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DHA/ARA

docosahexaenoic acid and arachidonic acid

Replacing Mother — Imitating Human Breast Milk in the Laboratory

Novel Oils in Infant Formula and Organic Foods:
Safe and Valuable Functional Food or Risky Marketing Gimmick?

A Research Project of The Cornucopia Institute

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Promoting Social Justice in the Food Chain

CORNUCOPIA INSTITUTE

Contents

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The Cornucopia Institute is dedicated to the fight for economic justice for the family-scale farming community. Through research, advocacy, and economic development, our goal is to empower farmers both politically and through marketplace initiatives.

The Organic Integrity Project will act as a corporate and governmental watchdog assuring that no compromises to the credibility of organic farming methods and the food it produces are made in the pursuit of profit. We will actively resist regulatory rollbacks and the weakening of organic standards, to protect and maintain consumer confidence in the organic food label.

Executive Summary

Information presented in this report will allow parents and caregivers to make better-informed decisions regarding their infants' food.

DHA and ARA in Infant Formula

Since 2002, infant formula manufacturers in the United States have produced and sold products fortified with docosahexaenoic acid and arachidonic acid (DHA/ARA). These polyunsaturated omega-3 and omega-6 fatty acids are important components of the human brain and eyes and are naturally present in human breast milk. Since breast milk is the gold standard for infant nutrition, the addition of DHA and ARA in infant formula might very well be beneficial.

What is troublesome, however, is that some infant formulas contain DHA- and ARA-containing oils that are novel foods—extracted from laboratory-grown fermented algae and fungus and processed utilizing a toxic chemical, hexane. These algal and fungal oils provide DHA and ARA in forms that are structurally different from those naturally found in human milk. These manufactured oils are known as DHASCO and ARASCO, which stand for docosahexaenoic acid single cell oil and arachidonic acid single cell oil.

These oils are produced by Martek Biosciences Corporation and appear to be added to infant formula primarily as a marketing tool designed to convince parents that formula is now "as close as ever to breast milk." Substantiating this thesis is a Martek investment promotion from 1996, which reads as follows: "Even if [the DHA/ARA blend] has no benefit, *we think it would be widely incorporated into formulas, as a marketing tool and to allow companies to promote their formula as 'closest to human milk* [emphasis added]."[1]

Scientists have conducted numerous studies that show little or no benefit to an infant's development from adding DHASCO and ARASCO to infant formula. Overall, research results are inconsistent and inconclusive. Meanwhile, the formula companies have advertised aggressively in an attempt to convince parents that their DHA/ARA formula provides the same nutrients, and therefore the same benefits, as breast milk.

A former employee for the Program for Women, Infants, and Children (WIC) in Texas explains: "Since they added these oils to formula, many new mothers seem to believe that formula is just as good for their babies as breast milk. It became much harder for us at WIC to convince mothers to breastfeed when formula ads claim that formula is as close as ever to breast milk."

Results of a survey conducted by the Department of Health and Human Services also suggest that DHA/ARA advertisements undermine efforts at promoting breastfeeding. In 2003, 12% of respondents agreed to the following survey statement: "Infant formula and breastfeeding are equally good ways of feeding an infant"; in 2004, after the infant formula companies began their advertisements for DHA/ARA-supplemented formula, the percentage agreeing with that statement doubled to 24%.[2]

Given the universal acceptance of the multiple and very significant benefits of breastfeeding over formula feeding, any advertisements or labeling claims that undermine breastfeeding are a detriment to public health. The scientific literature leaves little room for doubt: infants who are not breastfed are at increased risk of infectious diseases including bacterial meningitis, bacteremia, diarrhea, respiratory tract infection, necrotizing enterocolitis, otitis media, and urinary tract infection. They are also at increased risk of sudden infant death syndrome in the first year of life and are more likely to develop insulin-dependent (type 1) and non-insulin-dependent (type 2) diabetes mellitus. As adults, formula-fed infants are more likely to develop lymphoma, leukemia, and Hodgkin's disease, overweight and obesity, hypercholesterolemia, and asthma.[3]

The benefits of breastfeeding are not limited to infant health; mothers who do not breastfeed are more likely to develop type 2 diabetes, as well as breast and ovarian cancer, and are at an increased risk of maternal postpartum depression.[4]

The problems with DHASCO/ARASCO in infant formula go well beyond the way in which advertisements and labeling claims may contribute to the low rates of breastfeeding in the United States. FDA scientists who reviewed the novel oils have never affirmed their safety.[5] Included among FDA's reasons for not affirming the safety of these novel oils are the following issues:

> Some studies have reported unexpected deaths among infants who consumed formula supplemented with long-chain polyunsaturated fatty acids. These unexpected deaths were attributed to sudden infant death syndrome (SIDS), sepsis or necrotizing enterocolitis. Also, some studies have reported adverse events

and other morbidities including diarrhea, flatulence, jaundice, and apnea in infants fed long-chain polyunsaturated fatty acids.[6]

A subgroup of infants reacts very badly to DHA/ARA-supplemented infant formula, with watery, explosive diarrhea, among other side effects.

But the FDA has no legal power to stop the addition of ingredients such as DHASCO and ARASCO. The agency does not give approval for a novel ingredient in infant formula, it can only raise questions regarding a company's petition for an ingredient's generally recognized as safe (GRAS) status. While the FDA did not block the addition of Martek's DHASCO and ARASCO in infant formula, it also did not affirm their safety. The FDA allowed the ingredients on the market with a warning that manufacturers must perform rigorous in-market surveillance of DHASCO and ARASCO in formula.

At the request of the FDA and Health Canada, a panel of independent scientists was convened by the Institute of Medicine's Food and Nutrition Board to take a critical look at tests performed for new ingredients in infant formula. They point to problems with Martek's premarket safety tests for DHASCO and ARASCO.

In test rats, scientists found that 5 out of 13 studies indicated a statistically significant increase in relative liver weights at the highest doses of DHASCO and ARASCO. Results of the safety studies on rats also indicated an increase in spleen weight in the groups that were fed Martek's DHASCO and ARASCO.

The FDA expects infant formula manufacturers to perform postmarket surveillance, and parents are urged to report any adverse effects of the infant formula to the FDA. Marsha Walker, RN, IBCLC, a healthcare professional who also heads the National Alliance for Breastfeeding Advocacy, points out, "This is a huge uncontrolled experiment." She explains that a subgroup of infants reacts very badly to DHASCO and ARASCO-supplemented infant formula, with watery, explosive diarrhea, among other side effects.

Sam Heather Doak, a nurse in Ohio, says that the nursing staff at her local hospital's neonatal unit refers to DHASCO/ARASCO-supplemented formula as "the diarrhea formula." The FDA has received 98 reports from parents, caregivers, and health professionals who have witnessed or treated adverse effects that they linked to DHASCO/ARASCO formula, ranging in severity from vomiting and diarrhea, which disappeared as soon as the infant was given a non-DHA/ARA-supplemented formula, to babies treated in intensive care for severe dehydration and seizures. Here is one example:

> My son began taking Enfamil Next Step Prosobee Lipil [with DHA/ARA] formula. He began having severe, explosive diarrhea. His stool was watery, loose, frequent, and smelled horrible. He was obviously uncomfortable and gassy and his bottom became quite irritated from all the diarrhea. He had to drink Pedialyte to rehydrate and he lost a considerable amount of weight. The diarrhea has lasted almost three months! He has had three stool samples done since December, all showing no sign of infection, bacteria or parasite. I read about the adverse effects that infants were experiencing from the Lipil formula and took him off the Next Step immediately. Today was the first day in three months that he actually had a firm stool with no sign of diarrhea. … My baby is not an experiment. Mead Johnson should be ashamed of itself for allowing this to happen and the FDA should take responsibility for our health and the health of our children.

Hexane-Extracted DHA and ARA in Organic Foods

The USDA's National Organic Program has not approved Martek's algal DHA and fungal ARA oils for use in organic foods; therefore, the use of these ingredients in organic food is a violation of section 205.105(c) of the federal organic regulations. Other than vitamins and minerals,[7] all synthetic or nonorganic ingredients used in organic production must be approved by the National Organic Standards Board.

"I took [my infant son] off the Next Step [with DHA and ARA] immediately. Today was the first day in three months that he actually had a firm stool with no sign of diarrhea. … My baby is not an experiment."

- From an official adverse reaction report submitted to the FDA by the mother of an infant sickened by DHA/ARA formula.

When Martek petitioned to have "by-products of microorganisms" added to the national list—which would allow DHASCO and ARASCO in organic foods—the National Organic Program did not respond to this request and subsequently did not approve this addition to the list of approved ingredients. Furthermore, federal organic standards prohibit solvent-extracted ingredients in organic foods.[8]

Martek's petition to the FDA for GRAS status of its oils clearly states that hexane is used to extract these oils.[9] In addition to being added to organic baby formula, Martek's novel oils are now also found in a number of other organic foods such as Happy Baby organic baby food, Horizon and Stremick's organic milk, and NuGo organic nutrition bars. These food manufacturers appear to be adding these oils to their products illegally.

The Occupational Health and Safety Administration (OSHA) lists the solvent hexane as a serious concern for occupational health and safety, putting workers in oil extraction manufacturing plants at risk for damage to the nervous system. It is a highly explosive petroleum by-product of gasoline refining; in 2003, Martek's processing plant in Winchester, Kentucky, caused an explosion at a nearby wastewater treatment plant.[10] The U.S. Environmental Protection Agency (EPA) also lists hexane as one of 188 hazardous air pollutants.[11]

The effects of hexane exposure on consumers are uncertain. The assumption is that all hexane residues evaporate before reaching the consumer, but tests have shown that hexane residues do appear in some edible oils. Other hydrocarbon solvents, such as benzene, can interfere with human development, causing a spectrum of disorders including structural birth defects, hyperactivity, attention deficits, reduced IQ, and learning and memory deficiencies.[12] No such data is available for hexane, although it is also a hydrocarbon solvent.[13]

Parents expect that infant formulas, especially products designated as organic, have been rigorously tested and verified as safe by corporations marketing the products and by federal regulators. Serious questions remain concerning DHASCO/ARASCO supplementation in these products.

Furthermore, organic consumers hold the expectation that the products they are choosing are "natural" and subject to a more aggressive review by the National Organic Standards Board, charged with this duty by Congress. The addition of these laboratory-produced novel oils, along with the use of a synthetic processing aid (hexane), is especially troublesome in organic products, and The Cornucopia Institute hopes that this report will spark further investigations by the scientific, medical, and regulatory communities to address the concerns articulated.

Taking Action

The Cornucopia Institute is taking action. Cornucopia has filed a formal legal complaint with the U.S. Department of Agriculture alleging that certifiers accredited under the USDA's National Organic Program are allowing food manufacturers to sell foods with ingredients that have not been approved for use in USDA-certified organic foods. Cornucopia is also specifically requesting the USDA to verify that no hexane-extracted DHASCO and ARASCO is sold in organic foods and that no genetically engineered microorganisms are used in the DHASCO and ARASCO production process.

The Cornucopia Institute and the National Alliance for Breastfeeding Advocacy are petitioning the FDA to require formula manufacturers to add a warning label on DHA/ARA-supplemented formula, alerting parents to the possibility of side effects.

In addition, together with the National Alliance for Breastfeeding Advocacy, The Cornucopia Institute has filed a petition with the Federal Trade Commission alleging that DHA/ARA advertising is misleading and detrimental to public health by undermining efforts at increasing the low rates of breastfeeding in the United States.

The Cornucopia Institute and the National Alliance for Breastfeeding Advocacy are also petitioning the FDA to require formula manufacturers to add a warning label on formula containing DHASCO and ARASCO, and to include information regarding the possibility of adverse reactions on their web sites.

Purpose of the Report

This report by The Cornucopia Institute aims to provide further information to consumers regarding DHASCO and ARASCO supplementation in infant formula. Infant formula advertisements, labeling information, and web sites are designed to lead parents to believe that supplemental DHA and ARA are necessary for proper brain and eye development. Manufacturers claim that the addition of DHASCO and ARASCO to formula makes it "as close as ever to breast milk."

In the interest of balance, this report provides the other side of the DHA story, in three important ways:

1. The report explains the source of the DHA and ARA oils that are found in infant formula and reviews the FDA's response letter to Martek, in which FDA officials refused to affirm the safety of these oils.

2. The report reviews the premarket safety tests for DHASCO and ARASCO that were performed on rats and infants and points out red flags for concern, as well reviewing the Institute of Medicine's expert panel's findings regarding the inadequacy of these tests.

3. The report provides a review of scientific, peer-reviewed, articles that point to the uncertainty regarding benefits of adding DHASCO and ARASCO to infant formula. This review of the scientific literature provides information that is much more comprehensive than the corporate marketing departments' claims that DHASCO and ARASCO have been "proven" to benefit brain development.

The research and information presented in this report will allow consumers to make better-informed decisions regarding products, especially infant formula, with ARASCO and/or DHASCO. Readers may then consider whether the marketing claims inaccurately present the potential benefits of these products, while minimizing information about risk.