

NOSB COMMITTEE RECOMMENDATION
Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: <u>November 2008</u>	Substance: <u>Orange Pulp, Dried</u>																								
Committee: Crops <input type="checkbox"/> Livestock <input type="checkbox"/> Handling <input checked="" type="checkbox"/> 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)																									
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 type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/>																								
B. Substance Fails Criteria Category: 4 Comments: <u>The petition does not provide sufficient information to demonstrate that this material cannot be obtained organically in the appropriate form, quantity or quality (see specifics under category 4)</u>																									
C. Proposed Annotation (if any): _____ _____ 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 <i>Motion by: Steve DeMuri Seconded: Gerry Davis Yes:- 0 No - 5 Absent: - 1 Abstain: - 0</i>																									
<table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Crops</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Agricultural</td> <td style="padding: 2px; text-align: center;"><input checked="" type="checkbox"/></td> <td style="padding: 2px;">Allowed¹</td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">Livestock</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Non-Synthetic</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Prohibited²</td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">Handling</td> <td style="padding: 2px; text-align: center;"><input checked="" type="checkbox"/></td> <td style="padding: 2px;">Synthetic</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Rejected³</td> <td style="padding: 2px; text-align: center;"><input checked="" type="checkbox"/></td> </tr> <tr> <td style="padding: 2px;">No restriction</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Commercially Un-Available as Organic¹</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Deferred⁴</td> <td style="padding: 2px;"></td> </tr> </table>		Crops		Agricultural	<input checked="" type="checkbox"/>	Allowed ¹		Livestock		Non-Synthetic		Prohibited ²		Handling	<input checked="" type="checkbox"/>	Synthetic		Rejected ³	<input checked="" type="checkbox"/>	No restriction		Commercially Un-Available as Organic ¹		Deferred ⁴	
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1) Substance voted to be added as "allowed" on National List to § 205. _____ with Annotation (if any) _____ _____																									
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 Describe why material was rejected: Insufficient information was provided in the petition to demonstrate why this material is not available in sufficient form, quality and quantity, given the amount of organic oranges produced annually.																									
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: <table style="width:100%; border: none;"> <tr> <td style="width:50%; border: none;"><u>Julie Weisman</u></td> <td style="width:50%; border: none;"><u>9/16/2008</u></td> </tr> <tr> <td style="border: none;">Committee Chair</td> <td style="border: none;">Date</td> </tr> </table>		<u>Julie Weisman</u>	<u>9/16/2008</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;		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		

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 - Substance - Orange Pulp, dried

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?		X		No comparative description is provided as to the necessity of the material for use in organic handling.
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		X		Based on the results of an internet search, organic oranges, the source of the raw input for this substance, are widely available. Other than a cost factor, the petition did not satisfactorily explain why the organic form of the material cannot be obtained in the appropriate form to fulfill an essential function in a system of organic

function in a system of organic handling?				handling.
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		Organic oranges are available in relatively large quantities, but other than a cost factor, there is no compelling explanation as to the reasons that organic dried orange pulp could not be made available from organic raw oranges.
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:	X			Some regions of production of organic oranges discussed, but it was not a comprehensive discussion.
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.
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.