

NOSB RECOMMENDED DECISION FORM

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: _____		Substance: <u>Tetracycline</u>	
A. Evaluation Criteria (Applicability noted for each category; Documentation attached)		Criteria Satisfied? (see B below)	
1. Impact on Humans and Environment		Yes ☒	No ☐ N/A ☐
2. Essential & Availability Criteria		Yes ☐	No ☒ N/A ☐
3. Compatibility & Consistency		Yes ☐	No ☒ N/A ☐
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)		Yes ☐	No ☐ N/A ☒
B. Substance fails criteria? Criteria category: <u>2 and 3</u> Comments: Only marginally passes Criteria category #1		C. Proposed Annotation: <u>Tetracycline- For fireblight control only with expiration date of 10/21/2012</u> Basis for annotation: To meet criteria above: _____ Criteria: _____ Other regulatory criteria: _____ Citation: _____	
D. Final Board Action & Vote (State Actual Motion): <u>Add Tetracycline –For use only for fireblight control until 10/21/2012 as listed on the National List §205.601(i)</u>			
Motion: <u>D.Giacomini</u> Second: <u>T.Miedema</u> Yes: <u>13</u> No: <u>0</u> Abstain: <u>1</u> Absent: <u>1</u>			
Agricultural	☒	Nonagricultural	☒
Synthetic	☒	Not synthetic	☐
Allowed ¹	☒	Prohibited ²	☐
No restriction	☐	Deferred ⁴	☐
Provide a summary narrative here or attach a more complete narrative, and attach the original committee recommendation that includes the evaluation criteria checklist: Two forms of tetracycline are registered by the EPA for use in apples and pears for fireblight control. Previously, only one form was specifically listed on the NOP National List of allowed synthetic materials in organic crop production. This recommendation changes the listing to generic tetracycline and places an expiration date of 10/21/2012 on the use of all forms.			
1—substance voted to be added as “allowed” on National List to § 205.601(i) with Annotation (if any): <u>For fireblight control only with expiration date of 10/21/2012</u>			
2—substance to be added to “prohibited” paragraph of National List to § 205. _____ Describe why a prohibited substance: _____			
3—substance was rejected by vote for amending National List to § 205. _____ Describe why material was rejected: _____			
4—substance was recommended to be deferred § 205. _____ Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow-up _____			
E. Approved by NOSB Chair to transmit to NOP <u>Rigoberto Delgado</u> Chair <u>11/19/2008</u> Date			
F. NOP Action: <u>Include in FR to amend National List:</u> Return to NOSB Reason: _____ _____ Date _____			

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: November 2008

Substance: Tetracycline (oxytetracycline hydrochloride)

Committee: Crops ☒ Livestock ☐ Handling ☐ Petition is for: Adding Tetracycline (oxytetracycline hydrochloride), for fire-blight control only on the National List § 205.601(i).

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

- | | | | |
|--|---|--|------------------------------|
| 1. Impact on Humans and Environment | Yes ☒ | No ☐ | N/A ☐ |
| 2. Essential & Availability Criteria | Yes ☐ | No ☒ | N/A ☐ |
| 3. Compatibility & Consistency | Yes ☐ | No ☒ | N/A ☐ |
| 4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) | Yes ☐ | No ☐ | N/A ☐ |

B. Substance Fails Criteria Category: 2 & 3 Comments: Material only marginally satisfies Criteria #1. Fails Criteria #2 since other organically compliant disease control options exist. Pear and apple growers exporting to Europe, where antibiotics are not allowed, are already achieving some measure of fireblight control without the material. It fails Criteria #3 on compatibility with public perception that antibiotics are not used in organic production, and on consistency within the NOP regulations that do not allow antibiotic use in any other section of the Rule. The committee views this incompatibility and inconsistency with organic farming principles as potentially damaging to the reputation of the organic label overall. Considering the intense on-going public comment that the committee has been receiving on the negative public health impacts of these materials, the committee anticipates that a petition will be filed for the removal of tetracycline and streptomycin from the National List before their sunset date of October 2012. Adding a new form of tetracycline to the list at this time would be counterproductive.

C. Proposed Annotation (if any): _____

Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____

D. Recommended Committee Action & Vote (State Actual Motion): Adding Tetracycline (oxytetracycline hydrochloride), for fire-blight control only on the National List § 205.601(i)

Motion by: J.Moyer Seconded: T.Ellor Yes: 0 No: 6 Absent: 0 Abstain: 0

Crops	X	Agricultural		Allowed ¹	
Livestock		Non-Synthetic		Prohibited ²	
Handling		Synthetic	X	Rejected ³	X
No restriction		Commercially Un-Available as Organic ¹		Deferred ⁴	

1) Substance voted to be added as "allowed" on National List to § 205. _____ with Annotation (if any) _____

2) Substance to be added as "prohibited" on National List to § 205. _____ with Annotation (if any) _____

Describe why a prohibited substance: _____

3) Substance was rejected by vote for amending National List to § 205.601(i)(10) Describe why material was rejected: Material fails evaluation criteria 2 and 3 (See comments listed above in section B.

4) Substance was recommended to be deferred because _____ If follow-up needed, who will follow up _____

E. Approved by Committee Chair to transmit to NOSB:

Gerald Davis
Committee Chair

08/20/2008
Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance – Tetracycline (oxytetracycline HCl)

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		X		TR: Line 163-164
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		TR: Line 174-175
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		TR: Line 188-191
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		TR: Line 200-202
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X	X		No: TR Line 210-212 (Based on original EPA estimation) Yes: Potential detrimental effects on soil bacteria. Short term effects on pond sediment microorganisms from veterinary tetracycline mentioned in TR. Antibiotic resistance genes found in soil bacteria provide a gene pool that has been shown to be potentially transferable to human pathogens. 'Sampling the Antibiotic Resistome' by V. M. D'Costa et al. Science 20 January 2006 Vol. 311 No. 5759 pp. 374-377 and 'Mechanisms for Resistance in Soil' by Stuart B. Levy, et al.; Science 28 April 2006; Vol. 312, No. 5773 pg. 529. 'Antibiotic use for Plant Disease Management in the United States' Patricia S. McManus and Virginia O. Stockwell in <i>Plant Health Progress</i> 27 March 2001 http://apsnet.org/education/feature/antibiotic/top.htm .
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X	X		TR: Line 217-223 Potential detrimental effects expected to be mitigated with proper use in orchard system See also Question #6
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X	X		TR Line 232-256 Toxicological studies on rodents show no adverse effects, except to a limited extent at extremely high dosages. Human medicinal use side effects and allergic reactions do occur.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		TR: Line 261-270 Degradation half-life varies from 30 days (freshwater) to 10 weeks in pond sediments. Adsorbed and inactivated in dry soils.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	X	X		Chronic dietary intake and occupational exposure risks are considered to be negligible by EPA. EPA pesticide label regulation on minimizing allergic reaction risks concerning spray application workers. (TR: Line 275-293) Recently published scientific commentaries address concern with antibiotic resistance gene transfer from bacteria species in the agro-ecosystem to human pathogens, resulting in potential human health issues due to loss of efficacy in medicinal use antibiotics. 'Sampling the Antibiotic Resistome'

				by V. M. D'Costa et al. Science 20 January 2006 Vol. 311 No. 5759 pp. 374-377 and 'Mechanisms for Resistance in Soil' by Stuart B. Levy, et al.; Science 28 April 2006; Vol. 312, No. 5773 pg. 529. 'Antibiotic use for Plant Disease Management in the United States' Patricia S. McManus and Virginia O. Stockwell in <i>Plant Health Progress</i> 27 March 2001 http://apsnet.org/education/feature/antibiotic/top.htm .
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			X	
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			X	
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			X	

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production? Substance - Tetracycline (oxytetracycline HCl)

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X	X		Parent material formed by natural fermentation process. Material as formulated may or may not have undergone chemical change during manufacture.
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	X	X		See above- question #1. Tacit acknowledgement of chemical change during manufacture, as material is petitioned as a synthetic substance to be added to the National List.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X	X		See above- question #1
4. Is there a natural source of the substance? [§205.600 b.1]			X	
5. Is there an organic substitute? [§205.600 b.1]			X	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X	X		Available natural biological control materials are not adequate to control the serious damage caused by the fireblight organism. Effective natural products containing <i>Bacillus subtilis</i> , <i>B. pumilis</i> and others available for stone fruit (nectarine and peach) disease control.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
9. Is there any alternative substances? [§6518 m.6]	X			Peracetic acid for fireblight control is partially effective. Some Washington state pear growers (for European export) achieving some measure of fireblight control without tetracycline, which is not allowed by Euro. Organic rules. Hydrated lime is used in stone fruit for disease control. Copper fungicides only marginally effective due to phytotoxic properties on crop leaves and fruit. (TAP Line 314-330)
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Apple and pear varieties exist with limited to some resistance against fireblight. Careful soil site selection (well drained) is useful in disease control. (TAP Line 342-343)

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 3. Is the substance compatible with organic production practices? Substance - Tetracycline (oxytetracycline HCl)

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			X	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		X		Antibiotics of this type are disallowed for any other uses in the USDA/NOP regulations. Marketing claims of organic products of many kinds state that no antibiotics are used. Public perception to a high degree expects that no antibiotics are used.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]			X	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			X	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:				
a. copper and sulfur compounds;		X		
b. toxins derived from bacteria;	X			
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		
d. livestock parasiticides and medicines?		X		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]

Substance - _____

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. <u>Is the comparative description provided</u> as to why the non-organic form of the material /substance is necessary for use in organic handling?				
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?				
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling?				
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling?				
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:				
a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;				
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;				
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or				
e. Are there other issues which may present a challenge to a consistent supply?				

National Organic Standards Board (NOSB)

Tetracycline Hydrochloride Vote

Excerpts from

November 19, 2008 Transcripts

1st Vote, Motion to List Failed: pp.129 - 148

2nd Vote, Motion to Reconsider, Passed: pp 191 - 194

**3rd Vote, Motion to List with October 2012 Expiration date on
all forms of Tetracycline, Passed: pp 195 - 212**

MR. DAVIS: The next one would be materials. The first one on the list would be tetracycline, tetracycline hydrochloride to be specific. The committee met this morning and discussed the public comment that was received and the discussions yesterday on the relative merits of leaving the petition as is for - as a petition for adding tetracycline - oxytetracycline hydrochloride specifically, for fire blight control only on the national lands to apply 601I leaving it as it stands versus the idea of changing it to amend the annotation of the existing material on the list, which is tetracycline - oxytetracycline calcium. This is a different material, different CAS number, we felt it would be problematic to go about it that way to list - to present it

as a - just an addendum change - an annotations change,
excuse me - and prefer to just let it go forward as is.

MR. DELGADO: So you want to state the motion?

MR. DAVIS: The motion would be to -

MR. DELGADO: You are moving to add? You are
going with the addition of this material, correct?

MR. DAVIS: Right. The motion is to add this
material to the national list as stated on the
recommendation.

MR. MOYER: I'll second it.

MR. DELGADO: Seconded. It is moved and seconded
that - you have a question? State the question?

Let me state the question. I was confused by the
indication there. It is moved and seconded to add
tetracycline - oxytetracycline hydrochloride for fire blight
control only onto the national list, Section 205.601(I).

Discussion? Joe?

MR. SMILLIE: Sorry, but I'm a little bit confused
on this in two areas. The first area is, and correct me
where I'm wrong, Jerry and Jeff, but the first area is, if we
added it as an annotation which you are not going to do, but
if we had done that then it would provide a level playing

field for the petitioner but would not extend the use of tetracycline in general; it would sunset at the same time as the current material is going to sunset; is that correct?

MR. DAVIS: That is correct.

MR. SMILLIE: But you decided not to do that? You have decided not to change the annotation?

MR. DAVIS: We went with the original petition which was to add this material?

MR. GIACOMINI: Could we check with the program on that issue? It seems to me a reevaluation of this substance and this listing by the board could reset that clock. Could we please ask the program for clarification on that?

MR. DELGADO: Certainly -- comment on that for us. If we change the annotation would it extend in anyway the sunset provisions on that? Of the calcium materials in this case?

MR. GIACOMINI: If it's a reevaluation of an existing list to change an annotation, is that considered a review by this committee of this substance? And if that annotation is changed in the Federal Register would that reset the clock?

MR. MATTHEWS: We don't believe it would.

MR. DELGADO: The program does not believe that would be affected. So Joe, with that statement, is that clarified?

MR. SMILLIE: Rather than get caught up in parliamentary language, here is my intent, and sorry, maybe I'm not phrasing it properly. My intent is to offer a level playing field to the petitioner. That doesn't extend to the use of tetracycline. So my vote would be, I want to see the petitioner get a level playing field, but if that means extending the use of tetracycline I would vote no.

So I want to vote my intention, which is to give the petitioner a level playing field with a competitor who uses the same product currently allowed under the regulation, but if that's best accomplished by adding this material, then I could be comfortable with that. But if by adding the material we move the sunseting of that tetracycline farther along then I wouldn't be comfortable.

Am I explaining myself correct?

MR. DELGADO: Hugh.

MR. KARREMAN: I understand what you're saying totally, Joe, and as to the rationale, I feel the same way. I think that we need to look at this material in the way

we're looking at it, and it's tetracycline is the active compound. The salt of this particular tetracycline is kind of to level the playing field, but the active is tetracycline. So if it doesn't reset the clock - and it shouldn't, it should not, because tetracycline is already on there, and we are just kind of saying, well, this color of tetracycline is -- not to get any color, sorry, sorry -- but you know that this is just embellishing what is already there, but the main top one is going to go away, whenever it does. I agree with that and I hope it is that way, if that is the motion; I want to hear that for sure.

MR. DELGADO: Dan and Jeff.

MR. GIACOMINI: I agree with Joe and Hugh, and I think that as Gerry described, whether it was problematic depends on how the annotation is attacked. If the annotation is attacked by adding this substance to the list that is already there, of adding a second item in the parentheses, you have a CAS number problem, and you have other problems.

If the annotation is attacked by deleting that in the parentheses, I don't think you have that problem. I think you accomplish the same thing. I think you level the playing field, and I am - maybe I'm being a little

schizophrenic, but I have a problem adding a separate listing. I'm not comfortable adding another item in the annotation. I'm very comfortable deleting that between the parentheses, and at the same time I have no problem at all if at the next meeting we have a petition to remove tetracycline, and I vote for that to happen.

I have no contradictions in all those things.

MR. DELGADO: Joe.

MR. MOYER: Yes, two points. One is, I believe at the last meeting when this was discussed, the program did tell us that it reset the clock. So I do think I'd want a clarification on that before we vote.

The second point is, I think removing bracketed information on annotations is a little bit of a risky slippery slope. There are reasons that many of these annotations were put on, and different formulations of different material react differently in the environment, and within the context within which they are being applied.

And I just think we have to be careful as we look at all these materials that we don't just look at base ingredients and assume that everything else that is being done there is okay moving forward.

MR. DELGADO: Bea followed by Hugh.

MS. JAMES: I would agree with what Jeff just said, and because it was clear yesterday during comment that it was a separate CAS number that it should be looked at separately.

MR. DELGADO: Hugh?

MR. KARREMAN: I'm not an agronomist, obviously, but I would honestly, I understand what you are saying, Jeff, but it's tetracycline; it's not the hydrochloride. And it's a different CAS number. It could reset the clock. I would rather just see that parenthesis taken out of there. And it's tetracycline, whoever set it, let's kill it soon, but let's not reset clocks and all that if we don't have to.

MR. DELGADO: Barbara?

DR. ROBINSON: Well, I think to your point, Jeff, on the annotation, I think the point is that the annotation is for the purpose of the tetracycline, and the purpose is for fire blight control only. That's really what you are annotating here. It's tetracycline for fire blight control; that's what you want.

MR. DELGADO: It's actually not the annotation. Just for clarification, it's actually the title -

DR. ROBINSON: The original annotation says, tetracycline in parenthesis, oxytetracycline calcium complex. What you want - what you'd be doing is just removing that parenthetical, oxytetracycline calcium complex. So you'd be left with tetracycline for fire blight control only, which would allow the forms of tetracycline, which is what the petitioner has asked for: tetracycline.

MR. MOYER: But it does have a separate CAS number, and is for all intents and purposes.

DR. ROBINSON: Right, but EPA says that these forms are all functionally equivalent for fire blight control. That's what the petitioners said, so that's what we'd be allowing under the same clock.

MR. MOYER: And the second question was whether the clock will be reset as you stated, Jeff, and the question again is no - the answer is no.

DR. ROBINSON: And that's what we would put in the rule. That the clock does not change.

MR. DELGADO: The clock does not change. Bea followed by Jennifer and then Jerry.

MS. JAMES: So my question for Jerry then is, by creating this level playing field are we then making it so

that there are two forms of tetracycline that are being used?

MR. DELGADO: Jerry?

MR. DAVIS: Effectively I think the petitioner stated it accurately when they said that there would be two forms of tetracycline, but the overall use pattern of tetracycline would not increase. There would just be a substitutionary effect at the whim of the marketplace on which one they wanted to choose.

MR. DELGADO: Jennifer.

MS. HALL: Just for clarification, the -- is not here, did - oh, he said he was leaving, sorry - he did assess this and say yesterday that he did not intend to reset the clock; that the standing sense, that was fine.

MR. DELGADO: Steve.

MR. DeMURI: Jerry, there are other members that are experts in this area, are there other forms of tetracycline that would fall into this category later on?

MR. DELGADO: Jerry.

MR. DAVIS: I can't state that for sure. I don't remember from the EPA documents that we went over whether there are additional forms. You'd have to ask that maybe of the petitioner if you wanted to know that. There's none on

the marketplace that I know, but I don't know if there are technical forms that could arise.

MR. DELGADO: Could the petitioner please address that question?

MR. RICHARDSON: Paul Richardson with AgroSource. And there are currently only the oxytetracycline base material, oxytetracycline hydrochloride and oxytetracycline calcium registered with EPA. And those are the only forms that I would be aware of that would potentially be used in agriculture, and even the base is not used in agriculture, because its form is really just the hydrochloride or the calcium.

MR. DELGADO: Tina.

MS. ELLOR: And that was basically question and what came up in our discussions is that we didn't know how many forms there were, and if you took the parenthetical, you know -- we didn't know what kind of door we'd be opening, and really felt like we had to review all of those individually for their effects on the environment.

MR. DELGADO: Bea.

MR. DAVIS: In reading the EPA documentation they do not delineate the different forms of tetracycline as

having any different environmental or human health effects.

MR. DELGADO: Bea?

MS. JAMES: My question is, why do we want to create a level playing field for a material that we don't think should be on the list anyway - some of us?

MR. DELGADO: Joe.

MR. SMILLIE: Because it's just fair.

MS. JAMES: In one aspect.

MR. DELGADO: Hugh.

MR. KARREMAN: Bea, I guess the intent, roughly stated by a few of us here, is to get rid of tetracycline. His petition and his public comment basically said, he's squeezed out of market price because - it's to be just and fair. That's why I agree. And I'm not even in favor of this material, but I agree with that rationale.

MS. JAMES: So is our duty to be just and fair to the manufacturer or to the organic principles?

MR. KARREMAN: Well, right now, an organic producer, whatever the crop it's used on will be buying it from the other guy. It's not like they are not going to use it. He's just asking that he has fair competition in the marketplace. It's not like it's not allowed right now in

organic production; it is.

MR. DELGADO: Barry.

MR. FLAMM: One of the things we discussed at length in committee was the intent to remove them - these substances through the sunset process. And in that connection we discussed what kind of message approving any new form.

And the petition we had before us is what we addressed, and addressed carefully the second go-round. We did it at the last meeting, and then pulled the vote at the last minute, and we are sort of going around the same block again.

I'm concerned if we change the committee's deliberation on this.

MR. DELGADO: Barbara.

DR. ROBINSON: Mr. Chairman, we just consulted with our attorney, and it will change the clock. It will change the clock. It will change the clock. Your annotation change does change the clock.

MR. MATTHEWS: Yes, it's considered - even by removing the annotation it's looked at as if you have reconsidered the material and therefore the clock resets.

DR. ROBINSON: I apologize.

MR. DELGADO: Dan.

MR. GIACOMINI: If we are held to the standard of only reevaluating new material at sunset, and I understand that everybody is allowed to make their vote - I'm not aware of a lot of new information that has come to light or will or likely will come to light. We know what this does, and we would like to get it off. The way to get it off is a petition to remove. It's still a matter of what is fair and just and equitable. We're not adding anything new.

I question whether we are affecting the rate - the point in time when we can remove it by the fact that we are changing - resetting the clock and redoing sunset. I still think it's the right thing to do. I still hope somebody submits a petition to remove it.

MR. DELGADO: Hugh.

MR. KARREMAN: When is the sunset - when will the current listing go?

MR. DELGADO: Jeff.

MR. MOYER: Just to follow up on what Barry said, I think as a board we have to be careful about the message we send to the community when we reevaluate this, and that is

what we are doing is reevaluating it and extending the life expectancy of this material for another two years, we have to be careful about that. And that did come up in our deliberations in our committee - five more years. Three from the previous.

MR. DELGADO: Any other questions or comments?

The motion stands then as it is? Okay, I'll put the motion, and the question is on the motion to list tetracycline - oxytetracycline hydrochloride for fire blight control only on the national list, Section 205.601.

And we'll start taking the vote with Bea?

MS. JAMES: No.

MR. DELGADO: Jerry.

MR. DAVIS: No.

MR. DELGADO: Tina.

MS. ELLOR: No.

MR. DELGADO: Tracy.

MS. MIEDEMA: Yes.

MR. DELGADO: Joe.

MR. SMILLIE: No.

MR. DELGADO: Barry.

MR. FLAMM: No.

MR. DELGADO: Hugh.

MR. KARREMAN: No.

MR. DELGADO: Kevin.

MR. ENGELBERT: No.

MR. DELGADO: Jennifer.

MS. HALL: No.

MR. DELGADO: Steve.

MR. DeMURI: No.

MR. DELGADO: Julie.

MS. WEISMAN: No.

MR. DELGADO: Dan.

MR. GIACOMINI: No.

MR. DELGADO: Jeff.

MR. MOYER: No.

MR. DELGADO: And the chair votes no.

MR. MOYER: Mr. Chairman, we have one yes, 13
noes, and one absent.

MR. DELGADO: The noes have it, and the motion to
list tetracycline oxytetracycline hydrochloride in Section
205.601(I) of the list is lost.

Let's proceed with the next.

MR. DELGADO: Let's move on to our next topic. But before

that, it is my understanding that the chair of the Materials Committee would like to make a special motion; is that the case?

MR. GIACOMINI: Mr. Chairman, I move to reconsider the vote on the listing of tetracycline.

MR. SMILLIE: Second.

MR. DELGADO: It is moved and seconded to reconsider the vote on tetracycline.

MR. FLAMM: Discussion? Mr. Chairman, would you please explain the reasoning for that?

MR. GIACOMINI: We have new information regarding possible action on this petition that we think is worth considering at this time.

MR. DELGADO: Can we have background about the new information? And I would request the program to address that.

MR. GIACOMINI: Do we want to address that now or do we want to do that at the point in time that that further motion is made, the motion to reconsider?

MR. DELGADO: To reconsider, we'll do that and then we'll go on to vote that if the motion passes.

Any questions? Are we ready for the question on

the motion? The question is on the motion to reconsider tetracycline.

This is the vote that we just took. Is there any doubt on the part of the board as to what we are doing?

Okay, and the question is on the motion to reconsider the vote on tetracycline.

And I'll start the vote with Joe.

MR. SMILLIE: Yes.

MR. DELGADO: Barry.

MR. FLAMM: We're not going to have an explanation of why we are doing that?

(Simultaneous speakers.)

MR. DELGADO: Once again we are going through the motion to reconsider evidence on tetracycline.

Once we have approved the motion, if it is approved, then we will continue on to reconsider the motion and do the vote again. That's where we are.

It is the understanding -

(Simultaneous speakers.)

MR. FLAMM: Abstain.

MR. DELGADO: We'll continue then with Hugh.

MR. KARREMAN: Yes.

MR. DELGADO: Kevin.

MR. ENGELBERT: No.

MR. DELGADO: Jennifer.

MS. HALL: Yes.

MR. DELGADO: Steve.

MR. DeMURI: Yes.

MR. DELGADO: Julie.

MS. WEISMAN: Yes.

MR. DELGADO: Dan.

MR. GIACOMINI: Yes.

MR. DELGADO: Jeff.

MR. MOYER: Yes.

MR. DELGADO: Bea.

MS. JAMES: Abstain.

MR. DELGADO: Jerry

MR. DAVIS: Yes.

MR. DELGADO: Tina.

MS. ELLOR: Yes.

MR. DELGADO: Tracy.

MS. MIEDEMA: Yes.

MR. DELGADO: And the chair votes yes.

MR. MOYER: Okay, Mr. Chairman, we have 11 yeses

and one absent and two abstentions.

MR. DELGADO: The yeses have it, and the motion is agreed to.

MR. GIACOMINI: Mr. Chairman.

MR. DELGADO: Let us just confirm that we have the right number here.

The yeses have it, and the motion is agreed to.

And we'll start immediately with a motion, tetracycline if that's the case. Are you going to move that?

MR. GIACOMINI: I move to amend the motion on the listing of tetracycline to read, to change the annotation - the listing and annotation of tetracycline to read: tetracycline for use only in organic crop production for fire blight control until October 21st, 2012.

MR. DELGADO: Is there a second?

MS. MIEDEMA: Second.

MR. DELGADO: It is moved and seconded to - and let me make sure that I state this right - remove the annotation and replacing that with, for use - tetracycline for use only for fire blight control until October 21st, 2012, as listed on the national list, Section 205.601(I).

Is that correct?

MR. GIACOMINI: Yes.

MR. DELGADO: But we are replacing that with the annotation that it can be used only until October 21st, 2001. You have it there? Great.

Any other questions. Barry.

MR. FLAMM: Does that mean that all forms of tetracycline? And that changes the current list? And how do we do that?

MR. DELGADO: Good question, dan.

MR. GIACOMINI: This motion to change the annotation does a couple of different things, how many depends on how you add them up. The first thing that it does is, it removes the qualifier of what type of tetracycline can be used at this time.

The next thing that it does is, it sets an expiration date for the use of tetracycline in crop production for fire blight control.

The implication of that is that it pulls tetracycline out of the normal sunset process, and - i.e. think Methionine - it is now an expiration date for the use of tetracycline for this use. It is not a sunset item. And in order for it to continue use after that date it would have

to be re-petitioned, as we do with methionine, as we did at the last meeting.

Those are the things that this amendment would accomplish.

MR. FLAMM: But just for the record and for clarification, what we're voting on is all forms of tetracycline that will have the expiration date as listed; therefore, not requiring the normal sunset process.

MR. GIACOMINI: It moves it out of the normal sunset.

MR. FLAMM: Okay, so our vote would be based on those conditions.

MR. GIACOMINI: The first vote is the amendment to change the original motion. If this fails we would then need to revote on the original motion because we are looking to reconsider it. So the first thing is whether we are agreeing to change the original motion. The next vote that will be required is to vote on the new listing motion.

MR. FLAMM: But I think we ought to be what's in the record, what we are intending to do, so that it doesn't get changed down the road somehow.

MR. DELGADO: Okay, so with the comments of the

materials chair, the intent is clear.

Would you like to add another - just as a comment. Kevin?

Can you repeat that, we are having problems hearing you?

MR. ENGELBERT: I'm just concerned about the process that we're going through putting it back on the table after it has already been voted down.

MR. DELGADO: Hugh followed by Judy.

MR. KARREMAN: Let me ask this. If we are opening this back up, can we - I apologize for my scratchy voice today - okay, we put the date whatever it is something 2012, I mean technically right now could we make it 2010?

MR. GIACOMINI: The date - we could make it any date we want. The date chosen is the expiration date of the current sunset.

MR. KARREMAN: So in other words if this is alive and well right now it may not be shortly. If I were to make an amendment to make it die in 2009. I mean is that possible to do at this time if we are opening this back up? I just wanted to know that.

MR. DELGADO: Bea.

MS. JAMES: I support Hugh's suggestion.

MR. DELGADO: You haven't made an amendment, have you?

MR. KARREMAN: I just wanted to know if it's possible. I did not make an amendment. I just wanted to know if it was possible.

MR. DELGADO: Hugh.

MR. KARREMAN: All right, I will make an amendment. I will move that tetracycline's expiration date be changed from what's showing on the screen, if you could show that please, Valerie, from October 21st, 2012, to December 31st, 2009.

MR. DELGADO: Dan?

MR. GIACOMINI: I don't oppose it, but I think it's worth a board vote on that, so I'll say no.

MR. DELGADO: Okay. So we have a friendly amendment. Is there a second?

MS. JAMES: I second it.

MR. DELGADO: It has been moved and seconded to amend the motion by striking out the date of 10/21/2012 by December 31st, 2009.

Discussion? Jerry?

MR. DAVIS: I can appreciate the board members who really would like to see this material be off the list. I do not think that is fair to the pear growers to - unless they supposedly should have been, could have been, maybe found some other alternatives by now but they haven't. They are in their infancy in the alternate control measures, and they could really use the extra time to get it done.

MR. DELGADO: The program, followed by Joe.

DR. ROBINSON: Well, now you are going to veer off into some other areas, once you do this. Now you - a couple of things. Number one, if you do this, and you are successful just as a practical matter you are pushing the program on the rulemaking side of things, 2009.

And number two, the original tetracycline was on until 2012, even if we were successful in getting the rule out, first of all we'd have to answer to OGC as to now why we are doing that, and then you are liable to get a lot of push back in public comment for why you are interfering with an existing annotation there. It looks a little arbitrary and capricious on that side. Whereas before you were just taking advantage of an opportunity to do what - to eliminate a synthetic that you don't want on the list.

So - yes.

MR. DELGADO: Joe followed by Hugh.

MR. SMILLIE: I agree with what Gerry and Barbara have got to say. I think that the key, though, that's going too far, it's not being fair. Think about the methionine, that's an example, I think about this case. And we are going to act judiciously. We all agree we want it to go, but I don't think we should use this to push back. We've got 2012 already. We are sticking with 2012. We're just leveling the playing field. But then we get a drop-dead date, which is better than where we were before.

MR. SMILLIE: I agree with that, and if possible, I guess I will withdraw that amendment, if that's parliamentary -- possible, and stick with the date that we have here to allow the growers to hopefully find substitutes for that material prior to the end of 2012.

MR. DELGADO: Do you agree to withdraw the motion?

MR. KARREMAN: I am withdrawing the motion. If it is possible.

MR. DELGADO: It is possible. You have to have agreement of the second to do so. Any pressure?

MS. JAMES: I feel a lot of pressure, because I

don't see what the benefit is of us making this change and reopening it if we -

MR. DELGADO: Tina?

MS. ELLOR: The benefit would be that it would no longer be subject to the normal sunsets, and it would drop off. To me, that's a pretty significant benefit.

MS. JAMES: Well, I guess in my short time in observing sunset, things don't just drop off. And there's no point in not agreeing to go ahead and withdraw it, because if everybody else is saying, let's do it, it'd be a waste of a vote. So I accept that.

MR. DELGADO: It is withdrawn, and we're going back to the original motion of October 21st of 2012.

MR. KARREMAN: Is that date, correct date, program?

MR. DELGADO: It's been confirmed by the director.

Tracy, you had a question there?

Any other questions on this motion to amend? And I have to clarify that. Your motion was to amend the --

MR. GIACOMINI: The recommendation.

MR. DELGADO: -- the recommendation. So, and I want to make sure I understand, because your motion to amend

the recommendation presented by the Crops Committee, once it's amended, we'll have to do --

MR. GIACOMINI: We vote on the new recommendation as amended.

MR. DELGADO: Perfectly stated, and we'll do that.

So ready for the question. The question is on the amendment - on the motion to amend by adding the - by adding tetracycline for fire blight control only on the national list 205.601(I) until October 21st, 2012.

And we'll start our vote with Barry.

MR. FLAMM: Could you please restate the motion?

MR. DELGADO: We are voting to consider a motion to amend the recommendation of the Crops Committee by adding October 21st, 2012, as -

MR. FLAMM: And eliminating the -

MR. DELGADO: - and eliminating the different forms of tetracycline.

MR. KARREMAN: And eliminating sunset too.

MR. FLAMM: And all forms of tetracycline will be subject to this expiration date?

MR. DELGADO: As it's stated in the motion, you will have that expiration.

MR. FLAMM: And that expiration date is?

MR. DELGADO: October 21st, 2012.

MR. FLAMM: I just want to make sure it's in the record.

MR. DELGADO: Any questions from the rest of the board?

We'll start with the vote. Barry?

MR. FLAMM: I vote yes.

MR. DELGADO: Hugh.

MR. KARREMAN: Yes.

MR. DELGADO: Kevin.

MR. ENGELBERT: Abstain.

MR. DELGADO: Kevin abstain was the last one? Jennifer.

MS. HALL: Yes.

MR. DELGADO: Steve.

MR. DeMURI: Yes.

MR. DELGADO: Julie.

MS. WEISMAN: Yes.

MR. DELGADO: Dan.

MR. GIACOMINI: Yes.

MR. DELGADO: Jeff.

MR. MOYER:

MR. DELGADO: Bea.

MS. JAMES: Yes.

MR. DELGADO: Jerry.

MR. DAVIS: Yes.

MR. DELGADO: Tina.

MS. ELLOR: Yes.

MR. DELGADO: Tracy.

MS. MIEDEMA: Yes.

MR. DELGADO: Joe.

MR. SMILLIE: Yes.

MR. DELGADO: And the Chair votes yes.

MR. MOYER: Mr. Chairman, we have 13 yeses, one abstention, and one absent.

MR. DELGADO: The motion to amend is agreed to. Now we can go on to a discussion of the recommendation as amended.

(Simultaneous speakers.)

MR. GIACOMINI: We have amended the recommendation. Now we have to vote on the amended recommendation.

MR. DELGADO: It's procedure so, Mr. Chairman

would you like to submit the amended motion.

MR. GIACOMINI: It is on the record as - the motion has been made as it is.

MR. DELGADO: Without amending, before we amended it.

MR. GIACOMINI: The motion is in play. The motion is on the table already.

MR. DELGADO: The motion is on the table. So we don't have to present it to the board. Our parliamentarian here is stating that we have it before the board. So we have discussion -- it has been stated. Now the motion is to set - to list tetracycline - adding tetracycline for fire blight control only on the national list 205.601(I) until October 21st, 2012. That's the motion.

Questions?

MR. GIACOMINI: Clarification, is that the proper wording for the program to recognize that as an annotation change, saying, adding rather than - and that it's any kind of a separation.

DR. ROBINSON: We'll just change -- we understand it. It just changes the annotation. We got it.

MR. DELGADO: Questions? Jerry.

MR. DAVIS: Why is the 2012 date not attached to the part directly --

MS. FRANCES: It's just formatting.

MR. DAVIS: No, I mean why is it not part of that upper sentence?

MR. GIACOMINI: She just rewrote it under your other vote.

MS. FRANCES: That was an earlier committee vote.

MR. DAVIS: Okay, I get you. It's not going to show in two places when we're done. That's my question.

MS. FRANCES: I mean, obviously you're going to give me a final version of this.

MR. GIACOMINI: It'll only have one line saying what it is not.

MS. FRANCES: We'll get all this right.

MR. DELGADO: Ready for the question?

The question is on the motion to add tetracycline for fire blight control only on the national list Section 205.601(I) until October 21st, 2012.

And we'll start our vote with Hugh.

MR. KARREMAN: Yes.

MR. DELGADO: Kevin.

MR. ENGELBERT: Abstain.

MR. DELGADO: Jennifer.

MS. HALL: Yes.

MR. DELGADO: Steve.

MR. DeMURI: Yes.

MR. DELGADO: Julie.

MS. WEISMAN: Yes.

MR. DELGADO: Dan.

MR. GIACOMINI: Yes.

MR. DELGADO: Jeff.

MR. MOYER: Yes.

MR. DELGADO: Bea.

MS. JAMES: Yes.

MR. DELGADO: Jerry.

MR. DAVIS: Yes.

MR. DELGADO: Tina.

MS. ELLOR: Yes.

MR. DELGADO: Tracy.

MS. MIEDEMA: Yes.

MR. DELGADO: Joe.

MR. SMILLIE: Yes.

MR. DELGADO: Barry.

MR. FLAMM: Yes.

MR. DELGADO: And the chair votes yes.

MR. MOYER: Mr. Chairman, we have 13 yeses, one abstention, and one absent.

MR. DELGADO: The ayes have it and the motion is agreed. Right.

Well, that concludes our discussion and presentation on crops related materials, and we are free to continue on with livestock, and Dr. Karreman.