

NOSB RECOMMENDED DECISION FORM

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: November 2008		Substance: Orange Pulp, Dried																									
A. Evaluation Criteria (Applicability noted for each category; Documentation attached)		Criteria Satisfied? (see B below)																									
1. Impact on Humans and Environment		Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>																								
2. Essential & Availability Criteria		Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>																								
3. Compatibility & Consistency		Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>																								
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)		Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/> N/A <input type="checkbox"/>																								
B. Substance fails criteria?		C. Proposed Annotation: none																									
Criteria category: _____		Basis for annotation:																									
Comments:		To meet criteria above: ____ Criteria: _____																									
		Other regulatory criteria: ____ Citation: _____																									
D. Final Board Action & Vote (State Actual Motion): To add Orange Pulp, Dried to §205.606 of the National List - Agricultural (non-organic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."																											
Motion: Julie Weisman Second: Joe Smillie Yes: 13 No: 1 Abstain: 0 Absent: 1																											
<table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Agricultural</td> <td style="text-align: center; padding: 5px;"><input checked="" type="checkbox"/></td> <td style="padding: 5px;">Nonagricultural</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Crops</td> <td style="padding: 5px;"></td> </tr> <tr> <td style="padding: 5px;">Synthetic</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Not synthetic</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Livestock</td> <td style="padding: 5px;"></td> </tr> <tr> <td style="padding: 5px;">Allowed¹</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Prohibited²</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Handling</td> <td style="text-align: center; padding: 5px;"><input checked="" type="checkbox"/></td> </tr> <tr> <td style="padding: 5px;">No restriction</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Deferred⁴</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Rejected³</td> <td style="padding: 5px;"></td> </tr> </table>				Agricultural	<input checked="" type="checkbox"/>	Nonagricultural		Crops		Synthetic		Not synthetic		Livestock		Allowed ¹		Prohibited ²		Handling	<input checked="" type="checkbox"/>	No restriction		Deferred ⁴		Rejected ³	
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<p>A petition for the addition of Orange Pulp, Dried to the National List of Allowed Substances was received for review by the Handling Committee of the NOSB in the spring of 2008.</p> <p>Orange Pulp, Dried is produced from the byproduct remaining after the extraction of raw oranges for orange juice production. Most of the pulp generated by orange juice processing is recombined into the finished juice, but a relatively small amount remains that is not put back into product. This remaining material is washed, sorted, milled, and dried, then packaged for use by the food processing industry as a stabilizer or thickener in a variety of processed organic and conventional products.</p> <p>Although the material met the requirements of Categories 1, 2, and 3 of the substance evaluation criteria for consideration for listing, the Handling Committee originally voted unanimously to not recommend listing of this material due to failure to meet the requirements of Category 4 of the evaluation criteria, specifically because the petitioner did not provide persuasive information as to the lack of availability of organic orange pulp that could be used to produce an organic form of the dry ingredient. The Handling Committee recommendation to not list was posted on the NOSB website prior to the November 2008 NOSB meeting. A representative of the petitioning company, Fiberstar, attended the November 2008 NOSB meeting and presented information and documentation to the full board explaining the supply inadequacy of organic orange pulp to manufacture an organic form of the dry ingredient to fulfill industry needs. Many questions were asked by board members to explore the organic orange pulp supply issue. The explanation was compelling. The Handling Committee subsequently reconsidered its recommendation based on the new information, and voted to recommend listing of the material to 205.606. This material could potentially replace non-agricultural 205.605 materials currently listed that perform like functions in processed organic foods.</p> <p>It should also be noted that there were no objections made through public comment for the listing of this material. In fact, a number of public comments were made by industry members in support of its listing, primarily due to its potential to replace currently listed non-agricultural materials. It was also noted however, that this material would still be subject to commercial availability evaluations by potential users and their certifiers, and that an organic form of dried orange pulp would hopefully be available in the near future.</p>																											
1—substance voted to be added as "allowed" on National List on National List to § 205.606 with Annotation (if any): None																											
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 transmit to NOP

Rigoberto I. Delgado . December 12, 2008 .
NOSB Chair Date

F. **NOP Action: Include in FR to amend National List:**

Return to NOSB Reason: _____

Date

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: November 2008	Substance: Orange Pulp, dried
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Committee: Crops Livestock Handling Petition is for: **Inclusion of Orange Pulp, Dried 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 <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
5. Essential & Availability Criteria	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
6. Compatibility & Consistency	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
7. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>

B. Substance Fails Criteria Category: _____ **Comments:** _____

C. Proposed Annotation (if any): none

Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____

D. Recommended Committee Action & Vote (State Actual Motion): Recommend Orange Pulp, Dried for listing on §205.606

Motion by: Steve DeMuri Seconded: Gerry Davis Yes:- 5 No - 0 Absent: - 1 Abstain: - 0

Crops		Agricultural	<input checked="" type="checkbox"/>	Allowed ¹	<input checked="" type="checkbox"/>
Livestock		Non-Synthetic		Prohibited ²	
Handling	<input checked="" type="checkbox"/>	Synthetic		Rejected ³	
No restriction		Commercially Un-Available as Organic ¹		Deferred ⁴	

- 1) Substance voted to be added as "allowed" on National List to § 205.606 with Annotation (if any) - **no annotation**
- 2) Substance to be added as "prohibited" on National List to § 205. _____ with Annotation (if any) _____
Describe why a prohibited substance: _____
- 3) Substance was rejected by vote for amending National List to § 205. 606
- 4) Substance was recommended to be deferred because _____
_____ If follow-up needed, who will follow up _____

E. Approved by Committee Chair to transmit to NOSB:

<u>Julie Weisman</u> Committee Chair	_____ Date
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NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance - Orange Pulp, dried

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	According to the petitioner, the substance is produced from orange pulp by washing with water, stabilizing with heat, dewatering, mixing, drying, and grinding. No chemicals are used in the production process, only water.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		See number 1 above.
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Material is a component of an agricultural product
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		No, not according to the petitioner.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		This is an agricultural product
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		This is an agricultural product
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		This is an agricultural product
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		This is an agricultural product
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		This is an agricultural product
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		According to page 4 of the petition, dried orange pulp is GRAS when used in food in accordance with good manufacturing practices, and there are no known adverse reactions related to dried orange pulp.
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 - Orange Pulp, dried

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]			X	According to the manufacturing description on page 1 of the petition, the petitioned substance is produced from orange pulp by washing with water, stabilizing with heat, dewatering, mixing, drying, and grinding. No chemicals are used in the production process, only water.
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 above
3. Is the substance created by naturally occurring biological processes? [6502 (21)]			X	This is an agricultural product
4. Is there a natural source of the substance? [§205.600 b.1]			X	This is an agricultural product
5. Is there an organic substitute? [§205.600 b.1]			X	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		X		This is an agricultural product
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			
9. Is there any alternative substances? [§6518 m.6]		X		
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		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 3. Is the substance compatible with organic production practices?

Substance: Orange Pulp, dried

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		Material is being petitioned for inclusion on §205.606.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		Material is being petitioned for inclusion on §205.606.
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	According to page 1 of the petition, dried orange pulp is currently used as a moisture retention agent and fat substitute in baked goods, pastas, salad dressings, confectionery, processed cheese spreads, and frozen food entrees. It may also be used as flavor enhancing agent in non-carbonated beverages and fruit drinks.
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;				
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		

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 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 - Orange Pulp, dried

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?	X			In oral presentation at the Fall 2008 meeting, petitioner cites use of this material is potentially as a replacement for materials currently on 205.605 (emulsifiers, thickeners).
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 form to fulfill an essential function in a system of organic handling?	X			In oral presentation at Fall 2008 meeting, petitioner described difficulties in obtaining sufficient quantities of raw material in reasonable proximity to a processing facility. Most organic orange juice pulp goes back into orange juice production, and is not available for this use.
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 quality to fulfill an essential function in a system of organic handling?	X			See above
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 quantity to fulfill an essential function in a system of organic handling?	X			See comment 2 above. In oral presentation, petitioner described there is a 20:1 raw pulp to finished dry pulp ratio.
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:	X			
a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;	X			6,000 acres of organic oranges are located in Florida alone. Number of suppliers or other regions not discussed. In oral presentation, petitioner clarified that unless raw pulp is available adjacent to processing it deteriorates too quickly to be used to produce dry pulp.
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		No information provided regarding these factors.
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		X		No information provided regarding these factors.
e. Are there other issues which may present a challenge to a consistent supply?		X		Other than cost implications, no other factors discussed.