**NOSB COMMITTEE RECOMMENDATION**

Form NOPLIST1, Committee Transmittal to NOSB

For NOSB Meeting: May 2008  
Substance: Seaweed, Kombu (Laminaria Japonica, Laminaria Japonica var ochotensis, Laminaria Angustata, Laminaria Angustata var. longissima)

<table>
<thead>
<tr>
<th>Committee:</th>
<th>Crops □</th>
<th>Livestock □</th>
<th>Handling X</th>
<th>Petition is for: Addition on the National List § 205.606</th>
</tr>
</thead>
</table>

**A. Evaluation Criteria**  
(Applicability noted for each category; Documentation attached)

<table>
<thead>
<tr>
<th>Criteria Satisfied? (see B below)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes X</td>
</tr>
</tbody>
</table>

1. Impact on Humans and Environment  
2. Essential & Availability Criteria  
3. Compatibility & Consistency  
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)

**B. Substance Fails Criteria Category:**

<table>
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<tr>
<th>Comments:</th>
</tr>
</thead>
</table>

Basis for annotation: To meet criteria above: ______ Other regulatory criteria: ______ Citation: ______

**C. Proposed Annotation (if any):**

| ____________________________________________________ |
| ____________________________________________________ |

**D. Recommended Committee Action & Vote (State Actual Motion):**

Seaweed, Kombu (Laminaria Japonica, Laminaria Japonica var ochotensis, Laminaria Angustata, Laminaria Angustata var longissima) be added to 205.606

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

<table>
<thead>
<tr>
<th>Crops</th>
<th>Agricultural</th>
<th>X</th>
<th>Allowed¹</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Livestock</td>
<td>Non-Synthetic</td>
<td>Prohibited²</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Handling</td>
<td>Synthetic</td>
<td>Rejected³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No restriction</td>
<td>Commercially Un-Available as Organic¹</td>
<td>Deferred⁴</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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:**

<table>
<thead>
<tr>
<th>Julie Weisman</th>
<th>3/9/2008</th>
<th>Committee Chair</th>
<th>Date</th>
</tr>
</thead>
</table>
## 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

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]</td>
<td></td>
<td>X</td>
<td></td>
<td>Material is wild harvested (centuries of sustainable harvesting) hot water extracted, condensed, heat sterilized and filtered</td>
</tr>
<tr>
<td>2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]</td>
<td></td>
<td>X</td>
<td></td>
<td>See above</td>
</tr>
<tr>
<td>3. Is the substance harmful to the environment? [§6517c(1)(A)(i); 6517(c)(2)(A)]</td>
<td></td>
<td>X</td>
<td></td>
<td>Agricultural Product</td>
</tr>
<tr>
<td>4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]</td>
<td></td>
<td>X</td>
<td></td>
<td>Agricultural Product</td>
</tr>
<tr>
<td>5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]</td>
<td></td>
<td>X</td>
<td></td>
<td>Agricultural Product used as ingredient in food products and no longer in eco-system</td>
</tr>
<tr>
<td>6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]</td>
<td></td>
<td>X</td>
<td></td>
<td>Agricultural Product used as ingredient in food products and no longer in eco-system</td>
</tr>
<tr>
<td>7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]</td>
<td></td>
<td>X</td>
<td></td>
<td>Agricultural Product used as ingredient in food products and no longer in eco-system</td>
</tr>
<tr>
<td>8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]</td>
<td></td>
<td>X</td>
<td></td>
<td>Agricultural Product used as ingredient in food products and no longer in eco-system</td>
</tr>
<tr>
<td>9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]</td>
<td></td>
<td>X</td>
<td></td>
<td>Agricultural Product used as ingredient in food products and no longer in eco-system</td>
</tr>
<tr>
<td>10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]</td>
<td></td>
<td>X</td>
<td></td>
<td>See # 12</td>
</tr>
<tr>
<td>11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]</td>
<td></td>
<td>X</td>
<td></td>
<td>See # 12</td>
</tr>
<tr>
<td>12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]</td>
<td></td>
<td>X</td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]</td>
<td></td>
<td>X</td>
<td></td>
<td>Doubtful</td>
</tr>
</tbody>
</table>

1If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the substance formulated or manufactured by a chemical process?</td>
<td></td>
<td>X</td>
<td></td>
<td>[6502 (21)]</td>
</tr>
<tr>
<td>2. Is the substance formulated or manufactured by a process that</td>
<td></td>
<td>X</td>
<td></td>
<td>[6502 (21)]</td>
</tr>
<tr>
<td>chemically changes a substance extracted from naturally occurring</td>
<td></td>
<td></td>
<td></td>
<td>[6502 (21)]</td>
</tr>
<tr>
<td>plant, animal, or mineral, sources?</td>
<td></td>
<td></td>
<td></td>
<td>[6502 (21)]</td>
</tr>
<tr>
<td>3. Is the substance created by naturally occurring biological processes?</td>
<td></td>
<td>X</td>
<td></td>
<td>[6502 (21)]</td>
</tr>
<tr>
<td>4. Is there a natural source of the substance?</td>
<td>X</td>
<td></td>
<td></td>
<td>[§205.600 b.1]</td>
</tr>
<tr>
<td>5. Is there an organic substitute?</td>
<td></td>
<td>X</td>
<td></td>
<td>[§205.600 b.1]</td>
</tr>
<tr>
<td>6. Is the substance essential for handling of organically produced</td>
<td>X</td>
<td></td>
<td></td>
<td>[§205.600 b.6]</td>
</tr>
<tr>
<td>agricultural products?</td>
<td></td>
<td></td>
<td></td>
<td>[§205.600 b.6]</td>
</tr>
<tr>
<td>7. Is there a wholly natural substitute product?</td>
<td></td>
<td>X</td>
<td></td>
<td>[§6517 c (1)(A)(ii)]</td>
</tr>
<tr>
<td>8. Is the substance used in handling, not synthetic, but not organically</td>
<td></td>
<td>X</td>
<td></td>
<td>[§6517 c (1)(B)(iii)]</td>
</tr>
<tr>
<td>produced?</td>
<td></td>
<td></td>
<td></td>
<td>[§6517 c (1)(B)(iii)]</td>
</tr>
<tr>
<td>9. Is there any alternative substances?</td>
<td></td>
<td>X</td>
<td></td>
<td>[§6518 m.6]</td>
</tr>
<tr>
<td>10. Is there another practice that would make the substance unnecessary?</td>
<td></td>
<td>X</td>
<td></td>
<td>[§6518 m.6]</td>
</tr>
</tbody>
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<th>Question</th>
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<th>No</th>
<th>N/A¹</th>
<th>Documentation (TAP; petition; regulatory agency; other)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the substance compatible with organic handling? [§205.600 b.2]</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Is the primary use as a preservative? [§205.600 b.4]</td>
<td>X</td>
<td></td>
<td></td>
<td>Complicated, it has those effects but not because they were lost in processing</td>
</tr>
<tr>
<td>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]</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.
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<tr>
<th>Question</th>
<th>Yes</th>
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<th>N/A</th>
<th>Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the comparative description provided as to why the non-organic form of the material/substance is necessary for use in organic handling?</td>
<td>X</td>
<td></td>
<td></td>
<td>Essential ingredient in traditional Japanese cuisine. Well documented</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kombu has certain characteristics not available in other organic certified sea vegetables</td>
</tr>
<tr>
<td>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 <strong>form</strong> to fulfill an essential function in a system of organic handling?</td>
<td>X</td>
<td></td>
<td></td>
<td>Wild crop certification extremely complicated. Documented non-availability</td>
</tr>
<tr>
<td>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 <strong>quality</strong> to fulfill an essential function in a system of organic handling?</td>
<td>X</td>
<td></td>
<td></td>
<td>Quality not really an issue with Kombu…if it is lamanaria Japonica etc. it fulfills needed functions</td>
</tr>
<tr>
<td>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 <strong>quantity</strong> to fulfill an essential function in a system of organic handling?</td>
<td>X</td>
<td></td>
<td></td>
<td>Well documented</td>
</tr>
<tr>
<td>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);</td>
<td>X</td>
<td></td>
<td></td>
<td>Also phoned major Kombu distributors in the US and they confirmed petitioner information.</td>
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<td>Production only in Japan</td>
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<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Actual names were CBI</td>
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<td></td>
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<td></td>
<td></td>
<td>Petitioner did not claim any weather or other factors limited supply</td>
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<tr>
<td></td>
<td>X</td>
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