

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: <u>November 2008</u>	Substance: <u>Black Pepper Extract</u>																								
Committee: Crops <input type="checkbox"/> Livestock <input checked="" type="checkbox"/> Handling <input type="checkbox"/> Petition is for: <u>Inclusion of Black Pepper Extract on the National List § 205.606</u>																									
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): <u>Recommend Black Pepper Extract for listing on §205.606</u> <u>Motion by: Katrina Heinze Seconded: Julie Weisman Yes: - 0 No: - 6 Absent :- 0 Abstain: - 0</u>																									
<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 <u>Describe why material was rejected:</u> <u>Material was rejected because the petition did not demonstrate that this material may not be available in organic form. An internet search by the evaluator found that black pepper is available in organic form as the fruit of the plant and as an oil extract. The petitioner did not explain why these forms could not be further processed into the petitioned material.</u>																									
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>09/16/2008</u></td> </tr> <tr> <td style="border: none;">Committee Chair</td> <td style="border: none;">Date</td> </tr> </table>		<u>Julie Weisman</u>	<u>09/16/2008</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 - Black Pepper Extract

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	Page 2 of petition – The fruit, pepper corn, of the <i>Peper nigrum L.</i> plant is dried then milled into a powder. The powder is steam distilled to separate the pepper oil from the deoiled fruits. The black pepper oleoresin is extracted from the deoiled fruits with ethyl alcohol then concentrated. Further concentration and purification occurs with ethyl alcohol and alumina. The final piperine crystals are dried, milled and sifted to form the finished Pepper Extract Powder.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		Page 3 of petition – Only ethyl alcohol and alumina are used in manufacturing this material. “Alumina is considered to be non toxic.” Ethyl alcohol is a common compound and environmental impact is negligible.
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		See response to #1 above
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		Page 3 of petition – “Black pepper contains approximately 5-9% Piperine and is listed by the US Food and Drug Administration as a herb generally recognized as safe (GRAS). . .”
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 - Black Pepper Extract

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	Page 2 of petition – The fruit, pepper corn, of the <i>Peper nigrum L.</i> plant is dried then milled into a powder. The powder is steam distilled to separate the pepper oil from the deoiled fruits. The black pepper oleoresin is extracted from the deoiled fruits with ethyl alcohol then concentrated. Further concentration and purification occurs with ethyl alcohol and alumina. The final piperine crystals are dried, milled and sifted to form the finished Pepper Extract Powder.
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	Material is being petitioned for inclusion on §205.606; see category 4 below.
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			Material is being petitioned for inclusion on §205.606; see category 4 below.
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 - Black Pepper Extract

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; see category 4 below.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		Material is being petitioned for inclusion on §205.606; see category 4 below.
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	Page 1 of petition – “Black Pepper Extract. . .is used as a nutraceutical supplement to increase bio-availability of herbal extracts, water-soluble vitamins, fat-soluble vitamins, antioxidants, amino acids and mineral. . .”
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 - Black Pepper 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 did not provide information demonstrating why the non-organic form of the material is necessary 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 function in a system of organic handling?		X		<p>Petition page 3 – “Black Pepper Powdered Extract standardized to >95% piperine powdered extract is not available at this time as an organic product.”</p> <p>An internet search did not find any organic black pepper extract in this form but did locate organic black pepper and organic black pepper extract in an oil form.</p> <p>The petition does not provide sufficient information to demonstrate that this material cannot be obtained organically in the appropriate form, quantity or quality.</p>
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 above
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:		X		See above
a. Regions of production (including factors such as climate and number of regions);		X		See above
b. Number of suppliers and amount produced;		X		See above
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 above
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		X		See above
e. Are there other issues which may present a challenge to a consistent supply?		X		See above