

NOSB RECOMMENDED DECISION FORM

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: <u>May 2009</u>		Substance: <u>Lecithin, bleached for removal from the National List § 205.605b</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 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?	C. Proposed Annotation: _____																									
Criteria category: <u>2,4</u>	Basis for annotation:																									
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 synthetic extractants and bleaches.	To meet criteria above: _____ Criteria: _____																									
	Other regulatory criteria: _____ Citation: _____																									
D. Final Board Action & Vote (State Actual Motion): <u>It is moved that Lecithin, bleached be removed from § 205.605b of the National List</u>																										
Motion: <u>Steve DeMuri</u> Second: <u>Hue Karreman</u> Yes: <u>13</u> No: <u>1</u> Abstain: <u>0</u> Absent: <u>1</u>																										
No longer exempt Provide a summary attach a more and attach the recommendation that includes the evaluation criteria checklist:	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Agricultural</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Nonagricultural</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Crops</td> <td style="padding: 5px;"></td> </tr> <tr> <td style="padding: 5px;">Synthetic</td> <td style="padding: 5px; text-align: center;"><input checked="" type="checkbox"/></td> <td style="padding: 5px;">Not synthetic</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Livestock</td> <td style="padding: 5px;"></td> </tr> <tr> <td style="padding: 5px;">Allowed¹</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Prohibited²</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Handling</td> <td style="padding: 5px; text-align: center;"><input checked="" type="checkbox"/></td> </tr> <tr> <td style="padding: 5px;">No restriction</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Deferred⁴</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Rejected / Remove³</td> <td style="padding: 5px; text-align: center;"><input checked="" type="checkbox"/></td> </tr> </table>	Agricultural		Nonagricultural		Crops		Synthetic	<input checked="" type="checkbox"/>	Not synthetic		Livestock		Allowed ¹		Prohibited ²		Handling	<input checked="" type="checkbox"/>	No restriction		Deferred ⁴		Rejected / Remove ³	<input checked="" type="checkbox"/>	from prohibition <input checked="" type="checkbox"/> narrative here or complete narrative, original committee
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The petitioner requested the removal of both the unbleached and bleached forms of lecithin. During the May 2009 NOSB meeting, several experts and lecithin industry members provided informational presentations describing the types of lecithin available, and the methods of manufacture for each. It was explained that it is the "de-oiling" process, not the bleaching process, which truly differentiated the types and functionality of lecithin, and dictated in which products they could be used. At this time, there are now many forms of organic lecithin available, as well as organic and conventional non-synthetic gums, which make the use of this synthetic form of lecithin no longer essential in organic handling. The board voted to remove the "bleached" form of lecithin from 205.605(b), but in a separate vote, agreed to list "lecithin – de-oiled" in 205.606, making that form available to organic manufacturers who truly needed it, but subjecting its use to commercial availability scrutiny by certifiers. Both the petitioner and lecithin using handlers present at the NOSB meeting were satisfied with this recommendation.																										
1—substance voted to be added as "allowed" on National List on National List to § 205. _____ with Annotation (if any): _____																										
2—substance to be added to "prohibited" paragraph of National List to § 205. _____ 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 § 205. _____ Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow-up _____																										
5) Substance was recommended to be removed . Describe why material is to be removed. At this time there are many forms of organic lecithin available, as well as organic and conventional non-synthetic gums, which make the use of this synthetic form of lecithin no longer essential in organic handling.																										
E. Approved by NOSB Chair to transmit to NOP Jeff Moyer _____ <u>August 17, 2009</u> Chair Date																										
F. NOP Action: Include in FR to amend National List: Return to NOSB Reason: _____ _____ Date																										

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: Spring 2009

Substance: for removal from the National List § 205.605b

Committee: Crops Livestock Handling Petition is for: For removal of lecithin - bleached from the National List § 205.605 b

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

- | | | | |
|--|---|--|------------------------------|
| 4. Impact on Humans and Environment | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 5. Essential & Availability Criteria | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 6. Compatibility & Consistency | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 7. 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): _____

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

D. Recommended Committee Action & Vote (State Actual Motion): _____ It is moved that the Lecithin, bleached be removed from § 205.60b of the National List _____

Motion by: Julie Weisman Seconded: Steve DeMuri Yes: 5 No: 0 Absent: 1 Abstain: 0

Crops		Agricultural		Allowed ¹	
Livestock		Non-Synthetic		Prohibited ²	
Handling	<input checked="" type="checkbox"/>	Synthetic	<input checked="" type="checkbox"/>	Rejected / Remove ³	<input checked="" type="checkbox"/>
No restriction		Commercially Un-Available as Organic ¹		Deferred ⁴	

1) Substance as "allowed" on 205. _____ with _____

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. _____ 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** Describe why material is to be removed At this time there are many forms of organic lecithin available, as well as organic and conventional non-synthetic gums which make the use of this synthetic form of lecithin no longer essential in organic handling.

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?
§ 205.605 b**

Substance - Lecithin, bleached for removal from

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			Increased environmental concerns about the use of hexane and 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, bleached for removal from § 205.605 b

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. Lecithin is bleached via hydrogen peroxide and benzyl peroxide.
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 and bleaching agents, although theoretically this could be done using non-organic agricultural ingredients.
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 materials, such as gums which serve similar functions.
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?
for removal from § 205.605 b**

Substance - Lecithin, bleached

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 in handling, not crop 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 bleached 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, bleached for removal from § 205.605 b

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 (or is no longer) necessary for use in organic handling?	X			The petition describes on detail new methods for making organic lecithin that is light in color using only allowed methods.
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			There are now numerous varieties of light-colored, certified organic lecithin. The Technical Review in response to "Evaluation Question #5, identifies 4 manufacturers worldwide, of such lecithin.
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			Petitioner states that products made with organic lecithin and the listed material 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 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 lecithin sufficient to meet current requirements.
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);			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 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 temporarily restrict supplies; or			N/A	
e. Are there other issues which may present a challenge to a consistent supply?		X		