

**National Organic Standards Board
Handling Committee
Petitioned Material Proposal
Inositol**

April 1, 2012

Summary of Proposed Action:

Inositol is an important biologic compound that serves numerous biologic functions/roles including but not limited to the following: a structural component of cell membranes, messenger molecules in reactions/processes, assist in overall muscle function and cell growth. Inositol may be formed endogenously using glucose as a substrate or it may be obtained by the human body through dietary sources. In addition to the aforementioned roles, inositol has been found to influence fat accumulation within the liver/intestines, control triacylglycerol and esterified cholesterol levels, and impact insulin resistance. Due to its association with these biologic processes/conditions, inositol is often marketed as a dietary supplement for those with these afflictions. The category of dietary supplements in the United States are not required to be regulated by the FDA in order to assure the validity and safety of using a substance to treat conditions, and as long as no health claims are made on the supplement they may be sold to American consumers without restrictions.

Inositol is found naturally in many foods which include fruits, beans, grains, seeds, and nuts. Another notable source of inositol is human breast milk which has been found to contain high concentrations of inositol (1500- 4000 mM/L) as stated in the March 2012 Tap review. The FDA list inositol as Generally Recognized as Safe (GRAS) for human consumption by the under 21 CFR 184.1370 and also mandates that all infant formulas sold in the United States must contain a minimum 4mg/ 100 kilocalories of inositol in order to assure infants fed solely on formula sources acquire adequate nutrition to grow as successfully as breast-fed infants.

Commercial production of inositol is often obtained from hydrolysis and acidification that begins from the corn/rice steeping process by using the phytic acid extracted from the corn/rice, and then using this phytic acid in one of several different chemical processes that ultimately results in isolating inositol. Additional methods also include utilization of microbial byproducts and processes (yeast); however these reactions are also dependent on synthetic reactions, or reactions that would not normally occur in nature to produce the final product of isolated inositol. Therefore, while inositol is a natural compound, the methods by which we can obtain commercial quantities of inositol are synthetic.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)
“B” below)

Criteria Satisfied? (see

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

Substance Fails Criteria Category: [] Comments:

Proposed Annotation (if any):

Category 1. Adverse impacts on humans or the environment? Substance:

| 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 | | TR 3/9/12 |
| 2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3] | | x | | TR 3/9/12 |
| 3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i] | | x | | TR 3/9/12 |
| 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 | |
| 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. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4] | | x | | |
| 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:

| 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 | | | May be obtained through yeast hydrolysis |
| 3. Is the substance created by naturally occurring biological processes? [6502 (21)] | x | | | Yes, but can also be made synthetically |
| 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 | | | Yes, but only for infant formula as req in 21 CFR 107.100 |
| 7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)] | | x | | |
| 8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)] | | x | | Mass production is via synthetic pathways. Could be produced using organic yeast to provide organic inositol |
| 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 | | |

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NOSB Evaluation Criteria for Substances Added To the National List

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 | |
| 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 | | Nutritive, but not replacing nutrients |
| 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**

| 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); | | | | |
| b. Number of suppliers and amount produced; | | | X | |
| c. Current and historical supplies related to weather events such as | | | X | |

| | | | | |
|---|--|--|---|--|
| 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 | | | 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.