



BEYOND PESTICIDES

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November 9, 2011

National Organic Standards Board
Fall 2011 Meeting
Savannah, GA

Re. Comments on Petitions to allow ARA and DHA oils

Dear Board Members:

These comments are submitted on behalf of Beyond Pesticides. Beyond Pesticides, founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and groups around the world.

We oppose the recommendations of the Handling Committee to approve the petitions for adding Arachidonic (ARA) acid single-cell oil and Docosahexaenoic acid (DHA) from Algal Oil to food. We oppose the recommendations because the petitioned materials are formulated products rather than substances under the purview of the NOSB; ARA is and DHA may be extracted with hexane; and the addition of ARA and DHA to organic food is unnecessary. In addition, we recommend that the NOSB classify products of fermentation as agricultural and subject to certification requirements.¹

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

The petitions make it clear that they are not specific to ARA and DHA, but encompass “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.)

¹ The NOP has developed guidance for certified organic yeast, which could be applied to other fermentation products. “Guidance Certification of Organic Yeast”, July 22, 2011.
<http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5087121>

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.”

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.

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.² 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 —*Cryptocodinium cohnii* (hereinafter *C. cohnii*) and

² The TR (234-236) states, “A Swiss study that examined 41 vegetable oils for hexane residues, however, did detect hexane residues in 12% of oils tested using a detection limit of 0.01 mg/kg, indicating that residual hexane from processing of food-grade oils can occur, albeit at levels below accepted tolerances (Kantonales Laboratorium, 2004).” This indicates that Martek did not use the most sensitive procedure for detecting hexane.

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 NL, including the requirement that those from nonagricultural sources be included on §605 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.

Additionally, when DHA Algal Oil is added to products (e.g., Horizon chocolate milk), it appears on the label as “DHA Algal Oil,” not “DHA Algal Oil (DHA, high oleic sunflower oil, mixed tocopherols and ascorbyl palmitate).” (DHA petition, appendix 6.) Because it is a formulated product, DHA Algal Oil should be listed on food labels in a manner that discloses all ingredients.

2. Hexane-extracted oils may not be used in certified organic products.

ARA and DHA are or may be extracted with hexane. Hexane is prohibited by 21 CFR 205.270(c)(2), which states, “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.” Although 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.

3. The addition of ARA and DHA is not necessary.

There is no need to add ARA or DHA to organic foods. Consumers expect organic food to be free of unnecessary additives. Those who want to supplement their diet with additional ARA or DHA can do so with supplement products that will allow them to more accurately control the dose they receive.

In conclusion, because the petitioned materials are formulated products rather than substances under the purview of the NOSB, DHA is and ARA may be extracted with hexane, and it is unnecessary to add them to organic foods, we urge you to deny the petitions to allow the addition of "ARA Single-Cell Oil" and "DHA Algal Oil" to organic food. We feel that the petitioner could respond to these issues and submit an amended petition for the pure oils extracted in a manner consistent with 21 CFR 205.270(c)(2).

Sincerely,

A handwritten signature in cursive script, appearing to read "Terry Shistar".

Terry Shistar, Ph.D.
Board of Directors