# NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

| **For NOSB Meeting: May 2009** | **Substance: Propionic Acid - CAS 79- 09- 4** |
|---|---|

**Committee: Crops ☐ Livestock ☐ Handling X Petition is for: addition of Propionic Acid as a mold inhibitor for grains and feed to the National List § 205.605(b)**

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

| | | | | |
|---|---|---|---|---|
| 1. | Impact on Humans and Environment | Yes X | No ☐ | N/A ☐ |
| 2. | Essential & Availability Criteria | Yes ☐ | No X | N/A ☐ |
| 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 X |

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

**C. Proposed Annotation (if any):** _____

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

**D. Recommended Committee Action & Vote (State Actual Motion)**: To add Propionic Acid to the National List 205.605(b).

*Motion by: Steve DeMuri Seconded: Katrina Heinze Yes: ____ No: 4 Absent: 1 Recusal: 1*

| | | | | | |
|---|---|---|---|---|---|
| Crops | | Agricultural | | Allowed[1] | |
| Livestock | | Non-Synthetic | | Prohibited[2] | |
| Handling | X | Synthetic | X | 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. 605(b) Describe why material was rejected:_____

Substance's primary petitioned use is as a preservative for feed and grain, failing one of the criteria for listing (See Category 3 No. 5) Substance was also rejected because it failed criteria 2 -not considered to be essential, & other factors of Category 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:**

**Steve DeMuri** **March 17, 2009**
**Committee Chair** **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 | | Page 4 of the TR claims there are no adverse effects on the environment, and that it is only slightly toxic to birds, fish, aquatic invertebrates, and mammals. 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. |
| 2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3] | | X | | See 1 above |
| 3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i] | | X | | See 1 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 EPA's List 4B as an inert ingredient. |
| 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 chemical interaction with other materials used. |
| 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). |
| 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. |
| 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 due to it's acidic nature, which could cause corrosion of handling equipment, such as storage tanks and silos, where it might be used. |
| 9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2] | | X | | None indicated in the Technical Report. |
| 10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4] | | X | | US EPA R.E.D. Facts and page 5 of the Technical Review indicate contact with concentrated solutions of the substance may cause damage to the eyes, skin, and mucous membranes. It has been placed in Toxicity Category I for acute eye and dermal irritation effects. (I is the highest category, IV the lowest in degree of toxicity) It is placed in Category III for acute oral, dermal, and inhalation effects. However, under normal useage and concentrations, it is not considered toxic. It is a normal metabolite of the human body, and is rapidly absorbed from the mammalian GI tract and utilized by most organs and tissues. (page 4 & 5 of the TR) |
| 11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3] | | X | | See # 10 above. |
| 12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5] | | X | | Propionic acid was assigned GRAS status in May 1984. Page 3 of the Technical Review. |
| 13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5] | | X | | None indicated in the Technical Review. |

[1]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 -** Propionic 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 | | | 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 based ethylene (a synthetic ), is reacted with syn gas with a rhodium or cobalt catalyst. The distilled propionaldehyde is then treated with air or pure oxygen to partially oxidize it to propionic acid. The resulting product is then distilled. (Page 2 of the petition) |
| 3. Is the substance created by naturally occurring biological processes? [6502 (21)] | | X | | The petitioned form of the substance is not, but natural forms ARE available. |
| 4. Is there a natural source of the substance? [§205.600 b.1] | X | | | Propionic acid can be naturally produced by bacterial fermentation (pg 3 of TR) In fact, there is a large amount of naturally produced propionic acid available on the market. |
| 5. Is there an organic substitute? [§205.600 b.1] | X | | | Organic vinegar is available; or propionic acid derived from bacteria could conceivably be organic. There are other certified organic food mold inhibitors available on the market currently. |
| 6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6] | | X | | Good Manufacturing Practices and proper handling procedures could eliminate the need for this substance, and the availability of certified organic alternatives make this substance non-essential. |
| 7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)] | X | | | One wholly natural product that possibly could be substituted for propionic acid is vinegar. |
| 8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)] | | X | | The petitioned substance <u>is</u> synthetic. |
| 9. Is there any alternative substances? [§6518 m.6] | X | | | See #5 above. |
| 10. Is there another practice that would make the substance unnecessary? [§6518 m.6] | X | | | Yes, proper crop post harvest handling procedures and Good Manufacturing Practices, or the use of organic alternatives when necessary to inhibit mold growth in organic food. . |

[1]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 -** Propionic 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 | | It is a synthetic. |
| 2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)] | | X | | No, because it is a synthetic, and it's primary petitioned use is as a preservative. |
| 3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7] | | X | | Synthetically produced from a petroleum base. |
| 4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3] | X | | | There is no evidence or information available which indicates the substance adversely affects food nutritional quality. |
| 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 number3 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:<br>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 | | |

[1]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 -** Propionic Acid

| Question | Yes | No | 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? | | | 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:<br>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 | |