Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP)											
Date:	October 28 , 2010	October 28 , 2010									
Subject:	Response to Pect	in Petition									
Chair:	Daniel G. Giacom	ini									
The NOSB hereby recommends to the NOP the following:											
Rulema	king Action X										
Statement	of the Recommenda	ation (Inclu	ıding	Recount o	of Vot	e):					
The NOSB recommends that Pectin (low methoxy) be moved to 205.606 and united with Pectin (high methoxy) under 1 listing with a new annotation: "Pectin (non-amidated forms only)". The Handling committee voted 6 yes and 1 absent in its recommendation to the full board. The NOSB voted the material as non-synthetic; 13 yes 1 no, and voted for this recommendation 13 yes, 0 no, 1 abstention, 0 absent, and 0 recusals.											
Rationale Supporting Recommendation (including consistency with OFPA and NOP):											
Both high and low methoxy pectin result from the same origin and process which is an extraction and hence non-synthetic. The amidation process creates a synthetic. The placement of pectin on 205.606 is consistent with OFPA and the NOP.											
NOSB Vote:											
Moved:         Joe Smillie         Second:         Tracy Miedema											
Yes: 13	No: 0	Abstain:	1	Absent:	0	Recusal:	0				

## NOSB COMMITTEE RECOMMENDATION Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting:	_October 2010				Substance:Pectin (low-methoxy)			
Committee: Crops Livestock Handling X Petition is for: Moving Pectin (low-methoxy) from National List § 205.605 to 205.606								
A. Evaluation Criteria (Applicability noted for each category; Documentation attached)       Criteria Satisfied? (see B below)         1. Impact on Humans and Environment       Yes       No       N/A         2. Essential & Availability Criteria for moving 605 to 606       Yes       X       No       N/A         3. Compatibility & Consistency       Yes       No       N/A       X         4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)       Yes       No       N/A       X         B. Substance Fails Criteria Category:n/a       Comments:       Comments:       C       Vers of annotation (if any):n/a         Basis for annotation: To meet criteria above: Other regulatory criteria: Citation:       Citation:								
<ul> <li>D. Recommended Committee Action &amp; Vote (State Actual Motion):</li></ul>								
	Crops	Agricultur	al	Х	Allowed <sup>1</sup> X			
	Livestock	Non-Synt		X	Prohibited <sup>2</sup>			
	Handling X	Synthetic			Rejected <sup>3</sup>			
	No restriction	Commerc Available	ially Un- as Organic <sup>1</sup>	Χ	Deferred <sup>4</sup>			
1) Substance voted to be	1) Substance voted to be added as "allowed" on National List to § 205.606 with Annotation (if any)							
2) Substance to be added as "prohibited" on National List to § 205with Annotation (if any)  Describe why a prohibited substance:								
3) Substance was rejected by vote for amending National List to § 205Describe why material was rejected:								
4) Substance was recommended to be deferred because     E. Approved by Committee Chair to transmit to NOSB:								
Committee Chair Date								

Category 1. Adverse impacts on humans or the environment? Substance - <u>Pectin (low-methoxy)</u>

Question	Ye s	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]			X	Reviewed in original 1995material review; no changes
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]			X	
<ul> <li>3. Is the substance harmful to the environment?</li> <li>[§6517c(1)(A)(i);6517(c)(2)(A)i]</li> <li>4. Does the substance contain</li> </ul>			x	
List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]				
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]			X	
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			Х	
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]			Х	
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]			X	
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]			Х	
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			Х	
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			Х	
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			Х	

<sup>1</sup>If 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 -	Pectin (low-
<u>methoxy)</u>		

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			See attached Committee Summary included after Category 4 Checklist
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		See attached Committee Summary included after Category 4 Checklist
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		See attached Committee Summary included after Category 4 Checklist
4. Is there a natural source of the substance? [§205.600 b.1]	Х			See attached Committee Summary included after Category 4 Checklist
5. Is there an organic substitute? [§205.600 b.1]		Х		See attached Committee Summary included after Category 4 Checklist
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	Х			Jams & jellies cannot be made without pectin
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	Х			The non-amidated forms of pectin are non- synthetic
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	Х			See attached Committee Summary included after Category 4 Checklist
9. Is there any alternative substances? [§6518 m.6]		Х		See attached Committee Summary included after Category 4 Checklist
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		all of the guestions from 205.600 (b) are N/A—not applicable.

<sup>1</sup>If 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?	Su
Pectin (low-methoxy)	

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]			Х	Reviewed in original material review; no changes
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	
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]			Х	
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	
<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?			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	

<sup>1</sup>If 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 - Pectin (low-methoxy)

				-
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 necessary for use in organic handling?			Х	Reviewed in 1995 original material review; no changes
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 <u>form</u> to fulfill an essential function in a system of organic handling?			х	
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 <b><u>quality</u></b> to fulfill an essential function in a system of organic handling?			Х	
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 <b><u>quantity</u></b> to fulfill an essential function in a system of organic handling?			х	
<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>			Х	
b. Number of suppliers and amount produced;			Х	
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;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			Х	

## **Committee Summary:**

The petitioner requested that pectin (low-methoxy) be moved from 205.605 to 205.606 so that organic production methodology would be required and the material would be subject to commercial availability requirements. Pectin (high-methoxy) is already listed on 205.606. These two pectins have different food processing uses (i.e., low methoxy pectin binds with sugar at a lower brix level), but are manufactured using essentially the same process. The petitioner presented documentation that stated that the main difference between high and low methoxy is the degree of esterification that results only from a longer extraction period. This longer extraction process does not result in chemical change and hence the material is not synthetic. The origin of the raw material and the extraction process used are identical for both low and high methoxy pectins. The real difference in pectin products is whether they are amidated (chemically modified with ammonia after the extraction process) or not. In investigating the original NOSB analysis of low-methoxy pectin, it seems that they either thought it was always amidated or that it went through a second process, which may be why it was placed on 205.605(b). The EU organic regulation allows pectin, does not distinguish between high and low methoxy forms and prohibits amidated forms. The original technical review dated August 17<sup>th</sup>, 2009, and the subsequent supplemental technical review requested by the Handling Committee and dated July 30<sup>th</sup> 2010 supported the petitioners position. Therefore we think that Pectin (low-methoxy) be moved to 205.606 and combined with Pectin (high-methoxy) into one listing with a new annotation to read Pectin (nonamidated forms only).