



CORNUCOPIA
I N S T I T U T E

Questions and Answers About DHA/ARA and Infant Formula

What is DHA?

DHA, which stands for docosahexaenoic acid, is a type of fat. This particular fatty acid is abundant in the gray matter of the human brain and in the membranes of the retinal photoreceptors in the eyes.¹ It is a 22-carbon long-chain polyunsaturated fatty acid of the omega-3 family. Research suggests that DHA from a mother's breast milk benefits an infant's eye and brain development. For adults, some preliminary research points to cardiovascular and cognitive health benefits of DHA.

What are good sources of DHA?

For infants, the best source is undisputedly breast milk.

Adults can acquire preformed DHA from sources such as fish, fish oil, beef, and egg yolks. The human body can also synthesize DHA from other omega-3 fatty acids, such as those found in nuts, flaxseeds, canola oil, and other foods.

Where does the supplemental DHA in foods such as infant formula and organic milk come from?

The DHA in infant formula and organic milk comes from docosahexaenoic single cell oil (DHASCO). These oils are extracted with the toxic chemical hexane from laboratory-grown algae.

Is the DHA found in infant formula equivalent to the DHA found naturally in breast milk?

Algal DHA oils and fungal ARA oils contain DHA and ARA triglycerides that are not identical to those found in human milk. In human milk, DHA is carried as a single molecule on a triglyceride. In DHASCO, the fungal DHA oil, the majority of DHA appears as a single molecule on the triglyceride chain, similar to human milk; however, two DHA molecules do

appear on some triglycerides in DHASCO.² Many components of DHASCO, which contains only 40-50% DHA, are new to an infant's diet.

What is ARA?

ARA stands for arachidonic acid, which is a 20-carbon omega-6 fatty acid. Like DHA, ARA is also believed to be an important component of the central nervous system. If DHA is added, ARA must also be added to infant formula in order to maintain a balance of fatty acids.

Where does ARA in infant formula come from?

The ARA in infant formula comes from arachidonic single cell oil (ARASCO), which is extracted with the use of the toxic chemical hexane from a laboratory-grown soil fungus.

What company manufactures the DHA and ARA that is found in infant formula?

Martek Biosciences Corporation, based in Columbia, Maryland. Their DHA and ARA are also known as DHASCO and ARASCO—docosahexaenoic acid single cell oil and arachidonic acid single cell oil. These are "novel" and patented compounds.

How are Martek's DHA and ARA oils manufactured?

To obtain the DHASCO, microorganisms such as *Cryptocodinium cohnii* are first grown under tightly controlled fermentation conditions in a nutrient solution containing glucose and yeast extract.³ They are then harvested, and the oil is extracted by blending the dried algae with hexane, a toxic solvent that is a by-product of gasoline refining, in a continuous extraction process. The hexane then is removed from the oil by distillation techniques, using conventional oilseed processing equipment, which is suitable to perform the filtering, separation, and distillation.⁴

ARASCO can be obtained from species of fungus such as *Pythium insidiosum*, or *Mortierella alpina*, using similar production and extraction processes as for DHASCO.⁵

What do scientific studies show regarding developmental benefits of adding DHASCO and ARASCO to infant formula?

Studies in both preterm and term infants have not consistently shown an effect of long-chain polyunsaturated fatty acid supplementation on cognitive or behavioral performance.

Overall, the scientific evidence is insufficient to conclude that supplementation with DHASCO and ARASCO benefits development.⁶

What do scientific studies show regarding benefits to visual development?

There is also inconsistency in the findings on visual development, although there is somewhat more support in the scientific community that adding DHASCO and ARASCO benefits visual development.

I've heard claims that DHA and ARA in infant formula will make babies smarter. Is this true?

Although a number of trials have attempted to prove this thesis, no study has ever shown that infant-formula-fed babies were better off, developmentally or otherwise, than human-milk-fed babies.

Claims that DHA/ARA-supplemented infant formula will make babies smarter come from infant formula manufacturers, who, along with Martek, have been happy to profit from DHA/ARA-supplemented infant formula.

Is infant formula with DHASCO/ARASCO more expensive than formula without these oils?

Yes, infant formula with DHASCO/ARASCO is priced at 15 to 30% more than standard formula. The International Baby Food Action Network (IBFAN) estimates that infant formula supplemented with DHASCO/ARASCO costs parents an additional \$200 per year.⁷ This has cost American taxpayers millions of dollars in increased cost for providing "new and improved" infant formula to low income mothers eligible for subsidized feeding programs.

Have these oils been thoroughly tested for safety?

According to a panel of independent scientists convened by the Institute of Medicine, premarket safety tests for these oils were inadequate. They concluded that too few safety tests were performed. Certain tests were performed only on rats, when they should have been performed on nonhuman primates as well. No chronic toxicity or chronic carcinogenicity studies were performed, not even on rats. In fact, none of the "long-term" safety tests lasted for longer than 90 days. A more comprehensive testing protocol is currently taking place on our nations unsuspecting children.

What did the results of the premarket safety tests show?

Out of 13 tests performed on rats, 5 showed increased liver weights in rats fed the highest dose of Martek's DHA oils. Other study results showed increased spleen weights. There was also evidence of increased albumin and/or protein levels in rats fed Martek's DHASCO and ARASCO.

Have there been reported problems with DHASCO and ARASCO in infant formula?

Yes. Hundreds of reports have been submitted to the FDA regarding adverse reactions in infants consuming formula with DHASCO and ARASCO. Of these reports, 98 could be traced to the DHA and ARA oils (for example, by stating that symptoms disappeared as soon as the infant was given a non-DHA/ARA formula).

What are the adverse reactions experienced by some infants consuming DHA/ARA-supplemented formula?

Watery, explosive diarrhea, in many cases long-term, is the most commonly reported side effect. Vomiting, bloating, gastrointestinal discomfort, rashes, and seizures have also been reported. These are quite serious complications and a vulnerable population.

Why did FDA allow these oils to be added to infant formula?

Requirements for infant formula are found in the Federal Food, Drug, and Cosmetic Act, which states that “all manufacturers of infant formula must begin with safe food ingredients, which are either generally recognized as safe (GRAS)⁸ or approved as food additives for use in infant formula.”⁹

Martek’s DHASCO and ARASCO were granted GRAS status in 2001. The FDA has no authority to stop the addition of ingredients if they have GRAS status. However, the FDA itself did not affirm the safety of Martek’s DHASCO and ARASCO for use in infant formula, citing reports of “adverse events and other morbidities including diarrhea, flatulence, jaundice, and apnea in infants fed long-chain polyunsaturated fatty acids.”

I have read in marketing literature from infant formula manufacturers that DHA/ARA--supplemented infant formula is “as close as ever to breast milk.” Is this true?

Breast milk contains elements that simply cannot be grown or manufactured for infant formula—these elements include live cells, enzymes, and bioactive compounds.¹⁰ Many of these have profound immune enhancing properties. Moreover, breast milk is a dynamic fluid, meaning that it changes over time and depending on the infant’s needs. As the perfect food for babies, breast milk simply cannot be imitated by infant formula manufacturers; and any claims that their infant formula comes close to breast milk are false.

Manufacturers claim that it is “as close as ever to breast milk,” so does formula with DHASCO and ARASCO confer the same benefits as breast milk?

No. Formula-fed infants—whether the formula contains DHA/ARA or not—have increased rates in the incidence and/or severity of a wide range of infectious diseases including bacterial meningitis, bacteremia, diarrhea, respiratory tract infection, necrotizing enterocolitis, otitis media, urinary tract infection, and late-onset sepsis in preterm infants. Formula feeding is

correlated with an increase in incidence of insulin-dependent (type 1) and non-insulin-dependent (type 2) diabetes mellitus.¹¹

Formula-fed infants are also more likely to die of sudden infant death syndrome in the first year of life.¹²

As children and adults, formula-fed infants have an increased likelihood of developing lymphoma, leukemia, and Hodgkin's disease; overweight and obesity; hypercholesterolemia; and asthma.¹³

What are the current rates of breastfeeding in the United States?

Upon discharge from the hospital, 72.9% of mothers in the United States breastfeed, but only approximately half of mothers breastfeed one week after discharge from the hospital.

These numbers drop even more dramatically as the infant grows, with exclusive breastfeeding at 3 months of age at 38.7%, and only 13.9% at 6 months of age.¹⁴

Do federal regulations permit the addition of Martek's DHASCO and ARASCO oils to organic infant formula?

No, federal organic regulations prohibit hexane-extracted ingredients in organic foods.

The federal organic regulations also specify which nonagricultural products may be added to organic foods; DHASCO and ARASCO are not on the National List of Approved Substances, nor are "by-products of microorganisms."

Given the adverse reactions that these chemically processed ingredients have caused in some infants, Martek's DHASCO and ARASCO do not belong in organic products. Organic consumers trust that only safe and natural ingredients are used, especially in foods purchased for infants.

Why are there infant formulas on store shelves that are both certified organic and contain Martek's DHASCO and ARASCO?

These DHA and ARA oils appear to be added to the organic infant formula in violation of the federal organic standards. A formal legal complaint was filed in 2006, but a USDA compliance officer dismissed the complaint despite clear language in the federal regulations prohibiting these substances. Such dismissal of a formal legal complaint essentially gives a green light to manufacturers to add these illegal additives without fear of enforcement by the USDA. The Cornucopia Institute believes that such clandestine changes of the organic rules, subsequent to secret negotiations with industry lobbyists, were illegal.

This industry-friendly ruling by the USDA—again, apparently in conflict with the law governing organic food production and labeling—occurred after heavy lobbying from some of the largest

agribusiness concerns in the country. The Cornucopia Institute is currently researching avenues for redress.

What is hexane—the chemical used to extract Martek’s DHASCO and ARASCO?

Hexane is a chemical by-product of gasoline refining.¹⁵ It is used not only as an extraction solvent for edible oils, but also as a solvent for glues, varnishes, and inks and as a cleaning agent in the printing industry. Hexane is a neurotoxin and a hazardous air pollutant.

Is hexane a concern for consumer health?

The common assumption is that all toxic hexane residues evaporate from the oils before reaching the consumer. However, no test results for Martek’s DHASCO and ARASCO confirming this assumption are available to consumers. Scientists who have tested hexane residues in other oils have found residues in some samples.¹⁶

The effects of consuming foods that contain hexane-extracted ingredients are not known. As with most of the approximately 70,000 chemicals that are registered with the EPA for commercial use, hexane has been tested for its effects on workers (see below) but has not been tested for its effects on consumers.¹⁷

Other hydrocarbon solvents, like 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. No such data is available for hexane, which is also a hydrocarbon solvent.¹⁸ There is good justification, based on the precautionary principle, as to why hexane is banned in organic food products.

Is hexane toxic to workers in the processing plants?

Yes. The use of hexane presents occupational health hazards to workers in the manufacturing plants, according to the Occupational Health and Safety Administration (OSHA). Effects of exposure to hexane include headache, nausea, respiratory tract irritation, blisters, and blurred vision.¹⁹

Hexane is an occupational safety hazard for another reason: it is highly explosive. Deadly explosions in manufacturing plants have been linked to hexane. While no deadly explosion has occurred at Martek production plants, their use of this dangerously explosive solvent puts workers at risk.

Is hexane a pollutant?

Yes. Hexane is listed as a one of 188 Hazardous Air Pollutants by EPA.²⁰ Hexane, like other volatile organic compounds (VOCs), reacts with other pollutants, principally oxides of nitrogen, in the presence of sunlight to form ozone (O₃). While ozone is essential in the upper atmosphere, excess ozone at ground level—a major contributor to “smog”—is a serious pollutant.²¹

According to the EPA, there are also trace quantities of solvent in processing plants' wastewater.²² Martek was cited for polluting water with hexane from their Winchester, Kentucky, processing plant after it caused an explosion at a wastewater treatment plant.

Consumers assume when they purchase organic products that they are supporting a higher environmental ethic. The use of hexane as a processing agent in organic food production is a betrayal to these ideals.

Additional questions about the inclusion of DHA/ARA oils in organic foods:

Which official rule determines whether algal DHA and fungal ARA oils are allowed in organic foods?

Under section 6517(d) of the Organic Food Production Act of 1990, nonagricultural ingredients, like algal DHA and fungal ARA oils, must appear as an approved substance on the National List of Approved and Prohibited Substances (7 CFR 205.605).

Algal DHA and fungal ARA oils do not appear as approved nonagricultural substances on the National List and therefore appear to be added illegally.

Who decides which additives are on the National List and therefore allowed in organic foods?

The law specifies that the Secretary of Agriculture may not propose changes to the National List without input and recommendations from the National Organic Standards Board (NOSB), made up of 15 expert citizen members from the organic community. After receiving recommendations from the NOSB, the law states that the Secretary must publish any proposed changes in the Federal Register and seek public comment on proposals. Only after considering input from the public may the Secretary publish a revised National List in the federal register.

Algal DHA and fungal ARA oils were never recommended by the NOSB and no proposed rule change regarding these oils was ever made available for public review. They do not appear on the National List as approved substances.

If these oils do not appear on the National List of Approved and Prohibited Substances, why are we finding them in organic foods?

This appears to be a troubling case of corporate lobbying supplanting democracy. If a nonagricultural substance, like algal and fungal oil, does not appear on the National List as an approved substance, they cannot be legally added to organic foods. However, it appears that certain companies have lobbied top political appointees at the USDA to ignore these laws and regulations.

A compliance officer of the Agricultural Marketing Service, which oversees the National Organic Program, dismissed a formal legal complaint regarding algal DHA and fungal ARA oils.

Following this dismissal, the National Organic Program distributed this compliance letter to all certifiers. This sent a message that the USDA will not take enforcement action against those breaking the rules by adding these illegal additives, essentially giving a green light to food companies to break the law without compunction.

On what grounds did the compliance officer dismiss the formal legal complaint?

The compliance officer wrote 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.”

It is truly disturbing to see a compliance officer misrepresent the official federal regulations in order to dismiss a legitimate legal complaint, probably due to pressure of corporate lawyers and lobbyists. The official National List—as recommended by the National Organic Standards Board and reviewed by the public—states that “synthetic vitamins and minerals” are allowed in organic foods, but *does not include accessory nutrients*. Yet the compliance officer wrote that the “NOP determined that the use of synthetic vitamins, minerals and accessory nutrients are allowed,” adding “accessory nutrients” with no legal basis for doing so.

Basically, these oils contain fatty acids—not vitamins or minerals. This is clearly not a case of involuntary confusion regarding basic nutrition and the difference between vitamins, minerals and fatty acids. It appears that the compliance officer willfully misrepresented federal regulations in favor of corporate pressure to allow these illegal additives.

Back in 1995, the National Organic Standards Board did recommend that “vitamins, minerals and accessory nutrients” be allowed in organic foods. So wouldn’t it be permissible to include accessory nutrients in organic foods based on this recommendation?

No, for several reasons.

The National Organic Standards Board does not determine final regulations. They recommend amendments to the National List, which do not become official until they are published in the Federal Register. Before such rule changes can take place, the Secretary of Agriculture is required by law to share the proposed changes with citizens, by publication in the Federal Register, and consider public input. “Accessory nutrients” do not appear in the official, published regulations and no formal public comment period took place.

The NOSB never voted to list “accessory nutrients” on the national list, but recommended they be allowed *only when required by law or recommended by professional organizations*. Algal DHA and fungal ARA oils are neither required by law nor have they been recommended by a professional organization. In fact, the Institute of Medicine has published a book on novel ingredients in infant formula, in which scientists express reservations concerning the safety of DHA and ARA oils.

Finally, algal DHA and fungal ARA oils contain only 40-50% DHA and ARA fatty acids, and are therefore not pure nutrients. As food products it is unclear whether they would even qualify as “accessory nutrients.”

Given our prior experiences in working with the USDA and their adjudication of formal legal complaints, we have to operate on the assumption that high-level political appointees reviewed and approved this erroneous application of the law.

¹ Salem ,N.J., Kim, H.-Y., Yergey, J.A. (1986) Docosahexaenoic acid: membrane function and metabolism. In *Health Effects of Polyunsaturated Fatty Acids in Seafoods*, pp. 263–317. Academic Press, New York.

² Martek Biosciences Corporation. Opinion of an expert panel on the Generally Recognized As Safe status of ARA and DHA single cell oils for infants and children. December 1999. Page 10. Available online at <http://www.fda.gov/ohrms/dockets/dailys/00/mar00/030900/rpt0003.pdf>. Last accessed on July 17, 2007.

³ Patent 5,374,657 by David J. Kyle, Martek Biosciences Corporation.

⁴ Opinion of an expert panel on the Generally Recognized As Safe status of ARA and DHA single cell oils for infants and children. Martek Biosciences Corporation. December 1999. Section 5.1.3

⁵ Patent 5,374,657 by David J. Kyle, Martek Biosciences Corporation.

⁶ McCann, J.C., Ames, B.N. (2005) Is docosahexaenoic acid, an n-3 long-chain polyunsaturated fatty acid, required for development of normal brain function? An overview of evidence from cognitive and behavioral tests in humans and animals. *American Journal of Clinical Nutrition* 82, 2: 281-295.

⁷ International Baby Food Action Network. (2004) Breaking the rules, stretching the rules 2004: evidence of violations of the international code of marketing of breastmilk substitutes and subsequent resolutions, edited by Yeong Joo Kean and Annelies Allain. Available online at <http://www.ibfan.org/english/pdfs/btr04.pdf>. Last accessed on July 17, 2007.

⁸ Under sections 201(s) and 409 of the Act, and FDA's implementation of regulations in 21 CFR 170.3 and 21 CFR 170.30, the use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food. <http://www.cfsan.fda.gov/~dms/grasguid.html>

⁹ FDA (2007) Infant formula. Available online at <http://www.cfsan.fda.gov/~dms/inf-toc.html>.

¹⁰ Food and Nutrition Board (2004) Infant formula: evaluating the safety of new ingredients Food and Nutrition Board, Institute of Medicine, National Academies Press. Page 44.

¹¹ American Academy of Pediatrics (2005) Breastfeeding and the use of human milk. *Pediatrics* 115, 2: 496–506

¹² American Academy of Pediatrics (2005) Breastfeeding and the use of human milk. *Pediatrics* 115, 2: 496–506

¹³ Ip, S., Chung, M., Raman, G., Chew, P., Magula, N., DeVine, D., Trikalinos, T., Lau, J. (2007) Breastfeeding and maternal and infant health outcomes in developed countries. Evidence Report/Technology Assessment No. 153 (Prepared by Tufts-New England Medical Center Evidence-based Practice Center, under Contract No. 290-02-0022). AHRQ Publication No. 07-E007. Rockville, MD: Agency for Healthcare Research and Quality.

¹⁴ United States Centers for Disease Control and Prevention. NIS National Immunization Study 2005 data. Available online at http://www.cdc.gov/breastfeeding/data/NIS_data/data_2005.htm.

¹⁵ EPA (200) Technology Transfer Network Air Toxics web site. Hexane. Available online at <http://www.epa.gov/ttn/atw/hlthef/hexane.html>.

¹⁶ Joint Campaign Basel City (specialist laboratory) and Basel Country. Vegetable oils / fatty acid composition, hexane residues, declaration, pesticides (organic culinary oils only). Available online at <http://www.labor.bs.ch/files/berichte/Report0424.pdf>. Last accessed on October 22, 2007.

¹⁷ Oleskey, C., McCalley, M. A guide to biomonitoring of industrial chemicals. Center for Children's Health and the Environment. Available online at <http://www.childenvironment.org/pdfs/bmguide.pdf>.

¹⁸ Oleskey, C. and McCalley, M. A guide to biomonitoring of industrial chemicals. Center for Children's Health and the Environment. Available online at <http://www.childenvironment.org/pdfs/bmguide.pdf>.

¹⁹ OSHA. Occupational safety and health guideline for n-hexane. Available online at <http://www.osha.gov/SLTC/healthguidelines/n-hexane/recognition.html>.

²⁰ EPA (2007) Technology Transfer Network Air Toxics web site. The Clean Air Act Amendments of 1990 List of Hazardous Air Pollutants. Available online at <http://www.epa.gov/ttn/atw/orig189.html>. Note: EPA is required to control 188 hazardous air pollutants.

²¹ EPA (2007) Ground Level Ozone. Available online at <http://www.epa.gov/air/ozonepollution/>.

²² The source of these residues is direct contact steam in the distillation stripper and desolventizer-toaster. Midwest Research Institute and EPA (1995) Emission factor documentation for AP-42 Section 9.11.1 Vegetable oil processing final report for U. S. Environmental Protection Agency Office of Air Quality Planning and Standards Emission Factor and Inventory Group.