



C O R N U C O P I A
I N S T I T U T E

April 14, 2008

TO: David Trykowski, Office of Compliance, National Organic Program
RE: Complaint concerning multiple possible violations of the National Organic Program's regulatory standards by Abbott Laboratories, PBM Nutritionals, Nurture/HappyBaby, Dean Foods/Horizon Organic, Stremicks Heritage Foods, and NuGo Nutrition (other organically labeled foods may also use these materials).

Dear Mr. Trykowski,

The Cornucopia Institute is filing this complaint with your office concerning possible violations of National Organic Program (NOP) regulatory standards. Several manufacturers are currently selling organic infant formula, organic dairy products, and organic nutrition bars containing DHASCO and ARASCO produced by Martek Biosciences. DHASCO and ARASCO are not on the National List of Approved and Prohibited Substances (7 CFR 205.605).

While microorganisms are on the National List of Approved and Prohibited Substances, by-products of microorganisms are not. Martek's DHASCO and ARASCO are indisputably by-products of an alga and fungus, respectively.

In addition, The Cornucopia Institute has reason to believe that these oils are solvent extracted and therefore also illegal in organic foods.

Handlers that are adding Martek's DHASCO and/or ARASCO to organic foods include:

- Abbott Laboratories (Similac organic infant formula with DHA and ARA)
- PBM Products (Ultra Bright Beginnings organic with DHA and ARA; Parent's Choice organic with DHA and ARA, Earth's Best with DHA and ARA)
- Nurture, Inc. (Happy Baby Organic baby food with DHA)
- Horizon Organic (fluid organic milk with DHA)
- Stremicks Heritage Foods (fluid organic milk with DHA)
- NuGo Nutrition (NuGo Nutrition Bars)

We are aware that a previous legal complaint, submitted by David Cox of Lane, Alton & Horst, LLC, was dismissed in a letter by compliance officer William Bent dated April 3, 2007. We believe that this dismissal has no legal basis—the federal organic regulations clearly prohibit DHASCO and ARASCO and we hereby request a thorough investigation of the allegations outlined in this letter.

DHASCO and ARASCO are not on the National List: Martek’s algal DHASCO and fungal ARASCO do not appear on the National List of Approved and Prohibited Substances. Therefore, the use of these substances in organic food is a violation of section 205.105(c), which prohibits the use of synthetic and non-synthetic substances, not on the National List, in the processing of organic foods.

In a formal comment to the NOP filed on behalf of Martek, attorney Martin Hahn acknowledges that DHASCO is not allowed in organic foods under the existing regulations. This comment was posted in response to a proposed rule change in 2005 that would add “microorganisms” to the National List. (see the attached letter filed by attorney Martin Hahn on behalf of Martek to add “byproducts of microorganisms” to the National List and thereby make Martek’s oils legal ingredients in organic foods).

Mr. Hahn acknowledges in this letter that Martek’s DHASCO would not fall under the category of “microorganisms,” because DHASCO is a byproduct of microorganisms. Therefore, he urges the NOP to add the category “byproducts of microorganisms” in the regulations, which would then allow DHASCO to be legally added to organic foods. He writes: “it would be reasonable to establish a regulatory framework that would also allow the DHA-rich oil extracted from the biomass to be added to foods labeled as ‘organic’ or ‘made with organic ingredients.’”

NOP acknowledged these concerns but did not add “byproducts of microorganisms” to the list of allowed synthetic ingredients, instructing Martek to submit a petition to the NOSB for further evaluation. As such, Cornucopia believes that Martek’s DHASCO and ARASCO remain illegal ingredients in certified organic foods.

NOP compliance officers do not have the legal authority to ignore or misinterpret the federal organic regulations when investigating a formal legal complaint. Mr. Bent responded to attorney Cox that the “NOP determined that the use of synthetic vitamins, minerals and accessory nutrients are allowed in the production of products to be sold, labeled or represented as organic under the NOP, provided they are used in full compliance with FDA rules and regulations and the National List.” This is a misunderstanding and/or misrepresentation of the official organic regulations (section 205.605), which clearly do not include “accessory nutrients” as approved nonagricultural substances.

Hexane extraction: According to Martek’s Generally Recognized as Safe (GRAS) petition to the FDA, which was necessary to gain approval for adding these oils to infant formula, hexane is used to extract DHASCO and ARASCO from fermented algae and fungus (see attachment below, pages 37 and 42 of Martek’s “Opinion of an Expert Panel on the Generally Recognized As Safe (GRAS) Status of ARA and DHA Single Cell Oils for Infants and Children”).

Hexane is a chemical by-product of gasoline refinement, a toxic air pollutant regulated by EPA, an occupational hazard according to OSHA, and a highly explosive solvent. In addition, patent documents filed with the U.S. government also indicate that hexane is a part of the processing protocol for DHASCO and ARASCO.

As we understand the organic regulations, solvent-extracted ingredients are not allowed in organic products unless the ingredient is listed on the National List of Approved and Prohibited Substances. If the ingredient is considered an agricultural product, Section 205.270 (Organic Handling Requirements) states that a “handler of an organic handling operations must not use in

or on agricultural products intended to be sold, labeled or represented as ... ‘organic’ ... (2) a volatile synthetic solvent or other synthetic processing aid not allowed under §205.605.”

A synthetic solvent may be allowed if it is listed under §205.605. Hexane is not listed in section 205.605.

Given Martek’s description of the processing procedure to obtain DHASCO and ARASCO, we have reason to believe that hexane-extracted ingredients are added to organic foods. We ask that you investigate whether these manufacturers are adding hexane-extracted DHASCO and ARASCO to organic foods.

Genetically engineered microorganisms: We would also request the USDA to investigate whether ARASCO comes from genetically engineered fungus. According to the patent application for ARASCOⁱ (patent 6,749,849), newly identified strains of the fungus *Mortierella sect. schmuckeri* can be used to produce ARASCO with high productivity; these strains can be “obtained by genetically-engineering microorganisms to produce increased amounts of arachidonic acid.”

The patent application shows that genetic engineering is performed on fungus for the production of ARASCO. The application specifically states, “A ‘mutated microorganism’ is a mutated parental microorganism in which the nucleotide composition of such microorganism has been modified by mutation(s) that occur naturally, that are the result of exposure to a mutagen, or that are the result of genetic engineering.” While Martek’s web site states that its ARASCO come from non-genetically engineered sources, we would like the USDA to investigate so as to ensure consumers that no genetically engineered organisms are used to produce oils for organic infant formula and other organic food products.

Additionally, we request that the USDA investigate the possibility that algae and fungus used to extract DHASCO and ARASCO are cultivated with the use of growth media that contain genetically engineered material. As described in the patent application, the growth medium for algae varies but must contain a carbon source, which may come in the form of “molasses, high fructose corn syrup, hydrolyzed starch or any other low cost conventional carbon source used in fermentation processes.”ⁱⁱ

Given the widespread availability and low cost of high fructose corn syrup, we suspect that this may be a regularly used growth medium for the oils. For fungus to produce ARASCO, the patent application states that “suitable complex nitrogen sources include, for example, corn steep liquor, protein hydrolysates, microbial biomass hydrolysates, soy tone, soy meal, fish meal, meat meal, meat extract, peptone, tryptone, yeast extract, yeast and whey.”

Since most corn and soybeans in the United States are genetically engineered, we ask the USDA to investigate whether the algae and fungus used to extract oils for organic foods are grown in genetically engineered media, which would violate the NOP regulations.

If the USDA finds violations of the organic standards: The Cornucopia Institute asks that the USDA take appropriate action if violations are found. DHASCO and ARASCO do not appear on the National List of Approved and Prohibited Substances, and NOP compliance officers have no legal authority to override the federal regulations in order to dismiss a formal legal complaint.

We request that the USDA notify all manufacturers of infant formula containing Martek's DHASCO/ARASCO that are labeled "certified organic" and all foods containing Martek's DHASCO that are labeled as "certified organic," with two requests:

First, all such products should be immediately removed from store shelves.

Second, these manufacturers should be prohibited from adding Martek's DHASCO/ARASCO or DHASCO to products with the organic label.

Cornucopia requests that the USDA weigh the following in assessing the need for penalties. According to §205.100(c)(1), any operation that “knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$10,000 per violation.”

Furthermore, §205.100(c)(2) states that making “a false statement under the Act to the Secretary, a governing State official, or an accredited certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.”

We are troubled that the compliance office dismissed the earlier legal complaint, by either willfully misinterpreting the federal organic regulations or inadvertently confusing basic nutrients. The National List only allows for vitamins and minerals in accordance with 21 CFR 104.20. DHASCO and ARASCO are not vitamins or minerals, they are oils rich in omega-3 and omega-6 fatty acids, respectively. This is basic nutritional knowledge and there is no legal basis for a USDA compliance officer to dismiss a complaint based on a lack of this basic knowledge.

If this was not a case of confusing basic nutrients, then it appears to have been a willful misinterpretation of the federal organic regulations, which is even more troubling.

The Cornucopia Institute requests that the USDA’s Office of Compliance make a timely, full, and good faith effort in this investigation. Please keep The Cornucopia Institute apprised of the status of and progress of your investigation into this formal complaint. We take this matter very seriously.

It should be noted that nothing in this formal complaint shall be interpreted as a waiver of our right to appeal under the Adverse Action Appeals Process cited above.

You may contact us at your convenience.

Sincerely,



Charlotte Vallaeys
Farm & Food Policy Analyst
The Cornucopia Institute

5.1.3 EXTRACTION AND PURIFICATION OF DHASCO. The DHASCO oil is extracted from the algal biomass and processed using methods and procedures that have been well established in the edible oils industry. In order to protect this DHA-rich oil, which is much more prone to oxidation than typical vegetable oils, the Martek process has been designed to use the lowest effective temperatures and shortest times for each process step, and the oil is continuously protected from oxygen by nitrogen blanketing or vacuum.

The diagram in Figure 5.1.3-1 pictorially describes the DHASCO oil processing procedure. The oil is first extracted by blending the dried biomass with hexane in a

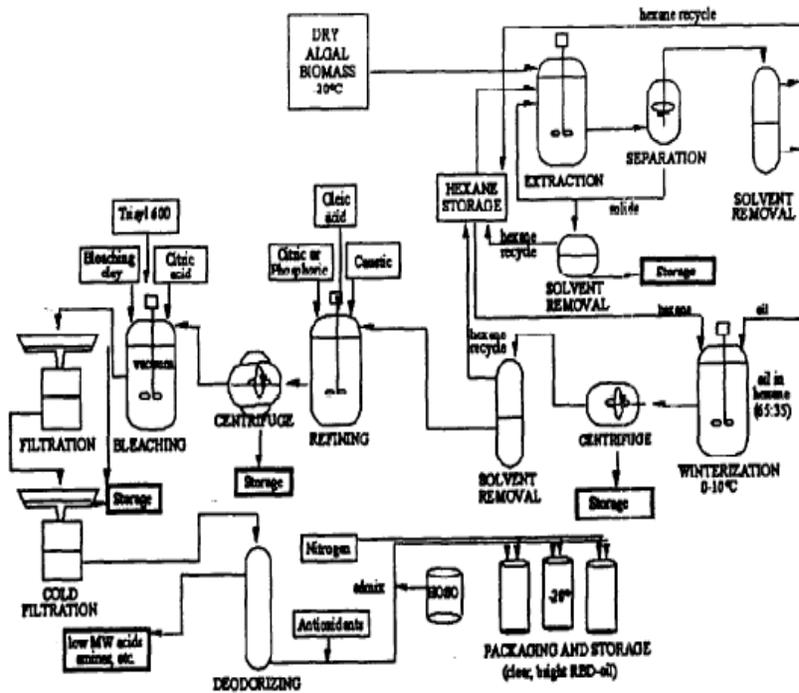


Figure 5.1.3-1. Flow chart of DHASCO oil processing.

continuous extraction process. The miscella (hexane:oil mixture) is separated from the de-oiled solids, filtered, and desolventized under vacuum to begin removal of the hexane. The oil is then winterized to remove a higher melting oil fraction by placing the miscella in a jacketed vessel, cooled and gently mixed. The chilled miscella is then centrifuged to remove higher melting solids and desolventized again to remove remaining volatiles. This winterized DHASCO is then refined to remove free fatty acids and phospholipids by mixing with citric or phosphoric acid while heating to facilitate removal of phospholipids. The free fatty acid level of the oil is adjusted using oleic acid, and the acids are neutralized by addition of aqueous sodium hydroxide. The mixture is heated and then centrifuged to remove the phospholipids and soaps of free fatty acids from the refined oil. The refined DHASCO is transferred to a vacuum bleaching vessel where citric acid, Trisyl 600 (activated silica) and bleaching clay are added to adsorb any remaining polar materials

times for each process step, and the oil is continuously protected from oxygen by nitrogen blanketing or vacuum.

The diagram in Figure 5.2.3-1 pictorially describes the ARASCO oil processing procedure. The oil is first extracted by blending the dried biomass with hexane in a continuous extraction process. The miscella (hexane:oil mixture) is separated from the de-oiled solids, filtered, and desolventized under vacuum to reduce the volatiles. The crude ARASCO is then refined to remove free fatty acids, phospholipids and other impurities. The oil is first mixed with phosphoric acid, with heating, and the free fatty acids are neutralized by addition of aqueous sodium hydroxide. The mixture is heated and held before centrifugation to remove phospholipids, soaps of free fatty acids or other impurities from the refined oil. The refined ARASCO is transferred to a vacuum bleaching vessel, where Trisyl 600 (activated silica) and bleaching clay are added to adsorb any remaining polar materials and pro-oxidant metals and to break down lipid oxidation products. The mixture is heated under vacuum and filtered using filter aid. Finally, the oil is deodorized under vacuum using a thin film packed tower continuous deodorizer. The deodorized ARASCO is then diluted to a standard 40% arachidonic acid concentration by the addition of high oleic sunflower oil and mixed with antioxidants (mixed natural tocopherols and ascorbyl palmitate). The oil is packaged in either nitrogen-purged containers and frozen or vacuum packaged. Following analytical release testing, a Certificate of Analysis is generated and included with each shipment.

5.2.4 PRODUCTION OF *M. ALPINA* BY GIST-BROCADES. In a partnership Agreement with Gist Brocades (GB), Martek is also supplied with crude ARASCO for further processing in its plant. The fermentation process employed by GB is fundamentally similar to that described in Section 5.2.2. The manufacturing process is performed in accordance with cGMP and Kosher requirements. In the GB process, ammonia and ammonium sulfate are used as nitrogen sources instead of yeast extract or hydrolyzed protein. At the end of the fermentation process, the broth is pasteurized to kill the production microorganism and to inactivate any enzymes which could degrade the final oil quality. The broth is then filtered in a membrane filter press, and the cake is washed with process water. The filter cake is squeezed to remove excess water and fed into a single screw expander type extruder. The resulting material is then dried with a vibrating continuous fluid bed dryer. The dried material is extracted with hexane and the crude ARASCO oil is produced upon removal of the residual solvent by evaporation. This crude oil is delivered to Martek's oil processing facility for final purification according to Section 5.2.3 above. Incoming crude oil has to meet certain quality specifications before being accepted by Martek.

5.2.5 PROCESS CONTROLS. All processes are documented according to cGMP with CCPs. Laboratory personnel use laboratory notebooks to record the results of lab tests and sterility checks, whereas production personnel record the continuous batch monitoring results in the batch records themselves, according to cGMP. Significant process-related data points are recorded and plotted on control charts. These data points are regularly monitored and reviewed to ensure that they are within Martek's recognized standard processing parameters.

ⁱ U.S. Patent Office. Patent 6,749,849. William R. Barclay. June 15, 2004.

ⁱⁱ Patent Application 5,374,657, December 1994. David J. Kyle, Martek Corporation.