

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: <u>March 2007</u>	Substance: <u>Natamycin</u>
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Committee: Crops Livestock Handling Petition is for: _____
 on the National List § 205.605

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 type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/>
3. Compatibility & Consistency	Yes <input type="checkbox"/> No <input checked="" 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: 2 & 3 **Comments:** Category 2: No information was provided that indicated the petitioned substance was essential for organic production or handling. Category 3: Substance is being petitioned as a preservative. Synthetic materials whose sole purpose is as a preservative are not consistent with organic principles.

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 listing of Natamycin on § 205.605(b)
 Motion by: Julie Weisman Seconded: Andrea Caroe Yes: 0 No: 5 Absent: 0 Abstain: 0

Crops		Agricultural		Allowed ¹	
Livestock		Non-Synthetic		Prohibited ²	
Handling	<input checked="" type="checkbox"/>	Synthetic	<input checked="" type="checkbox"/>	Rejected ³	<input checked="" type="checkbox"/>
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. 605 Describe why material was rejected: See B above
 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 February 19, 2007
 Committee Chair Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? **Substance - Natamycin**

Question	Yes	No	N/A¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		x		TAP line 176 – “There is no information available from EPA or FDA to suggest that adverse environmental effects result from the manufacture, use, or disposal of natamycin.”
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		x		TAP line 176 – “There is no information available from EPA or FDA to suggest that adverse environmental effects result from the manufacture, use, or disposal of natamycin.”
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		x		TAP line 176 – “There is no information available from EPA or FDA to suggest that adverse environmental effects result from the manufacture, use, or disposal of natamycin.”
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			x	Material is not a pesticide formulation.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]				Unknown not addressed in TAP
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			x	TAP line 176 – “There is no information available from EPA or FDA to suggest that adverse environmental effects result from the manufacture, use, or disposal of natamycin.”
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			x	
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		x		“Neither natamycin nor its degradation products presented a toxic risk. Finally, the very long history of safe use of natamycin as food additive confirms that natamycin is a safe fungicide for preventing growth of moulds and yeasts in foods and beverages.” See submitted petition page 92 (Section 5.7 of journal article)
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]			x	Not enough information provided in petition or TAP
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	x			TAP line 197 – “The WHO Food Additives Series on natamycin reports the results of two studies where humans showed an adverse effect to oral doses of natamycin.” “The Joint FAO/WHO Expert Committee on Food Additives (JECFA) reviewed the safety of natamycin in 1968, 1976 and 2001 JECFA assigned an Acceptable Daily Intake value (ADI) of 0.3 mg/kg body weight per day. This ADI was reaffirmed by JECFA during the latest review of natamycin in 2001.” (Submitted petition page 92, journal article section 5.8)
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		x		See #10 above
12. Is the substance GRAS when used according to FDA’s good		x		Petition page 6 – “Natamycin is a GRAS . . .food additive accepted as a mold and yeast inhibitor by FDA; see 21 CFR

<p>manufacturing practices? [§205.600 b.5]</p>			<p>172.155 . . .Natamycin also is used for other non-sterile products, . . .See Appendix 2 for the letter from (manufacturer of natamycin) describing the self-affirmation process of the supplier . . .”</p> <p>TAP line 63-73 – “. . . The petitioner also refers to self-affirmation of GRAS status by the manufacturer of natamycin.”</p>
<p>13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]</p>		<p>x</p>	<p>TAP lines 253-259 – “No information was found that indicates that natamycin contains residues of heavy metals or other contaminants in excess of FDA tolerances. . .”</p>

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 - Natamycin

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			TAP 141-143 – “. . . a chemical process is used to extract the natamycin from the fermentation medium. . .”
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		TAP 141-143 – “. . . the extraction steps do not alter the identity of the natamycin produced by the microbial culture.”
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	x			TAP 26-27 and 154 – “Natamycin is a naturally occurring antimicrobial . . .” and “Natamycin can be isolated from the bacterium <i>Streptomyces natalensis</i> .”
4. Is there a natural source of the substance? [§205.600 b.1]	x			See question #3 and TAP 162-165 – “Natamycin can also be isolated from related <i>Streptomyces</i> bacteria. . .”
5. Is there an organic substitute? [§205.600 b.1]		x		TAP 170 – “No other organic agricultural products were identified that could be substituted for the petitioned substance.”
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		x		Preservatives are not required in organic production of handling of bread
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		x		TAP 159-165 -- “. . . there is no information indicating that natural sources produce natamycin in quantities sufficient for commercial uses.” TAP 170 – “No other organic agricultural products were identified that could be substituted for the petitioned substance.”
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	x			See submitted petition pages 49 and 50 for copies ingredient listing from the current label for conventional product.
9. Is there any alternative substances? [§6518 m.6]		x		None mentioned
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	x			Alternative practices (for example – freezing or short distribution patterns) allow for production of bread without use of this material.

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Category 3. Is the substance compatible with organic production practices? Substance - Natamycin

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		Substance is being petitioned as a preservative
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		x		Substance is being petitioned as a preservative
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			TAP 221 – “No information was identified that states or implies that natamycin changes the nutritional quality of food.”
5. Is the primary use as a preservative? [§205.600 b.4]	X			TAP 228 – “All information provided in the petition indicates that natamycin would be used as a food preservative.”
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		TAP 236-237 – “. . . (Natamycin) is not intended to recreate or improve flavors, colors, textures, or nutritive values lost in 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	Petitioned substance is not a crop material
b. toxins derived from bacteria;			X	Petitioned substance is not a crop material
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	Petitioned substance is not a crop material
d. livestock parasiticides and medicines?			X	Petitioned substance is not a crop material
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			x	Petitioned substance is not a crop material

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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 - Natamycin

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	Petitioned substance is not an agricultural substance
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	Petitioned substance is not an agricultural substance
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	Petitioned substance is not an agricultural substance
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	Petitioned substance is not an agricultural substance
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:			X	Petitioned substance is not an agricultural substance
a. Regions of production (including factors such as climate and number of regions);			X	Petitioned substance is not an agricultural substance
b. Number of suppliers and amount produced;			X	Petitioned substance is not an agricultural substance
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	Petitioned substance is not an agricultural substance
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	Petitioned substance is not an agricultural substance
e. Are there other issues which may present a challenge to a consistent supply?			X	Petitioned substance is not an agricultural substance