Formal Recommendation by the
National Organic Standards Board (NOSB)
to the National Organic Program (NOP)

Date: **December 2, 2011**

Subject: **Docosahexaenoic acid (DHA) algal oil petition**

Chair: **Tracy Miedema**

The NOSB hereby recommends to the NOP the following:

Rulemaking Action	X
Guidance Statement	
Other	

Statement of the Recommendation (Including Recount of Vote):

1) Classify DHA from Algal Oil as a "nonagricultural/non-synthetic" substance appropriate for listing under 7 CFR §205.605(a).
   Vote: 12 Yes, 2 No. Motion carried.

2) List the petitioned substance as "DHA from Algal Oil, not hexane extracted; other ingredients that are agricultural must be organic" to the National List at 7 CFR, §205.605(a)
   Vote: 10 Yes, 4 No. Motion carried.

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

DHA algal oil was petitioned for inclusion on the National List of Approved Substances at §205.605, and reviewed at the November 2011 meeting. The Handling Committee's recommendation is attached.

The Handling Committee requested and reviewed a Technical Report (TR). The Handling Committee agreed with the TR's finding that the substance could be considered a nonsynthetic, nonagricultural substance and proposed that it be listed on the National List in its generic form, "DHA from algal oil."

At the November meeting, the Handling Committee presented an addendum to their initial proposal, regarding the "other ingredients" contained in the formulation. This document was modified slightly during the meeting (attached).

The Handling Committee recommendation, addendum and updated language for the actual listing on the National List were considered by the full board at the public meeting in Savannah, Georgia. The applicable statutory review

criteria were discussed, and each of the supplemental review factors that guided the Handling Committee's analysis described in the addendum were read into the record and extensive testimony and debate was conducted. The board discussed the findings of the TR and petition. Portions of both documents were read into the record as well. After discussion and vote on the classification of the material a motion to list the petitioned substance as "DHA from Algal Oil, not hexane extracted; other ingredients that are agricultural must be organic" was considered.

NOSB Votes:

Motion to classify DHA from Algal Oil as a "nonagricultural/non-synthetic" substance appropriate for listing under 7 CFR §205.605(a)

Moved: T. Miedema		**Second:** K. Heinze		
Yes: 12	**No: 2**	**Abstain: 0**	**Absent: 0**	**Recusal: 0**

Motion to list the petitioned substance as "DHA from Algal Oil, not hexane extracted; other ingredients that are agricultural must be organic" to the National List at 7 CFR, §205.605(a)

Moved: J. Foster		**Second:** S. DeMuri		
Yes: 10	**No: 4**	**Abstain: 0**	**Absent: 0**	**Recusal: 0**

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: Fall 2011	**Substance:** DHA from Algal Oil

Committee: Crops 0 Livestock 0 Handling X Petition is for: inclusion on the National List 7 CFR, §205.605

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

		Criteria Satisfied? (see B below)		
1.	Impact on Humans and Environment	Yes **X**	No **0**	N/A **0**
2.	Essential & Availability Criteria	Yes **X**	No **0**	N/A **0**
3.	Compatibility & Consistency	Yes **X**	No **0**	N/A **0**
4.	Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes **0**	No **0**	N/A **X**

B. Substance Fails Criteria Category: _____ Comments: _____

C. Proposed Annotation (if any): _ not hexane extracted; other ingredients that are agricultural must be organic

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 MIedema _____ *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, not hexane extracted; other ingredients that are agricultural must be organic

Motion by: _Tracy MIedema _____ *Seconded:_Katrina Heinze* _____ *Yes: 7* _____ *No: _0* _____
Absent: _____ *Abstain:* _____

Crops		Agricultural		Allowed[1]	x
Livestock		Non-Synthetic	x	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(a) _____ with Annotation (if any) **X**

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 _____

Approved by Committee Chair to transmit to NOSB:
Committee Chair: Steve Demuri **Date: December 1, 2011**

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? **Substance -** _ DHA from Algal Oil

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [1] [§205.600 b.2]			x	The TR evaluated the petitioned substance and concluded that there are no adverse effects under this criterion. *See TR lines* 409-407 and 430-455; *see also* 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." *See generally TR lines 430-455* (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"); *see also lines* 407-409 (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		*See* Question 2 above, citing *TR lines* 407-409 and 430-455
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?[2] [§6518 m.1]		x		No detrimental interactions were noted in the TR. *See TR lines 123-151* (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. *See TR at lines 496-524* The TR contains a chart at lines 775-776 that lists more

[1] 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.

[2] 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]				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. 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)…" *See TR at lines 463-494* With regard to infant formula, no studies were cited that found adverse events reported to FDA have been treated as *de minimis* and below the threshold of regulatory significance by FDA. *See TR at lines 463-494; See also* #11 below
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		x		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." *See TR at lines 804-06* The TR cites reports of adverse events for adults based on excessive consumption via fish oil sources. *See TR at lines 457-524.* 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 *de minimis* and below the threshold of regulatory significance by the FDA *See also #12 below.*
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	x			*See e.g. TR Line 670* ("DHA Algal Oil is a substance which is considered GRAS (FDA, 2001)"); *TR lines 75-85* (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). 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).
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		x		The TR concluded the available literature demonstrates no heavy metal or other harmful residues have been detected in the petitioned product. *See TR lines 403-424*

[1]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[1]	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," *line 278,* but the DHA extraction process is a "chemical process." *See TR at 279*
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		*See TR line 298* ("the substance should be considered non-synthetic."); *see also TR lines 288-292* (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. *See TR lines 278-279*
4. Is there a natural source of the substance? [§205.600 b.1]		x		DHA is found in fish flesh, eggs and marine algae. *See TR lines* 327-341 (noting fish, shellfish and egg sources). However, DHA must be extracted from the natural materials using extraction technologies. *See TR lines* 330-338 (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. *See e.g. TR at line 685* ("DHA and EPA are *components* 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. *See TR at lines 399-419* 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. *See TR line 298* ("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. *See TR lines* 327-341 (noting fish, shellfish and egg sources). Fish sources of DHA require the animals be

[§6518(m)(6)]				"cooked, then strained and pressed to extract the oil and other liquids." *TR at line 331* The TR noted that several factors can cause fish oil additives to "increase fishy off-flavors in milk," *see TR at lines 905-907,* 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. *TR at lines 910-917* 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. *See TR at line 455* 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." *See TR at lines 49-54.*
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.

[1]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[1]	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. *See TR at lines 49-50* The TR determined the petitioned substance be a "nonsynthetic." *For a lengthy description of the manufacturing process of this substance, please See TR lines 225-272*
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			*See TR line 49*. ("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		*See TR line 49*. ("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		*See TR line 49*. ("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.

[1]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

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. Is the comparative description provided 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 **form** 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 **quality** 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 **quantity** 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: a. Regions of production (including factors such as climate and number of regions); b. Number of suppliers and amount produced;			x 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 temporarily restrict supplies; or			x	
e. Are there other issues which may present a challenge to a consistent supply?			x	

Addendum to Handling Committee Recommendation for the Listing of DHA from Algal Oil

Addendum to Handling Committee Recommendation for the Listing of Arachidonic acid (ARA) from Fungal Oil

Following the posting of the NOSB Handling Committee unanimous recommendation to list DHA from algal oil and ARA from fungal oil[1] to www.regulations.gov on October 18, 2011, and the closing of the public comment period on November 13, 2011, the Committee received a "Memorandum to the National Organic Standards Board" ("memorandum") from the National Organic Program ("NOP") dated November 15, 2011. Later the same day, the Handling Committee conducted a conference call during which the NOP requested that the Committee revisit its recommendations in light of the memorandum and supplement its findings previously completed and posted on www.regulations.gov.

Based on to the NOP request, the Committee has reviewed the memorandum and the existing record and now issues this addendum to its "Recommendation to List "Arachidonic acid (ARA) from fungal oil" and "DHA from algal oil" on 7 C.F.R. §205.605(a) This entire document is incorporated into the posted recommendations.

The NOP memorandum requests the NOSB "develop a policy" regarding the "other ingredients" that are found in substances listed on 7 C.F.R. §205.605(a). Although the NOP proposes that review of what the memorandum refers to as "other ingredients" be conducted "from this point forward," we do not understand the NOP to be suggesting that a policy that is not yet developed can be applied to presently pending matters. Nor did the NOP memorandum cite any specific provisions of the OFPA, or provide any analysis, that would assist in developing or implementing such evaluative criteria.

The NOP did suggest two possibly relevant questions for future boards to consider, which we do not review here because no notice of these questions has previously appeared in the public record and minimal fairness and transparency principles forbid their consideration or imposition at this time and by this board.

Instead we consider the NOP direction a request to *make explicit that certain criteria are already imposed* by the OFPA and 7 C.F.R. Part 205 regarding the review of "other ingredients" in a compound petitioned substance, and that the results of that review are currently only implicit in the currently posted recommendation. "Other ingredients" (or components of compound substances that are petitioned) that are *allowed* are those that are authorized for use in food by the following criteria that we make explicit here[2]:

(1) the National List (7 C.F.R. §§'s 205.600-606) or;

(2) mandatory federal requirements (7 U.S.C. §6519(f)) or;

(3) FDA (GRAS) or otherwise (infant formula, food additive, colors etc.) 7 U.S.C. §6517(c) and 7 U.S.C. §6519(f) or;

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[1] The vote tally on the ARA-related petition was 6 affirmative and one absent.

2 A version of these factors appeared in the comment filed by Martek Biosciences on November 13, 2011

(4) EPA (7 U.S.C. §6517(c) and 7 U.S.C. §6519(f) or;

(5) any other federal regulatory agency with primary jurisdiction over that substance (7 U.S.C. §6519(f) or;

And any component or ingredient would be *disallowed* if:

(6) prohibited by federal regulatory action (7 U.S.C. §6517(d)) or;

(7) the direct product of excluded methods under (7 C.F.R. §205.105) or;

(8) contains any toxic heavy metals or toxic residues (7 U.S.C. §6510(a)) and; (Petition pgs. 7-8)(metals and impurities not present or removed)

(9) the component or ingredient was *not* disclosed in the Petition (72 Fed. Reg. 2168)

We note that the Petitions, Technical Reviews and our own Checklist review revealed that the petitioner's manufacturing process follows a HAACP protocol, a cGMP protocol acceptable to the FDA and that there are no detectable residues of extraction solvents, pesticide residues, PCB's or any heavy metals. Additionally, the record shows that, like many other products on the National List, oxidation retardants are used, and that the antioxidants perform no antioxidant function in final formulated food products. Lastly we note the processing aids identified in the petition are approved generally for use in food products and they are not specifically prohibited by any federal regulatory action, or the OFPA or 7 CFR Part 205.

In sum, based on the review criteria listed above, the following "other ingredients" are allowed in the petitioned substance because they respectively appear on the National List, or are allowed by FDA. None are prohibited by regulatory action. None are the product of excluded methods. None contain detectable heavy metal residues. Each of the "other ingredients," listed below was fully disclosed in the petitions.

"DHA from Algal Oil": Tocopherols, Ascorbyl palmitate, rosemary extract, high oleic sunflower oil, sunflower lecithin.

"Arachidonic acid (ARA) from fungal oil": Tocopherols, Ascorbyl palmitate, citric acid, rosemary extract, sunflower oil.

Lastly, it is the intent of the Handling Committee that "Arachidonic acid (ARA) from fungal oil" and "DHA from algal oil," upon listing on the National List, authorize formulations containing "other ingredients" if and only if the NOSB and NOP are provided notice that such materials meet the 9 criteria listed above.

Motion *that "Addendum to Handling Committee Recommendations for the Listing of DHA and ARA Nov 19 2011" be appended to each of the published recommendations for these materials. Motion made by Tracy Miedema. Seconded by Steve DeMuri Vote 5 Yes, 1 abstain, 1 absent*

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This document is not intended to set precedent but merely to show the work that the Committee completed on these two materials. [statement added December 1, 2011 and unanimously approved by Handling Committee]