

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: March 2007

Substance: Fructooligosaccharides (FOS), short chain

Committee: Crops Livestock Handling Petition is for: § 205. 605, Committee recommends an evaluation by the Livestock committee for addition to § 205. 603, livestock feed on the National List

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 checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. Essential & Availability Criteria | Yes <input type="checkbox"/> | No <input checked="" 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 Category: 1 and 2 Comments:

1. TAP 200-207 "...Systemic responses and laxative thresholds were similar regardless of whether fructooligosaccharides was administered occasionally or regularly."
2. Committee recognizes that the substance is used for a value added quality and is not essential for final product."

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 listing of Fructooligosaccharides (FOS), short chain on § 205.605(b)

Motion by: Julie Weisman Seconded Andrea Caroe Yes: 1 No: 4 Absent: 0 Abstain: 0

Crops		Agricultural		Allowed ¹	
Livestock		Non-Synthetic		Prohibited ²	
Handling	<input checked="" type="checkbox"/>	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: Short-chain Fructooligosaccharides

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		TAP 171 “There is no information available from EPA or FDA to suggest that environmental contamination results from the manufacture, use, misuse, or disposal of short-chain fructooligosaccharides.”
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		TAP 171 “There is no information available from EPA or FDA to suggest that environmental contamination results from the manufacture, use, misuse, or disposal of short-chain fructooligosaccharides.”
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		TAP 171 “There is no information available from EPA or FDA to suggest that environmental contamination results from the manufacture, use, misuse, or disposal of short-chain fructooligosaccharides.”
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			TAP 200-207 “...Systemic responses and laxative thresholds were similar regardless of whether fructooligosaccharides was administered occasionally regularly.”
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]	X			TAP 200-207 “...Systemic responses and laxative thresholds were similar regardless of whether fructooligosaccharides was administered occasionally regularly.”
12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]		X		TAP 250-256 “FDA reviewed the information provided in the GRAS notice and indicated that the Administration has no questions regarding GTC Nutrition’s conclusion that fructooligosaccharides is GRAS under the intended conditions of use (FDA 2000).” Tap 78-79 “FDA stated, however, that it has not made its own determination regarding the GRAS status of the subject use of fructooligosaccharides.”
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		TAP 266 “Short-chain fructooligosaccharides does not contain residues of heavy metal or other contaminants in excess of FDA tolerances.”

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 Short-chain Fructooligosaccharides

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			TAP 142-143 TAP 148-150 Sub-committee noted that it is an enzymatic process
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			TAP 143 “Commercial formulations of short-chain Fructooligosaccharides are not obtained from a naturally occurring source. The manufacturing process converts sucrose to short-chain fructooligosaccharides.”
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		TAP 132-133 “Although fructooligosaccharides occurs in nature, commercial formulations of short-chain fructooligosaccharides are manufactured.”
4. Is there a natural source of the substance? [§205.600 b.1]	X			TAP 155 “Fructooligosaccharides occurs naturally in nature.”
5. Is there an organic substitute? [§205.600 b.1]		X		TAP 165 “No other organic agricultural products were identified that could be substituted for the petitioned substance.”
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		Committee recognizes that the substance is used for a value added quality and is not essential for final product.”
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			TAP 155 “Fructooligosaccharides occurs naturally in nature.”
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			Committee recognizes that common fruits and vegetables are a natural source of fructooligosaccharides.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Consumption of more fruits and vegetables would add the value added quality to diet.

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Category 3. Is the substance compatible with organic production practices. Substance **Short-chain Fructooligosaccharides**

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			205.605 (b) nutrients, vitamins and minerals are listed.
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]			X	Not used in organic production.
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			TAP 220 “An increase in carbohydrates occurs when short-chain fructooligosaccharides is added to food or animal feed.”
5. Is the primary use as a preservative? [§205.600 b.4]		X		TAP 229 “Short-chain fructooligosaccharides is being petitioned for use as an ingredient in food and feed products to provide a selective energy source in the guts on humans and animals. It is not being petitioned for use as a preservative.”
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			TAP 239-240 ‘It is not being petitioned for use to recreate or improve flavors, colors, textures, or nutritive values lost in processing. ‘
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	*Note: on 3/22/06 petitioner makes note of use in animal feed. Livestock committee should consider evaluation of sFOS for 205.203 livestock production for feed.
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	

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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 - Short-chain Fructooligosaccharides

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	