# National Organic Standards Board Policy Development Committee

# Materials Petitioned for Addition to the National List Two Tiered Voting

# February 22, 2010

#### I. Introduction

In order to align NOSB material reviewing committees (Crops, Livestock, and Handling) with classification of materials definitions and procedures, and to correctly categorize materials petitioned to be included on the National List, the Policy Development Committee recommends establishment of a two tier voting process for materials petitioned to be added to the National List.

# II. Background

During board discussions regarding the Definition of the Classification of Materials, the importance of a synthetic or non-synthetic determination for petitioned materials has proven to be a critical component of material classification. According to archived NOSB meeting transcripts and written recommendations, in the past, material reviewing committees and the NOSB voted in two stages, the first for whether a petitioned material was synthetic or non-synthetic, and the second for or against listing of that petitioned material. At some point in time, this two tier voting procedure was abandoned, and only the vote to list or not currently remains. The reason for this change is not clear, but the Policy Development Committee was asked to consider re-establishment of a two tier voting process for materials petitioned for addition to the National List.

#### III. Relevant Areas in the Rule:

Sections §205.600, §205.601, §205.602, §205.603, §205.604, §205.605, and §205.606.

# IV. Discussion:

During the petitioned material evaluation process, it is important that the reviewing committee, to the best of it's ability, classify substances as non-synthetic or synthetic to provide for correct placement on the National List, and to provide direction to the organic industry on matters impacted by material classification, such as commercial availability scrutiny. Since this determination can be complex at times, a vote of reviewing committee members, and then the full NOSB, will help assure that the majority opinion regarding classification will rule. In this recommendation, applicable sections of the NOSB Policy and Procedure Manual have been revised to include a two-tier voting procedure for materials petitioned to be added to the National List for crop production, livestock production, or for handling operations. Sunset material recommendations and petitions to

remove materials from the National List would not be impacted by this recommendation. Additionally, the form used by the NOSB to transmit material recommendation results to the National Organic Program has been modified to include the synthetic / non-synthetic vote. The vote tally format for the listing / non-listing recommendation remains the same.

# V. Recommendation:

The Policy Development Committee recommends that a two tiered voting approach for materials petitioned to the National List be re-established, and that the Policy and Procedure Manual be revised to incorporate this change, as attached.

# VI. Committee Vote:

Motion: Steve DeMuri Second: Barry Flamm

Yes: 4 No: 0 Absent: 1 Abstain: 0

# **OUTLINE FOR WRITING COMMITTEE RECOMMENDATIONS**

This section provides an outline to be used by committees in writing a recommendation document. These guidelines not only allow consistency in the content of NOSB recommendations, but should also provide the NOSB, and the public, a fast manner to weigh the advantages and disadvantages of a proposal.

Recommendations not related to material petitions or sunset reviews, should include the following sections:

#### I. Introduction:

This section consists of a brief summary of the recommendation, its main issues and its relevance to the organic community. This section should also mention the goals and intent of the proposed recommendation.

#### II. Background:

This section should present the issues that justify the development of the recommendation as well as any relevant work done by the NOSB in the past.

#### III. Relevant areas in the Rule:

This section should mention any areas of the Rule or OFPA which provide the basis for the recommendation.

# IV. Discussion:

This section should be used to expand on the intent of the recommendation. It is also a place to emphasize the SWOT of the recommendation (strength, weaknesses, opportunities and threats). No recommendation is 100% perfect and this section can serve to clarify the tradeoffs and advantages of a recommendation. Thus, it is advisable to mention all major alternatives reviewed by the committee. If appropriate, different stakeholders groups should be identified indicating how each group's needs are met or affected.

# V. Recommendation:

This is the core, or deliverable, of the recommendation.

# VI. Committee Vote:

This section should present the names of the members who moved and second the motion to approve the recommendation. It should also list the votes including number of abstentions and absences. As a norm, a motion should always be presented in the affirmative. In the case of recommendations for petitions to add materials to the National List, two votes should be taken and recorded, the first for a synthetic or non-synthetic material classification, and the second to list or not list the material. The record should list the number of synthetic and non-synthetic votes, and yes and no votes for listing, and the number of abstentions and absences.

### Minority opinion:

If applicable, the dissenting opinion(s) of committee or task force members shall be reported. A member of a committee can present a minority report to the committee recommendation.

Such document should include reasons for opposing a proposed recommendation and cite where the opposition points are in the recommendation. In addition, the minority report could, provide alternative approaches or solutions from those given in the recommendation, or recommend an amendment to the recommendation. The minority opinion will be included as a separate document at the end of the recommendation.

# PROCEDURES FOR PRESENTING COMMITTEE RECOMMENDATIONS

NOSB committees and task forces will follow the outline presented below in order to present draft policy and/or material recommendations at meetings of the Board:

Introduction—A brief summary of the issue or statement of the problem.

<u>Background</u>—An explanation with sufficient detail and rationale to support a proposed recommendation, including reasons why the recommendation should be adopted, historical context, and the regulatory framework pertinent to the issue.

Recommendation—The concise text of the recommended action.

<u>Committee vote</u>—The vote of the committee or task force shall be reported. <u>In the case of recommendations for petitions to add materials to the National list, two votes will be recorded, one for synthetic or non-synthetic material classification, and the other for listing or not.</u>

<u>Minority opinion</u> – If applicable, the dissenting opinion(s) of committee or task force members shall be reported.

# NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: Substance:							
Committee: Crops  Livestock  Handling  Petition is for:							
on the National List § 205.							
A Fredrication Cultonic (A							
A. Evaluation Criteria (Applicability noted for each category; Documentation attached)  1. Impact on Humans and Environment  Yes No No NA							
Essential & Availa					No 🗆	N/A [	
Compatibility & Compatibi	•				No 🗆		
	4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) Yes No N/A						
B. Substance Fails Crite	ria Category:	Comments	s:				
C. Proposed Annotation	(if any):						
C. Troposed Annotation	(II ally).						
Pacie for appotation: To	moot critoria abov	ro: Oth	ner regulatory criteria:	Citation:			
basis for annotation. To	Theet chiena abov	e Oii	ler regulatory criteria	Citation.			
D. Recommended Comm	nittee Action & Vo	te, including clas	sification recommenda	tion (State Act	tual Mo	tion):	
Classification of the Material Classification of the material		Non- synthetic	: Absent	:: At	ostain		
Motion by:			Yes: No:			Δhstain:	
						Abstairi.	
Crop		Agricultural Non-Synthetic	Allowed Prohibite				
Lives		Synthetic	Rejected				
	-	Commercially Ur	n- Deferred				
Available as Organic <sup>1</sup> Deletted							
1) Substance voted to be added as "allowed" on National List to § 205with Annotation (if any)							
2) Substance to be added	d as "prohibited" on	National List to §	205with Annota	tion (if any)			
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 recomm	4) Substance was recommended to be deferred because						
If follow-up needed, who	If follow-up needed, who will follow up						
F. Ammend by Committee	aa Chain ta tur	it to NOCD.					
E. Approved by Committee	ee Chair to transm	III TO NUSB:					
Committee Chair			Date				

# **EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST**

Category 1. Adverse impacts on humans or the environment? Substance \_\_\_\_\_

Our effect	V	NI.	1	B
Question	Yes	No	N/A	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment				
from manufacture, use, or disposal? [§205.600 b.2]				
Is there environmental contamination				
during manufacture, use, misuse, or disposal? [§6518 m.3]				
3. Is the substance harmful to the				
environment?				
[§6517c(1)(A)(i);6517(c)(2)(A)i]				
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1 ) (B)(ii); 205.601(m)2]				
5. Is there potential for detrimental chemical				
interaction with other materials used? [§6518 m.1]				
6. Are there adverse biological and chemical				
interactions in agro- ecosystem? [§6518				
m.5]				
7. Are there detrimental physiological effects				
on soil organisms, crops, or livestock? [§6518 m.5]				
8. Is there a toxic or other adverse action of				
the material or its breakdown products? [§6518 m.2]				
Is there undesirable persistence or				
concentration of the material or				
breakdown products in				
environment?[§6518 m.2]				
10. Is there any harmful effect on human				
health? [§6517 c (1)(A) (i); 6517 c(2)(A)I; §6518 m.4]				
11. Is there an adverse effect on human				
health as defined by applicable Federal				
regulations? [205.600 b.3]				
12. Is the substance GRAS when used				
according to FDA's good manufacturing				
practices? [§205.600 b.5]				
13. Does the substance contain residues of				
heavy metals or other contaminants in				
excess of FDA tolerances? [§205.600				
b.5]				

If 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 \_\_\_\_\_

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
Is there a natural source of the substance? [§205.600 b.1]				
2. Is there an organic substitute? [§205.600 b.1]				
Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]				
4. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]				
5. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]				
6. Is there any alternative substances? [§6518 m.6]				
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]				
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]				
9. Is there any alternative substances? [§6518 m.6]				
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]				

If 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 \_\_\_\_\_

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
Is the substance compatible with organic handling? [§205.600 b.2]				
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]				
Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]				
Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]				
5. Is the primary use as a preservative? [§205.600 b.4]				
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]				
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:  a. copper and sulfur compounds;				
b. toxins derived from bacteria;		,		
<ul> <li>c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?</li> </ul>				
d. livestock parasiticides and medicines?				
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?				

If 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 <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
l. Is the comparative description provided as to why the nonorganic form of the material /substance is necessary for use in organic handling?				
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 <u>quality</u> 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 <u>quantity</u> to fulfill an essential function in a system of organic handling?				
Does the industry information provided on material / substance non-availability as organic, include ( but not limited to) the following:     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?				

# NOSB RECOMMENDED DECISION FORM Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting:		Substance:							
Evaluation Criteria (Documentation attached; committee recommendation attached)     Criteria Satisfied?									
In Impact on humans and environment     Yes No (see B below)     Availability criteria     Yes No (see B below)									
3. Compatibility & consistency Yes No (see B below)									
		C. Proposed Annota	C. Proposed Annotation:						
B. Substance fails criteria?									
Criteria category:	-	Basis for annotation	Basis for annotation:						
Comments:		To meet criteria abo	ove: Criteria:						
		Other regulatory crit	Other regulatory criteria: Citation:						
. Final Board Action & Vote:	. Final Board Action & Vote: Motion by: Second:								
Vote:	Agricultural	Nonagricultural	Crops						
Yes:	Synthetic	Not synthetic	Livestock						
No:	Allowed <sup>1</sup>	Prohibited <sup>2</sup>	Handling						
Abstain:	No restriction	Deferred4	Rejected <sup>3</sup>						
Substance voted to be ad	lded as "allowed" on Na	ational List							
Annotation:									
Substance to be added to	"prohibited" paragraph	n of National List							
Describe why a prohibited su	ıbstance:								
Substance was rejected by	3) Substance was rejected by vote for amending National List								
Describe why material was re	Describe why material was rejected:								
4) Substance was recommer	4) Substance was recommended to be deferred								
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:									
, NOSB Chair Date									
F. NOP Action: Include in FR to amend National List:  Return to NOSB Reason:									
, NOP Director Date									
, NOT DIRECTOR DATE									

#### PROCEDURES FOR THE MATERIALS REVIEW PROCESS FOR NOSB MEMBERS

- Upon receipt of the TAP reviews each member should read the report prepared by the contractor, along with the submitted petition, additional information and recommendations of the contracted panel of experts.
- Questions or clarification of the review may be answered by further review of the literature provided by the TAP contractor or by the Chair of the committee contacting the contractor directly. Questions regarding the process can be directed to the Chair of the Materials Committee.
- 3. The materials are either directed to the processing, crops or livestock committee(s) depending on the specified use(s) of the material as stated in the petition. NOSB members assigned to those committees shall conduct a thorough review of the material and vote on whether it is synthetic or nonsynthetic and if it should be allowed or prohibited for specific use as either a crop, livestock or processing material. Materials may be followed by an annotation which restricts their use. Recommended annotations applicable to the material must be voted on by committee.
- 4. Committee draft recommendations will be submitted to the NOP at least thirty (30) days prior to the next NOSB meeting where the material will be considered.
- 5. The Chair of each committee will present the Board with the committee's written votes and recommendations during the Materials Review process at the NOSB meeting. The recommendation should come in the form of a motion which must be seconded by an NOSB member to move forward. The process will follow Robert's Rules of Order in which the Chair would open the motion for discussion. The Chair shall ask if any Board members have conflicts of interest. After discussion board members will vote on the motion.
- 6. NOP staff will record the votes of the each NOSB member and announce whether or not the motion passed.
- 7. If the motion fails the Board Chair asks for a new motion and the procedure is repeated until a final motion is passed by a 2/3 majority.
- g Company, California, 1986.

Formatted: Highlight