



# National Organic Coalition

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## NOC MEMBERS

*Beyond Pesticides*

*Center for Food Safety*

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*Food & Water Watch*

*Maine Organic Farmers and Gardeners Association*

*Midwest Organic and Sustainable Education Services*

*National Cooperative Grocers Association*

*Northeast Organic Dairy Producers Alliance*

*Northeast Organic Farming Association - Interstate Council*

*Organic Seed Alliance*

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*Rural Advancement Foundation International -USA*

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National Organic Standards Board  
Handling Committee  
USDA National Organic Program  
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## Handling Committee, NOSB:

The National Organic Coalition (NOC) is concerned that the Martek petitions for ARA and DHA currently before the Board do not fit the criteria for placement of materials on the National List. The petitioned items are not “substances”, they are formulated, brand name products. Petitions should specifically address a single substance in language that creates a narrow, unambiguous definition of the substance. The definition of a substance can be provided through an annotation of its listing on the National list which might provide information about allowable manufacturing processes; however, it should not be left to the NOSB to determine which process or processing aid the petitioner wishes to see as the annotation. This is the responsibility of the petitioner. The Martek petitions for ARA and DHA should be returned to the petitioner for further clarification.

The National List is made up of generic materials, not formulated products that may have proprietary or patented processing procedures for its manufacture. A processed product that uses numerous processing aids and/or ingredients would go through the typical certifier or third party materials review process. This includes verifying that the main ingredients and all processing aids are acceptable, meaning that they meet all requirements for use in organic production under the Organic Foods Production Act.

There are precedents in the current National List for spelling out the specific manufacturing system, such as the annotation for Acids in §605.a. To review and act upon the current petitions as presented, stretches the review process beyond the scope intended by OFPA and the NOP regulation, which is the consideration of single ingredient materials.

Further explanation of our position is contained in the points below.

**1. The petitioned items are not “substances”—they are formulated, brand name products**

The petitions make it clear that they are not for ARA and DHA, but for “ARA Single-Cell Oil” and “DHA Algal Oil”, which have respectively ARA and DHA as “primary components”. (See responses to question 7 regarding CAS number.) “ARA Single-Cell Oil” in turn is listed as the primary ingredient of ARASCO, and “DHA Algal Oil” is listed as the primary ingredient of Martek DHA-S and DHASCO. (See product information, Appendix 10 of DHA Petition.)

However, it is not clear whether the “ARA Single-Cell Oil” that is listed as an ingredient of ARASCO is actually the product that has ARA as its primary component or the ARA material itself. The confusion arises because the additional ingredients in ARASCO (high oleic sunflower oil, tocopherols, and ascorbyl palmitate) are also the additional ingredients in “ARA Single-Cell Oil”. Similarly, it is not clear whether the “DHA Algal Oil” that is listed as an ingredient in Martek DHA-S and DHASCO is the material with DHA as its primary component or DHA itself because the additional ingredients in Martek DHA-S (high oleic sunflower oil, sunflower lecithin, rosemary extract, mixed tocopherols and ascorbyl palmitate) and DHASCO (high oleic sunflower oil, mixed tocopherols and ascorbyl palmitate) appear to be the same additional ingredients in “DHA Algal Oil”.

At any rate, it appears that ARA and DHA do not stand alone. Because of their susceptibility to oxidation, some form of antioxidant must be added to keep them from degrading. The sunflower oil is added to provide a product uniform in ARA/DHA potency, so it is clearly part of the formulation.

For further clarification, since there are numerous ingredients in DHA Algal Oil, it should appear on the label as DHA Algal Oil (DHA, high oleic sunflower oil, mixed tocopherols and ascorbyl palmitate) so that all ingredients are disclosed for the consumer. Currently, the product used in Horizon Organic Chocolate Milk and other products do not disclose these DHA Algal Oil secondary ingredients in the Organic Chocolate Milk ingredients listing.

Because “ARA Single-Cell Oil” and “DHA Algal Oil” are formulated products, whose active ingredients could be made from a range of additives (see below), it is inappropriate for the NOSB to consider the petitions as they have been submitted. ARA and DHA are the active ingredients and, as such, they are substances that are appropriate for review by the NOSB. Assuming that these substances were approved by the NOSB and included on the National list, certifiers and third party materials reviewers would then need to decide whether formulated products that include ARA or DHA are allowable, based their review of the additional ingredients.

## 2. Some additives are “ingredients” and some are “processing aids”

ARA and DHA are extracted from fungal and algal cells, respectively. The extraction and purification processes involve the addition of substances not intended to be present in the final product. These are often called “processing aids”. The manufacturing process also involves the addition of materials that are intended to be in the final product—the sunflower oil and antioxidants. These are generally called “ingredients”.

The extraction process used in making ARA involves the addition of hexane, which is later removed by evaporation using heat and vacuum. Martek says hexane is undetectable in the final product, with a detection limit of 0.3 ppm. After extraction, the oil is purified. “Food acid and base”—the acid may be citric acid, for example, and the base specified was sodium hydroxide—are added to help remove metals and other undesirable components of the oil as precipitates and heavier gums or soaps that can be removed by centrifuge. Then filter aids, also known as adsorbents and chelators—such as citric acid, silica, and clay—are added, and subsequently filtered out with other residual soaps, metals, and oxidation products. A deodorizer is used with heat and vacuum to remove volatile components that might cause off-flavors. Finally, the antioxidants are added, and the ARA potency is adjusted with high oleic sunflower oil.

The processes for refining extracting and refining DHA are somewhat similar. Two different organisms are used as sources for DHA--*Crypthecodinium cohnii* (hereinafter *C. cohnii*) and *Schiziochytrium* sp. *C. cohnii* is treated with hexane as a solvent in a process somewhat similar to that used for ARA extraction. Again, Martek says the hexane is undetectable in the final product, with a detection limit of 0.3 ppm. *Schiziochytrium* is treated with a (non-GMO) enzyme to rupture the cell walls and release the oil. (The pH may need to be adjusted first, which would require the addition of a “food acid or base”.) In this case, isopropyl alcohol is added to break up the emulsion formed by the enzymatic process into an oil layer and a water layer, which are separated by centrifuge, the alcohol going with the water phase. Antioxidants are added before the drying process, which involves adding nitrogen gas in a vacuum. Martek says no isopropyl alcohol is detectable in the final product, with a detection limit of 1 ppm.

DHA from both processes then goes through the same refining process that is used for ARA—which again involves the addition of citric (or some other) acid, sodium hydroxide, as well as adsorbents and chelators (such as citric acid, silica, diatomaceous earth, and clay). Finally, the antioxidants are added, and the DHA potency is adjusted with high oleic sunflower oil.

Thus, in the language of food processors, the following are used as “processing aids”: hexane, isopropyl alcohol, citric acid, sodium hydroxide, nitrogen gas, silica, diatomaceous earth, and clay.

The following are added as “ingredients”: high oleic sunflower oil, sunflower lecithin, rosemary extract, mixed tocopherols and ascorbyl palmitate.

Both ingredients and processing aids are subject to the provisions of the National List, including the requirement that, those from nonagricultural sources be included on §604 of the National List, and those that are from agricultural sources either be listed on §606 or be sourced organically. In the case of the DHA and AHA algal oil products, it is certifiers and third party materials reviewers, not the NOSB, who are authorized to make decisions about whether specific sources of processing aids and ingredients conform with the listing on the National List .

### **3. Allowable processing aids should be specified in annotations**

Hexane is prohibited by 21 CFR 205.270(c)(2) “A volatile synthetic solvent or other synthetic processing aid not allowed under §205.605: *Except*, That, nonorganic ingredients in products labeled “made with organic (specified ingredients or food group(s))” are not subject to this requirement.”

As the petitions specifically mention that hexane is used as an extractant, and hexane is a “volatile synthetic solvent,” the Handling Committee and the NOSB as a whole should judge whether the extracted and refined ARA and DHA are compatible with the organic handling standard §270(c)(2).

Note that while the petitions contain references to residues of solvents in the finished product, in terms of the regulation of organic foods, the concept of residues is irrelevant. In organic terms, the question is whether the use of the processing aid is compliant with the standards that govern the composition and manufacture of processed products that carry the organic label.

In conclusion, NOC urges the NOSB to reject the petitions for Martek ARA and DHA. NOSB is authorized by OFPA and the NOP regulation to review only substances, not formulated products such as those presented in these petitions.

Thank you for your attention to this matter.

Sincerely,



Liana Hooded,  
Director

cc: National Organic Standards Board  
Miles McEvoy  
Melissa Bailey  
Ruihong Guo