

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: March 2007

Substance: Koji Mold

Committee: Crops Livestock Handling Petition is for: _____

Inclusion on the National List § 205. 605 / 606

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

- | | | | |
|--|------------------------------|-----------------------------|------------------------------|
| 1. Impact on Humans and Environment | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. Essential & Availability Criteria | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 3. Compatibility & Consistency | Yes <input 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 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): ___The Handling Committee recommends responding to the petitioner that Koji Mold is already listed on § 205.605(a) under the listing "Microorganisms – any food grade bacteria, fungi, and other microorganism." The petition is for inclusion on § 205.606. The Handling committee recommends continued inclusion on § 205.605 instead in acknowledgement that OFPA does not provide production practices or standards for this type of production as agricultural. Evidence to this is found in the regulation where the definition for non-agricultural includes bacteria. This contradicts considering non-plant life as agricultural (specifically livestock).

Motion by: Julie Weisman Seconded: Andrea Caroe Yes: 4 No: 1 Absent: 0 Abstain: 0

Crops		Agricultural	<input checked="" type="checkbox"/>	Allowed ¹	
Livestock		Non-Synthetic		Prohibited ²	
Handling	<input checked="" type="checkbox"/>	Synthetic		Rejected ³	X
No restriction		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. 606 Describe why material was rejected It is already listed on 605a under the heading "Micro-organisms."

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:

Julie Weisman
Committee Chair

February 19, 2007
Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance - Koji Mold

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]				
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]				
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]				
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]				
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]				
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]				
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]				
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]				
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]				
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]				
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]				
12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]				
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]				

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 - Koji Mold

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)]				
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)]				
3. Is the substance created by naturally occurring biological processes? [6502 (21)]				
4. Is there a natural source of the substance? [§205.600 b.1]				
5. Is there an organic substitute? [§205.600 b.1]				
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]				
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]				
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]				
9. Is there any alternative substances? [§6518 m.6]				
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]				

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 - Koji Mold

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]				
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]				
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]				
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]				
5. Is the primary use as a preservative? [§205.600 b.4]				
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]				
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:				
a. copper and sulfur compounds;				
b. toxins derived from bacteria;				
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?				
d. livestock parasiticides and medicines?				
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?				

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 - Koji Mold

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?				
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?				
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?				
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?				
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);				
b. Number of suppliers and amount produced;				
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;				
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or				
e. Are there other issues which may present a challenge to a consistent supply?				