

NOSB RECOMMENDED DECISION FORM

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: October 2010	Substance: <u>Formic Acid</u>																								
A. Evaluation Criteria (Applicability noted for each category; Documentation attached) Criteria Satisfied? (see B below)																									
1. Impact on Humans and Environment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																								
2. Essential & Availability Criteria	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																								
3. Compatibility & Consistency	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																								
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/>																								
B. Substance fails criteria? Criteria category: _____ Comments: _____	C. Proposed Annotation: <u>for use solely as a pesticide within honeybee hives.</u> Basis for annotation: _____ To meet criteria above: <u>X</u> Criteria: _____ Other regulatory criteria: _____ Citation: _____																								
D. Final Board Action And Vote Regarding Synthetic / Non-synthetic: <u>Motion that Formic Acid be considered a synthetic substance.</u>																									
Motion by: <u>Kevin Engelbert</u> Seconded: <u>Tina Ellor</u> Yes: <u>14</u> No: <u>0</u> Absent: <u>2</u> Abstain: <u>0</u>																									
E. Final Board Action & Vote (State Actual Motion): <u>Motion to add Formic Acid, CAS # 164-18-6, to the National List § 205.603(b) for use as a pesticide solely within honeybee hives.</u>																									
Motion: <u>Kevin Engelbert</u> Second: <u>Tina Ellor</u> Yes: <u>14</u> No: <u>0</u> Abstain: <u>0</u> Absent: <u>0</u>																									
<table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Agricultural</td> <td style="padding: 5px; text-align: center;"><input checked="" type="checkbox"/></td> <td style="padding: 5px;">Nonagricultural</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Crops</td> <td style="padding: 5px;"></td> </tr> <tr> <td style="padding: 5px;">Synthetic</td> <td style="padding: 5px; text-align: center;"><input checked="" type="checkbox"/></td> <td style="padding: 5px;">Not synthetic</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Livestock</td> <td style="padding: 5px; text-align: center;"><input checked="" type="checkbox"/></td> </tr> <tr> <td style="padding: 5px;">Allowed¹</td> <td style="padding: 5px; text-align: center;"><input checked="" type="checkbox"/></td> <td style="padding: 5px;">Prohibited²</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Handling</td> <td style="padding: 5px;"></td> </tr> <tr> <td style="padding: 5px;">No restriction</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Deferred⁴</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Rejected³</td> <td style="padding: 5px;"></td> </tr> </table>		Agricultural	<input checked="" type="checkbox"/>	Nonagricultural		Crops		Synthetic	<input checked="" type="checkbox"/>	Not synthetic		Livestock	<input checked="" type="checkbox"/>	Allowed ¹	<input checked="" type="checkbox"/>	Prohibited ²		Handling		No restriction		Deferred ⁴		Rejected ³	
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Provide a summary narrative here or attach a more complete narrative, and attach the original committee recommendation that includes the evaluation criteria checklist: <u>See Committee Recommendation below.</u>																									
1—substance voted to be added as “allowed” on National List on National List to § 205.603(b) with Annotation (if any): <u>for use solely as a pesticide within honeybee hives.</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																									
Daniel G. Giacomini	October 28, 2010																								
Chair	Date																								
F. NOP Action: <u>Include in FR to amend National List:</u> Return to NOSB Reason: _____ _____ <div style="text-align: right;">Date</div>																									

NOSB COMMITTEE RECOMMENDATION
Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: Fall 2010

Substance: Formic Acid

Committee: Crops Livestock Handling Petition is for: adding Formic Acid, CAS # 164-18-6, on the National List § 205.603(b) for use as a pesticide solely within honeybee hives.

A. Evaluation Criteria (Applicability noted for each category; Documentation attached)	Criteria Satisfied? (see B below)
4. Impact on Humans and Environment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
5. Essential & Availability Criteria	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
6. Compatibility & Consistency	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
7. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/>

B. Substance Fails Criteria Category: _____ Comments: With the annotation, Formic Acid does not fail any category based on information contained in the petition, which was the only source of information provided. Even though the Livestock Committee conducted additional research, the Committee has requested a Technical Review of Formic Acid, and will reevaluate the recommendation when the TR becomes available. Given the current situation in apiculture with regard to mites, the recommendation of the 2001 NOSB, the position of the Apiculture Working Group, and the fact that with the annotation Formic Acid meets all the Evaluation Criteria, the Livestock Committee firmly believes that Formic Acid warrants being added to the National List § 205.603

C. Proposed Annotation (if any): for use as a pesticide solely within honeybee hives

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

D. Committee Recommendation Regarding Synthetic / Non-synthetic: Motion that Formic Acid be considered a synthetic substance.

Motion by: Kevin Engelbert Seconded: Tina Ellorl Yes: 6 No: 0 Absent: 2 Abstain: 0

E. Recommended Committee Action & Vote (State Actual Motion): Motion to add Formic Acid, CAS # 164-18-6, to the National List § 205.603 for use as a pesticide solely within honeybee hives.

Motion by: Daniel G. Giacomini Seconded: Jennifer Hall Yes: 5 No: 0 Absent: 3 Abstain: 0

Crops		Agricultural		Allowed ¹	<input checked="" type="checkbox"/>
Livestock	<input checked="" type="checkbox"/>	Non-Synthetic		Prohibited ²	
Handling		Synthetic	<input checked="" type="checkbox"/>	Rejected ³	
No restriction		Commercially Un-Available as Organic ¹		Deferred ⁴	

1) Substance voted to be added as "allowed" on National List to § 205.603 with Annotation (if any) for use solely as a pesticide within honeybee hives.

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. _____ Describe why material was rejected: _____

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

F. Approved by Committee Chair to transmit to NOSB:

Kevin K. Engelbert
Committee Chair

August 3, 2010
Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance - Formic 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		No references found stating that the production and transporting of formic acid cause environmental contamination. Petition pg. 13
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Because formic acid is used only in the hive, no environmental residues are expected to occur outside the hive. Petition pg. 11 No references found stating that the use of formic acid in honey production poses an environmental risk. Petition pg. 13
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			Formic acid is a strong acid, and as such the potential for chemical interaction does exist, but on the Material Safety Data Sheet (MSDS) the substance is rated 0 (stable) for Reactivity Petition pg. 48 & 51
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		See 3 above
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		See 3 above with regard to soil interactions. Formic acid is used in conventional livestock agriculture as a preservative and antibacterial agent in livestock feed, and sometimes added to poultry feed to kill salmonella bacteria. Petition pg. 4
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		No known ecotoxicity data, but the breakdown products are less toxic than formic acid itself. Petition pg. 52 & 53
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]	X			Short term degradation products are not likely, but long term degradation products may arise. Petition pg. 53 Although, no references found stating that the use of formic acid poses an environmental risk. Petition pg. 13
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	X			If mishandled there are potential acute and chronic health effects involving skin and mucous membrane contact, along with inhalation and ingestion The substance may also be toxic to organs with repeated or prolonged exposure. Petition pg. 48 If handled properly and used according to label instructions, no harm to human health can be expected, and formic acid is a natural constituent of many foods. Petition pg. 15 & 11
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	
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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 - Formic 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			Petition pgs. 6 & 7
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		Petition pgs. 6 & 7
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		Petition pgs. 6 & 7
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		The use of powdered sugar or Sucrose Octanoate Ester results in a short term increase in mortality rates of mites outside the hive, but no impact inside the hive. Petition pg. 16
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		See 7. above
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		Drone comb removal helps control mites by removing a large portion of the mites, but does not remove them all, especially if the hive produces a small number of drones.. Petition pg. 29

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 - Formic 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			Formic acid is produced by bees and other insects as a venom, but in tropical regions the mites reproduce year round and consequently the mite populations can increase too rapidly for the honey bees to contend with. Petition pgs. 4 & 24 Formic Acid allowed in Canada & Europe. Canadian General Standards Board, Organic Production Systems Permitted Substances List, pg. 16 & EU-Regulation2092/91, 1804/1999 Annex C: Beekeeping and Beekeeping Products; Paragraph 6.3(e) Petition pgs. 9 & 10
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			Honey bees produce minute levels of formic acid, which is found naturally in honey , and no increase in the levels of formic acid in honey are expected. Petition pgs. 10 & 17 Formic Acid allowed in Canada & Europe. Canadian General Standards Board, Organic Production Systems Permitted Substances List, pg. 16 & EU-Regulation2092/91, 1804/1999 Annex C: Beekeeping and Beekeeping Products; Paragraph 6.3(e) Petition pgs. 9 & 10
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 - Formic Acid

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?			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 production or destroy crops or supplies;			X	

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	