

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance Chitosan (poly-D-Glucosamine)

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		Hydrochloric acid, sodium hydroxide, mild organic acid, e.g., acetic, are used in the manufacture of this product. TAP pg. 2, lines 81-95, pg 3 All the material can be neutralized. Misuse or disposal with neutralizing first could be detrimental. TAP pg 4, lines 126-146
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Raw material for Chitosan is crustacean shell waste byproduct. TAP Pg2, lines 81-81 EPA exemption from tolerance; abundant in environment, TAP pgs 4-5, lines 151-155.
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		This form of chitosan could cause negatively charged particles to stick to plant surfaces but this is not likely. This material (non ionized form) is found in the environment as chitosan and chitin. Soluble chitosan is not highly reactive. TAP pg 5, lines 161-184.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		This material (non ionized form) is found in the environment as chitosan and chitin. Soluble chitosan is not highly reactive. TAP pg 5, lines 161-184.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			May have adversely impact soil; shown to be antimicrobial, antifungal, and antiviral. Enhances plant growth. As an adjuvant, the quantity of material used is insufficient to result in above effects. TAP pg5, lines 189-205
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		Chitosan is non-toxic to mice rates and rabbits. TAP pg 5, lines 154-155. Breakdown products are non-toxic. TAP pg 6, lines 214-217
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		Not persistent, highly biodegradable due to chitinases and chitosanases that occur naturally in environment. TAP pg 8, lines 222-226
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		Not known to be toxic to humans; used as a dietary supplement. TAP pg 6, lines 231-234
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 Chitosan (poly-D-Glucosamine)

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			An adhesive adjuvant formulated with lactose, bentonite, and casein is available as are two that are formulated with pine-based functional agents. It is not known if these products are synthetic. TAP pg 6, lines 243-254
5. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
6. Is there any alternative substances? [§6518 m.6]		X		There are three adjuvants marketed as organic but it is unknown if they are synthetic. None are on the National List. TAP pg 6-7, lines 259-264
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Various IPM practices, e.g., stock selection, irrigation management, air flow, etc., exist to reduce the extent of outbreaks. IPM practices do not eliminate severe outbreaks from ever occurring. At that time other methods may be necessary to prevent losses. TAP pg 7, lines 269-292

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Category 3. Is the substance compatible with organic production practices?

Substance Chitosan (poly-D-Glucosamine)

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	X		Is made from renewable resources. TAP pg 2, lines 81-83. As an adjuvant, it is consistent with organic farming. It is used at a very low rate as a sticking agent; used after other methods of disease control. TAP pg 1, lines 26-28. As an adjuvant, it is expected to reduce the number if and quantity by application of copper sulfate. TAP pg 7, lines 269-273 At higher levels of use the material is a plant growth enhancer and a plant defense booster. TAP pg 1, lines 37-44. It is a flocculant, a hydrating agent, a pharmaceutical agent in biomedicine, an antimicrobial in food wrap, and a soil amendment (Oregon, with no amount restrictions). TAP pg 2, lines 51-55
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X	X		Consistent with other materials on National List – derived from naturally occurring materials and reduces waste products from other industries. TAP pg 4, lines 145-146 It is a plant growth enhancer and a plant defense booster. TAP pg 1, lines 37-44. It is a flocculant, a hydrating agent, a pharmaceutical agent in biomedicine, an antimicrobial in food wrap, and a soil amendment (Oregon, with no amount restrictions). TAP pg 2, lines 51-55
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			An adhesive adjuvant for use in organic crop production – a sticking agent. TAP pg 1, lines 31-34

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>August 2005</u>	Substance <u>Chitosan</u> (poly-D-Glucosamine)																				
A. Evaluation Criteria (Documentation attached; committee recommendation attached) <table style="width: 100%;"><tr><td style="width: 50%;">1. Impact on humans and environment</td><td style="width: 50%;">Criteria Satisfied? Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)</td></tr><tr><td>2. Availability criteria</td><td>Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)</td></tr><tr><td>3. Compatibility & consistency</td><td>Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)</td></tr></table>		1. Impact on humans and environment	Criteria Satisfied? 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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B. Substance fails criteria? Criteria category: _____ Comments: _____	C. Proposed Annotation: _____ Basis for annotation: To meet criteria above: _____ Criteria: _____ Other regulatory criteria: _____ Citation: _____																				
D. Final Board Action & Vote: Motion by: _____ Second: _____ <table style="width: 100%;"><tr><td style="width: 15%;">Vote:</td><td style="width: 15%;">Agricultural</td><td style="width: 15%;">Nonagricultural</td><td style="width: 15%;">Crops</td><td style="width: 15%;">X</td></tr><tr><td>Yes: _____</td><td>Synthetic</td><td>Not synthetic</td><td>Livestock</td><td></td></tr><tr><td>No: _____</td><td>Allowed¹</td><td>Prohibited²</td><td>Handling</td><td></td></tr><tr><td>Abstain: _____</td><td>No restriction</td><td>Deferred⁴</td><td>Rejected³</td><td></td></tr></table> <div style="margin-left: 100px;">1—substance voted to be added as “allowed” on National List</div> <div>Annotation: _____</div> <div style="margin-left: 100px;">2—substance to be added to “prohibited” paragraph of National List</div> <div>Describe why a prohibited substance: _____</div> <div style="margin-left: 100px;">3—substance was rejected by vote for amending National List</div> <div>Describe why material was rejected: _____</div> <div style="margin-left: 100px;">4—substance was recommended to be deferred</div> <div>Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow-up. _____</div>		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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F. NOP Action: Include in FR to amend National List: <input type="checkbox"/> Return to NOSB <input type="checkbox"/> Reason: _____ <table style="width: 100%;"><tr><td style="width: 50%;">_____ Richard H. Mathews, Program Manager</td><td style="width: 50%;">_____ Date</td></tr></table>		_____ Richard H. Mathews, Program Manager	_____ Date																		
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NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

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Committee: Crops <input checked="" type="checkbox"/> Livestock <input type="checkbox"/> Handling <input type="checkbox"/>																																									
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<p>D. Recommended Committee Action & Vote: Motion by: <u>Rose</u></p> <p style="margin-left: 150px;">Seconded: <u>Gerry</u></p> <p>Poly-D-Glucosamine (Chitosan) [CAS NO. 9012-76-4] is synthetic and allowed as an insecticidal soap [205.505.(e)6]</p> <table style="width: 100%;"> <tr> <td style="width: 15%;">Vote:</td> <td style="width: 15%;"></td> <td style="width: 15%;">Agricultural</td> <td style="width: 15%;"></td> <td style="width: 15%;">Nonagricultural</td> <td style="width: 15%;"></td> <td style="width: 15%;">Crops</td> <td style="width: 15%; text-align: center;"><input checked="" type="checkbox"/></td> </tr> <tr> <td>Yes: <u>3</u></td> <td></td> <td>Synthetic</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Not synthetic</td> <td></td> <td>Livestock</td> <td></td> </tr> <tr> <td>No: <u>0</u></td> <td></td> <td>Allowed¹</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Prohibited²</td> <td></td> <td>Handling</td> <td></td> </tr> <tr> <td>Abstain: <u>0</u></td> <td></td> <td>No restriction</td> <td></td> <td>Deferred⁴</td> <td></td> <td>Rejected³</td> <td></td> </tr> <tr> <td>Absent: <u>1</u></td> <td></td> <td colspan="6"></td> </tr> </table> <p style="margin-left: 150px;">1—substance voted to be added as “allowed” on National List</p> <p>Annotation: _____</p> <p style="margin-left: 150px;">2—substance to be added to “prohibited” paragraph of National List</p> <p>Describe why a prohibited substance: _____</p> <p style="margin-left: 150px;">3—substance was rejected by vote for amending National List</p> <p>Describe why material was rejected: _____</p> <p style="margin-left: 150px;">4—substance was recommended to be deferred</p> <p>Describe why deferred; if follow-up is needed. If follow-up needed, who will follow up _____</p>		Vote:		Agricultural		Nonagricultural		Crops	<input checked="" type="checkbox"/>	Yes: <u>3</u>		Synthetic	<input checked="" type="checkbox"/>	Not synthetic		Livestock		No: <u>0</u>		Allowed ¹	<input checked="" type="checkbox"/>	Prohibited ²		Handling		Abstain: <u>0</u>		No restriction		Deferred ⁴		Rejected ³		Absent: <u>1</u>							
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