### NOSB RECOMMENDED DECISION FORM

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: May 2009	Substance: Lecithin-	Substance: Lecithin- unbleached – for amending the listing to "Lecithin – deoiled" in 205.606									
A. Evaluation Criteria (Applicabili	ity noted for each categ	y noted for each category; Documentation attached) <u>Criteria Satisfied? (see B below)</u>									
1. Impact on Humans and Env	vironment			Yes X	No 🗌	N/A					
2. Essential & Availability Crite	eria			Yes X	No 🗌	N/A					
3. Compatibility & Consistency											
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) Yes ${f X}$ No $\Box$ N/A $\Box$											
B. Substance fails criteria?	C. Proposed Annota	C. Proposed Annotation: Deoiled									
Criteria category: Comments:		To meet criteria at Other regulatory cr									
D. Final Board Action & Vote (	Final Board Action & Vote (State Actual Motion): To AMEND the listing of Lecithin - unbleached in section 205.606 of the										
National List, to "Lecithin				[		<b></b>					
section 205.606 of the Nation	onai List.	Agricultural	Х	Nonagricultural		Crops					
Motion: <u>Julie Weisman</u> Second: Yes: <u>13</u> No: <u>1</u> Abstai	<u>Joe Smillie</u> in: <u>0</u> Absent:	Synthetic		Not synthetic		Livestock					
1		Allowed <sup>1</sup>	Х	Prohibited <sup>2</sup>		Handling	Х				
Provide a summary narrative her complete narrative, and attach the		No restriction		Deferred4		Rejected <sup>3</sup>					
committee recommendation that		on criteria check	list:								
This material, Lecithin – unbleached, was petitioned to be removed from the National List, section 205.606. After reviewing numerous public comments on this material, and receiving several thorough expert presentations and explanations during the May 2009 NOSB meeting, the board held a lively discussion regarding the appropriate action to take with respect to removing or amending the listing of unbleached lecithin on the National List. Bleached lecithin was also petitioned to be removed, from 205.605(b), with the Handling Committee recommending and the full board voting to remove bleached lecithin because organic forms of lecithin had become available. The board decision on bleached lecithin is detailed in a separate recommendation.											
National List 205.606. The expert explanations and presentations given at the full board meeting brought to light the fact that it was the "de-oiling" process, not necessarily the bleaching process, which truly differentiated types and potential uses of lecithins in a variety of products. In some cases, de-oiled lecithin was the only form appropriate for certain products and de-oiled lecithin is NOT currently available as organic in sufficient quantity or quality. Several handlers claimed the removal of de-oiled forms of lecithin from the National List would leave them without an option for some of their products. This manufacturing information was apparently either not available, not well explained, or not understood by previous boards who considered the listing of lecithin, hence the dual listing of lecithin - the unbleached form in 205.606, and the bleached form in 205.605(b). In 6/00 comments on the proposed rule, a previous board asked that unbleached lecithin be listed as agricultural, needing to be organic when available. Their line of thinking is similar to what this board has recommended.											
After much discussion, the board a Remove Lecithin – unble Add "Lecithin – de-oiled	eached from 206.606, a										
This essentially amends the listing of "Lecithin – unbleached" in 205.606 to "Lecithin – deoiled" in 205.606 of the National List. Allowing use of de-oiled forms only restricts the use of non-organic lecithin to only those forms not currently available as organic, and moving the material to 205.606 subjects it to certifier commercial availability scrutiny. Potential users of the de-oiled forms must prove to their certifier that it is the only form of lecithin appropriate for their products, and that no organic alternatives are available. The petitioner (a lecithin supplier) was satisfied with this recommended action, and the lecithin using manufacturers present at the board meeting indicated this amended listing would meet their needs as well. See May 2009 NOSB meeting transcripts for full discussion details.											
1—substance voted to be added as "allowed" on National List on National List to § 205.606 with Annotation (if any): Lecithin - Deoiled. 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											
E. Approved by NOSB Chair to tra Jeff Moyer NOSB Chair	Insmit to NOP	·		Ma Date	ay 6, 200	09	<u>.</u>				
	to amend National Lis										
				Da	ate						

#### Revised Committee Recommendation to amend "Lecithin – unbleached" to "Lecithin – de oiled" on 205.606. Revised May 5, 2009 during the full board meeting May 2009:

#### NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1	Committee Transmittal to NOSB

For NOSB Meeting:	or NOSB Meeting: <u>Spring 2009</u> Substance: <u>Lecithin, unbleached,</u>									
Committee: Crops 🗌 Livestock 🗌 Handling X Petition is for <u>: amending the listing of Lecithin, unbleached, to</u> lecithin, deoiled on the National List § 205. 606										
A. Evaluation Criteria (Applicability noted for each category; Documentation attached)       Criteria Satisfied? (see B below)         4. Impact on Humans and Environment       Yes X       No       N/A         5. Essential & Availability Criteria       Yes X       No       N/A         6. Compatibility & Consistency       Yes X       No       N/A         7. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)       Yes X       No       N/A         8. Substance Fails Criteria Category:       Comments:										
Motion by. <u>Julie Wes</u>	<u>sman</u> Seconded.		res. <u>5</u> 1	10. <u>0</u> Absent	<u>1</u>	Abstain. <u>0</u>				
	Crops	Agricultural	Х	Allowed <sup>1</sup>	Χ					
	Livestock	Non-Synthetic		Prohibited <sup>2</sup> /Removal						
	Handling	Synthetic		Rejected <sup>3</sup>						
	No restriction	Commercially L Available as Or	Jn- ganic <sup>1</sup>	Deferred <sup>4</sup>						
2) Substance to be ac Describe why a pro	1) Substance voted to be added as "allowed" on National List to § 205.606 with Annotation (if any) De-oiled         2) Substance to be added as "prohibited" on National List to § 205with Annotation (if any)         Describe why a prohibited substance:									
	ected by vote for amend commended to be defer	-	o § 205	Describe why material w	/as reje	ected:				
,										
If follow-up needed, who will follow up										
E. Approved by Cor <u>Steve De</u> Committee Chair	nmittee Chair to trans <u>Muri</u>	<u>N</u>	1 <u>ay 5, 2009</u> ate							

#### NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

## Category 1. Adverse impacts on humans or the environment? <u>Lecithin – deoiled in 205.606</u>

Substance - Lecithin, unbleached, amend to

Questian	Vee	Na	N/A <sup>1</sup>	Decumentation
Question	Yes	No	N/A	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]	Х			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]	Х			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]		х		
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]		х		See above
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		х		See # 3 and #6 above
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		х		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]		х		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]		х		

#### Category 2. Is the Substance Essential for Organic Production? Substance - <u>Lecithin, unbleached, amend to</u> Lecithin – deoiled in 205.606

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]		х		
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]	х			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]	х			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.

# Category 3. Is the substance compatible with organic production practices? Substance - Lecithin, unbleached, amend to Lecithin – deoiled in 205.606

Question	Yes	No	N/A <sup>1</sup>	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)]	х			
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.
<ul><li>7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:</li><li>a. copper and sulfur compounds;</li></ul>		х		
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		х		
d. livestock parasiticides and medicines?		х		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		х	+	

#### 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, amend to Lecithin – deoiled in 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/ <u>is no longer</u> necessary for use in organic handling?	х			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 <u>can</u> /cannot be obtained organically in the appropriate <u>form</u> 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 <u>can</u> /cannot be obtained organically in the appropriate <u>guality</u> 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 <u>can</u> /cannot be obtained organically in the appropriate <u>quantity</u> to fulfill an essential function in a system of organic handling?	х			Petitioner states that there is currently unsold inventory and additional capacity available to make organic fluid lecithin sufficient to meet current requirements.
<ul> <li>5. Does the industry information provided on material / substance non- availability/<u>availability</u> as organic, include ( but not limited to) the following:</li> <li>a. Regions of production (including factors such as climate and number of regions);</li> </ul>			N/A	
b. Number of suppliers and amount				See number 2 above
produced; 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;	<u>x</u>		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?		х		

#### Original Committee Recommendation and Evaluation Checklist from March 17, 2009 for Removal of Lecithin – unbleached from §205.606 NOSB COMMITTEE RECOMMENDATION

		Form NC	PLIST1. Commi	ittee Tr	ansmittal to	NOSB						
For NOSB Meeting:	For NOSB Meeting:Spring 2009 Substance:Lecithin, unbleached_fluid											
Committee: Crops Livestock Handling X Petition is for: <u>for removal from listing of Lecithin, unbleached,</u> on the National List § 205. 606												
A. Evaluation Criteria (Applicability noted for each category; Documentation attached) Criteria Satisfied? (see B below)												
8. Impact on Humans and Environment Yes <b>X</b> No N/A												
9. Essential & A	9. Essential & Availability Criteria Yes 🗌 No 🗴 N/A 🗌											
10. Compatibility	10. Compatibility & Consistency Yes X No 🗌 N/A 🗌											
11. Commercial S	11. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) Yes D No X N/A D											
commercially availab	B. Substance Fails Criteria Category: <u>2, 4</u> Comments: <u>Numerous varieties of organic lecithin are now</u> 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 606of the National List											
Basis for annotation	on: To meet criteria a	bove: <u>X</u>	Other regu	ulatory	criteria:	Citation:						
D. Recommended (	Committee Action 8	Vote (State	Actual Motion):									
Motion by: <u>Julie Wei</u>	Motion by: <u>Julie Weisman</u> Seconded: <u>Joe Smillie</u> Yes: <u>5</u> No: <u>0</u> Absent: <u>1</u> Abstain: <u>0</u>											
	Crops Livestock	Agricult Non-Sy			Allowed <sup>1</sup>	d <sup>2</sup> /Removal	X					
	Handling	X Synthe		Х	Rejected		^					
	No restriction	Comme	ercially Un- le as Organic <sup>1</sup>	Λ	Deferred							
<ol> <li>Substance voted t</li> <li>Substance to be a</li> </ol>												
,						(ii airy)						
Describe why a pro	ohibited substance:											
3) Substance was rej	3) Substance was rejected by vote for amending National List to § 205Describe why material was rejected:											
4) Substance was rec	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: <u>At this time there are many forms of</u> 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 Co	mmittee Chair to tra	insmit to NO	SB:									
				2000								
Committee Chair	<u>anuli</u>	_	<u>March 17,</u> Date	2009								

#### NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

## Category 1. Adverse impacts on humans or the environment? removal from § 205.606

Substance - <u>Lecithin, unbleached, fluid for</u>

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]	Х			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]	Х			See above
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		х		"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]		х		
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		х		
6. Are there adverse biological and chemical interactions in agro- ecosystem? [§6518 m.5]		х		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]		х		See above
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		х		See # 3 and #6 above
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		х		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]		х		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]		х		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]		х		

# Category 2. Is the Substance Essential for Organic Production? Substance - <u>Lecithin, unbleached, fluid for</u> removal from § 205.606

Question	Yes	No	N/A <sup>1</sup>	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.

# Category 3. Is the substance compatible with organic production practices? Substance - <u>Lecithin, unbleached, fluid</u> for removal from § 205.606

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
A letter advector as a server of the with				(TAP; petition; regulatory agency; other)
1. Is the substance compatible with	V			
organic handling? [§205.600 b.2] 2. Is the substance consistent with	Х			
organic farming and handling? [§6517	х			
c (1)(A)(iii); 6517 c (2)(A)(ii)]	^			
C(T)(A)(III), 0517 C(2)(A)(II)]				
3. Is the substance compatible with a				Substance is used handling, not production.
system of sustainable agriculture?			Х	5, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1,
[§6518 m.7]				
4. Is the nutritional quality of the food				There is no published evidence to suggest that unbleached fluid
maintained with the substance?	Х			lecithin has any impact on the nutritional quality of the food in which it
[§205.600 b.3]				is used. ( TR p. 7, line 319)
5. Is the primary use as a		Х		The primary use of lecithin is as an emulsifier. (TR p.7, lines 325-
preservative? [§205.600 b.4]				326.)
6. Is the primary use to recreate or				Although lecithin does have an effect on texture and dispersion of
improve flavors, colors, textures, or		Х		ingredients in a food, it is not used "recreate or improve" qualities
nutritive values lost in processing				that were lost in processing.
(except when required by law, e.g.,				
vitamin D in milk)? [205.600 b.4]				
7. Is the substance used in		X		
production, and does it contain an		х		
active synthetic ingredient in the following categories:				
a. copper and sulfur compounds;				
b. toxins derived from bacteria;		Х	[	
c. pheromones, soaps, horticultural				
oils, fish emulsions, treated seed,		Х		
vitamins and minerals?				
d. livestock parasiticides and	L		+	
medicines?		х		
e. production aids including netting,				
tree wraps and seals, insect traps,		Х		
sticky barriers, row covers, and				
equipment cleaners?				

#### 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 (or is no longer) necessary for use in organic handling?	х			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 be obtained organically in the appropriate <u>form</u> 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 be obtained organically in the appropriate <b><u>guality</u></b> to fulfill an essential function in a system of organic handling?	х			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 be obtained organically in the appropriate <u>guantity</u> to fulfill an essential function in a system of organic handling?	х			Petitioner states that there is currently unsold inventory and additional capacity available to make organic fluid lecithin sufficient to meet current requirements.
<ul> <li>5. Does the industry information provided on material / substance non-availability as organic, include ( but not limited to) the following:</li> <li>a. Regions of production (including factors such as climate and number of regions);</li> </ul>			N/A	
b. Number of suppliers and amount produced;	х			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		