

**FORMAL RECOMMENDATION BY THE
NATIONAL ORGANIC STANDARDS BOARD (NOSB)
TO THE NATIONAL ORGANIC PROGRAM (NOP)**

Date: August 17, 2005

Subject: Chitosan

Chair: Jim Riddle
(sign)

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X

Guidance Statement:

Other:

Statement of the Recommendation (including Recount of Vote):

The NOSB recommends that chitosan be added to 205.601 for use in organic crop production with the following annotation, "as an adjuvant only."

Board vote – August 16, 2005

13 yes, 0 no, 1 absent

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

Rationale provided in text of recommendation below.

Response by the NOP:

Updated 2/25/05

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	X		Other available wholly natural adjuvants leave residues on produce thus the adjuvant is unacceptable (the combination of lactose, bentonite, and casein). [personal knowledge – Gerald Davis] The two that are formulated with pine-based functional agents may be synthetic and contain List 3 compounds. TAP pg 6, lines 243-254; personal knowledge – Brian Baker – OMRI]
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		No, the adjuvant is necessary to accomplish the function.

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 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 and quantity of applications 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:		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			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 (poly-D-Glucosamine)</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 checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)</td> </tr> <tr> <td>2. Availability criteria</td> <td style="text-align: right;">Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)</td> </tr> <tr> <td>3. Compatibility & consistency</td> <td style="text-align: right;">Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)</td> </tr> </table>			Criteria Satisfied?	1. Impact on humans and environment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)	2. Availability criteria	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)	3. Compatibility & consistency	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)																	
	Criteria Satisfied?																									
1. Impact on humans and environment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)																									
2. Availability criteria	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)																									
3. Compatibility & consistency	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)																									
<p>B. Substance fails criteria?</p> <p>Criteria category: _____</p> <p>Comments: _____</p>	<p>C. Proposed Annotation: <u>as an adjuvant only</u></p> <hr/> <p>Basis for annotation: its use is being limited to levels that produce the necessary function but do not enhance plant growth</p> <p>To meet criteria above: <u>X</u> Criteria: <u>3</u></p> <p>Other regulatory criteria: _____ Citation: _____</p>																									
<p>D. Final Board Action & Vote: Motion by: <u>Nancy Ostiguy</u> Second: <u>Goldie Cauglan</u></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;"><input checked="" type="checkbox"/></td> </tr> <tr> <td style="padding: 5px;">Yes: <u>13</u></td> <td style="border: 1px solid black; text-align: center;">Synthetic <input checked="" type="checkbox"/></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: <u>0</u></td> <td style="border: 1px solid black; text-align: center;">Allowed¹ <input checked="" type="checkbox"/></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: <u>0</u></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> <tr> <td style="padding: 5px;">Absent: <u>1</u></td> <td colspan="4"></td> </tr> </table> <p style="padding: 5px;">Annotation: <u>as an adjuvant only</u></p> <p style="padding: 5px;">2—substance to be added to "prohibited" paragraph of National List Describe why a prohibited substance: _____</p> <p style="padding: 5px;">3—substance was rejected by vote for amending National List Describe why material was rejected: _____</p> <p style="padding: 5px;">4—substance was recommended to be deferred Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow-up: _____</p>		Vote:	Agricultural	Nonagricultural	Crops	<input checked="" type="checkbox"/>	Yes: <u>13</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>				
Vote:	Agricultural	Nonagricultural	Crops	<input checked="" type="checkbox"/>																						
Yes: <u>13</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>																										
<p>E. Approved by NOSB Chair to transmit to NOP:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border-top: 1px solid black; padding-top: 5px;">Dave Carter, NOSB Chair</td> <td style="width: 50%; border-top: 1px solid black; padding-top: 5px;">Date</td> </tr> </table>		Dave Carter, NOSB Chair	Date																							
Dave Carter, NOSB Chair	Date																									
<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;"> <tr> <td style="width: 50%; border-top: 1px solid black; padding-top: 5px;">Richard H. Mathews, Program Manager</td> <td style="width: 50%; border-top: 1px solid black; padding-top: 5px;">Date</td> </tr> </table>		Richard H. Mathews, Program Manager	Date																							
Richard H. Mathews, Program Manager	Date																									

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: <u>August 2005</u>	Substance <u>Chitosan</u> (poly-D-Glucosamine)																								
Committee: Crops <input checked="" type="checkbox"/> Livestock <input type="checkbox"/> Handling <input type="checkbox"/>																									
<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 checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)</td> </tr> <tr> <td>2. Availability criteria</td> <td style="text-align: right;">Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)</td> </tr> <tr> <td>3. Compatibility & consistency</td> <td style="text-align: right;">Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)</td> </tr> </table>			Criteria Satisfied?	1. Impact on humans and environment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)	2. Availability criteria	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)	3. Compatibility & consistency	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)																
	Criteria Satisfied?																								
1. Impact on humans and environment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)																								
2. Availability criteria	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)																								
3. Compatibility & consistency	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (see B below)																								
<p>B. Substance fails criteria?</p> <p>Criteria category: _____</p> <p>Comments: _____</p>	<p>C. Proposed Annotation: <u>c</u></p> <hr/> <p>Basis for annotation: material is a production aid (EPA regs); restricted to petitioned use</p> <p>To meet criteria above: _____ Criteria: _____</p> <p>Other regulatory criteria: _____ Citation: _____</p>																								
<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%; border-collapse: collapse;"> <tr> <td style="width: 15%;"><u>Vote:</u></td> <td style="width: 15%;"></td> <td style="width: 15%; border: 1px solid black; text-align: center;">Agricultural</td> <td style="width: 15%; border: 1px solid black; text-align: center;">Nonagricultural</td> <td style="width: 15%; border: 1px solid black; text-align: center;">Crops</td> <td style="width: 15%; border: 1px solid black; text-align: center;"><input checked="" type="checkbox"/></td> </tr> <tr> <td>Yes: <u>3</u></td> <td></td> <td style="border: 1px solid black; text-align: center;">Synthetic <input checked="" type="checkbox"/></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>No: <u>0</u></td> <td></td> <td style="border: 1px solid black; text-align: center;">Allowed¹ <input checked="" type="checkbox"/></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>Abstain: <u>0</u></td> <td></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>Absent: <u>1</u></p> <p style="margin-left: 150px;">1—substance voted to be added as “allowed” on National List</p> <p>Annotation: <u>as an adjuvant only</u></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>		<u>Vote:</u>		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	
<u>Vote:</u>		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																					
<p>E. Approved by Committee Chair to transmit to NOSB:</p> <p>_____ Committee Chair</p> <p style="margin-left: 300px;">_____ Date</p>																									