

UNITED STATES DEPARTMENT OF AGRICULTURE
USDA NATIONAL ORGANIC PROGRAM

In the Matter of:)
)
NATIONAL ORGANIC STANDARDS)
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(NOSB) BOARD MEETING)
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Wednesday,
September 18, 2002

The Radisson Barcelo Hotel Washington
Washington, D. C.

The above-captioned matter convened, pursuant
to Adjournment, at 8:00 a.m.

MEMBERS PRESENT:

- OWUSU BANDELE
- KIM BURTON
- DAVE CARTER
- GOLDIE CAUGHLAN
- ANN COOPER
- DENNIS HOLBROOK
- MARK KING
- ROSALIE KOENIG
- MICHAEL LACY
- RICHARD MATHEWS
- KEVIN R. O'RELL
- NANCY OSTIGUY
- JIM RIDDLE
- BARBARA ROBINSON
- GEORGE SIEMON

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P R O C E E D I N G S

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8:13 a.m.

CHAIRMAN CARTER: Okay. Let's get started.

We're 10 minutes behind. We're going to reconvene the meeting here and just a couple of quick announcements.

Mike Lacy informed me yesterday that his aunt had passed away and so he will be leaving some time tomorrow afternoon and so just, Mike, we just want to let you know our thoughts are with you.

MR. LACY: Appreciate that. Thank you. I'm actually going to have to leave this afternoon.

CHAIRMAN CARTER: Okay. This afternoon. So, he'll be excused for an emergency family.

The other thing is just as a point of procedure here. As we go through and we're going to finish up this morning with the discussion then on the Livestock Committee recommendations on the materials, then we will go back, start in with the Crops and go through the action items, and I've been fairly good, I mean, fairly lenient as we go through the discussion, if there's points people in the audience want to raise that we bring that up during the discussion after the Board has talked. When we actually get into the discussion on the materials and the action, the action

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1 items, if those of you that have questions or comments
2 from the audience that you want to bring up, I'd ask
3 that you grab a member of the Board and convey that to
4 them because we do have a number of materials and we're
5 going to have to move through this, you know, fairly
6 rapidly, and we don't want to exclude any discussion,
7 but the Board is the one that has the obligation to
8 take the action on that and so we need to try and keep
9 that action -- that discussion moving.

10 With that, yeah?

11 MR. BANDELE: I thought there were a few that
12 were not discussed yesterday in Processing as well.

13 CHAIRMAN CARTER: That's right. That's
14 right. Good point. So, the Processing met last night
15 and has that all taken care of. So, with that, George,
16 let's go back and cover the Livestock Committee.

17 MR. SIEMON: Okay. Well, I'm just about --
18 Jim's out getting these copied right now for you all
19 for the votes and such. So, rather than go through the
20 ones yesterday, I'll just give you that handout in a
21 few minutes about what those action votes were, so
22 you'll get that.

23 So, I was going to start off with this
24 heparin. I'm sorry I'm jumping around. I've just got

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1 them in a certain order. Heparin is something to
2 prevent blood from clotting. It's clearly a synthetic,
3 and we voted to not add it to the list on a vote of 3
4 to 0 with 3 absence. We had quite a few of these votes
5 that there was absent people, and that's largely
6 because there was a good alternative in sodium citrate,
7 and sodium citrate is already listed as a processing
8 aid and therefore available to livestock. So, that's
9 where we are on heparin.

10 Okay. Any questions?

11 MS. KOENIG: I guess I just had a question.
12 Why would it be automatically available to livestock?

13 MR. SIEMON: We passed in Austin, right?

14 CHAIRMAN CARTER: I'm sorry. I missed the
15 question.

16 MR. SIEMON: The question is, we passed in
17 Austin, did we not, that any materials that's available
18 for human use is available for livestock use, is that
19 correct? That was our intention.

20 MS. KOENIG: I'll have to go back to the
21 Minutes on that one.

22 MR. SIEMON: Okay. The next one is atropine,
23 A-T-R-O-P-I-N-E, and again this one's a synthetic that
24 we said should not be added to the list. It's used in

1 treating poisoning by either organophosphates or toxic
2 plants, and we just thought the poisoning was rare
3 enough and the vote was 5 to 0 to not allow it as an
4 antidote.

5 Any other comments from the committee? I
6 wasn't here for this vote. So, we looked into it at
7 first, but there were some people who said larkspur and
8 toxic plants, such as larkspur, mostly on the West
9 Coast, that this was a problem.

10 Is there any other logic, Jim, or anybody?
11 Why did we --

12 MR. RIDDLE: I know on the previous one, when
13 you said there was a vote, 3 in favor but 3 absent, I
14 just wanted to make it clear to the rest of the Board
15 that that was the original vote, but there have been
16 other committee meetings since then and the people who
17 were absent have had a chance to kind of weigh in, but
18 it's not reflected in that vote. So, I just wanted to
19 make that clear.

20 MR. SIEMON: We didn't revote.

21 MR. RIDDLE: Right. We didn't revote, but
22 they were asked if they concurred and reviewed these
23 draft recommendations.

24 CHAIRMAN CARTER: I'm sorry. Owusu?

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1 MR. BANDELE: One of the reviewers had a
2 concern, which I had, also, that, you know, in this
3 particular case, if it's used for like pesticide
4 poisoning, would not that animal already be not
5 eligible for organic sales?

6 MR. SIEMON: That's right, and so it got down
7 to just for toxic plants is the only use for it because
8 the animal would already be disqualified.

9 MS. OSTIGUY: George?

10 MR. SIEMON: Yeah?

11 MS. OSTIGUY: I'm not sure. You said you
12 voted against this, right? No, you were absent?

13 MR. SIEMON: No. Heparin, I was -- I voted
14 --

15 MS. OSTIGUY: Not heparin. Atropine.

16 MR. SIEMON: Okay. I'm sorry.

17 MS. OSTIGUY: The one --

18 MR. SIEMON: Yeah. I was absent.

19 MS. OSTIGUY: Well, then the vote must be
20 recorded wrong because I voted in favor of this.

21 MR. SIEMON: I have 5 in favor. You voted to
22 not --

23 MS. OSTIGUY: Oh, in favor of it. Yes, okay.
24 5 in favor of it, correct.

1 MR. SIEMON: 5 in favor of not adding it to
2 the list.

3 MS. OSTIGUY: Okay. Oh, no. Other way
4 around. I would like this on the list.

5 MR. SIEMON: Okay. All right. Then the
6 information I have is wrong, and then we have 4 that
7 voted to not put it on the list, 1 voted to put it on
8 the list, and 1 absent.

9 Okay. The next one is F-U-R-O-S-E-M-I-D-E.
10 This one is one that we decided to return the TAP for
11 further information, and we gave a list of the things
12 that we want to ask for more information for and that
13 was a vote of 5 to 0, 1 absent as well. That's one of
14 the phone calls that I was absent on. So, any other
15 board members have any other comments about that? It's
16 something used for edema and just thought the
17 information was inadequate.

18 MR. RIDDLE: Yeah. I guess I'd just comment
19 on this. You'll see once you get the handouts what we
20 found inadequate with the TAP review on furosemide, but
21 it was pretty common in these reviews that there were
22 citations from manufacturer websites being presented as
23 scientific evidence and then language directly cut from
24 those citations and placed in the Executive Summaries

1 as if it were analysis of the TAP contractors. We
2 found that to be unacceptable. It didn't describe the
3 method of manufacture, the environmental impact, really
4 no discussion of its historical use or alternatives,
5 and it didn't address the seven criteria, and this one
6 in particular stood out as being grossly inadequate.

7 MR. SIEMON: Okay. The next one is activated
8 charcoal, which is being looked at by both committees,
9 Processing and the Livestock. We definitely thought
10 that it should be added to the list with the annotation
11 as -- this one you'll have to help me on. I don't --
12 as disinfectants, sanitizer and medical treatments as
13 applicable. Jim Riddle, is that it?

14 MR. RIDDLE: Oh, yeah. That's actually what
15 category under the list, under .603 that would fall
16 under, .603(a). It's a medical treatment.

17 MR. SIEMON: That's really not annotation.
18 That's where it belongs.

19 MR. RIDDLE: Right.

20 MR. SIEMON: I just couldn't understand that.

21 MR. RIDDLE: Right.

22 MR. SIEMON: Yeah. Under .603(a). The vote
23 was 6 to 0, nobody absent. We agreed it was synthetic
24 due to high heat and purification process, and Jim, I

1 don't see where it says vegetative on this sheet of
2 paper. We said vegetative sources only.

3 MR. RIDDLE: It should. It's on the draft.

4 MR. SIEMON: It's not on the final here.

5 MR. RIDDLE: Well, then it needs to be added
6 back. Somehow that got --

7 MR. SIEMON: So, our only restriction was
8 from vegetative sources on activated charcoal.

9 MR. RIDDLE: On that, we looked into it and
10 there are sources available from hardwood charcoal as a
11 medicinal. So, it is something that is being used by
12 veterinarians and producers now.

13 CHAIRMAN CARTER: Owusu?

14 MR. BANDELE: The reason for not allowing the
15 animal products was concern with diseases and things of
16 this nature?

17 MR. RIDDLE: Yeah. Right. And also, to be
18 consistent with our recommendation on the feed
19 ingredients, we said that bone charcoal would not be
20 allowed back in May, and so concern there, but then
21 also there could be sources from coal and petroleum and
22 thought that that was not consistent with principles or
23 the intent, especially when there is vegetative sources
24 available.

1 MR. SIEMON: Okay. Here's your copies
2 coming, so you all can see.

3 Okay. The next one is mineral oil. There
4 was two requests here, and one is a dust suppressant
5 and we deferred that decision, and the other one was
6 for topical and as -- well, --

7 MS. CAUGHLAN: George, you're deferring the
8 dust. Is that your -- going to ask for more questions
9 in the TAP or what's the reason for the deferral?

10 CHAIRMAN CARTER: The reason for that was
11 that the TAP really didn't address what, you know, the
12 other alternatives. There was concern that if you had
13 some -- the dust suppressant from cell oil or something
14 like that, it could go rancid, but they didn't really
15 give the whole range.

16 MR. RIDDLE: It was really not addressed in
17 the TAP, this use of that material, even though it was
18 petitioned for both uses.

19 CHAIRMAN CARTER: Yeah. Rose?

20 MS. KOENIG: I just have a question, maybe an
21 interpretation. What was confusing to me is that it
22 was already listed as a lubricant in the rule, and, you
23 know, I just didn't know. Was it a lubricant for some
24 other reason, other than what we're looking at it

1 already for?

2 PARTICIPANT: We were confused by the same
3 thing.

4 CHAIRMAN CARTER: That's a good question.

5 MR. SIEMON: It's my opinion that was meant
6 for non-livestock when they did that, and it's just an
7 error, but --

8 MS. KOENIG: Did you look at the Minutes when
9 that was approved? Was that put on -- when was it
10 added to the list or was it in the original proposed
11 rule?

12 MR. SIEMON: You might remember, I don't
13 know. Because we were dealing with the issue as a
14 bloat treatment, is really what we looked at it as, and
15 we don't think that's -- I don't know if that's a
16 lubricant or not, so to speak.

17 MS. KOENIG: The way I read it, that is
18 exactly what you were doing, was lubricating the
19 intestine, I mean, so that everything would pass
20 through. So, I mean, I just -- it just seems redundant
21 that you would put -- it already says it's a lubricant
22 and then you're going to add it as an internal
23 lubricant.

24 MR. SIEMON: I agree.

1 MS. KOENIG: So, we've got to clarify what
2 the rule was meant -- you know, the purpose of what it
3 really says before we add it again for the same purpose
4 or maybe a different purpose, and we have to clarify
5 it.

6 MR. SIEMON: Yeah. In my mind, we're making
7 the same decision a second time here on this.

8 CHAIRMAN CARTER: Kelly?

9 MS. SHEA: When the TAP review was done in
10 1995, the recommendation was that it be allowed also
11 for bloat and compaction. I believe that at one point,
12 the OTA Livestock Committee had submitted a suggestion
13 that it just be moved to the A part of the rule, so
14 it's under -- instead of being under Topical, it's
15 under Livestock Health Care, and it might be as easy as
16 leaving it as it is in the rule but moving it to a
17 different section because isn't A enteron for health
18 care? Right. And then B is -- it's in the Topical
19 section right now. So, they just got put in the wrong
20 section.

21 CHAIRMAN CARTER: Thank you, Kelly.

22 MR. SIEMON: Either way, we're clarifying
23 that we're recommending that it be a synthetic and it
24 be allowed for bloat control in livestock treatment and

1 the vote on that was 4 to 0 to 1 abstaining and 1
2 absent.

3 Anything else about mineral oil?

4 (No response)

5 MR. SIEMON: The next one is kaolin pectin,
6 and again we're saying to add this as a synthetic to
7 the .603(a), and I'm a little confused about the
8 synthetic natural, but basically it can be either one,
9 but we're approving the synthetic, therefore the
10 natural's also, but that's not quite true. There's a
11 difference between what -- Jim, help me out with the
12 natural synthetic. That's the point I'm confused on.

13 MR. RIDDLE: On the processing list, you have
14 two types of pectins allowed for processed product,
15 food products, both natural pectin and synthetic
16 pectin, and so to be clear, we want -- and consistent,
17 we're saying that either one of those formulations
18 would be allowed for livestock use.

19 MR. SIEMON: And that's following the
20 processing lead again on that one.

21 MS. KOENIG: I would -- I just went back
22 through the Minutes, and, you know, I can't -- I don't
23 see where -- I saw where we added a lot of stuff as
24 feed additives and incidentals in feeds as far as

1 allowing those things from processing, but I don't see
2 anything specifically where it says medical use. I
3 understand, and I can, I guess, concur with your --

4 MR. SIEMON: Well, where is that motion? I'd
5 like to --

6 MS. KOENIG: Well, I don't know. I mean, the
7 committee is saying this.

8 MS. BROWN-ROSEN: I'd have to find out when
9 it was -- what meeting the recommendation was made, but
10 basically it was saying that anything that's allowed
11 into 205.605 would be -- because it's allowed for
12 humans, it would be allowed for livestock, and I'd have
13 to go back and see what meeting we made that
14 recommendation on.

15 MS. BURTON: May?

16 MS. BROWN-ROSEN: No, I don't remember.

17 PARTICIPANT: They all run together.

18 MS. BROWN-ROSEN: It's also posted in that
19 draft for comment.

20 PARTICIPANT: The feed ingredients.

21 MS. KOENIG: But is it feed -- see, I see it
22 as feed ingredients, but I don't see it in terms of
23 medical stuff and that's really stretching what was
24 said, and I don't feel comfortable.

1 MS. SHEA: It wasn't supposed to be feed
2 because feed's supposed to be 100 percent organic. It
3 was meant for livestock health --

4 CHAIRMAN CARTER: Come to the microphone,
5 Kelly.

6 MR. SIEMON: It was meant for livestock feed
7 additives is what you're saying, but feed additives are
8 a constant thing while a health thing is a very
9 infrequent thing.

10 MS. SHEA: If you remember, Dave, we were
11 slipping notes to you at the May meeting saying that
12 the problem with the recommendation the way it was
13 worded is that it allowed things on 205.605 to --
14 205.606 to be allowed in livestock feed, and the issue
15 is there are two things on 205.605, like kaolin,
16 pectin, ditamious earth and so forth, that are used
17 in livestock production, not as feed or as a feed
18 supplement but in some cases as a health care item, and
19 because that seven-point recommendation is posted for
20 comment now, maybe that change from feed, which is
21 supposed to be organic, except in the case of
22 supplements which are vitamins and minerals and such,
23 to livestock production, feed to production, then would
24 remove the need for TAP reviews on things like kaolin

1 and pectin.

2 MR. SIEMON: But nevertheless, we have done
3 the review, and we're making a decision independently
4 of that earlier motion. So, this one again is -- I'm
5 going to keep moving.

6 MS. KOENIG: The only thing is in terms of
7 clarification, and maybe I can wait till discussion,
8 but back to that -- I'm just making sure that what
9 you're interpreting is true because you don't want to
10 not approve something assuming that the rule says that
11 you can use something and then you -- so, back to
12 whatever --

13 MR. SIEMON: But we're not. We're making
14 recommendations anyway.

15 MS. KOENIG: But you said with the heparin or
16 something. I mean, I don't -- I just don't want to
17 just run through these things in a haphazard fashion
18 without --

19 MR. SIEMON: The heparin.

20 MS. KOENIG: Isn't that the one that you said
21 that was an alternative that was already on the list?

22 MR. SIEMON: Sodium citrate. Yes, you're
23 right. Sodium citrate is already on the list.

24 MS. KOENIG: But again, is that going to be

1 sufficient? Is it on the list to be used as -- for
2 medical purposes rather than feed supplement? That's
3 why I say, have you thought about that?

4 MR. SIEMON: Right on. I agree. On this
5 one, you're absolutely right. It's in the processing.
6 We're making a decision on a recommendation on heparin
7 based on the fact. Our understanding was that sodium
8 citrate was available. If it is not available, we may
9 change our decision on it.

10 MS. KOENIG: Should we then defer?

11 MR. SIEMON: We need to find it in the
12 Minutes.

13 MS. OSTIGUY: Well, what we could do, George,
14 is defer the decision on heparin till October, figure
15 out whether or not we want to suggest word alterations
16 to the motion that we did in May that only said feed
17 additives or figure out how we want to handle it.

18 MR. SIEMON: We could do that or we could try
19 to fix it right in this meeting, if we could.

20 CHAIRMAN CARTER: Yeah. We have time tonight
21 to look at it. So, you know, we can make a note of
22 that.

23 MR. SIEMON: Okay. So noted about --

24 CHAIRMAN CARTER: Because, you know, if we

1 need to defer, we do have a meeting coming up in a
2 month, although it's only a two-day meeting. So,
3 everybody get a lot of sleep before you come there
4 because we'll be going all night.

5 Okay. Back to kaolin pectin.

6 MR. SIEMON: Any questions on that?

7 CHAIRMAN CARTER: Just a second. Rick had
8 something on -- oh, you're back on heparin?

9 MR. BANDELE: Well, there may be other
10 reasons. I mean, that was one reason. So, I mean, if
11 there are other reasons why the committee would not
12 want to approve it, then it would not have to be
13 deferred, if they found that to be true.

14 CHAIRMAN CARTER: Right. We can talk about
15 that tonight. That's the discussion we'll have
16 tonight.

17 Okay. Back on kaolin pectin. Rick?

18 MR. MATHEWS: On this one, I would recommend
19 that the annotation not be recommended to the
20 Department for the following reason. First of all, all
21 naturals are allowed unless prohibited. So, you don't
22 need to be addressing the natural. Secondly, you're
23 asking to put this in a section of the regulation that
24 addresses synthetics. So, you don't need to say that

1 it's allowed in synthetics because it's in the
2 synthetics section. So, all you have to do is just say
3 kaolin pectin under synthetics is okay.

4 MR. SIEMON: I agree. That's no problem.

5 CHAIRMAN CARTER: Okay.

6 MR. SIEMON: Okay. The next one is this,
7 whatever it is. Go ahead. Let's hear it. Let's hear
8 it. All right. As you can see, we declared this a
9 synthetic. We said that it should be added to .603(a).
10 Basically, pepto-bismol, and this is a calf one, and
11 we'll hear later when we talk about dairy replacement,
12 we definitely want to see what we can do to get
13 materials through for younger calfs.

14 Any questions on this one?

15 (No response)

16 MR. SIEMON: Okay. Next one is magnesium
17 hydroxide. Again, while it can be either natural or
18 synthetic, again like Rick just said, we don't need any
19 of these annotations, and the vote, as you can see, was
20 5 to 0. It's a laxative antacid.

21 All right. Next one is corpyleneglycol.
22 This is what -- a synthetic that's used to treat acute
23 ketosis in ruminants, and the vote was 3 to 0 with 3
24 absent, and the annotation was only for treatment of

1 acute ketosis in ruminants.

2 Any questions on that one? Is there a
3 veterinarian in the house who can tell us what ketosis
4 is that may not be here tomorrow when we discuss it?

5 PARTICIPANT: Ketosis involves starvation for
6 the digestive system.

7 MR. SIEMON: Well, I didn't know there was
8 anybody here that might not be tomorrow. Nancy, you
9 want to -- ketosis?

10 MS. OSTIGUY: I'm sort of drudging up very
11 old stuff. It's actually, if I remember correctly, an
12 acid imbalance that can kill you. I can't --

13 MR. SIEMON: Dan? Dan can tell us maybe.

14 DR. LEITERMAN: Good morning. I'm Dan
15 Leiterman with Crystal Creek. The definition for
16 ketosis is a liver shutdown where it can't convert
17 glycogen out of the muscle back into the bloodstream.

18 MR. SIEMON: It's a crisis.

19 MS. KOENIG: There was alternatives, like
20 dextrose or possibly insulin, that could -- I mean,
21 it's not as fast reacting, I guess.

22 DR. LEITERMAN: Alternatives for treating
23 ketosis would be IV glucose or other sugars that you
24 give internally. If the liver's not functioning, then

1 you have to try and get sugars into the bloodstream
2 directly. Alcohols sometimes are used in drenches but
3 sometimes may not be allowed for organic use.

4 MS. KOENIG: But it said that dextrose would
5 have been a natural alternative. What is -- do you
6 know what the -- I mean, it appeared that it was a
7 little -- I think, if I remember from the TAP, it's
8 slightly slower acting.

9 DR. LEITERMAN: Yes, it's slower acting when
10 it's given orally. If it's given IV as a glucose or a
11 dextrose in the vein, it's very fast acting. It's time
12 consuming to give an IV primarily because you're
13 looking at 20 to 30 minutes to stand there and hold the
14 bottle and the cow likes to move around a lot. So, a
15 lot of the producers like to give an oral drench.

16 MS. KOENIG: That's what -- I was under the
17 impression that this would be a chemical -- I guess
18 chemical, whatever you want to call it, pharmaceutical,
19 that farmers were -- like they don't want to call the
20 vet. So, they have it handy so that they can self-
21 treat the animal versus --

22 DR. LEITERMAN: In both conditions, it can be
23 used as a preventative, if they see conditions coming
24 on where they could prevent it from becoming an acute

1 situation, and secondly, when they give the IV, if they
2 do call the vet, stabilize the animal, sometimes they
3 relapse repeatedly within hours and nursing care with
4 propylene glycol would be helpful.

5 MR. SIEMON: Some of the alternatives
6 required veterinarian to be there every four hours and
7 that seemed to be unrealistic versus something -- have
8 them be out once and have this as a supplement.

9 DR. LEITERMAN: Right. There are some issues
10 with propylene glycol that would draw attention, but,
11 frankly, there's not a lot of alternatives. One of the
12 alternatives I looked into was grain solubles, but
13 grain solubles cannot be procured without knowing that
14 they're GMO-free. So, propylene glycol serves quite a
15 purpose even though there's some things that may raise
16 questions.

17 CHAIRMAN CARTER: One of the individuals that
18 submitted a comment on this had said that there are
19 suitable substitutes for the product available; that
20 is, honey, sugar, molasses, maple syrup and other
21 simple sugars. Can you --

22 DR. LEITERMAN: Right. Simple sugars are, to
23 some degree, an alternative. The challenge is getting
24 it into the bloodstream without function of the liver.

1 Although sugars, the more complex, even though they
2 are simple, require liver function to convert from
3 glucose to the liver into glycogen and then back.
4 Alcohol is the only realistic alternative to propylene
5 glycol, where it can go into the bloodstream through
6 the ruminal wall without liver function.

7 PARTICIPANT: The people taking the notes
8 need to know your name.

9 DR. LEITERMAN: Dan Leiterman with Crystal
10 Creek.

11 MR. SIEMON: Okay. I'd like to move on to
12 calcium propionate, again to be added to .603(a) as a
13 synthetic. Dan, are you going to be here tomorrow?

14 DR. LEITERMAN: Yes, I will.

15 MR. SIEMON: Okay. Great. This is for the
16 treatment of milk fever, and this is a different form
17 of treatment that can be used in a paste form. It's a
18 lot more applicable for farmers to use. You can see
19 again the vote was 5 to 0 with 1 missing.

20 Any questions on this?

21 MR. RIDDLE: I would just like to point out
22 that the committee also considered its use as a mold
23 inhibitor or a feed additive -- or a preservative and
24 recommended against that. So, it would not be added to

1 the list for that use at all.

2 MR. SIEMON: Don't we then need --

3 MR. RIDDLE: As a medical treatment.

4 MR. SIEMON: Then we need to make that a
5 formal motion, don't we?

6 MR. RIDDLE: Well, it's down there as the
7 last item in the summary, but it might be clearer to
8 move that up. That was part of the vote.

9 MR. SIEMON: Then we should make that so it's
10 in the record real clear. So, that should be a second
11 motion. We have enough trouble with records here.

12 MR. RIDDLE: We'll move that up.

13 MR. SIEMON: That'll be a motion as well on
14 this one.

15 MR. MATHEWS: And I can tell you that one of
16 our long-range plans is to create a list. Actually, I
17 guess we've actually got it through Emily and others,
18 the list already shows what you have acted on, so that
19 people know whether you've approved it or disapproved
20 it. So.

21 MR. RIDDLE: That would help to move that up.

22 MR. MATHEWS: Yeah. I mean, it would help to
23 go on the record that you've looked at it for this
24 purpose and you have said no.

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1 MR. SIEMON: Ready to move on?

2 CHAIRMAN CARTER: Yes.

3 MR. SIEMON: Okay. Next on the list is cell
4 oil carbohydrates. We call this a natural, and
5 therefore we want that to be allowed. 3, none against,
6 and 3 absent. And the next one, use derivatives, is
7 right in the same category, and then we get to the
8 tougher ones. We were not real happy with -- on the
9 chelates, the TAP review, but we definitely -- they're
10 synthetics, and we want to have them added to the .603
11 but just the proteinated and polysaccharide chelates
12 only and not amino acids. Really, this is already in
13 our motions in Austin. We allowed these already, but
14 we just noted that they should be reviewed. So, by
15 rights, all were -- this should be just that we're
16 prohibiting amino acids, should be the motion, not
17 allowing the other ones, because Emily pointed out
18 they're already allowed by our feed additive clause.

19 We did -- and that kind of answers our
20 concerns as a committee, that we were disappointed in
21 the TAPs for them. They're already allowed. So, now
22 it's just a matter if we want to get a better TAP to
23 prohibit those two classes.

24 Did you have a comment?

1 MS. BROWN-ROSEN: Well, I just wondered. The
2 protionated, if you read the definition, they also are
3 amino acid forms. So, you're specifically allowing one
4 and not the other or are you just sending it back for
5 more review?

6 MR. SIEMON: Well, that's a good question,
7 and I don't know if you all got some of the comments
8 that we got about the poorness of this TAP. So, it's
9 my understanding that we were just letting this stand
10 or compared to sending it back for more information on
11 protionated. I mean, it's not --

12 CHAIRMAN CARTER: Okay. Dan, can you come
13 forward again? That was Emily Brown-Rosen, by the way,
14 for the record.

15 DR. LEITERMAN: This is Dan Leiterman again.
16 The impetus for asking for protionates is that I
17 understand the concern with amino acid chelates, and I
18 agree with that. Protionates is a general term in the
19 industry that could be all inclusive of single amino
20 acid and/or natural existing long-chain proteins.

21 If you were to look at the options in the
22 industry, there's some very good proteinated chelates
23 out there and just for the panel here to understand,
24 the reason that we're requesting this is because

1 chelation is a natural process in the intestinal tract.

2 When animal are sick or stressed, chelation does not
3 function well, and the delivery of those trace minerals
4 is directly supportive to immune function.

5 So, in the process of trying to do natural
6 therapies to animals to support their own immune
7 system, it's essential that we deliver these to them so
8 that they can actually get into their system properly.

9 Using an existing natural protein rather than a
10 synthesized amino acid still allows us to deliver the
11 trace minerals to the animal properly, so that they can
12 help with their own repair process.

13 MR. SIEMON: Does protionated mean it's from
14 a certain source or what's the difference between the
15 two?

16 DR. LEITERMAN: According to regulations, if
17 you use an amino acid, you have to specify that it's an
18 amino acid chelate. Protionates, common knowledge for
19 protionates is an all-inclusive term that could
20 possibly involve amino acids, but generally in the
21 industry is recognized as an existing long-chain
22 protein. The people that have amino acid complexes use
23 that as a proprietary selling point and want to label
24 it that way and industry insists on it. So, the people

1 using protionates generally are looked at as a less
2 available source of the chelate than the amino acids.
3 You can specify, if you'd like, protionates if they're
4 going to be allowed to be natural long-chain proteins
5 rather than amino acid sources.

6 MR. RIDDLE: I have a question for Dan. The
7 way I heard you talk about this, for the protionates,
8 for medical use?

9 DR. LEITERMAN: Both medical therapeutic and
10 for preventative. It's common in the industry to use a
11 low level of chelates in stress situations to prevent
12 problems. It's cost prohibitive to use a lot of it.
13 One of the nice things of using chelates is that
14 they're very available and we have less coming through
15 in the manure. So, waste issues are also addressed
16 with that.

17 MR. RIDDLE: So, our recommendation is not
18 saying where on .603 that we're recommending it be
19 added. I'm just wondering if we should be more
20 specific to the NOP on that.

21 MR. SIEMON: You mean choose between feed or
22 health or both?

23 MR. RIDDLE: Right.

24 MR. SIEMON: And our recommendation is for

1 both right now, right?

2 MR. RIDDLE: Well, that's what I'm not clear
3 on. That's what I'm questioning. Maybe we should look
4 at that if we're having to meet again tonight.

5 DR. LEITERMAN: Our biggest application of
6 that tends to be preventative rather than therapeutic,
7 and then when we do get into having to apply therapy,
8 it's used in therapeutic, but to help reduce costs at
9 the producer level, we like to use it as a preventative
10 level.

11 MR. RIDDLE: But when you're saying
12 preventative, that could be routine?

13 DR. LEITERMAN: That's routine.

14 MR. RIDDLE: Part of the feed ration.

15 DR. LEITERMAN: Right.

16 MR. RIDDLE: Okay.

17 DR. LEITERMAN: Bob, are you going to be here
18 tomorrow?

19 DR. BURESH: Probably not tomorrow.

20 DR. LEITERMAN: Bob's a livestock
21 nutritionist. Do you have anything else to add to the
22 discussion on this? I don't know. You're a livestock
23 nutritionist.

24 DR. BURESH: Livestock and chickens.

1 DR. LEITERMAN: And chickens.

2 DR. BURESH: I'm Bob Buresh with Tyson, and
3 we are growing some organic chickens now. So, there
4 are trace mineral complexes that are proteionated, just
5 like you said, whether it be a protein complex or an
6 amino acid complex, that make it more available, and
7 for poultry, some people do use those as a routine part
8 of the ration just as a more available source of that
9 particular trace mineral. We don't particularly use it
10 because it is much more expensive, and we're using the
11 standard trace minerals that have already been
12 approved, like for the vitamin trace mineral packages,
13 but I don't think, you know, with other than the amino
14 acid stipulation, you know, which seems to draw some
15 concern at this point, as long as, like you said, you
16 have a defined protein attachment to the trace mineral,
17 it should be -- you know, things should be -- meet all
18 the requirements, I guess.

19 MR. RIDDLE: I have another question. Either
20 Bob or Dan. You know, I think we've got some good
21 information now on the protionated forms, but with the
22 polysaccharides, the TAP review really didn't go into
23 that at all, and can you -- please, Dan, if you can
24 just -- okay -- explain what those are? Are those

1 readily available to producers? Are they commonly
2 used?

3 DR. LEITERMAN: Polysaccharides are
4 available. They're not commonly used. They're not as
5 effective as a protionate, and all it is is using a
6 carbohydrate source to attach the metal to rather than
7 proteins. So, that's the only difference, but in the
8 industry, they don't seem to pass through the gut as
9 easily. What you're trying to do is protect that
10 nutrient in the front end of the digestive tract, so it
11 gets to the lower tract where you want it, and
12 carbohydrates tend to not hold up as well. So,
13 proteins are a better source.

14 MR. RIDDLE: Do you know what the source of
15 carbohydrates commonly is?

16 DR. LEITERMAN: No, I don't.

17 MR. SIEMON: And so, when I just have a
18 protionated -- are you saying we could annotate that to
19 be only natural long-chain protionate or is that
20 getting away from --

21 DR. LEITERMAN: Or you could annotate it and
22 say with the exception or not to include isolated amino
23 acids.

24 CHAIRMAN CARTER: Just a second. I think

1 Richard had something.

2 MR. MATHEWS: And this is for Dan or Bob or
3 both. The committee is recommending the annotation,
4 proteinated and polysaccharide chelates only. Amino
5 acid chelates are prohibited. The question that I have
6 for you is kind of two.

7 First of all, does that take care of the
8 problem from the standpoint that we're not going to
9 have somebody confused about what the annotation means
10 in light of the fact that there was discussion about
11 protionated sometimes is interpreted as amino acid?

12 Then the second question related to that is,
13 is there anything else besides these? Because the way
14 I read it is you've got two that are allowed, two
15 classes, I guess, that are allowed. One class is
16 disallowed, and so I'm looking at the annotation from
17 the best annotation that we could be presenting. So,
18 can you -- either of you give me some comments on that?

19 DR. LEITERMAN: I haven't thought through
20 that totally. So, I may not have the wording properly,
21 but you're on the right track. I'm recommending that
22 you allow proteinated chelates annotated to exclude
23 amino acid protionates.

24 MR. MATHEWS: Okay. But I guess my concern

1 is --

2 DR. LEITERMAN: Am I saying that right?

3 MR. MATHEWS: My concern is that we also
4 identify polysaccharide. Is there a fourth, a fifth, a
5 sixth --

6 DR. LEITERMAN: Not that I'm aware of.

7 MR. MATHEWS: -- class?

8 DR. LEITERMAN: No.

9 MR. SIEMON: But the action to be taken here
10 is to prohibit amino acid chelates and amino acid
11 proteinated chelates, not to allow the other ones,
12 because they're already allowed by the AFCO decision we
13 made in May. That's my understanding.

14 MR. MATHEWS: Okay. My only questions were
15 based on what I'm reading off of the motion, and so the
16 restriction would really read, amino acid chelates are
17 prohibited. That's all you would need as an
18 annotation.

19 MR. SIEMON: Unless you added amino acid
20 proteinate chelates as well which I just heard you
21 might want to clarify.

22 PARTICIPANT: He's saying it covers the same
23 thing.

24 MR. SIEMON: Okay. That's fine.

1 MR. MATHEWS: That's what I'm trying to --
2 that's all I'm trying to do.

3 MR. SIEMON: That's what the motion would be.
4 If there were three or four other sources, it doesn't
5 matter, they're all allowed. This is the only one
6 we're dealing with and that's prohibited.

7 CHAIRMAN CARTER: Okay. Rose?

8 MS. KOENIG: I guess I had just a general
9 problem, and I understand that we blanketly allowed
10 this group in Austin, but even with that in mind, it
11 seems like there is confusion, based on what Rick said.

12 I don't know why we cannot -- I mean, I personally
13 would like to see the TAP go back. I would like them
14 to work on the specific lists of minerals that fall
15 under this. Why can't we just list them out and that
16 would not confuse anyone? Instead of saying it's a
17 group, the group idea is what's confusing because is it
18 in the group or not in the group? So, just
19 specifically list them out, I mean, and then it's
20 clear, and it would be clear that the ones that were
21 amino acid forms weren't there and in terms of
22 certifiers and inspectors, I mean, our objective should
23 be to make the rule and the list as clear as possible,
24 and by grouping things, it does not make it clear.

1 It's obvious, even an expert that you are, you're -- I
2 know you know your stuff. I'm just saying that there's
3 a sense of confusion that I get from everyone in this
4 room. So, how can we expect growers -- they may be
5 smarter, but --

6 DR. LEITERMAN: I think part of that's
7 already covered in the regulations through the feed
8 industry. What went on the label for ingredients,
9 you're using a chelated amino acid, it has to be listed
10 that way.

11 MR. SIEMON: Chelated amino acid?

12 DR. LEITERMAN: Right.

13 MR. SIEMON: Not as the individual?

14 DR. LEITERMAN: So, even though it may fall
15 into a protionate category, it cannot be listed that
16 way. So, if they're going to use a protionate, it's a
17 long-chain protein molecule.

18 MR. SIEMON: Oh, then that's clear.

19 DR. LEITERMAN: So, in the feed industry as a
20 general rule, when you see protionate on a label, you
21 know that you've dropped down a notch on the
22 performance of the product.

23 MR. SIEMON: And just so you know, the list
24 is like -- if I remember from Austin, it was like 50.

1 Emily, wasn't it about like 50? There's 50 under each
2 one of these groupings, isn't it? 50 different --

3 MS. BROWN-ROSEN: It's not 50, but there's a
4 lot of different materials.

5 MR. SIEMON: Yeah. It's a large number, and
6 we're not going to do a review of all those nor are we
7 going to put all those on the list, if that's what
8 you're asking.

9 MS. KOENIG: Yeah. But, I mean, there has to
10 be some -- I don't know. In my mind, there should be
11 some better system.

12 MR. MATHEWS: In the TAP review, when you saw
13 the list of the nutrients and trace minerals that were
14 listed, all of those are applicable to whether it's a
15 synthetic amino acid or whether it's a protionate or
16 whether it's polysaccharide.

17 CHAIRMAN CARTER: Okay. Bob had something,
18 and then Mark.

19 DR. BURESH: Like you said, you have to make
20 the ruling to allow this list because these companies
21 that are producing them are coming up with these new
22 chelates continually. That's their big business. So,
23 I mean, you've got to have it to where it's in certain
24 categories and not list specific amino acid chelates.

1 But the second thing, and this is my lack of
2 knowledge of the actual vitamin trace mineral
3 allowance, is these sometimes are -- can be included in
4 a standard trace mineral premix, you know. I'm just
5 buying a trace mineral premix, and is that as part of a
6 standard trace mineral premix when that was approved,
7 the sources of trace minerals within that premix, were
8 those reviewed, or is it just a trace mineral premix is
9 allowable --

10 MR. SIEMON: The individual trace minerals
11 have to be approved.

12 DR. BURESH: Okay. That's what --

13 MR. SIEMON: Whoever's producing the -- the
14 farmer buys the package, they have to make sure there's
15 no prohibited materials in that package.

16 DR. BURESH: Okay.

17 MR. SIEMON: If that's your question.

18 DR. BURESH: Yeah. That's the question. The
19 same with the vitamins. What the source of the
20 individual vitamins were, and that's --

21 MR. SIEMON: We have adopted a broad
22 inclusion of the AFCCO materials partially, and now
23 actually we're just going at trying to see which ones
24 do we want to prohibit. So, on this one, the motion

1 will be just to prohibit amino acid chelates as a feed
2 or for any use, right? That's the motion that we'll
3 have on this. On amino acid chelates? That's my
4 understanding, that it's for all uses.

5 CHAIRMAN CARTER: Okay. Mark?

6 MR. SIEMON: That's a good question, though,
7 because of fears about feed.

8 Dan, is there -- on health care, is there any
9 significant disadvantage to not allowing amino acid
10 chelates on health care purposes compared to the other
11 ones?

12 DR. LEITERMAN: Well, proteinated chelates
13 are a very viable option, and we would not miss amino
14 acid chelates for health care issues.

15 CHAIRMAN CARTER: Kelly Shea?

16 MS. SHEA: I understand that that's your
17 position. In December of 2000, Horizon Organic and
18 Organic Valley worked together on a petition for --
19 there are actually some brand name products called
20 Zimpro and Forplex that are chelated minerals that are
21 used for health care for hoof health, especially in
22 pastured animals and some other issues. At that point,
23 Eric Sideman, chairing the OTA -- the NOSB Livestock
24 Committee, told us that we did not need to submit that

1 petition at the time because amino acids were being
2 dealt with by the Board, specifically methamine was
3 being dealt with, and he told me at that time that he
4 thought that those were naturals, that they didn't need
5 to be petitioned.

6 So, at the meeting in Austin in May, when the
7 Livestock Committee had their seven-point feed
8 recommendation and it listed a number of things from
9 AFCO that would be prohibited, it was EDDI and the
10 proteinated chelates, and the reason in the middle of
11 the meeting that the Livestock Committee's
12 recommendation changed to allowing those things until
13 they were prohibited was because of Eric Sideman's
14 remembrance of the situation with Zimpro and Forplex,
15 and so now we're talking about prohibiting them, and
16 I'm just wondering if the Livestock Committee is
17 intending to also prohibit farmers from using products
18 like Zimpro and Forplex for herd health, and I just
19 want to make sure they've considered that.

20 MR. SIEMON: Those are amino acid chelates?

21 MS. SHEA: They're chelated. They're called
22 chelated minerals, and in the AFCO Section, they are
23 listed as a -- we don't have the AFCO book in front of
24 us, but Rosie, to your point, I think you're exactly

1 right, that it would be hasty today to prohibit these
2 things that are being used by organic farmers today
3 without making sure we know what we're prohibiting.

4 MS. BROWN-ROSEN: The current Armery position
5 is that all vitamin and mineral sources should be
6 approved, of any source, under -- for veterinary health
7 care use because sometimes the vet needs an emergency
8 injection of Vitamin E, and, you know, that's our
9 advisory board says all forms should be available for
10 health care. So, that's what we've been operating
11 under.

12 CHAIRMAN CARTER: Okay. Dan? He had his
13 hand up, George.

14 MR. SIEMON: That's fine. But so I
15 understand that in order for this to be used for herd
16 health, we would have to approve it for herd health.
17 Right now, it's not allowed for herd health. It's only
18 allowed for feed additives. So, in order for it to --
19 to answer Kelly, it is not allowed right now. In order
20 to be allowed, we'd have to approve it for --
21 specifically for herd health.

22 DR. LEITERMAN: The clarification that I
23 would require is if the Zimpro/Forplex and the Zinc
24 Methionine that she's -- Kelly's referring to are amino

1 acid complexes. I need clarification if those can be
2 used for both therapeutic application and/or as a feed
3 supplement. My understanding right now is that they
4 cannot be used on a daily basis in feed. Maybe there's
5 somebody here that can clarify that, but that was
6 impetus of the requesting for protionates, was the
7 understanding that synthetic amino acid chelates could
8 not be used in feed on a daily basis.

9 MR. SIEMON: They're all three allowed right
10 now, the way the standards are today, and actually
11 these substances were given to us in the guise of herd
12 health issues. Really. That's where this whole list
13 came from, is herd health issues. Now, it may not be
14 the TAP review reflected that, but this list was
15 generated from our whole concern about herd health
16 substances. So, I'm a little confused now myself, you
17 know.

18 CHAIRMAN CARTER: Okay.

19 MR. SIEMON: So, we do have to sort through
20 the feed and the herd health uses here is what we have
21 to sort through.

22 CHAIRMAN CARTER: Okay. Owusu?

23 MR. BANDELE: I just had a question. I mean,
24 as a plant person, I'm not understanding. If a product

1 is approved for feed but not for herd health, I mean,
2 isn't that moot?

3 MR. SIEMON: Yes.

4 MR. BANDELE: I mean, couldn't the farmer
5 feed it and get the herd health benefit or is there a
6 difference in concentration?

7 MR. SIEMON: Yes. I agree with that.

8 MR. RIDDLE: We haven't mentioned the fact
9 that the amino acid chelates are produced from excluded
10 methods or GMOs and that was the main reason why we
11 recommended they be prohibited and that was well
12 covered in the TAP.

13 CHAIRMAN CARTER: Okay. David, you had
14 something. You need to come to the mike and identify
15 yourself.

16 MR. ENGEL: David Engel. Jim, all amino
17 acids are produced that way. So, when you go into the
18 protionated, the metal, the polysaccharides, you're all
19 using amino acids and then something else. The amino
20 acids all come from the same source. That's Number 1.

21 Number 2. What Owusu just said would, to my
22 point, too, George, you know, if it's an additive that
23 it's approved as, then that's what it's used as, you
24 know. What it comes out of the back end of the cow as

1 or what it does inside the cow, it's herd health, feed,
2 it doesn't make any difference, it's the same thing.

3 MR. SIEMON: And we don't have a category
4 that covers all the uses, but now we're talking about
5 if we don't allow amino acid chelates in feed, we need
6 to allow them in herd health. That's the question
7 we're facing now.

8 MR. ENGEL: But the simple way that I thought
9 that this had been taken care of and that I would
10 highly recommend is that in Austin, there was the
11 seven-point document, actually that was in D.C. the
12 year before, and then apparently there was some more
13 action done on it in Austin, and that the AFCO listings
14 were carte blanche, except for, and then you had your
15 animal byproducts and maybe some other things, too. I
16 don't know. But if it's on the AFCO list, we should be
17 able to use it. That's been our position.

18 MR. SIEMON: Okay. We need to move on.

19 CHAIRMAN CARTER: Okay. Richard had a
20 comment, though.

21 MR. MATHEWS: See if I can bring some
22 clarification without confusing. I think what George
23 is trying to say is that when we look at .603, we
24 really run A through F and feeds are in one of them,

1 and the -- well, let's see. What have we got here? We
2 got feed additives is Paragraph B.

3 MR. SIEMON: B.

4 MR. MATHEWS: C is feed supplements.

5 MR. SIEMON: B is topical external pesticides
6 or local anesthetics.

7 MR. MATHEWS: So, anything that you're adding
8 could end up in more than one of these categories. The
9 recommendation in the motion being forwarded is that
10 these chelated trace minerals be allowed in organic
11 livestock production, and so what George is really
12 trying to clarify at this point is, it's okay to say it
13 can be used in organic livestock production, but there
14 is no category that takes in and allows for all uses.

15 Because of the way that the national list is
16 structured, the Board needs to be deciding which one of
17 the A through F you want to put this in, and it could
18 go into multiple places is what I hear George trying to
19 say.

20 MR. SIEMON: I do, but shouldn't something be
21 approved as a B automatically be approved as herd
22 health would be what we're hearing common sense saying
23 and what -- how can we get that common sense in the
24 rule when it's divided into these different classes?

1 Under the medical treatments, we have anything approved
2 in the feed can be used as a medical treatment. Do we
3 need that clause in there or is that too obvious?

4 MR. MATHEWS: Well, we can do it like it's
5 already been done in a number of other situations which
6 is to list it in both spots.

7 MR. SIEMON: Both spots. Okay.

8 MR. MATHEWS: Just tell us which of the spots
9 you want us to list it and that's what the Board would
10 be voting on. You would be voting for it to be in
11 feed, you'd be voting it in topical, you might be
12 voting it some place else.

13 MR. SIEMON: So, then with that in mind, it
14 would seem to me that under the Feed Additive Section,
15 we want to prohibit amino acid chelates, and then under
16 the Herd Health Section, it looks to me like we'd want
17 to allow chelated minerals for medical purposes. It
18 would take two motions and that would include amino
19 acids, if we hear evidence that the amino acids are
20 necessary for herd health.

21 CHAIRMAN CARTER: Okay. Jim?

22 MR. MATHEWS: Yeah. I still have a question
23 about the GMO availability.

24 MR. SIEMON: But that's covered in the whole

1 rule. That's already covered.

2 MR. MATHEWS: Well, no, but are the
3 proteinated chelates available and from non-GMO
4 sources? Are we recommending --

5 MR. RIDDLE: Amino acid chelates.

6 MR. MATHEWS: -- something that doesn't even
7 exist?

8 MR. SIEMON: Both.

9 MR. MATHEWS: I want to know about both. The
10 TAP review led us to believe that the one was and the
11 other wasn't.

12 MR. SIEMON: Tell me which one.

13 MR. MATHEWS: Well, the amino acid would very
14 likely be GMO and the protonated wouldn't, and Dave
15 Engel said the opposite.

16 CHAIRMAN CARTER: And Dan is nodding his
17 head.

18 DR. LEITERMAN: My preference is not GMO
19 protein sources and yeast is typically what's used and
20 there's plenty of that out there with documented non-
21 GMO sourcing.

22 MR. RIDDLE: But it's true that the amino
23 acids likely would be.

24 DR. LEITERMAN: My understanding is that the

1 amino acid chelates are a synthetic amino acid, and I
2 don't -- it could be GMO sourcing. I don't know. But
3 I'm talking about -- I want to make one point very
4 clear. I'm talking about protionates and that's a
5 long-chain molecule. I'm not interested in requesting
6 for single amino acid chelates. I just want to make
7 sure that we can use protionates in whatever form we
8 choose to use them.

9 MR. SIEMON: Dan, I think you said it
10 earlier, but are amino acid chelates needed for herd
11 health treatment? Therapeutic uses?

12 DR. LEITERMAN: Not as long as protionates
13 are available.

14 MR. SIEMON: All right. Then that makes our
15 world simpler. We're just going to deal with the two.
16 We'll prohibit them in the feed and we'll allow only
17 the two in medical would be the right solution.

18 DR. LEITERMAN: I want to be able to use
19 protionates in feed as well, George.

20 MR. SIEMON: That's -- they're already
21 approved.

22 DR. LEITERMAN: Okay.

23 MR. SIEMON: So, that would be the two
24 motions we would need on this, if the committee, after

1 they revisit this, still feels that way.

2 MS. KOENIG: I still -- I looked again
3 through the TAP, and I think part of the reason -- I
4 mean, you know, I'd like to think that I've memorized
5 the rule and every single thing we do in Minutes, but I
6 don't. So, I rely on that TAP to give me guidance to
7 figure out what motions we have made. There's nothing
8 in here based -- as far as I read, and I looked back,
9 based on the decisions we made in May. Okay. So, that
10 was kind of confusing to me because, you know, we did a
11 lot at that time and that -- you know, if the TAP was
12 written correctly and researched, those are obvious
13 things. I mean, the person doing the TAP review needs
14 to find out what the Board has taken action on or else
15 it leads me as a reviewer down the wrong road. Okay.
16 So, my feeling is based on this TAP report, I can't
17 really make a decision because the information wasn't
18 accurate, based on even what we did as our own
19 policies. So, why are we rushing into making the
20 decision on something that could have, you know,
21 effects?

22 I understand there's a need in industry, but,
23 I mean, I think this haphazard asking one person in the
24 audience is not the way that we want to conduct

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1 ourselves.

2 MR. SIEMON: Okay. Let's move on. Potassium
3 sorbate. This has been requested as a use in a
4 preservative in aloe vera. It's a synthetic substance.
5 It's the scary word of preservative. So, there's
6 definitely been a lot of concern about this, and we did
7 a lot of discussion about what the alternatives would
8 be, small packaging, freezing. Basically, the issue
9 is, no matter how well -- how it's packaged, once it's
10 opened up, aloe vera will start to mold and it -- so,
11 our recommendation was to be allowed only as a made-
12 with label, which just -- there's no difference between
13 made-with or organic as far as the herd health, you
14 all.

15 So, this is only for livestock use. This is
16 an issue that could come up in the human field. We're
17 only dealing with it for livestock use. I don't -- you
18 know, the committee wanted to do the made-with organic.

19 I'd like to see the material allowed. The made-with
20 organic doesn't make a lot of sense to me. It's either
21 allowed in aloe vera for livestock use or it's not is
22 basically what it boils down to, but this is just the
23 way it's showing. I don't know if that was us trying
24 to interact with what might happen with the human

1 market or strictly a livestock decision.

2 Jim and Dave or anybody else, comments on the
3 made-with side? Anything? Nancy?

4 MS. OSTIGUY: I think that was part of what
5 was going on, is we didn't know what the Processing
6 Committee was doing at that point. We didn't want to
7 contradict what the Processing Committee did, yet in
8 some ways, we're dictating. So, we were in sort of an
9 odd situation, that we weren't sure where the
10 Processing Committee was going.

11 MR. SIEMON: But the recommendation is the
12 same. We want to be able to allow this in livestock
13 products, whatever category it falls into.

14 MR. LACY: Yes, the Processing Committee in
15 this case did discuss potassium sorbate. It wasn't
16 directly petitioned to the committee. We have not made
17 a formal recommendation on it for human use. It was
18 our understanding in reading the petition that it was
19 essentially for livestock use in this case.

20 MS. OSTIGUY: What's going to be interesting,
21 though, is my understanding, is that what is available
22 for purchase, aloe vera as currently available is
23 purchased by people for their internal use and for
24 their livestock, for the livestock internal use. If we

1 approve potassium sorbate as an additive in for
2 livestock use, it's going to be that same material that
3 people are going to consume.

4 MR. LACY: Right, but that wouldn't
5 necessarily approve the label, and it hasn't been
6 petitioned for that use.

7 MS. OSTIGUY: Well, but people that -- but
8 what's going to happen is that people are going to buy
9 it off label in essence. So, what you're going to do
10 is -- in essence, people are going to consume --

11 MR. LACY: Call your local vet to get your
12 aloe vera free.

13 MS. OSTIGUY: No, no, you don't have to.
14 It's available on the shelf. This is not going to be
15 available via a vet. It's going to be available on the
16 shelf. That's how it's bought.

17 MR. LACY: I guess my point is, though, it's
18 petitioned, therefore it would be labeled as organic.
19 I understand what you're saying, though.

20 CHAIRMAN CARTER: Okay. Owusu had his hand
21 up first.

22 MR. BANDELE: Could you comment on the
23 chemical preservative issue that one of the reviewers
24 stated?

1 MR. SIEMON: You mean that it's not --
2 there's no -- none allowed? That was a -- help me out
3 here. That was taken out of the wrong context. That's
4 the one where they --

5 MR. MATHEWS: I'm not familiar with the
6 issue.

7 MR. SIEMON: Okay.

8 MS. BURTON: It probably meant no
9 preservative in the processing versus livestock, I
10 would assume.

11 MR. SIEMON: Jim, this is where you're
12 referring to some Canadian standards or something else,
13 wasn't it? What page is it? Owusu, what page is it?

14 MR. BANDELE: I was looking at the reviewer's
15 three recommendations. It's on the last page of the
16 TAP.

17 MR. SIEMON: Well, on Page 24 is what I was
18 referring to. I mean, this is how poor some of these
19 TAPS are. He just pulls out of thin air this
20 definition of organic and says no chemical
21 preservatives, and this is from -- somebody looked up
22 this website and it's really got very little to do with
23 the rule. That's what you're referring to.

24 MR. BANDELE: Yeah.

1 MR. SIEMON: Yeah. We looked up that website
2 and it wasn't -- I think it was the Canadian standards
3 or something. I can't remember where it was.

4 Okay. The last thing in your packet --

5 CHAIRMAN CARTER: Just a minute. Jim had
6 another comment.

7 MR. SIEMON: Oh, okay.

8 MR. RIDDLE: Hearing what Nancy was saying, I
9 think when the Livestock Committee meets, we should
10 refine our recommendation for the annotation, and I
11 think, you know, allowed only for livestock therapeutic
12 products formulated using aloe vera.

13 MR. SIEMON: Okay. The last thing in your
14 packet is just this about MDUCA. This is the issue
15 about off-label use or whatever you want to call it
16 that's taken out of part of one of your TAPs, and this
17 is just a little explanation maybe to help out on some
18 of the confusion over that subject. Okay.

19 MR. RIDDLE: Which is the whole off-label use
20 subject that was discussed yesterday.

21 MR. SIEMON: Yeah. Okay. That's the big
22 world.

23 CHAIRMAN CARTER: Okay. Thank you, George.
24 Then, let's go back to Processing Committee.

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1 There were two issues that you guys resolved last
2 night.

3 MR. LACY: Well, one we've already discussed
4 which was the potassium sorbate. The Livestock
5 Committee did ask us to look at that material, but
6 again it wasn't petitioned to the committee. So, we
7 don't have a formal recommendation. The only
8 recommendation on that material will be from the
9 Livestock Committee, and you're going to have to give
10 me a minute here, Dave, to pull up some information.

11 (Pause)

12 MR. LACY: Okay. Finally, I've got it up.
13 We talked primarily last night about activated carbon.
14 We discussed it before, and so I'm just going to give
15 like a brief overview of what we talked about, and I
16 would encourage committee members to chime in and add
17 their two cents, and then we'll review the
18 recommendation.

19 But essentially, it was petitioned to remove
20 the brown color from white grape juice concentrate.
21 So, in looking at it, you know, what we found is there
22 are several different sources, from animal charcoal to
23 gas-black, furnace-black, lamp-black, just naming a
24 few. Activated charcoal is one which is prepared from

1 wood and vegetables. So, vegetative sources in this
2 case. It's used in this particular case to filter
3 white grape juice. So, that's essentially just the
4 liquid passing through a porous media, column, bed,
5 what have you.

6 One of the things we also noted that was
7 indicated in the TAP is that it can be produced,
8 activated carbon can be produced from like a broad
9 array of different agricultural byproducts. We also
10 found that there are natural commercial available
11 sources. Those would include nutshells, fruit pits,
12 peach pits, oat hulls, rice hulls. Soybean hulls was
13 another one. Tree species were listed as something
14 that could produce wood in this particular case and
15 then be converted into charcoal. So, we focused on
16 that as natural alternatives and talked about that a
17 little bit.

18 One thing here, and excuse me, I'm looking
19 over something I summarized very late last night, one
20 of the reviewers had mentioned or the TAP indicated
21 that when you look at the different bases or the way in
22 which it's chemically activated, that being activated
23 carbon in this case, is that you could do it by using
24 different acids or bases and one would be acidic acid

1 that could be found in vinegar. Potassium hydroxide,
2 sodium hydroxide, both of which are in 205.605(b) are
3 both also mentioned as potential bases.

4 One of the reviewers, I believe, indicated
5 that it could be possible to have organic acidic acid
6 from vinegar. Another indicated that essentially in
7 this case, if you want -- they believe that activated
8 carbon could be produced as an organic ingredient,
9 also. It is grasped by FDA. Again, it was petitioned
10 to remove brown color essentially caused by oxidation.

11 So, the primary purpose really in this case,
12 it was felt by one of the reviewers and information in
13 the TAP was really to improve the flavor and color.
14 Alternatives that were listed, some of them, whiter-
15 color grape varieties, cold-pressing, freezing,
16 centrifuging, enzyme treatments, things of that nature,
17 but the TAP also noted that it was difficult to judge
18 really how that would be effective without some very
19 specific color and flavor specifications. So, it
20 wasn't clear, you know, how viable the alternatives
21 were in that sense.

22 One of the reviewers did note, and I've sort
23 of highlighted this, was that they felt that carbon or
24 activated carbon appears to provide like a more

1 controllable and effective and maybe even more cost
2 effective approach than the listed alternatives in the
3 TAPs, and then, also, another reviewer noted, and I
4 know this isn't one of the key criteria, but I wanted
5 to bring this up, that they felt the disallowance of
6 activated charcoal in this particular case would affect
7 the organic sweetener industry in a pretty big way.
8 It's just one of the things that they threw in.

9 The reviewers in the committee unanimously
10 found activated carbon to be synthetic. So, that was
11 unanimous throughout. The reviewers also unanimously
12 voted to add it to the national list. One reviewer
13 suggested that it should be as a processing aid only
14 and also suggested that it meet Codex purity
15 requirements. Another was just for filtering water was
16 the annotation, and then the third was no restrictions
17 at all. So, it kind of ran the gamut there. But they
18 all did say it should be added to the national list.

19 The only -- I mean, I looked at the
20 environmental part of it. We discussed it last night.

21 The TAP indicated that, you know, environmental
22 effects is generally considered to be beneficial even.

23 So, we didn't see any real concerns there. We looked
24 at this as we reviewed it from the committee

1 perspective and considered activated charcoal to be
2 similar in some ways, if you will, to other filtering
3 aids on the national list that have been reviewed, such
4 as ditamatiuous earth, pearl light, but we didn't find
5 any specific references depicting them as necessarily
6 viable alternatives in this case.

7 So, our recommendation is for 205.605(b),
8 synthetics allowed, activated carbon from vegetative
9 sources only -- okay. There went my computer screen.

10 MS. BENHAM: Activated carbon from vegetable
11 sources only for use as a food-filtering aid.
12 Committee vote, 5 approved, 1 disapproved, 1 recused.
13 The conclusion is this recommendation supports the
14 views of activated carbons from vegetative sources only
15 as a food-filtering agent while recognizing the vast
16 array of agricultural byproducts natural sources.

17 MR. MATHEWS: That's why I love Catherine.
18 She's always there to balance out.

19 MR. LACY: I knew there was a reason I gave
20 you that disk earlier.

21 CHAIRMAN CARTER: Okay. Questions?

22 MR. RIDDLE: Just a clarification or
23 addition. I think that the annotation should say
24 vegetative sources, and I heard vegetable sources.

1 MR. LACY: No. It says vegetative.

2 MR. RIDDLE: Okay. Okay. Good. I know I
3 heard it in the explanation, but when I heard the
4 annotation itself, and I voted for this material. I
5 actually believe I made the motion to put it on the
6 list here, and part of that reasoning is that it is a
7 processing aid and has been reviewed and does belong on
8 the list. I think it fits in with the procedures that
9 we have followed and I hope continue to follow, you
10 know. I have some reservations about it just
11 personally, you know. Highly-clarified foods, you are
12 removing some nutrients. When you remove color, you're
13 removing some nutrients and bioflavonoids and some of
14 the beneficial properties but that's just a personal
15 choice issue.

16 I think, you know, we've got to look at the
17 very large picture here, and I see this material as
18 quite compatible with organic principles. There is a
19 question about our annotation. Currently, this is
20 allowed internationally in the EU under Codex and for
21 filtering purposes, but there's no annotation about
22 source, from vegetative sources only, and Tim asked me
23 this morning if that, you know, could cause any
24 problems with trade, international trade, and it

1 certainly wouldn't as far as our products going into
2 other markets. It could or could not in terms of
3 foreign products coming into this market.

4 Being as it's going to be on our list, that
5 will facilitate equivalency right there, just the fact
6 that it's on the list, and whether our negotiators
7 would choose to hold that up as a sticking point, I
8 think, it would be pretty unlikely that it be held up
9 as a barrier or reason to exclude products coming in
10 from other markets.

11 CHAIRMAN CARTER: Richard?

12 MR. MATHEWS: I'd like to comment on that
13 trade issue. If the material specifically says plant
14 sources only, Tim's right, it doesn't cause a problem
15 for the products going over there. Products coming
16 this way, however, could face the problem. I can't say
17 what the negotiators would do about it, but it would be
18 a sticking point, and I think that probably the side
19 that we would take is that we're not going to put our
20 own growers at a disadvantage.

21 So, if you're allowing -- if we're going to
22 prohibit, I should say, anything other than from plant
23 source, then we would have to say to our foreign
24 trading partners, it has to be from a plant source.

1 Otherwise all of the American producers who are
2 producing competing products are put at a disadvantage,
3 and so that's -- I think that's the way we would look
4 at it in negotiations.

5 CHAIRMAN CARTER: Okay. Mark?

6 MR. LACY: Well, I was just going to follow
7 up to Jim's point, that I couldn't find any
8 restrictions listed in the international standards.
9 So, that is correct, and so if what Richard's saying is
10 true, we may want to discuss that point.

11 MR. MATHEWS: Well, obviously, I'm kind of
12 speculating because I'm not one of the negotiators, but
13 I do know that the discussions that we've had back in
14 the office and with FAS and others is that we're not
15 inclined to put our own producers at a competitive
16 disadvantage with foreign producers, and if you put on
17 an annotation and you don't want us to hold the line on
18 that annotation, then we would be putting our own
19 producers at a competitive disadvantage, and if you're
20 not going to require us to hold the line on the
21 annotation, why have the annotation?

22 CHAIRMAN CARTER: Rose?

23 MS. KOENIG: I mean, I assume that this is
24 similar to when we asked about the Chilean nitrate

1 including it, and we talked to Keith and Keith would be
2 the one that would know, correct, or is he the one that
3 --

4 CHAIRMAN CARTER: Well, he's the one that
5 we've got working on these issues.

6 MS. KOENIG: Okay. Because my impression and
7 that was something that we would have had on the list
8 where other people don't have it, I guess it's the
9 reverse, and his -- you know, he made it appear, and
10 again, you know, he said it, I think, yesterday that
11 that should not be put into our decisionmaking factors
12 because those things will probably get ironed out and
13 like the individual decisions are not as important as
14 the whole program.

15 PARTICIPANT: Well, just to use the Japanese
16 as an example, the Japanese have said we accept your
17 program with these three materials exceptions. So,
18 they've said these three materials aren't suitable to
19 us. So, we've got an export certificate program going
20 on with the certifying agents that allows them to issue
21 a certificate saying that while this was produced to
22 the NOP, it was produced without the use of these three
23 prohibited substances.

24 So, what Keith is really saying when it comes

1 to the Chilean nitrate is that the producer can receive
2 a certificate from a certifying agent saying I did not
3 use Chilean nitrate.

4 CHAIRMAN CARTER: Okay.

5 MR. LACY: Other comments from committee
6 members?

7 MS. BURTON: I only had one comment. On the
8 annotation, we had said from food only, and I know it's
9 widely used in water and other -- coffee and other
10 applications. I just wanted to make sure that wouldn't
11 limit the annotation in any way. I don't know if it
12 would or not.

13 MR. LACY: In other words, it says -- I think
14 what you're referring to, Kim, is for use as a food-
15 filtering aid. In other words, so you're saying maybe
16 it should say just as a filtering aid.

17 MS. BURTON: Filtering aid, don't narrow it
18 down so much because it's widely used in municipal
19 water.

20 While we're on this, and I will be recusing
21 myself and my comment is not about the material, more
22 about the process of this, this material is one of
23 those borderline materials that both the NOP has
24 struggled with, whether it needs to be petitioned, the

1 industry's struggled whether it needed to be
2 petitioned. From our -- from my standpoint and other
3 people's standpoint, there has been a precedent set
4 that these sorts of materials needed to be petitioned.

5 It is a processing aid. There is a synthetic use,
6 even though it's a processing aid to a processing aid,
7 and it's a grasp and it's a secondary direct additive.

8

9 The precedent has been set by previous boards
10 and the intent of organics to review materials such as
11 this, and it's this Board's authorization and
12 recommendations on how we review -- what we do with
13 these materials. So, I firmly stand by the process of
14 this.

15 CHAIRMAN CARTER: Thank you, Kim.

16 Okay. Any other discussion from the Board?

17 (No response)

18 CHAIRMAN CARTER: Okay. Does that finish
19 your --

20 MR. LACY: That's it.

21 CHAIRMAN CARTER: Okay. I believe that that
22 finishes all of our review and discussion then before
23 we get into the actual action. So, even though --
24 potential action. So, even though it's 30 minutes

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1 prior to when it's called for, why don't we take a 15-
2 minute recess?

3 (Whereupon, a recess was taken.)

4 CHAIRMAN CARTER: Okay. Let's get started.

5 Okay. A couple of things just as we get into
6 the discussion here. Our transcriber has handed me a
7 note saying that it would be extremely helpful, and
8 she's having difficulty getting a clear transcript here
9 because of discussion going on in the audience or
10 conversation in the audience as well as noise out in
11 the hall. So, if we could ask that if you do need to
12 have a conversation, please take it out into the hall.

13 We'll keep the doors closed here because I know one of
14 the things there was some discussion about the length
15 of time it took to get a transcript from the May
16 meeting up on the website, and we're doing everything
17 we can right now to get it up as quick as possible, but
18 --

19 PARTICIPANT: I think you're talking about
20 that group over there that keeps talking.

21 CHAIRMAN CARTER: Well, I didn't want to
22 mention Kelly and, you know, -- no finger pointing.

23 The other thing is George has got a
24 PowerPoint set up here, so any of the committees that

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1 want to use that as part of their presentation, he said
2 feel free to do that.

3 So, with that, then Mr. Bandele, we will
4 start in with the action on the Crops Materials.

5 MR. BANDELE: Okay. Yesterday, I handed out
6 the action of the Crops Committee. The first one on
7 the list is Chilean nitrate for use in spirulina
8 agriculture production. It was really, you know, from
9 my end of it, it was a tough decision because the
10 petitioners had been certified organic over the last
11 several years, and in fact, one of the TAP reviewers
12 recommended a sunset clause to allow them to use that
13 until an alternative would be found. But that
14 notwithstanding, the committee voted 5 to 0 not to
15 change the current annotation which allows for Chilean
16 nitrate use not to exceed 20 percent of the total
17 nitrogen supplied to the crop. So, that would be the
18 motion that the committee would put forward.

19 CHAIRMAN CARTER: Okay. So, restate the
20 motion as a formal motion.

21 MR. BANDELE: The motion is not to change the
22 current annotation, which allows for Chilean nitrate
23 use not to exceed 20 percent of the total nitrogen
24 supplied to the crop.

1 CHAIRMAN CARTER: Okay. You've heard the
2 motion, not to change the current annotation. Is there
3 a second?

4 MS. OSTIGUY: Second.

5 CHAIRMAN CARTER: It's been seconded by
6 Nancy.

7 Discussion? Okay. Kim?

8 MS. BURTON: I understand that the sticky
9 situation that we're in because the producer has been
10 using a product and actually it's been certified even
11 though it's not allowed under the current annotation,
12 and I also have to -- I feel somewhat -- I'm siding
13 with the sunset because there is a product currently
14 being out there supplied as a certified organic product
15 to the consumer, and this decision is basically just
16 going to cut that off, and there are no viable
17 alternatives at this point, and the producers are
18 trying alternatives. They just don't have any.

19 So, I believe that some type of a sunset
20 clause to let them try to come into compliance with
21 that 20 percent annotation is applicable.

22 MR. SIEMON: I'd like to hear again why you
23 all aren't recommending it for the new use. I can't
24 even say it. I'm sorry.

1 MR. BANDELE: Some of the reasons --

2 MR. SIEMON: What's your logic? I need to
3 understand your logic.

4 MR. BANDELE: The logic is that currently 20
5 percent is allowed. Number 1. Secondly, there are
6 serious concerns in terms of the mining. It's a mined
7 material, and, of course, the same could be said for
8 rock phosphate, calcium, etc., and also, as I pointed
9 out yesterday, previous NOSB Board saw this as a
10 problem, allowed the 20 percent as a compromise, but
11 also stated that the producers would have to, you know,
12 find alternatives and over-reliance on the Chilean
13 nitrate could in their estimation be grounds for
14 decertification, coupled with the fact that the
15 European Union, Japan, and many areas in the U.S., it's
16 not allowed currently.

17 MR. SIEMON: But the historical restriction
18 on nitrogen has been to encourage rotation of manures,
19 livestock production. This is such a unique whole
20 other production system, I don't know if that logic
21 follows as well as it did in the cropping world. The
22 dependency, like you said just now.

23 MR. BANDELE: There are certainly some unique
24 features about this, George and Kim, and I have the

1 same concerns that you have in terms of them being, you
2 know, certified in the past.

3 MR. SIEMON: I agree with Kim as well.

4 CHAIRMAN CARTER: Okay. Discussion on the
5 motion? Rose?

6 MS. KOENIG: I would just say that again it's
7 sort of a philosophical issue in terms of the spirit of
8 what organics is and then the current cropping system
9 that exists. You know, we looked at this product for
10 awhile, and I remember when Eric was on the Board. He
11 was on the Crops Committee, and he brought in the
12 issues of hydroponic systems and the fact that it
13 wasn't a soil-based system and much of the rule and the
14 principles of organics do consider soils within a
15 system.

16 You know, this does -- it is a different type
17 of system and that's what you as board members, I
18 think, have to weigh in in terms of your decision. I
19 think the biggest impact again is really in my mind, as
20 we start getting into consistency issues, wherein our
21 rule, we have all these exceptions for different types
22 of cropping systems, and there's arguments in each case
23 as to, you know, where you lie with that. That's
24 really your own personal judgment.

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1 So, I just say, you know, vote your
2 conscience in terms of what you think is what the
3 spirit of the law is and how the rule is to be
4 interpreted.

5 CHAIRMAN CARTER: Okay. Discussion? Kim?

6 MS. BURTON: I was just going to make a
7 motion to amend the annotation, if that's appropriate
8 at this time.

9 CHAIRMAN CARTER: Okay. It is.

10 MS. BURTON: I would like to make a motion to
11 amend the annotation for sodium nitrate to read:
12 unless use is restricted to no more than 20 percent of
13 the crop's total nitrogen management or for use in
14 spirulina production until the year 2006.

15 PARTICIPANT: Some indication that you were
16 changing the percentage in that annotation.

17 CHAIRMAN CARTER: Unrestricted use.

18 MS. BURTON: In spirulina production until
19 2006.

20 MR. SIEMON: I'll second that.

21 CHAIRMAN CARTER: Okay. It's been moved by
22 Kim, seconded by George.

23 Now, discussion on the amendment only. Okay.
24 Rose?

1 MS. KOENIG: I just -- the only thing is that
2 I agree with what you were saying in the sense that the
3 present companies have been certified, but the rule on
4 Chilean nitrate has been out there at the 20 percent
5 level in terms of research towards alternatives.
6 Again, the sunsets are useful if on products -- sort of
7 the reason why we have the following -- you know, the
8 directive, because there is certain research on this
9 product that is necessary if we're going to either
10 remove it or change it from the 20 percent status.

11 The question becomes, do we use a directive
12 and add it to a directive so that in five years, if it
13 -- you know, after the growers could come back and say
14 we've done the research now, and we know there's no
15 alternatives. In my mind, when you give exceptions or
16 even a sunset, in a way, it does not force people to
17 necessarily look at alternatives, although it does keep
18 it in production. So, again, philosophically.

19 MS. BURTON: And I think it does force the
20 producers to look at alternatives and to come back to
21 us with that scientific research as to why those
22 alternatives work, and it also puts in force the
23 Board's -- I guess for us to look more closely at
24 hydroponics, and we keep going back and forth and back

1 and forth and it is different than a soil-based system,
2 and we've not really looked at it in depth. So.

3 CHAIRMAN CARTER: Mark, George, and then Jim.

4 MR. KING: Well, I think Kim's point is
5 relevant in that we're looking at two different things.
6 One, are we comfortable with the sunset clause in
7 general? Perhaps three. Two, the time frame in this
8 case, 2006. (A) is it enough time? (B) is it too
9 much? Does it send the right message? Then, three,
10 that of hydroponics. I mean, that's something that we
11 haven't discussed extensively as a Board and really, to
12 my knowledge, hasn't been discussed extensively in the
13 industry.

14 So, I guess my point to the amendment is I
15 think it's in good spirit, and certainly I can support
16 the message there, but I think there are some deeper
17 issues as Rose brings them up, and I would just like to
18 say that I think this directive is a good thing, that
19 it records where we're at right now, not just as a
20 committee but puts it in front of the Board and perhaps
21 the industry and says these are some of the areas where
22 we think we need information moving forward. So that,
23 in 2006, we don't go through the same exact process.

24 CHAIRMAN CARTER: Okay. George?

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1 MR. SIEMON: Just that, you know, it's not
2 about protecting any of the producers. It's we will no
3 longer have an organic product available. If we make
4 this decision, we're taking a product away from the
5 consumer here.

6 CHAIRMAN CARTER: Okay.

7 MR. SIEMON: There's no alternatives, and the
8 fact that there might be alternatives in the future is
9 why we review materials. Right now, there are no
10 alternatives, and we haven't passed judgment against
11 hydroponics, so we shouldn't be trying to mix subjects.
12 This is about this material for these production
13 practices, and there are no alternatives.

14 CHAIRMAN CARTER: Okay. Jim?

15 MR. RIDDLE: Yeah. I really appreciate the
16 amount of effort, good faith effort that the
17 petitioners have put in and, you know, attending board
18 meetings and explaining their processes, and, you know,
19 I have no doubt that it's both a good product and a
20 good production system that you develop, but in my
21 mind, it's not organic, and that's -- it really doesn't
22 fit well with the organic principles as enumerated by
23 the NOSB. Until we really -- if we have principles for
24 organic hydroponic production, you know, then it could

1 be revisited, but the petitioners have been tuned in.
2 This is not a surprise vote, and it -- the fact that it
3 has been certified, contrary to the annotation, doesn't
4 carry a lot of sympathy or weight with me. I think it
5 is -- has been quite predictable that come October
6 21st, all products have to be produced and labeled
7 according to the rule. That's not a surprise.

8 So, I guess I speak in opposition to this
9 amendment in all due respect.

10 CHAIRMAN CARTER: Okay. Just a second.
11 Rose, you did have -- okay. Then George?

12 MR. SIEMON: Is the philosophical problem
13 here hydroponics or the dependency on outside
14 fertility? I just need to hear. Because if it's
15 outside fertility, the whole organic vegetable
16 industry's dependent on manure from confinement
17 operations that's outside fertility. They're bringing
18 it in constantly. I just don't see there's a big
19 difference between mining that. It's outside fertility
20 being brought in. It's dependency on outside fertility
21 on a big level.

22 CHAIRMAN CARTER: Okay. Rick?

23 MR. MATHEWS: Go ahead with that.

24 CHAIRMAN CARTER: Okay. Rose?

1 MS. KOENIG: I think again, as Eric
2 articulated and as I think I agree with, I know I agree
3 with, principally with crops, and I guess I would
4 consider this to fall in most in line with crops since
5 we have three choices, livestock, processing.

6 CHAIRMAN CARTER: I don't want this one.

7 MS. KOENIG: So, when you really look at
8 crops, I mean, the spirit of the rule as written, you
9 know, are soil-based systems. I'm not arguing that
10 this doesn't -- may not necessarily fit within those
11 parameters, but basically, you know, and plus recycling
12 of nutrients, using cover crops not applicable in this
13 situation, you know, even, you know, certainly manures
14 and compost and such, would be, you know, a better
15 system.

16 I think that at present, the way that it
17 stands, there are no standards for hydroponics. If the
18 producers used some kind of fertility product or with
19 inclusion of sodium nitrate at 20 percent, it could fit
20 nicely within the rule, maybe not philosophically in
21 all aspects.

22 MR. SIEMON: It would be allowed now if they
23 could do the 20 percent.

24 MS. KOENIG: If they can do 20 percent and

1 follow all the rule, I don't see where it wouldn't fit.
2 The fact is, it's -- the 20 percent -- again, what Jim
3 has stated. The 20 percent is in the rule. It's been
4 presented to the public for quite some time. AS we
5 heard from California producers, they went from more
6 dependency on the product to complying with the rule,
7 finding that they could even alter their cropping
8 systems --

9 MR. SIEMON: Some advantages.

10 MS. KOENIG: -- and found advantages. That's
11 the type of things, the goals, I guess, that we're
12 trying to obtain. So, I mean, I don't know if that
13 helps answer your question.

14 CHAIRMAN CARTER: George?

15 MR. SIEMON: I just wanted to -- since we
16 were bringing up hydroponics, it's my memory, which is
17 not very good, about Orlando in '95, that we dealt with
18 hydroponics on tomatoes. Does anybody remember that?
19 Did we make a decision?

20 CHAIRMAN CARTER: Somebody can remember the
21 decision and just for the audience here -- okay.

22 MR. SIEMON: I'm asking about hydroponics and
23 previous decisions by NOSB. Previous decisions by NOSB
24 on hydroponics. Should be NOP.

1 CHAIRMAN CARTER: Marty Mesh?

2 MR. MESH: I was fighting sodium nitrate at
3 the time. The decision that the Board made in Orlando
4 was that --

5 CHAIRMAN CARTER: Please. Quiet so we can
6 get this on the record.

7 MR. MESH: Was that in theory, a hydroponic
8 system that complied with the regulations could be
9 considered organic. In the context of the argument or
10 discussion that you're having now, that somebody could
11 use up to 20 percent of sodium nitrate and then the
12 rest of the fertility would be kelp, seaweed, fish, you
13 know, blood meal, any other type of nutrient source in
14 that context is the '95 decision on hydroponics, saying
15 that if somebody complied with the regulations of the
16 rule, that the Board considered hydroponic, an organic
17 hydroponic system possible.

18 CHAIRMAN CARTER: Okay.

19 MR. MESH: So, it has been addressed before.

20 MR. MATHEWS: Marty, you should have
21 identified yourself.

22 MR. MESH: My name's Marty.

23 MR. MATHEWS: And I second what Marty just
24 said, and you'll note that back in May, I think it was

1 May 2nd, we posted on the Web that we consider
2 hydroponics to be covered by the National Organic
3 Standards. The issue on this particular thing is that
4 when Chilean nitrate was originally approved on this
5 Board, there was question still, even though in '95,
6 the Board had said yes to hydroponics. There was still
7 question as to whether it was appropriate or not and
8 that needs to be taken into consideration when you're
9 talking about whether or not the level is appropriate
10 for a hydroponic system. That's really the question
11 here. Is it an appropriate level for a hydroponic
12 system?

13 CHAIRMAN CARTER: Just for the record, here's
14 what the record of the '95 meeting was. Headed,
15 "Specialized Standards for Hydroponic Production in
16 Soilless Media. Hydroponic production in soilless
17 media to be labeled organically produced shall be
18 allowed if all provisions of the OFBA have been met."

19 MR. SIEMON: Okay. So, we shouldn't debate
20 hydroponics or not. Like Rick said, we should debate
21 what the materials allowed in hydroponics.

22 MR. MATHEWS: The debate is whether or not
23 the Chilean nitrate is allowed, hydroponics is allowed.
24 The debate is whether or not a higher level of an

1 allowed substance is allowed in hydroponic systems.

2 CHAIRMAN CARTER: Only in regard to the
3 question that was asked from the Board. Zea Sonnabend?

4 MS. SONNABEND: Yes. That is correct, and
5 there are some unresolved issues of hydroponics that
6 the Board should put on their work plan still, but most
7 of them would be solved with the greenhouse standards
8 document because they concern the three-year
9 transition, you know, whether you can be exempt from a
10 three-year transition in a hydroponic system.

11 CHAIRMAN CARTER: Okay. Only to illuminate
12 further, if you have something additional to add. Eric
13 Kindberg?

14 MR. KINDBERG: Only to concur with the thing
15 in '95. Just wanted to indicate that, you know, there
16 are other systems that aren't -- that are hydroponic
17 but in the nature of not being in a greenhouse. In
18 other words, you've got watercress production, you've
19 got lotus root production. You've got water chestnut
20 production, and so these systems, you know, now
21 speaking directly to the 20 percent nitrogen being
22 Chilean nitrate, I don't think from experience of
23 having produced a lot of water crops, I don't think
24 that that's a detrimental factor.

1 CHAIRMAN CARTER: Okay. Now, discussion just
2 on the amendment. Remember, we're just debating the
3 amendment, which is a sunset clause. Okay. Now, Kim,
4 you had your hand up?

5 MR. BANDELE: I have something on the sunset
6 clause.

7 CHAIRMAN CARTER: Okay. Owusu, then Rick,
8 and then Mark.

9 MR. BANDELE: Two points of clarification.
10 One is that the -- just so the committee will know, the
11 Board will know, the one reviewer who visited the
12 hydroponic plant where the spirulina was being produced
13 was the one that did recommend a sunset clause. I did
14 want everybody to have -- to know that.

15 Secondly, George, in response to your
16 question about the hydroponics, you're right that a lot
17 of that is still not resolved, but the committee did
18 not deal with that issue. In other words, we were
19 strictly dealing with the Chilean nitrate issue, and we
20 did not, you know, use that as, you know, -- I mean,
21 did not vote against it because it was a hydroponic
22 system.

23 MR. SIEMON: Well, they're awfully
24 intertwined either way.

1 CHAIRMAN CARTER: Okay. Richard, and then
2 Mark.

3 MR. MATHEWS: The way I understand this is
4 that you want to have a four-year sunset. Everything's
5 automatically sunset at five years. So, why would we
6 have a four-year sunset? That doesn't seem to make a
7 lot of sense to me.

8 MS. BURTON: The intention was a three year.

9 MR. MATHEWS: Well, here's another thing.
10 We're saying that the clock starts ticking October 21st
11 on all of these materials. Are we going to review
12 everything all in one year? I don't think so. You're
13 going to start these reviews kind of, I would hope, on
14 a staggered system, and how you select what gets into
15 that staggered system is really going to be, you know,
16 decided through some kind of a policy or guidance
17 document that you're going to create on how you're
18 going to go about doing the five-year review.

19 So, to me, the annotation of four years is
20 unnecessary.

21 CHAIRMAN CARTER: Okay. And I don't think
22 there will be any doubt that there's going to be a lot
23 of staggering as we go through this. She would like --
24 Kim would like to make an amendment to the annotation

1 or do you just want to correct your original one?

2 MS. BURTON: I will just correct my original.

3 For use in spirolena production until October 21st,
4 2005.

5 CHAIRMAN CARTER: Okay. Till October 21st,
6 2005. Does that meet who -- let's see. George, you
7 seconded that?

8 MR. SIEMON: Yes, I seconded it.

9 CHAIRMAN CARTER: Does that meet with your
10 approval? Are you still willing to second that? If
11 not, the original amendment stands, unless the seconder
12 agrees to the change. We have to vote on the --

13 MR. SIEMON: I guess so. I want to go with
14 what Rick said, honestly. So, but that doesn't -- I
15 don't -- can I ask a question before I say yes?

16 CHAIRMAN CARTER: Okay.

17 MR. SIEMON: So, when you say that's
18 staggered, there's nothing that says that in three
19 years, we can't say in advance thinking, we're going to
20 redo Chilean nitrate now?

21 MR. MATHEWS: Nothing to prevent any
22 substance from coming back before the Board at any
23 time.

24 MR. SIEMON: Okay. Well, I'll second the

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1 amendment.

2 CHAIRMAN CARTER: Okay. So, it's seconded
3 now. The maker of the original amendment has changed
4 it to 2005 from 2006. That's what's on the table now.
5 Okay. October 21st, yeah.

6 MR. MESH: Quick question. When you say
7 everything's sunsetted, I mean, everything's rereviewed
8 automatically, you encourage the Board to stagger the
9 materials. Does that mean if in three years, they
10 started the process and voted against the material, at
11 that point, the material would go off the list or does
12 it mean at the end of two more years, the material
13 would go off the list?

14 MR. MATHEWS: What happens is that five years
15 from October 21 of 2002, everything automatically comes
16 off the list. The list ceases to exist with the
17 substances that are there, by statute. By statute,
18 everything the Board has approved goes away at the
19 five-year time frame.

20 Now, anything you add after October 21 is
21 obviously going to last a little bit longer than the
22 other things, but everything that's on that list this
23 time will come off in five years. The Board, if they
24 want to keep any of those materials, are going to have

1 to do a renewal for another five-year period or for
2 some other period of time. You've already identified
3 some that you automatically want to come off in less
4 than a five-year period.

5 CHAIRMAN CARTER: Okay. All right.

6 Discussion on the motion to amend? Mark?

7 MR. KING: Well, it's about the amendment,
8 and that is, concerning specifically the unrestricted
9 use in this case, and can somebody provide -- I'm
10 looking through the TAP and some other information --
11 the levels at which this is used in spirolena
12 production? Amount?

13 CHAIRMAN CARTER: Identify yourself.

14 MR. KING: In other words, is this the 100
15 percent of the nitrogen source? To what degree is it
16 applied in terms of number of pounds per pond size,
17 yada, yada?

18 MR. MOREHEAD: My name is Kelly Morehead.
19 It's not 100 percent of the nitrogen source because
20 there are some composts and manures that are used as a
21 source of phosphate, and we don't use rock phosphate in
22 this system. So, there's some nitrogen there.

23 As far as the number of ponds, I can speak
24 only for our facility. It's about half of our ponds

1 which would be about 27 ponds, each one holding 400,000
2 liters, and I don't know if that's very useful
3 information for you, but did that answer your question?

4 MR. KING: Sort of. How much would you apply
5 to those ponds that included Chilean nitrate?

6 MR. MOREHEAD: Well, we would maintain a
7 level equal to what would be in the natural spirolena
8 lake which would be about -- well, it's a little less.
9 We use about one gram per liter. So, in 400,000
10 liters, that's about what, 400 kilos. 880 pounds. But
11 we would replace by analysis what was lost, and so in
12 terms of the whole budget for nitrogen, clearly Chilean
13 nitrate would be the lion's share of what's used while
14 we try and work out alternatives, and we believe we can
15 achieve those eventually, but we're not at that -- we
16 have been working on it, but we're not ready yet and
17 we're just going to have to pull a whole system if we
18 can't do it.

19 MR. KING: When you say lion's share, is it
20 possible to assign a numerical value to that or does it
21 vary based on conditions? Lion's share Chilean
22 nitrate?

23 MR. MOREHEAD: It's above 90 percent, I would
24 suppose. Probably close to 90 percent because there's

1 a contribution from the manures for -- in getting the
2 phosphate into the system.

3 CHAIRMAN CARTER: Okay. Thank you.

4 Rose?

5 MS. KOENIG: I have just another question. I
6 think somebody asked it yesterday to you, because you
7 said you had dual --

8 CHAIRMAN CARTER: Stay at the mike, please.

9 MS. KOENIG: You had two systems. You had,
10 you know, both -- I guess a good chunk was also
11 conventionally grown, and somebody had asked you what
12 is the difference between the two, and you had referred
13 to just the nutrient management system, but do you use
14 other inputs, such as -- you know, are there other
15 prohibited substances used like in disease control
16 mechanisms or is it relatively --

17 MR. MOREHEAD: No, and I'm glad you asked me
18 that because I didn't answer that very thoroughly.

19 For example, I just mentioned the phosphorous
20 management. The chelators on the trace minerals are
21 different. We use EDTA chelated nutrients in the
22 regular production system. So, of course, the
23 labeling's different and the processing is separated.
24 So, it's not just the nitrogen source that's switched.

1 MS. KOENIG: Have you used a filtering
2 system, like with some of the fish emulsion-type
3 products that would supply you nitrogen? Do you have
4 -- have you tried -- I mean, there's one thing in terms
5 of just attempting to just use a product, you know,
6 substituting a product that would be approved for
7 organic use and just saying, okay, well, we tried fish
8 emulsion, but we put it in, it didn't work, because you
9 were saying that the residues would cause, you know, in
10 the processing end of it, but were those products
11 applied using like a filter or a different mechanism
12 that would change, you know, the consistency of that
13 product? How did you do that experimentation?

14 MR. MOREHEAD: We have a series of 500
15 liters, 4 foot by 8 foot experimental ponds that we
16 work with, and absolutely, we filtered through a 400-
17 mesh screen which is the same size screen that catches
18 the spirolena to make sure that we wouldn't get large
19 amounts through there, and the challenge that we had
20 with fish emulsion is that it's very high in
21 unsaturated fatty acids. That's what you smell, the
22 fishy smell, and spirolena is some -- through some
23 mechanism, it's able to incorporate those fatty acids
24 directly into its cell, and when you harvest the --

1 even though the conditions in the pond would be
2 sufficient to oxidize the free fatty acids floating
3 about, and they wouldn't get caught, the spirulina held
4 it and it smelled very fishy, and it wasn't sellable as
5 a human grade product because of that, unfortunately.

6 So, with the other -- the chicken sources is
7 not so bad, and there's a possibility that maybe some
8 natural urea products, like cow urine, I guess you'd
9 call it, is available. They're looking at that to try
10 and see if we could use that as a source. So, the
11 answer is yes, indeed, we did -- we do filter it, but
12 what we're trying to do is to come up with a product
13 that won't be palatable to the consumer because it's
14 used in drinks and such.

15 CHAIRMAN CARTER: Okay. Thank you.

16 Okay. Let's start to prepare to vote on the
17 amendment. Owusu?

18 MR. BANDELE: I had a question before. The
19 27 ponds, those include both your conventional and your
20 organic at this point?

21 MR. MOREHEAD: We have 54 ponds total
22 operating and about 27 are in organic production.

23 MR. BANDELE: Now, the 800 -- you said 800
24 pounds of Chilean nitrate or 800 pounds of actual

1 nitrogen?

2 MR. MOREHEAD: Oh, that would be Chilean
3 nitrate. 880, that's a standing amount that sits
4 there. It's equivalent of the reservoir, and then we
5 would add back. So, we use over 50 tons of Chilean
6 nitrate annually, I would estimate. It's a very
7 productive agriculture system, and there's a lot of
8 material that's grown in a small area. That's the way
9 it is in nature, too.

10 CHAIRMAN CARTER: All right. Are you
11 prepared to vote on the amendment? Do you understand
12 the amendment? Catherine, do you have it written down?
13 I mean, I can -- I've got it --

14 MS. BENHAM: Unless restricted to 20 percent
15 of the crops in nitrogen management for unrestricted
16 use in spirolena production until October 5th, 2005.

17 CHAIRMAN CARTER: Yes. 21st.

18 MS. BENHAM: 21st.

19 CHAIRMAN CARTER: Yeah. Okay. Do you
20 understand? Yes?

21 MS. KOENIG: Two just points of
22 clarification. So, is it going to be confusing the way
23 it's linked in the rule with that 2005 sunset that --
24 are we revisiting both of them in 2005 or are we just

1 revisiting spirolena in 2005? Then I had another
2 question.

3 MS. BURTON: Just the spirolena.

4 MS. KOENIG: So, I think that somehow it
5 needs to either be separated or clarified because it
6 could be confusing as if we're going to visit --
7 revisit both.

8 CHAIRMAN CARTER: Why don't you just change
9 it to say unless the use is no more than 20 percent of
10 crop's total need or until October 21st, 2005, for
11 unrestricted use in spirolena?

12 MR. SIEMON: Kelly, can I ask you one
13 question just maybe to give -- just bearing in mind
14 what Mark's saying. How much spirolena do you get per
15 pond? What's the harvest like on a day or anything?
16 What's the average yield? I don't know.

17 MR. MOREHEAD: Typically about every seven,
18 six or seven days, we would pull 100 kilos or 220
19 pounds out of a pond, and the way this is done, it's
20 going through filtration screens and the water that the
21 spirolena was grown in is returned to the pond after
22 harvest.

23 CHAIRMAN CARTER: Rose, let's get ready to
24 vote. Read the amendment. I just jotted it down as

1 chicken scratches here.

2 MS. BENHAM: For clarification.

3 CHAIRMAN CARTER: Okay.

4 MS. BENHAM: Unless restricted to 20 percent
5 of the crop's nitrate management, or --

6 CHAIRMAN CARTER: Comma.

7 MS. BENHAM: Comma.

8 CHAIRMAN CARTER: Or until October 21st,
9 2005, for unrestricted use in spirulina production.

10 MS. KOENIG: I just -- well, first thing is
11 that I wanted to just clarify the understanding in
12 terms of the sunset versus not having the sunset.
13 Okay. So, by having the sunset, it will change the
14 annotation of the current rule to include spirulina.
15 Okay. And then, upon -- in three years and that would
16 be looked at again specifically for spirulina. So, we
17 are in fact adding to the list with the sunset.

18 CHAIRMAN CARTER: That's correct.

19 MS. KOENIG: Okay. So, the goal, I guess
20 what I'm understanding through the thought process, is
21 it allows the producers to continue to produce their
22 product, even though the current rule does not allow
23 them to produce it that way, and like all other
24 hydroponic growers, in theory, they should be following

1 the rule. Okay. So, we're making an exception for
2 growers who have not followed the rule consciously.
3 Okay. So, just to clarify that.

4 The other option is not -- as our original
5 motion, which is not to have the sunset. So, what is
6 the implications of that? Okay. That doesn't -- in
7 that case, you're saying, okay, the rule stands. The
8 20 percent stands. That was the intent of the 1995
9 NOSB at that position, knowing the same information
10 that we know today, because really the same
11 constraints, as I understand, probably existed in the
12 system.

13 So, in the great wisdom of that 1995 vote,
14 we're finding today that there's been some change of
15 heart, maybe because the producers have come to these
16 various meetings, that we feel we have to make that
17 exception, and that's again something that -- that's a
18 valid consideration, just making sure that you're
19 conscience of that consideration.

20 Finally, if we don't -- if we go with our
21 original annotation, implication of that is it still
22 comes up. Okay. The difference we're saying is that
23 those producers, if we leave the standard as such, it
24 says that those -- we're not saying that those

1 producers are going to go out of business. We're
2 saying that you can use it at 20 percent, which was the
3 wishes of the 1995 Board. You had X amount of time to
4 kind of look at these alternatives. If we determine
5 it's not viable in the system, then maybe the system
6 isn't appropriate for organic production. It could
7 still be revisited, which it probably will be because
8 it's on the list. Okay. So, it's going to be
9 revisited anyway.

10 At that time, the producers could come back
11 and say, look, we did all this research and now we can
12 conclusively say not only our own personal research but
13 researchers at university. We brought in experts, you
14 know. We have firm things to make our decision. At
15 that point, we could add it on for spirulina. So, it
16 doesn't mean when we make these decisions that we're
17 driving people out of business forever, but it does
18 have economic consequences.

19 CHAIRMAN CARTER: Okay. Rick?

20 MR. MATHEWS: The comment that over the last
21 seven years, looking to see if there are alternatives
22 to the Chilean nitrate for levels above 20 percent, the
23 comment that maybe these hydroponic systems aren't
24 suitable to organic, I don't think that's necessarily

1 the right way to look at it. It might be, and I think
2 that the producers of these products and the consumers
3 of these products and there are far more consumers of
4 the products than there are producers of the products,
5 all the manufacturers who might use these products in
6 their products, would say it's not that the system
7 isn't appropriate for organic agriculture but maybe the
8 annotation is inappropriate for the system of organic
9 agriculture.

10 CHAIRMAN CARTER: Are you prepared to vote on
11 the amendment? Call the question. The question's been
12 called. Seeing no hands up, we'll just proceed to
13 vote, and before we vote, I'll ask if anyone on the
14 Board has a conflict of interest on this issue?

15 (No response)

16 CHAIRMAN CARTER: Okay. None declared.
17 Okay. On the amendment only, Bandele?

18 MR. BANDELE: No.

19 CHAIRMAN CARTER: Burton?

20 MS. BURTON: Yes.

21 CHAIRMAN CARTER: Caughlan?

22 MS. CAUGHLAN: No.

23 CHAIRMAN CARTER: Cooper?

24 MS. COOPER: Yes.

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1 CHAIRMAN CARTER: Goldburg? Absent.
2 Holbrook?
3 MR. HOLBROOK: No.
4 CHAIRMAN CARTER: King?
5 MR. KING: No.
6 CHAIRMAN CARTER: Koenig?
7 MS. KOENIG: No.
8 CHAIRMAN CARTER: Lacy?
9 MR. LACY: Yes.
10 CHAIRMAN CARTER: O'Rell?
11 MR. O'RELL: Yes.
12 CHAIRMAN CARTER: Ostiguy?
13 MS. OSTIGUY: No.
14 CHAIRMAN CARTER: Riddle?
15 MR. RIDDLE: No.
16 CHAIRMAN CARTER: Siemon?
17 MR. SIEMON: Yes.
18 CHAIRMAN CARTER: The Chair votes no.
19 Motion fails then on a vote of 8 to 5 with
20 one absent. 8 against, 8 nos, 5 yes. 5 to 8. Excuse
21 me.
22 Okay. So, we're back to the original
23 recommendation from the committee which is not to
24 change the annotation.

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1 Discussion on the motion?

2 (No response)

3 CHAIRMAN CARTER: Okay. If you're ready to
4 vote? Okay. Owusu, your original motion was from the
5 committee? Just go ahead and read the recommendation
6 as you made it in the original motion.

7 MR. BANDELE: The motion was not to change
8 the current annotation which allows for Chilean nitrate
9 use, not to exceed 20 percent of the total nitrogen
10 supplied to the crop.

11 CHAIRMAN CARTER: Okay. If you're ready to
12 vote? Bandele?

13 MR. BANDELE: Yes.

14 CHAIRMAN CARTER: Burton?

15 MS. BURTON: Yes.

16 CHAIRMAN CARTER: Caughlan?

17 MS. CAUGHLAN: Yes.

18 CHAIRMAN CARTER: Cooper?

19 MS. COOPER: Yes.

20 CHAIRMAN CARTER: Goldberg, absent.
21 Holbrook?

22 MR. HOLBROOK: Yes.

23 CHAIRMAN CARTER: King?

24 MR. KING: Yes.

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1 CHAIRMAN CARTER: Koenig?
2 MS. KOENIG: Yes.
3 CHAIRMAN CARTER: Lacy?
4 MR. LACY: Yes.
5 CHAIRMAN CARTER: O'Rell?
6 MR. O'RELL: Yes.
7 CHAIRMAN CARTER: Ostiguy?
8 MS. OSTIGUY: Yes.
9 CHAIRMAN CARTER: Riddle?
10 MR. RIDDLE: Yes.
11 CHAIRMAN CARTER: Siemon?
12 MR. SIEMON: No.
13 CHAIRMAN CARTER: And the Chair votes yes.
14 Okay. That one passes by a vote of 12 to 1
15 with one absent.
16 Okay. Next issue?
17 MR. BANDELE: So, really, it's really the
18 same motion for the second petition. Do we need to do
19 that? Do it that way?
20 CHAIRMAN CARTER: What's that?
21 MR. RIDDLE: I would like to reconsider that
22 one because we weren't discussing it in that context.
23 CHAIRMAN CARTER: Yeah. All right.
24 MR. BANDELE: So, in the context of the

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1 petition to prohibit the use of Chilean nitrate in crop
2 production, again the committee voted 4 to 1 not to
3 change the current annotation which allows for Chilean
4 nitrate use not to exceed 20 percent of the total
5 nitrogen supplied to the crop.

6 CHAIRMAN CARTER: Okay. You've heard the
7 motion. Is there a second?

8 MS. KOENIG: Second.

9 CHAIRMAN CARTER: Rose seconded. Discussion?
10 Okay. Jim?

11 MR. RIDDLE: Yes. Well, I'm opposed to this
12 motion and for a number of reasons. In my
13 understanding of organic agriculture, nitrogen
14 shouldn't come in a bag. It should come from the
15 natural system and the nitrogen cycle, and I think
16 there are some problems revealed in the TAP with the
17 material. Certainly concerns about sodium build-up,
18 even with the restrictions that are placed on it, and
19 under the current annotation, that can be an issue. It
20 does also circumvent the natural nitrogen cycle and can
21 inhibit nitrogen fixation of legume plants which are
22 required under the rule.

23 The mining process itself from all the
24 evidence that was presented certainly has negative

1 environmental impacts. I think there are some problems
2 where we're putting U.S. producers at a competitive
3 disadvantage by allowing this material. Yeah. That
4 makes us all then have to jump through hoops to show
5 that we're not using it on farms that are exporting
6 simply because some farms are being allowed to use it.

7 That means that all producers have to prove that they
8 aren't using it, and I think that does have economic
9 ramifications all through the system that are negative.

10 So, I favor removing the material from the
11 list for international harmonization purposes and
12 clearly alternatives do exist. It's used to
13 shortcircuit the natural farming systems, natural
14 nitrogen cycles. So, I will be voting against this
15 amendment or this recommendation, this motion.

16 CHAIRMAN CARTER: Okay. Other discussion?
17 Owusu?

18 MR. BANDELE: According to the TAPs, it's my
19 understanding that the sodium build-up would normally
20 not be a problem in the geographic locations where it's
21 being utilized. It may not be a part of the nitrogen
22 cycle, but it is a natural product. We did have
23 concerns with mining, but again that could be the same
24 with a lot of the other compounds, such as the rock

1 phosphate.

2 We felt that it wasn't really putting the
3 U.S. farmers at a disadvantage because those were the
4 farmers who were petitioning to use the product, and as
5 far as -- I mean, in my way of thinking, if the farmers
6 are big enough to export to Japan and the European
7 Community, I don't think that they would be
8 economically disadvantaged. They'd be in the position
9 to incur whatever minimal costs would be associated
10 with having to document that they in fact did not use
11 that product.

12 Again, though, the committee did recognize
13 the problems with the Chilean nitrate, but in view of
14 the directive that Rose is putting forth, I think we
15 are addressing some of those issues. So, it's not that
16 we were completely comfortable with the product, but at
17 this particular point, we didn't feel as though we had
18 enough information to ban its use.

19 CHAIRMAN CARTER: Okay. Mark?

20 MR. KING: Yes. I'm just looking at the
21 alternatives listed in the TAP, and while I agree with
22 a lot of what Jim said concerning it's a sustainable
23 system and organic principles, I look at the
24 alternatives listed, and two things come to mind.

1 One is that I'm not sure in looking at them
2 that any of them are "better" for the environment in
3 this particular case because we don't have details on
4 how they're harvested and manufactured, and secondly,
5 you know, I realize economics is not one of the
6 criteria, but I look at the cost of Chilean nitrate as
7 a source of nitrogen in this particular case, and it
8 is, you know, roughly almost half the cost of other
9 products out there.

10 So, you know, perhaps we could look at the
11 sunset or looking at where we're at with it. I am
12 uncomfortable with it concerning the mining and
13 environmental effects, nitrate build-up, things of that
14 nature, but it would be nice to -- for example, sea
15 bird guana is listed as an alternative in this case.
16 It does cost more, but, you know, what's involved in
17 the harvest of that? Is it similar to this product?
18 Are we doing, you know, the industry any good by
19 looking at that as an alternative? Just some thoughts
20 that come to mind.

21 CHAIRMAN CARTER: Okay. Owusu?

22 MR. BANDELE: Yeah. I failed to point out
23 one other point. It's my understanding that any
24 readily-available source of nitrogen, such as blood

1 meal, could also inhibit the activity of the rhisobian
2 that picks nitrogen.

3 CHAIRMAN CARTER: Rose?

4 MS. KOENIG: I think Owusu pretty much kind
5 of summarized both yesterday and today some of our
6 concerns with the alternative. Again, mostly with
7 blood meal, in terms of analysis, you know, 1400 versus
8 1600, it's probably the most easily exchanged, you
9 know, in terms of analysis and that's why I had asked
10 the fellow yesterday about whether they were using
11 blood meal, and he expressed, you know, some -- he
12 didn't see the same effect, but more importantly in
13 some of the -- you know, blood meal is another
14 controversial area, especially in light of, you know,
15 mad cow. He said that they were using pork blood. But
16 still, a lot of people are not comfortable with the
17 animal byproduct on here.

18 So, you know, in terms of alternatives, I
19 think we're just not there yet. Hence, the kind of
20 directive, and again, I'll go back to the history, in
21 1995, and this is what made the decision easier for me,
22 and again philosophically, I have a great problem with
23 it, but again, I felt like let's look at the wisdom of
24 the past, you know, the history of the NOSB. They put

1 in a 20 percent clause, and I said to myself, what's
2 changed since then? Well, there really hasn't been a
3 lot of research on this.

4 The TAP probably would look very similar X
5 amount of years ago. So, hence, the directive of
6 research for the next Board to maybe make a better
7 decision.

8 CHAIRMAN CARTER: Okay. Kim, and then
9 Dennis.

10 MS. BURTON: Rosie, I totally support your
11 directive, and I support the continued use of Chilean
12 nitrate. I also think it warrants comment on the
13 number of people that have responded to the continued
14 use of this from all levels of this industry, whether
15 it be from the State of California or congressmen or
16 users or farmers.

17 So, to ban this product at this time I just
18 think is inappropriate.

19 CHAIRMAN CARTER: Dennis?

20 MR. HOLBROOK: One of the things that we need
21 to consider about this particular product and one of
22 the things that has been testified, also, is the fact
23 that this is utilized at a time of the year when other
24 nitrogen sources are not readily available by virtue of

1 cool temperatures and inactivity of the microorganisms.

2 So, there is a definite need, especially in
3 that particular time of the year, for that particular
4 purpose, and, you know, we don't have as many tools out
5 there as we need anyway and to reduce the tools that we
6 have is, in my opinion, is a mistake.

7 CHAIRMAN CARTER: Okay. George, Jim, then
8 let's start to prepare to vote on it.

9 MR. SIEMON: We're just going to go back to
10 '95. This is really hotly contested and a whole lot of
11 talk about a five-year-type period of time to get used
12 to it, and if you read Craig Wheatley's, he said that,
13 and he says the use of a farm plan process to reduce
14 the use over time. We're now seven years later, and we
15 -- have we seen the reduction in the 20 percent? Are
16 we going to encourage production? Are we going to go
17 back to the wisdom of '95? Wow, was it hot then? How
18 can we get people to wean themselves away from it? So,
19 if you're going to go back to that wisdom, we're seven
20 years later, and we're going to endorse the thing to go
21 on for another five years. So, I don't want to use the
22 wisdom of '95 because it was barely passed then, and it
23 was with this farm plan to reduce the use of.

24 CHAIRMAN CARTER: Okay. Jim?

1 MR. RIDDLE: Another thing that was passed in
2 '95 was with the condition that it be reviewed in two
3 years and that has finally happened now, seven years
4 later, and in light of that, I would like to offer an
5 amendment to the current listing which is under
6 205.602(h), sodium nitrate, unless use is restricted to
7 no more than 20 percent of the crop's total nitrogen
8 requirement, until October 21st, 2005, and that gives
9 three years for this anticipated directive that we'll
10 be discussing that Rose is putting forward, gives time
11 for the research. It is consistent with the original
12 Board's recommendation that this is going to be on an
13 expedited review. I should stop after I made that
14 motion and see if there's a second before I start
15 discussing it. Sorry, Mr. Chair.

16 CHAIRMAN CARTER: Okay. Restate the motion.

17 MR. RIDDLE: Yeah. To add to the current
18 annotation until October 21st, 2005.

19 CHAIRMAN CARTER: Okay. Motion to add a
20 sunset clause of 2005. Is there a second to the
21 motion?

22 PARTICIPANT: Second.

23 CHAIRMAN CARTER: Okay. Motion is seconded.

24 Now, you may --

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1 MR . RIDDLE: Well, yeah. I think it is
2 consistent with the existing annotation and certainly
3 sends the message that George was just talking about,
4 you know, phase out, reduce use.

5 CHAIRMAN CARTER: Okay. Rose, I know I got
6 some people in the audience who want to address this,
7 but unless you're called upon by the Board to come
8 forward and respond to a question, --

9 MS. KOENIG: Well, again, what you're saying,
10 Jim, is not necessarily phase out. What I understand
11 is you're saying it would be rereviewed. It would be
12 expedited. That doesn't assume that it's phased out.

13 MR. RIDDLE: That's true.

14 MS. KOENIG: Okay. So, then the question is
15 what? At present, we're doing it in 2005. I mean,
16 2007. But as Rick said, there's going to be a problem
17 in terms of timing. We could put it in there, but the
18 objective of this policy directive is to encourage
19 research, to encourage data collection. So, then the
20 question is, does three years give enough time?

21 I certainly think in terms of the economic
22 impacts and assessments as written in the policy
23 directive, that, yes, there's plenty of time in three
24 years to gather that kind of data. The problem comes

1 in terms of environmental impacts and assessments, and
2 there lies the greatest problem within the TAPs, the
3 environment -- you know, what are the environmental --
4 how much salt is accumulated and etc.?

5 I personally, having the knowledge of
6 research, in terms of securing funding and actually
7 conducting this research, I don't think three years is
8 enough time to do that. So, why restrict this again
9 into -- I'd rather see it come up in five years or
10 within that period of four to five years, not
11 conditionally put it to three years, allowing again the
12 types of data that we need and the future Board's going
13 to need to make a more educated decision on this
14 product.

15 CHAIRMAN CARTER: Okay. Mark?

16 MR. KING: I just had a question concerning
17 Jim's motion here, and that is to you, Rick, concerning
18 sunset clauses. If we state, for example, if we were
19 to look at this and say, you know, it's 10/21/2005.
20 That simply means that it would be reviewed at that
21 point, and to add to the -- well, and then one more
22 thing. If we say something like to be removed from the
23 national list, does that hold any weight? If we say to
24 be removed from the national list 10/21 of 2005, it's

1 my understanding all that means is that it'll be
2 reviewed. So, I think it's relevant to the sunset.

3 CHAIRMAN CARTER: Rick?

4 MR. MATHEWS: Putting the date in there to me
5 means that it comes off the list at that time. If even
6 -- whether you use the word "removed" or not, that's
7 really the end of the time in which the product can be
8 used. So, going along with what Rose is talking about,
9 even if the research hadn't been done, the Board before
10 October 21st, 2005, would have to have had a TAP review
11 done which really means that they have to start the TAP
12 review in 2004 in order to avoid -- actually even
13 sooner than that if the attorneys, after October 21st,
14 hold us to proposed rule and final rule because the
15 thing could come off the list before we even have a
16 chance to do the rulemaking process or you have the
17 chance to do the TAP review.

18 So, three-year window for this product means
19 you're going to have to start pretty soon to review it
20 again, which means you won't have the research that
21 Rose is saying that you need in order to do an adequate
22 determination on the suitability of the product.

23 MR. KING: So, it appears there was some
24 wisdom in the five year?

1 MR. MATHEWS: I think there was some wisdom
2 in the five year.

3 CHAIRMAN CARTER: Okay.

4 MR. MATHEWS: And you're hurting yourself by
5 constricting that.

6 CHAIRMAN CARTER: Okay. If you're ready to
7 vote? Okay. We're voting on the amendment only, which
8 is, to amend it to create a sunset clause until October
9 21st, 2005.

10 Okay. Bandele?

11 MR. BANDELE: No.

12 CHAIRMAN CARTER: Burton?

13 MS. BURTON: No.

14 CHAIRMAN CARTER: Caughlan?

15 MS. CAUGHLAN: No.

16 CHAIRMAN CARTER: Cooper?

17 MS. COOPER: No.

18 CHAIRMAN CARTER: Goldberg, absent.

19 Holbrook?

20 MR. HOLBROOK: No.

21 CHAIRMAN CARTER: King?

22 MR. KING: No.

23 CHAIRMAN CARTER: Koenig?

24 MS. KOENIG: No. I guess no.

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1 CHAIRMAN CARTER: Lacy?
2 MR. LACY: Yes.
3 CHAIRMAN CARTER: O'Rell?
4 MR. O'RELL: No.
5 CHAIRMAN CARTER: Ostiguy?
6 MS. OSTIGUY: No.
7 CHAIRMAN CARTER: Riddle?
8 MR. RIDDLE: Yes.
9 CHAIRMAN CARTER: Siemon?
10 MR. SIEMON: No.
11 CHAIRMAN CARTER: Chair votes no.
12 Okay. So, the motion fails. The amendment
13 fails.
14 So, we're back to the original motion. Okay.
15 Discussion on the original motion?
16 (No response)
17 CHAIRMAN CARTER: Seeing none -- oh, yeah?
18 Seeing some.
19 MR. KING: I just want to go back to Rose's
20 point and not to beat it up, but, okay, now we're at
21 the five-year point, all right, and now we're looking
22 at this particular directive. How do we ensure --
23 what's that?
24 PARTICIPANT: Something similar. We have to

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1 --

2 MR. KING: All right. My question is, how
3 can we ensure in some fashion, efficient fashion, Dave,
4 that this could be followed through with in the next
5 five years? Do we want to consider that as even --

6 CHAIRMAN CARTER: It's not germane to this
7 motion, but it's certainly a definite issue. So, put
8 it in the parking lot.

9 MR. KING: Okay.

10 CHAIRMAN CARTER: Yeah. Let's park that for
11 right now because that's something we need to address.

12 Okay. If you're ready to vote, Owusu, would
13 you just repeat the motion?

14 MR. BANDELE: The motion is not to change the
15 current annotation which allows for Chilean nitrate use
16 not to exceed 20 percent of the total nitrogen supplied
17 to the crop.

18 CHAIRMAN CARTER: Okay. That's what we're
19 voting on. Richard?

20 MR. MATHEWS: Vote not to change the
21 annotation has already been done. The issue now is
22 whether or not to remove the material from the list is
23 the way I was following this.

24 MR. SIEMON: That was for the early and

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1 strictly, but it's true --

2 MS. BENHAM: The motion would be to leave the
3 list as -- to leave the rule as is.

4 MR. SIEMON: To not remove it.

5 MS. BENHAM: To not remove it. To not remove
6 Chilean nitrate from the national list.

7 CHAIRMAN CARTER: Parliamentary issue is,
8 yeah, you don't need to vote on it, you just don't
9 bring it up. I mean, it's been brought up. It's been
10 a motion. I was trying to think this through, to
11 expedite it. Okay. So, let's just proceed to vote.

12 Okay. So, on the motion, Bandele?

13 MR. BANDELE: Yes.

14 CHAIRMAN CARTER: Burton?

15 MS. BURTON: Yes.

16 CHAIRMAN CARTER: Caughlan?

17 MS. CAUGHLAN: Yes.

18 CHAIRMAN CARTER: Cooper?

19 MS. COOPER: Yes.

20 CHAIRMAN CARTER: Goldberg, absent.
21 Holbrook?

22 MR. HOLBROOK: Yes.

23 CHAIRMAN CARTER: King?

24 MR. KING: Yes.

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1 CHAIRMAN CARTER: Koenig?
2 MS. KOENIG: Yes.
3 CHAIRMAN CARTER: Lacy?
4 MR. LACY: Yes.
5 CHAIRMAN CARTER: O'Rell?
6 MR. O'RELL: Yes.
7 CHAIRMAN CARTER: Ostiguy?
8 MS. OSTIGUY: Yes.
9 CHAIRMAN CARTER: Riddle?
10 MR. RIDDLE: No.
11 CHAIRMAN CARTER: Siemon?
12 MR. SIEMON: Yes.
13 CHAIRMAN CARTER: And the Chair votes yes.
14 Okay. The motion carries with a vote of 12
15 to 1 with one person absent.
16 MR. BANDELE: Okay. I'm going to defer to
17 Rose at this point with the record.
18 MS. KOENIG: Okay. So, again, this is kind
19 of a stab at perhaps the way, you know, in my vision
20 how we want to deal with materials issues that we
21 consider have some problems or, you know, not
22 necessarily even problems. It's a way of -- you know,
23 if there's issues that were not clear, yet we voted in
24 favor of something, to somehow record those so the

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1 public can have access to the information. Perhaps it
2 could be put up on the website for researchers to
3 access.

4 CHAIRMAN CARTER: Procedurally, go ahead and
5 make a motion, though, before you discuss it.

6 MS. KOENIG: So, the motion is as read. The
7 NOSB requests the -- all right. So, the motion would
8 be exactly as is. The Crops Committee asks for the
9 adoption of the following policy directive to USDA.
10 The NOSB requests the following information and data in
11 regards to sodium nitrate. This information should be
12 addressed for the upcoming mandated review of the
13 product in approximately 2007.

14 1. Economic impacts and assessment. So,
15 these are A, B, C, D, and E. Approximate number of
16 farms utilizing the materials, the geographical
17 distribution of the farms utilizing the material, the
18 size of the farm operations utilizing the material,
19 list of crops to which the material's applied, and
20 methods and timing of material application.

21 2. Environmental impacts and assessment.
22 Sodium and nitrogen accumulation in soils, the impact
23 of sodium nitrate on water quality, the impact of
24 sodium nitrate on soil microorganisms, the impact of

1 sodium nitrate on soil quality, comparison of approved
2 alternatives, naturals and listed synthetics, in
3 various cropping systems, which would include
4 spirulina, just -- it's not written there, but I
5 checked it to make sure that it would be applicable to
6 like a spirulina case, and it would, and then
7 development of best management practices for materials.

8 CHAIRMAN CARTER: Okay. You've heard the
9 motion. Is there a second to the motion?

10 MS. OSTIGUY: Second.

11 CHAIRMAN CARTER: Who seconded?

12 MS. OSTIGUY: I did.

13 CHAIRMAN CARTER: Okay. Nancy seconded it.

14 Okay. Now, discussion on the motion?

15 George?

16 MR. SIEMON: Yes. My concern is that no
17 where do we identify what the real problem here is.
18 There's a reduction in yield if you don't have it.
19 There's a reduction in quality. You won't have
20 broccoli in July in California. I mean, this doesn't
21 answer my real questions yet, which is what is the crux
22 of the problem? I hear that during the heat, you know,
23 but really, what is the issue? Lack of yield? Slower
24 harvest? I mean, if we're going to go this far, I'd

1 like to know really what the real problem is. When we
2 don't use this, what is the disadvantage to not having
3 it?

4 MS. OSTIGUY: Offer an amendment.

5 MR. SIEMON: I had under economic impacts to
6 identify the problem, then I had yield size. I didn't
7 have the whole -- identify the end result from not
8 allowing the use of it, specifically the yield quality
9 problems, availability. What are the specific issues?

10 CHAIRMAN CARTER: Are you -- I mean, --

11 MR. SIEMON: I'd be glad to make that motion.

12 CHAIRMAN CARTER: Okay. Let's see if Mark
13 can state a motion here.

14 MR. KING: Well, I'm attempting to just
15 suggest where it might go, this motion.

16 CHAIRMAN CARTER: Okay. We're in the process
17 of formulating a motion here.

18 MR. KING: Right. And the Crops Committee
19 asked for the adoption of the following policy due to
20 or because of dah-dah-dah and then state two or three
21 specifics as George is suggesting.

22 MS. KOENIG: The only thing I would say is
23 under E, your information would actually come from,
24 because you're comparing approved alternatives of

1 various cropping systems. Basically, that is going to
2 show you in -- because, you know, that covers those
3 issues because the question is not, you know, how great
4 the yield is in sodium nitrate. We know that it's
5 helpful in crop growth.

6 CHAIRMAN CARTER: I'm trying at this point to
7 help because George is trying to make a motion here,
8 and let's just see if we can get wording.

9 MR. SIEMON: You've got environmental impact
10 and assessment. I'm just worried under environmental,
11 it won't get to the specific question. You won't have
12 broccoli in July if you don't allow this. You know,
13 that's what I'm trying to really get clear here.

14 CHAIRMAN CARTER: Okay.

15 MR. SIEMON: So, I --

16 MS. KOENIG: Perhaps you can just document --
17 put an F and document yield of current use and
18 alternatives.

19 MR. SIEMON: How about -- say that again.

20 MS. KOENIG: Document -- F, under Economic
21 Impacts and Assessments, document current yield and
22 alternatives.

23 MS. OSTIGUY: Or you can just take E from
24 Section 2 and make it an F under Section 1 because then

1 you would be doing the comparison under the Economic
2 Impact and Assessment, also.

3 CHAIRMAN CARTER: I'm trying to see if
4 somebody's made a motion here.

5 MR. SIEMON: I'm trying to make a motion, but
6 I'm trying to get the right --

7 CHAIRMAN CARTER: Suggestion. I'm sorry,
8 Owusu, but --

9 MR. SIEMON: Moving E up to I.

10 MS. OSTIGUY: I would move that we move --
11 no. We actually duplicate E in Section 2 as F in
12 Section 1.

13 CHAIRMAN CARTER: Okay. Amendment to the
14 original motion to take the language in Section E of
15 Roman Numeral II and duplicate that as Section F in
16 Roman Numeral I. Is there a second to the amendment?

17 MR. SIEMON: Second.

18 CHAIRMAN CARTER: It's been seconded. Okay.
19 Discussion on the amendment? Owusu?

20 MR. BANDELE: Okay. I still think that that
21 comparison of the actual yields would be more
22 appropriate under Section 2, and I would think that if
23 you said like environmental and crop impacts --

24 CHAIRMAN CARTER: It remains there. It's

1 just being duplicated. It's duplicated. So, you're
2 just repeating that language under those sections.

3 MR. BANDELE: Okay.

4 CHAIRMAN CARTER: Okay. Discussion on the
5 amendment? Okay. Mark?

6 MR. KING: Go ahead, Goldie.

7 MS. CAUGHLAN: This is just very tiny.
8 You've mandated the review of the product. I think
9 it's an inappropriate way to refer to it. It's not a
10 product. It's sodium nitrate.

11 MR. HOLBROOK: But it needs to be open to
12 anything, should be applicable to anything that we want
13 to review.

14 MS. CAUGHLAN: That's not what it says in
15 this particular -- that's not what this is.

16 CHAIRMAN CARTER: This motion is -- I agree
17 with you, Dennis, but this motion is specific to sodium
18 nitrate.

19 MS. CAUGHLAN: So, it's just a housekeeping
20 thing.

21 CHAIRMAN CARTER: We can take the specific
22 and apply it to the general as we go forward. This may
23 be -- yeah. Mark?

24 MR. KING: Well, I support the motion because

1 I think it does add some, you know, credence to what
2 we're looking at from an economic perspective, but I
3 asked the question concerning George's original
4 concern.

5 Is it necessary for the Board or the
6 committee in this case to state the reasons or the need
7 for this information or is that just obvious?

8 MR. SIEMON: The need for this information.
9 You want it more specific than this motion allows? Is
10 that what you're referring to?

11 MR. KING: Well, we don't state that
12 specifically. We just say that these are the areas
13 we'd like, which I support, okay, that we would like to
14 explore. Is it necessary for us to state why? In
15 other words, in looking at future scenarios where this
16 might also be an issue.

17 CHAIRMAN CARTER: Okay. Now, all we're
18 talking about here is the amendment. Okay. So, you
19 know, when we pass that, then we can -- Dennis? On the
20 amendment.

21 MR. HOLBROOK: Well, I just wanted to state
22 the fact that, you know, one of the reasons why this
23 whole process came about out of the Crops Committee is
24 because we didn't feel like that the TAP reviews were

1 giving us the type of information, and we revisit this
2 in five years, the TAP reviews are going to be the
3 same, you know, The additional information needs to be
4 put there so that we can determine whether these things
5 need to be changed or not.

6 CHAIRMAN CARTER: Okay. Owusu, and then
7 Richard.

8 MR. BANDELE: Just a minor point. I think it
9 says comparison of approved alternatives. I know it's
10 implied that it's, you know, with systems using sodium
11 nitrate, but I think maybe we should state that because
12 as it's stated, that could be really interpreted as
13 just a comparison of the alternatives, not necessarily
14 including the sodium nitrate.

15 CHAIRMAN CARTER: Are you offering that as a
16 friendly amendment to the amendment or making that --

17 MR. BANDELE: Yes.

18 CHAIRMAN CARTER: -- as a formal amendment?

19 MS. OSTIGUY: I would take it as a friendly
20 amendment.

21 CHAIRMAN CARTER: Friendly amendment? Is
22 that okay with the seconder?

23 MR. SIEMON: Yes.

24 CHAIRMAN CARTER: Okay. It's okay with the

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1 second. So, it so states.

2 PARTICIPANT: Can you read it back?

3 MS. BENHAM: The friendly amendment is what?

4 CHAIRMAN CARTER: Okay. The friendly
5 amendment is the comparison of --

6 MR. BANDELE: Comparison of approved
7 alternatives, natural and listed synthetics, in various
8 cropping systems with systems using sodium nitrate.

9 MS. BENHAM: I'm sorry, Owusu. Read it
10 again.

11 MR. BANDELE: Just add with systems using
12 sodium nitrate or Chilean nitrate, I guess. Sodium
13 nitrate.

14 CHAIRMAN CARTER: Sodium nitrate.

15 MR. BANDELE: But should we not say Chilean,
16 though, because you could theoretically have a
17 synthetic sodium nitrate, could you not? So, Chilean
18 would make that distinction.

19 CHAIRMAN CARTER: Okay. So, --

20 MS. CAUGHLAN: Then that -- excuse me --
21 should be --

22 PARTICIPANT: For the whole thing.

23 MS. CAUGHLAN: Thank you.

24 CHAIRMAN CARTER: We can take that as a

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1 typographical thing. That does not need to be
2 addressed in the amendment. So, just where it says
3 sodium, put in Chilean.

4 Okay. So, you understand the amendment?

5 Okay. Let's proceed to vote on the amendment, which
6 is, to duplicate the language under 2-E as new 1-F with
7 the addition of the words comparison to -- with systems
8 using Chilean nitrates.

9 MR. SIEMON: In both cases, though.

10 CHAIRMAN CARTER: In both cases. That's
11 correct.

12 Okay. Bandele?

13 MR. BANDELE: Yes.

14 CHAIRMAN CARTER: Burton?

15 MS. BURTON: Yes.

16 CHAIRMAN CARTER: Caughlan?

17 MS. CAUGHLAN: Yes.

18 CHAIRMAN CARTER: Cooper?

19 MS. COOPER: Yes.

20 CHAIRMAN CARTER: Goldberg, absent.
21 Holbrook?

22 MR. HOLBROOK: Yes.

23 CHAIRMAN CARTER: King?

24 MR. KING: Yes.

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1 CHAIRMAN CARTER: Koenig?
2 MS. KOENIG: Yes.
3 CHAIRMAN CARTER: Lacy?
4 MR. LACY: Yes.
5 CHAIRMAN CARTER: O'Rell?
6 MR. O'RELL: Yes.
7 CHAIRMAN CARTER: Ostiguy?
8 MS. OSTIGUY: Yes.
9 CHAIRMAN CARTER: Riddle?
10 MR. RIDDLE: Yes.
11 CHAIRMAN CARTER: Siemon?
12 MR. SIEMON: Yes.
13 CHAIRMAN CARTER: Chair votes yes. Passes
14 unanimously.
15 MS. BENHAM: What's the total, please?
16 CHAIRMAN CARTER: 13 to nothing with 1
17 absent, one person absent.
18 MS. BENHAM: Okay.
19 CHAIRMAN CARTER: Okay. Back to the original
20 motion. Jim?
21 MR. RIDDLE: Yeah.
22 CHAIRMAN CARTER: Motion as amended.
23 MR. RIDDLE: Right. A couple of things on
24 this. One concern I heard from the committee, lack of

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1 information about the impact of the mining and
2 manufacturing process, and I would certainly like to
3 see that be studied in this interim period and request
4 for that. So, I would like to offer an amendment to
5 the second section, Environmental Impact and
6 Assessment, to add a new Item G, impact of Chilean
7 nitrate mining and manufacturing process.

8 CHAIRMAN CARTER: Okay. You've heard the
9 motion. Is there a second?

10 MS. KOENIG: I'll second it.

11 CHAIRMAN CARTER: Okay. Rose seconded.
12 Repeat the motion.

13 MR. RIDDLE: To add a new Item G, impact of
14 the Chilean nitrate mining and manufacturing process.

15 CHAIRMAN CARTER: Okay. Discussion on the
16 motion? Nancy?

17 MS. OSTIGUY: Do we really need research on
18 this or is this a matter of it not being in the TAP and
19 the data are available? Because it would seem that
20 that operation has been going on. I don't know. It's
21 a question.

22 CHAIRMAN CARTER: Do you want to call forward
23 somebody from the audience to answer that?

24 MS. OSTIGUY: Yes.

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1 CHAIRMAN CARTER: Okay.

2 MS. OSTIGUY: If someone can tell me if the
3 data exist.

4 MR. DAVIS: Gerald Davis, Cal Organic Farms.

5 I talked with the people in Chile that
6 manufacture the material, and they do have
7 environmental impact statements. I'm not sure if it's
8 quite as -- the same as what we're used to in this
9 country as far as detail and extent, but that data does
10 exist.

11 MS. OSTIGUY: So, there are at least some
12 data out there?

13 MR. DAVIS: Yes.

14 CHAIRMAN CARTER: Okay. All right. Let's
15 proceed to vote on the -- only if somebody in the Board
16 wants to call you forward to speak to it. Okay. Okay.

17 Okay. Then let's proceed to vote on the
18 motion, okay, and the motion is to add G, impact of the
19 mining and manufacturing process.

20 Okay. Bandele?

21 MR. BANDELE: Yes.

22 CHAIRMAN CARTER: Burton?

23 MS. BURTON: Yes.

24 CHAIRMAN CARTER: Caughlan?

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1 MS. CAUGHLAN: Yes.

2 CHAIRMAN CARTER: Cooper?

3 MS. COOPER: Yes.

4 CHAIRMAN CARTER: Goldberg, absent.

5 Holbrook?

6 MR. HOLBROOK: Yes.

7 CHAIRMAN CARTER: King?

8 MR. KING: Yes.

9 CHAIRMAN CARTER: Koenig?

10 MS. KOENIG: Yes.

11 CHAIRMAN CARTER: Lacy?

12 MR. LACY: Yes.

13 CHAIRMAN CARTER: O'Rell?

14 MR. O'RELL: Yes.

15 CHAIRMAN CARTER: Ostiguy?

16 MS. OSTIGUY: Yes.

17 CHAIRMAN CARTER: Riddle?

18 MR. RIDDLE: Yes.

19 CHAIRMAN CARTER: Siemon?

20 MR. SIEMON: Yes.

21 CHAIRMAN CARTER: Chair votes yes. Passes

22 13-0, 1 absent.

23 Okay. Nancy?

24 MS. OSTIGUY: I have a question about the

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1 date in light of comments that Rick has made concerning
2 the sunset clause after five years. This is both
3 specific to this and generic. If the lawyers are going
4 to say that after five years, that items that are on
5 the list are off the list, how are we going to actually
6 have processed everything since we have, I'm not sure,
7 N number of items that are currently on the list that
8 we're going to lose in five years? It would seem to me
9 we'd have to start tomorrow to review everything if
10 we're going to meet that deadline or is there a vague
11 possibility that we're going to be able to say we start
12 and if we haven't got to it yet, it stays in place?
13 Sort of like what EPA does.

14 MR. MATHEWS: That's the road that we haven't
15 really gone down yet. I know that Kim has agonized
16 over it a great deal. We've had some discussions, but
17 it's kind of one of those back burner things right now,
18 but it is one of those things that are getting closer
19 to being brought to the front of the stove.

20 MS. OSTIGUY: My concern is that if we put a
21 2007 deadline here for research information, it's going
22 to be a bit too late for the TAPs and such, and I
23 realize that it says approximately, but the -- I wanted
24 to bring that up, that we need the information much

1 sooner than this. It does mean if we're going to ask
2 people to do research projects within either ARS or the
3 land grant process, we have to have the money ASAP if
4 we're going to be able to produce data for the Board
5 before a TAP is done.

6 CHAIRMAN CARTER: Okay. Jim?

7 MR. RIDDLE: Yeah. As an inspector, I have
8 problems with approximate dates, also. I don't think
9 it's really necessary here, and I would just offer a
10 hopefully friendly amendment to delete in approximately
11 2007 and just end that sentence after mandated review
12 of the product. Material, whatever. Of the material.
13 I'm sorry. That got changed. It's not on my copy
14 yet.

15 CHAIRMAN CARTER: Okay. Can we just accept
16 that with concurrence or do we need to vote on that?
17 The maker of the motion, you're the maker of the
18 motion. Is that friendly? Okay.

19 Katherine has got -- she's got furrowed brow
20 over there. So, yes, she's growling. That's not a
21 good sign. Okay.

22 MS. BENHAM: So, the friendly amendment is to
23 remove --

24 CHAIRMAN CARTER: Okay. So, Katherine, now

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1 the language in that first -- the main paragraph would
2 say the NOSB requests the following information and
3 data in regard to sodium nitrate -- Chilean nitrate --
4 let me read -- okay. Chilean nitrate. This
5 information should be addressed for the upcoming
6 mandated review of the material. Okay.

7 MR. RIDDLE: Delete the words "in
8 approximately 2007".

9 MR. MATHEWS: Do we have to do a voice vote?
10 Can we just say for anybody against it?

11 CHAIRMAN CARTER: For the record, we need to
12 do -- I've been told we need to do it.

13 MR. MATHEWS: Okay.

14 CHAIRMAN CARTER: For the record.

15 MR. MATHEWS: Because we're really taking a
16 lot of time on this, you all. This is eating a lot of
17 time up here.

18 PARTICIPANT: No. We have to have the voice
19 vote because when we go to do the record and it -- the
20 last time, it was just a nightmare trying to figure out
21 what really did happen, even from the transcript,
22 because it's not there.

23 The one thing I did want to say is that Nancy
24 hit on something earlier, that, you know, does this

1 kind of stuff need to -- do you need to be telling the
2 reviewers that you need this kind of stuff in there,
3 and I think that what I would like to do is I would
4 like to task the Board into taking a look at where we
5 are on how we develop TAPs now and look at those
6 procedures, look at what's already been provided to the
7 reviewers, look at the contract, and then come back to
8 us with recommendations as to what we should be doing
9 to change the current procedures so that information
10 like this does show up in the TAP review, if it is at
11 all available.

12 I don't know how big that problem is, but it
13 seems to be that there's a problem and so it's probably
14 a project the Board should be working on.

15 CHAIRMAN CARTER: Okay. Now, let's not get
16 too mired in this discussion. Let's vote on the -- you
17 know, because I think that's a very important issue,
18 but let's stay germane to the motion here.

19 Okay. So, you're ready to vote on the -- no?
20 Okay.

21 MR. RIDDLE: Yes. There was just one other
22 thing, and I brought up yesterday, was hoping would be
23 on this list, and that is the impact of this material
24 on international trade. It's not ever going to be

1 addressed by a TAP review. So, I think it is a logical
2 thing to add in here, and so I would like to move to
3 add to Number 1 a new Item G, impact on international
4 trade.

5 CHAIRMAN CARTER: Okay. Motion. Is there a
6 second?

7 MS. CAUGHLAN: I'll second it.

8 CHAIRMAN CARTER: Okay. Goldie seconded it.
9 Okay. Discussion on the motion? Impact on
10 international trade. Dennis?

11 MR. HOLBROOK: Well, I think it stands to
12 reason that the people already know that this is not
13 being accepted in international trade. So, why would
14 they be impacted? I mean, they're probably not growing
15 for the international trade if they're using it. So,
16 why is that even necessary?

17 CHAIRMAN CARTER: Okay. Jim?

18 MR. RIDDLE: Well, it has huge impact when
19 it's on our list and not on other lists, not just for
20 the producers who use it but also for the producers who
21 don't use it, and I don't think that's been studied. I
22 think it's a valid area of research to look into the
23 impacts on our producers.

24 CHAIRMAN CARTER: Okay. Rose?

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1 MS. KOENIG: I'm in total agreement with what
2 Jim says, and I just want to -- I guess if it's not
3 clear, the objective of this -- we're not saying that
4 when it gets rereviewed, that every single one of these
5 things are going to be studied. We're just trying to
6 pinpoint areas that, if people have resources and the
7 ability to look at these things, these are the things
8 that we acknowledge that are controversial or need
9 supportive data in the review.

10 CHAIRMAN CARTER: Okay.

11 MS. KOENIG: So, I wouldn't worry so much
12 about --

13 MS. BURTON: I would contradict that because
14 I think this next Board is going to see this and say
15 where's the comparison on international trade, and as a
16 manufacturer, if I want to export, I can have an
17 export-only label, and I can work with my farmers and
18 growers to remove Chilean nitrate and not use it. So,
19 although I, you know, am not opposed to an impact, I
20 just -- I hate to bog down the system if it's really
21 necessary.

22 CHAIRMAN CARTER: Okay. Goldie, and then
23 let's prepare to vote on the motion. We need to move
24 this along.

1 MS. CAUGHLAN: Just a comment. If that isn't
2 the intent, then it should not be a directive that
3 requests.

4 MS. KOENIG: Well, it requests, but it
5 doesn't require and that's why I used request rather
6 than require.

7 CHAIRMAN CARTER: Okay. On the amendment,
8 which is, to add a new Section G, the impact on
9 international trade.

10 Bandele?

11 MR. BANDELE: Yes.

12 CHAIRMAN CARTER: Burton?

13 MS. BURTON: No.

14 CHAIRMAN CARTER: Caughlan?

15 MS. CAUGHLAN: Yes.

16 CHAIRMAN CARTER: Cooper?

17 MS. COOPER: Yes.

18 CHAIRMAN CARTER: Goldberg, absent.

19 Holbrook?

20 MR. HOLBROOK: No.

21 CHAIRMAN CARTER: King?

22 MR. KING: Yes.

23 CHAIRMAN CARTER: Koenig?

24 MS. KOENIG: Yes.

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1 CHAIRMAN CARTER: Lacy?

2 MR. LACY: Yes.

3 CHAIRMAN CARTER: O'Rell?

4 MS. OSTIGUY: Yes.

5 CHAIRMAN CARTER: Ostiguy?

6 MS. OSTIGUY: No.

7 CHAIRMAN CARTER: Riddle?

8 MR. RIDDLE: Yes.

9 CHAIRMAN CARTER: Siemon?

10 MR. SIEMON: Yes.

11 CHAIRMAN CARTER: Chair votes yes. It passes
12 10 to 3, with 1 absent.

13 Okay. We're back to now the motion as
14 repeatedly amended. Okay. If you're prepared to vote,
15 we will --

16 MS. BENHAM: Excuse me. Is this on the
17 previous friendly amendment, the NOSB requests the
18 following information in regard to Chilean nitrate?

19 CHAIRMAN CARTER: This is on the full thing
20 as we've now largely rewritten it.

21 MS. BENHAM: So, we're going back to that
22 one?

23 CHAIRMAN CARTER: Yes. This is the issue.
24 Okay. Everybody understands that?

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1 Okay. Bandeled?

2 MR. BANDELE: Yes.

3 CHAIRMAN CARTER: Burton?

4 MS. BURTON: Yes.

5 CHAIRMAN CARTER: Caughlan?

6 MS. CAUGHLAN: Yes.

7 CHAIRMAN CARTER: Cooper?

8 MS. COOPER: Yes.

9 CHAIRMAN CARTER: Goldburg, absent.

10 Holbrook?

11 MR. HOLBROOK: Yes.

12 CHAIRMAN CARTER: King?

13 MR. KING: Yes.

14 CHAIRMAN CARTER: Koenig?

15 MS. KOENIG: Yes.

16 CHAIRMAN CARTER: Lacy?

17 MR. LACY: Yes.

18 CHAIRMAN CARTER: O'Rell?

19 MR. O'RELL: Yes.

20 CHAIRMAN CARTER: Ostiguy?

21 MS. OSTIGUY: Yes.

22 CHAIRMAN CARTER: Riddle?

23 MR. RIDDLE: Yes.

24 CHAIRMAN CARTER: Siemon?

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1 MR. SIEMON: Yes.

2 CHAIRMAN CARTER: Chair votes yes. Passes
3 13-0, 1 absent.

4 PARTICIPANT: There's one material down.

5 CHAIRMAN CARTER: In all seriousness, as we
6 go through this, really be judicious when you weigh in.
7 We want to get everybody's comment. Try and keep them
8 brief, to the point, so we can get through the
9 discussion because we got a lot of work to do. So,
10 okay.

11 Owusu?

12 MR. BANDELE: I do like to keep us off
13 schedule.

14 PARTICIPANT: Technically, you're still on
15 schedule.

16 MR. BANDELE: Since the Chair voted against
17 the next recommendation, I'm going to defer to Dennis
18 to make that amendment.

19 CHAIRMAN CARTER: Okay. Okay.

20 MR. HOLBROOK: The next material is ozone,
21 and we discussed this in committee. It was for
22 multiple uses, I guess. Basically, it was used for one
23 as a product that could be used to flush and clean out
24 irrigation drip systems and that the committee voted 3

1 to 2 to add ozone to the list with the following
2 annotation, to be used for cleaning irrigation lines
3 only.

4 As used for weed control, the committee voted
5 5 against to prohibit -- 5 to prohibit this use and
6 also for the use as a soilborne pathogen control, the
7 committee also voted 5 to 0 to prohibit this use.

8 So, the motion, I guess, at this point in
9 time to be made is that the committee would like you to
10 add ozone to the national list with the following
11 annotation, to be used for cleaning irrigation lines
12 only.

13 CHAIRMAN CARTER: Okay. The motion is that
14 this is a synthetic product to be added to the national
15 list only for the purpose of cleaning irrigation lines.

16 MR. HOLBROOK: Correct.

17 CHAIRMAN CARTER: Is there a second to the
18 motion?

19 MS. KOENIG: I'll second.

20 CHAIRMAN CARTER: Rose seconded.

21 Discussion? Nancy?

22 MS. OSTIGUY: I was one of the two committee
23 members that voted against this. My concern has to do
24 with the release of ozone into the atmosphere, worker

1 exposure. It's a respiratory irritant, quite severe
2 respiratory irritant, and the release of the material
3 in the irrigation water on the soils, such that we have
4 the same impact on the soils potentially, at least in a
5 limited area, as we would if we used it for pathogen
6 control or for weed control. The primary concern will
7 be -- would be altering the -- both microorganisms and
8 other organisms making up the soil profile.

9 CHAIRMAN CARTER: Okay. Kim?

10 MS. BURTON: It was my understanding that the
11 generators used to manufacture this, that they would
12 default if there was a problem with the ozone
13 releasing, at least that's what the TAP reflected.

14 MS. OSTIGUY: Right. But the --

15 MS. BURTON: To me, it seemed like that was
16 somewhat addressing that problem from a malfunction
17 standpoint.

18 MS. OSTIGUY: That the material's
19 intentionally released at the end of the line.

20 MS. BURTON: Right. That was my one -- as
21 far as the material being released from the end of the
22 line, when it comes in contact with water, it also
23 dissipates. So, to me, this is a widely-used product,
24 material, used in food processing and water quality,

1 that whole -- so, I did not feel like that was as much
2 of an impact and that it shouldn't be disallowed just
3 because of the potential to get into the soil, and
4 there wasn't enough evidence to me that it was really
5 going to damage the soil.

6 CHAIRMAN CARTER: Okay. Rose?

7 MS. KOENIG: I think the distinction, Kim, is
8 that as stated in the amendment, the -- and using --
9 and I don't want to put concentrations down, but the
10 difference between pathogen and weed application is in
11 terms of concentrations, how much you have to add to
12 actually get through to kill those and the non-specific
13 activity of those things.

14 Additionally, there are alternatives to
15 pathogen and weeds, although sometimes pretty
16 frustrating alternatives, but in terms of disinfecting
17 the line, the major alternative is chlorine, and we
18 felt that ozone had benefits over chlorine. So, that
19 was really the justification of one versus the other,
20 in addition to what Nancy said.

21 CHAIRMAN CARTER: Okay. George, you had your
22 hand up.

23 MR. SIEMON: Well, I did have my hand up, but
24 it's kind of got answered. I just wanted to understand

1 why you didn't allow it for the other issues, but I
2 think I've heard the reasons why right here in your two
3 comments because it would help me just to understand
4 why just this one. Is there anything else that hasn't
5 been mentioned about why?

6 MS. KOENIG: I just said that.

7 CHAIRMAN CARTER: Okay. Owusu?

8 MR. BANDELE: Yes. I was the other nay vote
9 on this, and I had the same concerns that Nancy had.
10 Additionally, there's a lot of variation in results
11 both in the weed control and in the soil. To me, it
12 would be hard to distinguish. In other words, a person
13 could increase the concentration under the pretext of
14 cleaning the lines and thereby using it for the weed
15 control and soilborne pathogens as well. So, that was
16 one of my major concerns along those lines.

17 Secondly, I thought that there were in terms
18 of cleaning the lines, besides chlorine, I think citric
19 acid, there was some other alternatives that could be
20 used, and I thought the idea was that if in fact there
21 were alternatives, then why add an additional one? So,
22 those were the reasons that I voted against it.

23 CHAIRMAN CARTER: Okay. Other discussion?

24 (No response)

1 CHAIRMAN CARTER: Seeing no hands up, are
2 you prepared to vote? We'll proceed to vote. Okay.
3 The motion then is a synthetic, to add it as a
4 synthetic product to the national list only for the
5 purpose of cleaning irrigation lines, is that correct?

6 PARTICIPANT: Correct.

7 CHAIRMAN CARTER: Okay.

8 PARTICIPANT: Do you want a separate vote on
9 synthetic?

10 CHAIRMAN CARTER: No. Our manual says that
11 we all take care of it in one motion.

12 Bandelet?

13 MR. BANDELET: No.

14 CHAIRMAN CARTER: Burton?

15 MS. BURTON: Yes.

16 CHAIRMAN CARTER: Caughlan?

17 MS. CAUGHLAN: Yes.

18 CHAIRMAN CARTER: Cooper?

19 MS. COOPER: Yes.

20 CHAIRMAN CARTER: Goldberg, absent.

21 Holbrook?

22 MR. HOLBROOK: Yes.

23 CHAIRMAN CARTER: King?

24 MR. KING: No.

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1 CHAIRMAN CARTER: Koenig?
2 MS. KOENIG: Yes.
3 CHAIRMAN CARTER: Lacy?
4 MR. LACY: No.
5 CHAIRMAN CARTER: O'Rell?
6 MR. O'RELL: Yes.
7 CHAIRMAN CARTER: Ostiguy?
8 MS. OSTIGUY: No.
9 CHAIRMAN CARTER: Riddle?
10 MR. RIDDLE: Yes.
11 CHAIRMAN CARTER: Siemon?
12 MR. SIEMON: Yes.
13 CHAIRMAN CARTER: Chair votes yes. Passes
14 with 9 ayes, 4 nays, 1 person absent. Remember 9 is
15 the magic number at this meeting for a two-thirds vote.
16 Okay. We're now ahead of schedule. We'll
17 work on that.
18 PARTICIPANT: Is that the last of the
19 crops?
20 CHAIRMAN CARTER: That's the last of the
21 crops.
22 So, is this a good break for lunch, and we'll
23 come back and dive into livestock. Okay. That's
24 right. So, okay, we will break for lunch.

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1 We do have the folks here from Center for
2 Food and Nutrition, and yes, in fact, that would be a
3 great idea, if --

4 PARTICIPANT: Why don't we do that now?

5 CHAIRMAN CARTER: Yeah. That's what we'll
6 do. We're going to have lunch with -- so, if we'll
7 have the folks for the Center for Food and Nutrition
8 just come up and introduce yourselves for the record?

9 MS. SMITH: Hello. My name is Patricia
10 Smith, and I work for the Virginia Tech Center for Food
11 and Nutrition Policy. Is there anything else you need?

12 I have a co-worker with me who is responsible
13 for actually writing some of the reports that you'll
14 review this afternoon. Her name is Regina Jacobs, but
15 unfortunately she's in the bathroom right now.

16 CHAIRMAN CARTER: Okay. That doesn't need to
17 be on the record. She's out of the room.

18 Okay. We will recess then until 1:00.

19 (Whereupon, at 11:30 a.m., the meeting was
20 recessed for lunch, to reconvene this same day,
21 Wednesday, September 18th, 2002, at 1:00 p.m.)

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A F T E R N O O N S E S S I O N

1:00 p.m.

CHAIRMAN CARTER: Let's see. Waiting for

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1 Mark. Waiting for Nancy. Waiting for Rick.

2 Okay. We will reconvene. Right now before
3 we get into the next batch of materials, just two quick
4 things. I've been introducing folks from NOP.
5 Yesterday, I introduced the crew that was here, but
6 today, Toni Strother is here, and so anyway just want
7 to recognize Toni and all the work that he does.

8 (Applause)

9 CHAIRMAN CARTER: Also, somebody asked a
10 question as we were breaking, that the first motion
11 that we had was a -- that we acted on was a 5 to 8
12 vote, and what did that mean in terms of, you know, the
13 requirement that we have 9. Since that vote failed,
14 there were 8 no votes and 5 yes votes, it failed
15 anyway. You have to have 9 votes to the affirmative to
16 change something, otherwise it doesn't. So, that's
17 where that comes in. So, everything is in accordance
18 here.

19 Now, I'm just kind of killing time while
20 George wraps up a phone call here.

21 MR. SIEMON: We're ready.

22 CHAIRMAN CARTER: Oh, there he is. Okay.
23 Okay. Let's move into Livestock Materials.

24 MR. SIEMON: Okay. We're going to go in the

1 order of what we gave out this morning, the packet, if
2 that's okay with everybody, and I'm going to put it on
3 the board there so the peanut gallery can actually see
4 what we're talking about, having been out there a whole
5 lot, and as I've already confessed my inadequacy on
6 scientific materials.

7 CHAIRMAN CARTER: Okay. Point of order.
8 There's a hum.

9 MR. SIEMON: It's not the PowerPoint, is it?
10 No, it can't be that.

11 CHAIRMAN CARTER: The microphone's off.

12 MR. SIEMON: I don't think you can, can you?

13 CHAIRMAN CARTER: Right here.

14 MR. SIEMON: It's not working now, Jim.

15 (Pause)

16 CHAIRMAN CARTER: Proceed, George.

17 MR. SIEMON: The first one.

18 CHAIRMAN CARTER: Yes, you need to go down.
19 Instead of going through the order that they're on the
20 sheet, go through the order of the agenda, as they are
21 in the agenda, because we need to handle the materials
22 that are on the Wednesday agenda on Wednesday.

23 MR. SIEMON: Okay. Then I'm going to --

24 CHAIRMAN CARTER: Sorry. Didn't mean to

1 throw you a curve ball.

2 MR. SIEMON: -- see what the right order is
3 then. I had them in order.

4 CHAIRMAN CARTER: Today's materials, but the
5 first one that was up is propylene glycol.

6 MR. SIEMON: Okay. Well, there was a little
7 rhyme and reason but that's fine. Let's go there.
8 Okay. I would rather -- let's do it --

9 CHAIRMAN CARTER: Propylene glycol.

10 MR. SIEMON: Okay. All right. Propylene
11 glycol. I had hoped that up here, we're going to have
12 -- we got to sort through what our concerns were here
13 with what we actually want for annotations here. For
14 example, in this case, up there on the annotation,
15 which is not in your papers, it says only -- it's the
16 same. The annotation here, synthetic, to be added to
17 the .603, and then to be only for treatment of acute
18 ketosis in ruminants, and now, as we did earlier, we
19 have to put an A or a B or a C on here, right? This is
20 A. So, this is clearly a .603(a), synthetic, to be
21 added with the annotation only for treatment of acute
22 ketosis in ruminants. We heard earlier what ketosis
23 was in part.

24 CHAIRMAN CARTER: Okay. And in all respect

1 to, you know, appreciate the effort to try and keep the
2 audience informed here, but it's interfering with our
3 transcript.

4 MR. SIEMON: Turn it off?

5 CHAIRMAN CARTER: I guess we need to turn off
6 the PowerPoint.

7 MR. SIEMON: No problem.

8 CHAIRMAN CARTER: Yeah. So we can get a
9 good, clean record.

10 PARTICIPANT: Unless they can give you one
11 that doesn't hum.

12 MR. SIEMON: No. Okay. Do I make the
13 motion?

14 CHAIRMAN CARTER: Yes, you do.

15 MR. SIEMON: I make the motion. It's a
16 synthetic. It would be added to .603(a) with the
17 annotation only for treatment of acute ketosis in
18 ruminants.

19 CHAIRMAN CARTER: Okay. You've heard the
20 motion. Is there a second?

21 PARTICIPANT: Second.

22 CHAIRMAN CARTER: Okay. It's been moved and
23 seconded that propylene glycol is added to 205.603(a),
24 synthetic substances, allowed for use in organic

1 livestock production, only for the treatment of acute
2 ketosis.

3 Okay. Discussion on the motion?

4 MR. SIEMON: And I do have Hugh's phone
5 number, you all, so you'll know what he said. He said
6 he'd be available this afternoon, if anybody wants to
7 request any information from Hugh.

8 CHAIRMAN CARTER: Okay. Discussion? Rose?

9 MS. KOENIG: I guess it was just the same
10 question I had posed earlier. We had TAP that said
11 that, you know, dextrose and insulin would be natural
12 alternatives, and I didn't really, I guess, get a good
13 enough answer as to why. It seemed like they're not
14 used because veterinarians have to administer those
15 perhaps and that propylene glycol is -- you know, might
16 be something that's on the farm that a farmer would
17 administer. That's the only thing I could glean from
18 assumptions, but, so, I'd like maybe the Livestock
19 Committee person might be able to explain that a little
20 bit better, and why are we going to add it if there
21 appears to be some natural alternatives?

22 MR. SIEMON: What was the natural
23 alternative?

24 MS. KOENIG: Again, the TAP had indicated the

1 sugar dextrose, insulin, because the glycol's actually
2 a precursor that elicits an insulin response, that
3 perhaps insulin or other forms that would provide the
4 precursors for glucose, that, you know, dextrose or
5 other precursors of glucose could fix the problem,
6 perhaps not at the same, you know, rate, but it was
7 pretty much acting in a similar fashion in terms of the
8 biological process within the animal.

9 CHAIRMAN CARTER: Okay.

10 MR. SIEMON: Maybe one thing I might ask is,
11 if you all are reading a TAP concern, it might be
12 helpful if everybody says on Page 23. --

13 MS. KOENIG: Okay. So, I'm looking at Page
14 5.

15 MR. SIEMON: -- it just might help.

16 MS. KOENIG: Sorry. Specific -- under
17 Specific Use, it talks a little bit about, you know,
18 what it does, and the role of insulin in that process,
19 and then under Action, it talks about how you can --
20 and I think it was a veterinarian that talked about how
21 you can intravenously administer dextrose or glucose,
22 which is allowed already, every 8 to 12 hours.

23 MR. SIEMON: And so --

24 MS. KOENIG: To basically address the ketosis

1 problem.

2 CHAIRMAN CARTER: Okay. Mike?

3 MR. LACY: I think that Dr. Leiterman
4 answered that pretty well this morning. We might get
5 him to come once again and explain that this is an
6 emergency situation where the liver shuts down and
7 there is little, if any, absorption of those simple
8 sugars, and then the dextrose, it says, must be
9 administered IV every 8 to 12 hours.

10 MR. SIEMON: Which is a very intensive --

11 DR. LEITERMAN: I appreciate the kind
12 thought. I do not have a doctorate. Thank you.

13 The point of the propylene glycol, it is a
14 precursor to sugar, and because of the nature of
15 ketosis, the liver does not function, and when the
16 liver does not function, it cannot take glucose and
17 convert it into glycogen, store it in the muscle where
18 it has to then be retrieved back by the liver and put
19 back into the system.

20 So, because of that dysfunction of the liver,
21 we have to give them some kind of an energy source that
22 does not require liver function and that's why
23 propylene glycol has such an attraction.

24 CHAIRMAN CARTER: Kevin?

1 MR. O'RELL: Also in the TAP, Rosie, where
2 you were referencing that, it says that the dextrose or
3 glucose alternative is a temporary fix.

4 DR. LEITERMAN: The situation with ketotic
5 animals is that if it's not addressed properly quickly,
6 they can die quickly. So, sometimes getting a vet
7 there to do an IV is a good thing to do, and other
8 times, if they can catch the situation early with an
9 oral drench, they can stave off both the situation of
10 having to call the veterinarian and it's also used
11 after a post-vet treatment, so that the animal doesn't
12 relapse. So, that's the function of it.

13 CHAIRMAN CARTER: Further discussion? Owusu,
14 then Kim.

15 MR. BANDELE: I have a question. As far as
16 the liver not functioning, is that in the most extreme
17 cases or is that in all cases with the ketosis?

18 DR. LEITERMAN: That's an issue with all
19 cases of ketosis at varying levels.

20 CHAIRMAN CARTER: Kim?

21 MS. BURTON: Just a comment. This material
22 has always been rejected in the processing industry.
23 In fact, we have a number of annotations where you
24 specifically can't have propylene glycol, particularly

1 with flavors or something like that. So, it is
2 something that's, you know, on the radar screen, and it
3 has been disallowed in the past.

4 CHAIRMAN CARTER: Jim?

5 MR. RIDDLE: And this is a pretty tight
6 annotation that's being proposed here, and one thing
7 that's not pointed out that did concern me, it is
8 highly toxic to felines, but that seems to be the only
9 species. So, we certainly don't want to be giving it
10 to organic calfs.

11 CHAIRMAN CARTER: For some of us that aren't
12 cat lovers, no.

13 Mark?

14 MR. KING: Two things, and I'm sorry to keep
15 bringing you back and forth, you know. Aerobics here.
16 When we say acute ketosis, are we talking specifically
17 where the animal could be potentially -- you know,
18 death is threatening, and then secondly, if you could
19 address one of the reviewers, which is on Page 23, and
20 I quote, "Ketosis may be prevented by avoiding
21 overfeeding and overconditioning of cows, avoiding
22 abrupt ration changes, and feeding good quality
23 forages. Incidence of ketosis averages 12 to 14
24 percent. Even with these practices, however, incidence

1 of ketosis averages 12 to 14 percent."

2 CHAIRMAN CARTER: Okay.

3 MR. SIEMON: I can't quite recall. How
4 related is ketosis during calving?

5 DR. LEITERMAN: Ketosis, much like milk
6 fever, tends to occur as a problem right after
7 freshening and, unfortunately, in the past, it's been
8 associated with high grain feeding rates, where the
9 liver becomes impacted with fat and doesn't function
10 because of that, but we're finding also with grazing
11 herds, that we can have the same type of situation
12 happen with low grain rations, with grass-based
13 animals. So, the grazers are finding it very helpful
14 to have that available, also.

15 CHAIRMAN CARTER: Mark?

16 MR. KING: Just the first part, if we could
17 clarify that. When we say acute, --

18 DR. LEITERMAN: That means that's serious and
19 death is potential.

20 CHAIRMAN CARTER: Okay. Owusu?

21 MR. BANDELE: Yeah. Can -- what was the
22 reason why it's not allowed in -- prohibited in
23 processing? Do you recall?

24 PARTICIPANT: It's a volatile synthetic

1 solvent, and there were alternatives. We basically
2 eliminated it out of any processing materials.

3 MR. SIEMON: Just going into all these
4 materials, I think we have to remember that some of
5 these are approved for humans, you know. Now we're
6 talking about approving it for a rare use in animals.
7 That's a whole other filter.

8 MS. BURTON: I'm not saying I disagree.

9 MR. SIEMON: I know.

10 MS. BURTON: I would just make that note,
11 that it is -- it has been a contentious material.

12 MR. SIEMON: But my point is, to me, if it's
13 approved for humans, that's an extra -- that's a real
14 light that this is a subject that's gone through a lot
15 of scrutiny.

16 Eric, do you have something that's not been
17 covered?

18 MR. KINDBERG: To my understanding, after 25
19 years of dealing with cattle, one way or another, dairy
20 and non-dairy, when you say acute, that means it's
21 going to die. Okay. It's as simple as that. I mean,
22 if you have an acute analysis, you're in the hospital,
23 you're on your deathbed. So, that's where you have to
24 recognize that's different from therapeutic and all

1 these other things. Acute means it's a life or death
2 thing.

3 The propylene glycol is a carrier in the
4 thing. It's a preservative, you know. I understand
5 the problem with that, but the truth of the matter is
6 ketosis is conglomerated into this thing of milk fever,
7 ketosis, and for somebody to make an analysis when the
8 cow has just gone down, in many cases, I don't know
9 about these beef herd you talk about, I never had much
10 trouble in beef herd, but you talk about dairy herds,
11 is what you're talking about, and when they've gone
12 down, they're usually about to give birth, just gave
13 birth, gave birth two hours ago or 24 hours ago, and
14 it's a life and death situation. I mean, you either
15 have to do something and there's no breeding, it's too
16 late to worry about breeding, it's all over. So,
17 you're dealing with an instantaneous thing, and what
18 I'm saying is that certainly the Board could consider
19 that that cow, you know, withdrawal or total rejection
20 for the future and in a way, it might not be bad to do
21 that because the truth is, there's some inherent
22 genetic system usually wrong. It's not just high
23 feeding, it's because the animal was bred for very,
24 very high production, perhaps then demanding high

1 feeding.

2 MR. SIEMON: Okay. Any other discussion?

3 (No response)

4 CHAIRMAN CARTER: Okay. If there's none,
5 we'll proceed to vote.

6 MR. SIEMON: Okay.

7 CHAIRMAN CARTER: The motion being propylene
8 glycol should be added to the 205.603(a), list of
9 synthetic substances, allowed for use in organic
10 livestock production with the following restriction,
11 only for treatment of acute ketosis in ruminants.

12 Okay. Okay. Are there any conflicts?
13 Anybody declare a conflict on this one?

14 (No response)

15 CHAIRMAN CARTER: Okay. Then we're going to
16 start moving down the list, so we don't always put
17 Owusu on the hot seat every time.

18 So, we'll call -- start with Burton.

19 MS. BURTON: Yes.

20 CHAIRMAN CARTER: Caughlan?

21 MS. CAUGHLAN: Yes.

22 CHAIRMAN CARTER: Cooper?

23 MS. COOPER: Yes.

24 CHAIRMAN CARTER: Goldberg, absent.

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1 Holbrook?

2 MR. HOLBROOK: Yes.

3 CHAIRMAN CARTER: King?

4 MR. KING: Yes.

5 CHAIRMAN CARTER: Koenig?

6 MS. KOENIG: Yes.

7 CHAIRMAN CARTER: Lacy?

8 MR. LACY: Yes.

9 CHAIRMAN CARTER: O'Rell?

10 MR. O'RELL: Yes.

11 CHAIRMAN CARTER: Ostiguy?

12 MS. OSTIGUY: Yes.

13 CHAIRMAN CARTER: Riddle?

14 MR. RIDDLE: Yes.

15 CHAIRMAN CARTER: Siemon?

16 MR. SIEMON: Yes.

17 CHAIRMAN CARTER: Bandele?

18 MR. BANDELE: A cool yes.

19 CHAIRMAN CARTER: A cool yes. Okay. Yes,
20 nonetheless, and the Chair votes yes. Okay. That
21 passes 13 to 0 with 1 absent.

22 MR. SIEMON: All right. We'll go to
23 magnesium hydroxide, and Jim Pierce, you're going to
24 have to help me if there's been any change in these

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1 annotations since we don't have our screen now.

2 Okay. This again is a synthetic that we're
3 recommending to be added to .603(a), and I don't think
4 we need any annotations on this, and this is an
5 antacid, Roluids antacid laxative, as your sheet shows,
6 and any other members, any other input on this?

7 CHAIRMAN CARTER: Okay. Go ahead and make a
8 motion.

9 MR. SIEMON: I make the motion.

10 CHAIRMAN CARTER: That?

11 MR. SIEMON: That -- oh, I make the motion
12 that this be added to .603(a) as a synthetic.

13 PARTICIPANT: Second.

14 CHAIRMAN CARTER: It's been moved and
15 seconded. Magnesium hydroxide should be added to
16 5.603(a) as an allowable synthetic.

17 MR. SIEMON: 603.

18 CHAIRMAN CARTER: 205.603(a). Okay.

19 Discussion on the motion?

20 MS. BURTON: Clarification?

21 CHAIRMAN CARTER: Okay. Kim?

22 MS. BURTON: Can you explain to me -- all the
23 reviewers deemed it non-synthetic. Can you explain why
24 your committee thought it was a synthetic?

1 MR. SIEMON: I'm going to have to call on my
2 committee here because this is one I wasn't in on, and
3 it could be natural or synthetic. So, help me out.
4 Anybody help me out?

5 CHAIRMAN CARTER: I have to find my notes.

6 MR. SIEMON: I've got -- I wasn't -- I've got
7 my underline, but I wasn't on the call.

8 CHAIRMAN CARTER: Nancy, go ahead.

9 MS. OSTIGUY: It's a chemical reaction was
10 the committee's reasoning on that. What you're doing
11 is you're mixing sodium hydroxide with magnesium salt
12 or hydration of reactive magnesium oxide. In either
13 case, you get the precipitate. We could have gone
14 either way, and we went ahead and said it was synthetic
15 and put it on the list.

16 MR. SIEMON: And if you look at the last
17 statement, Summary of Opinion, we were trying to deal
18 with the difficulty in knowing which it is, and we
19 think it should be approved even if it was a synthetic.

20 MS. KOENIG: If it's a natural, you wouldn't
21 need to approve it.

22 MS. OSTIGUY: Correct.

23 CHAIRMAN CARTER: Further discussion? Okay.
24 Zea's been called to the mike, again identifying

1 herself for the record.

2 MS. SONNABEND: Zea Sonnabend with Armery and
3 CCOF. In general, the carbonate and the sulfate forms
4 of minerals are considered the natural forms that come
5 from the ground. The hydroxide and oxide are almost
6 always chemically reactive and have always been
7 considered synthetic historically.

8 CHAIRMAN CARTER: Okay. Thank you.

9 Further discussion?

10 (No response)

11 CHAIRMAN CARTER: Okay. We will proceed to
12 vote then.

13 Caughlan?

14 MS. CAUGHLAN: Yes.

15 CHAIRMAN CARTER: Cooper?

16 MS. COOPER: Yes.

17 CHAIRMAN CARTER: Goldberg, absent.

18 Holbrook?

19 MR. HOLBROOK: Yes.

20 CHAIRMAN CARTER: King?

21 MR. KING: Yes.

22 CHAIRMAN CARTER: Koenig?

23 MS. KOENIG: Yes.

24 CHAIRMAN CARTER: Lacy?

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1 MR. LACY: Yes.

2 CHAIRMAN CARTER: O'Rell?

3 MR. O'RELL: Yes.

4 CHAIRMAN CARTER: Ostiguy?

5 MS. OSTIGUY: Yes.

6 CHAIRMAN CARTER: Riddle?

7 MR. RIDDLE: Yes.

8 CHAIRMAN CARTER: Siemon?

9 MR. SIEMON: Yes.

10 CHAIRMAN CARTER: Bandele?

11 MR. BANDELE: Yes.

12 CHAIRMAN CARTER: Burton?

13 MS. BURTON: Yes.

14 CHAIRMAN CARTER: The Chair votes yes. 13
15 passes, 13 to 0, 1 absent.

16 MR. SIEMON: Okay. Heparin. Epinephrin.
17 Excuse me. Okay. This one, we've declared it a
18 natural, but we've put it on the prohibited list,
19 except for, and whether that's the right way to
20 approach this or not, that's -- Jim, is that not right?

21 MR. RIDDLE: I was going to ask you to slow
22 down.

23 MR. SIEMON: Okay. Sorry.

24 MS. BURTON: When you give us the material,

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1 can you give us what page it's on in your handout?

2 MR. SIEMON: I, unfortunately, don't have it
3 in the same handout. So, if somebody else could help
4 me with that. Page 4? Mine are all loose. Well, I
5 guess I can tell right here. I can do that, yeah. I
6 can do that.

7 CHAIRMAN CARTER: Well, if we need to slow it
8 down, we can.

9 MR. SIEMON: You betcha. I was just trying
10 to show the rest --

11 PARTICIPANT: Give us a chance to get all our
12 paperwork together.

13 MR. SIEMON: No problem. Okay. Epinephrine.
14 This is what we talked about earlier, made from the
15 adrenal gland of hogs. We declared it a natural, but
16 the way we went at it was to put it as a prohibited
17 natural, except for, and whether that's the right way
18 to go at it or not, that's the way we did it.

19 Were there any other uses, committee, that we
20 were concerned about why we went that way or were there
21 any other uses? Of course, being a hormone, we were
22 quite concerned about allowing this. So, we were
23 trying to make it very narrow, but are there other uses
24 to be concerned about? Let me look on my -- just

1 understand why we have that -- it says it can be used
2 to stimulate heartbeat, to treat bronchitis, other
3 allergic reactions, emphysema, as well as the treatment
4 of eye disease, glaucoma, hair transplants, interoptic
5 bleeding. So, I guess there is reason to have a narrow
6 field.

7 Okay. So, I guess the motion is to put
8 epinephrine on the prohibited list with an exception to
9 be used for this anaphylactic shock, to be used only
10 once in an animal's lifetime.

11 CHAIRMAN CARTER: Okay. Is there a second?

12 PARTICIPANT: Second.

13 CHAIRMAN CARTER: It's been moved and
14 seconded that epinephrine should be added to 205.604,
15 non-synthetic substances, prohibited for use in organic
16 livestock production, except for emergency treatment of
17 anaphylactic shock, to be used only once in an animal's
18 lifetime.

19 Discussion on the motion? Goldie?

20 MS. CAUGHLAN: What is the rationale for the
21 once in an animal's lifetime tag? I don't --

22 MR. SIEMON: Well, I'll let -- Jim Riddle,
23 that has been one of your concerns. Did you put that
24 one in there on this one?

1 MR. RIDDLE: No. I missed this call.

2 MR. SIEMON: Okay.

3 MR. RIDDLE: I was absent there. So, I don't
4 have the background. Dave?

5 CHAIRMAN CARTER: Well, some of the rationale
6 that was used on these ones for once in a lifetime was
7 to have some tools available for emergency treatment
8 with the thought, though, that if you were getting into
9 cases of repeated treatment, then, you know, there's a
10 certain threshold that you just need to take that
11 animal out of an organic system and put it into a
12 conventional. You've got other problems, you know,
13 with that, and so that was sort of the rationale that
14 flowed through on a number of these.

15 MS. CAUGHLAN: I should think that -- well, I
16 should think that it might better be dealt with in the
17 sense of it's documented. It's made a part of the
18 record, and that if there is an abuse as in any other
19 situation, if there's an abuse, that that's going to
20 come out in terms of the inspection of the --

21 MR. SIEMON: I agree with you, honestly. I
22 think it's an extra annotation. So, I --

23 CHAIRMAN CARTER: Okay.

24 MS. BURTON: I, too, have a problem with it.

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1 I think from a logistics standpoint, and I'm certainly
2 not a livestock person, to document and to try to track
3 that this only will be used once in a cow's lifetime, I
4 think, is kind of -- it's a very strict and crazy
5 annotation in my mind. I don't agree with it.

6 MR. SIEMON: Okay. I'd be glad to remove
7 that part.

8 CHAIRMAN CARTER: Oh, no. We need to have an
9 amendment. The motion is on the table. If someone
10 wants to --

11 MS. BURTON: I would so move that we remove
12 the once in a lifetime prohibition.

13 CHAIRMAN CARTER: Okay. It's been moved.
14 Second?

15 MS. CAUGHLAN: I'll second it.

16 MR. SIEMON: I accept that.

17 CHAIRMAN CARTER: Okay. It's been moved and
18 seconded. Goldie seconded it.

19 MR. SIEMON: Accepted.

20 CHAIRMAN CARTER: Okay.

21 MS. CAUGHLAN: It's a friendly amendment, I
22 would assume, is that correct?

23 CHAIRMAN CARTER: I think this is something
24 that's substantive that we need to vote on.

1 MS. CAUGHLAN: No, I understand.

2 MR. SIEMON: I accept it, whatever that's
3 worth it.

4 CHAIRMAN CARTER: Okay. So, discussion on
5 the motion. The motion is the once in a lifetime
6 issue. Sounds like the basis for a song. Okay. We
7 will proceed to vote on the amendment, which is to
8 strike the words "to be used only once in an animal's
9 lifetime." Okay.

10 Cooper?

11 MS. COOPER: Yes.

12 CHAIRMAN CARTER: Goldberg, absent.

13 Holbrook?

14 MR. HOLBROOK: Yes.

15 CHAIRMAN CARTER: King?

16 MR. KING: Yes.

17 CHAIRMAN CARTER: Koenig?

18 MS. KOENIG: Yes.

19 CHAIRMAN CARTER: Lacy?

20 MR. LACY: Yes.

21 CHAIRMAN CARTER: O'Rell?

22 MR. O'RELL: Yes.

23 CHAIRMAN CARTER: Ostiguy?

24 MS. OSTIGUY: Yes.

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1 CHAIRMAN CARTER: Riddle?

2 MR. RIDDLE: Yeah.

3 CHAIRMAN CARTER: Siemon?

4 MR. SIEMON: Yes.

5 CHAIRMAN CARTER: Bandele?

6 MR. BANDELE: Abstain.

7 CHAIRMAN CARTER: Burton?

8 MS. BURTON: Yes.

9 CHAIRMAN CARTER: Caughlan?

10 MS. CAUGHLAN: Yes.

11 CHAIRMAN CARTER: The Chair will vote no.

12 So, it passes 11 to 1, 1 abstention, one absent.

13 Okay. So, now the motion is on the table
14 simply to add it to the list of substances prohibited
15 for use in livestock production.

16 MR. SIEMON: Except for --

17 CHAIRMAN CARTER: Except for emergency
18 treatment of anaphylactic shock. Excuse me.

19 MR. SIEMON: That's right.

20 CHAIRMAN CARTER: Yes, okay. Nancy first,
21 then -- actually, I'm going to call on Ann. Ann has
22 not weighed in on too many of these. So, she gets
23 first crack at this one.

24 MS. COOPER: Well, one of the things that a

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1 couple of them said is withholding production after
2 administration of this drug, and yesterday, we talked a
3 couple of times about even double withhold, but there
4 -- some of them are talking about five-day withdrawal.

5 CHAIRMAN CARTER: Okay. So, is there an
6 amendment?

7 MR. SIEMON: Can we ask for -- there is no
8 withholding now required. There is none. So, we are
9 time doubling zero. So, coming up with another number
10 would be an option.

11 MS. COOPER: In the TAPs, it recommended it.

12 CHAIRMAN CARTER: What page?

13 MS. CAUGHLAN: I'm on the computer, but it
14 would be Page 23, Reviewer 1, "I would include that a
15 five-day withholding period be imposed", and it was
16 actually in two places I just saw. It was just a TAP
17 reviewer recommendation.

18 MS. COOPER: Also, on Page 23 in two places.

19 CHAIRMAN CARTER: Okay. Is there a motion or
20 is that just -- you're just bringing that to our
21 attention?

22 MS. COOPER: I guess just discussion.

23 CHAIRMAN CARTER: Okay. Nancy?

24 MS. OSTIGUY: This is something that the

1 reviewer came up with. The material is rapidly
2 metabolized, and the justification was to avert some
3 fears, "to avert fears some people might have
4 concerning any hormone use."

5 The material disappears very rapidly. If you
6 are going to be using this in the milking cow, you are
7 going to watch the animal after having administered
8 this anyway because there's a chance of triggering a
9 heart attack. So, the animal is not going to be milked
10 until that material is out of the system, you know.
11 They're not going to be put back on line until
12 afterwards.

13 CHAIRMAN CARTER: Okay. There is no
14 amendment on here. So, you're free to discuss any part
15 of the original motion.

16 Owusu?

17 MR. BANDELE: I was concerned about the --
18 well, two TAP reviewers, I think, voted not to allow it
19 and they cited that there needed to be some
20 clarification on the hormone issue. So, I would like
21 for someone on the committee to address that.

22 CHAIRMAN CARTER: George?

23 MR. SIEMON: Well, technically, hormones are
24 just not allowed for growth promoters but not

1 specifically is there any prohibition against hormones
2 in general, and in fact, the national list has
3 oxytocin, which is a hormone allowed. So, there's just
4 constantly a concern for it and that's why we made such
5 a narrow little field for it, but to my knowledge,
6 there's nothing that we're going against the rule about
7 here.

8 CHAIRMAN CARTER: Nancy?

9 MS. OSTIGUY: This is a general point about
10 the TAP and, I think, apropos to the general vote.
11 When George was introducing this, he read off a list of
12 when epinephrine is used. Both citations on Page 2
13 have the specific uses. That list is human uses. The
14 list is not in livestock as we are asking.

15 We don't use this for hair transplant
16 surgeries. So, it's used in emergency conditions when
17 you're looking at livestock. It's not used for
18 glaucoma. It's not used for eye diseases, you know.
19 We need to have the uses under which we are going to
20 use it more clearly defined in the TAP.

21 CHAIRMAN CARTER: Although some of us did
22 enjoy the discussion about hair transplants a little
23 too much.

24 Okay. Other discussion?

1 (No response)

2 CHAIRMAN CARTER: Okay. Are you ready to
3 vote on the motion? The motion as it now stands is
4 epinephrine should be added to 205.604, non-synthetic
5 substances, prohibited for use in organic livestock
6 production with the following recommendation,
7 prohibited, except for emergency treatment of
8 anaphylactic shock.

9 Okay. We will start off with Holbrook.

10 MR. HOLBROOK: Yes.

11 CHAIRMAN CARTER: King?

12 MR. KING: Yes.

13 CHAIRMAN CARTER: Koenig?

14 MS. KOENIG: Yes.

15 CHAIRMAN CARTER: Lacy?

16 MR. LACY: Yes.

17 CHAIRMAN CARTER: O'Rell?

18 MR. O'RELL: Yes.

19 CHAIRMAN CARTER: Ostiguy?

20 MS. OSTIGUY: Yes.

21 CHAIRMAN CARTER: Riddle?

22 MR. RIDDLE: Yes.

23 CHAIRMAN CARTER: Siemon?

24 MR. SIEMON: Yes.

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1 CHAIRMAN CARTER: Bandele?
2 MR. BANDELE: Yes.
3 CHAIRMAN CARTER: Burton?
4 MS. BURTON: Yes.
5 CHAIRMAN CARTER: Caughlan?
6 MS. CAUGHLAN: Yes.
7 CHAIRMAN CARTER: Cooper?
8 MS. COOPER: Yes.
9 CHAIRMAN CARTER: Goldberg, absent.
10 The Chair votes aye. Passes 13 to 0 with 1
11 member absent.
12 MR. SIEMON: Okay. Let's go to the next page
13 in your packet. Kaolin pectin. As far as I know,
14 that's --
15 CHAIRMAN CARTER: Give us a moment.
16 MR. SIEMON: Okay. I'm sorry. I don't have
17 your packet. I thought it was next.
18 MS. CAUGHLAN: Page 13.
19 PARTICIPANT: 10
20 MS. CAUGHLAN: 10. Sorry.
21 MR. SIEMON: Okay.
22 CHAIRMAN CARTER: Okay. Proceed, George.
23 MR. SIEMON: Just trying to figure out one
24 part of it. Our recommendation is to add it to .603(a)

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1 as a synthetic, and this is kaolin pectin. We talked a
2 little bit about it earlier. Again, I was just trying
3 to get it clear what it is, why we wanted to call it a
4 synthetic natural. That's what we talked about
5 earlier.

6 So, that's the motion, is to add it. I don't
7 -- do we need this, allowed when formulated from
8 either?

9 PARTICIPANT: No.

10 MR. SIEMON: So, we just need to just add it,
11 is all we do. No restrictions.

12 CHAIRMAN CARTER: Right.

13 MR. SIEMON: So, the motion is to add kaolin
14 pectin to .603(a).

15 MS. OSTIGUY: Second.

16 CHAIRMAN CARTER: Okay. It's been moved by
17 George, seconded by Nancy. Kaolin pectin should be
18 added to 205.603(a), synthetic substances, allowed for
19 use in organic livestock production.

20 Okay. Discussion on the motion? Rose?

21 MS. KOENIG: I just -- I had -- I think in
22 processing, sorry, that the pectin that's allowed is a
23 certain form. Both forms. Okay. So, that would just
24 go out. Okay.

1 CHAIRMAN CARTER: Okay. Other discussion?

2 MS. BURTON: So, again, the reason this is --
3 even though the reviewer said it's a natural, the
4 reason would be because of the pectin in it that deems
5 it synthetic?

6 MR. SIEMON: We don't think we're conclusive.
7 So, we're being cautious, over-cautious here.

8 MS. BURTON: And for what reason? Do you not
9 know the manufacturing process of pectin?

10 MR. SIEMON: Jim and Mike, help me out here.

11 MR. RIDDLE: Well, there could be two
12 different manufacturing processes or sources of the
13 pectin, one being synthetic, one being natural, and to
14 be consistent with the Processing Committee list, which
15 has both listed, we're -- the natural form would be
16 allowed by definition. So, we're making sure that the
17 synthetic form would be allowed as well with this
18 recommendation.

19 MS. BURTON: Okay. So, if this material, if
20 they were using natural kaolin and natural pectin, then
21 it wouldn't even need to be reviewed, is that correct?

22 Is that commercially available to the livestock
23 industry?

24 MS. OSTIGUY: If I remember correctly, when

1 we asked, we were told no, that there is no a natural
2 form.

3 CHAIRMAN CARTER: George? Mike?

4 MS. BURTON: I just hate to put something on
5 the list if it's commercially available in a natural
6 form.

7 CHAIRMAN CARTER: Okay. Any other questions?

8 (No response)

9 CHAIRMAN CARTER: Prepared to vote? Okay.

10 We will proceed to vote.

11 King?

12 MR. KING: Yes.

13 CHAIRMAN CARTER: Koenig?

14 MS. KOENIG: Yes.

15 CHAIRMAN CARTER: Lacy?

16 MR. LACY: Yes.

17 CHAIRMAN CARTER: O'Rell?

18 MR. O'RELL: Yes.

19 CHAIRMAN CARTER: Ostiguy?

20 MS. OSTIGUY: Yes.

21 CHAIRMAN CARTER: Riddle?

22 MR. RIDDLE: Yes.

23 CHAIRMAN CARTER: Siemon?

24 MR. SIEMON: Yes.

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1 CHAIRMAN CARTER: Bandele?

2 MR. BANDELE: Yes.

3 CHAIRMAN CARTER: Burton?

4 MS. BURTON: Abstain.

5 CHAIRMAN CARTER: Caughlan?

6 MS. CAUGHLAN: Yes.

7 CHAIRMAN CARTER: Cooper?

8 MS. COOPER: Yes.

9 CHAIRMAN CARTER: Goldberg, absent.
10 Holbrook?

11 MR. HOLBROOK: Yes.

12 CHAIRMAN CARTER: Okay. Then it passes --
13 the Chair votes yes. Sorry. 12 to 0, 1 abstention,
14 one absent. Okay. And I'm sorry. I did not ask for
15 conflicts of interest on these. So, you need to prompt
16 me on that before the votes. So.

17 MR. SIEMON: Okay. I was going to move to
18 the bismuth.

19 PARTICIPANT: Page 11.

20 MR. SIEMON: Page 11. Okay. Okay. We've
21 declared this a synthetic and to recommend to add it to
22 .603(a). Read through it, see if there's any
23 questions. There's no annotations. So, the motion is
24 to add this to .603(a), this substance.

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1 CHAIRMAN CARTER: Okay. The motion is to add
2 bismuth subsilicates to be added to 205.603(a), allowed
3 for use in organic livestock production.

4 MS. OSTIGUY: Second.

5 CHAIRMAN CARTER: Okay. It's been seconded.

6 Discussion on the motion?

7 MR. SIEMON: Pepto-Bismol.

8 (No response)

9 CHAIRMAN CARTER: Okay. Ready to vote?

10 Gosh. Anybody got a conflict on this one?

11 (No response)

12 CHAIRMAN CARTER: Okay. Proceed to vote.

13 Koenig?

14 MS. KOENIG: Yes.

15 CHAIRMAN CARTER: Lacy?

16 MR. LACY: Yes.

17 CHAIRMAN CARTER: O'Rell?

18 MR. O'RELL: Yes.

19 CHAIRMAN CARTER: Ostiguy?

20 MS. OSTIGUY: Yes.

21 CHAIRMAN CARTER: Riddle?

22 MR. RIDDLE: Yes.

23 CHAIRMAN CARTER: Siemon?

24 MR. SIEMON: Yes.

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1 CHAIRMAN CARTER: Bandele?
2 MR. BANDELE: Yes.
3 CHAIRMAN CARTER: Burton?
4 MS. BURTON: Yes.
5 CHAIRMAN CARTER: Caughlan?
6 MS. CAUGHLAN: Yes.
7 CHAIRMAN CARTER: Cooper?
8 MS. COOPER: Yes.
9 CHAIRMAN CARTER: Goldberg is absent.
10 Holbrook?
11 MR. HOLBROOK: Yes.
12 CHAIRMAN CARTER: King?
13 MR. KING: Yes.
14 CHAIRMAN CARTER: Chair votes yes. Passes,
15 13 to 0 with 1 member absent.
16 MR. SIEMON: While we're on a roll, I just
17 lost my papers.
18 CHAIRMAN CARTER: Don't lose the momentum.
19 MR. SIEMON: I was going to -- I know. I was
20 going to go to flunixin next.
21 PARTICIPANT: Page 2.
22 MR. SIEMON: Okay. I really did lose my
23 papers. So, here they are. Thank you.
24 Okay. This is a synthetic that we're wanting

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1 to recommend to be added to .603(a), and as far as I
2 know with no -- oh, yeah. With a double withholding
3 time. Was there a withholding time, Jim Pierce?

4 MR. PIERCE: Yes.

5 MR. SIEMON: Okay. Background. So, we're
6 saying to add it to the .603(a) with a double
7 withdrawal requirement.

8 CHAIRMAN CARTER: Okay.

9 MR. SIEMON: Okay. So, the motion is that.

10 CHAIRMAN CARTER: Okay. Is there a second to
11 the motion?

12 MS. OSTIGUY: Second.

13 CHAIRMAN CARTER: Okay. Thank you, Nancy.
14 It's been moved and seconded. It's on the table for
15 discussion.

16 MR. SIEMON: When we -- aspirin's a very
17 valuable thing, but this -- the problem is it's not
18 aspirin that's used. We use that -- I used -- we got
19 it passed in '95, aspirin, but it works out it's not
20 aspirin that's used a lot. It's this substance right
21 here. So, in part, I think the intent all along was to
22 -- that this is what we passed when we did aspirin,
23 but it's really used a lot to get animals over crisis,
24 and as we heard yesterday, get them back on their feet

1 and get them eating and get them going again. So, --

2 CHAIRMAN CARTER: Okay.

3 MR. SIEMON: -- that's its use.

4 CHAIRMAN CARTER: Okay. Rose, then Mark.

5 MS. KOENIG: I didn't feel like the TAP was
6 adequate in the case of this product in terms of how
7 it's made and some of the logical impacts of the
8 process. Additionally, this was the one that I
9 mentioned yesterday that we're actually -- it looks
10 like -- it appears that we're actually trying to
11 approve a brand name which is the active plus the
12 incipients, I guess, and so I just feel this is one I
13 would feel more comfortable sending the TAP back and
14 really relooking at the situation before we go ahead
15 and approve something that, Number 1, it may not even
16 be an available tool in October, if we haven't dealt
17 with the policy of all the other preservatives and such
18 that are within the formulation of this product.

19 CHAIRMAN CARTER: Okay.

20 MR. SIEMON: But we are dealing with flunixin
21 here, not --

22 MS. KOENIG: Well, then, first of all, then I
23 think we should strike the banimine trademark.

24 MR. SIEMON: I agree.

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1 CHAIRMAN CARTER: On the sheet, we have
2 stricken the banimine.

3 MR. SIEMON: This is flunixin, and as far as
4 the problem we have with incipients, I think that's a
5 problem we have with all these substances we're going
6 to face today. The TAP -- inadequacy of the TAP,
7 that's another question.

8 MS. KOENIG: Well, I don't know. The ones
9 that were prior to this that I voted on, I felt
10 relatively comfortable with, based on, you know, the
11 information was given and, you know, I just think now
12 we're entering in my mind the gray zone, and these are
13 things that are I just didn't feel with the TAP at hand
14 that they were of sufficient quality to start making, I
15 guess, recommendations on things that I felt were just
16 a different level of medications. You know, Pepto-
17 Bismol, I mean, maybe it's because I've used it, I feel
18 more comfortable with it, but, additionally, some of
19 the other ones are more -- you know, kaolin pectin, I
20 mean, to me, that was not that much of a controversy,
21 but, additionally, this says it was not labeled for
22 lactating cows.

23 I know I got a copy of that Internet, I
24 think, downloading of that law that we talked about

1 yesterday, but I still don't -- you know, I got that
2 information late. I would like to confirm the
3 information on it. I would like to, I guess, have seen
4 an analysis of those. There's some prohibited
5 substances on the back in terms of food-producing
6 animals that I kind of looked, based on what I could
7 see was listed, it didn't contain all those.

8 But just, you know, in terms of my own
9 analysis, I'm just not comfortable, and I feel like it
10 could be revisited. I think there could be questions
11 reasked in the TAP and we could revisit this one in
12 October, and I just caution, I guess caution the Board
13 to maybe be conservative on some of these
14 pharmaceuticals that are known to have waiting periods
15 because in my mind, if it has a waiting period, the
16 first thing that goes up to my head is that it's a
17 different class of compound.

18 CHAIRMAN CARTER: Okay. I appreciate the
19 sentiment and everything, but if you really want
20 something done, you need to make a motion to have it
21 done.

22 MS. KOENIG: Oh, okay. Sorry. You should
23 have told me that in the beginning. My motion -- well,
24 did you get a second to the motion?

1 CHAIRMAN CARTER: Yep. You can move to
2 defer.

3 MS. KOENIG: Doesn't he have to defer the
4 motion? No.

5 CHAIRMAN CARTER: No. You can make a motion.
6 It is entirely appropriate for any member of the Board
7 to make a motion to defer this petition until October.

8 MS. KOENIG: I would make a motion to defer
9 this petition till October, pending additional
10 information.

11 CHAIRMAN CARTER: Okay. Is there a second?

12 MR. BANDELE: Second.

13 CHAIRMAN CARTER: Seconded by Owusu.

14 Okay. Discussion on the motion to defer.
15 George?

16 MR. SIEMON: Okay. I just need to understand
17 what additional information you need. I know you just
18 said it, but I was trying to read through. We've
19 already -- it's already got to be under FDA guidelines.
20 So, that's the move -- whatever that word is, is not
21 relevant here because we're already saying whatever
22 their guidance. We're not dealing with the banimine.
23 I agree with you about withholding. We should -- our
24 alertness should go way up. But what is the -- what

1 information specifically would we request?

2 CHAIRMAN CARTER: Okay. I don't know if you
3 were directing that question toward any other member of
4 the Board.

5 MR. SIEMON: Well, I guess I'm asking Rose or
6 Jim, unless somebody else has some comments. I'd just
7 like to hear what is it we need to know.

8 CHAIRMAN CARTER: Kevin, go ahead.

9 MR. O'RELL: I just -- when you said George,
10 we're not considering banimine in the TAP, it says that
11 banimine is the only patented form of flunixin, and so
12 we are dealing with banimine.

13 MR. SIEMON: But every -- there's many
14 substances we pass, but there might be only one
15 patented brand name.

16 MR. O'RELL: I'm pointing out that, you know,
17 we dismissed the brand name, but it goes into the -- on
18 Page 3 in How Made of the Tap, it tells the other
19 ingredients that are accompanied with flunixin in
20 banimine. I don't know if you saw that, Rose.

21 MR. SIEMON: I still don't know how that
22 relates to all the other drugs we have that could be
23 the very same -- you know, these incipients and who
24 owns the license and all that.

1 CHAIRMAN CARTER: Jim, and then Kim.

2 MR. RIDDLE: Specifically, I voted for this
3 material on the Livestock Committee to move it forward,
4 but when I had read through it, I shared the same
5 concerns that Rose has brought up, that really the TAP
6 does not describe how the material is made. So, that's
7 one thing, if we are going to defer it, that we would
8 specifically request, is more information on that.

9 The historic use by organic farmers does not
10 address use by organic farmers at all. So, I'd like
11 that as well as the seven criteria. So, I think if the
12 contractor goes back through those criteria and re-
13 examines this material, does some further research, I
14 think that would give quite a bit of guidance right
15 there.

16 CHAIRMAN CARTER: Kim, then Owusu.

17 MS. BURTON: I agree. We discussed at length
18 yesterday about, you know, if we're not comfortable
19 with the TAP, and we do have a meeting in a month, that
20 we could defer this and come back, and this Board's
21 responsibility is to be prepared when we come to a
22 vote. So, I'd support Rosie in that.

23 CHAIRMAN CARTER: Okay. Owusu?

24 MR. BANDELE: In the review, it's stated that

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1 there were alternatives, Number 1, and secondly, all
2 three of the reviewers voted not to allow it. So, in
3 view of that, I think either a strong case should be
4 made for -- a stronger case should be made for its
5 inclusion.

6 CHAIRMAN CARTER: Okay. Further discussion
7 on the motion to defer? Mike?

8 MR. LACY: Just in George's and the Livestock
9 Committee's defense, we did have a long in-depth
10 discussion with a veterinarian that is very
11 knowledgeable in organic care of livestock, and I think
12 that his quote was that as far as relieving pain for
13 animals, if there was one thing in his bag, he needed
14 this.

15 MR. KING: I have a question which will help
16 me decide whether or not I could actually vote on this
17 or not today, and that is, this is considered an NSAID,
18 non-steroidal anti-inflammatory. So, I guess, other
19 than the delivery, because it's my understanding this
20 is an injectable, correct, how is this different than
21 like ibuprofen or Advil, scientifically speaking, in
22 how it works in the animal?

23 CHAIRMAN CARTER: Okay. Anybody care to
24 answer? Expertise?

1 MR. SIEMON: My understanding is as compared
2 to aspirin, it's more like the other forms, like
3 Tylenol-type. It's a different level than aspirin.
4 That's what you're asking? You're asking what's the
5 comparison to aspirin?

6 PARTICIPANT: Call the question.

7 CHAIRMAN CARTER: Okay. Question has been
8 called. Okay. So, if there are no other discussion,
9 we will proceed to vote. Okay. The motion is simply
10 to defer the petition for flunixin, I always have
11 trouble saying nixin, from any further review.

12 Okay. Lacy?

13 MR. LACY: No.

14 CHAIRMAN CARTER: O'Rell?

15 MR. O'RELL: Yes.

16 CHAIRMAN CARTER: Ostiguy?

17 MS. OSTIGUY: No.

18 CHAIRMAN CARTER: Riddle?

19 MR. RIDDLE: Abstain.

20 CHAIRMAN CARTER: Siemon?

21 MR. SIEMON: No.

22 CHAIRMAN CARTER: Bandele?

23 MR. BANDELE: Yes.

24 CHAIRMAN CARTER: Burton?

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1 MS. BURTON: Yes.

2 CHAIRMAN CARTER: Caughlan?

3 MS. CAUGHLAN: Yes.

4 CHAIRMAN CARTER: Cooper?

5 MS. COOPER: Yes.

6 CHAIRMAN CARTER: Goldberg, absent.

7 Holbrook?

8 MR. HOLBROOK: Yes.

9 CHAIRMAN CARTER: King?

10 MR. KING: Yes.

11 CHAIRMAN CARTER: Koenig?

12 MS. KOENIG: Yes.

13 CHAIRMAN CARTER: The Chair votes yes.

14 Passes on a vote of 9 yes, 3 nos, 1 abstention, 1
15 absent.

16 MR. SIEMON: Okay. Do we have clear what
17 we're asking for from the notes here? I,
18 unfortunately, still didn't get much about --

19 CHAIRMAN CARTER: Okay. Anybody else got a
20 comment? Kim?

21 MS. BURTON: How we've done this in the past
22 is that the Board will send to me comments on this TAP,
23 and then I will put them in a form that's communicative
24 to the contractor.

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1 MR. SIEMON: So, are the minutes going to be
2 the guide for --

3 MS. BURTON: No. You have a responsibility
4 after this meeting to send me your comments on this and
5 what direction --

6 MR. SIEMON: So, not the Board, the Livestock
7 Committee?

8 MS. BURTON: The Board.

9 MR. SIEMON: The Board.

10 MS. BURTON: The entire Board.

11 CHAIRMAN CARTER: The entire Board, but we've
12 got to do it -- don't wait for the minutes. We've got
13 to do it quickly because we've got to get them going.

14 Rose, and hen Nancy.

15 MS. KOENIG: Can I just suggest there may be
16 a number of these that -- can you e-mail those back to
17 us just so that we can kind of see the comments you're
18 going to send to them?

19 CHAIRMAN CARTER: Okay. Nancy?

20 MS. OSTIGUY: It's more of a logistics
21 question. Our next meeting is basically 30 days from
22 now.

23 CHAIRMAN CARTER: Yes.

24 MS. BURTON: Are we realistically going to

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1 get information back, such that we would be able to
2 review this or do this again in October? Are they
3 going to have time? Just a question.

4 CHAIRMAN CARTER: It's a legitimate question.

5 I would think we would need to consider that and be
6 very judicious in what we defer back. My opinion is if
7 we're asking them for some additional clarification
8 information, they have to be able to do that within 30
9 days, unless we send them 30 TAPs. So, but that's just
10 an opinion.

11 MS. OSTIGUY: The contractor's here. I
12 suppose we could ask them. If we send you back some
13 reviews, do you have the staff available to work on
14 those immediately and to get back to us at least --

15 CHAIRMAN CARTER: Could you come to the
16 microphone? We need that on the record. If you could
17 introduce yourself for the record and then the question
18 that Kim asked.

19 MS. SMITH: My name is Patricia Smith from
20 the Center for Food and Nutrition Policy, and yes, we
21 could get you back as many as possible, depending on
22 how many you send us, and if you prioritize them, that
23 would be very helpful.

24 CHAIRMAN CARTER: Okay. George, proceed.

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1 MR. SIEMON: What's the process for this?
2 What's the process? The Board has to write a letter.

3 MS. BURTON: The process is that after this
4 meeting, you all go back through this TAP review and
5 send your comments to me on all of the --

6 MR. SIEMON: The Livestock Committee?

7 MS. BURTON: The whole entire Board, all of
8 us.

9 MR. SIEMON: Oh.

10 MS. BURTON: If you have comments on some of
11 the --

12 MR. SIEMON: All right. I didn't understand.

13 MS. BURTON: I will put them together in a
14 form and send them to the contractor and copy the Board
15 on that.

16 MR. SIEMON: Okay. That's fine.

17 MS. BURTON: I would like them by next
18 Friday. I don't have a calendar in front of me.

19 CHAIRMAN CARTER: Okay. So, by the 27th.

20 MR. SIEMON: We'll move on to the X-Y-L-E --

21 CHAIRMAN CARTER: I would even encourage,
22 just as a point of -- if you could get them to Kim by
23 Wednesday. That's a week from today and that at least
24 gives them a couple of days of that work week to --

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1 okay.

2 MR. SIEMON: Xylazine. Did I do all right?
3 What page is that one? Anybody help me out? I'm
4 sorry.

5 PARTICIPANT: 3.

6 MR. SIEMON: 3? There's two substances here.
7 One's the antidote to the other. Our recommendation
8 is that it should be added to 205.603(a) with the
9 restriction of double the withhold, and we had also the
10 once in a lifetime. So, before I make the motion, this
11 is a sedative used for operation basis. I guess I have
12 to make the motion what the committee did, right?

13 CHAIRMAN CARTER: You need to bring forward
14 what the action was of the committee, and then if --

15 MR. SIEMON: Okay. The motion --

16 CHAIRMAN CARTER: -- they decide they want to
17 amend that, they can.

18 MR. SIEMON: The motion is to add these two
19 substances to .603(a) with the restriction of once in
20 an animal's lifetime and withhold time shall be double
21 the FDA requirement.

22 CHAIRMAN CARTER: Okay. Is there a second?

23 MR. KING: Second.

24 MS. RICHARDS: Okay. Mike seconded. The

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1 motion being, xylazine should be added to 205.603,
2 synthetic substances, allowed for use in organic
3 livestock production with the following restrictions,
4 for emergency medical use, to be administered by a
5 licensed practitioner, once in the animal's lifetime,
6 withhold time shall be double the FDA requirements, and
7 that tolazoline should be added to 205.603, synthetic
8 substances, allowed for use in organic livestock
9 production with the following restrictions, to
10 counteract the effects of xylazine, to be administered
11 by a licensed practitioner, once in an animal's
12 lifetime, withhold time shall be double the FDA
13 requirements.

14 So, I'm just trying to get the exact motions
15 on the record here. So, proceed with discussion.

16 Richard?

17 MR. MATHEWS: Yeah. That probably should
18 read 205.603(a), as George had indicated.

19 CHAIRMAN CARTER: Okay. Okay. Goldie, then
20 Kim.

21 MS. CAUGHLAN: Well, again, the same
22 objection that I had to the other one, once in an
23 animal's lifetime. I just -- I would move that that be
24 stricken.

1 CHAIRMAN CARTER: Okay.

2 MS. OSTIGUY: Second.

3 CHAIRMAN CARTER: Motion to strike the once
4 in a lifetime. Who seconded?

5 MS. OSTIGUY: I did.

6 CHAIRMAN CARTER: Okay. Nancy seconded.

7 Okay. Discussion on the amendment only.

8 This is to strike the once in a lifetime. Richard?

9 MR. MATHEWS: The question is, are you doing
10 this one material at a time or the striking of once in
11 a lifetime for both with the same vote?

12 CHAIRMAN CARTER: Okay.

13 MS. CAUGHLAN: Well, I think for protocol, it
14 appears to be.

15 CHAIRMAN CARTER: It was one motion. So, the
16 one motion covered both xylazine and --

17 MR. MATHEWS: Okay.

18 CHAIRMAN CARTER: -- tolazoline.

19 MR. MATHEWS: But you are removing it in both
20 places?

21 MS. CAUGHLAN: Correct.

22 MR. MATHEWS: Okay.

23 CHAIRMAN CARTER: With that clarification,
24 yes.

1 MS. CAUGHLAN: That was my intent.

2 CHAIRMAN CARTER: She nodded her head which
3 means yes. Okay. Nodding because heads get into
4 transcripts.

5 MS. CAUGHLAN: Yes, yes.

6 CHAIRMAN CARTER: Nancy?

7 MS. OSTIGUY: Yes, I agree.

8 CHAIRMAN CARTER: Okay. All right. Mark?

9 MR. KING: Question concerning the amendment
10 as well as the original motion, and that's, in the TAP,
11 it indicates, and it's on Page 1, both the xylazine and
12 the whatever are not approved by FDA for use in food-
13 producing animals. So, (a) what good does it do to
14 have withhold time shall be double FDA requirements;
15 (b) it's not approved for conventional, why are we
16 considering it for organic?

17 MR. SIEMON: It does have withhold by FDA,
18 though. So, this is where we get into this whole
19 confusing -- there is withholding required by FDA. So,
20 this is where we're in this --

21 MR. KING: And that is what?

22 MR. SIEMON: Well, it says here for 72 hours
23 for milk, 30 days for meat.

24 MR. KING: Got it. Sorry.

1 CHAIRMAN CARTER: Okay.

2 MR. SIEMON: So, it's a darn good question.

3 PARTICIPANT: Are we voting on the change?

4 CHAIRMAN CARTER: We're voting on the once in
5 a lifetime.

6 PARTICIPANT: Then we have more discussion?

7 CHAIRMAN CARTER: Just once in a lifetime.

8 MR. SIEMON: Just once in a lifetime only.

9 CHAIRMAN CARTER: Okay. Seeing nobody
10 leaning --

11 MR. SIEMON: Call the question.

12 CHAIRMAN CARTER: -- forward, we will proceed
13 to vote. On the amendment to strike once in a
14 lifetime. Well, first of all, on this, does anybody
15 have a conflict?

16 (No response)

17 CHAIRMAN CARTER: Hearing none. Okay.

18 O'Rell?

19 MR. O'RELL: Yes.

20 CHAIRMAN CARTER: Ostiguy?

21 MS. OSTIGUY: Yes.

22 CHAIRMAN CARTER: Riddle?

23 MR. RIDDLE: Yes.

24 CHAIRMAN CARTER: Siemon?

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1 MR. SIEMON: Yes.

2 CHAIRMAN CARTER: Bandele?

3 MR. BANDELE: No.

4 CHAIRMAN CARTER: Burton?

5 MS. BURTON: Yes.

6 CHAIRMAN CARTER: Caughlan?

7 MS. CAUGHLAN: Yes.

8 CHAIRMAN CARTER: Cooper?

9 MS. COOPER: Yes.

10 CHAIRMAN CARTER: Goldberg, absent.

11 Holbrook?

12 MR. HOLBROOK: Yes.

13 CHAIRMAN CARTER: King?

14 MR. KING: No.

15 CHAIRMAN CARTER: Koenig?

16 MS. KOENIG: Yes.

17 CHAIRMAN CARTER: Lacy?

18 MR. LACY: Yes.

19 CHAIRMAN CARTER: The Chair votes no, and the

20 motion carries 10 to 3, one person absent. Okay. So,

21 the language is stricken.

22 Now we're back to the motion as amended then.

23 MS. BURTON: I have a question. You have in

24 this annotation to be administered by a licensed

1 practitioner. Is that part of the requirements of this
2 drug, and is it required that we put it in the
3 annotation that it's only to be administered?

4 MR. SIEMON: I don't believe it's required.

5 MS. BURTON: It's not in the --

6 MR. SIEMON: To put in here because it's
7 covered somewhere else in the rule.

8 MS. BURTON: Is it covered under -- by the --

9 PARTICIPANT: It's a veterinarian-only drug.

10 MS. BURTON: Right. Is it? So, that's my
11 question. Is it? Yes. So, then I move to strike to
12 be administered by a licensed practitioner.

13 CHAIRMAN CARTER: Okay. Motion has been to
14 strike the words "to be a licensed practitioner" in
15 xylazine and tolazoline..

16 MR. SIEMON: Strike to be administered by a
17 licensed practitioner.

18 CHAIRMAN CARTER: Yeah. Okay. To strike
19 those words since it's already required. Okay. Is
20 there a second to the motion?

21 MR. SIEMON: Before we make a second,
22 shouldn't we also do this for emergency medical use,
23 also? That's also covered some place else. In the
24 absence of illness, you're not supposed to apply

1 synthetic.

2 MS. BURTON: My question was, is this
3 required to be administered only by a licensed
4 practitioner, a veterinarian, in other words.

5 CHAIRMAN CARTER: So, the motion is just to
6 strike the words "to be administered by a licensed
7 practitioner". Is there a second? Is there a second?

8 MS. CAUGHLAN: Sure. I'll second it.

9 CHAIRMAN CARTER: Okay. Been moved and
10 seconded.

11 Discussion on the motion to strike?

12 (No response)

13 CHAIRMAN CARTER: Okay. If you're ready to
14 vote?

15 Ostiguy?

16 MS. OSTIGUY: Yes.

17 CHAIRMAN CARTER: Riddle?

18 MR. RIDDLE: Yes.

19 CHAIRMAN CARTER: Siemon?

20 MR. SIEMON: Yes.

21 CHAIRMAN CARTER: Bandele?

22 MR. BANDELE: Yes.

23 CHAIRMAN CARTER: Burton?

24 MS. BURTON: Yes.

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1 CHAIRMAN CARTER: Caughlan?

2 MS. CAUGHLAN: Yes.

3 CHAIRMAN CARTER: Cooper?

4 MS. COOPER: Yes.

5 CHAIRMAN CARTER: Goldberg's absent.

6 Holbrook?

7 MR. HOLBROOK: Yes.

8 CHAIRMAN CARTER: King?

9 MR. KING: Yes.

10 CHAIRMAN CARTER: Koenig?

11 MS. KOENIG: Yes.

12 CHAIRMAN CARTER: Lacy?

13 MR. LACY: Yes.

14 CHAIRMAN CARTER: O'Rell?

15 MR. O'RELL: Yes.

16 CHAIRMAN CARTER: Chair votes yes. Passes,
17 13 to nothing, 1 person absent.

18 Okay. We're back now to the motion as doubly
19 amended. Any discussion on the motion?

20 MS. COOPER: Yes. I'm still confused, and it
21 does say this in a couple places, that the drug isn't
22 approved for use in food-producing animals in the
23 United States, but it's one of the most widely-used
24 sedatives in non-organic farming. So, I'm a little

1 confused if it's not even allowed, is that true? Is it
2 not allowed?

3 CHAIRMAN CARTER: Okay. Knowledgeable. The
4 question's asked. David, do you have the answer to
5 that?

6 MR. ENGEL: It keeps going back to this
7 MDUCA.

8 CHAIRMAN CARTER: That's okay. Just tell us
9 again. Identify yourself and tell us.

10 MR. ENGEL: My name is David Engel. I'm the
11 husband of a veterinarian. I just -- all I know is
12 that that phenomena, Ann, is very, very common,
13 extremely common. I mean, it's -- I was amazed in the
14 early '80s when I started learning about this stuff,
15 when she got out of vet school. It's really, really
16 common.

17 MS. OSTIGUY: It's not only common in
18 veterinary medicine, but we do the same thing with
19 humans. We approve something for a particular use. A
20 doctor is legally allowed to prescribe it for something
21 different. Even though it was not specifically
22 approved for high blood pressure, you can use it for
23 high blood pressure.

24 CHAIRMAN CARTER: Okay. Rose?

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1 MS. KOENIG: I have a question and then I may
2 make a change in the motion, but the lidocaine and the
3 procaine, I guess it is, that are both local
4 anesthetics that are currently on the list, there was
5 no discussion as to whether those are viable
6 alternatives. Was it not explored by the TAP? I mean,
7 if the TAP's person here, I mean, I don't -- again,
8 this area is way beyond my scope of knowledge. So, I
9 don't know if maybe they're not even local anesthetics
10 versus major operative stuff, but is that the --

11 PARTICIPANT: They're not the same.

12 MR. RIDDLE: This is a sedative to put the
13 animal down to operate and then the other is to
14 counteract that to bring them back up.

15 MS. KOENIG: So, currently, we basically have
16 nothing on the list, so that is accurate in terms of --
17 and there's no other chemical that can be used as -- it
18 says there's no alternative. Is there nothing else
19 that could put an animal down?

20 PARTICIPANT: The audience is shaking their
21 heads yes.

22 PARTICIPANT: That's a true statement. There
23 is no known alternatives.

24 CHAIRMAN CARTER: As far we were able to

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1 determine at the committee level, that's a true
2 statement, and George just said get a rope.

3 MR. SIEMON: Well, this is what they use for
4 castration in horses, right? This is a complete knock-
5 out. So, there is an alternative. They always did it
6 with ropes in the old days. Tie them up, throw them
7 down.

8 CHAIRMAN CARTER: Don't think we want to go
9 there.

10 Okay. Are you ready to vote on the motion as
11 doubly amended? I will just repeat the motion.

12 MR. RIDDLE: Just one more comment. This is
13 the first time that we're actually moving one forward,
14 it appears, with the double withhold requirement, and I
15 did some work for the committee last night, it's on the
16 bottom of the page there, to give some justification
17 that Rick had requested, if we're going to be
18 suggesting or recommending a double withhold. So,
19 there's five different items to help justify taking
20 this position. So, I just wanted to point that out to
21 the members of the Board, that that will carry forward
22 with this recommendation.

23 CHAIRMAN CARTER: Okay. Rose?

24 MS. KOENIG: I just have one question before

1 I vote. Can the committee convince me that you
2 thoroughly looked at those restricted chemicals on the
3 -- what do you call it -- MDUCA, whatever? Because I
4 just -- again, somebody had pulled it out of one of the
5 TAPs, it's now in the back of the total sheets that we
6 have gotten. That there were some -- the following
7 prohibitions currently applied to the use of drugs in
8 food-producing animals, and again it lists that list.

9 Have you thoroughly gone through that list in
10 committee and confirmed that that list has -- is --
11 none of those substances are a part of xylazine and
12 tolazoline?

13 CHAIRMAN CARTER: Discussion? I would call
14 on Jim, who is a resource person to the committee.
15 Identify yourself.

16 MR. PIERCE: I'm Jim Pierce. I pulled this
17 MDUCA piece off the magnesium hydroxide TAP. It's in
18 one of the other ones, too, but for the life of me, I
19 couldn't find it.

20 I talked about this with Dr. Karreman. He
21 spoonfed me this stuff. Almost all of these drugs
22 listed on the back side that are prohibited in food-
23 producing animals are prohibited in the U.S., period.

24 MS. KOENIG: What do you mean by prohibited?

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1 They're not drugs in the U.S.?

2 MR. PIERCE: They're not allowed at all for
3 livestock, veterinary use in the U.S. They're
4 prohibited substances.

5 PARTICIPANT: These are really the uglies.
6 These are the hormones.

7 MS. BURTON: The materials on that list,
8 you're saying, are prohibited in the U.S.?

9 MR. PIERCE: That's correct.

10 MS. BURTON: Okay.

11 CHAIRMAN CARTER: Okay. Further discussion?
12 Okay. Owusu?

13 MR. BANDELE: Point of clarification. The
14 note that assisted with requirements of EU and Codex.
15 I mean, that's with the double withhold. That's not
16 with the actual use.

17 PARTICIPANT: Correct.

18 MR. BANDELE: So, you could not use that.

19 MR. RIDDLE: Oh, no. You could. Do a double
20 withhold. Any veterinary medications are -- need to be
21 a double withhold.

22 CHAIRMAN CARTER: Mark?

23 MR. KING: Just a very quick comment in
24 support of the double withhold that Jim had brought up,

1 and I'm looking on Page 31 of the TAP for milk
2 production. It says, "Detectable radioactivity in milk
3 was found after 72 hours after administration of the
4 following", and it lists the products. So, just in
5 support of that as part of the motion.

6 CHAIRMAN CARTER: Okay. Are we ready to
7 proceed to vote? Okay.

8 PARTICIPANT: Motion?

9 MR. MATHEWS: Just a second.

10 CHAIRMAN CARTER: Richard. I'm sorry.

11 MR. MATHEWS: Mark, in my understanding then
12 that you're saying that your support of the double time
13 frame is because the material was actually showing up
14 in samples beyond the FDA time frame?

15 MR. KING: Well, it's not clear that it's
16 "beyond", but certainly it is saying was found up to 72
17 hours. So, that --

18 MR. MATHEWS: Which material?

19 MR. KING: Well, look at Page 31.

20 MR. MATHEWS: I don't have that.

21 MR. KING: Xylazine in this particular case.

22 MR. MATHEWS: Okay. But xylazine is a 120
23 hours anyway.

24 PARTICIPANT: 120 hours is your double, is it

1 not?

2 PARTICIPANT: No.

3 PARTICIPANT: That's existing FDA withhold
4 times.

5 MR. SIEMON: It says 72 hours. Where's --

6 PARTICIPANT: That's the other --

7 PARTICIPANT: If someone has a problem, they
8 should make a motion to take it off, but otherwise --

9 MR. MATHEWS: I'm just asking a question
10 because I was just trying to get clarification because
11 if -- what it's been pointed out is that that is in
12 xylazine, and xylazine already has a 120. So, if the
13 latest time frame was 72, that tells us one thing. If
14 it had been found in the tolazoline, that one has a 72.
15 So, if it's still found on the 72, that tells you
16 something even more significant than the other way.
17 So, that's all I was trying to get at because if it's
18 still being found beyond the time that the FDA was
19 using as a withdrawal, I was going to say that that is
20 the kind of thing that would go down into the Summary
21 of Opinion that talks about justification. That's why
22 -- all I was trying to do was clarify when.

23 MR. SIEMON: Okay. Do you want me to read
24 these motions then?

1 CHAIRMAN CARTER: Okay. Go ahead.

2 MR. SIEMON: Xylazine shall be added to
3 205.603(a), synthetic substances, allowed for use in
4 organic livestock production with the following
5 restrictions, for emergency medical use.

6 Tolazoline --

7 CHAIRMAN CARTER: Withhold time.

8 MR. SIEMON: Oh, withhold time shall be
9 double the FDA requirements. I'm sorry.

10 And then, tolazoline, whatever, shall be
11 added to 205.603(a), synthetic substances, allowed for
12 use in organic livestock production with the following
13 restrictions, to counteract the effects of xylazine and
14 withhold time shall be double the FDA requirements.

15 CHAIRMAN CARTER: Okay.

16 MR. SIEMON: One vote.

17 CHAIRMAN CARTER: That is the motion. One
18 vote for all of that. So, proceed to vote.

19 Riddle?

20 MR. RIDDLE: Yes.

21 CHAIRMAN CARTER: Siemon?

22 MR. SIEMON: Yes.

23 CHAIRMAN CARTER: Bandele?

24 MR. BANDELE: No.

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1 CHAIRMAN CARTER: Burton?
2 MS. BURTON: Yes.
3 CHAIRMAN CARTER: Caughlan?
4 MS. CAUGHLAN: Yes.
5 CHAIRMAN CARTER: Cooper?
6 MS. COOPER: Yes.
7 CHAIRMAN CARTER: Goldberg is absent.
8 Holbrook?
9 MR. HOLBROOK: Yes.
10 CHAIRMAN CARTER: King?
11 MR. KING: Yes.
12 CHAIRMAN CARTER: Koenig?
13 MS. KOENIG: Abstain.
14 CHAIRMAN CARTER: Lacy?
15 MR. LACY: Yes.
16 CHAIRMAN CARTER: O'Rell?
17 MR. O'RELL: Abstain.
18 CHAIRMAN CARTER: Ostiguy?
19 MS. OSTIGUY: Yes.
20 CHAIRMAN CARTER: Chair votes yes.
21 MR. SIEMON: Okay. These are all --
22 PARTICIPANT: Hold on. Got to get the count.
23 MR. SIEMON: I'm sorry.
24 CHAIRMAN CARTER: Okay. It passes, 10 to 1,

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1 2 abstentions, one absent.

2 MR. SIEMON: Okay. Just all these substances
3 have come from the veterinarians who've said these are
4 things they need. So, the next one is this
5 butorphanol. Where did you find out how to say them?

6 MS. KOENIG: Page 1.

7 MR. SIEMON: This is a synthetic that's used
8 in pain reliever related to operations, not that it
9 says that here, but that's what its normal use is. The
10 motion is butorphanol shall be added to 205.603(a),
11 synthetic substances, allowed for the use in organic
12 livestock production with the following restrictions,
13 for emergency medical use by licensed practitioner,
14 withhold time shall be double the FDA requirement.

15 So, that's the motion I'm making.

16 MS. OSTIGUY: Second.

17 CHAIRMAN CARTER: Okay. It's been moved by
18 George, seconded by Nancy. It's open for discussion.
19 Okay. Kim first, then Nancy.

20 MS. BURTON: I'd like to strike by a licensed
21 practitioner.

22 MS. OSTIGUY: Second.

23 CHAIRMAN CARTER: Okay. It's been moved and
24 seconded to strike the words "by a licensed

1 practitioner." So, that would just finish with "for
2 emergency medical use only. Withhold time shall be
3 double the FDA requirement." Okay.

4 MR. SIEMON: Nancy, you made that second?

5 MS. OSTIGUY: Hm-hmm.

6 MR. SIEMON: Okay.

7 CHAIRMAN CARTER: Yes. Okay. Discussion on
8 the motion to strike those four words.

9 MR. SIEMON: Can we say from all the rest of
10 the TAPs avoid this?

11 CHAIRMAN CARTER: No.

12 MR. SIEMON: All right.

13 PARTICIPANT: It's okay. We'll catch it.

14 CHAIRMAN CARTER: Yeah. Okay. Anybody have
15 a conflict on this one?

16 (No response)

17 CHAIRMAN CARTER: Hearing none, no hands
18 raised, we will proceed to vote.

19 MS. KOENIG: I thought we were voting on the
20 motion to strike that.

21 CHAIRMAN CARTER: Yes, that is. We're
22 proceeding on the motion to strike, yes. Okay.

23 Siemon?

24 MR. SIEMON: Yes.

1 CHAIRMAN CARTER: Bandele?
2 MR. BANDELE: Yes.
3 CHAIRMAN CARTER: Burton?
4 MS. BURTON: Yes.
5 CHAIRMAN CARTER: Caughlan?
6 MS. CAUGHLAN: Yes.
7 CHAIRMAN CARTER: Cooper?
8 MS. COOPER: Yes.
9 CHAIRMAN CARTER: Goldberg, absent.
10 Holbrook?
11 PARTICIPANT: Out of the room.
12 CHAIRMAN CARTER: Out of the room.
13 King?
14 MR. KING: Abstain.
15 CHAIRMAN CARTER: Koenig?
16 MS. KOENIG: Yes.
17 CHAIRMAN CARTER: Lacy?
18 MR. LACY: Yes.
19 CHAIRMAN CARTER: O'Rell?
20 MR. O'RELL: Yes.
21 CHAIRMAN CARTER: Ostiguy?
22 MS. OSTIGUY: Yes.
23 CHAIRMAN CARTER: Riddle?
24 MR. RIDDLE: Yes.

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1 CHAIRMAN CARTER: The Chair votes yes.
2 Passes. Holbrook? This is on a motion to strike the
3 words "by a licensed practitioner."

4 MR. HOLBROOK: Yes.

5 CHAIRMAN CARTER: Yes? Okay. Okay. So, it
6 passes.

7 MR. SIEMON: All these things are just
8 extremely rare --

9 CHAIRMAN CARTER: 12 to 0, 1 abstention, 1
10 absent.

11 MR. SIEMON: Okay.

12 CHAIRMAN CARTER: Okay. Okay. So, we're
13 back then on the substance itself. We're on the
14 material.

15 MR. SIEMON: Any discussion?

16 MS. KOENIG: I have just a question again in
17 terms of, okay, now I guess we'll do the local
18 anesthetic. Is there anything on our list,
19 alternatives that already deal with this type of issue?

20 MR. SIEMON: Not that I'm aware of, but I'm
21 open to any input.

22 PARTICIPANT: We wouldn't have brought it
23 forward if there were.

24 MS. KOENIG: So, this is -- so, just tell me

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1 how it is usually used, in what cases.

2 MR. SIEMON: Boy. Is there anybody here that
3 can answer that? Anybody at all on the -- I was
4 thinking about a major operation like a twisted --

5 CHAIRMAN CARTER: Identify yourself.

6 MS. ZUCK: Leslie Zuck, PCO. It's a pain
7 reliever administered through, you know, injection.

8 MR. SIEMON: But what kind of emergency would
9 bring this on?

10 MS. ZUCK: Operations, of course, but also
11 when an animal's down, a cow is down, and they're in
12 some sort of pain. It could have been they had a
13 trauma. We don't know what it is. You relieve their
14 pain. Their immune system can catch up and fix what it
15 is. You get them up on their feet. That's the main
16 thing with a cow that's down, you've got to get them up
17 on their feet, and it is also used for horses. It can
18 be administered orally as well. It works when aspirin
19 doesn't work. Aspirin isn't something that's really
20 used very much for, you know, animals. It's not --
21 doesn't really -- it's not effective in those cases.
22 It's not like -- aspirin will work for a headache, but
23 when you have a trauma, a major accident, maybe the cow
24 got, you know, cut on the fence, something like that,

1 and they're down, you know. That's where we use them,
2 where our producers use it.

3 CHAIRMAN CARTER: Okay. Mark?

4 MS. ZUCK: It's not a local anesthetic.

5 CHAIRMAN CARTER: Then Rick.

6 MS. ZUCK: It's a pain -- I heard someone say
7 that.

8 MR. KING: Just a quick question. How does
9 this differ from just straight morphine?

10 CHAIRMAN CARTER: Anybody answer that
11 question? Kelly Shea says she can answer it.

12 MS. SHEA: Two things. I'd like to remind
13 the Board that Dr. Karreman left his phone number with
14 the Board specifically to be called for these
15 technological questions. Because of Becky's advanced
16 pregnancy, he had to return, and Dr. Karreman has
17 stated that because of robberies of veterinarians and
18 doctors that keep morphine and other heroin derivatives
19 in their pharmacies, that in general, the practice is
20 not to keep products like that in their pharmacies, and
21 I'd just recommend that the Board call Dr. Karreman
22 with some of these questions.

23 CHAIRMAN CARTER: Okay. Thank you, Kelly.

24 Okay. Other discussion? Rick?

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1 MR. MATHEWS: It seems to me from reading the
2 summary document here that this is -- are you intending
3 that this be used in the case of surgery, and is that
4 what you consider to be an emergency? I've heard
5 emergency being the cow is down. We're now talking
6 about surgery. I guess part of the question that I
7 have is, how do you define emergency, and this says for
8 emergency use, but would the practitioner be able to
9 consider a surgery that might not be needed because of
10 life-threatening at the time be considered emergency?
11 That's all I'm trying to say.

12 CHAIRMAN CARTER: Nancy?

13 MS. OSTIGUY: If we've done surgery, then
14 we're getting into -- I suppose then we get into the
15 issue of we'd make the decision of whether or not the
16 animal still is organic, but for humane practices, you
17 would control pain. You know, we know full well that
18 animals, humans, recover much more quickly, if you
19 control pain.

20 MR. MATHEWS: But that doesn't sound like
21 emergency. That sounds like humane treatment and the
22 wording --

23 MS. OSTIGUY: But if --

24 MR. MATHEWS: -- in the annotation is

1 emergency.

2 CHAIRMAN CARTER: Owusu?

3 MR. BANDELE: On the first page of the TAP,
4 it says organic farmers have petitioned the use of this
5 for cattle in order to ease them prior to surgery. So
6 that to me would be an intended reason for the TAP.

7 MS. ZUCK: I have Hugh on the phone, and his
8 first thing was butorphanol is synthetic morphine.
9 That clears up a lot of it.

10 MR. SIEMON: What's the typical operation
11 it's used for, and are there some operations it could
12 be used for that we --

13 CHAIRMAN CARTER: Just for the record, Leslie
14 Zuck is translating via cell phone to Dr. Karreman.
15 Okay.

16 MR. SIEMON: What is the kind of operations
17 this commonly used for? Is there any uses we should be
18 concerned about? Two questions.

19 MS. ZUCK: What is the typical operation that
20 this would be used for, and are there any uses that we
21 should be considered about? Any other uses that we
22 should be concerned about?

23 CHAIRMAN CARTER: Can you hear me now?

24 MS. ZUCK: The typical operation that it

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1 would be used for is one that he just finished right
2 now.

3 PARTICIPANT: She had the baby.

4 MS. ZUCK: Abdominal surgeries, torsion of
5 the what? Twisted stomach. That's common. Caesarean
6 section. You didn't have one of those, did you? Any
7 invasive surgery. They're talking about the difference
8 between emergency surgery versus just, you know, I
9 guess, surgery. Surgery is emergency. Okay.

10 CHAIRMAN CARTER: Okay.

11 MR. SIEMON: Any concerns we should have?

12 CHAIRMAN CARTER: Okay. Questions for Dr.
13 Karreman while we got him on the phone? Kim?

14 MS. BURTON: Are there alternatives to this
15 material?

16 MS. ZUCK: Are there alternatives to this
17 material? Yeah. Yeah. Other than aspirin. He said
18 no, there are no alternatives in the field, unless you
19 would use inhalation-type things that you would use in
20 the hospital, inhalation, as anesthetics, anesthesia.

21 CHAIRMAN CARTER: Okay. Rose?

22 MS. KOENIG: I -- just those two that are
23 listed as far -- I don't understand the difference
24 between -- it sounds like it's used with the chemical

1 that we just approved in combination when you're doing
2 surgery. So, my question is, if we approve something
3 that knocks them out, do we need something -- I mean,
4 is this post-operative, and then can you use the local
5 --

6 MS. ZUCK: We just did xylazine and
7 tolazoline. Right. She's wondering why do you need
8 this if you have that. Is it something that's post-
9 operative?

10 MS. KOENIG: And then, what about lidocaine?

11 MS. ZUCK: Lidocaine is just a local
12 anesthesia at the incision line to numb up the area.
13 Xylazine is a sedative, that if you have an animal
14 that's all jumpy and spooky, you can actually approach
15 the animal. You give them that first. Okay. You can
16 do minor surgery with xylazine. Butorphanol is for a
17 major surgery. Abdominal, you know, invasive-type
18 surgery. You can do something like stitch up a leg or
19 something with the xylazine. Is that what you're
20 saying? Or an udder. Okay. Xylazine gives some pain
21 relief but not complete pain relief. Doesn't knock
22 them out, in other words.

23 CHAIRMAN CARTER: Okay. Mark?

24 MR. KING: Could you have him just for the

1 record state the advantages of this product over just
2 regular morphine?

3 MS. ZUCK: What would be the advantages to
4 this product over regular morphine? Commercially a lot
5 more available. There's only been one study in 30
6 years with morphine in cows. What Kelly said about if
7 people knew you kept morphine in your veterinary
8 clinic, you'd be subject to thievery. Those three.

9 CHAIRMAN CARTER: Okay. Other questions
10 while we got Dr. Karreman on the phone?

11 (No response)

12 CHAIRMAN CARTER: Okay. Thank him very much.

13 MS. ZUCK: Thanks.

14 CHAIRMAN CARTER: Okay. Rick?

15 MR. MATHEWS: Well, this -- the discussion
16 brings me back to the issue that I was trying to
17 address, was in your annotation, you're saying for
18 emergency medical use. So, I think my question now is,
19 shouldn't that really say for use in conjunction with
20 surgery rather than an emergency medical use?

21 MS. OSTIGUY: I would agree with that, and I
22 will actually move to delete emergency medical use and
23 substitute for use during surgery.

24 MR. HOLBROOK: I'll second that.

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1 PARTICIPANT: Major surgery.

2 MS. OSTIGUY: Major surgery.

3 CHAIRMAN CARTER: Okay. Just moved by Nancy
4 and seconded by Dennis.

5 MR. MATHEWS: Okay. I didn't say during
6 surgery because I don't know if it's used before,
7 during or after. That's why I used the word "in
8 conjunction with".

9 MS. OSTIGUY: You could just change it with
10 to for. So, used for major surgery.

11 MR. MATHEWS: Well, now we got a new problem.
12 Now you're saying for use for major surgery, and I ask
13 you to define major surgery.

14 MS. OSTIGUY: Okay. Well, just do surgery.

15 CHAIRMAN CARTER: Okay. So, now, just to
16 clarify so that Katherine doesn't come and whomp me
17 over the side of the head here, --

18 MR. SIEMON: Going to anyway.

19 CHAIRMAN CARTER: -- that the wording then,
20 the motion on here, is for -- to delete for emergency
21 medical use and substitute the words "for surgery".
22 Okay.

23 MS. BURTON: Just a comment on annotations
24 again. If we're going to allow it and we're going to

1 allow a licensed veterinarian to administer it, why are
2 we dictating how and when if it's not just for
3 emergency treatment? So, that's my comment. I would
4 just as soon not have any annotation if we're going to
5 say it's only for surgery because we're not
6 veterinarians, and we don't know if that's the only
7 time this would be administered.

8 MR. O'RELL: If I could second that, I would.
9 I could see, you know, setting a broken leg that
10 wouldn't technically be surgery, that you'd want to
11 knock the animal out. I think we do need to leave it
12 general.

13 CHAIRMAN CARTER: Okay. Speaking to the
14 motion?

15 PARTICIPANT: I'm willing to withdraw the
16 motion.

17 CHAIRMAN CARTER: Okay. Motion is withdrawn.
18 Is the seconder willing to withdraw the second? Okay.
19 So, now we're back to the following restrictions for
20 emergency medical use substitute amendment. Okay.

21 MS. OSTIGUY: No. What I'd like to do then
22 is just delete for emergency medical use since it only
23 can be used by a veterinarian.

24 MR. LACY: Second.

1 CHAIRMAN CARTER: Okay. It's been moved by
2 Nancy, seconded by Mike. Just a second. Livestock
3 production with the following restrictions, withhold
4 time shall be double the FDA requirement.

5 Okay. Now, discussion on that motion to
6 strike the language and have substitute or just strike
7 the language. Excuse me.

8 (No response)

9 CHAIRMAN CARTER: Okay. Seeing nobody, we'll
10 go --

11 MS. CAUGHLAN: Well, is -- excuse me. Just
12 --

13 CHAIRMAN CARTER: Goldie?

14 MS. CAUGHLAN: -- word, making sure that it
15 reads. So, it would read, with the following
16 restrictions: withhold time shall be double FDA
17 requirements?

18 CHAIRMAN CARTER: Change restrictions to
19 singular. Okay. All right.

20 Owusu?

21 MR. BANDELE: Xylazine would be for other
22 types of minor -- of relatively minor -- see, to me, if
23 the petitioner was requesting just use for surgery, I
24 don't really see the rationale for broadening that

1 utilization, if there are other alternatives.

2 CHAIRMAN CARTER: Okay.

3 MR. SIEMON: He said that it has a pain
4 reliever effect, but it's a sedative that you give
5 another drug to and then the effects of it are gone.
6 This is for after the operation, so they have a pain
7 reliever for the first day or so. I missed your point
8 then. I'm sorry.

9 MR. BANDELE: The point is that the
10 petitioners petitioned for use in surgery.

11 MR. SIEMON: Right.

12 MR. BANDELE: And the doctor said, I assume I
13 interpreted what he said as meaning that the other --
14 for example, the xylazine could be used in the cases
15 not as severe. So, I'm saying that why should we
16 broaden the use when the petitioners did not ask for
17 that broad use? See, I'm really concerned with opening
18 up this whole -- even though, you know, I'm trying to
19 deal as best I can, but I think in terms of -- just a
20 minute -- as far as the -- you know, we're opening up
21 the door here for animals and yet with the plant
22 situation that Marty brought up where there would be no
23 -- detectable residue would also be less, then that
24 doesn't seem to be a go.

1 I know that's two different things, but I do
2 have some reservations about these broad sweeping uses.

3 CHAIRMAN CARTER: Okay. Kim?

4 MS. BURTON: The petition says for surgical
5 situations which to me is different than surgery as a
6 justification. Surgical situation. Again, it's a
7 veterinarian's call when they need this material.
8 Either we approve it or we don't. If you want for
9 emergency treatment only, then you put that in there,
10 but I think that's the call of a veterinarian.

11 CHAIRMAN CARTER: Okay.

12 MS. KOENIG: Where do you see that? I see
13 they would -- like to treat livestock in need of
14 surgery with

15 MS. BURTON: Look at the very back of the
16 TAP, the petitioner's petition. Turn it over
17 completely. Flip it. There you go.

18 MS. KOENIG: Oh, yes. This comprehensive
19 document.

20 CHAIRMAN CARTER: So, now we're just voting
21 on the motion to strike the language for emergency
22 medical use and changing restrictions to restriction.
23 Okay. If you're ready to vote? Back to the top of the
24 list.

1 Bandele?
2 MR. BANDELE: Abstain.
3 CHAIRMAN CARTER: Burton?
4 MS. BURTON: Yes.
5 CHAIRMAN CARTER: Caughlan?
6 MS. CAUGHLAN: Yes.
7 CHAIRMAN CARTER: Cooper?
8 MS. COOPER: Yes.
9 CHAIRMAN CARTER: Goldberg, absent.
10 Holbrook?
11 MR. HOLBROOK: Yes.
12 CHAIRMAN CARTER: King?
13 MR. KING: Yes.
14 CHAIRMAN CARTER: Koenig?
15 MS. KOENIG: Abstain.
16 CHAIRMAN CARTER: Lacy?
17 MR. LACY: Yes.
18 CHAIRMAN CARTER: O'Rell?
19 MR. O'RELL: Yes.
20 CHAIRMAN CARTER: Ostiguy?
21 MS. OSTIGUY: Yes.
22 CHAIRMAN CARTER: Riddle?
23 MR. RIDDLE: Yes.
24 CHAIRMAN CARTER: Siemon?

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1 MR. SIEMON: Yes.

2 CHAIRMAN CARTER: The Chair votes yes. It is
3 11 to 0, 2 abstentions, 1 absent. For the motion, yes.
4 The motion to delete.

5 So, now we're back to the material as
6 amended.

7 MR. SIEMON: And I understand the only thing
8 left now is the withhold time shall be double the FDA
9 requirement.

10 CHAIRMAN CARTER: That's the only restriction
11 on there at this time.

12 MR. SIEMON: Okay.

13 CHAIRMAN CARTER: Yes.

14 MR. SIEMON: Any more discussion?

15 (No response)

16 CHAIRMAN CARTER: Okay. Are we ready to
17 vote?

18 MR. MATHEWS: Well, just one more
19 clarification. The document itself doesn't say
20 .603(a), but for our purposes, we want to clarify that
21 that is .603(a).

22 MR. SIEMON: Thank you. Yep.

23 MR. MATHEWS: Okay.

24 MR. SIEMON: Yep.

1 CHAIRMAN CARTER: Okay. Burton?
2 MS. BURTON: Yes.
3 CHAIRMAN CARTER: Caughlan?
4 MS. CAUGHLAN: Yes.
5 CHAIRMAN CARTER: Cooper?
6 MS. COOPER: Yes.
7 CHAIRMAN CARTER: Goldberg, absent.
8 Holbrook?
9 MR. HOLBROOK: Yes.
10 CHAIRMAN CARTER: King?
11 MR. KING: Yes.
12 CHAIRMAN CARTER: Koenig?
13 MS. KOENIG: Abstain.
14 CHAIRMAN CARTER: Lacy?
15 MR. LACY: Yes.
16 CHAIRMAN CARTER: O'Rell?
17 MR. O'RELL: Yes.
18 CHAIRMAN CARTER: Ostiguy?
19 MS. OSTIGUY: Yes.
20 CHAIRMAN CARTER: Riddle?
21 MR. RIDDLE: Yes.
22 CHAIRMAN CARTER: Siemon?
23 MR. SIEMON: Yes.
24 CHAIRMAN CARTER: Bandele?

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1 MR. BANDELE: Abstain.

2 CHAIRMAN CARTER: Chair votes yes. Passes,
3 11 to 0, 2 abstentions, 1 absent.

4 MR. SIEMON: Okay. Can I just ask, in
5 looking at the agenda, we're going to do this all
6 afternoon basically, Livestock's just going to keep
7 going until we're through all of them?

8 CHAIRMAN CARTER: Yep. Well, no, until we're
9 through with our list for the day.

10 MR. SIEMON: All the way down to mineral oil.

11 CHAIRMAN CARTER: Yeah. We can't take -- if
12 they're on the agenda for tomorrow, we can't really --

13 MR. SIEMON: Oh, I see.

14 CHAIRMAN CARTER: So, if you want to take a
15 break?

16 MR. SIEMON: I'm just saying there's an
17 afternoon session. That's the same thing on-going.
18 I'm just trying to see. So, this is -- okay.

19 CHAIRMAN CARTER: But if you want to take a
20 break?

21 MR. SIEMON: Well, it's 2:46.

22 CHAIRMAN CARTER: Somebody wants to take a
23 break. We'll take a 15-minute recess.

24 (Whereupon, a recess was taken.)

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1 CHAIRMAN CARTER: Come back to the table
2 here.

3 I'm confident that we can get done ahead of
4 schedule today, but a friend of mine always likes to
5 remind me that confidence is that feeling you get
6 shortly before you're fully aware of the situation.

7 We do have an individual here that has joined
8 us with the Aloe Vera Information -- what's the name of
9 the group, sir? The International Aloe Vera Science
10 Council, who got his signals confused and thought there
11 was public comment today and then action later on
12 rather than yesterday and today, and so I've had a
13 request during the break to allow him to make some
14 comments. We could either do that or just have him
15 available for some questions, you know, as we go
16 forward. So, I'll just kind of leave it to the --
17 don't want to, you know, start a habit of just starting
18 and doing public comments as we go forward.

19 MR. RIDDLE: I'd prefer that we ask some
20 questions and it probably won't make any difference in
21 the outcome but just to not break precedent.

22 CHAIRMAN CARTER: Okay. So, just to
23 recognize then that we do have that resource available
24 to answer some questions on this particular subject.

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1 George, it's a good thing you came back
2 because Nancy was ready to take over the committee.

3 MR. SIEMON: Well, probably that might be the
4 best thing. Have we moved to potassium sorbate?

5 CHAIRMAN CARTER: We have.

6 MR. SIEMON: Okay. Here's a touchy one. The
7 motion as reads is potassium sorbate should be added to
8 205.603(a), (b), (c), (d). Which would it be? (a)? (a).
9 The medical. Synthetic substances, allowed for use in
10 organic livestock production with the following
11 restrictions, allowed only in livestock therapeutic
12 products formulated using organic aloe vera which is
13 labeled made with organic (specified ingredients or
14 food groups).

15 CHAIRMAN CARTER: Okay. That's the motion.
16 Is there a second?

17 MS. OSTIGUY: Second.

18 MS. RICHARDS: Nancy seconded.

19 MS. OSTIGUY: And I'd like to move that we
20 delete the restriction.

21 CHAIRMAN CARTER: Okay.

22 MS. OSTIGUY: So, delete --

23 CHAIRMAN CARTER: The seconder now has made a
24 motion to delete the restriction, allowed only in

1 livestock therapeutic products formulated using organic
2 aloe vera which is labeled made with organic, etc., and
3 so on.

4 MR. SIEMON: Boy.

5 MS. BURTON: I'll second it.

6 CHAIRMAN CARTER: Okay. Been seconded by
7 Kim.

8 Okay. Nancy, speak to your motion.

9 MS. OSTIGUY: Basically, I don't think that
10 we can do this is why I moved to remove it. You know,
11 if we were talking about human use, where it would go
12 into the Processing Committee, then yes, I -- we could
13 do this but not livestock. We either approve it or
14 not.

15 CHAIRMAN CARTER: Okay.

16 PARTICIPANT: Didn't we do this yesterday?

17 CHAIRMAN CARTER: We discussed it yesterday.

18 MS. BURTON: Are you saying the reason you
19 can't do it, you can't add a restriction to potassium
20 sorbate or you cannot --

21 MS. OSTIGUY: The made in organic or made
22 with organic. Excuse me.

23 MR. SIEMON: So, it's your objective to
24 eliminate the made with or is it to eliminate the

1 restriction of only organic aloe --

2 MS. OSTIGUY: I'm sorry. No. Just the
3 portion, the made with organic.

4 MR. SIEMON: Okay. So, you want to -- your
5 motion is to eliminate the which is labeled made with
6 organic on?

7 MS. OSTIGUY: Yes.

8 CHAIRMAN CARTER: Okay.

9 MS. OSTIGUY: I'm sorry.

10 MR. SIEMON: That makes more sense.

11 MS. OSTIGUY: I'm sorry.

12 CHAIRMAN CARTER: Okay. So, now the motion
13 then is just to strike the words "which is labeled made
14 with organic (specified ingredients or food groups)."
15 Okay.

16 Jim?

17 MR. RIDDLE: I support that motion now that
18 it's clarified. The one question I have for Nancy and
19 other members of the committee and possibly our expert
20 on the subject as well is, how about also removing the
21 word "organic" in front of aloe vera so that it's
22 allowed only in livestock therapeutic products
23 formulated using aloe vera?

24 MR. SIEMON: What's the advantage of that?

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1 MR. RIDDLE: That we're not requiring organic
2 aloe vera as a health input. We don't require other
3 organic medications per se.

4 CHAIRMAN CARTER: Okay. Is that a friendly
5 amendment?

6 MR. RIDDLE: I'll offer that as a friendly
7 amendment. Try that approach.

8 MR. SIEMON: Because we are concerned what
9 happens to aloe.

10 MS. OSTIGUY: So, what you're saying is that
11 non-organic aloe vera would be available for
12 therapeutic uses in livestock.

13 CHAIRMAN CARTER: Just a second. Okay.
14 That's agreeable with the maker. How about the
15 seconder?

16 MS. BURTON: That's fine.

17 CHAIRMAN CARTER: Okay. Okay. So, now the
18 motion. The motion is allowed only in livestock
19 therapeutic products formulated using aloe vera. We're
20 striking the word "organic" out of there as well as all
21 of the language after the word "vera". Okay? Okay.
22 To that motion to strike. Okay. Goldie?

23 MS. CAUGHLAN: No.

24 CHAIRMAN CARTER: Okay. You're just waiting.

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1 Kim?

2 MS. BURTON: Since you're hesitating, I had a
3 side conversation --

4 MR. SIEMON: He who hesitates is lost.

5 MS. BURTON: -- during the break about
6 labeling therapeutic restrictions that aren't
7 recognized by the -- I guess it would be the FDA, and
8 in this case, we're saying that aloe vera is a
9 recognized therapeutic in livestock, and I want to know
10 if that's really true. If it's not, then we should
11 also strike the word "therapeutic".

12 CHAIRMAN CARTER: Okay. Knowledge of whether
13 this is authorized by FDA as a therapeutic?

14 MS. BURTON: Potassium sorbate specifically
15 with aloe? I guess I need to look at that.

16 CHAIRMAN CARTER: Do you know the answer to
17 that? You have to come to the microphone and identify
18 yourself for the record.

19 MR. LOVELACE: Don Lovelace. I'm President
20 and CEO of Lily of the Desert Organic Aloeceuticals,
21 and I'm here on behalf of the International Aloe Vera
22 Science Council as one of their members.

23 The FDA recognizes in their official
24 monograph for topical use of aloe vera, cuts, burns,

1 abrasions, and then they recognize aloe as a carrier
2 for other types of ingredients, and there's a lot of
3 work that's being done there today in that area.

4 When you use a specific term "therapeutic", I
5 can't answer that, whether they say it is a therapeutic
6 ingredient, but I know it's recognized for cuts, burns,
7 abrasions, topically as well as a carrier for internal
8 and orally-ingested product.

9 MS. KOENIG: Your label calls it a
10 nutritional supplement. I'm sorry. That's not your
11 label. That's Crystal Creek.

12 MR. LOVELACE: That would be under DSHEA,
13 under the Dietary Supplement Health Education Act. It
14 would be a dietary supplement, but if it's labeled as a
15 drink or a juice, it's going to be under food which
16 would be the FDA.

17 MR. SIEMON: Okay. But we're talking about
18 livestock here.

19 CHAIRMAN CARTER: Okay. Rose?

20 MS. KOENIG: I just had a question, I guess,
21 to the committee and then perhaps the gentleman could
22 even answer it. So, what was the idea by originally
23 including organic aloe vera? Is there a large enough
24 industry to supply the sources of -- you know, what was

1 the --

2 MR. SIEMON: Well, there's -- the petitioner
3 -- they use organic at this time. I don't know how
4 much.

5 MR. LOVELACE: I have a letter here from my
6 SC as a handout and the estimated U.S. organic aloe
7 market's about \$75 million annually.

8 MS. KOENIG: So, there's definitely
9 sufficient supply. It's not -- so, I don't see why we
10 wouldn't require organic.

11 MS. BURTON: Can I talk about why the
12 justification to this and maybe this is going to add
13 clarification. This TAP came to the Processing
14 Committee to review because it's also used in organic
15 aloe juice in the processing area. The petition was
16 specifically for livestock, and since we didn't have
17 anybody petitioned for use in processing, we are not
18 going to make a recommendation on this. So, we are not
19 going to do anything, and this annotation about made
20 with organic label makes no sense because we're going
21 to do nothing until this industry shows us use that
22 this material is needed, and it is a preservative and
23 so we want a thorough tap or we need a petition done
24 before we can act on it.

1 So, I think the justification to remove
2 organic is -- if the processing area does nothing with
3 it and they're using aloe juice for human health, this
4 product might go away. You might not have an organic
5 aloe juice anymore, quite simply put.

6 CHAIRMAN CARTER: Rose?

7 MS. KOENIG: I guess I don't understand that
8 logic. I don't understand why we can't. If we know
9 that there's an industry out there, I mean, it's our
10 mandate, I think, to encourage the use of organic
11 products, you know, in our rule, especially when we
12 know that they're obviously commercially available.
13 So, why wouldn't -- I don't understand why you have to
14 link the two to processing.

15 MS. BURTON: Well, because naturals are
16 allowed in livestock without being organic and aloe
17 vera could be used with the potassium sorbate and not
18 be organic. It could be a conventional organic, but if
19 you want to push it, then you certainly could make an
20 amendment to it.

21 CHAIRMAN CARTER: Okay. Mark?

22 MR. KING: Just a comment in terms of both
23 things to Rosie's and Kim's comments, and that is, that
24 because we haven't been petitioned for a specific use

1 in the food industry, so to speak, it hasn't been
2 considered by the Processing Committee, and until such
3 time we receive that, based on, you know, language in
4 the Act that tells us what we must do, I think the
5 point here is that unless that happens, there may not,
6 as Kim has said, be organic aloe vera.

7 With that in mind, if we leave the term
8 "organic" in here, then essentially this whole motion
9 is a moot point. Sorry.

10 CHAIRMAN CARTER: Other discussion on the
11 motion?

12 (No response)

13 CHAIRMAN CARTER: Okay. The motion as it
14 stands -- okay. Nancy?

15 MS. OSTIGUY: I need to have that run by me
16 again because I guess I don't understand how the motion
17 would be moot if we put organic aloe vera in there, and
18 since I'm one of the makers of the motion, I --

19 MR. KING: Well, I guess I could add to that,
20 I mean, actually it may not be if you look at
21 commercially available. Okay.

22 MS. OSTIGUY: Step back. Sort of explain the
23 steps.

24 MR. KING: Okay.

1 MS. OSTIGUY: I'm lost.

2 MS. KOENIG: Me, too.

3 MR. SIEMON: I'll try one more time. Organic
4 livestock use of aloe vera is like 1/50th or some
5 number like that of all the organic aloe. What they
6 were saying is if potassium sorbate was not approved
7 for human use of aloe vera, would that damage the
8 overall production of organic aloe so much that it may
9 not be available since you lost 49/50th of the
10 marketplace. We don't want to be doomsayers. We're
11 trying to protect for livestock. We don't normally
12 require organic, and, of course, one would say that
13 hopefully it would be organic.

14 CHAIRMAN CARTER: Okay. Other discussion on
15 the motion?

16 (No response)

17 CHAIRMAN CARTER: Okay. We will proceed to
18 vote, the motion being to strike the word "organic" and
19 all of the words after the word "vera". Okay?

20 MS. CAUGHLAN: Clarification. How about
21 therapeutic? That was the motion. I don't know if
22 it's seconded. I don't know who seconded it.

23 MR. SIEMON: Nancy made it, Kim seconded.
24 Kim made the friendly, I believe.

1 MS. CAUGHLAN: The suggestion was made for
2 substitution of the health care rather than
3 therapeutic.

4 MS. BROWN-ROSEN: You're saying (a) or --

5 MR. SIEMON: It's in (a).

6 CHAIRMAN CARTER: Okay. Now, we're rapidly
7 becoming confused here.

8 MR. SIEMON: No, we're not.

9 MS. BENHAM: So, the friendly motion to
10 remove the word "organic" in front of aloe vera and
11 everything after vera.

12 MR. RIDDLE: Let's just deal with that vote
13 and then come back.

14 CHAIRMAN CARTER: Yeah. I agree. We're just
15 going to vote on this one. Then if we want to strike
16 therapeutic, we'll take that as a separate motion.
17 Okay.

18 Okay. Does anybody have a conflict on this
19 issue?

20 (No response)

21 CHAIRMAN CARTER: Okay. We will proceed to
22 vote then.

23 Burton?

24 MS. BURTON: Yes.

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1 CHAIRMAN CARTER: Caughlan?
2 MS. CAUGHLAN: Yes.
3 CHAIRMAN CARTER: Cooper?
4 MS. COOPER: Yes.
5 CHAIRMAN CARTER: Goldberg, absent.
6 Holbrook?
7 MR. HOLBROOK: Yes.
8 CHAIRMAN CARTER: King?
9 MR. KING: Yes.
10 CHAIRMAN CARTER: Koenig?
11 MS. KOENIG: Yes.
12 CHAIRMAN CARTER: Lacy?
13 MR. LACY: Yes.
14 CHAIRMAN CARTER: O'Rell?
15 MR. O'RELL: Yes.
16 CHAIRMAN CARTER: Ostiguy?
17 MS. OSTIGUY: Yes.
18 CHAIRMAN CARTER: Riddle?
19 MR. RIDDLE: Yes.
20 CHAIRMAN CARTER: Siemon?
21 MR. SIEMON: Yes.
22 CHAIRMAN CARTER: Bandele?
23 MR. BANDELE: Yes.
24 CHAIRMAN CARTER: Chair votes yes. It passes

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1 13 to nothing, 1 person absent.

2 Okay. Now, back to the motion as amended.

3 MR. SIEMON: Yes. This is a preservative
4 used in aloe vera, and aloe vera is used for many
5 purposes in livestock which, as we heard earlier,
6 internal as well as external, and the problem is no
7 matter how you package it, it will mold once it's
8 opened. So, we had discussions about teeny little
9 packages. We had discussions about some technology and
10 still we came back to this seemed to be the functional
11 unit for livestock production.

12 CHAIRMAN CARTER: Okay. Now, Nancy?

13 MS. BURTON: And at least for me, the big
14 issue on mold was the production of microtoxins.

15 CHAIRMAN CARTER: Okay. Kim?

16 MS. BURTON: I'm still uncomfortable with the
17 word "therapeutic" unless I can see that there's a link
18 to being able to use that as a therapeutic, medicinal,
19 in livestock. I would move that we strike the word
20 "therapeutic" and just put livestock products.

21 CHAIRMAN CARTER: Okay. Motion to strike the
22 word "therapeutic". Is there a second?

23 MS. KOENIG: I guess --

24 PARTICIPANT: Second.

1 CHAIRMAN CARTER: It's been seconded. Now,
2 discussion on the motion. Okay. Rose?

3 MS. KOENIG: I guess the only thing is in --
4 where it's located, then it wouldn't be used as -- I
5 mean, just theoretically, it's some kind of feed
6 additive or nutritional source. The reason why you
7 want it is for medical kind of use. So, the section
8 we're putting it under --

9 MS. BURTON: We were talking at the break,
10 and is this applicable to what we were discussing with
11 allowing a material on a national list that's not
12 federally recognized for that use?

13 DR. BURESH: Bob Buresh with Tyson. I guess
14 my first comment came up originally about some of the
15 other compounds, but I wasn't -- I'm not familiar with
16 this particular compound, but I know with many of the
17 feed additives or compounds that we use, the FDA
18 strictly regulates a lot of that stuff, and for you to
19 have a health claim on at least things that go in the
20 feed, once you have a claim that says it treats or
21 cures or promotes something other than just as a source
22 of a nutrient, FDA takes regulation over it.

23 So, I mean, I don't know about atypical. I
24 mean, this is -- I'm not sure about the potassium

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1 sorbate in particular. But I know once you start
2 tying a health claim to it, you know, you better have
3 it approved through the FDA as having that same claim.

4 CHAIRMAN CARTER: Other discussion on the
5 motion to strike the word "therapeutic"?

6 Jim?

7 MR. RIDDLE: Yeah. I understand the issue.
8 I just -- and I don't disagree with it. It's just I
9 don't like how it reads without the word "therapeutic"
10 in there because then you're talking about allowed only
11 in livestock products. This is not a livestock
12 product. That has a certain use in the rule, the term
13 "livestock product". So, I think we need something
14 else to replace it there.

15 PARTICIPANT: The suggestion was livestock
16 health. That's not insinuating that it's therapeutic.

17 MR. RIDDLE: Health care, medicinal
18 treatment. Medical treatment is the category that's
19 chosen, (a).

20 CHAIRMAN CARTER: Rick?

21 MR. MATHEWS: I've got a question.
22 Regardless of what the annotation is, where were you
23 planning to put this?

24 MR. SIEMON: I was just going to bring that

1 up. I had said (a) earlier. The petitioner, if I
2 understand it, is labeled as a feed supplement
3 additive. So, this goes -- that makes it difficult.
4 You would think it would go under additives, but then
5 earlier, we hit the issue, do we need to have a clause
6 that acknowledges that feed substances can often be
7 used for medical purposes, too? So, I'd almost have to
8 say (d) at this time.

9 MR. MATHEWS: Well, then the question I have
10 is that some of the discussion was making me believe
11 that maybe it's a topical-type treatment which would
12 then be (b).

13 MR. SIEMON: I think it's (a) and (d). (b)?
14 Oh, gosh. Let's just do all -- (a), (b), and (d).

15 MS. OSTIGUY: It's more than (b) because they
16 do give it internally.

17 MR. SIEMON: It's (a), (b) and (d). It's a
18 therapeutic, it's a topical, and it's a feed. So, it's
19 (a), (b) and (d).

20 MR. MATHEWS: Okay. Well, then, let me offer
21 this. If you're going to say add it to 205.603(a), (b)
22 and (d), we don't have to address livestock therapeutic
23 products. It just says --

24 MR. SIEMON: Drop all annotations.

1 MR. MATHEWS: -- use in organic livestock
2 production, except for you would still have to address
3 whether or not you want to have that aloe vera issue in
4 there, but you wouldn't need the allowed only in
5 livestock therapeutic products.

6 MS. OSTIGUY: I think one of the things that
7 the Livestock Committee was intending was that this was
8 only to be used in aloe vera.

9 MR. SIEMON: So, we'd have potassium sorbate-
10 in aloe vera products.

11 CHAIRMAN CARTER: The motion that's on the
12 table is simply to strike the word "therapeutic". If
13 the maker of the motion would accept it, you would just
14 strike the words "with the following restriction,
15 allowed only in livestock therapeutic products." So,
16 it would say then, "allowed for use in organic
17 livestock production, formulated using aloe vera."
18 Does that --

19 MR. SIEMON: I think we could make it
20 simpler, just -aloe vera products.

21 MS. OSTIGUY: How about allowed in aloe vera
22 used only in livestock?

23 MR. KING: You could say only for use in aloe
24 vera products.

1 MS. BURTON: I will accept that.

2 CHAIRMAN CARTER: Okay. So, then the amended
3 language -- the amendment then would be potassium
4 sorbate should be added to 205.603(a), (b) and (d),
5 synthetic substances, allowed for use --

6 MS. BURTON: Only in aloe vera.

7 MR. SIEMON: Only for use in aloe vera
8 products.

9 CHAIRMAN CARTER: Okay. Only for use in aloe
10 vera products. So, okay. The motion then to change
11 the language is on the table. Any discussion on that?

12 (No response)

13 CHAIRMAN CARTER: Seeing none, we'll proceed
14 to vote.

15 MR. SIEMON: Can -- a friendly motion that
16 it's (a), (b) and (d), also, at the same time?

17 CHAIRMAN CARTER: That's part of the
18 amendment that's on there. Okay. Now, this is just on
19 the amendment. We're going to take this as two votes.
20 So, okay. So, we start off with Caughlan.

21 MS. CAUGHLAN: Yes.

22 CHAIRMAN CARTER: Okay. Comment? Is it a
23 point of procedure or point of clarification?

24 MS. ZUCK: About what you just said.

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1 CHAIRMAN CARTER: Okay.

2 MS. ZUCK: Leslie Zuck, PCO. This goes to
3 your suggestion to put it in (a), (b) and (d). I mean,
4 is there any reason why you wouldn't look down to
5 reserved, pick out (f), say as preservatives, and under
6 that, say potassium sorbate for use in aloe vera
7 products only? I mean, we're talking about excipients.
8 I don't know. It is a different -- you are talking
9 about potassium sorbate as a preservative. There isn't
10 nothing there, but you have reserved. You can pick out
11 (f). You can say -- you have that option to say as a
12 preservative, and then you don't have to put it under
13 all those other places and make it confusing.

14 CHAIRMAN CARTER: Okay. I'm thinking
15 procedure here. Okay. It's hard to catch me thinking.

16 MS. SHEA: This is Kelly Shea. I would just
17 like the Board to consider if we're setting a precedent
18 here. The rule says that naturals are allowed in
19 livestock production, and some of the discussion over
20 the last couple of days by this Board has been the
21 subject of excipients and the subject of some board
22 policy to deal with excipients, and I would just like
23 the Board to consider, if there's a precedent-setting
24 action going on here, taking a natural that's allowed

1 in livestock production and looking at some of the
2 ingredients in it and putting them on the list.

3 MR. SIEMON: So, your concern is that this is
4 -- we're not talking about aloe vera. We're talking
5 about the excipient in aloe vera. So, you're saying
6 rather than --

7 MS. SHEA: That's exactly my point.

8 MR. SIEMON: Instead of looking at them as a
9 big group, we're looking at them one at a time. Is
10 that your concern?

11 MS. SHEA: I'm just sharing that the Board
12 has had discussions over the last few meetings about
13 whether or not we're even going to "go there" as far as
14 excipients and minor ingredients and some of the things
15 that are on the list of livestock items.

16 MS. BURTON: I believe this is clearly an
17 ingredient and it's a preservative. It's one that we
18 do want to list. It's labeled.

19 CHAIRMAN CARTER: Okay. So, now, let me do
20 this. Let's proceed to vote. We've got the language
21 here. We'll vote on this amendment. Then if somebody
22 wants to add an additional amendment to strike (a), (b)
23 and (d) and substitute (f) or (q) or whatever, that it
24 would be a new (g). Okay? Okay. So, we're now just

1 voting on the language change as it's been proposed.

2 Okay. I started off with Caughlan voting yes.

3 Cooper?

4 MS. COOPER: Yes.

5 CHAIRMAN CARTER: Goldberg, absent.

6 Holbrook?

7 MR. HOLBROOK: Yes.

8 CHAIRMAN CARTER: King?

9 MR. KING: Yes.

10 CHAIRMAN CARTER: Koenig?

11 MS. KOENIG: Yes.

12 CHAIRMAN CARTER: Lacy?

13 MR. LACY: Yes.

14 CHAIRMAN CARTER: O'Rell?

15 MR. O'RELL: Yes.

16 CHAIRMAN CARTER: Ostiguy?

17 MS. OSTIGUY: Yes.

18 CHAIRMAN CARTER: Riddle?

19 MR. RIDDLE: Yes.

20 CHAIRMAN CARTER: Siemon?

21 MR. SIEMON: Yes.

22 CHAIRMAN CARTER: Bandele?

23 MR. BANDELE: Yes.

24 CHAIRMAN CARTER: Burton?

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1 MS. BURTON: Yes.

2 CHAIRMAN CARTER: The Chair votes yes.
3 Passes, 13 to nothing, 1 absent.

4 Now, the floor would be open for a motion to
5 change the lettering there, if you want.

6 MR. SIEMON: It makes a lot of sense just to
7 unify this, but I'm just afraid there's other materials
8 here that need to be unified at the same time, you
9 know, that there's multiple uses. So, I kind of wonder
10 what NOP's input is on this since they're --

11 CHAIRMAN CARTER: The question's been asked.
12 NOP's guidance.

13 MR. MATHEWS: Well, that's very valid,
14 George, and I guess I have two thoughts on that.
15 Number 1. One of the things that we need to be doing
16 down the road is having the Board revisit the way the
17 entire national list is structured, so as to make it
18 more user-friendly. The second thought is that just
19 because the rest of it might not be consistent with
20 this, of putting it in one spot, doesn't make starting
21 to make improvement wrong. So, I support the idea of
22 putting it in one spot.

23 CHAIRMAN CARTER: Jim?

24 MR. RIDDLE: I'd move that this be placed in

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1 a new Section (g).

2 MS. OSTIGUY: Call it preservatives.

3 MR. RIDDLE: It could be preservatives.

4 Well, it's going to read potassium sorbate, and then we
5 could change the annotation as a preservative only for
6 use in aloe vera products.

7 MS. OSTIGUY: So, we're not going to do a
8 general category.

9 MR. HOLBROOK: I'll second that.

10 CHAIRMAN CARTER: Okay. So, the motion is to
11 have -- then to strike and create a new category,
12 Section (g), that would be entitled Potassium Sorbate.

13 MR. SIEMON: No, preservatives.

14 CHAIRMAN CARTER: Preservatives? That's what
15 -- the motion was to establish the category called
16 Potassium Sorbate. That's why I want to get that
17 clarified. Okay. So, the motion then is to create a
18 new Section (g), Preservatives, then listening
19 potassium sorbate as -- okay.

20 MS. BURTON: I'll second it.

21 CHAIRMAN CARTER: Okay. That has been moved
22 by Jim, seconded by Kim. It's open for discussion.
23 Okay. Rose?

24 MS. KOENIG: I guess I'm in agreement in the

1 fact that I think we need to really think about what
2 we're doing because the implications -- we've gone from
3 taking something that was used as a preservative and a
4 therapeutic, you know, drug to making a category of
5 preservatives for livestock. I'm just not sure we want
6 to go there. I think we need to really think about the
7 issue. I mean, this to me is a product, you know, with
8 all due respect to the gentleman in the back, that I
9 don't think is -- you know, if we don't get it on the
10 list in October, I don't think the industry is going to
11 die.

12 CHAIRMAN CARTER: Okay.

13 MS. KOENIG: It just seems like there's
14 implications in terms of the things we talked about in
15 processing, although it's not being petitioned for
16 processing. So, I'd rather err on the side of caution.

17 CHAIRMAN CARTER: Okay. George, Kim, and
18 then Mark.

19 MR. SIEMON: Would it be better, and I don't
20 have the title, to have something for substances that
21 can be used in the various categories as governed by
22 law? In other words, then it would -- there might be
23 other things in the future, and then underneath that
24 have preservatives because there's going to be other

1 ones that cut across these (a), (b), (d). Should we
2 have a place where they all fit at this time compared
3 to preservatives? I'm talking about just the main
4 title now. Instead of preservatives, should it be come
5 general?

6 CHAIRMAN CARTER: You need to couch it as
7 either you're speaking in favor or against the motion
8 right now.

9 MR. SIEMON: Well, if I was smart enough, I'd
10 figure out the friendly motion, but I'm not.

11 CHAIRMAN CARTER: Okay.

12 MS. BURTON: In the past, this Board has
13 really deferred to the NOP to put it in the appropriate
14 place, and we've made recommendations, but really it's
15 up to them to determine where to put it. We know it
16 needs to be in (a), (b) and (d). Should they choose to
17 start a new category, then I believe --

18 CHAIRMAN CARTER: Okay.

19 MS. BURTON: -- they can do that, but if
20 that's going to stop -- we have a motion to move
21 forward with this annotation. I would hate to not move
22 forward with it just because we don't know where to put
23 it.

24 CHAIRMAN CARTER: Yeah. Okay. Mark?

1 MR. KING: Okay. Just -- well, all right.
2 Concerning, I guess I can support creating a new
3 section or the recommendation to create a new section,
4 but specific to if we were to call it preservatives, I
5 mean, I just look at one of the criteria as, you know,
6 that this substance's primary use is not as a
7 preservative or to recreate, dah-dah-dah. But even so,
8 in livestock, do we want to have synthetic
9 preservatives present?

10 MS. CAUGHLAN: My confusion is coming from
11 exactly the opposite. It seems to me that any time we
12 talk about the delivery of therapeutic substances,
13 health care products, medicines, that it is to be
14 expected that there will need to be types of
15 preservation, preservatives, for them, and so I was
16 coming at this wondering why we are approving potassium
17 sorbate and linking it necessarily, limiting it to
18 aloe, when in fact if it is an effective, safe enough
19 product, I would question why we would necessarily want
20 to limit it that way, and I'm not sure that we're
21 prepared to make that decision or distinction because
22 I'm not sure we have that thorough a review, and I
23 don't think we do.

24 CHAIRMAN CARTER: Other?

1 MR. SIEMON: I'd like to just speak in favor
2 of the motion because we can always come back and
3 retitle (g) or work with it with NOP's recommendations.

4 CHAIRMAN CARTER: Okay.

5 MR. SIEMON: Can I call the question?

6 CHAIRMAN CARTER: Okay. Call the question.
7 So, the question is simply to strike (a), (b) and (d)
8 and insert (g). Okay. That's all we're voting on
9 right now.

10 MR. SIEMON: And not what the title for (g)
11 is?

12 CHAIRMAN CARTER: And (g) is, yeah, a new
13 section, Preservatives, under which potassium sorbate
14 would be listed. Okay. To the motion.

15 Cooper?

16 MS. COOPER: Yes.

17 CHAIRMAN CARTER: Goldberg, absent.

18 Holbrook?

19 MR. HOLBROOK: Yes.

20 CHAIRMAN CARTER: King?

21 MR. KING: No.

22 CHAIRMAN CARTER: Koenig?

23 MS. KOENIG: No.

24 CHAIRMAN CARTER: Lacy?

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1 MR. LACY: No.

2 CHAIRMAN CARTER: O'Rell?

3 MR. O'RELL: No.

4 CHAIRMAN CARTER: Ostiguy?

5 MS. OSTIGUY: No.

6 CHAIRMAN CARTER: Riddle?

7 MR. RIDDLE: Yes.

8 CHAIRMAN CARTER: Siemon?

9 MR. SIEMON: Yes.

10 CHAIRMAN CARTER: Bandele?

11 MR. BANDELE: Yes.

12 CHAIRMAN CARTER: Burton?

13 MS. BURTON: Yes.

14 CHAIRMAN CARTER: Caughlan?

15 MS. CAUGHLAN: Abstain.

16 CHAIRMAN CARTER: The Chair votes yes.

17 Motion fails, 7 to 5, 1 abstention, 1 absent. Okay.

18 Now, the motion that's on the table,

19 potassium sorbate should be added to 205.603(a), (b)

20 and (d), synthetic substances, allowed for use in

21 organic livestock production, in products, in aloe

22 vera, I guess, is the -- we've had a number of --

23 products formulated using aloe vera. Okay.

24 MR. SIEMON: Only for aloe vera products.

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1 CHAIRMAN CARTER: Aloe vera products. Let's
2 just say aloe vera products.

3 MR. SIEMON: Only for use in aloe vera
4 products.

5 MR. MATHEWS: Only for use in aloe vera
6 products is the way the language went.

7 CHAIRMAN CARTER: Okay. Allowed for use in
8 organic livestock production.

9 MR. KING: Should it say -- this is just
10 amending my own. Should it say for use only in aloe
11 vera products? Is that grammatically --

12 MR. MATHEWS: Well, you've got the language
13 in there with the following restriction, and then the
14 restriction is only for use in aloe vera products.

15 CHAIRMAN CARTER: Okay. Rose?

16 MS. KOENIG: Can I table that motion and put
17 forth a new motion?

18 CHAIRMAN CARTER: Well, you could put forward
19 a substitute motion.

20 MS. KOENIG: Okay. I'd like to put forth a
21 substitute motion. A motion to defer the material and
22 till October, I guess, bring it back to the Livestock
23 to come forward with a policy on preservative and
24 excipients as a total policy.

1 CHAIRMAN CARTER: Okay. So, a motion has
2 been made to defer this until October, with the
3 directive to come back with a policy on preservatives
4 and excipients.

5 MS. CAUGHLAN: Second.

6 CHAIRMAN CARTER: It's been seconded by
7 Goldie. Discussion on the motion to defer? Nancy?

8 MS. OSTIGUY: I have a question on what that
9 is going to do to change what kind of decision we'd
10 make today. We are still facing the situation where
11 this material is -- the way it's being used is as a
12 therapeutic which is really where part of the problem
13 is because if we're going to label it as a therapeutic,
14 then we run into trouble with FDA, and then if it was a
15 therapeutic, we'd actually have it under a category
16 potentially maybe of excipients. So, we'd label that
17 new category excipients.

18 Well, we can't do that because the FDA
19 doesn't recognize this as a therapeutic in animals. If
20 we don't do it as a therapeutic, then it belongs under
21 feed. We already have then the solution because it can
22 go under feed.

23 MS. KOENIG: Well, I think that is precisely
24 -- the way that you're mentally going through this, to

1 me, suggests that we don't have the information at
2 hand, maybe we're not -- we haven't thought through the
3 process enough of exactly where this thing should fit,
4 and I agree in the sense that once we start sort of
5 categorizing something, that's not to say that we're
6 always going to have to do it that way, but --

7 MS. OSTIGUY: Well, I guess I don't
8 understand what we're going to come back with, other
9 than what I just said, is we can't do it as a
10 therapeutic because the FDA does not recognize this as
11 a therapeutic. Therefore it gives us one option really
12 and that's to put it in (d).

13 MS. KOENIG: So, you want it in (d), not in a
14 separate category under preservative?

15 CHAIRMAN CARTER: The only thing that's
16 germane right now is just the motion to defer.

17 MS. OSTIGUY: Well, I'm trying to figure out
18 what the purpose -- what are we going to be bringing
19 back to the Board since I'm on the Livestock Committee.

20 MR. MATHEWS: Parity.

21 MS. OSTIGUY: Well, that's what I'm asking
22 for. I've no clue what I'm bringing back.

23 MS. KOENIG: I mean, basically, the motion
24 states that there would be a policy development. Now,

1 whether this thing fits within policy, that's to be
2 determined, but at that point, then we can either make
3 it in (d) or put it within our new policy on the two
4 types of products, if that's how -- if they have to be
5 -- if we need a category for preservative and we need a
6 category for excipients or we want to do both those. I
7 don't know what, but that's just a suggestion.

8 CHAIRMAN CARTER: George?

9 MR. SIEMON: First of all, we're not at all
10 confident we're going to have a proposal on excipients
11 by October, and with the agenda that we have, it's in
12 the public notice and everything else. Second off,
13 isn't -- didn't we say that this is on the label? This
14 is required to be on the label, and is the definition
15 of excipients relatively things not on the label?

16 CHAIRMAN CARTER: Kevin?

17 MR. O'RELL: This would be required on the
18 label because it's providing a function in the finished
19 product. So, it's required by the FDA to be labeled,
20 and we're talking about a product that is used for
21 humans that also has a role in livestock, and I think
22 we're all in agreement to allow or it seems to be that
23 we're okay with the voting on the ingredient. We're
24 just having a problem where you put it, and I don't

1 know if that should hold us up till next month.

2 CHAIRMAN CARTER: I would concur because,
3 with all due respect, NOP will always tell us where to
4 put it.

5 (Laughter)

6 MR. RIDDLE: I oppose the motion to defer. I
7 think the Livestock Committee has worked long and hard
8 on this and there's no reason, no good reason. We're
9 not sending it back for further TAP information or
10 anything like that. I think we've done our work, and
11 we should be ready to vote on it.

12 CHAIRMAN CARTER: Okay. I take that as a
13 move to vote. Okay.

14 MS. ROBINSON: There's nothing that prevents
15 the Board --

16 CHAIRMAN CARTER: You need to speak into the
17 microphone here.

18 MS. ROBINSON: Why can't you --

19 CHAIRMAN CARTER: Introduce yourself, please.

20 MS. ROBINSON: Oh, no. Barbara Robinson.
21 Why can't you go ahead and vote? That doesn't prevent
22 the Board from, in October, developing, you know, if
23 you have a stroke of genius between now and October and
24 come up with a policy or a new category, -- huh?

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1 MR. RIDDLE: You're optimistic.

2 MS. ROBINSON: You can still do that in
3 October, if there's time, and then you can go back and
4 say, hey, move that.

5 MS. KOENIG: I just didn't want to be pinned
6 in a corner.

7 MS. ROBINSON: Is the purpose of this
8 potassium sorbate just as a mold inhibitor? Because
9 that might be the category we come up with rather than
10 preservative, which you seem to object to, but mold
11 inhibitor might go over better.

12 MR. O'RELL: Maybe a microbial because it
13 also has some antimicrobial -- because it also has some
14 effective --

15 MS. ROBINSON: That's as far as I could help
16 you out. If you're going to throw more stuff in here,
17 I'm done.

18 CHAIRMAN CARTER: The question has been
19 called. This is parliamentary procedure. When
20 somebody calls the question, I take that as an informal
21 thing. We don't have to vote on the motion to call.
22 So, okay, we'll proceed to vote on the motion then to
23 defer.

24 MS. KOENIG: I will rescind that motion.

1 CHAIRMAN CARTER: Okay. The motion has been
2 rescinded. The seconder, whoever seconded it, I forget
3 --

4 PARTICIPANT: That's fine.

5 CHAIRMAN CARTER: Okay. So, now we are back
6 to the original motion that's on the table, which is
7 potassium sorbate to be added to 205.603(a), (b) and
8 (d), synthetic substances, allowed for use in organic
9 livestock production. Okay.

10 PARTICIPANT: Then only for use in aloe vera
11 products.

12 CHAIRMAN CARTER: Only for use in aloe vera
13 products. Okay. Okay. We will proceed to vote.
14 Okay. I forget where I started last time around.

15 Cooper?

16 MS. COOPER: Yes.

17 CHAIRMAN CARTER: Goldberg's absent.

18 Holbrook?

19 MR. HOLBROOK: Yes.

20 CHAIRMAN CARTER: King?

21 MR. KING: Yes.

22 CHAIRMAN CARTER: Koenig?

23 MS. KOENIG: Yes.

24 CHAIRMAN CARTER: Lacy?

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1 MR. LACY: Yes.

2 CHAIRMAN CARTER: O'Rell?

3 MR. O'RELL: Yes.

4 CHAIRMAN CARTER: Ostiguy?

5 MS. OSTIGUY: Yes.

6 CHAIRMAN CARTER: Riddle?

7 MR. RIDDLE: Yes.

8 CHAIRMAN CARTER: Siemon?

9 MR. SIEMON: Yes.

10 CHAIRMAN CARTER: Bandele?

11 MR. BANDELE: Yes.

12 CHAIRMAN CARTER: Burton?

13 MS. BURTON: Yes.

14 CHAIRMAN CARTER: Caughlan?

15 MS. CAUGHLAN: Yes.

16 CHAIRMAN CARTER: Chair votes yes. Passes,

17 13 to 0, 1 absent, no abstentions.

18 MR. SIEMON: Okay. Now, we're going to go to

19 -- that one got me rattled, now I can't find my papers.

20 Cell wall carbohydrates. Please tell me what page

21 that is.

22 PARTICIPANT: 15.

23 (Pause)

24 MR. SIEMON: All right. Everybody have that?

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1 This one we declared a natural. So, I don't know what
2 -- do we need a motion? We need to vote on it as a
3 Board as a natural? Okay.

4 CHAIRMAN CARTER: Make the motion.

5 MR. SIEMON: The motion from the Livestock
6 Committee is cell wall carbohydrates are a natural.

7 MS. OSTIGUY: Second.

8 CHAIRMAN CARTER: Okay. It's been moved by
9 George, seconded by Nancy, that cell wall carbohydrates
10 are a natural.

11 MR. SIEMON: Was that okay, I changed the
12 wording? It says should be considered.

13 CHAIRMAN CARTER: It should be considered a
14 natural. I think that keeps with the spirit of it.

15 So, discussion on the motion? Owusu?

16 MR. BANDELE: I thought one of the TAP
17 reviewers pointed out that it was not clear in terms of
18 the extraction method, thereby causing problems in
19 calling it a natural.

20 CHAIRMAN CARTER: I believe you're right.

21 Kim?

22 MS. BURTON: My justification for considering
23 it a natural, even though we don't have the
24 manufacturing process in front of it, is that it's

1 derived from baker's yeast and that is an allowed
2 natural in the processing.

3 CHAIRMAN CARTER: First of all, Jim.

4 MR. RIDDLE: It wasn't clear in the TAP
5 review, but there was follow-up research and the
6 information gathered from the producer indicated
7 extraction is aqueous, so water extraction, and that is
8 in your Summary of Opinion on the Board's report or the
9 committee's report.

10 CHAIRMAN CARTER: Mark?

11 MR. KING: Well, my question was similar.
12 Jim's answer may have covered it. But if someone else
13 from the committee wants to add to it, that I'm noting
14 two of the reviewers thought it was synthetic, and the
15 committee's saying that it's not, and so Jim, help me
16 here. I'm looking at Page 35, and I think you may have
17 just answered this, where it's synthetic or non-
18 synthetic, the reviewers are saying, "However, the
19 compound that's being petitioned here is not the yeast
20 but it's CWC." Right. Cell wall carbohydrates.
21 Specifically, dah-dah-dah.

22 So, that's his justification for saying it's
23 synthetic, and I guess I don't know if there's a
24 scientific justification for that. Maybe it was

1 clarified in your call, I don't know.

2 CHAIRMAN CARTER: Other discussion? Owusu?

3 MR. BANDELE: Jim, could you -- is there any
4 more detail available for the extraction method? Why
5 I'm asking, for example, when we dealt with the calcium
6 oxide, just the fact that it was burnt deemed it
7 synthetic, and I'm just wondering, you know, is there
8 anything else in that process that may in fact deem it
9 synthetic?

10 MR. RIDDLE: Yeah. I don't have any more
11 information. Jim Pierce, do you, on the extraction
12 method? Any more detail in terms of it being aqueous,
13 but any more information or, Dan, would you?

14 MR. SIEMON: It's basically a separation
15 process, right?

16 CHAIRMAN CARTER: Jim Pierce?

17 MR. PIERCE: We've asked the manufacturer for
18 the extraction method. There's four steps. A non-GMO
19 brewer's yeast which is hydrolyzed with a non-GMO
20 enzyme to rupture the cell walls. Step 2, the mixture
21 is subject to a water extraction to remove the cell
22 solubles and enzymes. Step 3, a further water-
23 extracted phase is used to purify the cell wall
24 composition differentiating the products. D. The cell

1 wall material is then spray dried and packaged.

2 For the record, you'll get the yeast
3 derivatives next and that's a further extraction to get
4 not just the cell walls but the actual nanosaccharides.
5 Oligosaccharides.

6 CHAIRMAN CARTER: Mark?

7 MR. KING: So, it's just yeast, the enzyme,
8 water extraction, water extraction, spray dried. I can
9 understand that.

10 MR. PIERCE: It's a very delicate product.
11 It has to be handled carefully.

12 MR. KING: That's fine. Thank you.

13 CHAIRMAN CARTER: Okay. Now, are we --

14 MR. SIEMON: Rose has a question.

15 MS. KOENIG: Yeah. I guess I was -- so, I
16 can understand where the enzymes break it up, you
17 probably put it in -- is it a water with some kind of a
18 base or something or an acid in it that -- I mean, you
19 centrifuge it, I assume, but --

20 MR. PIERCE: They didn't really say, and they
21 actually put all over this e-mail that it's
22 confidential as far as it goes.

23 CHAIRMAN CARTER: Dan?

24 DR. LEITERMAN: This is Dan Leiterman. The

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1 request to the manufacturer was to list any compounds
2 that they were using in that process. So, what we see
3 is the list that they provided, and my guess is in
4 their processing with the aqueous, that they're using
5 different temperatures and pressures to help with that
6 extraction. It's clear to me it's an enzymatic
7 hydrolysis of the cell wall ruptured and then just
8 extracted with water.

9 MR. KING: I just bring this up for point of
10 consistency in looking at natural versus synthetic, so
11 that we just have it on the record.

12 CHAIRMAN CARTER: Okay. Go ahead.

13 MR. KING: Instead of looking at how the
14 Board assesses a natural versus a synthetic, that's the
15 only reason I brought that up.

16 MS. CAUGHLAN: The heat that might be applied
17 could change its status.

18 MR. SIEMON: But there's one thing when using
19 heat to cause a chemical reaction and make it more
20 effective as compared to the separation process.

21 CHAIRMAN CARTER: Nancy?

22 MS. OSTIGUY: Same thing. We're not doing
23 any kind of chemical reaction which would be the
24 definition of synthetic.

1 MR. SIEMON: Are we ready to call the
2 question?

3 CHAIRMAN CARTER: I've been ready to call the
4 question for quite some time.

5 MR. SIEMON: Okay. Go on.

6 CHAIRMAN CARTER: Okay. Are we ready to
7 vote? Okay. Then we will proceed to vote on cell wall
8 carbohydrates as a natural. Okay.

9 Holbrook?

10 MR. HOLBROOK: Yes.

11 CHAIRMAN CARTER: King?

12 MR. KING: Yes.

13 CHAIRMAN CARTER: Koenig?

14 MS. KOENIG: Yes.

15 CHAIRMAN CARTER: Lacy?

16 MR. LACY: Yes.

17 CHAIRMAN CARTER: O'Rell?

18 MR. O'RELL: Yes.

19 CHAIRMAN CARTER: Ostiguy?

20 MS. OSTIGUY: Yes.

21 CHAIRMAN CARTER: Riddle?

22 MR. RIDDLE: Yes.

23 CHAIRMAN CARTER: Siemon?

24 MR. SIEMON: Yes.

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1 CHAIRMAN CARTER: Bandele?

2 MR. BANDELE: Yes.

3 CHAIRMAN CARTER: Burton?

4 MS. BURTON: Yes.

5 CHAIRMAN CARTER: Caughlan?

6 MS. CAUGHLAN: Yes.

7 CHAIRMAN CARTER: Cooper?

8 MS. COOPER: Yes.

9 CHAIRMAN CARTER: Goldberg? Oh, she's
10 absent. Sorry.

11 And Carter, yes. So, that passes 13 to 0, 1
12 absent, no abstentions.

13 MR. SIEMON: Okay. The next one is the
14 logical use derivative which we just heard is yet a
15 further breakdown of these many components that I never
16 even dreamed yeast derivatives had, and the motion is
17 yeast derivatives should be -- yeast derivatives are
18 natural.

19 MS. OSTIGUY: Second.

20 MR. SIEMON: Okay. It's been moved and
21 seconded that yeast derivatives are a natural. Okay.

22 Discussion?

23 (No response)

24 CHAIRMAN CARTER: Are you ready to vote? I

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1 forgot to ask last time around, but does anybody have a
2 conflict of interest on this one?

3 (No response)

4 CHAIRMAN CARTER: Then we'll proceed to vote.
5 King?

6 MR. KING: Yes.

7 CHAIRMAN CARTER: Koenig?

8 MS. KOENIG: Yes.

9 CHAIRMAN CARTER: Lacy?

10 MR. LACY: Yes.

11 CHAIRMAN CARTER: O'Rell?

12 MR. O'RELL: Yes.

13 CHAIRMAN CARTER: Ostiguy?

14 MS. OSTIGUY: Yes.

15 CHAIRMAN CARTER: Riddle?

16 MR. RIDDLE: Yes.

17 CHAIRMAN CARTER: Siemon?

18 MR. SIEMON: Yes.

19 CHAIRMAN CARTER: Bandele?

20 MR. BANDELE: Yes.

21 CHAIRMAN CARTER: Burton?

22 MS. BURTON: Yes.

23 CHAIRMAN CARTER: Caughlan?

24 MS. CAUGHLAN: Yes.

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1 CHAIRMAN CARTER: Cooper?

2 MS. COOPER: Yes.

3 CHAIRMAN CARTER: Goldberg is absent.

4 Holbrook?

5 MR. HOLBROOK: Yes.

6 CHAIRMAN CARTER: Chair votes yes. This one
7 passes 13 to 0, 1 absent, no abstentions.

8 MR. SIEMON: Okay. Last but not least,
9 proteinated chelates. I'm just trying to remember what
10 we concluded this morning. Long time ago.

11 PARTICIPANT: I think it was inconclusive.

12 MR. SIEMON: Yeah. But we did change our
13 motion, what we learned from this morning, I thought.

14 MS. OSTIGUY: George, we need to present the
15 motion as is.

16 MR. SIEMON: Okay. Chelated trace minerals
17 should be added to 205.603, synthetic substance,
18 allowed for use in organic livestock production with
19 the following restrictions, proteinated and
20 polysaccharide chelates only. Amino acid chelates are
21 prohibited.

22 CHAIRMAN CARTER: Okay. Is there a second?

23 MS. OSTIGUY: Second.

24 CHAIRMAN CARTER: Okay. It's been moved by

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1 George, seconded by Nancy.

2 Now, we're on the table for discussion.

3 MS. OSTIGUY: I'd like to make a motion to
4 send this back to the Food and Nutrition folks for
5 additional information.

6 CHAIRMAN CARTER: Okay.

7 PARTICIPANT: I would second.

8 CHAIRMAN CARTER: Okay. It's been moved and
9 seconded to send this review back to the Center for
10 Food and Nutrition or to the contractors for further
11 clarification. Okay.

12 Discussion on the motion? Jim?

13 MR. RIDDLE: Yeah. Once again, we'll need to
14 set the procedure/guidelines or deadlines for getting
15 the further information request details to Kim by
16 Wednesday.

17 CHAIRMAN CARTER: Procedures in the previous
18 one apply to this one. Okay. Understand? Other
19 questions? Comments?

20 (No response)

21 CHAIRMAN CARTER: Proceed to vote to defer.
22 Koenig?

23 MS. KOENIG: Yes.

24 CHAIRMAN CARTER: Lacy?

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1 MR. LACY: Yes.

2 CHAIRMAN CARTER: O'Rell?

3 MR. O'RELL: Yes.

4 CHAIRMAN CARTER: Ostiguy?

5 MS. OSTIGUY: Yes.

6 CHAIRMAN CARTER: Riddle?

7 MR. RIDDLE: Yes.

8 CHAIRMAN CARTER: Siemon?

9 MR. SIEMON: No.

10 CHAIRMAN CARTER: Bandele?

11 MR. BANDELE: Yes.

12 CHAIRMAN CARTER: Burton?

13 MS. BURTON: Yes.

14 CHAIRMAN CARTER: Caughlan?

15 MS. CAUGHLAN: Yes.

16 CHAIRMAN CARTER: Cooper?

17 MS. COOPER: Yes.

18 CHAIRMAN CARTER: Goldberg, absent.

19 Holbrook?

20 MR. HOLBROOK: Yes.

21 CHAIRMAN CARTER: King?

22 MR. KING: Yes.

23 CHAIRMAN CARTER: Chair votes yes. That

24 passes on a motion of 12 in favor, 1 opposed, 1 absent,

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1 no abstentions.

2 MR. SIEMON: Okay. So, that means we can't
3 go into the substantive issues tomorrow, right?

4 CHAIRMAN CARTER: That's right.

5 MR. SIEMON: I'm disappointed.

6 CHAIRMAN CARTER: This is a historic day for
7 the NOSB.

8 Okay. Let's see. Any other issues then to
9 be talked about before we recess? Yeah. Rose?

10 MS. KOENIG: I don't know if I can bring it
11 up at this point, but at lunch, we talked to the fellow
12 from the EPA, and we talked a little bit through Rick,
13 regarding kind of the EPA/NOP issues which include the
14 List 3 inerts and also the labeling program that they
15 had initiated when Carolyn was there.

16 CHAIRMAN CARTER: I'm sorry. I missed the
17 first part of your comment.

18 MS. KOENIG: Okay. At lunch, I had lunch
19 with the fellow from EPA. He was here earlier but had
20 to leave at 1:30.

21 CHAIRMAN CARTER: Okay.

22 MS. KOENIG: And we talked about, you know,
23 what was the bottlenecks as far as moving the labeling
24 program forward and the -- some of the inert

1 discrepancies, I guess, for that.

2 So, he had -- we had thought about just
3 making a very small task force to kind of deal
4 specifically with those issues, and we talked to Rick
5 about doing that, getting the NOP sanction to do that.

6 CHAIRMAN CARTER: Okay.

7 MS. KOENIG: The EPA and NOP still have to
8 talk to make sure that between those agencies, that's a
9 formal -- that will be a formal mechanism, but what I
10 wanted to do is see if we could seek Board approval
11 pending the agency's approval, but this way, it would
12 allow us to get that small task force started with
13 perhaps a minor report in October and maybe some policy
14 stuff at the meeting in October.

15 Nancy and I volunteered to kind of represent
16 the NOSB on that small task force. We probably would
17 ask Eric as a past NOSB member, probably an individual
18 from Armery, and then maybe one or two other
19 individuals that have some expertise in these types of
20 issues.

21 CHAIRMAN CARTER: Okay.

22 MS. KOENIG: So, what I was trying to do was
23 get a board approval of developing that small task
24 force, if the two agencies agree that that can be done.

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1 CHAIRMAN CARTER: Okay. Do you want to make
2 that in the form of a motion then, that the Board
3 designate a task force?

4 MS. KOENIG: Yeah. I guess, unless -- so,
5 the motion would be that the Board would, I guess,
6 appoint Nancy and myself to head up a task force to
7 deal with the EPA/NOP-related issues, and the Board
8 would include up to five other individuals.

9 CHAIRMAN CARTER: Okay. The motion I'd
10 prefer is just to authorize the Chair to designate a
11 task force and that would give us some flexibility to
12 do that.

13 MS. KOENIG: Okay.

14 CHAIRMAN CARTER: Okay. Is there a second to
15 the motion?

16 PARTICIPANT: Second.

17 CHAIRMAN CARTER: Okay. The motion's been
18 made and seconded to authorize the Chair to appoint a
19 task force to work with EPA on the issues that Rose has
20 identified.

21 So, discussion on the motion?

22 (No response)

23 CHAIRMAN CARTER: Okay. If you're ready to
24 vote.

1 Lacy?
2 MR. LACY: Yes.
3 CHAIRMAN CARTER: O'Rell?
4 MR. O'RELL: Yes.
5 CHAIRMAN CARTER: Ostiguy?
6 MS. OSTIGUY: Yes.
7 CHAIRMAN CARTER: Riddle?
8 MR. RIDDLE: Yeah.
9 CHAIRMAN CARTER: Siemon?
10 MR. SIEMON: Yeah.
11 CHAIRMAN CARTER: Bandele?
12 MR. BANDELE: Yes.
13 CHAIRMAN CARTER: Burton?
14 MS. BURTON: Yes.
15 CHAIRMAN CARTER: Caughlan?
16 MS. CAUGHLAN: Yes.
17 CHAIRMAN CARTER: Cooper?
18 MS. COOPER: Yes.
19 CHAIRMAN CARTER: Goldberg, absent.
20 Holbrook?
21 MR. HOLBROOK: Yes.
22 CHAIRMAN CARTER: King?
23 MR. KING: Yes.
24 CHAIRMAN CARTER: Koenig?

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1 MS. KOENIG: Yes.

2 CHAIRMAN CARTER: Chair votes yes. Passes,
3 13 to nothing, no abstentions, 1 absent.

4 Okay. Other issues to talk about today?

5 MR. SIEMON: Well, in my -- were there
6 assignments that the Livestock Committee had? You kept
7 saying tonight, we're going to do something. I can't
8 remember that. What was the assignment? I'm serious.
9 There was something you were saying earlier we're
10 going to do tonight.

11 CHAIRMAN CARTER: I'm giving George homework
12 tonight.

13 MR. SIEMON: I'm getting homework instead of
14 drinking. I can't remember what they were. I'm sorry.
15 You said we'll have to take care of that tonight.

16 CHAIRMAN CARTER: Was it in relation to
17 furosemide?

18 MR. SIEMON: I'm sorry.

19 CHAIRMAN CARTER: Yeah. It seemed like one
20 of these.

21 MR. SIEMON: The convenient memory lapse.

22 CHAIRMAN CARTER: Yeah. Okay. Sending that
23 one back.

24 MR. SIEMON: Anybody help me out here?

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1 CHAIRMAN CARTER: Atropine, heparin, calcium
2 proportionate, activated charcoal, mineral oil. I
3 guess you're off the hook, George. It's beer-drinking
4 time tonight.

5 MR. SIEMON: I will look.

6 CHAIRMAN CARTER: Okay. Mark?

7 MR. KING: This is actually just more of an
8 announcement or a reminder, if you will. I mentioned
9 very briefly and not so enthusiastically yesterday that
10 we are looking at a guidance document to determine the
11 difference between things like handling, post-harvest
12 handling and processing, and if you have experience in
13 that area, ideas, input that you think would be
14 valuable, that's something that probably not just the
15 committee but the Board will be looking at in the
16 coming months to provide further guidance in the
17 industry. So, that's all.

18 CHAIRMAN CARTER: Anything else?

19 (No response)

20 CHAIRMAN CARTER: Okay. As I mentioned at
21 the outset this morning, Mike Lacy has had a death in
22 the family, so he's leaving this afternoon and will not
23 be here tomorrow. So, his absence will be excused, and
24 Mike, our thoughts are with you as you travel home.

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1 MR. LACY: Thank you.

2 CHAIRMAN CARTER: So, with that, at 4:00, we
3 stand recessed until 8:00 tomorrow morning.

4 (Whereupon, at 4:00 p.m., the meeting was
5 adjourned, to reconvene tomorrow morning, Thursday,
6 September 19th, 2002, at 8:00 a.m.)

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