



**CORNUCOPIA**  
I N S T I T U T E

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**Organic Infant Formula Ingredients Processed with Toxic Chemical  
FDA Reports Indicate Infants Sickened from Algae/Fungal-Based Nutritional Supplements**

**CORNUCOPIA, WI.** -- The Cornucopia Institute filed a legal complaint with the US Department of Agriculture (USDA) today, demanding that the agency enforce the organic regulations prohibiting toxic solvents from being used in the production of organic food. The Institute, a nonprofit food and farm policy research group, found that baby formula and other food manufacturers are using hexane-extracted omega-3 and omega-6 fatty acids (DHA/ARA) derived from algae and soil fungus.

Perhaps more startling, through a Freedom of Information request at the FDA, Cornucopia found algal- and fungal-based DHA/ARA have been linked to serious side effects such as virulent diarrhea and vomiting in infants consuming infant formula, many of whom required medical treatment and hospitalization.

“The federal organic regulations very clearly prohibit these oils in organic foods, so this is not a case of companies finding loopholes in the regulations. What we’re seeing is the latest in a long string of USDA actions that blatantly cater to industry interests at the expense of consumer safety,” said Mark Kastel, Codirector of the Cornucopia Institute, based in Cornucopia, Wisconsin. “USDA officials are simply allowing these companies to freely break the organic rules in their pursuit of profit,” he adds.

Organic products with the prohibited fatty acid supplements include Horizon Organic milk with DHA (Dean Foods) and organic infant formulas, including Similac Organic (Abbott Laboratories), Earth’s Best (Hain Celestial), and Bright Beginnings Organic (PBM Products).

Martek Biosciences Corporation produces these DHA and ARA supplements. They are extracted from fermented algae and soil fungus with the use of a highly explosive neurotoxic petrochemical solvent, hexane. The Occupational Safety and Health Administration lists hexane as a serious hazard to worker health and safety, and the Environmental Protection Agency

classifies it as a hazardous air pollutant. The National Organic Program strictly prohibits its use in the processing of organic foods and ingredients.

“Only a change in the regulations would make these oils legal in organic foods, and a regulation change requires citizen input,” said David Cox, a lawyer with the Columbus, Ohio law firm of Lane, Alton, and Horst. “USDA officials do not have the legal authority to decide on their own that they will not enforce the regulations, no matter how much industry is lobbying or pressuring them.”

The addition of DHA and ARA to organic infant formula is especially troublesome considering that Martek’s oils are linked to serious illness in some infants. “Through a FOIA request, we discovered that scores of parents have notified the FDA that their infants experienced symptoms such as serious cases of diarrhea, vomiting, and extreme gassiness from consuming DHA/ARA formula, often requiring medical intervention. These symptoms commonly disappeared as soon as the infants were given regular formula without these supplements,” said Charlotte Vallaey, the author of Cornucopia’s comprehensive report *Replacing Mother—Imitating Human Breast Milk in the Laboratory* ([www.cornucopia.org](http://www.cornucopia.org)).

While formula makers claim to add these oils because they “support brain and eye development,” scientific data to corroborate these claims are very weak. “Results of most of the well conducted clinical trials have not shown beneficial effects of DHA and ARA supplementation of formula milk on the physical, visual and neurodevelopmental outcomes of infants born at term,” according to Dr. Karen Simmer, professor in the School of Women’s and Infant’s Health at the University of Western Australia.

Breast-feeding advocates worldwide contend that DHA and ARA appear to be added primarily as marketing tools. DHA and ARA supplementation adds approximately \$200 annually to the cost of formula, which is absorbed by parents and publicly funded nutrition programs. Misleading claims that DHA/ARA supplemented formula is now “as close as ever to breast milk” also lead to the impression among many new mothers that formula is now equivalent to breastfeeding, which may contribute to lower rates of breastfeeding and higher formula sales.

“Adding these two fatty acids to formula does not make it ‘close to breast milk,’” said Jennifer Thomas, M.D., a pediatrician practicing in Racine, Wisconsin. “Breast milk has nutrients, live cells, and bioactive compounds that are absent from formula,” she added. “Formula advertisements featuring DHA and ARA make it a lot harder for me, as a pediatrician, to convince new mothers to breastfeed if they have seen advertisements or labels implying that formula is just as good as breast milk.”

But the serious side effects experienced by some babies remain the most pressing reason for keeping these oils out of organic infant formula. Cornucopia has filed a Freedom of Information request to look into how the USDA appears to have collaborated with lobbyists for Dean Foods and others in secretly allowing these materials, despite their explicit prohibition in the federal organic regulations. “It’s bad enough these materials are being added to conventional infant formula,” said Cornucopia’s Kastel. “This marketing gimmick has no place in organics, where mothers are looking for the safest, most nutritious and natural foods for their families.”

## **MORE:**

The Cornucopia Institute, together with the National Alliance for Breastfeeding Advocacy, has petitioned the FDA to require a warning label on all infant formula supplemented with Martek's DHA and ARA. Currently, parents of infants who experience adverse reactions to DHA/ARA formula have no way of knowing that these fatty acid supplements may be the cause.

Few parents know that Martek's supplements contain only 40 to 50% DHA and ARA, with the balance being sunflower oil, diglycerides, and "nonsaponifiable" materials. Many of these components are not found in human breast milk, and the triglycerides carrying DHA and ARA are not identical to those found in human breast milk—and have never been part of the diet for human infants. It is unclear why some infants cannot tolerate these laboratory-produced DHA/ARA supplements. But the evidence of side effects strongly suggests that more research is warranted.

People can urge the FDA to require a warning label by following the attached link and posting a comment:

[http://www.regulations.gov/search/search\\_results.jsp?css=0&N=0&Ntk=All&Ntx=mode+match+all&Ne=2+8+11+8053+8054+8098+8074+8066+8084+8055&Ntt=FDA-2008-P-0074-0001&sid=118F0F37D26B](http://www.regulations.gov/search/search_results.jsp?css=0&N=0&Ntk=All&Ntx=mode+match+all&Ne=2+8+11+8053+8054+8098+8074+8066+8084+8055&Ntt=FDA-2008-P-0074-0001&sid=118F0F37D26B)

The Cornucopia Institute and the National Alliance for Breastfeeding Advocacy have also petitioned the Federal Trade Commission (FTC), alleging that formula companies are engaged in misleading advertising. The ads touting benefits to brain and eye development appear to be based on shaky scientific evidence. Lawyers at the FTC had previously warned Martek and formula companies about overstating the benefits of DHA and ARA. In response to the petition by Cornucopia and NABA, the FTC is currently investigating the alleged false advertisements.

Parents and health care providers are encouraged to pass on reports of adverse reactions to infant formula or food products containing DHA and/or ARA to the FDA and to The Cornucopia Institute: [cultivate@cornucopia.org](mailto:cultivate@cornucopia.org)

Also today, The Cornucopia Institute filed a formal legal complaint with the USDA, calling for an investigation of Quality Assurance International (QAI). QAI is the nation's largest corporate organic certifier and has been at the center of a number of other scandals in the organic industry, most prominently the questionable certification of large factory farm milk production. Cornucopia charges QAI with lax oversight and improper certification of products containing DHA/ARA oils, including questioning whether or not QAI is complying with the law and has the technical qualifications to carry out their responsibilities.

The full formal complaints can be viewed at:

[www.cornucopia.org/DHA/USDA\\_DHA\\_LegalComplaint.pdf](http://www.cornucopia.org/DHA/USDA_DHA_LegalComplaint.pdf)  
[www.cornucopia.org/DHA/USDA\\_QAI\\_LegalComplaint.pdf](http://www.cornucopia.org/DHA/USDA_QAI_LegalComplaint.pdf)