

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date:

Subject:

Chair:

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement:

Other:

Statement of Recommendation: U

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

Committee Vote:

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

Statement of Recommendation: U . . .

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

Committee Vote:

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

**National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Nonanoic acid**

July 17, 2012

Summary of Proposed Action:

Nonanoic acid is a nine-carbon straight chain fatty acid which occurs at low levels in foods such as grapes, milk, oranges and apples. While there may be some non-synthetic sources of nonanoic acid, the petitioned material is a synthetic substance used as a topical insect repellent, with short term action requiring frequent treatment of livestock.

Nonanoic acid is an EPA registered fungicide and herbicide, and as such it does not appear on permitted substance lists in Canada, the European Union or Japan. There is potential for negative impact on the agro-ecosystem and soils. Further, there are a number of effective alternative treatments already available in addition to IPM and management practices. For these reasons the Livestock sub-committee is not recommending to add nonanoic acid to 205.603, insect repellent insecticide.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)
(see "B" below)

Criteria Satisfied?

- | | | | |
|--|------------------------------|--|---------------------------------------|
| 1. Impact on Humans and Environment
N/A | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | <input type="checkbox"/> |
| 2. Essential & Availability Criteria
<input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> X No | |
| 3. Compatibility & Consistency
<input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> X No | |
| 4. Commercial Supply is Fragile or Potentially Unavailable
N/A
as Organic (only for § 205.606) | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input checked="" type="checkbox"/> X |

Substance Fails Criteria Category: [3] Comments:

Nonanoic acid is an EPA registered fungicide and herbicide that can be used as a weed killer and blossom thinner.

Proposed Annotation (if any):

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

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Nonanoic acid (CAS112-05-0) as petitioned is synthetic
Motion by: Jean Richardson Seconded by: Colehour Bondera
Yes: 7 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Listing Motion: To add nonanoic acid (CAS 112-05-0) to 205.603, insect repellent, insecticide

Motion by: Jean Richardson Seconded by: Tracy Favre
 Yes: 0 No: 7 Absent: 1 Abstain: 0 Recuse: 0

Crops	<input type="checkbox"/>	Agricultural	<input type="checkbox"/>	Allowed¹	<input type="checkbox"/>
Livestock	<input checked="" type="checkbox"/>	Non-synthetic	<input type="checkbox"/>	Prohibited²	<input type="checkbox"/>
Handling	<input type="checkbox"/>	Synthetic	<input checked="" type="checkbox"/>	Rejected³	<input checked="" type="checkbox"/>
No restriction	<input type="checkbox"/>	Commercial unavailable as organic	<input type="checkbox"/>	Deferred⁴	<input type="checkbox"/>

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

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

Describe why a prohibited substance:

³Substance was rejected by vote for amending National List to § 205. . Describe why material was rejected:

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

Approved by Committee Chair to Transmit to NOSB

Wendy Fulwider, Committee Chair

July 17, 2012

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment?

Substance: Nonanoic Acid

Question	Yes	No	N/A¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]			X	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		The TR was not clear on this issue
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X	X		The TR (lines 333-338) suggests that beneficial nematodes may be affected negatively by this substance
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		
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			TR (lines 293-297) indicates potential wind drift impact on blossoms and weeds; TR (lines 333-338) concern over

				negative impact on nematodes in soil; lack of clarity on impact on beneficial nematodes and earthworms
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		
10. Are there any harmful effects on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]	X	X		TR (lines 383-385) indicates that the substance is an irritant, but was not evaluated for chronic toxicity.
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.

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production?

Substance: Nonanoic acid

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			
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		
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		
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			TR (lines 398-400 and 413-414; 421-441) indicates a wide range of natural substitute products.
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			
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			TR (lines 446-515) describes systems of Integrated Pest Management (IPM)

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

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices?

Substance: Nonanoic acid

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		
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:		X		
a. copper and sulfur compounds;				
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.

NOSB Evaluation Criteria for Substances Added To the National List

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: Name Nonanoic acid**

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
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?			X	
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?			X	
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?			X	
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?			X	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:			X	
a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt			X	

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			X	
e. Are there other issues which may present a challenge to a consistent supply?			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.