

DRAFT

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance Soy Protein Isolate

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		Figure 1 shows the manufacturing process; little environmental contamination is expected from manufacture, use, misuse or disposal. (Ostiguy)
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); 205.601m.2]		X		Not listed as a list 1, 2, or 3 inert by EPA; several soybean oils are on List 3. TAP pg 5, 6
5. Is there potential for detrimental chemical interaction with other materials used [§6518 m.1]		X		No potential for detrimental chemical interactions with organic farming system have been observed TAP pg 6
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		No potential for detrimental chemical interactions with organic farming system have been observed TAP pg 6
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		No detrimental effects are expected TAP 16
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		No adverse or toxic actions are expected TAP pg 7, 8
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		Readily degradable organic material TAP pg 6
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		Soy contains phytoestrogens. Controversy exists concerning the detrimental (estrogen mimic) and beneficial (cancer reduction and lowering of LDL/increasing HDL) impacts. - Ostiguy
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? [§205.600b.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.

DRAFT

Category 2. Is the Substance Essential for Organic Production? Substance Soy Protein Isolate

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is there a natural source of the substance? [§205.600 b.1]			X	
2. Is there an organic substitute? [§205.600 b.1]			X	
3. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
4. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			Other plant soil amendments are available; other fertilizers are manure, composted plant and animal materials
5. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
6. Are there any alternative substances? [§6518 m.6]	X			Other plant soil amendments are available; other fertilizers are manure, composted plant and animal materials
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Soil fertility and crop nutrient management practices listed in 205.203

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

DRAFT

Category 3. Is the substance compatible with organic production practices? Substance Soy Protein Isolate

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		Soy protein isolate has been petitioned for use as a fertilizer TAP pg 1; producers on organic farms “shall not use any fertilizers containing synthetic ingredients” OFPA 6508 (b)(1) or “use as a source of nitrogen: phosphorous, lime, potash, or any materials that are inconsistent with the applicable organic certification program” OFPA 6508 (b)(2)
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		Soy protein isolate has been petitioned for use as a fertilizer TAP pg 1; producers on organic farms “shall not use any fertilizers containing synthetic ingredients” OFPA 6508 (b)(1) or “use as a source of nitrogen: phosphorous, lime, potash, or any materials that are inconsistent with the applicable organic certification program” OFPA 6508 (b)(2)
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:				
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			“Soy protein isolate is being petitioned for use as a fertilizer”

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB RECOMMENDED DECISION

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: <u> May 2004 </u>	Substance: <u>Soy Protein Isolate</u>																				
<p>A. Evaluation Criteria (Documentation attached; committee recommendation attached)</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;"></td> <td style="text-align: right;">Criteria Satisfied?</td> </tr> <tr> <td>1. Impact on humans and environment</td> <td style="text-align: right;">Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)</td> </tr> <tr> <td>2. Availability criteria</td> <td style="text-align: right;">Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)</td> </tr> <tr> <td>3. Compatibility & consistency</td> <td style="text-align: right;">Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)</td> </tr> </table>			Criteria Satisfied?	1. Impact on humans and environment	Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)	2. Availability criteria	Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)	3. Compatibility & consistency	Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)												
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<p>B. Substance fails criteria?</p> <p>Criteria category: _____</p> <p>Comments: _____</p>	<p>C. Proposed Annotation: _____</p> <p>_____</p> <p>Basis for annotation:</p> <p>To meet criteria above: _____ Criteria: _____</p> <p>Other regulatory criteria: _____ Citation: _____</p>																				
<p>D. Final Board Action & Vote: Motion by: _____ Second: _____</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%; padding: 5px;">Vote:</td> <td style="width: 25%; border: 1px solid black; text-align: center;">Agricultural</td> <td style="width: 25%; border: 1px solid black; text-align: center;">Nonagricultural</td> <td style="width: 25%; border: 1px solid black; text-align: center;">Crops</td> <td style="width: 10%; border: 1px solid black; text-align: center;">X</td> </tr> <tr> <td style="padding: 5px;">Yes: _____</td> <td style="border: 1px solid black; text-align: center;">Synthetic</td> <td style="border: 1px solid black; text-align: center;">Not synthetic</td> <td style="border: 1px solid black; text-align: center;">Livestock</td> <td style="border: 1px solid black;"></td> </tr> <tr> <td style="padding: 5px;">No: _____</td> <td style="border: 1px solid black; text-align: center;">Allowed¹</td> <td style="border: 1px solid black; text-align: center;">Prohibited²</td> <td style="border: 1px solid black; text-align: center;">Handling</td> <td style="border: 1px solid black;"></td> </tr> <tr> <td style="padding: 5px;">Abstain: _____</td> <td style="border: 1px solid black; text-align: center;">No restriction</td> <td style="border: 1px solid black; text-align: center;">Deferred⁴</td> <td style="border: 1px solid black; text-align: center;">Rejected³</td> <td style="border: 1px solid black;"></td> </tr> </table> <p style="text-align: center; margin-top: 5px;">1—substance voted to be added as “allowed” on National List</p> <p>Annotation: _____</p> <p style="text-align: center; margin-top: 5px;">2—substance to be added to “prohibited” paragraph of National List</p> <p>Describe why a prohibited substance: _____</p> <p style="text-align: center; margin-top: 5px;">3—substance was rejected by vote for amending National List</p> <p>Describe why material was rejected: _____</p> <p style="text-align: center; margin-top: 5px;">4—substance was recommended to be deferred</p> <p>Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow-up. _____</p>		Vote:	Agricultural	Nonagricultural	Crops	X	Yes: _____	Synthetic	Not synthetic	Livestock		No: _____	Allowed ¹	Prohibited ²	Handling		Abstain: _____	No restriction	Deferred ⁴	Rejected ³	
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<p>E. Approved by NOSB Chair to transmit to NOP:</p> <table style="width: 100%; border: none; margin-top: 10px;"> <tr> <td style="width: 50%; border-bottom: 1px solid black; text-align: center;">Dave Carter, NOSB Chair</td> <td style="width: 50%; border-bottom: 1px solid black; text-align: center;">Date</td> </tr> </table>		Dave Carter, NOSB Chair	Date																		
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<p>F. NOP Action: Include in FR to amend National List: <input type="checkbox"/></p> <p>Return to NOSB <input type="checkbox"/> Reason: _____</p> <table style="width: 100%; border: none; margin-top: 10px;"> <tr> <td style="width: 50%; border-bottom: 1px solid black; text-align: center;">Richard H. Mathews, Program Manager</td> <td style="width: 50%; border-bottom: 1px solid black; text-align: center;">Date</td> </tr> </table>		Richard H. Mathews, Program Manager	Date																		
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NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: <u>April 2004</u>	Substance: <u>Soy Protein Isolate</u>																
Committee: Crops <input checked="" type="checkbox"/> Livestock <input type="checkbox"/> Handling <input type="checkbox"/>																	
A. Evaluation Criteria (Documentation attached; committee recommendation attached)																	
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B. Substance fails criteria? Criteria category: _____ Comments: _____	C. Proposed Annotation: _____ Basis for annotation: To meet criteria above: _____ Criteria: _____ Other regulatory criteria: _____ Citation: _____																
D. Recommended Committee Action & Vote: Motion by: <u>Nancy Ostiguy</u> Seconded: <u>Rose Koenig</u>																	
Reject TAP; the TAP did not address use of material as soil amendment																	
Vote: Yes: <u>3</u> No: <u>0</u> Abstain: <u>0</u>	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td style="width: 25%;">Agricultural</td> <td style="width: 25%;">Nonagricultural</td> <td style="width: 25%;">Crops</td> <td style="width: 25%;"><input checked="" type="checkbox"/></td> </tr> <tr> <td>Synthetic</td> <td>Not synthetic</td> <td>Livestock</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Allowed¹</td> <td>Prohibited²</td> <td>Handling</td> <td><input type="checkbox"/></td> </tr> <tr> <td>No restriction</td> <td>Deferred⁴</td> <td><input checked="" type="checkbox"/> Rejected³</td> <td><input type="checkbox"/></td> </tr> </table>	Agricultural	Nonagricultural	Crops	<input checked="" type="checkbox"/>	Synthetic	Not synthetic	Livestock	<input type="checkbox"/>	Allowed ¹	Prohibited ²	Handling	<input type="checkbox"/>	No restriction	Deferred ⁴	<input checked="" type="checkbox"/> Rejected ³	<input type="checkbox"/>
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1—substance voted to be added as “allowed” on National List Annotation: _____ 2—substance to be added to “prohibited” paragraph of National List Describe why a prohibited substance: _____ 3—substance was rejected by vote for amending National List Describe why material was rejected: _____ 4—substance was recommended to be deferred Describe why deferred; if follow-up is needed. If follow-up needed, who will follow up <u>Reject TAP; TAP did not address use of material as soil amendment; revise TAP to focus on the use of this material in/on soil; delete all information on soy protein isolate as a food; is soy protein isolate synthetic or non-synthetic? (Look at other materials that has been determined to be non-synthetic; is soy protein isolate processed more or less than other materials that have been determined to be synthetic or non-synthetic); FDA information needed (do not need information on use as a food); address its use as a soil amendment; what percent of soy is genetically modified; what is the genetic modification; if some soy is genetically modified, how is cross-contamination handled; if soy is genetically modified could the protein from the genetic modification be concentrated during processing into soy protein isolate; Figure 1 shows the basic manufacturing process, discuss the impact on the environment of an acid and a base used for neutralization during manufacturing (answer Category 1, question 1); Answer Category 1, question 5 – soy protein isolate is being used as a soil amendment – what action would this material have in soil, in the agroecosystem? Answer Category 1, question 8 – is soy protein isolate persistence? Can in concentrate? What are its breakdown products? Can these break-down products persist or concentrate in the environment? Revise remaining category 1 and 2 questions to address the use of material as a soil amendment and delete information on use as a food.</u>																	
E. Approved by Committee Chair to transmit to NOSB:																	
Committee Chair _____	Date _____																