

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: <u>May 2009</u>	Substance: <u>Wheat Germ</u>																								
Committee: Crops ☐ Livestock ☐ Handling ☒ Petition is for: Inclusion of <u>Wheat Germ</u> on the National List § <u>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 ☒ No ☐ N/A ☐																								
2. Essential & Availability Criteria	Yes ☒ No ☐ N/A ☐																								
3. Compatibility & Consistency	Yes ☒ No ☐ N/A ☐																								
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes ☒ No ☐ N/A ☐																								
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): Recommend <u>Wheat Germ</u> for listing on <u>§205.606</u> Motion by: <u>Steve DeMuri</u> Seconded: <u>Julie Wiseman</u> Yes: <u>6</u> No: <u>0</u> Absent: <u>0</u> Abstain: <u>0</u>																									
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1) Substance voted to be added as "allowed" on National List to § 205. <u>606</u> 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 § 205.606 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: <u>Steve DeMuri</u> Committee Chair <u>February 27, 2009</u> Date																									

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance – Wheat Germ

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

Category 2. Is the Substance Essential for Organic Production? Substance – Wheat Germ

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	
3. Is the substance created by naturally occurring biological processes? [6502 (21)]			X	
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	
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			Wheat germ is used as an ingredient for breads, other baked goods, vitamin blends and pet foods.
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 – Wheat Germ

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			This is an agricultural product
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			This is an agricultural product and can be grown sustainably
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	
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.

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 – Wheat Germ**

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?				The germ represents 2-2.5% of the wheat berry. Typical milling reasonably removes a much smaller percentage of germ from the berry. The germ has a short shelf-life, as little as three days, due to its high fat content. Once removed from the wheat berry, the wheat germ must be stabilized to prevent rancidity. Methods for stabilizing are steam (direct or indirect), toasting, infrared or chemical treatment (used for non-food grade applications).
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	Organic wheat germ in the appropriate form can be obtained
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	Organic wheat germ in the appropriate quality can be obtained
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			Petition page 3 – The petitioner has been able to find a source of approximately 4000 pounds annually of organic wheat germ. This amount does not meet the petitioner’s annual needs. An independent review found that the major organic flour millers are not producing organic wheat germ. The small amount of wheat germ by-product from a mill coupled with the short shelf-life of the germ make it impractical to produce.
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);		X		Regions of production/climate not a factor in availability
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	Weather not a factor in availability
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	Trade issues not a factor in availability
e. Are there other issues which may present a challenge to a consistent supply?		X		