

NOSB RECOMMENDED DECISION FORM

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: May 2008	Substance: Seaweed, Pacific Kombu																								
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? Criteria category: N/A Comments:	C. Proposed Annotation: None Basis for annotation: To meet criteria above: ____ Criteria: _____ Other regulatory criteria: ____ Citation: _____																								
D. Final Board Action & Vote (State Actual Motion) : To include Seaweed, Pacific Kombu to Section 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic"																									
Motion: Julie Weisman Second: Joe Smillie Yes: 14 No: 0 Abstain: 0 Absent: <u>1</u>																									
<table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Agricultural</td> <td style="text-align: center; padding: 5px;"><input checked="" type="checkbox"/></td> <td style="padding: 5px;">Nonagricultural</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Crops</td> <td style="padding: 5px;"></td> </tr> <tr> <td style="padding: 5px;">Synthetic</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Not synthetic</td> <td style="text-align: center; padding: 5px;"><input checked="" type="checkbox"/></td> <td style="padding: 5px;">Livestock</td> <td style="padding: 5px;"></td> </tr> <tr> <td style="padding: 5px;">Allowed¹</td> <td style="text-align: center; padding: 5px;"><input checked="" type="checkbox"/></td> <td style="padding: 5px;">Prohibited²</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Handling</td> <td style="text-align: center; padding: 5px;"><input checked="" type="checkbox"/></td> </tr> <tr> <td style="padding: 5px;">No restriction</td> <td style="text-align: center; padding: 5px;"><input checked="" type="checkbox"/></td> <td style="padding: 5px;">Deferred⁴</td> <td style="padding: 5px;"></td> <td style="padding: 5px;">Rejected³</td> <td style="padding: 5px;"></td> </tr> </table>		Agricultural	<input checked="" type="checkbox"/>	Nonagricultural		Crops		Synthetic		Not synthetic	<input checked="" type="checkbox"/>	Livestock		Allowed ¹	<input checked="" type="checkbox"/>	Prohibited ²		Handling	<input checked="" type="checkbox"/>	No restriction	<input checked="" type="checkbox"/>	Deferred ⁴		Rejected ³	
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Provide a summary narrative here or attach a more complete narrative, and attach the original committee recommendation that includes the evaluation criteria checklist:																									
<p style="color: blue;">There are certified organic seaweeds but they do not impart the same characteristics as Kombu. Although there are a number of specific varietal identifications of "Kombu" the common term Pacific Kombu was determined to be adequate and appropriate for identification. That petitioner was unable to locate a source of certified organic kombu. The separate inquiries of Board members supported this finding. It was felt that it might be possible in the future that Kombu could be certified organic under the "Wild Harvest" portion of the Rule (205.207). The Board concluded that the material satisfied the criteria of all four categories required for a material to be listed on 606.</p>																									
1—substance voted to be added as "allowed" on National List on National List to § 205.606 with Annotation (if any): <u>None</u>																									
2—substance to be added to "prohibited" paragraph of National List to § 205.____ 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 § 205.____ Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow-up _____																									
E. Approved by NOSB Chair to transmit to NOP <u>Rigoberto Delgado</u> , <u>July 10, 2008</u> Chair Date																									
F. NOP Action: Include in FR to amend National List: Return to NOSB Reason: _____ Date																									

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: May 2008	Substance: Seaweed, Kombu (<u>Lamanaria Japonica, Lamanaria Japonica var ochotensis, Lamanaria Angustata, Lamanaria Angustata var. longissima</u>)
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Committee: Crops Livestock Handling Petition is for: **Addition 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 type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" 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): Seaweed, Kombu (Lamanaria Japonica, Lamanaria Japonica var ochotensis, Lamanaria Angustata, Lamanaria Angustata var. longissima) be added to 205.606

Motion by: Joe Smillie **Seconded:** Steve Demuri **Yes:** 5 **No:** 0 **Absent:** 1 **Abstain:** 0

Crops		Agricultural	X	Allowed ¹	X
Livestock		Non-Synthetic		Prohibited ²	
Handling	X	Synthetic		Rejected ³	
No restriction		Commercially Un-Available as Organic ¹		Deferred ⁴	

1) Substance voted to be added as "allowed" on National List to § 205.606 with Annotation (if any) _____
 Petitioner satisfied all criteria for addition of Seaweed, Kombu to 205.606 _____

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:

<u>Julie Weisman</u> Committee Chair	<u>3/9/2008</u> 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 - Seaweed, Kombu to 205.606

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		Material is wild harvested (centuries of sustainable harvesting) hot water extracted, condensed, heat sterilized and filtered
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		See above
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Agricultural Product
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		Agricultural Product
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		Agricultural Product
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		Agricultural Product used as ingredient in food products and no longer in eco-system
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		Agricultural Product used as ingredient in food products and no longer in eco-system
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		Agricultural Product used as ingredient in food products and no longer in eco-system
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		Agricultural Product used as ingredient in food products and no longer in eco-system
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		See # 12
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		See # 12
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			Widely Eaten for Centuries. Kombu was marketed in the U.S. prior to October 15, 1994. The Dietary Supplement Health and Education Act (DSHEA) provides that supplement ingredients that were marketed in the U.S. prior to the enactment of DSHEA on October 15, 1994 are considered safe and are "grandfathered in" as safe for use.
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			X	Doubtful

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 - Seaweed, Kombu to 205.606

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		
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		
3. Is the substance created by naturally occurring biological processes? [6502 (21)]			X	Agricultural Product
4. Is there a natural source of the substance? [§205.600 b.1]	X			Agricultural Product
5. Is there an organic substitute? [§205.600 b.1]		X		Being petitioned for 205.606
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	Agricultural Product
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			Being petitioned for 205.606
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 – Seaweed, Kombu

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	
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]		X		Complicated, it has those effects but not because they were lost in processing
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;				
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 - Seaweed, Kombu to 205.606

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			Essential ingredient in traditional Japanese cuisine. Well documented Kombu has certain characteristics not available in other organic certified sea vegetables
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			Wild crop certification extremely complicated. Documented non-availability
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		Quality not really an issue with Kombu...if it is laminaria Japonica etc. it fulfills needed functions
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			Well documented
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			Also phoned major Kombu distributors in the US and they confirmed petitioner information. Production only in Japan
b. Number of suppliers and amount produced;	X			Actual names were CBI
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		Petitioner did not claim any weather or other factors limited supply
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			