and
20 flavors is up for sunset this year -- or in
21 2012. And as we all know, it's a very complex
22 subject. We've had several commenters suggest

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1 that the Handling Committee needs to form a
2 task force and work with NOP to wrestle with
3 the whole flavor issue. We intend to do that
4 as we move forward.

5 But, as far as sunset of the
6 flavors goes, as it currently stands with the
7 current annotation, the committee did vote to
8 relist that. The vote was six yes, zero no,
9 and one absent. And so the listing would be
10 flavors with its current annotation,
11 "non-synthetic sources only and must not be
12 produced using synthetic solvents and carrier
13 systems or any artificial preservative."

14 That's flavors.

15 MR. GIACOMINI: Comments or
16 questions?

17 Okay, Jay?

18 MR. FELDMAN: Thanks, Steve.

19 The Committee's comment that you
20 are recommending relisting but are also
21 communicating the belief that the full
22 category should not be relisted in five years,

1 is that correct? Am I reading the right
2 document?

3 MR. DeMURI: That's correct.

4 MR. FELDMAN: When next reviewed
5 for sunset. If not now, why not now? Why
6 then if not now? You know, why?

7 MR. GIACOMINI: Jay, mic.

8 MR. FELDMAN: We fully intend to
9 develop a task force working with the industry
10 and NOP to wrestle with the entire flavors
11 issue. There's a lot of organic flavors on
12 the market now, so we anticipate that a lot of
13 flavor should be moved over to 606 and off of
14 the 605(a) listing.

15 We fully intend, by the time the
16 next sunset comes along, we'll have all this
17 worked out, and it will be a moot point at
18 that point.

19 MR. GIACOMINI: Any more, further
20 questions?

21 (No response.)

22 MR. GIACOMINI: Mr. Chairman, we

1 are due for a break. Would you like to finish
2 up the two 605(a) items or would you -- if you
3 think they can be quick? If not --

4 MR. DeMURI: They should be
5 relatively quick, so we'll blow through them
6 here.

7 MR. GIACOMINI: Okay. Let's
8 proceed and break at the end of 605(a).

9 MR. DeMURI: All right, the next
10 205.605(a) item is magnesium sulfate with an
11 annotation, "non-synthetic sources only."
12 It's used a nutrient, a firming agent and a
13 flavor enhancer, first listed in 1995. It's
14 also used as a fermentation aid in the
15 processing of beer and malt beverages. It
16 naturally occurs in seawater and mineral
17 springs. Other sources are possible, but only
18 the nonsynthetic sources are allowed in this
19 listing.

20 There were no comments opposed to
21 relisting. There were several in favor of
22 relisting, and Handling Committee voted five

1 yes, zero no, with zero abstentions and two
2 absent, to relist the substance.

3 MR. GIACOMINI: Questions?

4 (No response.)

5 MR. GIACOMINI: Go.

6 MR. DeMURI: All right, the last
7 one on 605(a) is yeast. I'll let Joe handle
8 that. He's the yeast guy.

9 MR. SMILLIE: Yes, basically,
10 we're -- it's up for sunset. We've obviously
11 made a response and a recommendation to the
12 petition to move it to 606. We've talked
13 about that.

14 We want to relist it for sunset
15 and let the federal process make its way
16 through so that we don't lose it entirely
17 while we wait for the changes to happen to it,
18 as per our recommendations.

19 So the recommendation is to relist
20 yeast as a nonsynthetic allowed, 605(a).
21 Basically, there's no issues itself with the
22 material, so the Handling Committee recommends

1 a renewal of the following substances in the
2 use category published in the final rule:
3 "Yeast, nonsynthetic growth in petrochemical
4 substrate and sulfite waste liquor is
5 prohibited. Autolysate, bakers, brewers,
6 nutritional and smoked, non-synthetic smoke
7 flavoring process must be documented."

8 The vote was six for, no one
9 against, no abstentions, and one absent.

10 MR. GIACOMINI: Any further
11 discussion? Questions?

12 (No response.)

13 MR. GIACOMINI: Seeing none, we
14 will proceed for our break, 15 minutes. I
15 have 2:40 -- 2:55.

16 Please be prompt. We've got a lot
17 more work to do.

18 (Whereupon, the above-entitled
19 matter went off the record at 2:40 p.m. and
20 resumed at 3:00 p.m.)

21 MR. GIACOMINI: Take a seat. If
22 you're in the middle of a conversation, please

1 take it outside. We need to continue.

2 Steve.

3 MR. DeMURI: Thank you, Dan.

4 Okay, the next group, our nine
5 205.605(b) items that are up for sunset in
6 2012. As I mentioned, we'll be jumping around
7 a little bit on these, but John Foster has the
8 first two, chlorine materials and ferrous
9 sulfate.

10 So, John, why don't you go ahead
11 and do those two?

12 MR. FOSTER: Okay, thank you,
13 Steve, and thank you, Joe Dixon, for bringing
14 a little chocolate to perk me up.

15 So, chlorine materials up for
16 sunset, they've been used for a long time as
17 sanitation materials. At the time this
18 recommendation was put out, this was prior to
19 draft guidance issued by NOP, which came out,
20 I think, about two weeks ago, Draft Guidance
21 for Included Chlorine and for Other Materials.

22 I don't believe that the draft

1 guidance significantly changes it's
2 recommendation, or, if the draft guidance were
3 to become guidance, I don't think that would
4 change this recommendation at all, but that
5 draft guidance is helpful.

6 Chlorines are pretty much the most
7 common, very common equipment and food contact
8 sanitizers used in food processing and
9 handling. Recognized by the FDA as being
10 appropriate for their intended use, they've
11 been used -- as far as I know, always used --
12 in organic production along with non-organic
13 production.

14 The recommendation outlines just
15 the real basics of what's known about their
16 hazards. The Federal Register notice brought
17 forth no public comments against relisting.
18 Several commenters supported relisting the
19 material without change, no change to the
20 annotation.

21 We reviewed original
22 recommendations, all the historic documents,

1 past public comments, past NOSB discussions.
2 No new information came forward. And then the
3 last line of the discussion recognized that we
4 anticipated the NOP would provide further
5 guidance and clarification, which is in draft
6 form now.

7 We voted, as a committee, six in
8 favor and one absent, to relist as is the
9 chlorine. And that is, "Chlorine materials,
10 disinfecting and sanitizing food contact
11 surfaces, accept that residual chlorine levels
12 in the water shall not exceed the maximum
13 residual disinfectant limit under the Safe
14 Drinking Water Act." And then three chlorine
15 compounds are listed: calcium hypochlorite,
16 chlorine dioxide, and sodium hypochlorite.

17 The only thing I would add to this
18 is that in among the public comments submitted
19 in the period closing October 12th was one
20 very articulate suggestion that we look at
21 hypochlorous acid in the future as an
22 additional form of chlorine that has many

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1 benefits to it.

2 I don't think that changes, it
3 certainly was not working against this
4 recommendation. It was an adjunct to that,
5 but I think that's worth considering in future
6 work plans, and I'll bring that forward in the
7 committee after that.

8 That's it, Dan, on chlorine.

9 MR. GIACOMINI: Questions?
10 Comments? Jay?

11 MR. FELDMAN: Thank you.

12 Thanks, John.

13 I wanted to make a comment about
14 the background statement, and I don't know if
15 this has implications or if people would agree
16 that we should consider changing the language,
17 actually. I know this is a public document
18 for publication, so maybe this is with an eye
19 toward the future.

20 Obviously, chlorine raises a lot
21 of red flags in terms of environmental
22 contamination, public health threats, and we

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1 have to be very careful. I understand the
2 value it has in the organic industry as well
3 as the conventional side, but when we talk
4 about chlorine and we recognize that it's
5 acceptable and compatible, I think we should
6 not use language like 'the food safety
7 concerns outweigh the risks' because that's
8 not our standard.

9 Our standard is to protect against
10 adverse effects, as suggested on the checklist
11 that we use in reviewing these things, and to
12 look at harmful effects on the environment.
13 So language like 'support of food safety
14 concerns outweigh risks' and the 'protection
15 against' -- further down on that page, which
16 I can't find right now -- but "protection
17 against unreasonable adverse events" -- or
18 unreasonable risks. Unacceptable risks. It's,
19 "Review of the original recommendation,
20 historical documents, and public comments does
21 not reveal unacceptable risks to the
22 environment."

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1 Again, that isn't the standard to
2 which we're regulating under our statute.
3 We're regulating against harmful effects and
4 adverse effects. So, we have to be careful
5 when we a material like this, I think, to
6 categorize it in that way; otherwise, we slip
7 into another agency's, another statute's
8 standards. I'm not speaking against the
9 proposal. I just want to make sure that we
10 have clarity around what our responsibility is
11 when we do this.

12 The other issue I would raise is
13 whether we looked at the allowable levels on
14 food in addition to the effluent that's
15 associated with residuals as a result of use.
16 That may be in the NOP guidance, but is that
17 something you all considered when you went
18 through this?

19 MR. GIACOMINI: John.

20 MR. FOSTER: Yes, inasmuch as that
21 opening paragraph was supposed to be an
22 encapsulation of Committee discussion --

1 summary of our discussion. It's a summary of
2 the discussion. It's, I think, very
3 consistent with other Committee discussions.
4 Sometimes we touch on things that are not
5 precisely codified in law. We do it all the
6 time. We've done it a dozen times today.
7 This is a summary of discussion, that's all it
8 is.

9 Yes, we did consider some of the
10 food contact questions, concentrations in
11 contact with food, and that is spoken to in
12 some of the draft guidance.

13 I guess I agree that, yes, we
14 should be careful with language, but I think
15 this language accurately reflects the
16 discussion. It is a good summary. And so I'd
17 stand by it.

18 MR. GIACOMINI: Katrina.

19 MS. HEINZE: I was going to add to
20 what John said, that the residual levels of
21 chlorine has been a perennial topic when we
22 discussed sanitizers as a board, and it's

1 under constant review, so certainly that was
2 considered. It was heavily considered when
3 the Board initially listed those materials,
4 and nothing with regards to it has changed.

5 MR. GIACOMINI: Jay.

6 MR. FELDMAN: I guess my question
7 is why -- in point of information -- why are
8 we not annotating to a residual on food
9 residues but we're annotating to a residual in
10 drinking water?

11 MR. GIACOMINI: Katrina.

12 MS. HEINZE: That was heavily
13 reviewed and discussed at the original
14 listing. There is a lot of history to why it
15 is the way it is. It's also a part of why the
16 Program has issued guidance on these
17 materials, and so it's covered there. That's
18 not part of our sunset review.

19 The purpose of our sunset review
20 is to determine if our sunset as it currently
21 exists is, is there new information that we
22 have to consider that would affect us

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1 relisting this material? And speaking for me,
2 not for the committee, we felt that there was
3 not, and that it should be relisted as is.

4 MR. GIACOMINI: Jay.

5 MR. FELDMAN: Could we get some
6 clarification from the Department on this,
7 just to get on the record whether the current
8 guidance addresses issues of residuals?

9 I mean, I hear you, I hear about
10 the history. Unfortunately, the science is
11 changing on this daily. We're learning about
12 chlorinated compounds and their impact on
13 endocrine disruption, reproductive effects,
14 new science all the time. And so this is an
15 area we, especially in organics, we have to
16 hold to a high level of scrutiny. I just, you
17 know, I think the area of food residues as a
18 result has become a more critical issue.

19 I just want to make sure that it's
20 in our view, within our view, and I'm not
21 suggesting we should change this proposal, but
22 I think we need to have some clarity that this

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1 is an issue of concern in the short and long
2 term.

3 MR. GIACOMINI: So, you're asking
4 --

5 MR. FELDMAN: I'm asking whether
6 the guidance addresses residuals in food.

7 MR. GIACOMINI: Program?

8 MR. FOSTER: No, the guidance does
9 not address residues in food. The guidance is
10 a draft guidance that provides our
11 interpretation of the current listing of
12 chlorine materials on the National List and
13 recognizes that water is used in many
14 different ways in organic production and
15 handling -- as irrigation water, as processing
16 water, as an ingredient -- and, therefore, the
17 use of chlorine in all those different ways
18 that water is used is described in that draft
19 guidance.

20 I would say that the annotation on
21 chlorine materials needs some work, and that's
22 what the draft guidance is trying to provide,

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1 an interpretation of how chlorine can be used
2 in organic production and handling.

3 When it talks about residual
4 chlorine, it's talking about residual chlorine
5 in the water, not on the food product.

6 MR. GIACOMINI: Steve.

7 MR. DeMURI: And if I remember
8 correctly, back in '95 when all these
9 discussions were taking place, the Safe
10 Drinking Water Act came up because processors
11 wanted a method by which they could check
12 residual of rinse water on equipment, fruit
13 coming out of flumes, that kind of thing, and
14 that was a standard that was developed so they
15 could do that, to show their certifiers that
16 they had removed most of that chlorine from
17 their food contact surfaces.

18 MR. GIACOMINI: Further comment?

19 (No response.)

20 MR. GIACOMINI: Okay, Mr.

21 Chairman. Steve?

22 MR. DeMURI: John, you can carry

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1 on with ferrous sulfate.

2 MR. FOSTER: Let's see. Ferrous
3 sulfate -- I was about to say, fairly
4 noncontroversial, but --

5 (Laughter.)

6 MR. FOSTER: -- I'm never going to
7 say that again.

8 Perhaps less controversial is
9 ferrous sulfates used as food fortification.
10 No public comment came forward against
11 relisting. Again, several commenters in
12 public comment supported relisting the
13 material.

14 We reviewed original
15 recommendations, past public comments, past
16 NOSB discussions. Those did not reveal any
17 unacceptable risks to the environment, human
18 or animal health. No new information came
19 forward on a -- I did Google and Wikipedia
20 searches for recent revelations about ferrous
21 sulfate and found none. And so we did a
22 pretty straightforward recommendation to

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1 relist here.

2 "Ferrous sulfate for iron
3 enrichment or fortification of foods, when
4 required by regulation or recommended by an
5 independent organization" -- I don't know the
6 origin of the annotation, but it's certainly
7 consistent with our discussions around
8 nutrient vitamins and minerals. If for no
9 other reason, it would fit in there. I think
10 it's pretty clear that it's a mineral
11 supplement.

12 So we voted six for, none against,
13 one absent, to relist.

14 MR. GIACOMINI: Discussion?

15 (No response.)

16 MR. GIACOMINI: Seeing none -- Mr.
17 Chairman.

18 MR. DeMURI: Thank you. The next
19 one is pectin, low-methoxy. That's Joe
20 Smillie.

21 MR. SMILLIE: There's a mistake.
22 It's a 605(b) item. Whoops. It should be --

1 it's probably my mistake. I don't mean it's
2 your mistake, Lisa. We need to change that,
3 though. It's (b), "Synthetics allowed."

4 Pectin, low-methoxy, is currently
5 on 605(b), and basically, we're going to
6 relist it on 605(b) until the Program and the
7 federal process takes place and we move both
8 pectin methoxies to 606.

9 Again, not horribly controversial,
10 and again, we're moving something from a
11 synthetic allowed to an agricultural, which
12 hopefully in the future will be organic.

13 I've not received any comment on
14 this one. In our research on this material
15 for the petition, there seems to be some
16 agreement that there are some issues regarding
17 the interpretation of how it's produced and
18 all of that. But for this purpose, basically,
19 we're simply going to relist it on the sunset
20 process and, I think, let the NOP work their
21 process to move it to 606.

22 There was no comment that I know

1 of on this one, so basically, the
2 recommendation is to relist -- six yes, zero
3 no, no abstain, and one absent.

4 Everything else is correct in the
5 document. It's just the top on the synthetic
6 and non-synthetic.

7 MR. GIACOMINI: Kevin.

8 MR. ENGELBERT: Joe, I know we
9 don't have time to go into this right now, but
10 Thursday, could you have an explanation for
11 me, as brief as need be, about the history of
12 pectin, why it was put on 605 to begin with.

13 I know you talked about the
14 nonamidated and that process and why you now
15 believe it's on 606. But in keeping with
16 respect of previous boards' decisions and the
17 long-time listing of pectin on 605, I'd
18 appreciate more information on that. And I
19 know that you're now ruling that it's
20 agricultural, but also on Thursday, could you
21 let me know whether there was any thought to
22 making this an additional commercial

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1 availability issue on another 605 item?

2 MR. SMILLIE: Briefly, now, no,
3 because this one, I thought was much clearer,
4 that we believe that for whatever reasons --
5 and it's lost in the mists of time; it is 15
6 years ago, but they just didn't have the
7 information or misread the information for
8 their original decision.

9 I do have this email chain, which
10 I will lend to you, and if we need to discuss
11 it more on Thursday, we can. But basically,
12 I think that getting the permission of the
13 person that moved it and shepherded it through
14 that process in '95 and going back and reading
15 the transcripts, I think we discovered where
16 they -- I won't say "made a mistake" -- but
17 where their information was limited or they
18 had wrong information to make that original
19 decision.

20 So I don't think we're changing.
21 I think the chair of that committee at the
22 time, the person who moved it, would agree

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1 that we're making the right decision now. But
2 I'll give you the documents, and if you want
3 to discuss it some more, we can.

4 The other thing is back to where I
5 started my research on it, was the '95
6 transcripts, so it's all there.

7 MR. GIACOMINI: Further comments?

8 (No response.)

9 MR. GIACOMINI: Seeing none, next
10 item, Mr. Chairman.

11 MR. DeMURI: Okay, let me mention
12 that the transcripts that are in the record
13 for '95 really aren't transcripts. They're
14 meeting notes, so they're very skinny.
15 There's hardly any information in there at
16 all. It's not like a word for word verbatim
17 of what happened. It's just very brief notes
18 on what was said and what was done, so they're
19 almost useless.

20 All right, the next one is
21 phosphoric acid, and Joe Dixon reviewed that
22 for us.

1 MR. DIXON: Phosphoric acid is
2 annotated to restrict its use to the cleaning
3 of food contact surfaces and equipment only.
4 It's used in the cleaning of food-service food
5 contact surfaces to remove mineral scale and
6 encrusted matter in boilers and on other
7 equipment that produces steam. It reacts
8 chemically with minerals found in the deposits
9 and makes them more water-soluble and thus
10 easy to remove.

11 We reviewed the original
12 recommendation, the original TAP review,
13 historical documents and public comments. We
14 received a few comments in support of
15 relisting and none in opposition.

16 The Committee voted six in favor
17 of relisting, zero not in favor, one absent.

18 Any questions?

19 MR. GIACOMINI: Any questions?

20 Jay?

21 MR. FELDMAN: When you did this
22 review, did you look at any alternative

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1 materials that have come along or not come
2 along in the market?

3 MR. DIXON: I did do some basic,
4 you know, internet searches for information
5 about the material and its uses and stuff and
6 did talk to some of our facilities folks, and
7 nothing came up.

8 MR. FELDMAN: Related to that type
9 of a question, what was the public comment
10 based on this recommendation?

11 MR. DIXON: There was comment
12 from, I think, one or two food processors that
13 they use the substance, without elaboration.

14 MR. FELDMAN: Okay. No discussion
15 of alternatives and getting rid of it?

16 MR. DIXON: Not that I recall from
17 reading the comment. I can go back and double
18 check those, but --

19 MR. GIACOMINI: Any further
20 questions? Steve?

21 MR. DeMURI: Actually, a comment.
22 We do use phosphoric acid in all of our

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1 facilities that run organic, and it's one of
2 the few things you can use to do what Joe
3 described.

4 MR. GIACOMINI: All right.

5 MR. DIXON: Thank you, Steve.

6 MR. GIACOMINI: Okay, next.

7 MR. DeMURI: Thank you, Joe.

8 John, you're next.

9 Silicon dioxide -- John Foster.

10 MR. FOSTER: Silicon dioxide -- a
11 common additive in production of foods; often
12 uses a flow agent; also used as a filtering
13 agent in some processing; occasionally also
14 used as a desiccant both in food as well as in
15 pest control materials. It's generally what's
16 makes diatomaceous earth work as well as it
17 does.

18 Okay, so in 2007, there was public
19 comment noting that silicon dioxide was no
20 longer necessary due to the availability of a
21 certified organic alternative substance. This
22 would be -- this alternative is the same one

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1 that was put forward as being a replacement
2 for mono- and diglycerides, for what it's
3 worth, or actually, a similar product; same
4 manufacturer.

5 Unlike the public comment provided
6 in response to mono- and diglycerides, the
7 comments provided in this last public comment
8 period for silicon dioxide were not as
9 one-sided and not as substantive. All of
10 that's on regulations.gov. But there were
11 fewer comments, I think, three or four, and
12 they were fairly evenly split between
13 supporting the relisting and supporting the --
14 not relisting.

15 The science provided in the
16 comments provided about silicon dioxide was
17 not as thorough as it was for mono- and
18 diglycerides.

19 Let's see. Just before the April
20 NOSB meeting, several commenters in generic
21 fashion asked to relist it. But really, there
22 was much more discussion in this last, most

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1 recent public comment period.

2 We did a review, our kind of
3 standard review, of past recommendations, past
4 discussions, and didn't find any new science
5 that shows that changes to the risks to
6 environment, human or animal health, anything
7 new was uncovered, as far as I could tell.

8 The Handling Committee is also
9 aware of a petition to remove silicone dioxide
10 from the National List. That's in play.
11 However, the completed petition, it had been
12 submitted and sent back for more information,
13 and by the time the complete petition had been
14 provided, it was past the window in time to
15 consider for this meeting. But I'm assuming
16 it'll get handled in the spring meeting if the
17 petition now looks complete.

18 So, anyway, we're aware of that
19 petition. And at the time we wrote this
20 recommendation, it was still in the NOP review
21 process and it hadn't reached the Handling
22 Committee. It has now. We intend on

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1 reviewing that petition as soon as we can with
2 the work plan.

3 So, at the time of our discussion,
4 we recommended the renewal and inclusion of
5 silicon dioxide on the National List again, a
6 vote of six yes, zero no, and one absent.

7 MR. GIACOMINI: Jay?

8 MR. FELDMAN: Thanks, John.

9 Have you had a chance to look at
10 the petition? Do they talk about their
11 alternative? I assume it's a competitor?

12 MR. GIACOMINI: John?

13 MR. FOSTER: Yes, I've looked at
14 it and I haven't reviewed it to the detail I
15 would, you know, when we're going to review
16 it, but I have looked at it. It's a rice
17 product, certified organic. It has some of
18 the -- based on the petition, it has some of
19 the same characteristics, and I could see it
20 working as an alternative in some cases.

21 The comments that were submitted
22 in this last round, many of them spoke to

1 trialing this alternative as a replacement for
2 silicon dioxide. Some says it works fine;
3 others said it works okay and allows us to
4 reduce the amount of silicon dioxide but not
5 eliminate it.

6 So, I would expect that when we
7 review the petition in more detail as a
8 Committee, we'll definitely take into account
9 that public comment. It seems very relevant
10 and it may lead to -- when we review it as a
11 petitioned item, I could see it very much
12 affecting the decision.

13 I think there's some utility to
14 this alternative.

15 MR. GIACOMINI: Jay?

16 MR. FELDMAN: I'm just wondering
17 if that, if that petition could inform the
18 sunset deliberations -- I mean, could postpone
19 this decision until spring -- if there's
20 enough, if in your preliminary look at this,
21 it looks like there's sufficient data.

22 MR. FOSTER: I think it could

1 inform, but at this point, I'd be hesitant to
2 replace, to change our sunset decision based
3 on the petition, just because we haven't time
4 to give it its due. And I would be hesitant
5 to -- yes, I think it can inform, but I
6 wouldn't want to put off sunset necessarily.

7 Either the petition is going to be
8 enough to get us to remove it or it won't, but
9 I think it's a good petition.

10 MR. GIACOMINI: Jay?

11 MR. FELDMAN: I'm just suggesting
12 this because it might expedite -- as we know,
13 the petitions sometimes take a very long time.
14 So, if this could expedite the process and
15 inform, you know, a reduction in use of a
16 synthetic, then why not go for it? Because,
17 we still have the opportunity to revisit this
18 in the spring -- it's just something to
19 consider -- revisit it in the spring and allow
20 it to go through or relist it.

21 MR. GIACOMINI: Do you want to
22 respond?

1 MR. FOSTER: I would just defer to
2 the Chair. But it's a reasonable suggestion
3 though.

4 MR. GIACOMINI: Steve, respond?

5 MR. DeMURI: Yes, we'll discuss
6 it, but I'm inclined right now just to move
7 forward with it, to go through the sunset
8 process. We've put the work into it. We've
9 got a full plate coming up in the spring. I'd
10 hate to just start piling on.

11 MR. SMILLIE: I was just going to
12 echo what Steve said. I think we need to go
13 through with it. I think that the feedback is
14 good and we can see that there's progress
15 there. But you know, when you get a comment
16 that says, "Yes, I'm trying to use it, and
17 it's, I can substitute part of it but not all
18 of it", you know, that's the kind of comments
19 I really like to see because if somebody is
20 really working with it and they're saying,
21 "Yes, it's promising, but not quite yet; we're
22 getting there".

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1 So, I'd like to just have it
2 sunseted, and then we'll have a fuller
3 examination on the petition.

4 MR. GIACOMINI: As a inquiry, is
5 the product in the new petition unique enough
6 to justify the request of a new TR?

7 MR. FOSTER: The petition that I
8 was speaking to was a petition to remove
9 silicone dioxide.

10 MR. FELDMAN: Correct.

11 MR. FOSTER: So it's not
12 petitioning a new material to add to the
13 National List.

14 MR. FELDMAN: But it could justify
15 a new TR that evaluates the scientific basis
16 in the information that's available out there
17 alternatives?

18 MR. FOSTER: On alternatives, yes.
19 Yes, it could justify the request for a TR.

20 MR. GIACOMINI: Which would make
21 its way past the next spring meeting?

22 MR. DeMURI: Maybe not.

1 MR. GIACOMINI: Okay. Steve.

2 MR. DeMURI: We would request a
3 very specific TR --

4 MR. GIACOMINI: Miles, could you
5 turn yours off for one second? Thank you.

6 MR. DeMURI: It might be a short
7 turnaround on something with just a couple of
8 questions.

9 MR. GIACOMINI: Miles?

10 MR. McEVOY: We've already
11 requested a TR on silicon dioxide.

12 MR. GIACOMINI: Okay.

13 Further comments on this item?

14 (No response.)

15 MR. GIACOMINI: Next item, Mr.
16 Chairman.

17 MR. DeMURI: Thank you, Dan.

18 The next four are all Joe Dixon's,
19 so Joe, I'll just let you take those bang,
20 bang, bang, bang.

21 MR. DIXON: Thank you, Steve.

22 Sodium citrate is sort of

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1 shorthand for the three sodium salts of citric
2 acid, monosodium, disodium and trisodium
3 citrate, trisodium being most commonly used in
4 food. They're used as pH adjusters, buffering
5 agents, stabilizers, and I don't know how I
6 left this off here, but trisodium citrate is
7 used largely as an antioxidant in food
8 production.

9 The original technical review
10 found sodium citrate, the three substances, to
11 be consistent with OFPA criteria. These are
12 very widely used in organic food production;
13 no new information after review of the
14 original recommendation, historical documents,
15 public comments. We did receive three public
16 comments in support of the relisting of the
17 substance, none in opposition.

18 The Committee voted six in favor
19 of relisting; none opposing; and one absent.

20 MR. GIACOMINI: Comments?

21 Questions?

22 MR. DIXON: Any questions?

1 MR. GIACOMINI: Oh, I'm sorry.

2 MR. DIXON: I was just saying,
3 "Any questions?"

4 MR. GIACOMINI: Any questions?
5 Comments?

6 (No response.)

7 MR. GIACOMINI: All right. Next
8 item.

9 MR. DIXON: Sodium hydroxide --
10 annotated to prohibit its use in the
11 lye-peeling of fruits and vegetables. It is
12 lye. Its utility in food production is that
13 it's a very strong base used a pH adjuster.

14 Traditional pretzel producers will
15 tell you that it is the only additive to put
16 in the water to produce a traditional pretzel.
17 It's used in olive production and curing.
18 It's used in cocoa manufacture, in processing
19 with alkali. It is prohibited in lye peeling
20 of fruits and vegetables because of the
21 adverse environmental impact of that process.

22 Again, the information presented

1 in the original discussion recommendation TAP
2 review appears to hold up. We have received,
3 once again, three comments in support the
4 relisting of sodium hydroxide.

5 The Committee voted six in favor;
6 none against; with one absent.

7 Any questions on sodium hydroxide?

8 MR. GIACOMINI: Questions and
9 comments for the committee?

10 (No response.)

11 MR. GIACOMINI: Seeing none, move
12 ahead. Onward.

13 MR. DIXON: Sodium phosphates with
14 an annotation restricting their use to, only
15 in dairy foods -- used an emulsifier,
16 coagulant, stabilizer, an emulsifier,
17 sequestrant, and pH control agent in food
18 production.

19 It's used in dairy foods as an
20 emulsifier largely to keep them from
21 separating.

22 We have reviewed the original

1 technical review, the original recommendation,
2 and once again received three public comments
3 in support of the relisting of this material.
4 We had three very diligent materials
5 commenters and have found that it's still in
6 wide use in organic food production and that
7 there are no issues with this one.

8 The Committee voted six in favor
9 of relisting; none against; and one was
10 absent.

11 Questions? Comments?

12 MR. GIACOMINI: Questions and
13 comments?

14 (No response.)

15 MR. GIACOMINI: Move on.

16 MR. DIXON: All right.

17 Sulfur dioxide, with an annotation
18 restricting its use to wines labeled as, "Made
19 with organic grapes provided that the total
20 sulfite concentration does not exceed 100
21 ppm." -- the Program has received a petition
22 to remove the annotation and allow the use of

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1 sulfur dioxide in all wine production.

2 That is in process and will be
3 considered by the committee in due course.
4 I'm not sure if it's on the spring docket or
5 where that will sort of emerge, but we are
6 aware of that petition, but performing the
7 sunset review, regardless. Sulfur dioxide is
8 a preservative used for preventing the
9 oxidization of wine. It has been a part of
10 traditional wine-making for several hundred
11 years.

12 We have reviewed the original
13 technical review, the recommendation,
14 historical documents; other materials. I
15 mean, it's still used as it has been with very
16 little variation. It's very widely used in
17 wine production.

18 The Committee voted six in favor
19 of relisting with the existing annotation;
20 none against; and one member absent.

21 Questions?

22 MR. GIACOMINI: Jeff?

1 MR. MOYER: I'm just wondering,
2 Joe, about public comment. I did see
3 something in public comment about that, but
4 maybe it was about the petition to remove the
5 annotation. I don't remember.

6 Could you expand on that?

7 MR. DIXON: Yes, the public
8 comments that I saw were related to the
9 petition, which is not yet on the Board
10 agenda.

11 MR. MOYER: Thank you. I wasn't
12 sure.

13 MR. GIACOMINI: Any other
14 questions or comments?

15 (No response.)

16 MR. GIACOMINI: Next item, please.

17 MR. DeMURI: All right, that
18 finishes up the 205.605(a) and (b) items.

19 Now we're moving into the 205.606
20 items. The first one is a group of 18 colors
21 and annatto extract, which is related, of
22 course, and Katrina is going to handle both of

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1 those together.

2 MS. HEINZE: Okay, to follow up on
3 our earlier colors discussion, there are 19
4 colors on 205.606 that were listed in June of
5 2007. The 19 colors are listed in the
6 recommendation.

7 First, I'm going to talk about 18
8 of them, so all of them except for annatto,
9 which is handled in a separate recommendation
10 that I'll discuss in a minute. I won't go
11 into the history again for how these were
12 listed, but if you have questions, I can
13 follow up on that.

14 In the March 2007 meeting where we
15 reviewed colors, these 18 colors plus annatto
16 were recommended for listing by the NOSB. To
17 briefly summarize the public comment we
18 received at that meeting and the petitions
19 that were received, what we learned was that
20 to make color very specific varieties of a
21 particular raw material are needed and that
22 these specific varieties have to be high in

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1 color compounds.

2 A purple carrot would be a good
3 example. The purple carrot used to make
4 purple carrot color is a different variety
5 than the purple carrot that I might buy at my
6 farmer's market and eat. So there are very
7 specific varieties that are needed for color.

8 The other thing that we learned is
9 that processing of the raw material has to
10 happen in very close time proximity to when
11 it's harvested because you're going to lose
12 the color compounds very quickly. So a key
13 contributor to why some of these colors were
14 not available is that there was a disconnect
15 between where you could process a color and
16 where you could grow the raw material.

17 The other thing was that colors
18 are used at extremely low percentages in the
19 finished products, typically much less than
20 one percent, so there wasn't an incentive for
21 color manufacturers to get into this business
22 at that time, and there was certainly hope

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1 that as organic grew that that would change.

2 The final contributing factor was
3 that in cases where you could use similar
4 varieties, it was frankly more lucrative for
5 farmers to sell into the fresh market than to
6 sell to ingredient manufacturers because they
7 can get a better price for the raw material.
8 So the color manufacturers were not able to
9 contract for this, because farmers wanted to
10 have the flexibility.

11 The public comment we perceived in
12 support of relisting this -- we received nine
13 public comments supporting relisting these 18
14 colors; no public comments opposed to
15 relisting, and that was to the original sunset
16 publication. In addition, we received six
17 public comments at the spring meeting
18 supporting relisting these items as well as
19 the others, 606. Specific to this meeting, we
20 received two additional public comments
21 supporting relisting and none opposed. So in
22 all that public comment, we perceived none

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1 opposed to relisting.

2 I do want to highlight that we've
3 received several public comments over the
4 history of this listing that the CAS numbers
5 are incorrect. In a review of it, it looks
6 like the CAS numbers that are included in the
7 rule are the CAS numbers for the individual
8 color compounds.

9 So, for example, purple carrot
10 color has carotenoid, which has CAS number
11 whatever it is, but that's red. Any of these
12 colors that has red in it has the CAS number
13 for carotenoid. So I would concur with the
14 public comment, the CAS numbers are not right.
15 We included in this recommendation a request
16 to the Program that you sort through the CAS
17 numbers and do a technical correction when you
18 relist these to get the CAS numbers right
19 because I think that's very confusing for
20 folks who are trying to use the list.

21 With that, the Handling Committee
22 recommends a relisting, and I will briefly

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1 read the colors here. The following colors
2 are on 606:

3 Beet juice extract color;
4 Beta-carotene extract color from
5 carrots;
6 Black currant juice color;
7 Black-purple carrot juice color;
8 Blueberry juice color;
9 Carrot juice color;
10 Cherry juice color;
11 Chokeberry (aronia) juice color;
12 Elderberry juice color;
13 Grape juice color;
14 Grape skin extract color;
15 Paprika color;
16 Dried powder and vegetable oil
17 extract;
18 Pumpkin juice color;
19 Purple potato juice color;
20 Red cabbage extract color;
21 Red radish extract color;
22 Saffron extract color; and

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1 Turmeric extract color.

2 And then we also include at the
3 bottom that we're asking the Program to review
4 the CAS numbers and fix them.

5 This passed the committee five
6 yes; zero noes; two absent.

7 MR. GIACOMINI: Jeff?

8 MR. MOYER: I just wanted to say
9 that when these colors were first put on the
10 list, I was one of the folks who probably
11 voted against every one of them; I don't
12 remember exactly.

13 But I hope this is a case where
14 Joe is proven right in the future and I'm
15 proven wrong, and that the 606 listing on
16 these does spur people to find organic sources
17 of these materials to be used as colors. I
18 hope so.

19 MR. GIACOMINI: Further comments?
20 Jay?

21 MR. FELDMAN: As a follow-up to
22 that, what is the process during this review

1 for evaluating the alternatives, the organic
2 alternatives?

3 MS. HEINZE: Well, certainly, part
4 of the process is public comment, and I
5 appreciate the intro to annatto, which I'll
6 get to in a minute, because you'll see there
7 that we did receive public comment that there
8 are alternatives. So certainly public comment
9 informs us.

10 I also, as the reviewer, did an
11 internet search for each of these materials to
12 see if I could find an alternative, and did
13 not; and then, our familiarity with products.
14 So there is review.

15 I would ask you to hold that a
16 little bit because you'll see in our
17 recommendation, there's a reason annatto is
18 not included in these, and that's because we
19 believe that is a material where 606 has
20 worked.

21 MR. GIACOMINI: Jay?

22 MR. FELDMAN: Your statement talks

1 about the disincentive, really, for growers to
2 sell to the ingredient market as opposed to
3 the fresh market. So I'm wondering whether
4 annatto might be an exception, or it might be
5 a trend. We don't know. But I'm wondering
6 whether we could consider some other type of
7 incentive.

8 This might be a contract situation
9 where a formulator needs to contract for
10 organic production because the law knows you
11 can grow carrots organically or you can grow
12 a lot of these crops organically that could
13 then end up as colors. But we know that the
14 marketplace is not going to drive production
15 in that direction for obvious reasons.

16 MR. GIACOMINI: Katrina?

17 MS. HEINZE: I guess what I would
18 ask you to consider is, remember that all of
19 these materials have to be listed as
20 ingredients in the ingredient index of the
21 products that use them, so I think there is a
22 natural incentive for companies that use these

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1 materials to continue to make progress.

2 The other thing is, remember, you
3 have to prove to you're certifier. I mean, I
4 can tell you that the company I work for uses
5 a couple 606 items, and we go through a
6 rigorous process every year to -- okay, what
7 else is out there? What else can we try?
8 Because, it is about continuous improvement.

9 You'll see that that worked in
10 annatto, and these items that we've talked
11 about today have only been on the list for
12 five years. I know five years sounds really
13 long, but in this process it's really short.

14 I'm pleased to see that as a
15 Handling Committee we're moving things off the
16 list. I think that's great. We moved
17 lecithin off the list; you know, we're
18 recommending annatto. So I think we're making
19 progress. I'm hoping that in a couple years,
20 we'll prove that 606 is working nicely.

21 MR. GIACOMINI: Well, we're making
22 progress there, but unfortunately, I think on

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1 our time slot on our agenda, we're definitely
2 not. Rough looks, we are probably at least
3 two and a half hours behind schedule. We need
4 to continue to be thorough and not give
5 anything -- certainly not looking to cut off
6 any debates, but let's try to be as succinct
7 as possible.

8 So with that, I will be quiet and
9 move on to the next item.

10 MS. HEINZE: Okay, annatto.
11 Annatto extract color is the 19th color on the
12 list. Annatto extract color, water and oil
13 soluble, was added to the National List in
14 June of 2007, and this is the first time it's
15 been reviewed for sunset.

16 When this material was reviewed,
17 and I touched on this briefly during the
18 annotation change recommendation, we had a lot
19 of debate about the annotation for annatto.
20 Originally, the Handling Committee had
21 recommended that only organic oil be used for
22 the extraction. That was considered too

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1 restrictive, so it wasn't included in the
2 final Board recommendation.

3 There was a lot of discussion at
4 that meeting, as well, about a liquid form and
5 a powdered form and how to include both of
6 them in the annotation. If you read the
7 transcripts, the result of those two days of
8 discussions -- or the different discussions on
9 different days -- the final result was that it
10 reads, "Oil and water extracted," and doesn't
11 highlight the specific forms, even though we
12 were very aware of them and discussed them in
13 great detail.

14 In response to the sunset listing,
15 we received 10 public comments on the
16 relisting of annatto extract color. Five
17 supported the relisting. One handler
18 specifically identified that they had been
19 unable to source as organic a powdered version
20 of annatto extract color, which is necessary
21 for the product. They have a liquid form, but
22 it's not suitable for use in their product.

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1 They've also tested a 100-percent
2 ground annatto seed powder, so rather than an
3 annatto extract that's in a powdered form,
4 this is an annatto seed that's ground up.
5 This is highly variable in color and doesn't
6 meet the consumer desire for consistency.
7 This is used in a mac & cheese product, you
8 know, where consumers want a very uniform
9 looking product. Additionally, the use of the
10 seed powder resulted in off flavors that
11 consumers did not want.

12 Then we had three public comments
13 asking that annatto extract color be removed
14 from the National List because a sufficient
15 organic supply was now available.

16 And finally, one public comment
17 from a supplier of organic liquid annatto
18 extract color said that they had enough to
19 supply.

20 So needless to say, the public
21 comment was very mixed, and we knew that we
22 had to proceed with that. The initial take on

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1 the public comment was it looked like liquid
2 was available but powdered was not available.

3 So I did two things as a reviewer.
4 I did an internet search to see what I could
5 find. I found liquid organic annatto
6 available from the company that provided the
7 public comment. I called their customer
8 service number. They did not have a powdered
9 form available. This was in the spring. I
10 also found the ground up annatto seed powder
11 in organic form. But I did not find anything
12 else.

13 Then what I did what I called in
14 the recommendation an "informal market
15 survey," I want to be very transparent on what
16 this was. I went to my local grocery store,
17 and I walked up and down all the aisles, and
18 I picked up all the products that were orange
19 and looked at their ingredient deck to see
20 what they included. This was informal, but I
21 thought it was good.

22 What I found was that, in general,

1 things that I would have expected to use
2 powdered -- things like potato chips, cheese
3 puffs, I'm thinking Cheetos, but the organic
4 version, which my son loves, mac & cheese --
5 so things like that used a conventional
6 annatto, or least according to their
7 ingredient deck, they were not using an
8 organic form.

9 When I picked up things like
10 yogurt and cheese, like a Colby cheese, they
11 had organic annatto listed on their ingredient
12 deck. Those are products that I would expect
13 to use liquid annatto.

14 So my informal market survey
15 matched the information we received from the
16 public comment and seemed to indicate that
17 liquid was available but powdered was not.
18 Based on that, our recommendation -- you'll
19 see we have two recommendations, both listed
20 in the affirmative because that's our habit or
21 our practice -- so we recommended that the
22 liquid form of annatto extract, color water-

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1 and oil-soluble, be relisted.

2 That recommendation failed the
3 committee, with zero yes; five no; two absent.
4 Then we recommended that the powdered form,
5 water- and oil-soluble, be relisted. That
6 passed the committee, with five yes; zero no;
7 two absent.

8 Since that, we have received
9 additional public comment, which I thought I
10 had summarized here and I don't -- hold on.

11 We did receive public comment on
12 this, most supporting. We did receive a
13 public comment from the supplier of the liquid
14 annatto that says that they now have a
15 powdered version available. It's unclear to
16 me -- they said that it had become available
17 very recently, so it's possible that that was
18 after I did my research. It's unclear to me
19 why that didn't come up when I called their
20 800 number.

21 We have also received a petition
22 to remove annatto, from that supplier. We

1 have not had time to look at that at all.

2 So that's where we are. The
3 public comment supports these recommendations.
4 I do expect that we'll have some additional
5 public comment on this tomorrow.

6 MR. GIACOMINI: Additional
7 questions and comments? Jeff?

8 MR. MOYER: I support your
9 decision, but I have a question about the
10 procedure. Since 205.606 doesn't
11 differentiate between liquid and powdered, how
12 do we do that? How do we actually accomplish
13 what you're trying to accomplish, since it
14 doesn't differentiate between them in the
15 current listing?

16 MS. HEINZE: Yes, we discussed
17 that; and hence, the two recommendations.
18 Similar to our discussion of the
19 recommendation to change the annotation,
20 annotations on these colors were muddled up at
21 that meeting.

22 When you read the transcripts, at

1 least my read of the transcripts, it appears
2 that the intent of the Board at the time was
3 to list the liquid and powdered forms. But as
4 they thought of the words, this is what came
5 out. So we've specifically said that's why
6 we've listed our recommendations that way.
7 We're recommending relisting the liquid form
8 of the material that's currently listed and
9 relisting the powdered form of exactly what's
10 listed.

11 We're going to give it to the
12 Program, and they're going to figure out what
13 they need to do.

14 MR. GIACOMINI: Further questions
15 and comments?

16 (No response.)

17 MR. GIACOMINI: The Chair
18 appreciates and agrees with the work that the
19 Handling Committee has done on the yeast, on
20 colors, the other colors, on hops. The Chair
21 is still seeing this -- is very likely to
22 still see this as an annotation change.

1 Unless I can see it differently by
2 Thursday, I would be happy to walk anyone who
3 wants to through the process of appealing the
4 rule of the Chair, but I think I would be
5 leaning right now towards calling this motion
6 out of order unless someone can -- either in
7 public comment or somewhere else along the
8 line, someone can explain to me how this is
9 not an annotation change within the sunset
10 recommendation -- which we currently do not
11 allow in our procedures.

12 So I may be setting myself up for
13 a short night's sleep, but I just wanted to
14 let you know, that's where I'm leaning -- the
15 Chair is leaning at this time.

16 Katrina first?

17 MS. HEINZE: I would ask you to
18 note that we are not recommending an
19 annotation change. We are saying there's two
20 forms of this material available, and we are
21 recommending that one be relisted and one not
22 be relisted.

1 MR. GIACOMINI: Jeff?

2 MR. MOYER: Yes, that was the
3 reason for my question, Katrina, because
4 you're asking for something to be relisted
5 that isn't even listed. So that's why,
6 procedurally, should we be removing this from
7 the list but adding the powdered form in that
8 terminology? And then it's not an annotation
9 change, which we can't do.

10 But you're asking us to relist
11 something that doesn't even show up here, it's
12 not listed as a powdered form. That's why I'm
13 asking about the process or the procedure and
14 why I said I liked your part about dumping it
15 on them, to let them straighten it out, so
16 that we can get past Dan's concern as well.

17 MR. GIACOMINI: Further questions?
18 Comments?

19 MS. HEINZE: The Handling
20 Committee will discuss it, but two forms got
21 listed in March of 2007, and two forms were
22 debated and discussed.

1 MR. GIACOMINI: Further questions
2 or comments?

3 (No response.)

4 Mr. Chairman. Next item please.

5 MR. DeMURI: Yes, one last comment
6 on that. We talked about all that in
7 Committee and decided to push the envelope a
8 little bit and try to promote the growth of
9 organic, which I think is what we should be
10 doing. And so that's what we're going to do.

11 All right, next we have a few more
12 606 items. The next one is one that I'm going
13 to talk about, and that's
14 fructooligosaccharides, otherwise known as
15 FOS, which is what I will call it from now on.

16 FOS is produced on a commercial
17 scale by natural fermentation from a mixture
18 of sucrose using an enzyme derived from
19 Aspergillus. The sucrose is then combined
20 with the enzyme and heated, and once the
21 enzyme reaction is completed, the process is
22 filtered, concentrated and packaged.

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1 FOS is used as a prebiotic fiber
2 inclusion in food and feed processing and is
3 a selective source of energy by probiotic
4 bacteria in the guts of humans and animals.
5 You can find it in milk, bars, baby foods,
6 beverages, biscuits, confectionery, cookies
7 and yogurt, to name a few.

8 We had no only comments against
9 relisting of the material on 205.606, and
10 several in favor, so the Handling Committee
11 took a vote on this substance, and the vote
12 was five yes and zero no for a relisting, with
13 zero abstentions and two persons absent.

14 MR. GIACOMINI: Questions or
15 comments?

16 (No response.)

17 MR. GIACOMINI: Seeing none, next
18 item.

19 MR. DeMURI: The next one on the
20 docket is hops, and we all know who that one
21 goes to -- Mr. Smillie.

22 MR. SMILLIE: You'll notice the

1 first sentence listed in public comments
2 against relisting. We certainly did that.

3 Again, with our recommendation to
4 the petition, we're recommending that it be
5 taken off the list January 1, 2013, but while
6 that is in process, we think it's very
7 important to relist it as-is during the sunset
8 process.

9 Now, obviously, new information
10 has come to light, but that information also
11 leads us to believe that we need that
12 transition period, less than five years, and
13 we believe that the process we have in place
14 will do exactly that. We are trusting that
15 the Program will act expeditiously to meet
16 that January 1, 2013 guideline.

17 So with that, with that faith in
18 that process, we're recommending that hops be
19 relisted on 205.606.

20 MR. GIACOMINI: Comments or
21 question?

22 Just the one comment -- I think

1 the Program should take due note. Joe just
2 said he has confidence in his government and
3 the Program, so that's good.

4 (Laughter.)

5 MR. GIACOMINI: Next item.

6 MR. SMILLIE: It's the tone.

7 (Laughter.)

8 MR. GIACOMINI: Next item, Mr.
9 Chairman.

10 MR. DeMURI: All right. The next
11 one for 205.606 is inulin. This oligofructose
12 enriched, first listed in 2007, and it's
13 produced by extracting inulin from the roots
14 of the chicory plant with hot water, treating
15 a portion of the solution of extracted inulin
16 with enzymes to effect a mild hydrolysis to
17 obtain oligofructose, and then spray-drying a
18 solution of a mixture of the long-chain length
19 inulin and oligofructose to yield a dry
20 powder.

21 Everybody understand that?

22 The process is analogous to

1 extracting sugar from the roots of sugar beets
2 and creating maltodextrin from cornstarch.
3 It's very similar to that process.

4 It's an agricultural ingredient
5 added to yogurt products to improve the
6 absorption of calcium from the yogurt, to add
7 soluble dietary fiber, and to yield a
8 satisfactory texture and consistency of the
9 yogurt during its shelf life.

10 There were no public comments
11 objecting to our recommendation for the
12 relisting, and several that were in favor of
13 that.

14 The vote by the Handling Committee
15 was five yes and zero no for relisting, with
16 no abstentions and two persons absent.

17 MR. GIACOMINI: Comments or
18 questions?

19 (No response.)

20 MR. GIACOMINI: Next item, Mr.
21 Chairman.

22 MR. DeMURI: Okay, back to Joe for

1 high-methoxy pectin.

2 MR. SMILLIE: Right. High-methoxy
3 is on 205.606. We elicited no public comments
4 against relisting. Once again, we want to
5 move to relist until the Program takes our
6 recommendation on pectins for 606. But until
7 that time, same procedures -- we'd like to
8 make sure that it's relisted so that people
9 can continue using it. And hopefully, we'll
10 start to see some activity on organic pectin
11 in the very near future.

12 The vote was six yes to relist;
13 zero no; zero abstained; one absent.

14 MR. GIACOMINI: Comments or
15 questions?

16 (No response.)

17 MR. GIACOMINI: Next item, Mr.
18 Chairman.

19 MR. DeMURI: Okay. The next one,
20 John Foster is going to handle. It's
21 cornstarch.

22 MR. FOSTER: I just realized we've

1 already talked about cornstarch. That
2 conversation notwithstanding, we have, for
3 606, cornstarch up for sunset review.

4 We had no one bringing forth
5 comment against relisting. Several public
6 comments, again, were in generic faction,
7 requesting the relisting of this material.

8 It's obtained from the endosperm
9 of corn kernels, often included as an
10 anti-caking agent in baking powders. It's
11 also often used in powdered sugar and as a
12 thickening agent of soups or other liquid
13 foods, sauces, gravies, custards, dressings.

14 We reviewed original
15 recommendations. This is one that's been on
16 the 606 for a long time, pre-Harvey, and has
17 a fair amount of older documentation that we
18 looked at. Let's see -- did not find any
19 unacceptable risks to the environment. Again,
20 my favorite Google and Wikipedia searches
21 didn't unearth any big changes in its
22 production that, in my opinion, would question

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1 the classification as an agricultural
2 substance.

3 We looked at the basis for
4 previous and NOSB decisions, and again, we
5 just want to again remind everyone that if it
6 does go on the list, it should be subject to
7 commercial availability determinations by
8 ACAs.

9 That's going to be my mantra for
10 couple of years, I think.

11 MR. GIACOMINI: Questions,
12 comments on cornstarch? Jay?

13 MR. FELDMAN: Thanks, John.

14 I couldn't hear what you said
15 about classification materials and whether you
16 guys did an analysis of that and made a
17 finding on the synthetic/non-synthetic issue?

18 MR. FOSTER: Consistent with our
19 discussions around classification of
20 materials, this came out. We didn't do a
21 separate questioning of whether or not this
22 was to be reconsidered. But the determination

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1 has always been that it's been agricultural
2 and appropriate to be listed on 606.

3 MR. GIACOMINI: Katrina?

4 MS. HEINZE: It's my understanding
5 that review of classification is not part of
6 the sunset review at this time.

7 MR. GIACOMINI: Further questions
8 and comments? John?

9 MR. FOSTER: I should have also
10 said the vote was six to relist; none against;
11 and one absent.

12 MR. GIACOMINI: Thank you.

13 Anything else on that item?

14 (No response.)

15 MR. GIACOMINI: Seeing none, Mr.
16 Chairman.

17 MR. DeMURI: All right, our last
18 2012 sunset item for this meeting, and the
19 last one on 606, is whey protein.

20 Whey protein concentrate is used
21 in culture, dairy and yogurt products at a
22 level of less than one percent and typically

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1 used to maintain the physical texture and
2 consistency that would otherwise be
3 contributed by the fat; often used in nonfat
4 and low-fat yogurt as a fat replacer.

5 It's manufactured from mozzarella
6 cheese whey using an ultra-filtration process
7 to remove a large portion of the lactose and
8 minerals. The process does not involve the
9 use of any chemicals. Whey protein
10 concentrate is then spray-dried and sold as a
11 dry ingredient.

12 We received no public comments
13 objecting to the relisting of this material.
14 And again, we had several that favored its
15 relisting, usually as part of a general
16 comment on relisting what was up for sunset.

17 The Handling Committee voted five
18 yes and zero no for relisting, with zero
19 abstentions and two persons absent.

20 MR. GIACOMINI: Discussion? Joe?

21 MR. SMILLIE: I'm hoping to hear
22 that that's one of the target items for the

1 entrepreneurs out there, as we've got a
2 functioning organic dairy industry, and I
3 don't know of any ways that whey couldn't be
4 produced organically.

5 So I'm hoping that that will be a
6 target, unless during your research, you --
7 there's some reason why we shouldn't see that
8 as a target for dairy entrepreneurs to come up
9 with an whey, in which case, being on 606, if
10 that's available, they've got an exciting new
11 product to sell.

12 MR. GIACOMINI: Other comments and
13 questions?

14 (No response.)

15 MR. GIACOMINI: That may end up,
16 Joe, being a supply issue on the demand for
17 whey product versus the supply of what's
18 coming out of the organic cheese industry,
19 which has floundered, fluid milk and other
20 things, in the organic industry for
21 consumption.

22 So, Mr. Chairman, one more item.

1 MR. DeMURI: Thank you. Yes, our
2 last item for the day, Tracy's going to handle
3 for us. It's a discussion document on
4 nutrient vitamins and minerals.

5 MS. MIEDEMA: Thank you, Mr.
6 Chair. This is a discussion document, so we
7 won't be voting on it.

8 This topic of nutrient vitamins
9 and minerals, and more generally,
10 supplementation and nutrient fortification of
11 organic foods, was precipitated by a few
12 things. The big one was, as some of you who
13 were at the last meeting would remember, the
14 announcement by NOP revising a previously held
15 interpretation of 21 CFR 104.20, which
16 previously allowed certain accessory nutrients
17 to be included under that National List
18 listing of 605(b).

19 The reinterpretation was that,
20 first of all, the Program asked us to withdraw
21 our sunset consideration that we had presented
22 for the material. It is up for relisting in

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1 2012, so there's definitely some urgency
2 around the material generally. But the
3 Program asked us to table our recommendation
4 for the time being, kind of go back to the
5 drawing board and look more generally at
6 fortification policy.

7 So, in the spirit of really being
8 a conduit to the public, to business, to NGOs,
9 we took this opportunity of this meeting to
10 pose questions to the industry to help shed
11 light on nutrient fortification of organic
12 foods and some of the specifics around the
13 annotation. So -- let's take a quick look at
14 those, and I'll try to review what's come in
15 so far.

16 There were nine comments, I
17 believe, that came in during this session, and
18 I think one of the most illuminating things we
19 found is that there's a 21 CFR 101.9 listing
20 that is much more up to date than FDA uses as
21 nutritional guidelines for foods, it's
22 actually for labeling. Whereas, the 21 CFR

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1 annotation that we have hasn't been updated
2 since 1995.

3 The intent of that '95 FDA title
4 was really to prevent over-fortification or
5 under-fortification and just give some
6 restricting principle to fortification of
7 foods. At that same time in '95, that's when
8 the NOSB first added nutrient vitamins and
9 minerals to the National List.

10 I'm doing a little bit of recap
11 here from the last meeting, but I think it's
12 really important to go back to what the intent
13 of the NOSB was in '95 and to what happened
14 because that's the most salient point to why
15 we are where we are today.

16 In their '95 recommendation, it
17 was very clear that this topic of
18 fortification was not a static one. It was
19 very changeable. Research was burgeoning and
20 continues to burgeon, and there's a lot of
21 unknowns about human health. Processing of
22 food does things to our nutrients. We don't

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1 eat the same way we always have and always
2 did, and the science is just really blossoming
3 out there. When you read the '95
4 recommendation, there seems to be a real sort
5 of open door that organic foods shouldn't
6 become sort of static and nutritionally
7 inferior to the mainstream food system.

8 Now, the specific restricting
9 principle that the '95 Board used was
10 independent professional associations: If
11 they vet these nutrients, then that would
12 qualify a material. Well, it is a big wide
13 door open, and it was something that the
14 Program really couldn't work with at the time,
15 and they needed to find something that fit
16 more into a regulatory framework.

17 I don't know that we have a
18 crystal clear answer on why that particular
19 portion of the CFR was settled upon. In a
20 way, it doesn't necessarily matter; we are
21 where we are today. But what I believe we
22 could really agree on is that something

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1 changed from the time the board made their
2 recommendation to the time when the annotation
3 was listed -- or, the annotation was added,
4 sorry.

5 The confusion about the future
6 Programs and staff within the Program trying
7 to interpret that -- they went back to the
8 recommendation from the board and read one
9 thing, and to the CFR and read another.
10 There's also a little confusion just in
11 looking at the 21 CFR 104.2.

12 So, Organic Health did a really
13 nice job of charting out the differences
14 between the 21 CFR 104.2, the 21 CFR 101.9,
15 and our own TAPs that we perform for nutrient
16 vitamins and minerals, and none of these
17 columns of actual nutrients align across the
18 board.

19 So the upshot is we've got a lot
20 of great information that has poured in during
21 this session, and I believe it will be very
22 helpful as we move into the next phase for us

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1 as a board and the material sunseting, and
2 how we approach the sunset of nutrient
3 vitamins and minerals specifically.

4 I also hope that this material
5 that came in through the Federal Register
6 helps the Program, and I know on the first day
7 when they gave us our update yesterday, said
8 that there was revised guidance on this topic
9 was in clearance. I hope it's not too late to
10 incorporate the information that has come in,
11 because this was our one time to open the door
12 for that information to flow in.

13 We, in good faith, went ahead,
14 took your advice, put it out there, and
15 hopefully, that material will really become
16 informative to what you all are working on.

17 MR. GIACOMINI: Comments and
18 discussions?

19 (No response.)

20 MR. GIACOMINI: Seeing none -- oh,
21 Miles? Joe?

22 MS. MIEDEMA: Miles? Miles?

1 MR. GIACOMINI: Tracy, turn yours
2 off.

3 Joe? Or Miles, did you have a
4 statement?

5 MR. SMILLIE: I'm sorry; who was
6 first, Miles or me? Sorry.

7 MR. GIACOMINI: Fine. I'm only
8 the Chairman.

9 Go ahead, Miles.

10 MR. McEVOY: Okay. All the public
11 comment is going to be very, very helpful for
12 us in terms of how we move forward on this.

13 First of all, the draft guidance
14 that we have that's in clearance would be
15 published as draft guidance. There would be
16 a 60-day comment period, and additional
17 information would come in that we'd then be
18 able to publish as final guidance.

19 What that is specifically about is
20 our correction of our misinterpretation in the
21 past of the reference, "nutrient vitamins and
22 minerals," in accordance with 21 CFR 104.20.

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1 In addition, though, the actual annotation
2 that's in the NOP regulations is not aligned
3 with the original '95 recommendation from the
4 board.

5 So that's why we're asking the
6 Board to go back and look at the original
7 recommendation, update that recommendation,
8 and then make a recommendation, should that
9 annotation be changed to something that more
10 specifically addresses what substances the
11 Board wants to have to be allowed as nutrient
12 vitamins and minerals, or accessory nutrients
13 or nutrients in infant formula.

14 You know, more specifically, what
15 does the Board, with your statutory authority
16 of what's allowed in processed organic foods,
17 we want to that guidance from you or
18 recommendation from you. And then we can do
19 the rule making necessary to get that into the
20 Federal Register.

21 This also points to the
22 perspective of the Board. This is a perfect

1 reason why annotations should be looked at by
2 the Board during the sunset process, because
3 you have a perfect opportunity to make a
4 recommendation to fix this reference to
5 104.20. If that's not what the intent of the
6 NOSB, that you want something different than
7 that, then you could do that if you change
8 your policy to it to look at annotations
9 during this sunset review process.

10 MR. GIACOMINI: Joe?

11 MR. SMILLIE: Miles answered a
12 couple. I would just appreciate it -- I don't
13 know if the rest of the Board would like you
14 -- but, Tracy, if you could just walk us
15 through some of your overview of the responses
16 to the six questions.

17 MS. MIEDEMA: I'll do the best I
18 can here. The folks in the audience are
19 really the experts on this, and I feel like
20 much more of a conduit than an expert here.
21 But scientific developments -- we had a whole
22 host of scientific developments that were

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1 spelled out in various comments, especially in
2 the areas of brain development.

3 On the second question, legal
4 developments, one of the big developments is
5 the 21 CFR 101.9 revisions of 2005 that came
6 forward. You know, even the final rule
7 happened, so that's salient there.

8 The rationale was really the crux
9 of what we're trying to get at here. I've
10 started abandoning the idea that we need to
11 unravel what the rationale was because, you
12 know, it is what it is now, and the Program
13 needed to choose a restricting principle, and
14 that's what this is.

15 I guess where we could get some
16 really great guidance from the Program is,
17 what does the Program consider an acceptable
18 restricting principle since "independent
19 professional associations" was inadequate and
20 there seems to be a real feeling that what was
21 given by the Program, imposed upon this, was
22 also inadequate? So there's the two choices

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1 that don't work. What do you all think are
2 even in our realm of options of restricting
3 principles? Or do we drop the annotation
4 altogether?

5 The fourth question is a bit
6 philosophical, about whether we think organic
7 food should be fortified differently than
8 conventional food, and commenters weighed in.
9 Of the nine commenters, there was a strong
10 sentiment toward allowing more novel nutrients
11 into organic food.

12 Then questions five and six are
13 really questions that -- this has to do with
14 the role of the NOP, the role of the NOSB --
15 what is our statutory authority? Now, we know
16 that we can, from a statutory perspective,
17 make annotation change, but we can't currently
18 do that with our policy and procedures manual.

19 How much influence should the NOP
20 have had over that restricting principle? Can
21 they take something that the NOSB does and
22 kind of tweak it and mash it into a box to

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1 make it fit?

2 And that was kind of what we were
3 probing there.

4 MR. GIACOMINI: Just one
5 clarification there, Tracy. We can make
6 annotation changes, and it is within our
7 policy and procedure manual. It's just that
8 we're currently not allowed to do it in
9 conjunction, piggybacked -- however you want
10 to tie together -- with sunset. That's the
11 restriction, not that we can't do it, not that
12 we can't do it as the Handling Committee did
13 in a number of cases today. We can do it.
14 It's just whether we tie it to sunset. So to
15 say that we can do it is not quite accurate.

16 Any further questions or comments?
17 Kevin?

18 MR. ENGELBERT: Tracy, what has
19 triggered the surfacing of this issue of
20 nutrient vitamins and minerals and the request
21 from the Program for some recommendations from
22 the Board?

1 MS. MIEDEMA: Would you like to?

2 MR. GIACOMINI: Go ahead.

3 MS. MIEDEMA: Well, this is the
4 hornet's nest. We're going to kick it a
5 little here.

6 You know, the supplementation in
7 infant formula has helped precipitate this
8 issue. I can remember, three or four years
9 ago, public comment that was very volatile,
10 very emotional on this topic. It had to do
11 with hexane extraction within these accessory
12 nutrients. I think we used a very blunt tool
13 to deal with this when we really needed to
14 probably -- I'm talking about the Program --
15 needed to use more of a scalpel.

16 If we're talking about how
17 synthetics are produced, hexane is a big issue
18 all on its own. I don't think we should just
19 look at it in terms of one material on the
20 National List. If we have a problem with the
21 way synthetics are produced, we should look at
22 that more broadly. So that was part of it.

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1 And there was a fair amount of
2 media attention about a year ago, just some
3 real coalescing of some consumer concerns and
4 a very orchestrated and well-publicized effort
5 on the part of NGOs and watchdogs to gather
6 opinion. That's me editorializing. That's my
7 opinion.

8 MR. GIACOMINI: Kevin?

9 MR. ENGELBERT: I think it's
10 important to have this as part of the public
11 record. That's all. I thought that was it,
12 but I just think it's important that we're
13 transparent, this is how things are dealt with
14 and, you know, we will live up to our
15 responsibilities when they're put to us.

16 MR. GIACOMINI: Further comments?
17 Questions? Discussion?

18 (No response.)

19 MR. GIACOMINI: Okay, seeing none,
20 Mr. Chairman.

21 MR. DeMURI: I'm happy to report
22 that completes our presentations for today.

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1 MR. GIACOMINI: All right. The
2 Chair is looking at the clock. We are still
3 way behind. We are coming up on a scheduled
4 break, but I think we're going to try and see
5 if we can at least get through one more
6 committee before we do that, Materials
7 Committee.

8 Katrina.

9 MS. HEINZE: I do have three things
10 on the Materials agenda today. Two are
11 listed, so if folks need a break, we could
12 handle the first two and get to nano third.
13 So if that is necessary, wave to the Chair.

14 Okay, for the Materials Committee
15 update, there are two items listed on the
16 agenda today. I also want to provide an
17 update on a significant work plan item that
18 the committee has started around process
19 improvement for our materials process. I'd
20 like to start with that and then give the
21 update on classification of materials and our
22 progress. And then, finally, we'll talk about

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1 engineered nanomaterials in our recommended
2 guidance.

3 First, before we talk about that,
4 I want to thank Lisa Brines, the NOP National
5 List coordinator, for her collaboration with
6 our committee. Her work has significantly
7 improved our ability to track materials
8 through the process and stay on top of our
9 deadlines.

10 Personally, from the Chair who had
11 to do the bulk of that in the past, I am very,
12 very grateful, and I think Dan would second
13 that as the previous Materials Chair. Lisa is
14 doing a phenomenal job for us, and it is a
15 huge, huge improvement for the Board to have
16 her there helping us.

17 Second, I want to thank the
18 committee for their very thoughtful and
19 respectful debate on engineered nanomaterials
20 since the spring meeting that has taken up
21 every Committee call that we've had, countless
22 hours of email. Really, this is a topic where

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1 every single one of us recognized that our
2 consumers wanted us to take immediate action,
3 but on which we deferred on how to take that
4 action.

5 I really appreciate that everyone
6 was very engaged in the discussion and debate
7 and worked hard to develop a recommendation
8 that we all felt would have Board support, but
9 did it in a really respectful way. That
10 speaks to the quality of the folks that we
11 have on the Board, and I appreciate it.

12 Materials process -- the Board,
13 the NOSB identified at the spring meeting that
14 there was work to be done to improve our
15 petition, technical review, and evaluation of
16 materials. The Material Committee agreed to
17 put that on our work plan and to work in
18 collaboration with the NOP. I think Dan's the
19 one who always says, "The process is broken,"
20 so we are attempting to fix that.

21 So I just want to give the Board a
22 brief update on our progress so you know what

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1 to expect as we continue to work on this.
2 I'll expect we'll have a much more detailed
3 update at the spring meeting.

4 As a committee, what we did is we
5 spent part of one of our calls really giving
6 everyone a chance to talk about all the things
7 that they didn't like about the process or
8 that they had heard that other folks did not
9 like about the process, and we bundled that
10 into a series of categories or a series of
11 actions that we could take. I'll just list
12 these.

13 One was to really tackle the whole
14 petition process as a whole.

15 The second one was to tackle
16 pieces of the petition process and maybe fix
17 individual parts of the petition process.

18 Next was to revise the current
19 Materials Evaluation Checklist to handle some
20 of the more complex material evaluations that
21 we have now, such as annotation changes,
22 change of location on the list, material

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1 review, that don't fit neatly into that
2 checklist.

3 Next was to tackle the TR process
4 as a whole and then to tackle it in pieces.

5 And just finally, to look at the
6 whole process flow.

7 So those were the six things that
8 we ended up brainstorming.

9 We've had some preliminary
10 discussion on how to prioritize this, and we
11 looked at three things: whatever we decide to
12 work on, how it would impact the quality of
13 our Board reviews of the materials.

14 The second was, how easy would it
15 be to get done? We talked about wanting to
16 have some quick wins so we could really start
17 making progress on this and give folks on the
18 Board, as well as the public, some confidence
19 that we were improving our processes.

20 And then, finally, impacts on the
21 concerns we'd heard about the process.

22 So based on that, our current

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1 thought is that we have the capacity to tackle
2 working with the rest of the NOSB committees
3 and the Program -- probably two or three items
4 on our list -- and then that we could build a
5 roadmap for the next several years. So we're
6 thinking that we would kind of map out for
7 about two years, two or three years, here's
8 how we're going to tackle it to really make
9 some improvement.

10 We're intending to take what we
11 hear at this meeting, feedback we get from the
12 Board, as well as, you know, hallway chatter,
13 to finish getting input. And then we'll
14 finalize our roadmap, make sure that the rest
15 of the Board and the Program knows what that
16 is, and begin our work.

17 A preliminary thought right now is
18 that we would focus on revising the current
19 Materials Evaluation Checklist, as I talked
20 about, and then tackle the TR process in
21 pieces. Right now, we're looking at two
22 pieces.

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1 One is to develop a TR request
2 form -- and we've talked about it a lot when
3 we talked about materials today -- that TRs
4 are not one-size-fits-all. There's a lot of
5 unique circumstances. You know, "removal" is
6 different than "list"; "moving" is different.
7 Sometimes we want to look at alternative
8 materials. So, having a form that would make
9 it easier to request TRs but customize them to
10 a specific situation seemed like that would
11 have a lot of value. It is something that we
12 could accomplish fairly quickly.

13 And then the second was to define,
14 what does a good TR look like? I know the
15 Program has spent a lot of work on that, so
16 that's something that perhaps we could tweak
17 with the rest of the Board and really improve
18 the quality of our TRs, which will make our
19 reviews better.

20 That's kind of what we're looking
21 at. I wanted you to be aware. If you have
22 questions, I'd be happy to entertain them, but

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1 like I said, there will be more work on this.

2 MR. GIACOMINI: Questions or
3 comments? Steve?

4 MR. DeMURI: Maybe I missed it.
5 What's your target for having something to us?
6 Before the next meeting?

7 MS. HEINZE: I think our thought
8 is, we meet monthly, so at our next meeting,
9 we'd finalize what the plan is, get that to
10 you guys for some feedback. That would happen
11 for the vice chairs of the Crops, Livestock
12 and Handling Committees. And then if no one
13 disagrees, we'll start the work and hopefully
14 have some documents for the spring meeting if
15 not before.

16 MR. GIACOMINI: Questions or
17 comments?

18 (No response.)

19 MR. GIACOMINI: Seeing none, we
20 are at 4:40.

21 MS. HEINZE: Okay. Next is just a
22 quick update on classification.

1 When we were building the agenda
2 for today's meeting, we felt that it was
3 really important to give a verbal update
4 because there's been so much public interest
5 on classification. It's been an ongoing
6 dialogue between the Board and the public and
7 the Program, so we wanted to just make sure
8 that folks knew how we are progressing after
9 our recommendations of October 2009 and April
10 2010.

11 I'll be honest, we have not worked
12 on classification as much as we would have
13 liked, given the heavy sunset load that folks
14 had this summer. But we've refocused in the
15 last month, and we're picking things back up.

16 Really, the focus is on developing
17 some draft worksheets that would aid in
18 classification. We got very clear feedback
19 that we need different worksheets for crops,
20 livestock, and handling. We agree with that
21 and so we're starting to work on that.

22 We also received the NOP feedback

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1 on our recommendations at the end of
2 September. We really thank them for their
3 careful consideration of our two
4 recommendations. Just some key highlights
5 from those recommendations: they agreed that
6 worksheets should be by use of the material.
7 That matches the other feedback we got and so
8 we're going to work on that.

9 They did suggest that we include
10 livestock feed as a material use and consider
11 a separate worksheet for that. So we'll look
12 into that.

13 They did ask about one of our
14 guiding principles, which was that the same
15 material can be agricultural, non-synthetic or
16 synthetic depending on source and process, and
17 wondered if that was redundant from the first
18 one. It may be. We included that because
19 that was a really critical turning point in
20 the Material Working Group discussions and in
21 the Board discussions. So that's why we
22 included that.

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1 They supported our voting
2 practices on chemical change. We talked about
3 this a little bit earlier. They provided some
4 detailed feedback on our proposed definition.
5 Specifically, the Program did not agree with
6 the sentence that we added in our addendum in
7 April of 2010.

8 Then they had some additional
9 questions on the other definitions. Ideally,
10 those questions would have come up during all
11 our work on the document, but I do understand
12 we had a lot of personnel transition and you
13 got it to us as soon as you could.
14 Nevertheless, we do believe that most of those
15 questions, we did talk about in our
16 discussions. And what we're hoping is that,
17 as we work on the draft worksheets, all those
18 questions will be addressed and we can work
19 through it.

20 Specific to the April 2010
21 addendum, we did that addendum because of
22 public comments we'd received in November of

1 2009. And now it's possible that working
2 through the worksheets, we can address those
3 public comments in worksheets. But we'll be
4 working with the Program to figure that out.

5 We've also received a number of
6 comments in preparation for this meeting that
7 offer additional perspective on
8 classification. We appreciate that the public
9 is continuing to be engaged in the topic, and
10 we're going to focus on the worksheets and
11 incorporate your comments.

12 So we'll continue to work with the
13 other committees. I'm hoping to have draft
14 worksheets completed prior to the April 2011
15 meeting so we can get those finalized.

16 So that's our timeline. That's
17 our update. We didn't want folks to think
18 we'd forgotten this and had stopped working on
19 it.

20 Any questions?

21 MR. GIACOMINI: Questions or
22 comments?

1 (No response.)

2 MR. GIACOMINI: Okay, we are at
3 4:40, which is the timeframe, it's on the
4 agenda as recess, but it is also the timeframe
5 for our break. We can either try and complete
6 materials with the nanotechnology discussion
7 or take a break. We will take a break after
8 that, so it's really a matter of now or then.

9 What's the feeling of the Board?

10 MR. DeMURI: What time is the
11 shuttle leaving?

12 MR. GIACOMINI: 6:10. The bus is
13 leaving at 6:10. We need to try and shoot for
14 six o'clock here, folks. But that really
15 doesn't change whether you want -- I mean,
16 we're going to take another break before we
17 quit. There's no way to go that length of
18 time.

19 MR. ENGELBERT: Could we just take
20 individual breaks, Dan? Would that work so we
21 can just keep going if somebody has to leave?

22 MR. GIACOMINI: I think we've got

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1 a couple of pretty significant items here that
2 I would hate to have members of the Board
3 having to be gone for personal reasons.

4 Let's take a ten-minute break.

5 (Whereupon, the above-entitled
6 matter went off the record at 4:43 p.m. and
7 resumed at 4:52 p.m.)

8 MR. GIACOMINI: We're back in
9 session. A quorum is present.

10 Okay, Katrina, we're back to you
11 as Materials Chair.

12 MS. HEINZE: Okay, we have our
13 major item, which is engineered nanomaterials.
14 And I want to thank Dan for being our lead
15 person on this topic and championing it
16 through the debate. So Dan is going to
17 present it. Is that correct?

18 MR. GIACOMINI: Thank you.

19 The Materials Committee and this
20 Board have been working on nanotechnology,
21 with various documents being submitted for
22 discussion, vote, withdrawal, discussion, for

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1 two years. There was a request from public
2 comment for a scientific input on a technical
3 review. We thought that was a good idea, and
4 we did do that to proceed with help in
5 creating a definition of what, within
6 nanotechnology, we were most interested in.

7 Regarding this document, I want to
8 be real clear on some things -- and I
9 apologize, I don't think it will take any more
10 time, but I'm going to be a little redundant.
11 No one wants to allow nanotechnology in
12 organic production and processing now.
13 However, there is confusion into what it is
14 and what we are talking about.

15 When we come to define what we
16 want to prohibit, do we want to prohibit
17 homogenized milk? Do we want to prohibit
18 aspects of grain milling? The general feeling
19 is that we didn't. We then went to the TR and
20 we tried to craft a definition of what we
21 defined as engineered nanomaterials, as the
22 portion of intentionally created nano products

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1 that we felt the industry saw the most
2 importance in. That's been posted. I'm not
3 going to read it here.

4 But even within that definition,
5 we had debate, particularly over the use of
6 size. Do we limit it to 100 nanos? Do we
7 limit it to 300 nanos? Do we limit it to 500
8 nanos? We have an FDA document that talks
9 about 1,000 nanometers, but that document says
10 it's only relevant to that document and their
11 drugs, so we really don't know where that's
12 going to go.

13 But we also -- and simply the
14 debate over whether we even really include
15 size at all -- because there were members of
16 the committee who felt that it's really the
17 change in the functionality from the bulk
18 substance to the nanosubstance that is the
19 significant factor. So, do we want to be
20 constrained with a size limitation at all was
21 all part of our discussion.

22 We did include it in the

1 definition, but we were very specific in
2 saying that it was the small size that created
3 specific properties and compositions, such as
4 shape, surface properties, and chemistry.

5 No one wants nano in organic right
6 now. However, there's difference of opinion
7 and concern over what the Program is going to
8 be able to enforce. Of course there is
9 concern on the use of nano in the production
10 systems, but from the production system to
11 consumer consumption, there is just as much of
12 a concern over nano as contaminating organic
13 products, the products that are certified in
14 the various categories.

15 There's great concern over whether
16 the Program will be able to really enforce
17 aspects such as the contamination that would
18 come about from food contact surfaces and
19 primary packaging.

20 No one wants nano in organic
21 production and processing right now, but it is
22 unclear exactly how to handle what some people

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1 in public comment have criticized us for. But
2 we felt that it is valid to consider the 'what
3 ifs.' What if a factory with a single water
4 supply source or a farm with a single water
5 supply source has, from that supply,
6 nanofilter technology included in that water
7 supply, and there's some contamination of that
8 water? Do they lose organic certification?
9 Are they forced to close? Will they be forced
10 to move? What exactly is the consequence of
11 those types of 'what ifs?'

12 Those are the things that we are
13 asking the Program to evaluate. At the last
14 meeting, the Program requested that we bring
15 forth the Materials Working Group
16 classification of material document more as
17 guidance, to see how it worked, and we felt
18 that was a sound process to proceed with in
19 this situation because we would be very
20 concerned with putting forth a document that,
21 in the long run, the Program ended up in a
22 position where they couldn't enforce what we

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1 were requesting and the ramifications that
2 that could yield.

3 Nobody wants nano in organic right
4 now. But how do we restrict it? Do we
5 restrict it with a huge, solid wall? Or do we
6 restrict it with a huge solid wall with a door
7 in it that, right now, we lock? What is the
8 best way to proceed? There is certainly a
9 portion of the public comment that says, put
10 up the wall, and there is also other comment
11 that says, it is new technology and we are
12 concerned about it, but because of the fact
13 that it is new technology and we don't know
14 where it's going to go, let's not be quite so
15 ready to proceed to throw, as they say, the
16 baby out with the bathwater, without knowing
17 what we are going to be fully and completely
18 eliminating.

19 And again, no one wants nano in
20 organic right now. But as I just mentioned,
21 we don't know where it's going, and as a
22 result, we called for a symposium to discuss

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1 the issues that we've already talked about, to
2 discuss some of the developments of the
3 industry, not for the industry to be able to
4 come in and do a ganged-up cheerleading
5 expedition of how great nanotechnology is, but
6 at the same time, not just a trashing session
7 without a consideration of where certain
8 aspects of the industry might be going.

9 Thoughtful consideration, looking
10 at the questions that we've evaluated, that
11 we've considered, and trying to, again, as we
12 bring this forth, we're going to need to
13 continue to look at it as a Board, the Board
14 is constantly turning over members, and we're
15 going to need to get new members up to speed
16 as well.

17 No one wants nano in organic right
18 now. But Jay and I both sat down and we
19 counted the votes. And between all of these
20 different issues, there's a lot of differences
21 of opinions. Certain people like something
22 because of one thing that would be included.

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1 Certain people didn't like it because of
2 something else that was included. And both
3 Jay and I, independently looking at our best
4 guess of the votes, could not find a
5 definitive way of listing a prohibition or an
6 'it's a synthetic' recommendation that was
7 going to be long-term, lasting, that would
8 pass.

9 We were all concerned on the
10 committee that the worst possible thing we
11 could possibly do would be to come forth with
12 a nanotechnology document that failed. And
13 all across the organic press and the media
14 would be that the NOSB failed to restrict
15 nanotechnology. We wouldn't feel that that --
16 whether that's fair or not, that could be up
17 for debate, but we felt that one of the worst
18 possible things that we could do would be to
19 present a document that doesn't pass.

20 And remember, our documents
21 require a two-thirds vote. So we would need
22 10 people. We came up with a lot of eights and

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1 nines, but we didn't come up with any 10s.

2 So what is this document doing?
3 It is creating a definition which we believes
4 fits within the definition in terms of the
5 regulations in the category of 'synthetic'.
6 We believe that there is enough evidence that
7 the substances that qualify under this
8 definition are synthetic and fit under the
9 definition of 'synthetic' now.

10 We're requesting the Program to
11 recognize that anything currently on the list
12 is on the list in a bulk form and was never
13 reviewed by this board in a nano form, and
14 that the current listing on the National List
15 is not an allowance for a nanoparticle-size
16 substance.

17 It is also requesting the Program
18 to look at the level and ability of what they
19 are going to be able to enforce, and it is
20 requesting the Program to look at the what-if
21 situations so that the Board is well aware of
22 what they are going to be imposing on the

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1 industry if some of these unintended
2 contaminations arise in the future.

3 So we do not feel this is nothing.
4 We do not feel that this is a compromise in
5 that sense. It is a compromise versus the
6 pure, absolute prohibitions of 105 and always
7 just saying it's synthetic. But we feel that
8 it is giving the Program something to
9 recognize and prohibit now, and it is
10 requesting cooperation from the Program to
11 work together to resolve these issues so that
12 we can proceed forward in the future with
13 whatever further restrictions the Board
14 desires to request.

15 Any questions and comments?

16 MR. GIACOMINI: I think we could
17 have done that before the restroom break.

18 Okay, Joe?

19 MR. SMILLIE: I think the
20 enforceability issue is really key. We've got
21 to come up with something that's enforceable.
22 If it's a total, complete ban, we could do

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1 damage, and I think that my favorite aspect of
2 all the great points that you brought out is
3 we've got to make sure that it's enforceable
4 because, as the representative of the
5 enforcement wing here, we're going to see
6 complications, and I want to make sure that
7 whatever we come up with at the end of the
8 day, the certifiers can enforce.

9 MR. GIACOMINI: Jeff.

10 MR. MOYER: I think your point is
11 well taken, Dan, that this is a topic that we
12 have been discussing for several years. We
13 worked on it a few times in the past. I know
14 when I was chair, we worked on it.

15 I think the document that we have
16 in front of the Board today is a fairly
17 reasonable compromise that allows us to move
18 forward and do something because I agree with
19 you that the damage of doing nothing far
20 outweighs the damage of doing something good.

21 While this does close the door,
22 it's not as tight as some of us on the Board

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1 would like it to be. We have created a door.
2 Some of us don't like that. But the door is
3 closed and locked, and I think at this point
4 it's probably the only thing that we can do as
5 a board.

6 You do have broad support for this
7 document. That's why you're not getting a lot
8 of comment. We've beat this puppy pretty
9 hard.

10 MR. GIACOMINI: But this document
11 also does not eliminate the elimination of the
12 door. Right now, it sets it as synthetic. We
13 believe it's synthetic. It gives the Program
14 something to work with.

15 Yes, it's a possibility that the
16 door could be opened in the future, but
17 there's also the possibility that the Board
18 could remove the door.

19 MR. MOYER: Yes, I guess as a
20 follow-up, I would just say you repeatedly
21 said that we don't want nanotechnology now.
22 You said that more than once, and I just

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1 wanted to state that there are those of us who
2 say "now and forever," but we're realistic
3 enough to know that we have to do something.

4 MR. GIACOMINI: The reason we went
5 this route was to get the "at least now."

6 MR. MOYER: I got you. That's
7 what I said; we beat this puppy.

8 MR. GIACOMINI: No, this is a
9 document for voting to -- we called it
10 guidance. I guess the Program may have some
11 suggestions for things that we call guidance
12 documents in the future. But right now, to
13 our historical reference, we've referred to it
14 as a guidance document.

15 Kevin.

16 MR. ENGELBERT: So you're
17 convinced and the committee is convinced that
18 a simple recommendation banning nanotechnology
19 now and in the future, with the details left
20 to public comments and ANPR and the Program,
21 with guidance from the Board as needed, would
22 not pass; is that what you're saying?

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1 MR. GIACOMINI: With all the
2 considerations for the debate about size,
3 debate about enforceability, debate about the
4 'what ifs,' neither Jay or I -- and we are not
5 in lockstep; we're not necessarily on opposite
6 sides of the fence, but we're not exactly in
7 the same place either -- when we were doing
8 our best considerations, neither one of us
9 could come up with 10 votes in either way,
10 that or saying it's just synthetic.

11 Barry?

12 MR. FLAMM: I read all the
13 comments, and they seem to be strongly
14 oriented, except some of the ones directly
15 involved with the industry. Most of the
16 comments were very strongly in favor of doing
17 it now, and even if there's a symposium, learn
18 from that and improve, but shut the door now.

19 Has that influenced your -- has
20 the committee looked at this in light of these
21 very strong and direct comments?

22 MR. GIACOMINI: Well, those are

1 similar comments to what we've heard on all
2 the previous discussions with the documents
3 that we've put forth on this topic. The
4 initial 'we want it now' is fairly universal
5 until you start getting into the details of
6 it; of, what do you want now? What do you
7 want restricted now? What is the size of what
8 you want restricted now? Do you want to
9 include homogenized milk and grain dust or
10 not? Should it limit it to 100 nanometers, or
11 does it go up to a thousand? Should it
12 include processing contamination or not? What
13 happens to the factory if it's imposed on
14 them? Those are all the things.

15 There's a fairly universal, and
16 always has been, initial response of now, and
17 that's an easy first question to do in a
18 survey. But when you then get into the
19 details of the things that you are going to
20 include as the 'now', it starts breaking up in
21 a lot of different directions.

22 And even with the TR, even with

1 the other documents that we worked with, there
2 was enough consideration of different ideas
3 from size and everything else on the
4 committee, and in our counting, we could not
5 envision a definite passing recommendation
6 that would not put us in the potential
7 situation of a nine-vote affirmative that
8 failed, and we're put in a position of, the
9 NOSB could not restrict nano.

10 This restricts nano. It's not the
11 end, but we feel that it does give the Program
12 enough to restrict it now.

13 Jay?

14 MR. FELDMAN: Thanks, Dan.

15 I agree with Kevin and Barry on
16 this in terms of where I'd like to see things
17 go. I think we have to find a voice here that
18 is clear to the public, as Dan has said, and
19 we should hopefully do it as a consensus vote.

20 I mean, there are other ways to
21 achieve this, but again, I think there's
22 hesitancy on the part of those that see some

1 future need to provide them with an
2 opportunity to explore some of these issues in
3 more -- I don't know much more depth we can go
4 in after two years -- but to do some more work
5 on this.

6 For instance, we could achieve the
7 same thing by closing the door, banning it,
8 essentially, putting it into it as an excluded
9 practice, and then have the symposium, and
10 then come back and say, at the end of the
11 symposium, a petition could be fashioned if,
12 in fact, elements of what the Board had done
13 needed to change.

14 There are other ways of doing
15 that, but those who see a potential future
16 need feel that that biases the process against
17 some future opportunity to allow it, which I,
18 given where I'm at on this and the comments
19 you referred to, would fight. And you know
20 that, Dan. I think this falls in the same
21 category as GMO radiation and sewage sludge
22 basically.

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1 Having said all that, I'm curious
2 as to whether the Department thinks the 'now'
3 that we're trying to establish with, no use
4 now pending this symposium and some further
5 deliberation, is an enforceable proposal. I
6 don't know if the Department has looked at it
7 and whether we could get a response from NOP.

8 MR. GIACOMINI: Program?

9 MR. McEVOY: Yes, we need to look
10 at this a little more carefully before we make
11 a response to this, so this will be very
12 helpful. But we'll need to look at this very
13 closely before we can give you a definitive
14 answer on that.

15 MR. GIACOMINI: The other aspect
16 of what we did here is that we specifically
17 did not request any regulation change. We
18 felt that it can just be done within,
19 hopefully within the guidance accepting of
20 that definition, that that definition fits
21 within the current synthetic.

22 MR. McEVOY: And I think that's

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1 part of what we need to look at.

2 MR. GIACOMINI: Right.

3 MR. McEVOY: Can this be done
4 through just guidance or a policy memo, or do
5 we need to do some rulemaking in this area?
6 So we'll take a look at that and get back to
7 you as soon as we can.

8 MR. GIACOMINI: Joe?

9 MR. SMILLIE: Could you elaborate
10 on the enforceability of what we need to give
11 to you? In other words, the enforcement
12 aspect is what obviously bothers me about it.
13 You know, 'We want to ban nanotech.' But
14 enforceability of a complete ban, can you see
15 problems with that? I don't mean future
16 possible good uses of nanotech. I'm talking
17 about inadvertent contamination, unavoidable
18 environmental contamination, and that sort of
19 thing.

20 MR. McEVOY: So you're asking how,
21 how could we verify, or how could certifiers
22 verify that nanotechnology's not being used?

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1 Good question. In terms of all the inputs
2 that are currently being used, certifiers are
3 evaluating all of those inputs to determine if
4 they meet the NOP regulations.

5 Are there specific criteria that
6 they need to incorporate in terms of getting
7 statements from manufacturers that these
8 products have not been produced through
9 nanotechnology, kind of like what they do for
10 GMOs? Is there any kind of list of
11 nanotechnology products out there that an
12 independent organization has available or a
13 government organization has available? It's
14 relatively easy to find what genetically
15 modified products are out there, but I'm not
16 sure on terms of nanotechnology.

17 So those are some of the questions
18 in terms of how does a certifier verify that
19 nanotechnology has not been used as an input.

20 Then you're also bringing in
21 questions of contamination. We certainly have
22 questions in terms of contamination with GMOs.

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1 What is contamination? There is no tolerance
2 level for GMOs. GMOs are excluded and can't
3 be used in any part of organic production or
4 handling, but if there's the presence of GMOs
5 in an organically produced or handled product
6 and that presence isn't there from a
7 purposeful, intentional use of excluded
8 methods, it's not specifically prohibited.

9 We still have a lot of things to
10 work out on GMOs, so does that mean that we
11 don't move forward on prohibiting
12 nanotechnology? If that's what the organic
13 community expects, that nanotechnology is not
14 part of organic production handling, then it
15 seems like that's the recommendation that the
16 Board should come forward with. And then we
17 will figure out how to define, how to verify
18 that nanotechnology is not part of the
19 process.

20 So it will be a work in progress,
21 but it's something that's very important to
22 consider. How do you verify that

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1 nanotechnology is not part of the process?
2 How deep do we need to go? How deep do the
3 certifiers need to go to verify this?

4 MR. GIACOMINI: One more question.
5 Kevin?

6 MR. ENGELBERT: Just one more and
7 then I'm going to be quiet. I'm just very
8 concerned that time is going to elapse and
9 we're not going to accomplish anything,
10 because I'm afraid that all your concerns and
11 questions are never going to have definitive
12 answers. There's simply too many unknowns.
13 There are too many possibilities that can
14 never be anticipated.

15 In all honesty, I hope I'm wrong.
16 I hope that this is the right step to take,
17 but I'm concerned that not putting up a wall
18 immediately, right now, with no exceptions,
19 we're going to rue the day that that didn't
20 happen.

21 MR. SMILLIE: I don't want to go
22 on forever either, but it's my last meeting.

1 It's my last chance to say something about it.

2 You know, I'm against
3 nanotechnology completely, but I also realize
4 the contamination issue, not future possible
5 good uses of nanotech. I'm not there. I'm
6 talking about contamination. And putting
7 people out of business -- well, you just can't
8 do organic in that county because of the
9 nanofilters in the water supply, or whatever
10 the other contamination packaging issues come
11 up that we have to face.

12 We just went through, we are still
13 going through, the GMO vaccines issue. I
14 mean, there it is right in front of you. It's
15 the elephant in the room. You know, we want
16 the vaccines, they are GMO, we've got a huge
17 problem. That's the kind of lesson that we
18 have learned. We are learning that we've got
19 to be really careful about unforeseen
20 consequences of some of the outrights.

21 There's a couple of solutions to
22 it. We do want to reassure -- we do want to

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1 act. We want the ban on nanotechnology, and
2 maybe we're closer than we think we are about
3 getting the wording right. I don't know, I
4 didn't participate in the Materials Committee
5 discussions. But I think we're close. I
6 don't think it'll be forever.

7 I think we can come up with
8 something pretty soon that's going to work for
9 everyone, including the enforcement, and
10 prevent the kind of problem we discovered with
11 the GMO vaccines.

12 The other thing about GMOs, and
13 the analogy is, I think, a good analogy, is
14 now they're getting slicker at disguising the
15 GMOs so that it's not quite as easy to find
16 out the penetration of GMOs into our food
17 supply. I mean, that's the latest
18 development, and now it's getting harder to
19 track that penetration.

20 I'm sure we're going to experience
21 the same thing with nanotech penetration,
22 especially into the packaging, filters, all

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1 sorts of things. We're a small little
2 minority out in the trade world, and they're
3 going to move forward with their technologies
4 regardless of what we say. So we just have to
5 take that into account and figure out a way.

6 I like the analogy of the solid
7 wall with the locked door. You see, that's
8 what I would want to vote for. As far as
9 getting onto the voting thing, you've got to
10 be careful because we don't want the votes to
11 fail. But if there's two votes, I would vote
12 for terming it synthetic and locking the door.
13 I wouldn't want to vote for the wall; I'd want
14 to vote for the locked door. That would be my
15 preference as a voter on the NOSB.

16 We don't want to get into a --
17 what's that called? -- Mexican standoff,
18 where, you know, who's going to blink first as
19 to which option wins. I want everybody to
20 agree on the final option that we choose and
21 we get a solid unanimous vote from the NOSB.

22 That's all I have.

1 MR. GIACOMINI: Comments?

2 Anything further? Katrina?

3 MS. HEINZE: Dan, thank you so
4 much for leading this discussion. I thought
5 it would be useful if you could just go
6 through the bullet points of what our
7 recommendation actually does. I think that's
8 worth putting on the transcript.

9 MR. GIACOMINI: Okay. The
10 Materials Committee moved to accept this
11 document as a guidance document specifically
12 asking the NOP to accept as a working
13 definition:

14 Engineered nanomaterials:
15 substances deliberately designed, engineered
16 and produced by human activity to be in the
17 nanoscale range, approx 1-300 nm, because of
18 very specific properties or compositions, for
19 example, shape, surface properties, or
20 chemistry, that result only in that nanoscale.
21 Incidental particles in the nanoscale range
22 created during traditional food processing

1 such as homogenization, milling, churning, and
2 freezing, and naturally occurring particles in
3 the nanoscale range are not intended to be
4 included in this definition. All
5 nanomaterials, without exception, containing
6 capping reagents or other synthetic components
7 are intended to be included in this
8 definition.

9 o Point number 2: disallow the
10 engineered nanomaterial form of substances
11 currently on the NL since nothing on the NL
12 has been reviewed or a TR performed that
13 included any aspect of the manufacture, use
14 and disposal of the listed substances in a
15 nanomaterial form.

16 o Three: accept materials that
17 meet the working definition of engineered
18 nanomaterials as synthetic substances.

19 o Four: accept that engineered
20 nanomaterials may have unique properties that
21 distinguish them from all listings of these
22 substances in the bulk form, and that they are

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1 not allowed by a listing of the bulk form of
2 the substance on the National List, pending a
3 further recommendation from the NOSB, and
4 implementation thereof by the NOP, on the use
5 or prohibition of engineered nanomaterials in
6 organic production processing and packaging.

7 o Work with the NOSB to determine
8 whether enforcement of restrictions in primary
9 packaging and food contact surfaces is
10 possible, practical, and legal.

11 o Work with the NOSB to schedule a
12 symposium on the topic of engineered
13 nanomaterials to aid in evaluating (i) the
14 adequacy of the definition, (ii) any potential
15 areas of concern that may not be included in
16 this definition, (iii) the enforceability of
17 the various parts of the definition, (iv)
18 possible adjustments to the approximate size
19 constraints that may be needed, and (v) the
20 effect of different regulatory approaches,
21 including, but not limited to, a complete
22 §205.105 prohibition, a §205.105 prohibition

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1 unless as provided in the National List, or a
2 statement that these substance are synthetic
3 and all the prohibitions regarding that policy
4 would be in place; all for the purpose of
5 considering the development of a rule change
6 on their use or prohibition.

7 Katrina.

8 MS. HEINZE: Thank you. The
9 reason I asked you to do that is I voted
10 affirmatively for this document because it
11 asks the NOP to take specific action right
12 now. And we worded it very carefully that
13 way, right? We asked them to accept the
14 definition. We asked them to recognize that
15 it's synthetic. So, while this builds a
16 roadmap to help us figure it out, it also asks
17 the Program to take action right now so that
18 we can start working on this.

19 MR. GIACOMINI: Kevin.

20 MR. ENGELBERT: I'm going to break
21 my promise, sorry. One more quick comment,
22 Joe. I like the way we're doing analogies at

1 this meeting. It's really good.

2 (Laughter.)

3 MR. ENGELBERT: We're really
4 breaking new ground here. And I understand
5 the analogy with the wall and leaving the door
6 locked.

7 I still, even though GMOs may be
8 the elephant in the room and the wall was put
9 up, it may very well turn out that it was a
10 good thing it did and we aren't able to create
11 a door in the wall. But we still are going to
12 try now. And I would still rather have the
13 wall and have a door have to be created, not
14 just unlocked.

15 MR. GIACOMINI: It's not a rabbit
16 hole.

17 Any further comments?

18 Okay, Katrina, any more from
19 Materials? Materials is --

20 Joe, I'm sorry.

21 MR. SMILLIE: That's okay. Can you
22 scroll down? Up. Where am I?

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1 MR. GIACOMINI: One or the other.

2 MR. SMILLIE: It's the
3 second-to-last point that's not fleshed out
4 enough for me. I mean, I like the
5 recommendation. I'd vote for it, no problem,
6 it's good. But that last point, "Work with
7 the NOSB to determine whether" -- you mean the
8 NOSB?

9 MR. GIACOMINI: We're requesting
10 that they evaluate the process, evaluate --
11 that's the enforcement issue, right?

12 MR. SMILLIE: Yes, "Work with the
13 NOSB."

14 MR. GIACOMINI: Yes, to evaluate
15 the enforcement possibilities and to work with
16 us so that we understand really what is going
17 to be enforceable and what's not.

18 It's asking the NOP to work with
19 us after they evaluate what they're going to
20 be able to enforce.

21 MR. SMILLIE: Yes, so we're asking
22 them those specific questions?

1 MR. GIACOMINI: Yes.

2 MR. SMILLIE: So we're back to the
3 food contact substances and surfaces issue.

4 MR. GIACOMINI: Food contact
5 surfaces --

6 MR. SMILLIE: And substances.

7 MR. GIACOMINI: -- primary
8 packaging --

9 MR. SMILLIE: Right.

10 MR. GIACOMINI: -- and other
11 aspects of enforcement.

12 MR. SMILLIE: My point is the
13 same, though. Maybe it's too late, but I
14 would like to see a little more on that, a
15 little more prohibitory language or thoughtful
16 discussion on that point. But that's okay.
17 We can move on.

18 MR. GIACOMINI: Okay.

19 Further discussion on this topic?
20 Katrina?

21 MS. HEINZE: That is it for the
22 Materials Committee. Thank you.

1 MR. GIACOMINI: Thank you. Next
2 up is CACC: Joe Smillie, Chairperson.

3 MR. SMILLIE: Well, usually we've
4 got some heavy-duty recommendations. In this
5 case, we've got two small but, I think,
6 important recommendations. We'll try and get
7 through them as quickly as possible. They're
8 not as weighty items as what we've been
9 talking about, but they are important.

10 We're going to start off with our
11 recommendation on the 'Made With Organic'
12 claim. The history of that work plan item was
13 basically a request from the Program, not the
14 current Program but the previous Program, to
15 put it on our work plan.

16 At that time, it was felt that the
17 'made with' claim hasn't been properly
18 presented and that it needed a lot more impact
19 to it. They requested us to look at and
20 analyze the possibilities of creating an
21 alternate seal or a type of seal for the 'made
22 with' product.

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1 We looked at it, we had a couple
2 suggestions. We floated it out to the
3 community. And it was a hanging curve ball,
4 and it's in San Francisco Bay right now, and
5 the kayakers are looking for it.

6 So we went back and came out with
7 a recommendation that said, okay, well, seals
8 may be too dramatic, but we really do want to
9 honor that particular legal label claim and
10 make sure that the public knows that a product
11 that is a 'made with' product is actually
12 certified to the U.S. National Organic Program
13 regulation, and we want to be clear about
14 that.

15 That was the work, and Jennifer
16 took the lead on that, and she's going to be
17 presenting our recommendation.

18 MS. HALL: Thanks, Joe.

19 As Joe indicated, the original
20 request did come from the Program for us to
21 look at this and, I think, also with some hope
22 that it would help distinguish the legitimate

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1 'made with' products from some of the labeling
2 issues that are happening out there with
3 products that are masquerading as organic
4 because of different things we've been
5 unsuccessful from excluding from the
6 marketplace to date.

7 So we have continued to try and
8 work with your organic community to find
9 language that aptly represents the legitimate
10 status of the 'made with' category but does
11 not draw away from the higher categories, the
12 organic and 100-percent categories.

13 So that is what our intent was
14 with this new recommendation, and I think
15 people are fairly familiar with it. But the
16 core of it does come down to allowing, on the
17 principal display panel, a statement that
18 indicates to consumers at a glance the fact
19 that it has been inspected, that it has gone
20 through all of the rigor of the regulation.

21 Certainly, last time, we tried to
22 suggest that it might be appropriate to use

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1 the 'USDA Organic' seal, and that was not
2 warmly received, and understandably, that it
3 might add some confusion since the word
4 'organic' is so strongly stated on the seal.

5 So, we have come back with the
6 idea of putting a statement on there that says
7 "Certified to the USDA guidelines." In
8 discussion, clearly, initially we were looking
9 at just the 'made with' category but did not
10 want to be exclusive with that right and add
11 further confusion, that just that category
12 would have access to that statement. And so
13 we did suggest the option that any category
14 could use it that might want to.

15 The feedback -- one very
16 consistent item in the feedback that I
17 mentioned yesterday and will re-mention for
18 those who were not there who are now here, is
19 that on the document that we presented on
20 Thursday for a vote, we will change the word
21 'guidelines' to 'regulations' so that the
22 statement is "Certified to USDA regulations."

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1 That was the intent. It was poor wording, and
2 that is the beauty of getting feedback and
3 being able to re-do that and edit it to be
4 more accurate. So, definitely, thank you for
5 that.

6 The rest of the feedback was still
7 primarily negative. I think there was one
8 comment in support from Vermont, but the
9 remainder of it was still fairly negative,
10 ranging from folks who just purely didn't
11 think we needed it to those who still question
12 the legitimacy of it and/or the credibility of
13 the category.

14 Our committee did vote in favor of
15 it -- five yes; one absent; no noes; no
16 abstentions -- and though we've presented it
17 before, I think that I have a little different
18 perspective on it than maybe some, and I'd
19 like the opportunity, and I ask your patience,
20 to kind of explain a little bit of the scope
21 of perspective that I bring to it. I don't
22 think I've done a great job of that in the

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1 past, so bear with me.

2 I did write it out to make sure I
3 kind of hit the points because, even if the
4 Board does vote in favor of it, it clearly
5 would require the support of the full
6 community to make it successful. So I'd just
7 like the opportunity to kind of share my
8 thoughts about it.

9 Again, you know, we requested to
10 do this, and despite whether or not it's
11 requested, I still think it's a really
12 legitimate cause, and that we are not talking
13 about -- there was a comment that it was still
14 referencing the use of the seal. So, again,
15 I want to make it clear that we are not
16 promoting the use of the seal on the 'made
17 with' category products -- that we are
18 promoting the simple statement, "Certified to
19 the USDA regulations," on the principal
20 display panel to give it the legitimacy of the
21 USDA, and again, to make it easier to
22 recognize that fact on the front panel.

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1 So I just kind of want to review
2 some basics in my mind, and that is that the
3 regulation, as it was originally established,
4 does have three legitimate categories of
5 organic food production.

6 The 'made with' organic is a
7 minimum 70 percent, but in my mind, 70 percent
8 is a lot more than nothing. It is
9 considerably more organic content than
10 conventional and is still subject to
11 205.301(f)(1)-(3), which are the three items
12 that none of the products have. So I think
13 it's still head and shoulders above
14 conventional and is still a good product
15 category.

16 On a couple of levels, I think,
17 yesterday -- and perhaps we'll hear more --
18 organic has a little bit of a PR issue, and I
19 think that this category can help overcome
20 that. What it isn't, and how much it costs,
21 are still things of the organic category I
22 think could make some headway on. We're

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1 working, as always, on bolstering the
2 requirements, but I don't feel an equal
3 concern with making it more accessible to more
4 people.

5 An example of kind of the
6 perception that's out there -- I honestly just
7 found this as I was reading on the way here --
8 it's in the latest New York Times Magazine
9 that is completely dedicated to food issues.
10 This article is talking about incubator
11 businesses, food businesses in particular, and
12 talking about good food that is being sold for
13 a good value.

14 And I quote -- I'm using an
15 anecdote about one of the participants, the
16 owner of a shop they're talking about, telling
17 an interviewer that she didn't use organic
18 ingredients. "She finally admitted that
19 actually she does but avoids saying so
20 because, to many of her customers, it simply
21 sounds expensive."

22 I think that is a perception that

1 is out there most definitely. I constantly
2 hear in my work and from a lot of people that
3 organic is seen as elitist, and I don't think
4 that's a good place for us to be. So I think,
5 again, that this category can help, and that
6 we need to work on that perception. We have
7 food access issues in this country. We have
8 health issues in this country. Organic food
9 is better for people, organic food is better
10 for the planet, and how do we get it in more
11 mouths is one of my concerns.

12 While I don't disagree with some
13 of the comments suggesting a concerted
14 consumer education campaign, the majority of
15 the comments received from the community don't
16 lead me to believe that that will occur soon.
17 The gold standard bias toward 95 percent or
18 greater has been clearly articulated and is
19 understandable, but many people are cash-poor
20 right now, and making tough choices. We need
21 more affordable options for those who want to
22 consume or manufacture better foods, but are

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1 not a position to go the full extent every
2 time.

3 I include myself in that group of
4 people, struggling to deliver on my own
5 commitment to organics, given my own budget.
6 Like many consumers out there, I need an
7 option between the gold bar and a Hershey bar,
8 one that the industry supports with equal
9 commitment.

10 I fully agree that organic and 100
11 percent organic are more organic. I
12 respectfully disagree that the 70 percent
13 category is less credible by its nature. I do
14 believe we are in the process of potentially
15 making that true by consistently questioning
16 its value, and frowning on every attempt to
17 recognize it more fully.

18 There are those who treat the
19 'made with' organic category as though it is
20 cheating. To the contrary, from the
21 beginning, it has offered another available
22 organic production and labeling option.

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1 Mark Lipson shared yesterday the
2 goal that the Secretary added to the USDA's
3 strategic plan of 25 percent growth for
4 organic by 2015. While I'm not sure if that
5 is exclusively, in their mind, a revenue goal,
6 my goals would be 25 percent increase in the
7 number of consumers buying it -- in any and
8 all organic categories -- and the number of
9 acres in organic production. We will greatly
10 enhance our ability to achieve those increases
11 if the organic industry can embrace all of the
12 labeling categories.

13 USDA's slogan, "Know Your Farmer,
14 Know Your Food," is an important stride
15 forward in outward communication. It is also
16 the common goal of a marketing program to know
17 your customer. Without having to invest a
18 considerable amount in consumer research, we
19 have a variety of observed and reported cases
20 of customers telling us with their dollars,
21 with their shopping habits, what they want, by
22 choosing to purchase non-organic items that

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1 either mean more to them or are within their
2 budget.

3 The marketplace is still difficult
4 to navigate with confidence due to product
5 mislabeling. From my work and personal
6 interactions, I believe I represent a
7 significant percentage of current and
8 potential organic customers who need a
9 reliable way to identify legitimate and
10 credible 'made with' organic products.

11 We do have this 'made with'
12 organic tool at our disposal. I hope we can
13 fully recognize it as one of the original
14 labels under the National Organic Program and
15 the umbrella of the Agricultural Marketing
16 Service, and market it.

17 Thank you.

18 MR. GIACOMINI: Questions?
19 Comments? Katrina?

20 MS. HEINZE: Jennifer, I really
21 appreciate you going through the goals that
22 you have for this recommendation. I think

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1 that's very helpful, and I really do
2 appreciate the work.

3 You know, I was at Expo East for
4 the first time this year, and it was really a
5 fabulous experience. There was a lot of
6 chatter in the hall about the goals that you
7 have, and there was a lot of really good ideas
8 about what to do with labeling that might
9 address it.

10 It's clear from the public comment
11 that there isn't support for the
12 recommendation. I'm wondering if the
13 committee has considered throwing it to
14 industry, because I think they recognize the
15 goals and share the goals, but maybe as folks
16 who are labeling all the time, they might have
17 some creative ideas. I heard some very good
18 ones in the hall that I think industry could
19 really get behind and could support, to
20 accomplish the goals that you have.

21 MS. HALL: To answer your direct
22 question, we haven't talked about doing that.

1 There certainly may be room to do so, and we
2 can talk about that in committee before
3 Thursday.

4 MR. GIACOMINI: Miles.

5 MR. McEVOY: I appreciate the work
6 on this recommendation, but I think there's
7 some problems with the wording. For instance,
8 it says that the recommendation is "certified
9 to the USDA regulations" now. 'Certified'
10 what? Certified organic is what the category
11 says, 205.304. And, USDA -- what? There's
12 lots of USDA Programs. So if you want this to
13 mean something, it's got to clarify that it's
14 about organic or made with organic, just like
15 the regs say, 205.304.

16 The 'made with' category I think
17 is an important category, but we're seeing
18 some, what we would categorize as
19 misrepresentation in that category, and we're
20 trying to address that. We're working on
21 draft guidance to clarify what the
22 interpretation of the current regulations are.

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1 And as I've expressed previously, we see some,
2 what we think is misrepresentation by using
3 organic in the company or brand name of the
4 product on the principal display panel.

5 I'm not sure if this is the right
6 time to try to move this forward, when we're
7 trying to make sure that this category is
8 representing the category in an appropriate
9 way and not misrepresenting it, over-
10 representing it as the organic category.

11 So, those are just a couple of
12 comments.

13 MR. GIACOMINI: Response to Miles,
14 or any other comments?

15 Going once, going twice --

16 (No response.)

17 MR. GIACOMINI: Okay, Joe, back to
18 you.

19 MR. SMILLIE: The next item is a
20 small but a very important guidance
21 recommendation that we believe is going to
22 close what a lot of us consider to be a

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1 loophole in the regulations. It doesn't call
2 for a change. It calls for just a re-look at
3 this particular category, at this particular
4 regulation. John took the lead on this
5 document and will describe its intent.

6 MR. FOSTER: Thank you, Joe.
7 Being mindful of time, I'm hoping that this is
8 not particularly controversial, actually.

9 The intent was to just cull out --
10 I wouldn't necessarily call it a loophole --
11 I would call it something that hasn't gotten
12 enough attention in recent years. There's
13 been a lot of important things to focus on,
14 and this is just emerging as one of the
15 inevitable refinements that I think is to be
16 expected in any new program.

17 The idea is to ask the NOP to call
18 attention to the limitations on exclusions, as
19 noted in 205.101(b). It's the contention of
20 the recommendation here that there are
21 significant limitations on the kinds of
22 activities that should be covered by the

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1 exclusion and that they are limited by the
2 degree to which a product is packaged or
3 contained, and how those goods either stay or
4 don't stay in packages or containers.

5 I don't want to read through the
6 whole thing, but it asks NOP to clarify, to
7 look into this and be very clear as to whether
8 or not they see the current regulatory
9 language covering some of the activities that
10 are going on around trading, brokering, buying
11 and selling of things like hay and cattle and
12 bulk grains, bulk fluids.

13 It does not ask for regulatory
14 change, and that was one of the big advantages
15 of this, as I saw it, and as we as a committee
16 saw it.

17 It does ask -- let's see -- it
18 focuses on the fact that the limitations here,
19 the exclusions are relevant only if handling
20 operations or portions of them sell organic
21 agricultural products that are packaged or
22 otherwise enclosed in a container prior to

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1 being received or acquired by the operation,
2 and remain in the same package or container
3 and are not otherwise processed while in the
4 control of the handling operation. It's
5 important that the conjunction there is 'and',
6 not 'or', so both conditions have to be met.

7 The comments that have been
8 expressed have been generally favorable in
9 concept. However, there is some concern over
10 unintended consequences, and some question
11 about how far this would be construed as --
12 how far this would go. It wasn't the intent
13 to get all truckers, all transporters
14 certified, necessarily.

15 If, in the wisdom of the NOP, that
16 those activities that are a direct function
17 of, say, getting milk from a farm to a
18 processor or from a farm to an elevator. If
19 that's a direct activity of the farmer, of the
20 producer, it wasn't necessarily the intent to
21 make sure all of those trucking operations get
22 certified.

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1 I certainly don't want to be
2 responsible for any unintended aftereffects
3 here, but we focused mostly on discussions
4 around brokers, traders who are uncertified,
5 taking either title or possession, storing
6 products. And we want to work against those
7 who would misrepresent conventional products
8 mixed in with organic products by uncertified
9 operators.

10 We give some examples in here.
11 Again, I won't go through them all. We'd
12 prefer to spend time on questions. This
13 passed with a vote of four yes, zero no, and
14 one absent.

15 I'm going to call it good there,
16 and see if there's questions.

17 MR. GIACOMINI: Questions?
18 Comments?

19 (No response.)

20 MR. GIACOMINI: Well, if there's
21 no one else, I'll do it -- I'll go. I just --
22 I'm going to preface this and say, I

1 completely oppose organic fraud.

2 (Laughter.)

3 MR. GIACOMINI: And I don't want
4 to be misconstrued by anything I'm going to
5 say, but if there's a problem in the audit
6 trail or if there's a problem in some other
7 process in the inspection and certification of
8 these issues, I think they do need to be
9 addressed.

10 But a lot of these are farmers,
11 whether they're dairy farmers or livestock
12 farmers or grain farmers. I don't have a
13 direct access to a lot of organic grain
14 farmers, but I do know a lot of organic dairy
15 farmers, and things are pretty darned tight.
16 The added cost of every broker needing to be
17 certified or all the brokers who want to play
18 within the organic hay business, all the
19 truckers who are going to be hauling hay, the
20 cost of each one of those guys is going to go
21 up and the competition is going to go down.

22 I know dairymen and milk companies

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1 where the company hauling that milk has one
2 truck. If that truck -- if they're certified
3 and that truck breaks down and nobody else is
4 certified or nobody else that's certified is
5 willing to give them a truck, they can't haul
6 their milk.

7 I think the cost of this is going
8 to be outrageous, compared to the value of it.
9 I think if there's somebody that's buying
10 cows, buying 10 organic animals, taking them
11 to a facility, unloading 10 and loading 15
12 back up, that's fraud, and we need to fix it.
13 And I wish the book would get thrown at them.

14 But I don't think that just
15 because we say, they have to be certified --
16 and all the additional cost that's going to go
17 into that and all the dominoes that
18 potentially could be affected by this
19 recommendation -- I don't agree with it. I
20 think the impact and the cost on the farmer is
21 going to be huge and unnecessary.

22 Kevin?

1 MR. ENGELBERT: I think the
2 problem, from what I've been able to gather
3 from talking to people, listening to comment,
4 your recommendation, and the people that are
5 gaming the system, is that there has been a
6 possible misunderstanding or a lack of
7 enforcement, based on ownership versus
8 possession.

9 A milk company contracts with
10 someone to haul their milk, and there's no
11 reason for the hauler to be certified because,
12 the instant that milk is on the truck, it's
13 owned by the company. If their truck breaks
14 down and they have to hire somebody else, they
15 don't need to be certified either, because the
16 ownership is clearly from the farmer, and then
17 instantly to the company they sell to when
18 it's on the truck.

19 The same with cows; the same with
20 hay. If you've got a broker that is storing
21 it in his facility, then he's taking ownership
22 of it, and he needs to be part of the trail.

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1 But if he's just someone that's been
2 contracted to deliver from one owner to
3 another, then there's no broken audit trail.

4 I'm not sure the exact way we need
5 to go with this, but it's not as complicated,
6 I think, as it may appear.

7 MR. GIACOMINI: John.

8 MR. FOSTER: In those examples --
9 I don't think those examples would require
10 either Dan or Kevin -- I don't think this
11 would apply there. I really don't. I think
12 the definitions of 'handle' and 'handling
13 operation' and 'handler' sufficiently exclude
14 those kinds of activities. This is really
15 focused on uncertified operations, which
16 aren't what you're talking about.

17 You're talking about either
18 growers that are certified or processors,
19 receivers that are certified, and have a truck
20 or a fleet of trucks or whatever that's
21 already covered. This doesn't -- wasn't
22 intended on dealing with that. It's intended

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1 on dealing with operations that aren't
2 certified and have no audit trail and have no
3 oversight.

4 With respect to, Dan, your
5 comments about the cost, what we're asking is
6 the NOP to review what limitations already
7 exist in regulation. That's it. No new
8 language; just please look at the limitations
9 and see where they apply.

10 If -- if the NOP sees that there
11 are some uncertified operations that shouldn't
12 be uncertified, call that out. That's what
13 this is asking. No language change.

14 Enforcement of what already is
15 just hasn't had a spotlight on it. That's
16 all.

17 MR. GIACOMINI: So, a specific
18 example: A farmer grows alfalfa hay, and a
19 dairyman wants to buy it. The dairyman calls
20 the local broker that he works with, that he
21 regularly gets hay from, and says, I need a
22 load of alfalfa hay.

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1 The broker has access and
2 knowledge to hay in the marketplace. He goes
3 out. He secures a load of hay. He gets
4 someone with a truck, who's obviously and
5 oftentimes not the broker's truck but a
6 separate trucking company, gets somebody with
7 a truck to go haul that hay. It's picked up
8 at the farm and it's taken to the dairy
9 farmer, but the contract, the bill is actually
10 paid from the farmer. The dairyman is
11 actually paying the broker for the hay.

12 And you're saying: Would? Would
13 not? What?

14 MR. FOSTER: I'm just saying I'd
15 like the NOP to look at the limitations on
16 101(b), and if they apply, apply them.

17 MR. GIACOMINI: Okay.

18 Miles?

19 MR. FOSTER: That's what I like.

20 MR. McEVOY: We're looking into
21 this and working on guidance in this
22 particular area around the exemptions and

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1 exclusions.

2 I just want to mention that in the
3 Washington State Program, before the
4 implementation of the National Organic
5 Program, we had a much more restrictive
6 exemptions from who needed to be certified.
7 So brokers had to be certified and all the
8 currently excluded categories had to be
9 certified. We found that it really wasn't a
10 problem. We didn't have people opposing
11 getting certified. It actually -- most of
12 those people retained their organic
13 certification after they were no longer
14 required to be certified, because it helped
15 them out in terms of their own business
16 interests.

17 It clarified what the standards
18 are. They're verified. They have that
19 certificate. They don't have to disclose
20 where they're buying their product from. They
21 don't have to have that certificate from the
22 grower, because they can provide the

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1 certificate as a certified broker. And it
2 makes the audit trail much more complete, a
3 much more verifiable system.

4 So, anyway, I don't think it's
5 going to cause a lot of problems. We are
6 looking at this particular area to provide
7 more clarification. If there are operations
8 that should currently be certified that are
9 claiming that they're excluded from the
10 certification, we'll take a look at that. If
11 you believe there are operations like that,
12 you can file a complaint and we'll look into
13 it. So this could be very useful for the NOP
14 at this point.

15 MR. GIACOMINI: Kevin.

16 MR. ENGELBERT: With your example,
17 Dan, if I understand it correctly, if the
18 farmer pays the entire amount to the broker,
19 not just a commission, then he has taken
20 ownership of that hay, and he would be
21 responsible for the transaction certificate
22 for that hay, along with a certification of

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1 organic.

2 If that is cost-prohibitive, then
3 he should, the farmer, or, tell the -- to pay
4 directly to the farmer that is selling hay and
5 be responsible for the affidavit for that hay
6 and cut basically two checks, one for his
7 commission and one for the hay; right?

8 MR. GIACOMINI: Okay. Further
9 questions? Comments? Jeff.

10 MR. MOYER: I just wanted a point
11 of clarification from Miles. Am I to
12 understand that you said this document would
13 help you in carrying out your review of this
14 process?

15 MR. McEVOY: Yes. It provides the
16 Board's perspective on this particular area,
17 so yes. It could be very helpful for us, yes.

18 MR. GIACOMINI: Further comment,
19 questions? Joe?

20 MR. SMILLIE: That concludes the
21 CACC report.

22 MR. GIACOMINI: Thank you. Off to

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1 the last policy discussions of the day, and
2 we're supposed to be getting on the bus. I
3 understand it's going to be held up a little
4 late for us, but let's see what we can do.

5 Barry, Policy.

6 MR. FLAMM: Thank you. We'll do
7 our best to keep it down. We're scheduled for
8 40 minutes.

9 We have four recommendations,
10 three involving changes to the policy and
11 procedures manual, and one on the new member
12 guide. On the new member guide, Annette was
13 the lead on that in working with Lisa, but
14 Kevin has graciously agreed to make that
15 presentation.

16 The first one is a request that
17 you made, Mr. Chair, of the Policy Committee
18 to examine establishing ad hoc committees, et
19 cetera, and Steve will present that. He was
20 the lead on it.

21 MR. DeMURI: Thank you, Barry.

22 Well, this one was pretty simple, actually.

1 A request came to the committee to insert into
2 the policy manual a mechanism for establishing
3 ad hoc committees, something's that has been
4 done in the past. A good example would be the
5 joint materials and handling committee that's
6 worked on classification materials for the
7 last few years. It was put together as an ad
8 hoc committee, and we didn't really have a
9 mechanism for that. It just kind of happened.

10 So we did insert some language
11 into Section 4 of the NOSB policy and
12 procedure manual to allow for formation of ad
13 hoc committees. Hopefully, everybody's had a
14 chance to read that. I won't take it the time
15 to do that. It's just one paragraph of
16 verbiage in there.

17 We do understand that there has
18 been a request, possibly, for some changes to
19 that, to that insertion, and we would
20 entertain a friendly amendment to that when
21 the time comes, either today or Thursday when
22 we vote on it. So if the person that's

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1 interested in doing that would like to do
2 that, we'd be happy to entertain that friendly
3 amendment

4 MR. GIACOMINI: Yes, first of all,
5 the board, the Chair requested that you look
6 at the issue, not to definitely put it in.
7 The reason the Chair requested that was that
8 the burden of committee selection, within the
9 structure of a joint committee, is -- adds a
10 huge, cumbersome, geometric complexity to the
11 issue.

12 That didn't seem to be necessary.
13 It created a huge committee, and the logistics
14 of who was on what committee -- and where else
15 they could be because, by being on A, they
16 also had to be on C -- was a problem that I
17 faced in doing this.

18 I was also the person who, in
19 reviewing this, had a couple of suggestions,
20 and I will include it as a friendly amendment,
21 but to delete the last sentence of the
22 paragraph and to add the sentences, "Ad hoc

1 committees can be dissolved at the
2 recommendation of the NOSB chairperson, with
3 approval of the executive committee." And the
4 second sentence, "Ad hoc committee chairperson
5 is a nonvoting member of the executive
6 committee."

7 MR. DeMURI: Okay.

8 MR. GIACOMINI: Any other
9 questions or comments?

10 (No response.)

11 MR. GIACOMINI: The reason for the
12 first part is to match more the way the
13 committee was formed, and the reason for the
14 second is not adding one more person as a
15 voting member of the committee -- they may
16 already be a chairperson of another committee
17 -- but making sure that they're present on the
18 executive calls for updates.

19 Any further comments?

20 MR. DeMURI: I'd just say, I did
21 poll the committee informally.

22 MR. GIACOMINI: Okay.

1 MR. DeMURI: It was a little late
2 to do it formally. Everybody was in
3 agreement, so we thought that just a friendly
4 amendment would be the way to take care of
5 that.

6 MR. GIACOMINI: We'll do that on
7 Thursday.

8 Next item, Mr. Chairman.

9 MR. DeMURI: Okay. The second
10 item, I will take, and that's an item that was
11 on for discussion in the spring meeting.
12 That's NOP-NOSB collaboration. We wanted to
13 update that in the manual for number of
14 reasons, with the changes in NOP and more
15 resources, and we wanted to try to simplify
16 it.

17 In any case, we had several
18 discussions with Miles. He joined in one of
19 our calls, and it's been a moving target. In
20 fact, almost everything that we've recommended
21 has been implemented right now, in terms of
22 developing work plans, and we have technical

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1 expertise attending meetings, and those were
2 couple of key points. In developing this,
3 there was a collaboration between the NOP and
4 NOSB in doing this, and Lisa has just been
5 terrific in terms of helping out the
6 committee.

7 And, really, some process things,
8 but working closer and making sure everybody's
9 on board in terms of the work plans, that's
10 one point. And the other biggie is having NOP
11 technical people on our calls for assistance.

12 Any questions?

13 MR. GIACOMINI: Questions?

14 Comments?

15 (No response.)

16 MR. GIACOMINI: Next item please.

17 MR. FLAMM: The next item may not
18 go so quick. It's our review of the sunset
19 policy. Jay has been the lead on that in
20 working with, I think, all the committees and
21 talking to everybody.

22 MR. FELDMAN: Thanks, Barry.

1 This is an amazingly
2 noncontroversial proposal.

3 (Laughter.)

4 MR. FELDMAN: We expect this to go
5 very quickly and smoothly.

6 The proposal you have in front of
7 you passed unanimously, after a lot of
8 consultations, Barry noted, with a range of
9 people. I don't think we hit everybody, but
10 we did hit -- I believe we had gotten feedback
11 from all the committees.

12 The comments we've received -- I
13 count nine -- and with one exception, I think
14 everybody is in favor of some sort of
15 annotation during sunset, so that's a good
16 development.

17 You all may differ on this, but I
18 didn't see anything new from what we'd heard
19 during our discussion, during the discussion
20 document that we had discussed at the last
21 board meeting. But I broke the comments down
22 into three categories; maybe four.

1 We had some organizations that
2 basically supported the proposal as is, two
3 organizations. One suggested that we are very
4 clear about needing a TAP review in addition
5 to a TR, have the authority and utilize a TAP
6 review, which would include more perspectives
7 than we might get from a TR. And another one
8 of the supporters suggested we strengthen it
9 by providing for the authority to annotate
10 between the five-year period between sunset,
11 or during the five-year period between
12 sunsets.

13 There were four groups that
14 basically agreed with annotation but are
15 worried that their isn't sufficient
16 opportunity for public comments, should the
17 proposal to annotate emerge at the board
18 meeting. I will address all these issues. I
19 think the proposal -- I should've said up
20 front -- addresses these issues, and I think
21 we can discuss that.

22 And then I interpreted one comment

1 to suggest that we need to somehow restrict
2 the ability of board members to amend
3 annotations -- or come up with new annotations
4 -- during the board meeting.

5 Then, as I say, there's one
6 comment that was very clear in saying that the
7 proposal should not allow annotations except
8 during the petition process, which is the
9 authority we currently have.

10 So the kinds of comments that came
11 up -- I count about nine different types of
12 comments that span these categories or these
13 topic areas --

14 1. Respect the work of
15 previous boards, number one;

16 2. Ensure public comments on
17 possible annotation amendments introduced at
18 board meetings, even though committee rejected
19 those; concern that there is inadequate
20 opportunity in that situation for the public
21 to comment;

22 3. Annotations -- good idea,

1 but only through the petition process;

2 4. Allow annotations not
3 only to restrict but to expand the uses, an
4 issue the committee addressed and rejected;

5 5. That we should not be
6 concerned about the number of synthetics but
7 their compatibility with organic;

8 6. Add authority to annotate
9 between the five years, which I mentioned, and
10 there are some examples of where we needed to
11 do that, such as aquatic plant extracts and
12 micronutrients; and then --

13 7. Another issue on public comment in
14 support of removal. This goes to the 602 and
15 604 lists, that it would be more logical to
16 require public comment in support of their
17 removal rather than their continuing on the
18 list. Again, something we addressed I'll get
19 to it; and

20 8. Require the TAP reviews as a part
21 of the sunset process.

22 So that's an overview of the

1 issues that came up. I'd like to walk you
2 quickly through the process that we
3 established, which I believe addresses most of
4 these issues. We certainly, as a committee,
5 discussed all these issues.

6 So I'll go right to the specific
7 amendments, but let me preface all this by
8 saying that I think the committee believes
9 that being put in a position, as board
10 members, of either accepting or rejecting the
11 listing of a material in the National List
12 does not give us sufficient authority to
13 restrain and limit the use of materials that
14 may have value and compatibility with organic,
15 but whose uses have been expanded in such a
16 way, given their original listing, so as to
17 create potential problems for organic.

18 Formulations that we weren't aware
19 of or didn't exist at the time that the list
20 was originally created or that particular
21 substance was put on the list; situations in
22 which new science alerts us to a problem with

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1 a formulation -- this will become particularly
2 important as we scrutinize inert ingredients
3 or full formulations, as opposed to just
4 active ingredients, because one formulation
5 may not be problematic; another may. And, of
6 course, we're hoping for collaboration on that
7 with NOP and EPA.

8 There are questions of
9 essentiality that come into this. Some
10 formulations of a particular active ingredient
11 in a pesticide may be necessary or essential;
12 others may not. These may evolve over time,
13 so we'd want the ability to restrict those
14 limitations. I mean, we sort of had that
15 discussion today on annatto, and do we have
16 the authority to parse out different uses and
17 changes in the market for those individual
18 materials?

19 So this isn't a question of, I
20 don't think, trying to do anything other than
21 to protect the market, to be sensitive to
22 continuing needs for materials -- at the same

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1 time knowing that we have a statutory duty to
2 restrict to the extent possible the inputs
3 that we put on the National List of
4 synthetics. That's our duty as board members,
5 to constantly review that.

6 The use of the petition process --
7 Dan, you said it's broken -- that the repair
8 of it I think is necessary, but that shouldn't
9 preclude us -- I think the committee
10 unanimously thinks it should not preclude us
11 from using the sunset process to constrict or
12 restrict in certain ways continuing uses of
13 materials that are either deemed unacceptable,
14 because of adverse properties, or deemed
15 unnecessary, because of new data on
16 essentiality.

17 I believe I'm characterizing this
18 properly, that the program, the NOP concurs
19 with this idea, that they feel it is an
20 authority that we have under the statute, and
21 that the only thing precluding us from moving
22 forward is the adoption of this policy as a

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1 board.

2 So, getting back to where I
3 thought I was a few minutes ago, and that is
4 the steps followed in the sunset process, I
5 just want to walk you through how we apply
6 this orientation to the process. It's
7 interesting, when you actually look at the
8 number of words of edits to the actual
9 language in the policy Program manual, there
10 aren't that many edits, really. And the edits
11 in your document, which start on page 5, Steps
12 followed in sunset process, are in italics.
13 The deleted text, in most cases, is in
14 parentheses, although I see we have some
15 things in parentheses that we don't intend to
16 delete. Hopefully, that's obvious.

17 So the first step in this process
18 is, as it's always been, a public notice is
19 placed in the Federal Register, Advance Notice
20 of Proposed Rulemaking of the Pending Sunset.
21 Nothing has changed there. We go through that
22 same process. The public has 60 days. The

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1 committee may request a third-party technical
2 review in anticipation of scientific evidence
3 and claims likely to be made during the public
4 comment.

5 Here's where the suggestion comes
6 in -- to add TAP review as well.

7 Secondly, the public comments are
8 collected and forwarded to the NOSB. Again,
9 this is part of our current process.

10 Three, "The appropriate NOSB
11 committee begins review of the material in an
12 intent to provide a recommendation to the
13 entire board" -- again, current process, and
14 here's where the change begins, "to the entire
15 board for the material's removal, renewal" --
16 and this is the new language -- "or renewal,
17 with the addition of an annotation. The review
18 is conducted based on force of evidence." And
19 the rest of the process is the same as it
20 currently is. "The committee may request a
21 third-party technical review if needed, verify
22 scientific evidence and claims made during the

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1 public comments through the ANPR."

2 And then the fourth step probably
3 has the largest number of edits in it. This
4 is a process that emerged out of the
5 discussion on the discussion document. It was
6 an attempt to merge concept of petition for
7 changes and separate that out from the
8 decision as to whether to list or delist, so
9 that people at the committee level, with the
10 benefit of full board discussion and the
11 benefit of public input, could discuss those
12 specific annotations, prior to making a
13 determination as to whether it was appropriate
14 to annotate or not.

15 So the new language says, "The
16 recommendation may consist of (1) a simple
17 motion to remove or renew the listing of the
18 substance, or (2) a motion to renew
19 accompanied by an amendment containing the
20 addition of an annotation to the listing. If
21 there is to be an annotation," -- so,
22 regarding the addition of an annotation --

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1 "the committee will utilize a two-step
2 process. First, vote on the amendment with
3 the annotation." This gives everybody an
4 opportunity to bring forward annotations and
5 debate whether that's legitimate or not.
6 That's where we hash out whether the
7 annotation is really viable, justifiable,
8 enforceable, all that stuff. "Should the
9 amendment prevail, then" -- I'm sorry, missed
10 a step there.

11 So we're debating this annotation.
12 We're voting. "The committee will first vote
13 on the amendment and then the motion to
14 renew." That gives someone who feels that,
15 for instance, there's a really problematic
16 annotation, or there's a very serious
17 annotation that needs to be adopted that is
18 not adopted in the first round of voting, that
19 person then has the ability to vote against
20 the relisting of that material. That's an
21 important ability.

22 At the same time -- hopefully, we

1 wouldn't get to that; hopefully, through
2 informed discussion, we'd be able to get to
3 consensus on those annotations -- but at least
4 you have an opportunity as a member of that
5 committee to, at the end of the day, looking
6 at the annotations with the science and the
7 data on production issues, essentiality, to
8 make an informed decision on whether you
9 believe that material should be relisted or
10 delisted.

11 So the committee is done with it.
12 It brings that package to the board meeting.
13 It publishes that in the Federal Register.
14 Once that goes to the board, the board has the
15 same opportunity -- to vote in a two-step
16 process. So,

17 "If the amendment prevails, the
18 board, in its consideration, will also first
19 vote on the amendment to annotate, and then
20 the motion to renew." Now here -- this is key
21 because obviously, as we all experience at
22 every meeting -- board discussion informs us,

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1 as does the public discussion, informs us on
2 whether we, the committee has done the right
3 thing. So we want to give the board the
4 opportunity to discuss that annotation fully,
5 and then the board members individually to
6 decide whether it's appropriate to list with
7 that annotation or delist.

8 So that really isn't a change. It
9 just brings the annotation ability into the
10 process.

11 Here's where there was a challenge
12 to the ability of the public to address a
13 change that we might consider through the
14 board voting process. And it's that last
15 sentence in number four. "If the amendment to
16 annotate does not advance out of committee,
17 the board will vote on the motion to renew,
18 and per its normal process, entertain
19 amendments from the board."

20 This is where there is a concern -
21 - as I heard and you heard from the public
22 comments -- that if someone were to bring

1 forward an amendment to annotate that was
2 rejected by the committee, then the board --
3 the public wouldn't have an opportunity to
4 vote on that amendment.

5 I don't think that's a correct
6 characterization of our process. Think about
7 it; we can change anything at a board meeting.
8 Anybody can raise their hand and propose an
9 amendment on anything. That's part of the
10 democratic process; Robert's Rules of Order.
11 We have that ability, and it could alienate
12 the public -- feeling left out of that
13 process.

14 But I think the reason that hasn't
15 happened, generally -- I mean, there's
16 probably some exceptions to that over the
17 history of the board -- the reason that hasn't
18 happened is because we have the ability in the
19 committee to present all the data that we
20 considered. And if we're doing our job
21 correctly, we've presented fully in the
22 background document to the proposal that we've

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1 published in the Federal Register, the full
2 range of opinions that were brought forward.
3 We've provided an opportunity for minority
4 opinions, and we have fully disclosed and are
5 fully transparent on the process.

6 So it is unlikely, first of all,
7 that any amendment that circumvented that
8 whole process and wasn't fully recorded in the
9 process would prevail at a board meeting. As
10 I said yesterday, we had this issue with
11 methionine. New issues came up at the board
12 meeting that may or may not have been
13 discussed at the committee level. We deal
14 with it as a board.

15 The other part of it here is that
16 the format of these board meetings offers a
17 second day of public comment, as we'll
18 experience tomorrow, so that if in fact a new
19 idea comes up during this process -- unlikely,
20 but if it does -- the public would have
21 another opportunity to comment on this.

22 So I think, I hope that we've

1 addressed the concern -- a valid concern --
2 that the public wouldn't have sufficient
3 opportunity to comment. In fact, I think this
4 offers perhaps even more opportunity for the
5 public to get into the details of the
6 discussion by virtue of the disclosure of the
7 annotation.

8 The rest of five and six are
9 really the current process. There are no
10 changes. You know, we have the NOSB business
11 meeting. It explains the process.

12 There's a second part to 6,
13 though, that is a change, and this is intended
14 to ensure that we don't inadvertently allow a
15 sunset material to delist by virtue of
16 inaction by the board. We do not want that to
17 happen. We want a fail-safe provision, should
18 the unlikely event occur -- and we are told by
19 NOP this is highly unlikely, because the OMB
20 does not typically intervene on these sunset
21 issues. But should that occur,
22 there's a fail-safe provision in here that

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1 enables the NOSB to take action, prior to that
2 material being delisted. We figured out the
3 time frame, and the final rule process would
4 not go forward without the board opportunity
5 to list, in the absence of an OMB decision or
6 NOP clearance, OMB clearance, OGC clearance,
7 or any other department or congressional
8 review.

9 And then the last -- I'm sorry,
10 got ahead of myself -- that's the last
11 section, that, "If the clearance process,"
12 number seven, "required for an annotation
13 during sunset is not able to be completed
14 prior to the substance's expiration under the
15 sunset process, the board has the authority to
16 revisit the question of the sunset's removal
17 prior to expiration."

18 I think this can work. I think --
19 you know, our discussion was robust, as we
20 like to say in these situations -- and I
21 believe we've addressed the public's concerns
22 here and have -- I guess we'll hear about that

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1 tomorrow again, but -- and have put in place
2 a process that enables us to fulfill our
3 statutory duty to remove when necessary, to
4 protect products needed in organic production,
5 and to do that in a way that is streamlined
6 and expeditious and turns us into a leaner
7 machine to move organic into a growth mode as
8 we move forward in the future.

9 So, thanks for listening.

10 MR. GIACOMINI: Comments and
11 questions? Jeff.

12 MR. MOYER: Jay, I just -- while I
13 fully support the concept of making annotation
14 changes at the time of sunset, as you're
15 mentioning here, I do have concerns about item
16 number four in that last sentence that you
17 mentioned, specifically as it pertains to
18 annotations coming to the board from within
19 this meeting without having the public -- and
20 I understand you're saying the public has an
21 opportunity to comment on that -- but
22 realistically, no offense to the people in the

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1 audience, but that's not the only public. I
2 mean, there's a much larger public that does
3 view or has an opportunity to view our
4 documents online and comment via electronic,
5 or however they want to do it.

6 So I have some issues with that,
7 and I understand and share the concerns that
8 we've heard from the public, and I think
9 there's a difference between -- what we've
10 done in the past at these meetings tends to be
11 a little bit more wordsmithing on documents or
12 an annotation that came up, and people want to
13 make some changes.

14 Those kinds of small changes done
15 in a transparent manner here at this board
16 meeting is one thing. Bringing something
17 completely from out of the blue almost in
18 terms of what the public would consider, and
19 then voting on that and making an annotation
20 change, which could drastically affect -- one
21 way or the other, positively or negatively,
22 depending on which side of the fence you're on

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1 -- business, I think, is unfair for us to take
2 on that responsibility.

3 MR. GIACOMINI: Jay?

4 MR. FELDMAN: I appreciate
5 responding to that.

6 You know, I'm happy to restrict,
7 in any way the board thinks necessary, the
8 ability of the board to participate in the
9 typical decision-making process. But what
10 you're describing, Jeff, is in no way written
11 in policy. We don't preclude board members,
12 that I could find, in policy from introducing
13 anything they want at a board meeting and
14 asking the board to vote on it. There is no
15 restriction on that ability.

16 But if there is --

17 MR. GIACOMINI: It's in sunset.
18 We don't allow annotations at sunset. That is
19 in our policy and it's there now. You can't
20 say it doesn't exist currently.

21 MR. FELDMAN: Right, but we're
22 talking about changing that.

1 MR. GIACOMINI: Right, we're
2 talking about changing it, but you can't say
3 it doesn't exist. It does. It's current.

4 MR. MOYER: Okay. Well, I would
5 argue that we don't vote on anything that
6 isn't in our agenda, which is why Dan brought
7 up the conversation that we had earlier on
8 inerts, and we're working out a way around
9 that.

10 But for us to just bring something
11 to the meeting without having the public
12 having access to that and then voting on it is
13 something we don't do. No.

14 MR. GIACOMINI: Jennifer.

15 MS. HALL: Thank you, Mr. Chair.
16 I share the same feeling, my only concern
17 being with that last sentence and the ability
18 to kind of change it on the fly here. A
19 little different in that I think that the
20 board's decision-making capacity on materials
21 is very different than other recommendations
22 that get further massaged through the Program,

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1 and then the draft rule comes out for them
2 that also has public testimony opportunity,
3 which, when we vote on materials, is not the
4 case.

5 So I see that landscape a little
6 bit differently.

7 MR. GIACOMINI: Steve.

8 MR. DeMURI: It could be a bit
9 cumbersome, but, for instance, on this 2012
10 batch of sunset, we had three meetings to go
11 through those. As long as you don't wait
12 until the last meeting to go through them all,
13 we can make an annotation change on the fly
14 and go through another process and try to
15 approve it at the next meeting. But that only
16 works if we don't wait till the 11th hour to
17 do that.

18 MR. GIACOMINI: John.

19 MR. FOSTER: So I remember very
20 clearly what I refer to in my head as the
21 'methionine incident' at the April meeting,
22 which I was really uncomfortable with. It

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1 felt rushed. I don't think we considered
2 things very well or very thoroughly. We
3 didn't think about ramifications. It got very
4 confusing very fast.

5 And while I agree with you, Jay,
6 there is an opportunity to, you know, at any
7 time, for a board member to bring up anything
8 he or she wants. But I don't want to codify
9 that. I don't want to legitimize that. Yes,
10 the process -- any board member can bring it
11 up any time and then can be outvoted. That's
12 true. We have that opportunity.

13 But I don't want to
14 institutionalize, I don't want to
15 institutionalize the conditions that led to
16 the methionine discussion. 'Discussion' is a
17 generous term, in my opinion. I don't want to
18 set it up to where that's going to happen
19 again. I don't want to support or encourage
20 that at all. I was really uncomfortable with
21 it, don't want to do anything. And I think
22 the language, as written in here, starts to

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1 codify that. I want to stay far away from
2 that.

3 MR. GIACOMINI: Tracy.

4 MS. MIEDEMA: Today, Miles raised
5 the idea of us making an annotation change
6 during sunset as a clarification that would
7 really be an elegant solution to a nagging
8 problem. And so we have the ability to make
9 that kind of change at this meeting and have
10 a potential fix for the future.

11 I think the one important catch
12 here is that we make those kinds of changes
13 before the posting of the Federal Register,
14 not during the meetings. There seems to be
15 all kinds of consensus in the room. I see
16 heads bobbing at the table. Are we there? It
17 sounds like, if we all agree on that part,
18 we've gotten to the heart of the matter.

19 MR. GIACOMINI: Jay?

20 MR. FELDMAN: I mean, if that's
21 the pleasure of the board. You know, I was
22 writing this and in consultation with people,

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1 conceptualizing this in the context of the
2 authority of board members sort of carrying
3 out their responsibility to weigh in on
4 decisions. And, you know, if you all envision
5 the process breaking down as a result of
6 people bringing things up outside the context
7 of the deliberations that go on at the
8 committee level, that's fine.

9 I mean, you can restrict this
10 whole proposal to the committee level and then
11 bring to the board the final decision of the
12 committee and then request the board to make
13 an up or down vote on that decision.

14 But, you know, typically, you want
15 to give your board members, who are on a four
16 other committees and don't have the time to be
17 engaged in all of these, you want to give them
18 the opportunity to weigh in some substantively
19 and then debate that with other board members
20 so as to inform that debate and enable the
21 board to make the best decision possible.

22 I guess there are ways of

1 restricting that, depending on how the board
2 feels about that. But, I think the key thing
3 is here -- yes, Tracy, I agree. The key thing
4 here is to enable the process to elegantly
5 address annotations. And if the board wants
6 to restrict its authority to change those
7 annotations at a board meeting, or proposed
8 annotations at a board meeting, the board is
9 welcome to do that.

10 I think that undermines, to some
11 degree, the ability of us as a full board to
12 participate and benefit from the incredible
13 expertise we have around the table.

14 MR. GIACOMINI: Barry.

15 MR. FLAMM: I think Jay has
16 explained very well what the purpose was, but
17 I think based on these comments, the committee
18 will get together tomorrow sometime, and we'll
19 look at that language again and try to satisfy
20 the comments that have been made.

21 MR. GIACOMINI: Tina.

22 MS. ELLOR: This is one matter I'm

1 completely schizophrenic on because I see the
2 usefulness of being able to deal with
3 annotations, especially during sunset, and I
4 have some particular materials in mind. On
5 the other hand, I know how much information we
6 need to make responsible decisions, and I
7 don't want that to happen, you know, in five
8 minutes on a Thursday afternoon during the
9 voting discussion. But I definitely
10 appreciate that. I think that some sort of
11 ability to make annotations is important.

12 MR. GIACOMINI: Any other? Miles.

13 MR. McEVOY: Yes, I would, I'm
14 concerned about the ability of the public to
15 comment on any proposed annotation changes
16 that the board is considering.

17 When we presented this issue to
18 the board previously, we said that statutorily
19 you had the authority to address annotations
20 during the sunset review process, but you want
21 to be very careful about that authority. If
22 you change your policy to allow that, I think

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1 you should use it very narrowly, very
2 carefully because you have a lot of work to
3 do, and mostly for clarifying annotations that
4 weren't quite right the first time.

5 But it has to be done, from our
6 perspective, in a very public manner. So if
7 you're going to propose a change annotation,
8 it should be published at least at the same
9 time frame so that the public has a chance to
10 comment on any proposed annotation changes.

11 This occurred, not during sunset,
12 but it occurred doing the tetracycline
13 petition process. During the petition
14 process, the annotation was changed
15 significantly to put an expiration date of
16 2012 for tetracycline at a board meeting, and
17 there were a lot of tree fruit growers that
18 did not have that information that that was
19 going to happen. They didn't have a chance to
20 do public comment.

21 So it's a very unfair process if
22 you don't allow some kind of public

1 notification of what you're intending to do,
2 and you just do it at the board meeting.

3 MR. GIACOMINI: Kevin.

4 MR. ENGELBERT: Yes, I think I can
5 safely say that we will address that last line
6 in number four, and we appreciate the input.
7 But make sure we all understand the board's
8 reasoning. And like, you know, Jay and Steve
9 eloquently stated, that was our position, but
10 we fully hear the Program and the rest of the
11 board members and the public.

12 MR. GIACOMINI: Arthur.

13 MR. NEAL: I just wanted to add
14 another point of clarification. When we begin
15 rulemaking on recommendations that we receive
16 from the board, particularly with material
17 recommendations, the consultation process in
18 terms of the informal back-and-forth that we
19 have is limited.

20 And so, if there are issues
21 surrounding a certain recommendation that we
22 received concerning a material, we would have

1 to wait until the board gathers back together
2 again before we can actually get the formal
3 input that we need from the board to clarify
4 something that either we did not understand or
5 that we believed would be a problem in moving
6 the docket forward.

7 MR. GIACOMINI: Any more comments?
8 Katrina.

9 MS. HEINZE: One is very small,
10 and one is related to what Arthur just said.

11 So, my very small one is, during
12 your presentation, I think I heard you say
13 that words in parentheses were to be deleted.
14 Did I hear that correctly?

15 MR. FELDMAN: Yes. Some of them
16 obviously are not. They're just references to
17 the charts and stuff.

18 MS. HEINZE: So, that may be the
19 only one, but that was totally not obvious to
20 me when I read this, and I should have, I
21 suppose, compared to two documents. I didn't.
22 And this may be asking too much, but it wasn't

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1 clear to me what's to be deleted.

2 Is there any way to go through and
3 do strikeouts instead, so that when we review
4 it on Thursday, it's more clear to us what's
5 being deleted? So, like I said, it was
6 totally small. It's just that surprised me.
7 I didn't catch it.

8 MR. FELDMAN: There are probably
9 better ways to do this, but it does say in the
10 text, "In parentheses indicates language to be
11 deleted." So, I mean, that was a suggestion
12 that came out of committee, and we can
13 certainly make it clearer. But all the
14 language you see in front of you is the
15 current language. Additions are in italics,
16 and deletions are in parentheses.

17 MS. HEINZE: Like I said, I just,
18 I should have caught it. I didn't.

19 MR. FELDMAN: Yes.

20 MS. HEINZE: I'm used to
21 strikeouts. I missed it.

22 My other is actually question for

1 the Program related to point number seven, and
2 whether you see that working or if there's --
3 you know, one of the suggestions that was
4 bandied about as we were talking about this
5 was that we vote on the annotation and then
6 vote to relist as is, similar to what we did
7 with, kind of related to what we did like with
8 yeast at this meeting.

9 MR. GIACOMINI: Well, that's what
10 we did with hops.

11 MS. HEINZE: Right.

12 MR. GIACOMINI: That's exactly
13 what we did with hops.

14 MS. HEINZE: Right, where we have
15 two completely separate votes that go to the
16 Program so that they can work them out,
17 understanding that our preference timing-wise
18 is that the annotation change happens first.
19 But I'm wondering if that would work better
20 for the Program and if they have concerns
21 about seven.

22 MR. GIACOMINI: Arthur.

1 MR. NEAL: When you're dealing
2 with sunset, it's best to give it to us the
3 way it needs to be, period. Because we're
4 dealing with a time line, we don't have time
5 for the back-and-forth. That's kind of the
6 reason things were set up the way that they
7 were.

8 I can understand the need to
9 clarify annotations or clarify the use of a
10 substance because it's been, there's a lot of
11 confusion around its use, but when you make
12 that recommendation during a sunset process,
13 you have to remember we're dealing with a time
14 line.

15 The board doesn't meet but twice a
16 year, so the time for us to get the feedback
17 we need once we start the rulemaking process
18 is limited because we can't do it just over
19 the telephone because the whole board is not
20 together and it's not considered a public
21 meeting that's been published in the Federal
22 Register.

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1 MR. GIACOMINI: Katrina.

2 MS. HEINZE: So I just need to
3 clarify. Would you prefer that we handle it
4 the way we did with hops where we have 'relist
5 as-is' and then a separate vote, or prefer how
6 I think I'm reading a recommendation, which is
7 that we would vote on the annotation change --
8 so what we did on hops -- and then vote to
9 relist that annotation change?

10 MR. GIACOMINI: Miles.

11 MR. FELDMAN: Yes, I think how
12 you're doing it with hops makes sense, and we
13 can work with that. You offered two scenarios
14 there, so I think -- yes, I'm not sure if I
15 got the distinction between the two scenarios.

16 MR. GIACOMINI: Arthur.

17 MR. NEAL: The way that it's
18 recommended, with the committee coming up with
19 a proposed amendment to the annotation and
20 that being voted on first, and then whether or
21 not a substance is going to be renewed and
22 that looked at by the board in a similar

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1 fashion makes sense. That means the public
2 will have already had an opportunity look at
3 it before the meeting.

4 If the board votes down the
5 annotation at the meeting, it's voted down.
6 Then they have to make a decision of whether
7 or not we renew or we do not renew. It's as
8 simple as that.

9 The trump card or the confusion
10 comes in when we start playing around with it
11 on the fly, and additional confusion is
12 introduced if the board is not sure about the
13 recommendation they're going to put forth to
14 the Program. There's confusion around that,
15 then we get it, and we're stuck with it.

16 (Laughter.)

17 MR. NEAL: When I say that -- the
18 USDA is stuck with it, and we all know that
19 the Secretary cannot add or remove. So that
20 means we can't make any changes to the
21 recommendation on the substance if we know
22 that there are problems with it. You got it?

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1 So, if there problems with it, we can't do
2 anything about it because the board did
3 recommend it the way that we received it.

4 MR. GIACOMINI: And if the only
5 reassertion for relisting was the new
6 annotated change and not the old listing, then
7 you don't have the authority, and you may not
8 have the time, in number seven, to relist the
9 old listing; would you?

10 MR. NEAL: Well, the one thing
11 that's a saving grace a little bit if it's a
12 simple, just kind of grammatical error, is the
13 public comment period in the proposed
14 rulemaking process? But even then, when it
15 comes down the materials, you know, that's
16 always been a point of contention between
17 USDA, the board, and the public, is that USDA
18 has tinkered with some language that we didn't
19 necessarily recommend to them or we didn't
20 approve.

21 So, to keep the confusion down, it
22 would be great if we can get the materials

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1 recommendations the way that they should be so
2 that we do not have to introduce, you know,
3 all the different factors into the puzzle.

4 MR. GIACOMINI: But even that
5 assumption you just made, that's assuming you
6 can get to the proposed rule. If you can't
7 get to the proposed rule with the language and
8 you did not have the authorization to relist
9 the old listing, you can't relist the old
10 listing, and it would go off the list and
11 disrupt the industry.

12 MR. NEAL: You're right, but
13 hopefully, we'll not --

14 MR. GIACOMINI: But that's what
15 we're dealing -- that's the potential we're
16 dealing with here.

17 Jeff.

18 MR. MOYER: Well, my point to --
19 I'm sorry -- my point to Katrina then is,
20 that's why I brought up about annatto, because
21 we're going to face that on Thursday when
22 you're making changes to this listing, when

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1 there is no dry powdered annatto here. And
2 we're doing the same thing with pectin too.
3 I mean, we're moving in. We're making major
4 changes at sunset to pectin.

5 MR. GIACOMINI: But we included
6 pectin in the sunset votes. We made a
7 recommendation, a changing recommendation --

8 MR. MOYER: Right, but --

9 MR. GIACOMINI: -- but we also
10 have a recommendation, a sunset
11 recommendation.

12 MR. MOYER: I understand that.

13 MR. GIACOMINI: We have the two,
14 just like we do with hops. We have the two.

15 MR. MOYER: Do we with annatto? I
16 don't think we do.

17 MR. GIACOMINI: No, we don't with
18 annatto.

19 MR. MOYER: This proposal requires
20 that you have the two votes at the same time,
21 so you're presenting the Program with a
22 decision to relist or delist, and that

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1 decision to relist may or may not be
2 accompanied by an annotation.

3 So it's one. It's a package that
4 goes to the Department. It's not a separate
5 process. Is sort of like, the analogy would
6 be the decision on synthetic, and then voting
7 on the material. In the committee, we first
8 vote on synthetic, and then we make the next
9 decision as to whether it's compatible and
10 meets all the other criteria.

11 MR. GIACOMINI: There's no
12 question, there's no question that the sunset
13 review process is the most likely time when
14 the board will find an aspect of an annotation
15 that needs to be changed. Now, there are
16 other ways to do it that we can deal with.
17 But that's going to be a predominant place
18 that they will find an aspect of an annotation
19 needs to be changed.

20 The problem with this entire
21 discussion, in my mind, and the problem with
22 this document is linking the two of them

1 together. We have a responsibility to
2 reassert a listing or non-listing or not
3 reassert the listing of existing listings in
4 the National List. That is entirely separate
5 from our discussion and consideration of an
6 annotation change.

7 The fact that were tying them
8 together is making them look like they are
9 really related. And there is a small time
10 when they are related, as you've heard
11 expressed in yours, where, if the annotation
12 that you think needs to be made fails, then
13 you want the opportunity to remove, to vote
14 down the relisting.

15 Well, the alternative that is you
16 have your annotation change, whether it does
17 -- and you get, let's say you even get that to
18 pass and you reassert the old listing but you
19 reassert the old listing because you assume
20 the annotation change that you voted on is
21 going to get through the Program.

22 If the Program comes back and

1 says, we can't make that change for whatever
2 reason, there's always the opportunity for the
3 recommendation, however it comes forth,
4 through repetition as the committees did on
5 their own initiative, however, to make a
6 recommendation for removal. You could always
7 do that once the Program says, we can't make
8 this change.

9 But when you make an annotation
10 change and then you link it to the sunset
11 document, if there's a problem with that
12 annotation change, they do not have the
13 authority to relist the existing listing, and
14 the solution in number seven is completely
15 unpractical.

16 We're dealing with them deciding
17 that they are going to make the deadline or
18 not to make the deadline; we have two meetings
19 a year; we got it done two months before the
20 meetings for posting documents. We could be
21 looking at a year to a year and a half before
22 their deadline for them to say, we don't know

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1 if we can make this; maybe you guys need to
2 reconsider this original listing.

3 MR. FELDMAN: Just for the record,
4 we developed this timeframe with the Program.
5 I mean, Melissa was, I think -- somebody --

6 MR. GIACOMINI: Tina, you were on
7 the list and I seem to have lost you.

8 MS. ELLOR: We can talk about this
9 more on Thursday, I realize, but there are
10 three things that have been very helpful in
11 how I'm looking at this. Number one is
12 Jennifer's point to how materials are
13 different from other recommendations.

14 Number two -- I mean, I can see an
15 instance very clearly, and I'm not falling on
16 one side or the other of how I feel about this
17 material, but sodium nitrate would be a
18 perfect thing to put through this stepwise to
19 see how it would come out and how it would
20 work. I would be more comfortable seeing that
21 work like hops has worked, but we do not have
22 a petition to change that annotation or do

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1 whatever.

2 The third thing is that this is a
3 very powerful tool, and it should be wielded
4 extremely prudently, so however we end up
5 wording this, it would be a very delicate
6 thing.

7 MR. GIACOMINI: Program?

8 MS. BAILEY: Yes, Melissa Bailey.
9 So, I was on, I think, two of the calls with
10 the Policy Development Committee and I think
11 --

12 Jay, could you just clarify what
13 you mean by the time line you were referring
14 to?

15 MR. FELDMAN: My question to you
16 was whether there would be sufficient time to
17 go through clearance so as to not force an
18 unintended delisting, and that's how we came
19 up with this language. And I believe, I mean,
20 my -- obviously, there's room for error here
21 -- but it was my belief that the Program
22 viewed this as a workable scenario.

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1 MR. GIACOMINI: It gets to the
2 question Katrina asked on reviewing number
3 seven.

4 MS. BAILEY: Yes, so I think in
5 that discussion, what I think I had tried to
6 communicate number of times with the clearance
7 process is that, I mean, internally we know
8 what we have to do to approve dockets to go
9 out, but that we don't control beyond the
10 Program how long the clearance process will
11 take once we get legal review of the dockets.
12 Then it comes back. We may have to make
13 changes. Then that has to go out for
14 departmental clearance and so on, all the way
15 up to OMB.

16 We just don't control that beyond,
17 I guess, our doors and the Program, so it's
18 hard to give a time line on those particular
19 aspect of it, which I think is what I had
20 tried to at least communicate on those calls.

21 MR. GIACOMINI: Katrina.

22 MS. HEINZE: I think some of the

1 confusion -- so, I'm going to try to ask the
2 question asked a while back, differently. How
3 I read number four was that the first vote
4 that the board took would be on the annotation
5 change. The second vote -- so let me finish
6 my whole question before you answer -- the
7 second vote that we took would be relisting of
8 the material with the annotation change.

9 What I'm hearing -- two questions.
10 One, was that your intention? Because what
11 I'm hearing from other folks is they would be
12 more comfortable if that second vote was to
13 relist the material as it's currently listed
14 on the National List, which goes back to my
15 original question to the Program, what the two
16 options are. Option number one is that the
17 second vote is to relist with the annotation
18 change, and option number two is to relist as
19 is.

20 So, as I understood the document,
21 number seven was option number one. We vote
22 to relist with the annotation change, and then

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1 if you can't get that through, you have to
2 come back to us to have us vote to relist with
3 the original listing because we didn't ever
4 vote on that.

5 So first, my question is to Jay:
6 Have I properly understood the document and
7 then articulated the question?

8 MR. FELDMAN: Yes.

9 MS. HEINZE: Okay.

10 MR. FELDMAN: The intent here is
11 to incorporate a failsafe provision so that,
12 should the Program have a problem either with
13 timing or content, the package would return to
14 the board, at which point the board could vote
15 to delist or relist. That's the intent here.
16 Whether it's adequately articulated or not,
17 that was the intent.

18 MR. GIACOMINI: Program?

19 MR. McEVOY: Yes, I think number
20 seven is certainly a problem. I would suggest
21 that you delete number seven in the last
22 sentence of number four, and then it's a

1 workable document.

2 We need to confer little bit about
3 this to vote, what exactly do we need? I
4 mean, there's a few different options that
5 could come out of looking at the annotation.
6 You could approve an annotation change, and
7 then you could also have two additional votes.
8 One could be to relist the material without
9 the annotation change, one could be to relist
10 material with the annotation change, and one
11 could be on the annotation change itself.

12 So I think we need to confer a
13 little bit to give you a recommendation of
14 what would be the best in terms of our
15 process, but I think separating it, at least
16 how you have it here, in those two different
17 sections -- an annotation vote and the
18 relisting vote -- is an important first step
19 in deleting that last sentence. And point
20 number seven in particular seems pretty
21 problematical from our perspective.

22 MR. GIACOMINI: And a successful

1 process of getting an annotation changed
2 through rulemaking by definition resets the
3 sunset clock. The new annotation change being
4 effected in rulemaking doesn't need a sunset
5 vote. It's only whether were going to keep
6 the existing listing. The clock for sunset is
7 our review of the material.

8 (Off mic comment.)

9 MR. GIACOMINI: That's correct,
10 but it's our review of the material and the
11 successful rulemaking that goes along with
12 that.

13 Our review of the material that
14 results in an annotation change and results in
15 subsequent rulemaking would reset the sunset
16 clock for that material. There's no reason to
17 include the new annotation change in a sunset
18 document. The only thing that matters is
19 whether we're reasserting the existing
20 listing.

21 Jeff, and then Joe, and then
22 Tracy.

1 MR. MOYER: My suggestion was
2 going to be that we as a board ask this to go
3 back to the committee. Whether they can do it
4 overnight or not, I don't know. There's a lot
5 of nuances here that are extremely important
6 and critical in this process, and I would even
7 be in favor of delaying a vote until spring,
8 if we had to, on this document to get right.

9 It's, there's a lot of pieces that
10 we've got to get right here, and I would feel
11 very uncomfortable. Even if we struck number
12 seven and the last line of number four, I
13 would feel very uncomfortable thinking that I
14 got it right.

15 And then, off the record, Dan, I
16 just wanted to tell you, Dan, I'm getting
17 thirsty.

18 (Laughter.)

19 MR. GIACOMINI: We all are, but I
20 think this topic deserves --

21 MR. MOYER: I understand.

22 MR. GIACOMINI: It came up in the

1 agenda when it did. It deserves its fair,
2 representative discussion just as whatever was
3 the first thing we talked about this morning.

4 MR. MOYER: I agree, Dan, I do
5 think there's a lot of wordsmithing in here
6 that we have to get straight.

7 MR. GIACOMINI: Joe --
8 I don't think there's that many.
9 It's whether the committee would agree to it
10 or not.

11 MR. SMILLIE: Yes, I thought I had
12 until this resetting of the clock speech that
13 you just gave, Dan, I thought I understood
14 everything perfectly until that.

15 One of the things that I think we
16 really need to take note of, because being
17 five years on the board and having seen what's
18 happened, is that when you restrict the use of
19 a material that's already in existence in the
20 industry, you can almost count on the fact
21 that OMB is going to get involved.

22 I mean, you're taking away

1 something from the industry that it's had, and
2 again, your document only allows for
3 restrictions, not expansions. So I think we
4 should anticipate those restrictive
5 annotations being problematic, not necessarily
6 with the Program but maybe with OMB, et
7 cetera. That's political reality.

8 So the intent you had, Jay, of
9 making it failsafe -- if the newly annotated
10 material doesn't go through, we automatically
11 renew the original -- if somehow the committee
12 can, you know, make that in the document very
13 clear, that would assuage my fears about
14 losing the whole thing because the annotation
15 doesn't go through. That's number one.

16 And number two is, definitely the
17 feeling of a community on the board is -- deal
18 with that at committee. Let the public here
19 about it. Those are the two things.

20 MR. GIACOMINI: Tracy and then
21 Kevin.

22 MS. MIEDEMA: I was just going to

1 respectfully ask that we do table this
2 discussion. We have spent over an hour, and
3 I think we're a bit fatigued. I don't know
4 that we're going to do any more of our best
5 thinking this evening and would request that
6 Policy Committee collaborate with the Program
7 tomorrow during breaks to flesh out these
8 details.

9 MR. GIACOMINI: Was that a motion?

10 MS. MIEDEMA: I'll make it a
11 motion.

12 MR. GIACOMINI: Please make it in
13 the form of --

14 MR. MOYER: I'll second it.

15 MR. SMILLIE: Second.

16 (Laughter.)

17 MR. GIACOMINI: Okay. It has been
18 -- give me my book here. I've got to make
19 sure I do this right -- to table; correct?

20 MS. MIEDEMA: Just the discussion.

21 MR. GIACOMINI: Table the
22 discussion?

1 MS. MIEDEMA: Yes.

2 MR. SMILLIE: Be careful. You're
3 not tabling it.

4 MR. GIACOMINI: That's why asked
5 her to specifically state the motion.

6 MS. MIEDEMA: Let me make this a
7 little less formal. I would respectively ask
8 that we move on.

9 (Laughter.)

10 MR. GIACOMINI: Okay. It's been
11 --

12 MR. SMILLIE: That's sounds like a
13 motion for an adjournment to me.

14 MR. GIACOMINI: The request has
15 been made for us to move on. That's not a
16 formal request in that sense, so the best
17 procedure is, is there any further debate?

18 MR. ENGELBERT: Just very quickly.

19 MR. GIACOMINI: Kevin?

20 MR. ENGELBERT: Just very quickly,
21 one. We have to bear in mind that sunset is
22 ongoing. None of these materials ever drop

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1 off the radar at any time during their
2 five-year period.

3 The other thing we want to bear in
4 mind is that we have something that we're
5 going through right now that's going to be
6 very similar, and that's methionine. Even
7 though it was a petitioned item, the process
8 that we went through was the same thing that
9 we'll be looking at with sunsets and the
10 potentials there.

11 So we've addressed that. We've
12 looked at it and I think it's all going to
13 come out all right. The only thing we may
14 have done differently is to have that failsafe
15 vote that, if it did not go through with the
16 new annotation, it would still stay on the
17 list with the old annotation. I agree with
18 Dan, I don't think this is that complicated.
19 I think we can get through that, and I think
20 it's important to do so.

21 The other last point is we need to
22 decide or we need to know, if this is voted on

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1 Thursday and passes, is it effective
2 immediately? Is it next meeting? Next year?
3 If we voted on it first, would it be effective
4 Thursday?

5 MR. GIACOMINI: It would go into
6 the policy and procedure manual for the next
7 meeting because it was the last thing voted on
8 at this meeting.

9 MR. ENGELBERT: Right, but I'm
10 saying --

11 MR. GIACOMINI: Right. It
12 wouldn't affect these votes.

13 MR. ENGELBERT: Right, unless it
14 was voted on.

15 MR. GIACOMINI: And as far as
16 being simple, delete seven, remove the
17 sentence on four, and change what you're
18 voting on in sunset to be the existing listing
19 and I think it would be a successful document.

20 Barry.

21 MR. FLAMM: Thank you. We plan to
22 get together tomorrow and address all the good

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1 questions and issues that came up together.

2 Mr. Chair, we do have one more
3 item on our Policy Committee agenda, and Kevin
4 is waiting anxiously to present it.

5 MR. GIACOMINI: Proceed at your
6 own risk, Mr. Chairman.

7 MR. FLAMM: I think Kevin can
8 probably do it pretty quickly.

9 MR. ENGELBERT: I'm happy and
10 honored to make the last presentation of a
11 recommendation at my last meeting. And I
12 think it's very uncontroversial. Some of us
13 are disappointed in that, but that's the fact,
14 so let's get right to it.

15 This is a proposed recommendation
16 on the new member guide. As you all know,
17 every year the new member guide is updated
18 with staff, NOP staff names, phone numbers, et
19 cetera. The outgoing executive director,
20 Valerie, made the suggestion to Lisa and
21 Annette that this might be a good time with
22 two new, fresh sets of eyes to completely go

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1 through the new member guide, and that's what
2 they did.

3 There's nothing on the
4 recommendation that is, well, here's what was
5 there before, here's what here now, because
6 the entire thing was completely gone over.
7 There were things moved. It's completely
8 different.

9 The proposed updates to the new
10 member guide are intended to help new board
11 members acclimate to their unique role in the
12 organic community in a variety of ways. It
13 serves as a general orientation for the new
14 members. It provides a streamlined view of
15 the organic regulatory framework.

16 It describes processes related to
17 one's role as an OSB member, including the
18 rulemaking and Federal Register process, the
19 National List, the role of public comment,
20 conflict of interest, technical information,
21 et cetera, et cetera.

22 It identifies useful technical

1 resources, including a list of recommended
2 reading, federal agencies, organic
3 organizations, ACAs, et cetera.

4 It improves the aesthetics and
5 navigation of the new member guide. It
6 reflects changes to the NOSB policy and
7 procedures manual. It suggests best practices
8 for efficiency and organization, and again, it
9 does update committee rosters and NOP staff
10 listings.

11 The one technical change that was
12 made throughout the document was the old
13 document referred to tabs all the way through.
14 That was taken out and replaced with technical
15 information, which is more of a blanket
16 statement for all of the information that the
17 policy or the board members receive and
18 research or whatever.

19 That's basically the gist of this
20 entire document. It's a refurbishing from top
21 to bottom. Again, Annette needs to be thanked
22 for her work on this, and also Lisa.

1 And I'd like to make one more
2 quick point. The transformation from Valerie
3 to Lisa has been completely smooth, and I
4 neglected to mention that when I was
5 presenting the Livestock Committee
6 recommendations in the discussion items.
7 That's simply a reflection of just how smooth
8 the transition has been and how appreciative
9 we all are of that.

10 MR. GIACOMINI: Jeff.

11 MR. MOYER: Kevin, I'm looking for
12 it now and can't seem to find it, but I saw
13 something in there about mentors being
14 assigned to new members. Is that something
15 that really is happening since we have it in
16 our new member guide? I don't know if new
17 members got assigned mentors.

18 MR. GIACOMINI: We call them
19 buddies.

20 MR. MOYER: Buddies?

21 MR. GIACOMINI: Yes. Go ahead,
22 Kevin.

1 MR. ENGELBERT: No, Dan, you can
2 address this because you basically did that
3 when you were making up assignments and
4 talking with people.

5 MR. GIACOMINI: Yes, we called
6 them buddies. We did assign. The only other
7 thing I would say for this document is, if
8 this document is going to be posted
9 potentially like this in a public setting, all
10 personal contact information needs to be
11 completely removed from it and put into
12 another document that would never be posted
13 quite like this.

14 Joe.

15 MR. SMILLIE: Motion to adjourn.

16 MR. GIACOMINI: It's been properly
17 moved and seconded too. We don't adjourn, we
18 recess. You want to go home? You don't want
19 to vote on anything or do anything?

20 MR. SMILLIE: All right. Move to
21 recess.

22 MR. GIACOMINI: We have completed

1 our business for the day. Meeting is in
2 recess.

3 (Applause.)

4 (Whereupon, the meeting was
5 recessed at 7:11 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

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Before: US Department of Agriculture

Date: 10-26-10

Place: Madison, Wisconsin

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R Gross

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