

**NOSB COMMITTEE RECOMMENDATION**  
Form NOPLIST1. Committee Transmittal to NOSB

**For NOSB Meeting: Fall 2011**

**Substance: DHA from Algal Oil**

**Committee: Crops • Livestock • Handling X Petition is for: inclusion on the National List 7 CFR, §205.605**

<b>A. Evaluation Criteria</b> (Applicability noted for each category; Documentation attached)	<b>Criteria Satisfied? (see B below)</b>
1. Impact on Humans and Environment	Yes <b>X</b> No • N/A •
2. Essential & Availability Criteria	Yes <b>X</b> No • N/A •
3. Compatibility & Consistency	Yes <b>X</b> No • N/A •
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes • No • N/A <b>X</b>

**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):** \_

**Motion is list the material as a non-synthetic, designating the material for §205.605(a)**

Motion by: Tracy Mledema Seconded: Katrina Heinze Yes: 7 No: 0  
Absent: \_\_\_\_\_ Abstain: \_\_\_\_\_

**Motion is to list the petitioned material, "DHA Algal Oil" on the National List 7 CFR, §205.605(a) as "DHA from Algal Oil"**

Motion by: Tracy Mledema Seconded: Katrina Heinze Yes: 7 No: 0  
Absent: \_\_\_\_\_ Abstain: \_\_\_\_\_

Crops		Agricultural		Allowed <sup>1</sup>	<b>x</b>
Livestock		Non-Synthetic	<b>x</b>	Prohibited <sup>2</sup>	
Handling	<b>x</b>	Synthetic		Rejected <sup>3</sup>	
No restriction		Commercially Un-Available as Organic <sup>1</sup>		Deferred <sup>4</sup>	

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:**

**Steve Demuri  
Committee Chair**

**October 7, 2011  
Date**

**NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST**

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

**Substance - \_ DHA from Algal Oil**

<b>Question</b>	<b>Yes</b>	<b>No</b>	<b>N/A<sup>1</sup></b>	<b>Documentation (TAP; petition; regulatory agency; other)</b>
1. Are there adverse effects on environment from manufacture, use, or disposal? <sup>1</sup> [§205.600 b.2]			x	The TR evaluated the petitioned substance and concluded that there are no adverse effects under this criterion. <i>See TR lines 409-407 and 430-455; see also</i> Question 2 below (statutory form of criterion)
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		x		The TR concluded that there are no adverse environmental impacts, noting that the sole solvent used is “recycled.” <i>See generally TR lines 430-455</i> (describing inputs, manufacturing process and waste byproducts); (disposal method for biomass substrate for algal growth “eliminates” any possibility of adverse environmental impact); (noting that algae are grown and not wild-harvested so possibility of “excessive harvesting” is inapplicable); (no information that algal oil production has “adverse impact on biodiversity”); <i>see also lines 407-409</i> (noting FDA GRAS notice reported no heavy metals or pesticides detected in petitioned substance)
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		x		<i>See</i> Question 2 above, citing <i>TR lines 407-409 and 430-455</i>
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			x	This is a substance used as an ingredient in an organic processed food. It is not used in production and contains no listed inerts.
5. Is there potential for detrimental chemical interaction with other materials used? <sup>2</sup> [§6518 m.1]		x		No detrimental interactions were noted in the TR. <i>See TR lines 123-151</i> (discussing combinations with substances)
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			x	This is a substance used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			x	This is a substance used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]			x	This is a substance used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]			x	This is a substance used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i;		x		The substance is widely added to food products, including infant formulas, for its healthful benefits. <i>See TR at lines 496-524</i> The TR contains a chart at lines 775-776 that lists more

<sup>1</sup> The criteria set forth in 7 CFR §205.600(b) are applicable solely to “synthetic substances used as a processing aid or adjuvant.” The petitioned substance is not a processing aid or adjuvant. *See TR at lines 49-50* The TR determined the petitioned substance be a “nonsynthetic.” *See TR at line 298* (“the substance should be considered non-synthetic.”) Accordingly, the criteria listed in §205.600(b) are inapplicable to the petitioned substance. *See e.g.* 7 CFR §205.600(c) (“Nonsynthetics...will be evaluated using the criteria [in the OFPA].”) However, the TR included review of most of these questions so the results are cited out of an abundance of caution.

<sup>2</sup> The criterion appearing at 7 U.S.C. §6518(m)(1), applies only to “interactions with other materials used in organic farming systems.” Because this substance is petitioned as a handling material, this criterion appears inapplicable.

§6518 m.4]			<p>than 10 countries, including the U.S., E.U., Canada, Japan, France, Belgium, U.K. etc. that have set reference intake levels of DHA for optimal health. The chart includes intake levels from leading organizations, such as the World Health Organization, World Association of Perinatal Medicine, Early Nutrition Academy and the Child Health Foundation.</p> <p>With regard to harmful effects, the TR reported that the scientific literature revealed no harmful effects for adults except those associated with “Consumption of high levels of DHA (in the form of fish oil)...” <i>See TR at lines 463-494</i></p> <p>With regard to infant formula, no studies were cited that found adverse events reported to FDA have been treated as <i>de minimis</i> and below the threshold of regulatory significance by FDA. <i>See TR at lines 463-494; See also #11 below</i></p>
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		x	<p>The petitioned substance is recognized as GRAS, and thus is considered safe under federal law, and is defined as a food additive that is properly used in foods, beverages and infant formula. It has no adverse impact on human health when used under normal conditions. The TR notes that specific GRAS notices were submitted by Petitioner that described DHA use levels for certain products, including infant formula and that “The notices were reviewed by FDA and at the time of submission, FDA had no questions about the proposed supplementation levels of DHA or the rationale behind adding DHA to the specific food products.” <i>See TR at lines 804-06</i></p> <p>The TR cites reports of adverse events for adults based on excessive consumption via fish oil sources. <i>See TR at lines 457-524.</i> The safety of the substance is also evident in that adverse events reported to FDA regarding infant formula that contains DHA have been treated as <i>de minimis</i> and below the threshold of regulatory significance by the FDA <i>See also #12 below.</i></p>
12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]	x		<p><i>See e.g. TR Line 670</i> (“DHA Algal Oil is a substance which is considered GRAS (FDA, 2001)”; <i>TR lines 75-85</i> (citing FDA GRAS Notices No. GRN 000041 and No. GRN 000137) The GRAS notices establish that FDA has no objection to the use of DHA Algal Oil under the conditions of use. (FDA, 2001).</p> <p>In addition to GRAS status, when DHA Algal Oil appears as an ingredient in infant formulas, the manufacturers submit premarket notification to FDA under section 412 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 412 of FFDCA describes the more stringent statutory requirements that apply to infant formula as compared to the regulation of other foods (FDA, 2006).</p>
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		x	<p>The TR concluded the available literature demonstrates no heavy metal or other harmful residues have been detected in the petitioned product. <i>See TR lines 403-424</i></p>

<sup>1</sup>If 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 - DHA from Algal Oil**

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	x			The TR concluded the algal oil is the product of a “naturally occurring biological process,” <i>line 278</i> , but the DHA extraction process is a “chemical process.” <i>See TR at 279</i>
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		<i>See TR line 298</i> (“the substance should be considered non-synthetic.”); <i>see also TR lines 288-292</i> (Applying National Organic Standards Board (NOSB) Joint Materials and Handling Committee draft policy: “extraction with a synthetic not on the National List would not result in a material being classified as synthetic unless either the extraction resulted in chemical change or the synthetic remained in the final material at a significant level.”)
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	x			The TR concluded that the petitioned substance is the product a biological process. <i>See TR lines 278-279</i>
4. Is there a natural source of the substance? [§205.600 b.1]		x		DHA is found in fish flesh, eggs and marine algae. <i>See TR lines 327-341</i> (noting fish, shellfish and egg sources). However, DHA must be extracted from the natural materials using extraction technologies. <i>See TR lines 330-338</i> (noting extraction methodologies). For example, while fish oil appears on 7 CFR §205.606, it is not known if the processing necessary to obtain or isolate the DHA from fish oil renders the final food additive a synthetic or non-agricultural, non-synthetic under 7 CFR §205.605. <i>See e.g. TR at line 685</i> (“DHA and EPA are <i>components</i> of fish oil but are not specifically regulated” by the GRAS specifications for fish oil)(italics in TR)
5. Is there an organic substitute? [§205.600 b.1]		x		There are no known certified organic sources of algal oil, nor certified organic sources of algal oil DHA. There are no certified organic sources of fish oil or DHA obtained from fish oil.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			x	DHA Algal Oil is the most widely used source of DHA in infant formula. Unlike fish oil sources of DHA, DHA from algal oil is vegetarian, carries no risk of containing harmful environmental contaminants like mercury and does not deplete wild fish or algae stocks. <i>See TR at lines 399-419</i>  In addition, DHA is currently widely used in organic foods. Consumers, seeing products labeled as both Organic and containing DHA have chosen to purchase these products. DHA is essential for consumers to continue to have access to these organic products.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		x		The petitioned substance is plant based non-synthetic, non-agricultural substance. There is no plant-based agricultural substitute for the petitioned substance..
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	x			The TR concluded the substance is a non-synthetic, non-agricultural substance. <i>See TR line 298</i> (“the substance should be considered non-synthetic.”).
9. Are there “alternatives to using the substance in terms of practices or other available materials”?		x		According to the TR, there are no other plant-based sources of DHA. <i>See TR lines 327-341</i> (noting fish, shellfish and egg sources). Fish sources of DHA require the animals be

[§6518(m)(6)]			<p>“cooked, then strained and pressed to extract the oil and other liquids.” <i>TR at line 331</i> The TR noted that several factors can cause fish oil additives to “increase fishy off-flavors in milk,” <i>see TR at lines 905-907</i>, and that the various types of fish oil each behave differently in formulation and several types of antioxidants to “prevent oxidation and development of off-flavors” have been studied. <i>TR at lines 910-917</i> Lastly, unlike animal-based DHA sources that require the animal be slaughtered, the TR notes the absence of any findings in the scientific literature that the algal source lessens biodiversity. <i>See TR at line 455</i></p> <p>The breadth of uses for the petitioned substance also suggests that another material is unlikely to always be an acceptable substitute—“DHA Algal Oil is as an ingredient as a source of DHA in foods, beverages, infant formulas, and as a dietary supplement. Some of the foods and products the petitioner lists as intended or current foods to supplement with DHA Algal Oil include: cookies and crackers, breads and rolls, meat products, condiments, beverages (including flavored milk and milk products, soy milk, other dairy products, and juices), pasta, dietary supplements, and infant formula.” <i>See TR at lines 49-54.</i></p>
10. Is there an “alternative[s] to using the substance in terms of practices” that would make the substance unnecessary? [§6518 (m)(6)]		x	The petitioned substance is a food additive and there are no “practices” that substitute for its presence.

<sup>1</sup>If 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 - DHA from Algal Oil**

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]	x			As noted earlier, the criteria set forth in 7 CFR §205.600(b) are applicable solely to “synthetic substances used as a processing aid or adjuvant.” The petitioned substance is not a processing aid or adjuvant. <i>See TR at lines 49-50</i> The TR determined the petitioned substance be a “nonsynthetic.”  <i>For a lengthy description of the manufacturing process of this substance, please See TR lines 225-272</i>
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			<i>See TR line 49.</i> (“The petitioned use of DHA Algal Oil is as an ingredient as a source of DHA in foods, beverages, infant formulas, and as a dietary supplement.”)
5. Is the primary use as a preservative? [§205.600 b.4]		x		<i>See TR line 49.</i> (“The petitioned use of DHA Algal Oil is as an ingredient as a source of DHA in foods, beverages, infant formulas, and as a dietary supplement.”)
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		<i>See TR line 49.</i> (“The petitioned use of DHA Algal Oil is as an ingredient as a source of DHA in foods, beverages, infant formulas, and as a dietary supplement.”)
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	The substance is not used in production.
b. toxins derived from bacteria;			x	The substance is not used in production.
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			x	The substance is not used in production.
d. livestock parasiticides and medicines?			x	The substance is not used in production.
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			x	The substance is not used in production.

<sup>1</sup>If 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 DHA from Algal Oil**

<b>Question</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)</b>
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	The substance is not petitioned for inclusion on 7 CFR §205.606
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 <b>form</b> 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 <b>quality</b> 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 <b>quantity</b> 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:			x	
a. Regions of production (including factors such as climate and number of regions);				
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			x	



temporarily restrict supplies; or				
e. Are there other issues which may present a challenge to a consistent supply?			x	