

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: Spring 2009

Substance: Lecithin, unbleached fluid

Committee: Crops Livestock Handling Petition is for: for removal from listing of Lecithin, unbleached, fluid 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 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 checked="" type="checkbox"/> N/A <input type="checkbox"/>

B. Substance Fails Criteria Category: 2, 4 Comments: Numerous varieties of organic lecithin are now commercially available which perform the same function as the listed material, but are made without the use of the synthetic extractants and bleaches.

C. Proposed Annotation (if any): "dry forms only" will be added to the current listing of Lecithin, unbleached on § 205. 606 of the National List

Basis for annotation: To meet criteria above: Other regulatory criteria: _____ Citation: _____

D. Recommended Committee Action & Vote (State Actual Motion): _____

Motion by: Julie Weisman Seconded: Joe Smillie Yes: 5 No: 0 Absent: 1 Abstain: 0

Crops		Agricultural		Allowed ¹	
Livestock		Non-Synthetic		Prohibited ² /Removal	<input checked="" type="checkbox"/>
Handling	<input checked="" type="checkbox"/>	Synthetic	<input checked="" type="checkbox"/>	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 _____

5) Substance was recommended to be removed (a suggested addition to accommodate petitions to remove) Describe why material is to be removed: At this time there are many forms of organic unbleached fluid lecithin available, as well as organic and conventional non-synthetic gums. These make the use of non-organic unbleached fluid lecithin, which is made with synthetic processing aids, no longer essential in organic handling. There is not enough information available at this time about the commercial availability of dry forms of organic unbleached lecithin. The annotation proposed in this recommendation will allow it's further use until it's next Sunset date.

E. Approved by Committee Chair to transmit to NOSB:

Steve DeMuri
Committee Chair

March 17, 2009
Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance - Lecithin, unbleached, fluid for

removal from § 205.606

Question	Yes	No	N/A¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]	X			Increased environmental concerns about the use of hexane and peroxides have resulted in legislation that could restrict oil processing operations that use them. (TR p. 6, lines 281-285)
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X			See above
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		“It is not likely to produce harmful degradation products in the short term.’ In the long term it may degrade, however, the TR (p.6, line 293) does not indicate that the long-term degradation products would be harmful.
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		The TR (p.3 lines 131-134) states that the EPA exempts from the requirement of a tolerance, the residues resulting from the use of lecithin as an inert or active ingredient in pesticides as long use is in accordance with good agricultural or manufacturing practices.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		See above
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		See # 3 and #6 above
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		See #3 and #6 above
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		The TR (p.6, lines 287-291) states that there is “no reasonable grounds to suspect that any form of lecithin poses a hazard to the public when used at levels that are now current.”
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		FDA approves all forms of lecithin for use in food with no limitation other than GMP. (TR p. 3 lines 128-129).
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 - Lecithin, unbleached, fluid for removal from § 205.606

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			According to the TR (pp. 4-5) Crude soy obtained by hexane extraction from soy flakes. It is then de-oiled using acetone.
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			See below
5. Is there an organic substitute? [§205.600 b.1]	X			TR identifies 4 manufacturers of organic lecithin. One in France, one in India and 2 in the U.S.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	X			A wide variety of organic products currently available could not be made with out an emulsifier. (See TR p.2) Lecithin is the primary emulsifier used in these products.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			According to both the petitioner and the TR , the organic forms are the only forms of lecithin that are being produced without using synthetic solvents. Theoretically the extraction could be done, producing a non-organic (i.e. natural) soy lecithin, but none are being produced at this time.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		There are four manufacturer known to the Technical Reviewer that are currently producing a variety of formulations of organic lecithin. (TR p.6, line 275)
9. Is there any alternative substances? [§6518 m.6]	X			A number of forms of organic lecithin which achieve a light color without bleaching, are now available in commercial quantities. In addition, there are now other organic and conventional non-synthetic, non-soy materials, such as gums and rice products which serve similar functions. There is no information given by the petitioner or in the TR suggesting that dry forms of organic unbleached lecithin are commercially available at this time.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			TR describes production process for organic substitute (p. 6) Oil obtained by expeller press instead of hexane extraction. Varieties of soy yielding lighter-colored oil, combined with filtration are used to achieve the same effect as bleaching.

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 - Lecithin, unbleached, fluid for removal from § 205.606

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	Substance is used handling, not production.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			There is no published evidence to suggest that unbleached fluid lecithin has any impact on the nutritional quality of the food in which it is used. (TR p. 7, line 319)
5. Is the primary use as a preservative? [§205.600 b.4]		X		The primary use of lecithin is as an emulsifier. (TR p.7, lines 325-326.)
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		Although lecithin does have an effect on texture and dispersion of ingredients in a food, it is not used “recreate or improve” qualities that were 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		
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 - Lecithin, unbleached fluid for removal from § 205.606

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/ is no longer necessary for use in organic handling?	X			The petition describes in detail new methods for making organic fluid lecithin in a range of shades using only allowed methods.
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance can /cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?	X			There are now numerous varieties of certified organic lecithin. The Technical Review in response to “Evaluation Question #5, identifies 4 manufacturers worldwide, of such lecithin. There is no information included on the petition or the TR indicating that dry forms of unbleached organic lecithin are commercially available at this time.
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance can /cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling?	X			Petitioner states that products made with organic fluid lecithin and non-organic fluid lecithin are indistinguishable. Panel testing has been conducted which confirms this, according to the petition.
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance can /cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling?	X			Petitioner states that there is currently unsold inventory and additional capacity available to make organic fluid lecithin sufficient to meet current requirements.
5. Does the industry information provided on material / substance non-availability/ availability as organic, include (but not limited to) the following: a. Regions of production (including factors such as climate and number of regions);			N/A	
b. Number of suppliers and amount produced;	X			See number 2 above
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may/no longer temporarily halt production or destroy crops or supplies;			N/A	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may/no longer temporarily restrict supplies; or			N/A	
e. Are there other issues which may/no longer present a challenge to a consistent supply?		X		