

# NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: November 2007

Substance: Grape Seed Extract

Committee: Crops  Livestock  Handling  Petition is for: Inclusion of Grape Seed Extract

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 checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |

**B. Substance Fails Criteria Category:** \_\_\_\_\_ **Comments:** \_\_\_\_\_

**C. Proposed Annotation (if any):** \_\_\_\_\_

Basis for annotation: To meet criteria above: \_\_\_\_\_ Other regulatory criteria: \_\_\_\_\_ Citation: \_\_\_\_\_

**D. Recommended Committee Action & Vote (State Actual Motion):** Motion to recommend the inclusion of Grape Seed

Extract on National List 205.606

Motion by: Joe Smillie Seconded: Andrea Caroe Yes: 3 No: \_\_\_\_\_ Absent: 2 Abstain: \_\_\_\_\_

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

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 § 205. \_\_\_\_\_ with Annotation (if any) \_\_\_\_\_

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 because \_\_\_\_\_

\_\_\_\_\_ If follow-up needed, who will

follow up \_\_\_\_\_

**E. Approved by Committee Chair to transmit to NOSB:**

\_\_\_\_\_  
Committee Chair

\_\_\_\_\_  
Date

**NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST**

**Category 1. Adverse impacts on humans or the environment?**      Substance - Grape Seed Extract

Question	Yes	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	This is an agricultural product.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]			X	This is an agricultural product.
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		
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		
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			X	This is an Agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	This is an Agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
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 used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]			X	This is an Agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		
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			FDA has determined that this product is GRAS in accordance with 21 CFR 170.36. This is stated letter from that Agency to the petitioner dated August 1, 2003.
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		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 2. Is the Substance Essential for Organic Production? Substance - Grape Seed Extract**

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)]			X	This is an agricultural product.
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	This is an agricultural product.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X			
4. Is there a natural source of the substance? [§205.600 b.1]			X	Petitioned substance is from a natural source.
5. Is there an organic substitute? [§205.600 b.1]		XX		
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	Petitioned substance is a wholly natural 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	

<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? Substance - Grape Seed Extract**

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]			X	
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]		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]		XX		This product adds nutritive value that would not otherwise be present, to meet consumer expectations. It does not replace a nutrient lost during processing.
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	

<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 - Grape Seed Extract

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			Petition, p. 2 "Justification Statement" cites health benefits of this material due to high level of anti-oxidants.
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 <b>form</b> to fulfill an essential function in a system of organic handling?	X			Petitioner states in a supplemental letter dated 2/23/2007 "...because of the scale of continuous runs required to produce very low-yielding quantities of grape seed extract, it is not economically viable or commercially feasible for either [producer] to produce certified organic grape seed extract."
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>quality</b> to fulfill an essential function in a system of organic handling?		X		
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>quantity</b> to fulfill an essential function in a system of organic handling?		X		Petitioner states in a supplemental letter dated 2/23/2007 that " very large volumes of grape seed [are]required...to produce a very low-yielding quantities of grape seed extract" (100 parts raw to 1 part finished) and for this reason it is not commercially feasible to produce certified organic grape seed extract.
5. Does the industry information provided on material / substance non-availability as organic, include ( but not limited to) the following: a. Regions of production (including factors such as climate and number of regions);	X			Petitioner states in a supplemental letter dated 2/23/2007 That additional factors of weather, trade and other issues cited in 12G are not currently relevant to this petition.
b. Number of suppliers and amount produced;	X			Petitioner reports that globally there are two sources of FDA-approved grape seed extract and neither offer this material as certified organic.
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			See # 5a above
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or	X			See # 5a above
e. Are there other issues which may present a challenge to a consistent supply?	X			See # 5a above