



CORNUCOPIA
I N S T I T U T E

April 14, 2008

TO: David Trykowski, Office of Compliance, National Organic Program
RE: Complaint concerning Quality Assurance International certifying organic foods containing DHASCO and ARASCO

Dear Mr. Trykowski,

The Cornucopia Institute is filing this formal complaint with your office concerning possible violations of National Organic Program (NOP) regulatory standards governing the conduct of an accredited certifying agent, Quality Assurance International (QAI). In particular, The Cornucopia Institute is requesting a full investigation into the activities and conduct of this accredited certification agent pertaining to its role as certifier of organic products containing Martek's DHASCO (docosahexaenoic single cell oil) and ARASCO (arachidonic acid single cell oil) oils.

Cornucopia has also filed a separate legal complaint regarding the food manufacturers that market certified organic products containing Martek's DHASCO and ARASCO. This legal complaint, titled "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" was filed on April 14, 2008.

Martek's oils are hexane-extracted byproducts of microorganisms (algae and fungus) and are not listed on the National List of Approved and Prohibited Substances (7 CFR 205.605). "Byproducts of microorganisms" are also not on the National List. In 2005, NOP proposed to add "microorganisms" to the list of approved synthetic substances, and Martek submitted a formal comment urging the NOP to also include "byproducts of microorganisms."

Martek's comment acknowledges that DHASCO is not allowed in organic foods under the existing regulations and would also not be allowed under the category of "microorganisms." Martek's attorney 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.'"

The NOP acknowledged Martek's concerns but did not add "byproducts of microorganisms" to the final rule, pointing out that "the NOP does not have enough information to address this commenter's concern."

The NOP instructed Martek to submit a petition to the NOSB for further evaluation. As of April 10, 2008, the NOP's publicly accessible database of petitioned substances does not include "byproducts of microorganisms," suggesting that Martek has not submitted a formal petition to the NOSB to add this category to the list of approved synthetic ingredients. As such, Cornucopia believes that DHASCO and ARASCO are not allowed in organic foods.

Furthermore, patent documents and Martek's petition to the FDA for Generally Recognized as Safe (GRAS) status, along with other documents, specify that DHASCO and ARASCO are extracted with the use of hexane, a neurotoxic petrochemical solvent that is listed as a hazardous air pollutant with the Environmental Protection Agency and an occupational hazard by the Occupational Safety and Health Administration. Hexane extraction is not allowed in organic food processing, with the only exception being ingredients listed on the National List of Approved and Prohibited Substances. As stated previously, DHASCO and ARASCO do not appear on the National List.

It is also important to note that DHASCO and ARASCO are oils containing high levels of the fatty acids DHA and ARA, these are not vitamins or minerals and therefore do not fall under 7 CFR 205.605(b)'s "nutrient vitamins and minerals" category. The National List of Allowed and Prohibited Substances clearly includes "nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods" and excludes "accessory nutrients."

The Cornucopia Institute believes that these novel ingredients should have been scrutinized by QAI, and that QAI had no legal basis for allowing food manufacturers to add these prohibited ingredients to organic infant formula and milk. QAI certified products produced by Abbott Laboratories (Similac Organic infant formula with DHA/ARA), PBM Nutritionals (Earth's Best Organic infant formula with DHA/ARA, Bright Beginnings Organic with DHA/ARA and Parent's Choice Organic with DHA/ARA), Dean Foods (Horizon Organic milk with DHA) and Stremicks Heritage Foods (organic milk with DHA).

The national organic regulations clearly state that certifiers must be qualified to carry out the provisions of the organic regulations to ensure that organic food manufacturers comply with all standards. 7 CFR 205.501(a)(1) states that certifiers must "have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part." This includes the certifiers' responsibility of not allowing prohibited substances as ingredients in organic foods; 7 CFR 205.501(a)(3) clearly states that certifiers "must carry out the provisions of the act and the regulations in this part, including the provisions of **§§ 205.402 through 205.406 and §205.670.**"

A basic knowledge of the substances on the National List (7 CFR 205.605) is therefore required of certifiers. By allowing nonapproved ingredients in organic foods, it appears that QAI is not qualified to implement the terms and conditions of the USDA's organic certification program. The Cornucopia Institute would like the USDA to take appropriate action if it determines that QAI allowed ingredients not on the National List—ingredients that were not only nonapproved but most likely hexane-extracted.

Furthermore, The Cornucopia Institute is concerned that QAI may have knowingly allowed nonapproved substances in organic foods. As noted earlier, Martek had petitioned the National Organic Program to include "byproducts of microorganisms" on the List. It seems unlikely that

QAI was unaware of Martek's attempts to make DHASCO and ARASCO legal ingredients in organic foods. We therefore request that the Compliance Office investigate whether QAI's failure to notice the addition of prohibited substances amounts to a willful violation on the part of QAI.

If the Compliance Office determines that QAI willfully violated the regulations, Cornucopia urges the NOP to take appropriate action as specified in the regulations. 7 CFR 205.665(d)(a) requires that "if the Program Manager has reason to believe that a certifying agent has willfully violated the Act or regulations in this part, that the Program Manager shall send **a written notification of proposed suspension or revocation of accreditation** to the certifying agent" (emphasis added).

Contact information for Quality Assurance International:

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The Cornucopia Institute requests that the USDA's Office of Compliance make a timely, full, and good faith effort in this investigation. We will willingly share any additional information and documents that we possess that may aid this effort.

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.

These DHA/ARA oils are novel ingredients that have been linked to serious side effects in infants, as documented in adverse reaction reports filed with the FDA by parents with affected infants. Parents who choose an organic infant formula for their babies expect these products to be thoroughly safe and processed without the use of toxic chemicals—DHASCO and ARASCO have shown to be neither.

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,



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The Cornucopia Institute
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