Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP)

Date: October 28, 2010

Subject: 2,4,7,9-Tetramethyl-5-decyne-4,7-diol (CAS# 126-86-3)

Chair: Daniel G. Giacomini

The NOSB hereby recommends to the NOP the following:

Rulemaking Action Guidance Statement Other

Not to list 2,4,7,9-Tetramethyl-5-decyne-4,7-diol CAS# 126-86-3) determined to be synthetic on the National List §205.601.

Statement of the Recommendation (Including Recount of Vote):

The recommendation is to consider 2,4,7,9-Tetramethyl-5-decyne-4,7-diol (CAS# 126-86-3) synthetic. The motion passed 14 yes, 0 no, no abstentions, no absences, and no conflicts of interest.

The recommendation is to list 2,4,7,9-Tetramethyl-5-decyne-4,7-diol (CAS# 126-86-3) on the National List 205.601 for use in organic agriculture. The motion was defeated 14 no, 0 yes, no abstentions, no absences, and no conflicts of interest.

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

Substance fails criteria 1 (impact on humans and environment), 2 (essential & availability criteria), and 3 (compatibility & consistency). Please see attached Crops Committee recommendation.

NOSB Vote:

To classify 2,4,7,9-Tetramethyl-5-decyne-4,7-diol (CAS# 126-86-3) as synthetic

Moved: Barry	Flamm	Second: Jeff Moyer				
Yes: 14	No: 0	Abstain: 0	Absent: 0	Recusal: 0		

NOSB Vote:

To add 2,4,7,9-Tetramethyl-5-decyne-4,7-diol (CAS# 126-86-3) to § 205.601 on the National List.

Moved: Barry Flamm		Second:	Jeff	Moyer				
Yes: 0	No:	14	Abstain:	0	Absent:	0	Recusal:	0
					1			

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting:	Fall 2010	Substance: 2,4,7,9-Tetramethyl-5-decyne -4,7-diol									
Committee: Crops 🗵 Livestock 🗌 Handling 🗌 Petition is for: adding 2,4,7,9-Teramethyl -5-decyne-4,7-diol											
on the National List § 205.601											
A. Evaluation Criteria (Applicability noted for each category; Documentation attached) Criteria Satisfied? (see B below)											
1. Impact on Hur	1. Impact on Humans and Environment Yes No N/A										
2. Essential & Av	2. Essential & Availability Criteria Yes 🗌 No 🖾 N/A 🗌										
3. Compatibility 8	3. Compatibility & Consistency Yes No X N/A										
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) Yes 🗌 No 🗌 N/A 🗵											
by either	B. Substance Fails Criteria Category: 1, 2, 3 Comments: According to the TR material is not allowed for use in organic crop production										
C. Proposed Annotat	tion (if any):										
Basis for annotation	: To meet criteria above:		Other regulate	ory crite	ria: Citatic	on:					
	mmittee Action & Vote, i eramethyl-decyne-4,7-diol					Actual Moti	ion):				
Classification of the mate	erial: Synthetic <u>X</u>	_ Non- synt	hetic		Absent:	Abstain					
Motion by: Jeff Moyer	Seconded: Tina Ellor										
model by con moyer		100.	1 110.	_0							
	Crops X	Agricultur	al		Allowed ¹						
	Livestock	Non-Synt	netic		Prohibited ²						
	Handling	Synthetic		Χ	Rejected ³	Х					
	No restriction	Commerc Available	ially Un- as Organic ¹		Deferred ⁴						
1) Substance voted to	be added as "allowed" on	National Li	st to § 205	w	ith Annotation (if an	y)					
			0.005								
2) Substance to be ac	lded as "prohibited" on Na	tionai list to	§ 205		Annotation (if any) _						
Describe why a pro	Describe why a prohibited substance:										
3) Substance was rejected by vote for amending National List to § 205. 601Describe why material was rejected: Adverse effects											
on humans and the environment, not compatable with organic production and alternatives are available.											
4) Substance was rec	4) Substance was recommended to be deferred because										
If follow-up needed, w	If follow-up needed, who will follow up										
E. Approved by Comr	E. Approved by Committee Chair to transmit to NOSB:										
Committee Chair	•		Date								

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance: <u>Tetramethyl decyne diol</u>

Question	Ye s	N o	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
 Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2] 			Х	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X			TAP lines 133-149: Trace amounts appear to be released to the environment via air and water. Potential concern from run off from fields after treatment.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	×			TAP lines 169-172: slightly toxic to fish and aquatic invertebrates and moderately toxic to aquatic plants. Has long half lives. Lines 184-5: Has ability to persist in the environment and interact with other chemicals and organic substances. Line 204: may have detrimental physiological effects on soil, organisms, crops or livestock.
 4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1) (B)(ii); 205.601(m)2] 	Х			List 3 Inerts of unknown toxicity. List 3 now obsolete.
5. Is there potential for detrimental chemical interaction with other materials used?[§6518 m.1]	Х			See 3 above. Also TAP lines 198-99, if solubilized in an organic solvent, there may be additional concerns about adverse effects on the agro ecosystem.
 Are there adverse biological and chemical interactions in agro- ecosystem? [§6518 m.5] 	Х			See 5 above.
 Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5] 	Х			TAP line 204
 Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2] 	Х			TAP lines 204-297
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]	Х			TAP lines 184-185
10. Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A)I; §6518 m.4]	X			TAP lines 312-329: severely irritating to eyes, mildly irritating to skin, inhalation may cause headache, drowsiness, or other effects to the central nervous system.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]	Х	Х		TAP lines 72-82, Petition: Has 3 EPA exemptions from the requirement of a tolerance when not more than 2.5% of the pesticide formulation.
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]		Х		Not approved by FDA as a food additive.
 Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5] 		X		TAP, Petition

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: <u>Tetramethyl</u>

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is there a natural source of the substance? [§205.600 b.1]			Х	TAP lines 122-123,128.
2. Is there an organic substitute? [§205.600 b.1]			Х	TAP 332-340: There are non-synthetic sapponins and microbial wetting agents on OMRI list.
3. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	TAP 332-340, 342-371: alternatives are available.
4. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			Х	Possibly. See TAP lines 332-340
5. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
6. Is there any alternative substances? [§6518 m.6]	Х			TAP lines 345-371: could use synethics already listed in 205.601
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			TAP lines 376-405: alternative practices such as bio controls, cultural measures(crop rotation, cover crops, sanitation,mowing,weeding,flame, pruning, mulches, others) natural substances, resistent varieties.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]				Duplicate question
9. Is there any alternative substances? [§6518 m.6]				Duplicate question
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]				Duplicate question

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: <u>Tetramethyl</u>

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, and biodiversity? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		Х		TAP: Wide range of known and potential adverse effects to biodiversity and agro ecosystem.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		Х		TAP line 184: Material is not readily biodegradable with ability to persist in the environment thus is not compatible with sustainable agriculture.
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]			Х	
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;		Х		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		
d. livestock parasiticides and medicines?		Х		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		Х		

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	Νο	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)				
1. Is the comparative description provided 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 <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?								
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?								