

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: March 2007

Substance: Inulin OFS

Committee: Crops Livestock Handling Petition is for: _____

Inclusion on the National List § 205.606

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

- | | | | |
|--------------------------------------------------------------------------------------|------------------------------|-----------------------------|------------------------------|
| 1. Impact on Humans and Environment | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. Essential & Availability Criteria | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 3. Compatibility & Consistency | Yes <input 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 type="checkbox"/> |

B. Substance Fails Criteria Category: _____ **Comments:** _____

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 Handling committee recommends that Inulin be considered for inclusion on § 205.605 so recommends that a TAP review be requested. Inclusion on § 205.606 is not being recommended since inulin is the product of an enzyme hydrolysis process and not an agricultural product.

Motion by: Julie Weisman Seconded: Andrea Caroe Yes: 5 No: 0 Absent: 0 Abstain: 0

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

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:

Julie Weisman
Committee Chair

February 19, 2007
Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance - Inulin OFS

| 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] | | | | |
| 2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3] | | | | |
| 3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i] | | | | |
| 4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2] | | | | |
| 5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1] | | | | |
| 6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5] | | | | |
| 7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5] | | | | |
| 8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2] | | | | |
| 9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2] | | | | |
| 10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4] | | | | |
| 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] | | | | |

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 - Inulin OFS

| 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)] | | | | |
| 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)] | | | | |
| 3. Is the substance created by naturally occurring biological processes? [6502 (21)] | | | | |
| 4. Is there a natural source of the substance? [§205.600 b.1] | | | | |
| 5. Is there an organic substitute? [§205.600 b.1] | | | | |
| 6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6] | | | | |
| 7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)] | | | | |
| 8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)] | | | | |
| 9. Is there any alternative substances? [§6518 m.6] | | | | |
| 10. Is there another practice that would make the substance unnecessary? [§6518 m.6] | | | | |

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 - Inulin OFS

| Question | Yes | No | N/A ¹ | Documentation (TAP; petition; regulatory agency; other) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|----|------------------|------------------------------------------------------------|
| 1. Is the substance compatible with organic handling? [§205.600 b.2] | | | | |
| 2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)] | | | | |
| 3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7] | | | | |
| 4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3] | | | | |
| 5. Is the primary use as a preservative? [§205.600 b.4] | | | | |
| 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] | | | | |
| 7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: | | | | |
| a. copper and sulfur compounds; | | | | |
| b. toxins derived from bacteria; | | | | |
| c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals? | | | | |
| d. livestock parasiticides and medicines? | | | | |
| e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners? | | | | |

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 - Inulin OFS

| 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? | | | | |
| 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 quality 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 quantity 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? | | | | |