

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: March 2007 Substance: Milled Flax Seed

Committee: Crops Livestock Handling Petition is for: Inclusion of Milled Flax Seed
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 checked="" 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 checked="" 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: Handling Committee members consider petitioners quality requirements to be overly stringent. Member of the Committee have direct knowledge of the abundance of organic flax seed grown in North America.

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 Flax Seed, Milled for inclusion on National List § 205.606

Motion by: Julie Weisman Seconded: Andrea Caroe Yes: 2 No: 3 Absent: 0 Abstain: 0

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	<input checked="" type="checkbox"/>	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. 606 Describe why material was rejected: Handling Committee members consider petitioners quality requirements to be overly stringent. Member of the Committee have direct knowledge of the abundance of organic flax seed grown in North America.

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 - Milled Flax Seed

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]			N/A	This is an agricultural product.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]			N/A	This is an agricultural product.
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		\X		
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	This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
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 used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]			X	This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
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.

Category 2. Is the Substance Essential for Organic Production? Substance - Milled Flax Seed

Question	Yes	No	N/A¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]			X	This is an agricultural product.
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	This is an agricultural product.
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]				Petitioned substance is from a natural source.
5. Is there an organic substitute? [§205.600 b.1]	XX			Petition p.4 “Availability of good....” States that there is not a sufficient quantity of organic flaxseed available that is of adequate quality for milling.
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	Petitioned substance is wholly natural.
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	
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 - Milled Flax Seed

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]		XX		This product adds nutritive value that would not otherwise be present. It does not replace nutrients lost during 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		
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 - Milled Flax Seed

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?	XX			Petition p. 1 Item B 4 states that material is necessary as a method of delivering fiber, phytonutrients and a vegetarian source of Omega-3 fatty acids to organic processed foods including baked goods, cereals, pasta, drinks and nutrition bars.
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?		XX		No information is given in this petition which indicates that organic flaxseed cannot be obtained in an appropriate form for use in organic processed foods.
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?	XX			Petition Justification Statement (5 th page) 1sr para. states there is a critical shortage of organically grown flax seed that is of suitable quality for milling (e.g. under 5% of dark seeds which are prone to oxidation and therefore, rancidity and loss of nutrients.)
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?		XX		Petition (8 th page) “Availability of ..” states that 75% of the organic flaxseed available was not suitable for milling based on analytical testing to determine oxidation levels. (Data in attachment D). However no information is given regarding tonnage of acceptable quality material that <u>is</u> available, relative to requirement.
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);		XX		Petition Justification Statement (5 th page) states that Flaxseed is grown in Western Canada and the U.S. States of North Dakota and Montana. There is no suggestion by petitioner that this is a factor in limiting the supply of suitable quality organic flaxseed.
b. Number of suppliers and amount produced;	XX			Petition (8 th page) reports that petitioner tested samples of organic flaxseed from four sources, only one of which was acceptable. No information is given on amounts of material involved.
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;		XX		This petition offers no information which suggests that there are weather-related issues which restrict supplies.
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		XX		This petition offers no information which suggests that there are trade-related issues which restrict supplies.
e. Are there other issues which may present a challenge to a consistent supply?		XX		Petition, p.4 cites short shelf-life and insufficient distribution networks as presenting a challenge to a consistent supply of organic milling quality organic flaxseed.