

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: <u>May 2008</u>	Substance: <u>Oat Bran Concentrate</u>																								
Committee: Crops <input type="checkbox"/> Livestock <input type="checkbox"/> Handling <input checked="" type="checkbox"/> Petition is for: <u>Inclusion of Oat Bran Concentrate on the National List § 205.606</u>																									
A. Evaluation Criteria (Applicability noted for each category; Documentation attached) Criteria Satisfied? (see B below)																									
1. Impact on Humans and Environment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																								
2. Essential & Availability Criteria	Yes <input checked="" 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 checked="" type="checkbox"/>																								
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/>																								
B. Substance Fails Criteria Category: 4 Comments: <u>The petition did not provide information demonstrating that this material cannot be obtained organically in the appropriate form, quantity, or quality.</u>																									
C. Proposed Annotation (if any): _____ _____ Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____																									
D. Recommended Committee Action & Vote (State Actual Motion): <u>For Inclusion of Oat Bran Concentrate on the National List § 205.606</u>																									
Motion by: <u>Steve DeMuri</u> Seconded: <u>Joe Smillie</u> Yes: <u>0</u> No: <u>6</u> Absent: <u>0</u> Abstain: <u>0</u>																									
1) Substance as "allowed" on 205._____ with	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td style="width: 25%;">Crops</td> <td style="width: 25%;"></td> <td style="width: 25%;">Agricultural</td> <td style="width: 25%;"><input checked="" type="checkbox"/></td> <td style="width: 25%;">Allowed¹</td> <td style="width: 25%;"></td> </tr> <tr> <td>Livestock</td> <td></td> <td>Non-Synthetic</td> <td></td> <td>Prohibited²</td> <td></td> </tr> <tr> <td>Handling</td> <td><input checked="" type="checkbox"/></td> <td>Synthetic</td> <td></td> <td>Rejected³</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>No restriction</td> <td></td> <td>Commercially Un-Available as Organic¹</td> <td></td> <td>Deferred⁴</td> <td></td> </tr> </table>	Crops		Agricultural	<input checked="" type="checkbox"/>	Allowed ¹		Livestock		Non-Synthetic		Prohibited ²		Handling	<input checked="" type="checkbox"/>	Synthetic		Rejected ³	<input checked="" type="checkbox"/>	No restriction		Commercially Un-Available as Organic ¹		Deferred ⁴	
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_____ voted to be added National List to § 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. 606 Describe why material was rejected: Material was rejected because the petition did not demonstrate why organic oat bran, which is widely available, cannot be processed into the needed form.																									
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:																									
<u>Julie Weisman</u> Committee Chair	<u>April 2, 2008</u> Date																								

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance - Oat Bran Concentrate

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		Per the attached MSDS appendix 3.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		Same as above
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Same as above
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		None listed in the petition, ingredient specification, or MSDS.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		This is an agricultural product, and petitioner claims it is inert.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		Substance is an agricultural product, is GRAS, and is intended as an ingredient of food products.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		Same as above
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		None per the MSDS.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		Same as above
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		Substance is an agricultural product, is GRAS, and is intended as an ingredient of food products.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		Substance is an agricultural product, is GRAS, and is intended as an ingredient of food products.
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			Statement attached to the petition (Appendix 5), indicates it is GRAS under 21 CFR 170.30(d).
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		None listed in the MSDS attached to the petition.

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 - Oat Bran Concentrate

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		The manufacturing process flow diagram is CBI deleted from the petition, but petitioner states the oat bran is milled to a concentrated form using a patented “aqueous” 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		See above
3. Is the substance created by naturally occurring biological processes? [6502 (21)]			X	This is an agricultural product
4. Is there a natural source of the substance? [§205.600 b.1]			X	This is an agricultural product
5. Is there an organic substitute? [§205.600 b.1]			X	Material is being petitioned for inclusion on §205.606; see category 4 below.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	This is an agricultural product
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			X	This is an agricultural product
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			This is an agricultural product being petitioned for inclusion on §205.606.
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	

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 - Oat Bran Concentrate

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		Substance is a food ingredient intended for human heart health improvement.
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)] **- Oat Bran Concentrate**

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		Petition did not provide sufficient comparative information explaining why the non-organic form of the material 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?		X		No information was provided in the petition demonstrating the unavailability of raw organic oat bran for further processing, nor of the absence of processors to manufacture the oat bran concentrate. An internet search by the evaluator, and phone calls to several suppliers by the evaluator, indicated that organic oat bran is commercially available.
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		No information provided.
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		No information provided.
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:		X		No information provided.
a. Regions of production (including factors such as climate and number of regions);		X		No information provided.
b. Number of suppliers and amount produced;		X		No information provided.
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		No information provided.
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		X		No information provided.
e. Are there other issues which may present a challenge to a consistent supply?		X		No information provided.