



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

April 21, 2010

Miles McEvoy  
Deputy Administrator  
National Organic Program

**RE: Complaint concerning possible violations of the National Organic Program's regulatory standards by various infant formula manufacturers and Dean Foods/WhiteWave**

Dear Mr. McEvoy,

The Cornucopia Institute is re-filing this complaint with your office concerning possible violations of National Organic Program (NOP) regulatory standards. Infant formula manufacturers are currently selling organic infant formula containing DHASCO ("DHA") and ARASCO ("ARA") produced by Martek Biosciences Corporation. DHA is also added to organic dairy products by Dean Foods/WhiteWave. Our previous complaint covering these materials was not properly addressed by the NOP.

DHA and ARA are synthetic ingredients that are not on the National List of Approved and Prohibited Substances (205.605). They are neither vitamins nor minerals, which do appear on 205.605. They do qualify as "accessory nutrients," which are not found on the National List, although they were once addressed in a recommendation, in 1995, by the National Organic Standards Board.

Since Board recommendations are not final until they have been adopted as a final rule by the USDA, we do not believe that a Board recommendation can take the place of the official organic standards as found in the Code of Federal Regulations. This Board recommendation was improperly referenced by the former NOP director who overruled a staff determination that these materials were inappropriately added to certified organic products.

Handlers that are adding ARA and/or DHA to organic foods include, but are not limited to:

- 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; Vermont Organics with DHA and ARA)
- Dean Foods/Horizon Organic (fluid milk with DHA)

Subsequent to the Office of the Inspector General's report of improprieties at the NOP under past management, and an article in the *Washington Post* outlining these improprieties, with specific reference to DHA/ARA, The Cornucopia Institute is respectfully requesting that the NOP re-evaluate the prior analysis of legal complaints filed in the past few years regarding the addition of DHA/ARA to organic foods.

We are aware that staff members under Dr. Barbara Robinson came to the conclusion that DHA and ARA should be prohibited in foods labeled "organic." We agree with this assessment. We are also aware that Robinson's decision to use a 1995 Board recommendation instead of the existing federal regulations as a reason not to enforce the standards followed a meeting she had with William J. Friedman, who was representing the infant formula industry's interests. This was entirely inappropriate, tainted the reputation of organic products and the certification/accreditation process, and is a decision that should be overturned as soon as possible.

Adding Martek's DHA and ARA to organic foods is a blatant violation of the official organic standards, as published in the code of federal regulations. It is truly appalling that these synthetic additives, which have never been reviewed by the NOSB or added to section 205.605, are now found in all organic infant formula, baby food and some Horizon organic dairy products marketed to families with toddlers and young children.

The addition of DHA/ARA to organic infant formula is especially troubling given reports by parents and health care professionals that these additives can lead to severe diarrhea, vomiting, and other reactions that sometimes required hospitalization, in some infants.

We also note that the vast majority of peer-reviewed, published scientific studies on this topic have concluded that the addition of DHA and ARA to infant formula confers no benefits to infant development. **These additives are neither required in formula by FDA regulations, nor are they recommended by respected independent professional associations such as the American Academy of Pediatrics.**

Of 18 peer-reviewed scientific studies on DHA/ARA included in two recently published meta-analysis studies, only one showed an advantage to infant cognitive development. The researchers of this one study were funded by a major pharmaceutical company that manufactures infant formula.

There are a number of brands of other dairy products, toddler foods and other organic foods that include DHA. These brands are not listed here, since we do not have a complete list of organic foods with Martek's DHA at this time. We would be open to collaborate with your office to develop a more comprehensive list.

The Cornucopia Institute requests that your office 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.

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,

A handwritten signature in cursive script that reads "Charlotte Vallaey".

Charlotte Vallaey  
Farm and Food Policy Analyst  
The Cornucopia Institute  
978-369-6409