

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: May 2008

Substance: Microcrystalline Cheese Wax

Committee: Crops Livestock Handling Petition is for: To include microcrystalline cheesewax (CAS#'s 64742-42-3, 8009-03-08, and 9010-79-1)" on the National List §205.601(o) as a production aid in log grown mushroom culture made without either ethylene-propylene co-polymer or synthetic colors.

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 type="checkbox"/> N/A <input checked="" type="checkbox"/>

B. Substance Fails Criteria Category: None 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): To include microcrystalline cheesewax (CAS#'s 64742-42-3, 8009-03-08, and 9010-79-1)" on the National List §205.601(o) as production aid in log grown mushroom culture made without either ethylene-propylene co-polymer or synthetic colors.

Motion by: JM Seconded: BF Yes: 6 No: 0 Absent: 0 Abstain: 0

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

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. _____ 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:

Gerald Davis
Committee Chair

April 2, 2008
Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Microcrystalline Cheese Wax

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 petition, the 3 components of cheesewax are byproducts of oil refining. It is recovered from crude oil through a series of filtration, solidifying, and solvent extraction steps. All of the solvent is recovered and none remains in the final product. Petition pages 16-18. The point was made that it is a natural product because it does come right from the ground and is not chemically changed—just separated out from the crude oil
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		Petition pages 16-18. The petition does not mention what kind of solvent is used in the separation of wax from oil, but does say that all of the solvent is recovered during the process.
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Microcrystalline wax: petition pages 44-101 Paraffin: petition pages 102-157 Petrolatum: petition pages 158-182 Blended wax: petition pages 183-212
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		CAS#'s 64742-42-3, 8009-03-08, and 9010-79-1 are all on EPA list 'Inert Ingredients Permitted for Use in Nonfood Use Pesticide Products: Last Updated January 7, 2008'. CAS# 8002-74-2 on EPA list 4A. CAS# 6231-60-7 does not appear on any EPA list.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		Not with materials used in Shiitake mushroom culture.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		Microcrystalline wax: petition pages 44-101 Paraffin: petition pages 102-157 Petrolatum: petition pages 158-182 Blended wax: petition pages 183-212
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		Microcrystalline wax: petition pages 44-101 Paraffin: petition pages 102-157 Petrolatum: petition pages 158-182 Blended wax: petition pages 183-212
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		Microcrystalline wax: petition pages 44-101 Paraffin: petition pages 102-157 Petrolatum: petition pages 158-182 Blended wax: petition pages 183-212
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		Microcrystalline wax: petition pages 44-101 Paraffin: petition pages 102-157 Petrolatum: petition pages 158-182 Blended wax: petition pages 183-212
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	X			Petition page 189: Fumes from molten material may cause mild respiratory irritation according to the MSDS.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		Petition page 40: 'wax meets FDA requirements in 21 CFR 178.3710 for use in non-food articles in contact with food and in 21 CFR 172.886 for use in food.'
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]		X		Not listed on GRAS lists found in 21CFR Part 182, Part 184, or Part 186.
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		Petition pages 16-17, 167

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? Microcrystalline Cheese Wax

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	X		No -petition pg 40-43: ‘Petroleum wax is derived from crude oil. It is the result of the decomposition of tiny aquatic plants and animals that lived in ancient seas millions of years ago.’ Yes -one of the components listed for one of the cheesewax products with CAS# 9010-79-1 is listed with the EPA as ethylene-propylene co-polymer which means that it is made by polymerizing ethylene. Also petition page 7 lists this component as synthetic. Formulations of cheesewax listed in petition do not contain this component or any colors, but do contain BHT as antioxidant preservative.
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		Components CAS#’s 6472-42-3, 8009-03-08, 8002-74-2 are separated out of crude oil by means of solvent extraction and filtration.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		Petition page 40. ‘Petroleum wax is derived from crude oil.’ Crude oil is transported to refineries where it is refined into finished products by complex processes.’ So it does not exist in nature in this form.
4. Is there a natural source of the substance? [§205.600 b.1]			X	
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		Petition page 3 says that beeswaxes are not approved by the FDA for use in and around food. . Beeswax is vulnerable to removal by bees, rodents, and other insects and melts in the heat.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	.
9. Are there any alternative substances? [§6518 m.6]	X			Styrofoam plugs.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		Not for ‘log grown’ Shiitake production.

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? Microcrystalline Cheese Wax

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			Cheese wax is permitted on organic cheese, yet this use will not contact food at all. It breaks down readily in the environment, shows little or no harmful effects to humans and animals, is not toxic to soil flora and fauna, does not dissolve readily in water and is the best alternative of materials available for this use.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			This material makes possible a system of utilizing low value and culled timber to produce high quality mushrooms directly from trees with very little material and energy inputs compared to indoor sawdust-based mushroom production systems currently certified organic. It is an important part of integrated and sustainable forest management practices systems.
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	
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			May be considered a production aid as it is used as a sealant to hold in moisture and to physically hold the spawn in place.

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)]

Microcrystalline Cheese Wax

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	
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	
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	
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	
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	
b. Number of suppliers and amount produced;			X	
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?			X	