

NOSB RECOMMENDED DECISION FORM

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: May 2009		Substance: Propionic Acid																									
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: 2 & 3 Comments: Organic alternatives and non-synthetics sources available; synthetics not allowed as preservatives	C. Proposed Annotation: _____ Basis for annotation: To meet criteria above: _____ Criteria: _____ Other regulatory criteria: _____ Citation: _____																										
D. Final Board Action & Vote (State Actual Motion): The motion presented to the committee is to list propionic acid on the National List §205.603. Motion: Hubert Karreman Second: Kevin Englebert Yes: 0 No: 14 Recuse: 1 Absent: 1																											
<table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Agricultural</td> <td style="padding: 5px;"></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;">☒</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;">☒</td> </tr> <tr> <td style="padding: 5px;">Allowed¹</td> <td style="padding: 5px;"></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		Nonagricultural		Crops		Synthetic	☒	Not synthetic		Livestock	☒	Allowed ¹		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: 																											
1—substance voted to be added as “allowed” on National List on National List to § 205._____ with Annotation (if any): _____ 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. 603 Describe why material was rejected: The material is synthetic and proposed to be used as a preservative, which is not allowed according to regulation. 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 Chair _____ Date _____																											
F. NOP Action: Include in FR to amend National List: Return to NOSB Reason: _____ _____ Date _____																											

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: May 2009

Substance: Propionic Acid

Committee: Crops ☐ Livestock Handling ☐ **Petition is for: animal feed preservation as a mold inhibitor**

on the National List § 205.603

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

- | | | | |
|--|---|--|---|
| 4. Impact on Humans and Environment | Yes ☒ | No ☐ | N/A ☐ |
| 5. Essential & Availability Criteria | Yes ☐ | No ☒ | N/A ☐ |
| 6. Compatibility & Consistency | Yes ☐ | No ☒ | N/A ☐ |
| 7. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) | Yes ☐ | No ☐ | N/A ☒ |

B. Substance Fails Criteria Category: 2 & 3 **Comments:** Organic alternatives and non-synthetics sources available; synthetics not allowed as preservatives _____

C. Proposed Annotation (if any): _____

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

D. Recommended Committee Action & Vote (State Actual Motion): _____

The motion presented to the committee is to list **propionic acid** on the National List §205.603. The Livestock Committee felt the technical review done by Science and Technology on this material fell short of their expectations. The committee was able to rely on a previous and thorough review of Calcium Propionate (attached) which also discussed, in detail, propionic acid. The Livestock Committee disagrees with the footnote on Category 2 items 4, 5, and 6, indicating that §205.600 (b) items under review do not apply to crops and/or livestock.

Motion by: Dan Giacomini **Seconded:** Jennifer Hall **Yes:** 0 **No:** 7 **Absent:** 0 **Abstain:** 0

Crops		Agricultural		Allowed ¹	
Livestock	☒	Non-Synthetic		Prohibited ²	
Handling		Synthetic	☒	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. _____ 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. 603 Describe why material was rejected: _____

Substance's primary petitioned use is as a preservative. As such it fails the evaluation criteria laid out in 205.600(b)(4): The substances primary use is not as a preservative Substance was also rejected because it failed criteria 2 & 3 .

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:

Hubert Karreman
Committee Chair

March 10, 2009
Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance - Propionic

Acid

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	X		There should not be any environmental contamination during the manufacture of the synthetic substance. The major impurity in the final product is acetic acid and it is present at less than 0.3% by weight. Scrubbers are used during the manufacturing process to capture fugitive emissions (Fugitive emissions are considered a pollutant under the clean air act) and the scrubber condensates are collected and re-distilled and the organic material collected are used as fuel or sold as solvents (pg 3 of TR)
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X	X		Propionic acid is used as a carbon source by many microorganisms and is metabolized to acetic acid, methane, carbon dioxide, and water (Lin et al., 1986). Based on this, the U. S. EPA has waived environmental fate data requirements for the currently registered uses of propionic acid. Therefore, any concerns over the improper storage, use, and disposal of propionic acid should be minimal (pg 3 of TR)
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		See #1 and #2 above.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		No, the substance itself is on List 4B
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		There is no information available to indicate that using propionic acid has detrimental physiological effects on soil, organisms, crops, or livestock. The registered uses of propionic acid indicate that it is used in either indoor treatments or limited outdoor uses for animal watering. On the basis of low toxicity and low potential for exposure, hazard to non-target organisms is expected to be minimal. Propionic acid is metabolized by microorganisms to acetic acid, methane, carbon dioxide, and water (Lin et al, 1986). (Pg 4 of TR)
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		There is no information available to indicate that propionic acid has adverse biological or chemical interactions in the agro-ecosystem. The U.S. EPA has reviewed the available eco-toxicity data on propionic acid and found that it is only slightly toxic to birds, fish, aquatic invertebrates, and mammals. (pg 4 of TR). As stated in the 2002 TAP Review for Calcium Propionate, propionic acid has the potential to be highly mobile in the soil but no major adverse effects were noted.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		There is no information available to indicate that using propionic acid has detrimental physiological effects on soil, organisms, crops, or livestock. The registered uses of propionic acid indicate that it is used in either indoor treatments or limited outdoor uses for animal watering. On

				the basis of low toxicity and low potential for exposure, hazard to non-target organisms is expected to be minimal. Propionic acid is metabolized by microorganisms to acetic acid, methane, carbon dioxide, and water (Lin et al, 1986).(pg 4 of TR)
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			One adverse reaction of propionic acid is that it is corrosive (Kung, Jr. et al., 2000). To be effective as a preservative, the material has to be evenly applied to silages, hays, and grains. If propionic acid is applied at harvest, it will likely cause corrosion to harvesting equipment such as forage harvesters or hay balers. In the case of the storage of grains, metal storage structures (i.e., metal grain bins) may be susceptible to rust and corrosion where the grain has been treated with propionic acid. (pg 5 of TR)
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]	X	X		Under anaerobic conditions, propionic acid is used as a carbon source by various microorganisms and is metabolized to acetic acid, methane, carbon dioxide, and water (Lin et al., 1986). Only two incident reports concerning propionic acid were: 1) detections in the tissue of mussel (<i>Mytilus edulis</i>) (Yasuhara and Morita, 1987) and 2) in ground water as the results of the break-down of petroleum pollution (Goerlitz et al., 1985).(Pg 5 of TR)
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	X			Propionic acid is in Toxicity Category III for acute oral toxicity, acute dermal toxicity, and acute inhalation toxicity and in Toxicity Category I for eye irritation and dermal irritation. Products containing greater than 63% propionic acid must include the following protective clothing label requirements: "Wear chemical-resistant gloves, chemical-resistant aprons, chemical-resistant footwear and goggles or face shield when loading application equipment unless a closed loading system is used. Avoid working near high concentrations of spray mist/vapor. Use with adequate ventilation. Wash thoroughly after handling." (pg 5 of TR)
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]				

⁴If 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 ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X			Propionic acid is produced synthetically by reacting ethylene (petroleum based) with a mixture of carbon monoxide and hydrogen to yield propionaldehyde. Either rhodium or cobalt is used as a catalyst in this reaction. The propionaldehyde is treated with air or pure oxygen in a carefully controlled reaction to reduce the propionaldehyde to propionic acid. The propionic acid is distilled to produce a purified product. (pg 3 of TR)
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		Petroleum is synthetic.
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			Propionic acid is naturally produced by bacterial fermentation (pg 3 of TR)
5. Is there an organic substitute? [§205.600 b.1]	X			Organic vinegar is available; or propionic acid derived from bacteria
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			In silage production, one wholly natural product that possibly could be substituted for propionic acid is vinegar. (pg 5 of TR)
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 # 5 above; also: "A synthetic form of lactic acid could be substituted for propionic acid. Lactic acid should be the primary acid in well-fermented silage and fermentations that produce lactic acid result in the fewest losses of dry matter and energy from the crop during storage" (pg 5 of TR)
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Yes, proper crop harvesting methods; "In the case of silages, corn, hay, or other crops could be harvested at the optimal moisture contents. Harvesting and ensiling these crops at the optimal moisture contents will result in the proper fermentation of the crops in the silos with minimal mold formation and spoilage. Other practices such as proper packing of silages and covering (use of plastic covers) in bunker silos are recommended for good silage production. Also, good management practices in the removal of silage from silos at feeding will result in lower incidences of mold formation and spoilage. Therefore, a number of good management practices are available to

				make well-fermented silages without the use of preservatives.” (pg 5 of TR)
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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 3. Is the substance compatible with organic production practices?

Substance -

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		§205.600(b)(4) states: Evaluation criteria for allowed and prohibited substances, methods, and ingredients. The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List: (b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria: (4) The substance's primary use is not as a preservative
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			Yes - in that it allows a crop to be either salvaged or saved and thus protect a potential feed for livestock (thus "sustaining" a natural resource)
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X	X		Yes, by reducing the effects of mold on the silage, food quality is preserved or maintained. No, it can have a corrosive effect on the metal bins that may hold such treated crops, or the machinery utilized for harvest, contaminating feed.
5. Is the primary use as a preservative? [§205.600 b.4]	X			Petitioned as a preservation method to inhibit mold growth as stated in item B number 3 of the petition.
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;		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. Is the comparative description <u>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: 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	