

January 2008

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

Charlotte Vallaey

Promoting Social Justice in the Food Chain



Contents

| | |
|---|----|
| Acknowledgments..... | i |
| Executive Summary..... | 1 |
| DHA and ARA in Infant Formula..... | 1 |
| Purpose of the Report..... | 3 |
| What Is DHA?..... | 3 |
| Algal DHA and Fungal ARA: Novel Products in the Human Diet..... | 4 |
| DHA in Infant Formula..... | 5 |
| The True Motivation for Adding DHA and ARA in Infant Formula: The Perfect Marketing Tool?.... | 5 |
| Infant Formula Manufacturers' "Quixotic Quest"..... | 8 |
| Breastfeeding versus Infant Formula: A Debate Blurred by Milk Money..... | 9 |
| FDA Concerns about DHA and ARA in Infant Formula..... | 10 |
| Inadequate Safety Tests by Martek?..... | 12 |
| Martek's Studies on Rats..... | 12 |
| Studies on Infants..... | 13 |
| Infants as Martek's Guinea Pigs?..... | 13 |
| FDA Adverse Reaction Reports: The Tip of the Iceberg?..... | 14 |
| The Scientific Community's Uncertainty..... | 16 |
| Excerpts from Scientific, Peer-Reviewed Articles..... | 17 |
| Concerns about DHA and Contamination: Breastfeeding's Benefits Outweigh Risks..... | 17 |
| DHA in Organic Foods..... | 21 |
| The Inappropriate Use of DHA and ARA in Organic Infant Formula..... | 21 |
| Is It Legal?..... | 21 |
| DHA in Organic Foods for Children and Adults..... | 22 |
| The Problem with Factory-Farmed DHA-Supplemented Milk..... | 23 |
| Hexane and Consumer Safety..... | 23 |
| Hexane: An Occupational Hazard..... | 24 |
| Hexane: An Environmental Hazard..... | 25 |
| Organic Certifier Refuses to Share Public Information..... | 25 |
| USDA Organic Program Must Take Action..... | 26 |
| Conclusion..... | 26 |
| Appendix A: Formula Advertisements and Labels..... | 28 |
| Appendix B: Infant Formula and DHA..... | 29 |
| Appendix C: Martek Uses Hexane to Extract Oils..... | 31 |
| Appendix D: Legal Complaint Letter to USDA..... | 33 |
| Appendix E: Petition to the Federal Trade Commission..... | 36 |
| Appendix F: Petition to the Federal Drug Administration..... | 39 |
| Sources..... | 42 |

Acknowledgments

The following staff and board members helped write, research, support, and edit this paper:

Charlotte Vallaey, Farm & Food Policy Analyst
Mark Kastel, Senior Farm Policy Analyst
Will Fantle, Research Director
Margaret Hannah, Board Member, Scientific Editor
Charles Angell, Design
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The Cornucopia Institute wishes to thank Marsha Walker, RN, IBCLC, National Alliance for Breastfeeding Advocacy.

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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

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.

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.

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.

What Is DHA?

DHA, which stands for docosahexaenoic acid, is a type of fat. It is a 22-carbon long-chain polyunsaturated fatty acid of the omega-3 family. This particular fatty acid is a component of the brain's gray matter and is also abundant in the membranes of the retinal photoreceptors in the eyes.¹⁴ DHA is naturally found in human breast milk,¹⁵ and dietary sources for adults include fatty fish such as salmon and mackerel. DHA can also be synthesized in the liver from alpha-linolenic acid (ALA), which is another type of omega-3 fatty acid found in flaxseeds, canola oil, and walnuts.

However, there is uncertainty in the scientific community over whether the rate of DHA synthesis in infants is sufficient to support optimal brain and retinal development—hence its abundance in human breast milk.¹⁶ But unless it is specifically added, the fatty acid DHA is not a normal component of milk-based or soy-based infant formulas.

Some scientists suggest that shore-based diets, which were

high in fish and therefore DHA, played a crucial role in human brain evolution. These scientists conclude that adequate dietary sources of DHA are absolutely essential for normal brain development in infants.¹⁷ While few scientists will question the importance of DHA in breast milk, the question of adding chemically extracted DHA-containing oils to infant formula is rife with doubts and concerns.

Human milk is a complex matrix of nutrients, and to closely imitate the balance of fatty acids, DHA should not be added to formula without also adding another type of fatty acid, ARA.¹⁸

ARA stands for arachidonic acid, which is a 20-carbon omega-6 fatty acid. Like DHA, ARA is believed to be an important component of the central nervous system. Adding DHA to formula leads to a reduction in the infant's tissue ARA, a reason why it is important to add ARA as well when adding DHA to formula.¹⁹

Overall, scientific studies show little if any benefit to cognitive development from formula fortified with manufactured sources of DHA and ARA, which may be due to any one of numerous possible reasons.²⁰ A review of these scientific studies can be found in the section titled "The Scientific Community's Uncertainty."

Algal DHA and Fungal ARA: Novel Products in the Human Diet

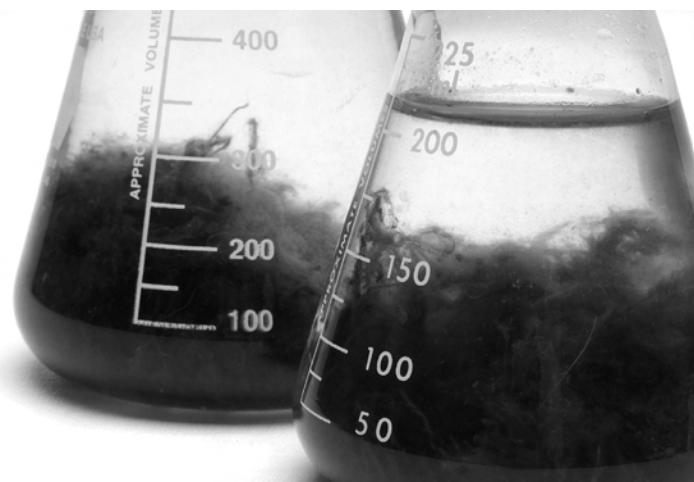
Recognizing an opportunity to profit from these important nutrients, Martek Biosciences Corporation developed a patented process using algae and soil fungus to extract DHA- and ARA-rich oils for use in infant formula and other foods. Martek calls these processed and patented oils DHASCO and ARASCO, which stand for docosahexaenoic acid single cell oil and arachidonic acid single cell oil.

To obtain DHASCO, microorganisms such as *Cryptothecodinium cohnii* are first grown under tightly controlled fermentation conditions in a nutrient solution containing glucose and yeast extract.²¹ They are then harvested, and the oil is extracted by blending the dried biomass with hexane, a toxic solvent that is a petroleum by-product of gasoline refining, in a continuous extraction process. The hexane is removed from the oil by distillation techniques, using conventional oilseed processing equipment, to perform the filtering, separation, and distillation.²²

Martek may also have a process that does not require hexane, although company officials declined to comment or provide further information.²³ However, the only type of algal DHA oil that has been approved for use in infant formula is DHASCO, which is hexane extracted, according to Martek's petition submitted to the FDA.²⁴

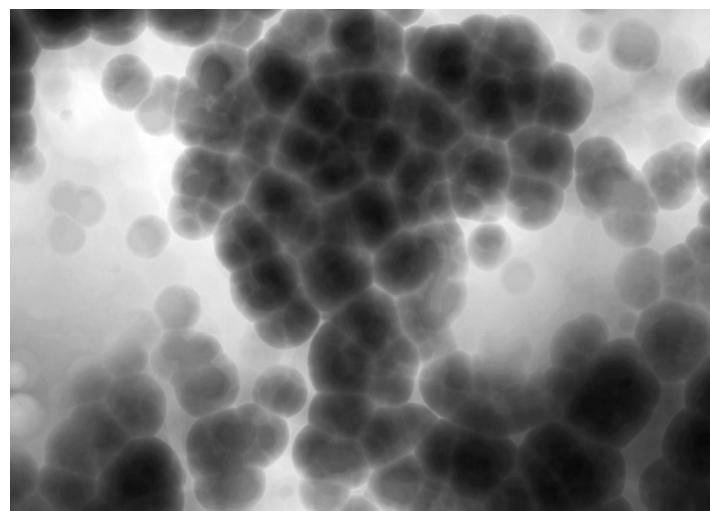
The ARA oils that are approved for use in infant formula are obtained from soil fungus species such as *Mortierella al-*

pina, using similar production and extraction processes as for DHASCO.²⁵ Again, Martek writes in its petition to the FDA that "the oil is first extracted by blending the dried biomass with hexane in a continuous extraction process."²⁶ There is no evidence that Martek is extracting ARASCO without the use of hexane, and their ARASCO is added at twice the levels of DHASCO to infant formula.



DHA in infant formula is extracted from fermented algae.

These manufactured oils are *novel* foods. Added to formula, they are new to the diet of human infants. It is important to note that DHASCO and ARASCO are structurally different from the DHA and ARA found in breast milk. First, although the DHASCO and ARASCO oils contain the fatty acids DHA and ARA, DHASCO and ARASCO are oils, not pure nutrients. In fact, DHASCO and ARASCO contain only 40–50% DHA and ARA, and are diluted with high-oleic sunflower oil. DHASCO and ARASCO contain 95% triglycerides and 5% diglycerides and nonsaponifiable materials.²⁷



ARA added to infant formula is extracted from fermented soil fungus.

Martek does not seem concerned with the effects that the remaining 50–60% of components in DHASCO and ARASCO may have on infants. Martek gives an example of a non-DHA compound found in DHASCO: 4-methyl sterols, and explains that “4-methyl sterols are found in the normal metabolic pathway of cholesterol biosynthesis in man.” Since these sterols are found naturally in fish and shellfish, Martek concludes that they do not pose a problem to infants. However, neither fish nor shellfish is a natural part of an infant’s diet, and metabolic pathways in adults may be somewhat different from those of infants. This is just one example of a non-DHA component in DHASCO, and we question the assumption by Martek that none of the many non-DHA components in DHASCO pose any problems.

Second, and perhaps most importantly, DHASCO and ARASCO 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 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.²⁸ This key structural difference seems not to concern Martek’s scientists, who write that “DHA will still be absorbed either as the free fatty acid or as the monoglyceride after processing by the baby’s lipase in the gut.”²⁹ It seems logical to consider the possibility that some infants are not able to digest triglycerides that have two DHA or ARA molecules, and that this should be investigated as a possible cause of the gastrointestinal distress that some infants experience after ingesting formula supplemented with DHASCO.

According to patent applications, Martek is also genetically engineering the algal and fungal microorganisms in an attempt to increase their oil production.³⁰ While Martek’s web site assures consumers that their DHA and ARA are not genetically modified, the company’s patents cover genetically engineered microorganisms for the production of DHA and ARA.³¹ It should be noted that genetically engineered ingredients are strictly prohibited in the federal organic regulations.

DHA in Infant Formula

The True Motivation for Adding DHA and ARA in Infant Formula: The Perfect Marketing Tool?

In its patent application, Martek calls its products “designer oils.” They were developed not by public interest researchers, but by a corporation that is ultimately accountable to its shareholders. Like all investor-owned corporations, Martek must not

only produce a marketable product, but a profit as well. That both the safety and the benefits of DHASCO and ARASCO in infant formula are in question by the FDA, the National Institute of Medicine, and countless scientists, appears to have been irrelevant in the corporation’s decision-making process.

Below is an excerpt from a market analyst regarding Formulaid, the initial brand name of Martek’s DHA/ARA blend for infant formula fortification:

Infant formula is currently a commodity market, with all products being almost identical and marketers competing intensely to differentiate their product. *Even if Formulaid 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].³²

A 1999 study, published in *The Lancet*, was available at the time that Martek submitted its petition to the FDA to include DHASCO and ARASCO in infant formula. The researchers concluded:

Babies fed formula with and without long-chain polyunsaturated fatty acids did not differ in cognitive or motor development, growth, infection, atopy or tolerance. Our trial *does not provide support for addition of long-chain polyunsaturated fatty acids to standard infant formula* but we are now doing further follow-up of this cohort [emphasis added].³³

Overall, scientific studies show inconsistent results on the question of whether DHA and ARA supplementation is beneficial and necessary in infant formula (see section titled “The Scientific Community’s Uncertainty”).

Scientists have also doubted the safety and criticized the premarket safety tests of Martek’s DHASCO. An expert panel of scientists, convened by the Institute of Medicine to address questions of safety of novel ingredients in infant formula, was a nuisance for Martek. In response to a notice by the FDA, which alerted Martek to the FDA’s plan to convene this panel, Martek expressed its view that some of the concerns described by FDA are “hypothetical” and that “convening a group of scientific experts to answer such hypothetical concerns would not be productive.”³⁴ Like many corporations potentially subject to governmental oversight, Martek attempted to placate regulatory concern and lobbied for minimum scrutiny.

While the FDA has not affirmed the safety of Martek’s DHASCO and ARASCO in infant formula, and scientists conclude that evidence of its benefits is inconclusive, Martek and infant formula manufacturers have been happy to profit from DHA/ARA formula. Advertisements suggest that DHA and ARA in infant formula are necessary for proper brain and eye development. An Enfamil Lipil ad boasts that “it’s the only brand that’s been shown in independent clinical studies to improve brain and eye development.”³⁵ Ads also claim that DHA/

ARA infant formula is “closer than ever to breast milk”³⁶ and “so much like breast milk in so many ways.”³⁷

As documented in the section titled “The Scientific Community’s Uncertainty,” no study has ever shown that formula-fed babies were better off, developmentally or otherwise, than human milk-fed babies. Given the safety concerns and doubts within the scientific community, it is clear that the infant formula manufacturers’ claims are marketing tools designed to sell more formula, and sell it at a higher price.



A market analyst for Martek wrote about DHASCO and ARASCO: “Even if [it] has no benefit, we think it would be widely incorporated into formulas as a marketing tool.”

According to the International Code of Marketing of Breastmilk Substitutes, which was adopted in 1981 by the World Health Assembly as a minimum standard to help protect and promote breastfeeding in all countries, promotional claims regarding infant formula should not be allowed.³⁸ This code is an international public health recommendation that is not binding.³⁹ When parents see that DHA/ARA formula is “as close as ever to breastmilk” with a claim that it will promote their babies’ brain development, they may be misled into believing that infant formula may in fact be better than human milk.

For this reason, in April 2004, Canada’s Food Inspection Agency ordered Mead Johnson to stop claims promoting the benefits of DHA/ARA in infant formula. The ads for Enfamil A+ claimed that it is “the only formula proven to result in higher early development scores.”⁴⁰

Unfortunately for infants, these claims—which are still rampant in the United States—seem effective in luring mothers away from breastfeeding. Kathy A. Eng, IBCLC, a former employee of the Program for Women, Infants and Children (WIC)

in Houston, Texas, says: “Since they added [DHA and ARA] 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 to convince mothers to breastfeed when formula ads claim that formula is as close as ever to breast milk.”

According to the National Alliance for Breastfeeding Advocacy, mothers have contacted health care providers asking the following: “I want the breast milk formula,” or “I want the formula with breast milk in it,” and asking questions such as “whose breast milk is in the formula?”⁴¹

Survey results by the Office of Women’s Health of the Department of Health and Human Services also suggest that DHA/ARA advertisements may undermine efforts at promoting breastfeeding. The survey’s purpose was to determine the public’s awareness of the benefits of breastfeeding before and after a government-sponsored advertisement campaign promoting breastfeeding. The results show a striking surge in the percentage of respondents who agreed that “infant formula and breast milk are equally good ways of feeding an infant.” In 2003, 12% of respondents agreed that both methods are equally good ways of feeding an infant; in 2004 the percentage points doubled to 24%.⁴²

In the last couple of years, formula manufacturers have increased their spending on advertising. According to figures quoted in a report by the Government Accountability Office, the annual expenditures by formula manufacturers on television and print ads in the United States increased from about \$29 million in 1999 to over \$46 million in 2004. In this five-year period from 1999 to 2004, infant formula companies spent a total of almost \$223 million on advertisements for formula.⁴³

While formula manufacturers freely advertise claims that are not based on sound science, they have also pressured the government to *not* advertise scientifically sound research findings regarding the benefits of breastfeeding. In August 2007, the *Washington Post* reported that the infant formula industry succeeded in pressuring government officials to change the content of advertisements that were aimed at increasing the rates of breastfeeding in the United States.⁴⁴

“Since they added [DHA and ARA] 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 to convince mothers to breastfeed when formula ads claim that formula is as close as ever to breast milk.”

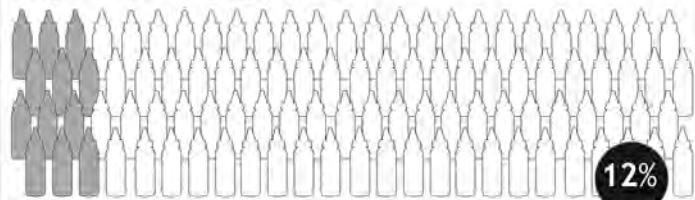
Kathy Eng, former WIC employee, Houston, Texas

The government's initial advertisements, which never aired due to industry pressure, were based on a comprehensive analysis of the benefits of breastfeeding, undertaken by scientists at the Tufts-New England Medical Center. The report found that breastfeeding is associated with fewer ear and gastrointestinal infections, as well as lower rates of diabetes, leukemia, obesity, asthma, and sudden infant death syndrome. When the Department of Health and Human Services wanted to advertise these findings, formula manufacturers lobbied to tone down the advertisements. They succeeded, and the advertisements that were eventually aired were watered down and ineffective. Moreover, the report by the Tufts-New England Medical Center scientists was never promoted by the Department of Health and Human Services, which commissioned the report, again, due to pressure from top political appointees and formula manufacturers.⁴⁵ While scientists in the Department of Health and Human Services have been silenced and told not to advertise these scientifically based correlations, infant formula manufacturers are continuing to pour millions of dollars into advertising something—DHASCO and ARASCO's role in supporting brain and eye development—that has only a very shaky basis in sound science.

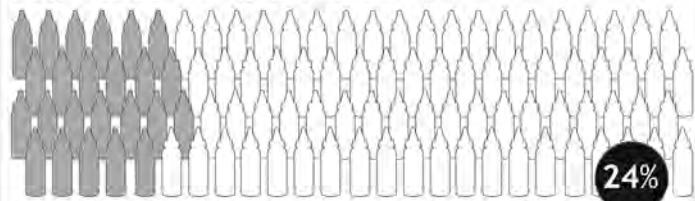
Department of Health and Human Services survey question:

"Breast milk and infant formula are equally good ways of feeding an infant."

Respondents who agree in 2003



Respondents who agree in 2004



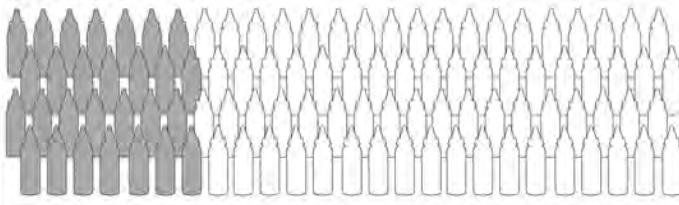
Source: Department of Health and Human Services Office for Women's Health

Formula Brands and DHASCO

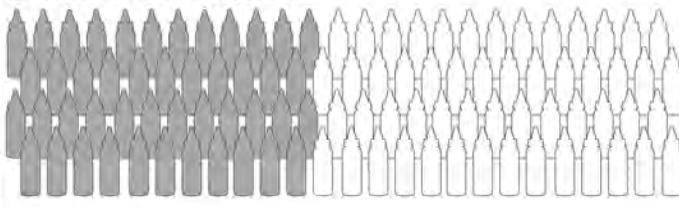
| Brand Name | Manufacturer | How much DHA, if DHASCO is added? (per 100 kcal) | Organic option? | Organic with DHASCO/ARASCO? | Organic without DHASCO/ARASCO available? | Any formula without DHASCO/ARASCO available? |
|-------------------|--------------------------|--|-----------------|-----------------------------|--|--|
| Earth's Best | The Hain Celestial Group | 17 mg | Yes | Yes | No | No |
| Similac | Abbott Laboratories | 8 mg | Yes | Yes | No | No |
| Enfamil | Mead Johnson | 17 mg | No | No | N/A | No |
| Parent's Choice | PBM Products | 17 mg | Yes | Yes | No | Yes |
| Bright Beginnings | PBM Products | 19 mg | Yes | Yes | No | No |
| Nestle Good Start | Nestle | 16 mg | No | No | N/A | Yes |

Infant formula manufacturers advertisement spending:

1999: \$29 million



2004: \$46 million



Each bottle represents \$1 million.

Source: Department of Health and Human Services Office for Women's Health

Infant Formula Manufacturers' "Quixotic Quest"

The Cornucopia Institute acknowledges that infant formula is a lifesaver for many infants who cannot be breastfed. Formula is a necessity for infants whose mothers have died or are seriously ill and for adopted infants. Moreover, sadly, some women simply cannot breastfeed due to economic pressures that demand that they return to work, where they are often unable to breastfeed. However, infant formula today is not just about saving the lives of a minority of unfortunate infants, it is an industry that must grow in order to satisfy investors.

Marion Nestle, a professor of nutrition at New York University and an expert on politics in the food industry, writes: "For formulas, the size of the market depends entirely on the number of babies born each year and the proportion that are not breastfed. But formula companies have no control over how many babies are born, so the only way they can increase sales is to discourage breast-feeding."⁴⁶ While breast milk is nutritionally superior to formula, its only disadvantage is that it is free and cannot be sold in the marketplace; therefore, no corporation can profit from encouraging breastfeeding.

Formula saves lives of infants who cannot be breastfed, but it can never confer the same benefits as breast milk. As pointed out by an expert panel of scientists from the Institute of Medicine's Food and Nutrition Board, the attempt to imitate human breast milk by adding ingredients to formula is a "quixotic quest," since human milk is a complex matrix of nutrients that varies among individuals and over time. Breast milk contains

elements that simply cannot be grown or manufactured for infant formula—these elements include live cells and bioactive compounds.⁴⁷

"Formula companies have no control over how many babies are born, so the only way they can increase sales is to discourage breast-feeding."

—Marion Nestle, Professor of Nutrition, New York University

The quixotic nature of the effort to imitate breast milk is demonstrated in the following scientific experiment, which involved DHA. In the late 1990s, a group of scientists from the University of Washington School of Medicine conducted a randomized clinical trial comparing breastfeeding, nonfortified formula, formula fortified with DHA from fish oil, and formula fortified with DHA and ARA from egg phospholipids.⁴⁸ They found that the infants who were given DHA-enriched formula actually had *lower scores on cognitive development tests*.⁴⁹ Moreover, additional analyses both in the formula groups and in the human milk comparison group *found significant negative correlations between DHA levels and vocabulary outcomes*. [emphasis added]⁵⁰



According to Institute of Medicine scientists, the attempt to imitate human breast milk by adding ingredients to formula is a "quixotic quest."

This study shows the complex nature of human milk, and the way in which nutrients interact with one another. A fatty acid, like DHA, may actually have negative effects if given in the wrong proportion in relation to other nutrients. What is known today is that adding DHA without adding ARA will disrupt a sensitive balance of fatty acids. Who knows what other components of breast milk are essential to provide a necessary balance to support the optimal growth and development of the

infant? Or how the addition of DHA and ARA may disrupt the fatty acid balance, given that there are other fatty acids present in breast milk that scientists haven't even identified and isolated yet?⁵¹ Questions abound regarding which other crucial nutrients are either missing from formula, added in wrong proportions, or present when they shouldn't be.

Moreover, this study points to the uncertainty of the infant formula manufacturing process and raises questions regarding the unknown side effects and consequences of feeding hexane-extracted DHASCO from microorganisms and hexane-extracted ARASCO from soil fungus to infants. Mother's breast milk is balanced in ways that scientists can only hope to fully comprehend; infant formula is therefore truly a "quixotic quest."

"There are more than a hundred fatty acids in human breast milk, many of which we are not yet able to identify with our current scientific technology."

—Dr. Jimi Francis, University of Nevada-Reno

Breastfeeding versus Infant Formula: A Debate Blurred by Milk Money

The addition of DHASCO and ARASCO to infant formula has led formula manufacturers to make the claims that this new formula is "as close as ever to breast milk." Medical professionals and breastfeeding advocates view such claims as detrimental to infant health if they make new mothers less likely to breastfeed. According to Dr. Lee Jong-Wook, who was the immediate past director general of the World Health Organization, "virtually all mothers can breastfeed provided they have accurate information, and support within their families and communities and from the health care community."⁵²

The benefits of breastfeeding over infant formula are widely accepted and undisputed. One scientific study found that promoting breastfeeding has the potential to prevent or delay 720 infant deaths in the United States every year, mostly by preventing infectious disease and sudden infant death syndrome.⁵³

The benefits of breast milk are numerous. The American Academy of Pediatrics writes that the advantages include "health, nutritional, immunologic, developmental, psychologic, social, economic, and environmental benefits." The Academy expressed that breast milk is superior to formula.⁵⁴

Scientific studies have shown the following risks associated with formula-feeding⁵⁵⁻⁵⁶:

- Formula-fed babies are at an increased risk for the incidence and/or severity of a wide range of infectious diseases including the following:

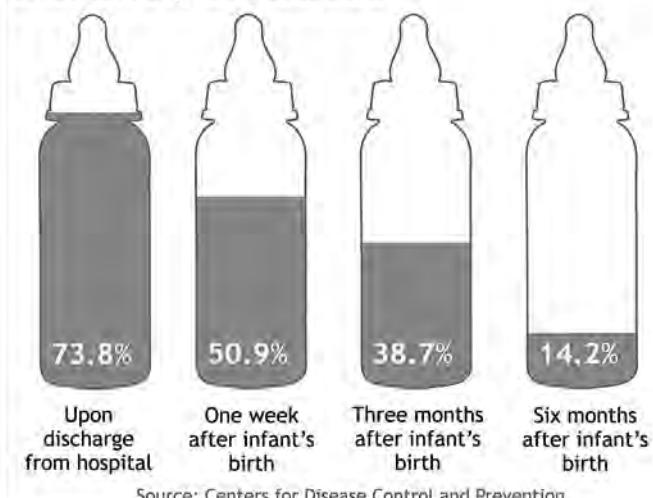
The following list is only a sample of respected organizations that recommend exclusive breastfeeding for the first six months of life:

- World Health Organization
- United Nations Children's Fund
- The American Academy of Pediatrics
- American College of Obstetricians and Gynecologists
- American Academy of Family Physicians
- Academy of Breastfeeding Medicine

The American Academy of Pediatrics points out that there are additional benefits associated with breastfeeding that go beyond infant and maternal health:

- Increased rates of breastfeeding could potentially decrease annual health care costs by \$3.6 billion in the United States.
- Increased rates of breastfeeding would decrease costs for public health programs such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC).
- Breastfeeding decreases parental employee absenteeism and associated loss of family income.
- Breastfeeding leaves more time for attention to siblings and other family matters as a result of decreased infant illness.
- Breastfeeding decreases the environmental burden for disposal of formula cans and bottles.
- Breastfeeding decreases energy demands for the production and transport of artificial feeding products.⁵⁸

Percentage of mothers who exclusively breastfeed:



breastfeeding at 3 months of age at 38.7% and only 14.2% by six months of age.⁵⁹ Given that there are approximately 4 million babies born in the United States every year, this means that approximately 2 million infants receive nothing but manufactured and imperfect infant formula as their only source of nutrition during their first weeks of life.

The issue of DHASCO/ARASCO in infant formula is therefore a difficult one. Given the presence of DHA and ARA in human milk, one could surmise that DHASCO/ARASCO in formula would likely be beneficial for infants. However, scores of scientists doubt whether adding DHASCO and ARASCO to formula benefits infant development. Moreover, concerns arise when infant formula manufacturers add hexane-extracted algal and fungal oils that are new to the human diet without receiving an affirmation from the FDA that they are safe.⁶⁰

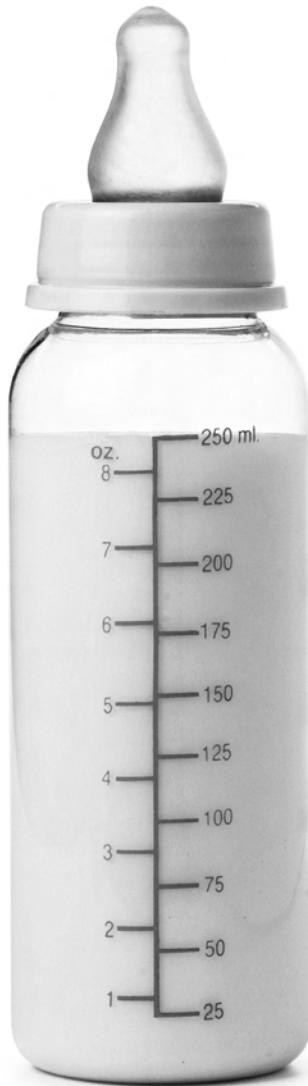
“While researchers fiddle with the balance of fatty acids in infant formula, and deal with the additional uncertainties of the complex cascade of interactions that each adjustment provokes within the omega families, breast milk will always be the simple, perfectly balanced source of each essential nutrient. And while researchers try to manipulate formula, infants participating in the trials are subjected to experimental nutrition during a critical developmental period. As a result they may never achieve their optimal cognitive and neurological potential. After all, they may be unlucky enough to be chosen for the cohort receiving the least successful formula.”⁶¹

International Baby Feeding Action Network

FDA Concerns about DHA and ARA in 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)⁶² or ap-

proved as food additives for use in infant formula.”⁶³ Because of this legal requirement for all infant formula ingredients to be generally recognized as safe, Martek needed to share with the FDA its basis for assuming that its oils are, in fact, generally safe. The FDA does not need to affirm the safety, it only has to cease raising further questions about the product. When it no longer asks questions, the door is opened for proposed ingredients to be added to formula.



The FDA did not affirm the safety of Martek’s DHASCO and ARASCO for use in infant formula. Among its reasons: studies showing adverse events including diarrhea in infants.

While the FDA “raises no further questions” about the GRAS status for most ingredients that are petitioned, it does not affirm the safety of all ingredients. For most food ingredients, the FDA will respond that “FDA has affirmed the GRAS status of [the proposed ingredient].” For other ingredients, like Martek’s DHASCO and ARASCO, the FDA responds that “the agency has not made its own determination regarding the Gen-

erally Recognized as Safe status of the subject use of DHASCO and ARASCO.”

But while the FDA does not have enough confidence in DHASCO and ARASCO to affirm their safety, they raised no further questions and therefore allowed Martek to add the novel oils to formula.

FDA did not affirm the safety of DHASCO and ARASCO, noting that 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 reported adverse events and other morbidities including *diarrhea, flatulence, jaundice, and apnea* in infants fed long-chain polyunsaturated fatty acids.⁶⁴ [emphasis added]

FDA officials also noted that it is the continuing responsibility of Martek to ensure that food ingredients that the firm markets are safe.⁶⁶ The FDA would expect any infant formula manufacturer who lawfully markets infant formula containing ARASCO and DHASCO to monitor, through scientific studies and rigorous postmarket surveillance, infants who consume such a formula.⁶⁷

Elsewhere on FDA’s web site, the agency mentions that “there are no currently available published reports from clinical studies that address whether any long-term beneficial effects [of DHA and ARA in infant formula] exist.”⁶⁸

The FDA has not affirmed the safety of Martek’s algal DHA and fungal ARA oils added to infant formula. In a written statement, FDA officials noted: “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.”⁶⁵ [emphasis added]

Inadequate Safety Tests by Martek?

Most premarket tests for DHASCO and ARASCO were performed by Martek itself, but some were performed by their customers, infant formula manufacturers, including Mead Johnson and Wyeth Ayerst. This is a familiar scenario to those observing the approval process for pharmaceuticals.

Martek pays the scientists to perform its safety tests, which raises serious concerns as to the independent and unbiased nature of these experiments. While true objectivity is never possible, the scientific method strives for impartiality, meaning that scientists should be unbiased and prepared to accept whatever outcome their studies reveal. When corporations pay scientists to prove a certain hypothesis—in this case, to get a product on the market and thereby begin the revenue stream that will reward the risk taken by its investors—it clearly puts the objectivity of the scientific model at risk.

This method of investigation, intended to protect the public, is dubious at best. One only has to look at the many drugs that have been pulled from the market after debilitating health impacts or deaths have resulted from their use.

The Cornucopia Institute does not wish to discredit scientific studies simply because they were performed by corporate-paid scientists; we intend only to point to the need for skepticism when study results are tied to corporate profit. Such skepticism is not unfounded.

In 2006, the Canadian Broadcast Corporation investigated a renowned scientist at a Canadian university and uncovered a pattern of scientific fraud that involved, among other topics, infant formula. The scientist, Dr. Ranjit Kumar Chandra, had been hired by Nestlé to prove certain claims regarding their infant formula. Articles were published in peer-reviewed scientific journals that were later found to be completely fabricated. Quite predictably, the results of these faked studies were exactly what the corporations had hoped for—and paid for. When fictitious results supported Nestlé and Mead Johnson's infant formulas, but not Abbott Laboratories' formula, the scientist explained: "Well, [Abbott] didn't really pay me enough to do [the study] correctly."⁶⁹

Parents should weigh and consider the outcome of the safety tests performed by Martek—while always keeping in mind that these tests were financed by a corporation seeking to profit from a certain outcome.

Furthermore, a panel of independent scientists, put together by the Institute of Medicine's Food and Nutrition Board, took a critical look at tests performed for new ingredients in infant formula. In their book titled *Infant Formula: Assessing the Safety of New Ingredients*, they point to problems with Martek's premarket safety tests. Martek's conclusions, as well as the Institute of Medicine's expert panel's critique and concerns regarding these tests, are presented below.

Martek's Studies on Rats

Scientists performed acute toxicity tests on rats, as well as short-term chronic toxicity studies (28-day and 63-day tests) and long-term chronic toxicity studies (90 days). The scientists concluded that the oils are not toxic because there were no deaths, except when the dose was almost 50 times as much as would be present in infant formula.

The scientists found no adverse developmental effects in studies on rats. Genotoxicity studies on rats also found no evidence of the oils being mutagenic, clastogenic, or genotoxic. The scientists found no toxins produced by the dinoflagellates from which they extract the oils.

Potential Problems with the Tests: First, the panel of independent scientists pointed to the problem of performing these studies solely on rats. They were concerned about the very limited number of premarket safety tests of polyunsaturated fatty acids, including DHA, performed on nonhuman primates.⁷⁰ The Institute of Medicine scientists point out that "it is difficult to feed infant formulas to a pre-weanling rat," which means that "the developmental tenets of timing, dose, and duration cannot be addressed."

Second, some of the studies on rats did show disconcerting results. Martek wrote that "out of thirteen subchronic toxicity studies, five indicated statistically significant increase in relative liver weights at the highest doses of ARASCO and DHASCO/ARASCO blend."⁷¹

Some of the studies on rats did show disconcerting results. Martek wrote that "out of thirteen subchronic toxicity studies, five indicated statistically significant increase in relative liver weights at the highest doses of ARASCO and DHASCO/ARASCO blend."⁷²

—Martek Biosciences Corporation

The scientists concluded that "these were not adverse toxicological effects,"⁷³ partly because an increase in liver weight in rats is common following a high-fat diet. When the Australia New Zealand Food Authority approved DHASCO and ARASCO, it noted that these changes were "entirely consistent with the physiological changes observed in response to the administration of high levels of long-chain polyunsaturated fatty acids, irrespective of source, and are not a manifestation of toxicity specific to the administration of either ARASCO or DHASCO."⁷⁴

Martek's scientists did perform additional studies to gain a better understanding of the increased liver weights and found that DHASCO and ARASCO actually did lead to higher liver weights compared with rats that were a high-fat diet without DHASCO and ARASCO. This difference was statistically significant. However, since "none of the mean relative liver weights were outside the historical normal range," the corporate-paid scientists concluded that DHASCO and ARASCO are safe, despite these findings of increased liver weights.⁷⁵

Third, results of the safety studies also indicated an increase in spleen weight in the groups that were fed DHASCO and ARASCO. According to Martek's notification to the FDA, the scientists did not look deeper into the reason for this increase in organ weight. They concluded that DHASCO and ARASCO are safe, despite these findings.

Fourth, no chronic toxicity or chronic carcinogenicity studies were performed on rats. In their notification to the FDA, Martek's scientists write that they "determined that chronic toxicity/carcinogenicity studies were not necessary for this nutrient." None of the "long-term" toxicity safety tests performed by Martek lasted for longer than 90 days.

Fifth, out of the 13 toxicity studies, 3 studies "reported a decrease in albumin levels and/or total protein levels." Martek disregarded these findings, because "this finding was not consistent across studies."⁷⁶

Sixth, the scientists also found a slight to moderate vacuolization (accumulation of vacuoles, components of living cells) in some, but not all, of the high-dose treatment groups. But since this was not different from the high-fat control groups, they attribute this to a high-fat diet and not to the DHASCO and ARASCO oils specifically.⁷⁷

Seventh, the Institute of Medicine's scientists note that "the literature cited in Martek's notification provides no mention of neurotoxicological effects in either the developing or the mature rat."⁷⁸

Studies on Infants

Martek sponsored 14 clinical trials on infants and reported that none showed adverse effects. Critics of Martek's safety tests have suggested that ethical considerations require infants to be pulled from scientific studies if they react negatively, and they would not be considered in the final analysis.⁷⁹ Others have pointed out that premarket safety tests with a limited number of infants would not necessarily reveal adverse reactions that occur only in a subset of the population. Only when hundreds of infants start consuming the product will clear evidence of adverse reactions occur.⁸⁰

The Institute of Medicine's expert panel raised concerns regarding these clinical trials. The panel writes that "it is not clear whether assessments of body composition, immune response,

auditory function, and temperament were conducted. Several of these tests are especially important to determine the safety of long-chain polyunsaturated fatty acids because theoretical safety concerns exist." Moreover, the independent scientists point out that certain safety tests that may identify problems have not been performed: "Neuronal- and glial-cell culture techniques were not reported in the GRAS Notification for long chain polyunsaturated fatty acids. These techniques may have identified unwanted effects of these ingredients on gene expression through microarray screening analysis."⁸¹

After reviewing Martek's petition for GRAS status, which contained these scientific findings, the FDA did not permit the use of DHASCO and ARASCO in infant formula for a couple of years. In 2001, the FDA raised no further questions regarding Martek's claim that its products are generally safe, despite the FDA's knowledge of the safety concerns included in the petition.

Infants as Martek's Guinea Pigs?



"We call it 'the diarrhea formula' at our local hospital," says Sam Heather Doak, a nurse in Ohio.

Martek's algal DHASCO and fungal ARASCO were never approved by the FDA yet are found in approximately 90% of all infant formula sold in the United States.⁸² Marsha Walker, RN, IBCLC, a healthcare professional who also heads the National Alliance for Breastfeeding Advocacy, points out that "this is a huge uncontrolled experiment." She explains that a subgroup of infants reacts very badly to DHASCO and ARASCO in infant formula: "This is similar to how some people react to Olestra. Most people experience no side effects, but some do. After consuming DHA/ARA formula, some infants experience watery, explosive diarrhea."

Sam Heather Doak, a nurse in Ohio, says that the nursing staff at her local hospital's neonatal unit refers to DHA/ARA-supplemented formula as "the diarrhea formula." Doak explains that she has seen some babies on DHASCO supplemented for-

mula with severe diarrhea. Vulnerable infants sometimes experience catastrophic impacts from such, sometimes prolonged, bouts of diarrhea.



Martek's DHASCO and ARASCO added to infant formula have been linked to diarrhea, bloating, vomiting, and gastrointestinal distress in infants.

Jimi Francis, Ph.D., is a researcher affiliated with the Allie M. Lee Cancer Research Laboratory, which is known for omega-3 research, at the University of Nevada at Reno. She specializes in infant nutrition. "We know that some infants are experiencing side effects like diarrhea, but we don't know what causes these negative reactions," she explains. While the research just hasn't been done to determine the cause of these side effects, she and others offer some possible explanations.⁸³

Scientists do know that long-chain polyunsaturated fatty acids like DHA interact with iron, which oxidizes the fats and causes them to go rancid. There may be interactions in the formula, but unfortunately, not enough research has yet been done on the oxidation of DHA in formula. Dr. Francis suggests that the way the formula is prepared and stored could affect the rate of oxidation. Some infants may be receiving more highly oxidized DHA than others, depending on how their formula was prepared and stored.

It seems worth exploring whether the structural differences between DHASCO/ARASCO and DHA/ARA from human milk, which are explained in the section titled "Algal DHA and Fungal ARA: Novel Products in the Human Diet," may explain why some infants experience adverse reactions. Is it possible that some infants may not be able to digest triglycerides with two DHA molecules, which is different from the naturally occurring single DHA structure found in human breastmilk?

Also, is it possible that some infants are more susceptible to adverse effects when consuming DHA from foods other than breast milk, due to the additional components found in DHASCO and ARASCO? These are just a few of many possible explanations for why some infants experience such negative side effects from DHASCo and ARASCO supplemented formula.

FDA Adverse Reaction Reports: The Tip of the Iceberg?

The Cornucopia Institute filed a Freedom of Information Act request to gain access to reports filed by parents, caretakers, and health professionals who witnessed and/or treated infants reacting adversely to infant formula with DHASCO and ARASCO. The FDA has received 98 such reports, ranging in severity from vomiting and diarrhea that disappeared as soon as the infant was given a non-DHA/ARA formula, to babies treated in intensive care for severe dehydration and seizures.

Most reports tell of diarrhea, vomiting, and abdominal pain in infants, anxious visits to hospital emergency rooms, unsuccessful medical tests attempting to find the source of the problem, and spontaneous disappearance of these distressing symptoms as soon as the baby received non-DHA/ARA-supplemented formula. In their reports to the FDA, anguished parents urge the FDA to take the product off the shelves, to keep non-DHA/ARA formula available, and to conduct better testing of these products to prevent the suffering of other helpless infants

Below is a representative sample of the 98 reports filed with the FDA, which reflect the distress and the suffering that DHA/ARA formula has caused to some infants and their parents or caregivers:

- "My son cannot tolerate the infant formulae with the DHA/ARA additives. Similac Advance, Enfamil Lipil, Good Start with DHA/ARA—every time he has tried a DHA/ARA formula he gets *extremely gassy, fussy and has terrible gas pains*. He does do better on the Similac Advance, which has less DHA/ARA than the other products. I can't find plain Similac in my local grocery store, as they only carry the DHA/ARA formulae. *Why did the FDA allow the formula companies to produce these formulae without long-term testing???*" [emphasis added]

- "We finally figured out that formula with DHA and ARA is to blame for *4 severe vomiting episodes in a 2 week period*. The first episode was on 6/26/04 and required a *trip to the pediatric emergency room for IV rehydration*. All 4 episodes started 1 to 2 hours after [baby's name] ingested Similac Advance (with DHA and ARA). The amount ingested on the 4 occasions ranged from as little as a couple of teaspoons to 8 ounces. The result of ingesting the formula was severe vomiting, sometimes projectile, that occurred every 3 to 6 minutes for a period of 1 to 2 hours. There also was some diarrhea associated with at least 2 of these events. During the vomiting episodes, [baby's name] was unable to keep down any sort of oral rehydrating

liquid. She became lethargic and almost unresponsive in 3 of the 4 episodes.” [emphasis added]

- “Mother normally used the Similac Alimentum powdered formula with iron and had no problems with her infant son; they could no longer find that formula in the stores and began using the Similac Alimentum Advanced with iron and DHA/ARA. Her son had *diarrhea and was extremely fussy for 9 days. They found some of the formula without the additives DHA and ARA and he returned to normal in one day.*” [emphasis added]
- “My son began taking Enfamil Next Step Prosobee Lipil 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.*” [emphasis added]

While some parents and health professionals report such incidents to the FDA, many physicians, nurses, or parents do not report such adverse effects when they see them. Scientists on the Institute of Medicine’s expert panel recognized this risk of underreporting as a problem.⁸⁴ Furthermore, they write that “formal regulatory guidelines for in-market surveillance do not exist for infant formulas. Surveillance is generally limited to consumer reporting of adverse events through toll-free numbers or Internet sites established by the manufacturer or the regulatory agency.”⁸⁵

Another concern with this type of in-market surveillance is that caretakers may not link a child’s problem to earlier intake of a certain type of infant formula. A parent or a nurse may assume that commercially available infant formulas containing DHASCO and ARASCO are perfectly safe.⁸⁶ They are also most likely unaware that the DHASCO and ARASCO in formula is structurally different from DHA and ARA naturally found in breastmilk. As a result, many adverse effects may go unrecognized and therefore unreported. Moreover, the number of reports to the FDA would likely be much higher if formula manufacturers would alert parents to the possibility that DHASCO and ARASCO may cause side effects in some infants.

“My baby is not an experiment.”

From official adverse reaction report submitted to the FDA’s MedWatch by the parent of an infant whose diarrhea was linked to DHASCO and ARASCO in infant formula.

Yet currently, infant formula manufacturers exacerbate this problem by remaining completely silent about the possibility that DHASCO/ARASCO could be implicated in infants’ diarrhea and other adverse reactions. On their web site for Enfamil, Mead Johnson gives advice to parents of infants experiencing diarrhea; yet the advice mentions nothing about the possibility that the diarrhea may be caused as a reaction to DHASCO/ARASCO. Instead, the advice suggests that if the cause of the diarrhea is not a virus or bacteria, then the infant is most likely lactose intolerant or allergic to cow’s milk. Their suggestion: switch to a lactose-free or a soy-based formula with DHASCO and ARASCO.⁸⁷



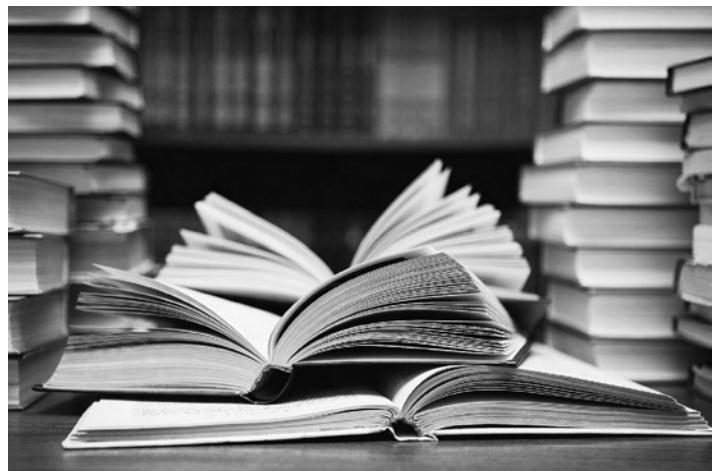
Infant formula manufacturers keep parents in the dark about the possibility that DHASCO and ARASCO may be to blame for certain adverse reactions to formula in infants.

Similarly, Abbott Laboratories suggests that diarrhea may be caused by protein sensitivity and recommends their Similac hypoallergenic formula, which still contains DHASCO and ARASCO. Their advice is very misleading, as they write, “Similac Alimentum starts to relieve colic symptoms in most babies in just 24 hours,” but the fine print specifies that this relief came after infants consumed formula without DHASCO and ARASCO. Instead of recommending that infants with diarrhea try a formula without DHASCO and ARASCO, they continue to recommend the DHA/ARA formula to parents.⁸⁸ In fact, Similac no longer makes any formula without DHASCO and ARASCO.

The Cornucopia Institute has filed a petition, together with the National Alliance for Breastfeeding Advocacy, with the FDA requesting that formula manufacturers both print a warning label on products containing Martek’s DHASCO and AR-

ASCO, and include information on the possibility of adverse reaction on their web sites. Such warning labels would not be unprecedented, as they were found on the packages of "fat-free" potato chips made with Olestra that caused similar reactions in a subset of the population.

The Cornucopia Institute urges parents of infants who consume formula with DHASCO/ARASCO and who experience diarrhea, vomiting, or other gastrointestinal problems to report these problems to the FDA. MedWatch is the FDA's Safety Information and Adverse Event Reporting Program. Given the absence of serious postmarket surveillance of infant formula, such voluntary reporting provides an important method of tracking problems with infant formula. Reports can be submitted online by following this link: <https://www.accessdata.fda.gov/scripts/medwatch-online.htm>.



A review of published studies shows that there is no conclusive evidence regarding the benefits to cognitive development from adding DHASCO/ARASCO to formula

The Scientific Community's Uncertainty

In advertisements and on their labels, infant formula manufacturers claim that DHA and ARA are necessary to support proper brain and eye development. However, from an analysis of peer-reviewed, academic journals, it becomes clear that the benefits of adding DHA and ARA to infant formula are uncertain.

The European Union's Scientific Committee examined the question of whether DHASCO and ARASCO are important enough to warrant a legal requirement for formula manufacturers to add these lipids in all formula. They concluded: "Having reviewed the available literature the Committee sees the evidence insufficient to set an obligatory minimum level of long-chain polyunsaturated fatty acids."⁹¹

A pediatrician and researcher at The University of Louisville wrote in the June 2007 issue of the *Journal of Perinatology* that "the breast-fed infant is the gold standard for infant formula research and development. The addition of long-chain polyunsaturated fatty acids and nucleotides to formula [is] intended to promote visual, neuro and immune development. *Studies in both preterm and term infants have not consistently demonstrated efficacy with long-chain polyunsaturated fatty acids supplementation of infant formulas* [emphasis added]."⁹⁰

A review article in the *American Journal of Clinical Nutrition*, from 2005, comes to the same conclusions: [Randomized clinical] trials have often not shown an effect of long-chain polyunsaturated fatty acid supplementation on cognitive or behavioral performance, and some reviewers have considered that, overall, the evidence was insufficient to conclude that long-chain polyunsaturated fatty acid supplementation benefited development [emphasis added].⁹¹

The panel of scientists who authored *Infant Formula: Evaluating the Safety of New Ingredients* similarly concludes that "there may be effects on cognitive outcome, although the effects are inconsistent, particularly in term infants."⁹²

The inconsistency of the results does not necessarily mean that DHASCO and ARASCO supplementation of infant formula is not beneficial. Scientists have offered many possible explanations to account for the wide range of study results.⁹³ The inconsistency of results and the shortcomings of the scientific tests only point to a greater truth: many questions regarding infant nutrition and polyunsaturated fatty acids remain unanswered within the scientific community. Only corporate advertisements seem to convey complete confidence that DHASCO



and ARASCO in infant formula benefit babies.

In fact, the claims by formula manufacturers that DHASCO and ARASCO benefit brain and eye development are based on isolated study results, almost exclusively paid for by the corporations. According to a *Wall Street Journal* article,⁹⁴ medical scholar John Ioannidis has documented how false conclusions are rampant in published scientific articles, especially when overeager scientists try to coax meaningful insight from their data sets. Especially when profits are at stake, as with DHASCO and ARASCO for use in infant formula, the pressure to find meaningful results from data sets is great. When it comes to novel ingredients in infant formula, it seems prudent to first reach scientific consensus regarding the ingredients' benefits. And when most scientists conclude that findings on the benefits of DHASCO and ARASCO in infant formula are inconsistent and inconclusive, the widespread use of these hexane-extracted, laboratory-produced algal and fungal oils should be seriously questioned.

Concerns about DHA and Contamination: Breastfeeding's Benefits Outweigh Risks

Martek claims that its source of DHA is free from environmental pollutants, such as mercury, that plague today's supply of seafood. They seem to imply that formula with DHASCO is purer than breast milk containing DHA from seafood in the mother's diet, which could be contaminated with pollutants. They now also sell DHASCO supplements for breastfeeding mothers, claiming that their source of DHA is more pure than other sources. There are several concerns with marketing these supplements to pregnant and breastfeeding women.

Indeed, methyl mercury exposure from the consumption of fish is a concern for pregnant and breastfeeding women today. However, pregnant and breastfeeding women do not have to take hexane-extracted DHASCO supplements as a source of DHA for their fetus or infant.

First, the potential exists to skew the fatty acid profile of breast milk in mothers who take these supplements. Maternal supplements with large concentrations of long-chain polyunsaturated fatty acids can offset the production of naturally made medium-chain fatty acids, disrupting the natural concentration of all fatty acids in the breast milk. Supplementation of long-chain polyunsaturated fatty acids during pregnancy could have a long term effect due to the fatty acids being stored in maternal fat and released postpartum into the breast milk, further disrupting the natural fatty acid balance. Research to examine these potential effects is certainly justified before the supplements are widely adopted.

Second, debate continues over the rate of conversion to DHA, but scientists generally agree that the human body can synthesize DHA from other omega-3 fatty acids, such as those found in flaxseed, egg yolks, nuts, and so forth.

Excerpts from Scientific, Peer-Reviewed Articles

- From the Annual Review of Nutrition (2005)

"Since 1990, several studies have examined the impact of formulas containing DHA or DHA plus ARA on visual function and neurodevelopmental outcome. Some of these studies have shown benefits but others have not. These results leave largely unanswered the question of whether these fatty acids are beneficial for either the term or preterm infant. However, evidence that preterm infants might benefit is somewhat more convincing than that for term infants. Despite the limited evidence for efficacy, formulas supplemented with DHA and ARA are now available and appear to be safe."⁹⁵

- Some scientists believe that benefits for preterm infants are somewhat more convincing. An article in the Cochrane Systems Database Review (2000), titled "Long-chain polyunsaturated fatty acid supplementation in preterm infants" reviews several studies:⁹⁶

"Studies from Dallas⁹⁷ and Memphis⁹⁸ suggest that early visual development is better in formula-fed infants who receive a long-chain polyunsaturated fatty acid supplement compared with those fed standard formula. However, the effects were not long-term, with no differences detected between groups after 4 months of age."

"In the largest study, by Mead Johnson,⁹⁹ no difference in visual acuity was demonstrated between long-chain polyunsaturated fatty acid supplemented and control infants at 2 and 4 months post-term."

"No difference in growth between supplemented and control infants was documented in the Dallas, Bologna, Alberta¹⁰⁰ and Wyeth¹⁰¹ studies while the Mead Johnson study documented higher weights in supplemented infants compared with controls at two months post-term."

continued on page 18

Additionally, sources of fish exist that are both high in DHA and typically low in mercury contamination. According to FDA data, the fish species with the highest levels of mercury contamination are mackerel king, swordfish, and shark, and should be avoided. Fish such as salmon are a good source of DHA and are typically low in mercury, although environmentalists note that salmon should be consumed sparingly to avoid overfishing and depletion of this popular fish. Low-mercury fish that provide DHA and are not currently at risk for depletion include canned anchovies (1.292 g DHA/100 g), North Atlantic mackerel (1.401 g DHA/100g), and canned sardines (0.509g DHA/100 g).¹¹¹

When the European Food Standards Agency recommended DHA in the diet of expectant mothers, Dr. Tim Draycott, a consultant obstetrician and gynaecologist, was quoted in a British newspaper as saying that any supplement should be added cautiously. Often, isolated research findings can lead to hype, with corporations profiting from claims that a food supplement is necessary. Pregnant mothers are especially easy targets for such claims. Dr. Draycott said that "apart from folic acid and perhaps iron for mothers suffering anaemia, the general rule is that less is more when it comes to supplements for expectant mothers."¹¹²

"Apart from folic acid and perhaps iron for mothers suffering anaemia, the general rule is that less is more when it comes to supplements for expectant mothers."

—Dr. Tim Draycott, obstetrician and gynaecologist

Parents who are concerned about chemical contamination of breast milk should keep in mind that the benefits of breastfeeding far outweigh the potential harm of chemicals in breast milk. Only in very rare cases of serious exposure to certain chemicals are women advised to cease breastfeeding to protect the health of the infant.

Moreover, infant formula feeding certainly does not eliminate the potential for an infant's exposure to chemicals and toxins. The National Alliance for Breastfeeding Advocacy compiled a list of infant formula recalls. The list of reasons for infant formula recalls is long, varied, and disconcerting: elevated levels of lead, incorrect instructions on the label, metal particles in powdered infant formula that could damage the baby's throat, hard plastic in the formula, contamination with rigid polyvinyl chloride (PVC), excessive magnesium content, incorrect labeling that did not identify potentially life-threatening allergens, high levels of arsenic, chlorine contamination, concentrated formula that is labeled "do not add water," salmonella

continued from page 17

The author of the review article concludes, "No long-term benefit has been demonstrated for preterm infants receiving formula supplemented with long-chain polyunsaturated fatty acids. There is some evidence that omega-3 long-chain polyunsaturated fatty acids supplementation of formula increases the early rate of visual maturation in preterm infants. Supplementation of formula with omega-3 and omega-6 long-chain polyunsaturated fatty acids does not impair the growth of preterm infants."¹⁰²

- A trial sponsored by Abbott Laboratories, Ross Division in 2001 concluded:

"These findings do not support adding AA+DHA to formulas containing 10% energy as linoleic acid and 1% energy as alpha-linolenic acid to enhance growth, visual acuity, information processing, general development, language, or temperament in healthy, term infants during the first 14 months after birth."¹⁰³

- An article in *Advances in Experimental Medicine and Biology* (2001) explains:

"Intervention studies with term infants that have attempted to improve the DHA supply of infant formula and hence infant development have not yielded consistent results. Some randomized studies have demonstrated improved visual and developmental indices in supplemented over unsupplemented infants, others have failed to demonstrate an effect."¹⁰⁴

- Scientists (including scientists from Abbott Laboratories) followed DHA and ARA supplementation and breastfed babies for 39 months and concluded:

"At 39 months, IQ, receptive and expressive language, visual-motor function, and visual acuity were not different among the 3 randomized formula groups or between the breastfed and formula groups."¹⁰⁵

continued on page 19

contamination, glass particles contamination, and deficiencies in vitamin D, vitamin B-6, vitamin C, and/or iron.¹¹³

Harmful bacteria that have contaminated infant formula include *Enterobacter sakazakii* and *Salmonella enterica*. According to the Food and Agriculture Organization of the United Nations, these bacteria have been found in powdered infant formula and are well-established causes of illness in infants, including systemic infection, necrotizing enterocolitis, and severe diarrhea.¹¹⁴ Several outbreaks of *Enterobacter sakazakii* have occurred in neonatal intensive care units worldwide.¹¹⁵ According to the FDA, powdered milk-based infant formulas are heat-treated during processing but are not subjected to high temperatures for sufficient time to make the final packaged product commercially sterile.¹¹⁶

In 2007, a group of 38 scientists published a report in a peer-reviewed journal expressing concern that the plastics chemical bisphenol A leaches from containers into food, including from the lining of metal cans into infant formula. Analyses by the Environmental Working Group showed that some formula-fed infants would be exposed to this chemical in excess of doses that caused serious adverse effects in animal tests.¹¹⁷

There is also a risk of contamination by certain heavy metals in infant formula—contamination that has been shown to far exceed levels found in breast milk. For example, an infant's exposure to the metal cadmium from soy formula is about 20 times higher than the levels generally found in breast milk. Cadmium is toxic to the male reproductive system, the kidneys, and the brain. Powdered formula is estimated to have 6 times the levels of cadmium than the average levels found in breast milk.¹¹⁸ According to a study by the Natural Resources Defense Council, metals such as cadmium, arsenic, and manganese are more likely to affect formula-fed infants, because these metals are water contaminants or contaminants in infant formula.¹¹⁹ A similar scientific study found higher blood levels of lead—a serious concern for developing infants—in formula-fed infants than in breastfed infants.¹²⁰ Lead is unlikely to contaminate breast milk, since it does not attach to fat.

Parents who are concerned about chemical contamination of breast milk should keep in mind that the benefits of breastfeeding far outweigh the potential harm of chemicals in breast milk.

In addition to the concerns about potential contaminants in infant formula itself we would be remiss in not underscoring the long-acknowledged risks of preparing formula with tap water. Although generally recognized as safe, municipal water supplies sometimes contain elevated levels of heavy metals, arsenic,

continued from page 18

- Likewise, researchers in Denmark compared infants fed formula with DHA¹⁰⁶ and gamma-linolenic acid, formula with DHA¹⁰⁷ only, and formula without fatty acid supplementation. When measuring visual acuity at four months of age, they found that "there was no statistical difference among the formula groups."¹⁰⁸
- A study published in Pediatrics in 2002 found that breastfed infants had "significantly higher developmental scores at 9 and 18 months than both formula groups." They found no significant differences in developmental scores between infants given DHA/ARA supplemented formula and nonsupplemented formula.¹⁰⁹

Some studies do come to the conclusion that DHA and ARA supplementation of infant formula supports visual acuity. Findings reported in a recent article in Early Human Development were that, at four years of age, infants who had formula supplemented with DHA and DHA+ARA had visual acuity levels that were comparable with breastfed babies, while infants that were given formula without DHA had significantly lower levels of visual acuity than all other groups.¹¹⁰

We do not claim that there are no benefits to adding DHA and ARA to infant formula; we simply point to the uncertainty in the scientific community regarding this question. When such doubt exists, the addition of novel ingredients in infant formula should raise serious concerns, especially when the FDA has not affirmed the safety of these ingredients and studies show possible risks.

Benefits of an Organic Diet for Pregnant and Breastfeeding Women

Since organic farmers are very limited in the types of pesticides they may use (primarily botanically based compounds that quickly break down in the environment), mothers who consume conventional—as opposed to organic—foods are at higher risk of consuming pesticide residues. The latest data from the FDA Pesticide Residue Monitoring Program shows that pesticide residues do occur on conventional foods. Some of these residues are of pesticides that were banned decades ago, such as DDT and dieldrin, which are extremely persistent and do not easily biodegrade in the environment. A study in Denmark and Finland found eight different organochlorine pesticides present in breast milk samples of nursing mothers.¹²¹

Included in the list of the five most frequently observed chemical residues on foods are malathion, chlorpyrifos-methyl, and endosulfan¹²²—all in use on today's conventional farms. Endosulfan, as a member of the organochlorine family, is easily transferred into a mother's breast milk, while malathion and chlorpyrifos-methyl are less likely to contaminate breast milk. However, according to the Department of Human and Health Services, animal studies have shown that even malathion can be transferred from a pregnant mother to the developing fetus and from a nursing mother to the infant through the mother's milk.¹²³ Since the FDA found pesticide residues on nearly 40% of domestically produced foods and on nearly 30% of imported foods,¹²⁴ organic diets seem to be a sensible choice for pregnant or breastfeeding mothers.

New research also shows nutritional benefits to breastfed infants when nursing mothers consume an organic diet. A study published in the British Journal of Nutrition showed that organic dairy and meat products in a mother's diet positively affect the nutritional quality of her breast milk—markedly increasing beneficial fatty acids. Specifically, a diet in which 90% or more of dairy and meat products are organic is correlated with measurably higher levels of conjugated linoleic acids (CLAs). Many CLAs are believed to have anticarcinogenic, antiatherosclerotic, antidiabetic, and immune-enhancing effects, as well as a favorable influence on body fat composition. For newborns specifically, CLAs are believed to especially aid immune system development. According to the authors of this study, which is the first to look at the correlation between the health status of newborns and the organic diets of their breastfeeding mothers, similar studies specifically addressing breast milk will be published in the near future.¹²⁵

A recently published article by researchers in the Netherlands showed a connection between a pregnant or breastfeeding mother's consumption of organic dairy products and a reduction in the risk of eczema in infants and children.¹²⁶

Other studies show that organic foods have higher levels of nutrients than conventional foods. Research has shown that organic foods have higher levels of certain nutrients and antioxidants.¹²⁷ Preliminary, unpublished findings of a four-year project led by Newcastle University in the United Kingdom suggest that levels of antioxidants in milk from organic cows were between 50% and 80% higher than in normal milk. Organic wheat, tomatoes, potatoes, cabbage, onions, and lettuce had between 20% and 40% more nutrients than their conventional counterparts.¹²⁸

For infants who must consume formula instead of human milk, the importance of choosing an organic formula cannot be overstated. A report by the National Research Council points out that infants and children are especially vulnerable to toxic substances such as pesticide residues, since they eat more food and drink more fluids per kilogram of body weight than adults. Moreover, their ability to detoxify xenobiotic compounds may be markedly different than adults.¹²⁹ Pesticide residues may do more harm to a small, developing infant than to a grown adult.

While most people think of pesticide residues occurring primarily on fruits and vegetables, pesticide residues have also become a concern in milk over the past few years. When the USDA's Pesticide Data Program tested for residues in milk in 2004, they found residues in all tested samples. They found the endocrine disrupting insecticide endosulfan in 18% of the samples. The synthetic pyrethroid insecticide was detected in 24% of samples, and this percentage jumped to 45% in 2005. None of the organic samples contained residues. The insecticide carbofuran was found in 8.8% of conventional milk samples but in none of the organic samples.¹³⁰

Conventional formula may contain milk from cows that have been treated with artificial, genetically engineered growth hormones. Such milk has been shown to contain elevated levels of insulinlike growth factor 1, a growth hormone that could severely affect an infant's development and health later in life.¹³¹ Studies have shown that formula-fed infants have higher plasma levels of insulinlike growth factor 1.¹³²

Parents also expect that the ingredients in organic formula are both safe and free of chemical processing agents. Martek's oils in organic infant formula are therefore a serious concern, since these oils appear to be neither clearly safe nor free of chemical processing agents. Hexane residues on DHA and ARA oils may be small, but there is no guarantee that they are nonexistent.¹³³

radium, and other toxic contaminants, in addition to the fluorine and other water-treatment chemicals. Private water supplies from wells vary widely in terms of bacterial contamination, and in rural areas, where most private and municipal sources come from groundwater, elevated nitrate levels and contamination with agrichemicals are widespread. Many of these compounds, even in minute doses, could act as endocrine disruptors and interfere with an infant's development.

Mothers who want to decrease the potential for chemical contamination of their breast milk and maximize its nutritional value can also turn to an organic diet.

DHA in Organic Foods

The Inappropriate Use of DHA and ARA in Organic Infant Formula

Martek's DHASCO and ARASCO are now found in organic infant formula, which appears to be a violation of the national organic standards. Pursuant to the legal concerns outlined in the following section ("Is It Legal?"), The Cornucopia Institute has requested an investigation by the USDA to make a determination regarding the appropriateness of the use of the novel oils, and hexane extraction process, in conjunction with the production of the following certified organic infant formulas:

Ultra Bright Beginnings™ Organic with 19 mg of DHA

Manufactured by PBM Nutritionals (sold in various supermarkets and pharmacies)

Parent's Choice Organic with DHA and ARA

Manufactured by PBM Nutritionals (distributed exclusively by Wal-Mart stores)

Earth's Best Organic Infant Formula with DHA and ARA

Manufactured by the Hain Celestial Group

Similac Organic Infant Formula with DHA and ARA

Manufactured by Abbott Laboratories, Ross Division

The Cornucopia Institute contacted the consumer hotline of these companies and asked specifically how the DHASCO and ARASCO oils are extracted. Representatives from Similac and PBM Nutritionals were not able to answer this question. The representative from the Hain Celestial Group, which manufactures Earth's Best, responded that no hexane is used in their oils. However, this representative also was not aware that the source of DHA/ARA in their infant formula is DHASCO and ARASCO, produced by Martek.

Is It Legal?

According to Martek's notification submitted to the FDA, Martek uses hexane to extract DHASCO and ARASCO from microorganisms.¹³⁴ Federal organic standards prohibit the use of synthetic solvents, including hexane, in the production of organic foods. Specifically, section 205.270 (Organic Handling Requirements) states:

[The] handler of an organic handling operation *must not use* in or on agricultural products intended to be sold, labeled or represented as "100 percent organic," "organic" or "made with organic (specified ingredients or food group(s)), or in or on any ingredients labeled as organic: (2) *a volatile synthetic solvent* or other synthetic processing aid not allowed under §205.605. [italics added]

The addition of Martek's algal DHASCO and fungal ARASCO oils to organic infant formula appears to be a violation of federal regulations.

The National Organic Program recognizes that certain foods must contain nonagricultural ingredients. For example, organic bread requires the use of yeast, which is not an agricultural product subject to organic production regulations. In order for a nonagricultural product to be allowed in organic foods, it must be approved and appear on the National List of Approved and Prohibited Substances. Since consumers of organic foods expect products that are safe and produced in an environmentally sustainable way, this rule ensures that no harmful chemicals, toxic substances, or environmentally detrimental processing procedures are used in the production of organic foods.

Martek's DHASCO and ARASCO do not appear on this national list, nor does the use of hexane as a processing aid for food production. Therefore, the use of these substances in organic food is a violation of section 205.105(c), which prohibits the use of synthetic and nonsynthetic substances not on the national list in the processing of organic foods.

In 2005, the National Organic Program included "micro-organisms—any food grade bacteria, fungus and other micro-organism" on a list of proposed substances to be added to the national list. Martek petitioned the NOP to add "by-products of microorganisms," which would allow the use of DHASCO and ARASCO in organic foods. The NOP did not respond to this petition, and while it added microorganisms to the list, it did not add "by-products of microorganisms."

Some certifiers have apparently argued that the rules prohibit the use of synthetic solvent extraction only for organic ingredients, but not for nonorganic ingredients in organic foods. However, the rule seems to clearly prohibit the use of hexane extraction for nonorganic ingredients in foods that are labeled “organic,” but not for nonorganic ingredients in foods that are labeled “made with organic ingredients.” This exception is articulated in section 205.270(c)(2): “*Except*, that, non-organic ingredients in products labeled ‘made with organic (specified ingredients or food group(s))’ are not subject to this requirement.” It does not say that nonorganic ingredients in products labeled “organic” are not subject to this requirement.

Federal organic regulations prohibit the use of nonapproved synthetic substances in organic foods and the use of hexane extraction in organic food processing. Martek’s DHA and ARA oils are both absent from the list of approved substances and are hexane extracted.

Infant formula, milk, and nutrition bars with Martek’s DHASCO and ARASCO are all labeled “organic,” not “made with organic ingredients”; therefore, hexane-extracted ingredients should not be allowed.

A USDA compliance officer, in response to a legal complaint as to whether hexane-extracted DHASCO and ARASCO are allowed in organic infant formula, claims that Martek’s oils “are covered under Section 205.605(b) *Synthetics Allowed* of the National Organic Program National List.”¹³⁵ The compliance officer at USDA writes that “Section 205.605(b) allows ‘nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods.’” This rule allows for “nutrient vitamins and minerals.” Martek’s DHASCO and ARASCO are oils containing fatty acids, they are *not* vitamins or minerals.

The section cited above creates a loophole that may allow a hexane-extracted vitamin or mineral, but not a hexane-extracted oil with fatty acids such as Martek’s DHASCO and ARASCO. Because of the USDA compliance officer’s confusion about the difference between vitamins, minerals, and fatty acids, the USDA was unwilling to look into the matter when it was first brought to its attention in 2006.

Martek seems aware that they are on shaky ground by selling hexane-extracted ingredients to infant formula manufacturers for use in certified organic formula. In a report filed with the Securities and Exchange Commission in May 2007,

Martek warns investors: “If our oils are unable to be used in organic food and beverage products, the opportunity for sales of our oils into the food and beverage market will be limited to non-organic products.”¹³⁶ If Martek were confident that its oils would definitely be allowed in organic foods, why would they feel compelled to warn investors of a potential breakdown of their business with organic manufacturers?

In this same statement, Martek acknowledges that its oils are currently used in products that bear the “USDA certified organic” seal but warns that “because the NOP regulations are subject to change and *interpretation*, there can be no guarantee that our oils will be acceptable for use in all organic products [emphasis added].”

The Cornucopia Institute has filed a formal legal complaint with the USDA, alleging that Martek’s DHASCO and ARASCO cannot legally be added to organic foods, because they are not on the National List of Approved and Prohibited Substances (section 205.605). The Cornucopia Institute’s legal complaint also requests an investigation by the USDA into the allegation that Martek uses hexane to extract its oils and that they are genetically engineering the algae and fungus to optimize production of oils from these organisms. Genetic engineering is also banned from organic food production.

DHA in Organic Foods for Children and Adults

While infants were the first consumers of Martek’s oils, the corporation has now signed deals with other food companies that add DHASCO to foods for children and adults. The Cornucopia Institute’s primary concern is that these oils are not on the National List of Approved and Prohibited Substances and are hexane extracted. That they do appear in organic foods is a violation of the organic standards and of consumer trust in the purity of organic foods.

Scientific studies provide convincing evidence that diets high in fish and DHA may benefit cardiovascular¹³⁷⁻¹³⁸ health and mental health.¹³⁹ The American Heart Association recommends that patients who must lower their blood triglyceride levels consume 2 to 4 grams of eicosapentaenoic acid (another beneficial fatty acid) and DHA per day. The American Heart Association writes that obtaining omega-3 fatty acids from whole foods is preferable, but that patients who must lower their blood triglyceride levels can benefit from capsules.¹⁴⁰ It should be noted that this is a small subset of the population at large.

Scientific evidence that DHA protects against asthma, cancer, eye deterioration, and arthritis may be promising, but research results are too preliminary and inconclusive to make credible claims. Furthermore, very little research has been done to assess any possible side effects of consuming DHASCO supplements, which is very different from consuming a diet rich in wholesome and natural sources of these fatty acids.

In addition to products designed for consumption by infants, Martek's DHASCO is found in the following:

- Horizon Organic milk
- Stremicks milk¹⁴¹ (sold on the West Coast)
- NuGo Nutrition Bars
- Happy Baby brand of organic baby foods

Both Stremicks and Horizon add 32 mg of Martek's algal DHASCO to an 8-ounce serving of milk.¹⁴² For comparison, a 100-gram piece (3.5 oz.) of wild salmon contains 138 mg of DHA.¹⁴³

Now, our milk will really go to their heads.

Introducing Horizon Organic® Milk Plus DHA Omega-3... to help support brain health.

Horizon Organic® Milk is now even more nutritious. That's because it's the only organic milk to include DHA*, an all natural Omega-3, which supports brain development and function throughout life. Each delicious glass is full of organic goodness, too. So, it's the easy way to make a difference for your whole family. Learn more at www.horizonorganic.com/DHA

* The only nationally available brand of organic milk with life'sDHA™. Not to be used as infant formula.

HORIZON
ORGANIC

Making a world of difference.

Horizon appears to be adding Martek's algal DHASCO in violation of federal organic standards that determine which ingredients are allowed in organic foods.

Hexane and Consumer Safety

The chemical hexane is a petroleum by-product of gasoline refining and is used not only as an extraction solvent for edible oils such as Martek's DHASCO and ARASCO, but also as a solvent for glues, varnishes, and inks and as a cleaning agent in the printing industry.¹⁴⁹

Very little research has been conducted concerning the po-

The Problem with Factory-Farmed DHA-Supplemented Milk

Previous research by The Cornucopia Institute revealed that Horizon Organic and Stremicks have obtained a significant amount of their milk from "factory-farm" dairies, which historically confine their cows to feedlots. Instead of allowing them to graze on pasture, as the organic standards require, these "organic" factory farms feed their cows significant amounts of organic grain-based "total mixed rations," corn silage, and/or hay silage.



Horizon's industrial-scale drylot facilities.

Various published scientific studies show that milk from cows that are fed total mixed rations and/or corn silage in confinement contains higher levels of detrimental saturated fatty acids and lower levels of beneficial polyunsaturated fatty acids compared with milk from cows that obtained most of their feed from pasture grazing.^{144, 145, 146, 147} For example, researchers found that "increasing the proportion of fresh grass in the diet [of lactating dairy cows] induced a linear increase in unsaturated fatty acids percentages at the expense of saturated fatty acids."¹⁴⁸

Some of Horizon and Stremicks milk is therefore likely to be lower in beneficial fatty acids, yet the company, ironically, now aims to profit from the claim that adding DHASCO to its milk makes it healthier. By adding Martek's fatty acids—which come from microorganisms, are produced in a laboratory, and extracted with the use of toxic hexane—the company claims that its milk will be healthier than legitimately produced organic milk, which is produced primarily from pasture-based family farms.

Horizon's and Stremicks' addition of hexane-extracted algal DHASCO represents an industrial model of food production, in which the processor attempts to compensate for the loss of nutritional quality—which results from economically convenient production methods ("factory farms")—by the addition of manufactured, supposedly equivalent nutrients.

tential effects of consumption of hexane residues in edible oils. The assumption has been that nearly all hexane residues evaporate before reaching the consumer.



Hexane, used in the processing of DHASCO and ARASCO for infant formula, is a chemical by-product of gasoline refining.

However, studies on hexane-extracted oils show that not all hexane is evaporated before consumption—residues do appear in foods. According to EPA reports,¹⁵⁰ small quantities of solvent (up to 0.2 percent by volume of oil) can be present in oil after extraction, even after solvent recovery by film evaporators and a distillation stripper. A Swiss team of scientists tested various oils and found hexane residues in some of the tested oils.¹⁵¹

The effects of consuming foods that contain hexane-extracted ingredients are not known. The Department of Health and Human Services does not include food residues as a common way in which people are exposed to hexane.¹⁵² 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.¹⁵³ And, it appears that no studies looking for synthetic breakdown constituents of hexane in food are available.

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.¹⁵⁴ No corresponding information is available for hexane, which is also a hydrocarbon solvent.¹⁵⁵

The possibility that this petrochemical solvent used to process infant formula ingredients has an effect on infant health should not be ruled out, particularly since infants are usually more vulnerable than adults to the effects of industrial chemicals. Moreover, there may be other compounds in algal and fungal oils, or residues of other processing aids, that are unknown and untested and may also affect infants.

We should also take a lesson from history: the knowledge of

what is dangerous and what is safe is constantly being updated, especially regarding industrial chemicals. Those who remember public spraying of the pesticide DDT will realize that it would not be the first time that a chemical, previously believed to be harmless and even beneficial, would be found to have unintended side effects and do harm. We cannot be too cautious when infants, including pre-term babies, are major consumers of hexane-extracted foods. The application of the “precautionary principle” is one of the prime factors that drive consumers, especially parents, to choose organic food.

Hexane: An Occupational Hazard

The Occupational Health and Safety Administration (OSHA) lists hexane as a serious concern for occupational health and safety, putting workers in oil-extraction manufacturing plants at risk.

Workers who come in dermal contact with hexane (a volatile liquid at room temperature) experience immediate irritation characterized by erythema and hyperemia, and they develop blisters after several hours.¹⁵⁶

At high exposure levels, humans experience vertigo, headache, and nausea (after 10 minutes of exposure to 5000 ppm hexane). At more moderate exposure levels, they show mild symptoms of narcosis (after exposure to 1000 ppm) and eye and upper respiratory tract irritation (after 15 minutes of exposure to 800 ppm).¹⁵⁷ For these reasons, OSHA sets the permissible exposure level to 500 ppm for workers with 8-hour workdays and 8-hour exposures to hexane.



Hexane is a highly explosive chemical substance. The plant that produces these ingredients for infant formula was linked to an explosion in 2003.

However, workers who are chronically exposed to hexane levels ranging from 400 to 600 ppm, with occasional exposures of up to 2,500 ppm, have developed polyneuropathy, a neurological disorder. In these cases, distal symmetrical muscle weakness is common, and nerve biopsies show nerve damage. A recently published peer-reviewed article in Environmental

Health Perspectives hypothesizes that occupational exposure to hexane may contribute to the development of Leber hereditary optic neuropathy, a disease that causes loss of vision.¹⁵⁸ Chronic exposure may also lead to blurred vision, restricted visual field, and optic nerve atrophy.¹⁵⁹



Hexane reacts with other pollutants to form ground-level ozone, the main component of smog and a hazard to human health.

Hexane is an occupational safety hazard for another reason: it is highly explosive. On August 29, 2003, two workers died when hexane gas in a Sioux City, Iowa, soybean processing plant ignited.¹⁶⁰ Explosions caused by hexane are not uncommon; explosions have occurred in South Africa (two dead),¹⁶¹ Italy (four dead),¹⁶² and Mexico (200 dead, 600 injured).¹⁶³

Even the truck drivers who are hired to transport hexane are put in danger; in 2001, a tanker truck carrying 4500 gallons of hexane exploded and burst into flames, not only setting fire to two homes, but also critically injuring the truck driver and the driver of another vehicle.¹⁶⁴

In 2003, Martek's processing plant in Winchester, Kentucky, caused an explosion at a nearby wastewater treatment plant. Disposal of the hexane used to process their infant formula additive was determined to be the cause of the explosion (see details below).¹⁶⁵

For organic consumers who are concerned with the conditions under which their foods are produced, the possibility that hexane-extracted DHASCO and ARASCO are added to organic foods raises serious ethical concerns. Consumers have a right to know if the DHASCO and ARASCO in their organic foods are extracted with hexane; consumer hotlines for the companies adding DHASCO and ARASCO to organic foods currently do not disclose this information.

Hexane: An Environmental Hazard

During the oil extraction process, some hexane is lost to the air. Hexane is listed as one of 188 Hazardous Air Pollutants

by the EPA.¹⁶⁶ The EPA defines hazardous air pollutants as airborne compounds "that cause or may cause cancer or other serious health effects, such as reproductive effects or birth defects, or adverse environmental and ecological effects."

Hexane is also a problem because, like other volatile organic compounds (VOCs), it reacts with pollutants, principally oxides of nitrogen, in the presence of sunlight to form ozone (O_3). While ozone is essential in the upper atmosphere, excess ozone at ground level is a serious pollutant that is a hazard to human health and the environment.¹⁶⁷

According to the EPA, processing plants' wastewater contains small quantities of hexane.¹⁶⁸ Martek's Winchester, Kentucky processing plant has already been cited for polluting water with hexane after it caused an explosion at a wastewater treatment plant. According to Jim Helm,¹⁶⁹ a supervisor for the fire marshal's office in Winchester, the explosion resulted from the introduction of hexane from Martek's production facility into the local sanitary sewer system. While nobody was injured in the explosion, it caused environmental damage by sending raw sewage into a local stream. In response to the fire marshal's report, Martek's director of finance said that "it was inadvertently getting into the waste stream," and Martek claims that it has corrected the problem.

Organic Certifier Refuses to Share Public Information

Quality Assurance International (QAI) is the USDA-accredited certifying agency that certified the organic infant formula manufacturers and organic foods that are adding hexane-extracted algal DHASCO and fungal ARASCO. QAI refuses to share its organic plan for these products.¹⁷⁰

Quality Assurance International allowed hexane-extracted DHA and ARA in organic formula, but when asked to produce a copy of one of the infant formula manufacturer's organic handling plans to ensure its compliance with the Organic Foods Production Act, they refused. QAI has been implicated in a string of other alleged improprieties in the organic industry.

According to the National Organic Program's regulations (7 USC 6506(a)(9)), certifiers "shall provide for public access

to certification documents and laboratory analyses that pertain to certification.” As part of the certification documents, a producer or handler of organic foods is required (7 USC 6513(a)) to submit an organic plan to the certifying agent, who “shall determine if such plan meets the requirements.” This plan “shall contain provisions designed to ensure that agricultural products are produced and handled in a manner that is consistent with the purposes of [the Organic Foods Production Act]” (7 USC 6513(h)).

When asked to produce a copy of one of the infant formula manufacturer’s organic handling plans to ensure its compliance with the Organic Foods Production Act, QAI refused and made available to the public only the certificate of organic certification, without any of the relevant supporting information. If even organic certifying agencies refuse to confirm for the public that no hexane-extracted oils are added to organic infant formula, assurance that hexane is not used in the production of organic foods is virtually impossible, and consumers are forced to simply trust corporations to follow the rules.

QAI, the largest certifier, serving mostly large corporate agribusiness, has been implicated in a string of other alleged improprieties in the organic industry.

USDA Organic Program Must Take Action

The Cornucopia Institute is concerned about the possible inclusion of inappropriate, risky, and unapproved ingredients in organic foods for several reasons.

Cornucopia filed a formal legal complaint requesting that the USDA investigate and rectify the alleged violations by formula manufacturers that add nonapproved DHASCO and ARASCO to organic formula.

Martek wrote in its petition to the FDA that it uses hexane to extract the oils that are added to infant formula. These oils are now found in organic infant formula and organic foods such as Horizon milk and some energy bars—an apparent violation of the organic standards. When contacted by phone, neither Martek nor the other companies could assure consumers that hexane-free DHASCO and ARASCO are used in organic products. When asked to investigate, the USDA refused.

The USDA's refusal was based on a misunderstanding of basic nutrition and how that relates to the federal organic standards; the compliance officer either was not aware of the differences between fatty acids, vitamins, and minerals, or simply wished to find an excuse to dismiss the request. The Cornucopia Institute has filed a legal complaint with the USDA asking for a comprehensive investigation into the allegations that hexane-extracted DHASCO and ARASCO are being added to organic foods.

Organic foods are certified not by the USDA directly, but by one of 55 domestic certifying agencies that are currently accredited by the USDA. All food products that carry both the USDA organic label and contain DHASCO and/or ARASCO were certified by QAI. QAI's allowance of Martek's DHASCO and ARASCO in organic foods may be a harbinger of future violations if it continues to ignore the standards and allow non-approved ingredients in organic foods, and if the USDA does not step in to strictly enforce the standards. The law requires that certifiers be qualified “to successfully perform the duties assigned” (7 CFR 205.501(a)(5)). QAI's actions illustrate that it has failed in this regard, and the USDA should take appropriate action against QAI.

Conclusion

Babies who are fed infant formula with Martek's DHASCO and ARASCO are consuming novel foods, never before incorporated into the human diet, which are extracted with the use of the toxic chemical hexane. DHASCO and ARASCO are derived from fermented algae and fungi.

While allowed on the market, the FDA has not approved or affirmed the safety of DHASCO and ARASCO that are added to infant formula. Scientists and pediatricians question the adequacy of the premarket testing that was performed on DHASCO and ARASCO for infant formula, and the National Academies of Sciences has published these concerns.

While infant formula manufacturers claim that DHASCO and ARASCO are “proven to aid in brain and eye development,”¹⁷¹ scientists do not agree—DHA and ARA in a mother's breast milk may benefit brain and eye development, but studies on adding DHASCO and ARASCO to formula show inconsistent and inconclusive results.

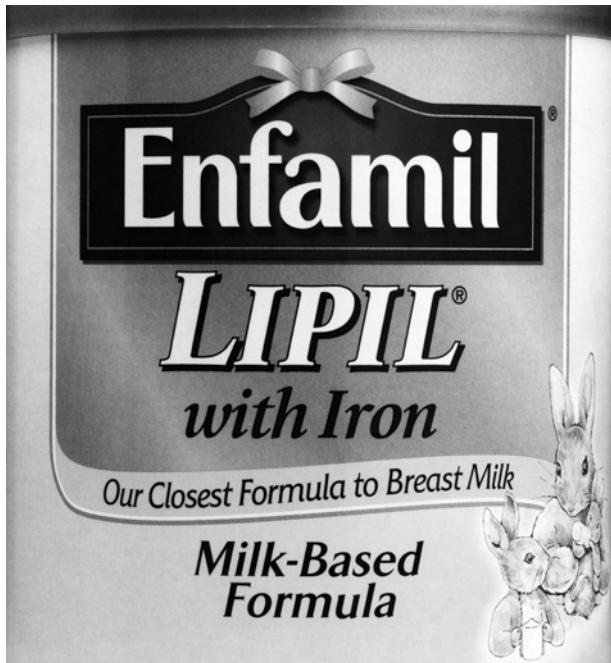
To extract DHASCO and ARASCO, Martek uses hexane, a toxic chemical by-product of gasoline refining that is classified by the EPA as a toxic pollutant.¹⁷² Martek also claims that it has developed an extraction process that does not use hexane but has been unwilling to say anything more on the subject. Trace amounts of hexane have been detected in some foods where it has been used as a processing agent. Adequate testing has not

taken place to determine whether this is a risk to infants, children, or adults.

The National Organic Program regulations prohibit ingredients that are extracted with organic solvents such as hexane, nor do the regulations allow the inclusion of “by-products of microorganisms” in organic foods. The Cornucopia Institute has filed a complaint with the USDA, alleging that the addition of Martek’s DHASCO and ARASCO to organic foods is a violation of the national organic standards.

Most importantly, this report provides an alternative source of information regarding DHASCO and ARASCO in infant formula for parents, children’s caretakers, and medical professionals. Infant formula manufacturers have consistently given only one side of this story; claims that DHASCO and ARASCO make formula “closer than ever to breast milk” and have been “proven to aid in brain and eye development” abound, while making no mention of safety concerns regarding the oils themselves and the possible processing contaminants. Moreover, members of the scientific community doubt the benefits to infant development of adding DHASCO and ARASCO to infant formula. Parents and caretakers who are either considering switching to infant formula or are already feeding their infants formula can use this report to make more informed health and nutritional decisions on behalf of their babies.

Appendix A: Formula Advertisements and Labels



*S*imilac® Advance® helps support both brain development like breast milk and the developing immune system.
(Kisses, hugs, and silly songs are up to you.)

Only Similac Advance with DHA and ARA has both*:

- A patented blend of special breast milk nutrients called nucleotides, which has been clinically shown to help support the development of a baby's immune system.
- Published long-term clinical research showing brain development like breast milk!

Compare levels of immunity supporting nucleotides*

| | | |
|-------------|-----------------|----------------|
| Breast milk | Similac Advance | Enfamil LIPIL® |
|-------------|-----------------|----------------|

No studies compare Similac and Enfamil immunity performance.

So much like breast milk in so many ways.™

*Similac is recommended for many benefits. You choose the food formula, ask your doctor about Similac Advance. *Among formulas with DHA and ARA, *Infants studied at 12 and 30 months of age, 2'-fatty acid nucleotide levels represent a worldwide average; for potentially available nucleotides in human milk, the full extent of bioavailability is not known. This graph illustrates comparative differences only based on added levels of nucleotides for Similac Advance and reported levels of nucleotides for Enfamil LIPIL. Enfamil and LIPIL are registered trademarks of Mead Johnson Nutrition Company. © 2008 Mead Johnson Nutrition Company.

www.SimilacAdvance.com

Appendix B: Infant Formula and DHASCO

Formula Brands and DHA

| Brand Name | Manufacturer | How much DHA, if DHASCO is added? (per 100 kcal) | Organic option? | Organic with DHASCO/ ARASCO? | Organic without DHASCO/ ARASCO available? | Any formula without DHASCO/ ARASCO available? |
|-------------------|--------------------------|--|-----------------|------------------------------|---|---|
| Earth's Best | The Hain Celestial Group | 17 mg | Yes | Yes | No | No |
| Similac | Abbott Laboratories | 8 mg | Yes | Yes | No | No |
| Enfamil | Mead Johnson | 17 mg | No | No | N/A | No |
| Parent's Choice | PBM Products | 17 mg | Yes | Yes | No | Yes |
| Bright Beginnings | PBM Products | 19 mg | Yes | Yes | No | No |
| Nestle Good Start | Nestle | 16 mg | No | No | N/A | Yes |

Similac Organic (Abbott Laboratories, Ross Division)

Similac has one choice of organic infant formula, and it contains DHASCO and ARASCO. Conventional or organic formula without DHASCO and ARASCO is no longer available.

Parents Choice Organic with DHA and ARA (Manufactured by PBM Nutritionals)

Ingredients: organic lactose, organic vegetable oils (palm or palm olein, high oleic (safflower or sunflower), coconut, soybean), organic nonfat milk, organic whey protein concentrate, **less than 1%**: soy lecithin, cryptechodinium cohnii oil*, mortierella alpina oil**, **vitamins:** ascorbic acid, ascorbyl palmitate, beta-carotene, biotin, calcium pantothenate, choline chloride, cyanocobalamin, folic acid, inositol, mixed tocopherol concentrate, niacin (niacinamide), pyridoxine hydrochloride, riboflavin, thiamine hydrochloride, vitamin A palmitate, vitamin D (cholecalciferol), vitamin E (dl-alpha tocopheryl acetate), vitamin K (phytonadione), **minerals:** calcium chloride, calcium hydroxide, cupric sulfate, ferrous sulfate, magnesium chloride, manganese sulfate, potassium bicarbonate, potassium hydroxide, potassium iodide, potassium phosphate, sodium citrate, sodium selenite, zinc sulfate, taurine, nucleotides: Adenosine-5'-monophosphate, cytidine-5'-monophosphate, disodium guanosine-5'- monophosphate, disodium inosine-5'-monophosphate, disodium

uridine-5'-monophosphate.

* A source of DHA.

** A source of ARA.

Earth's Best Organic Soy Formula with Iron (Manufactured by the Hain Celestial Group)

Ingredients: organic corn syrup, organic soy protein, organic high oleic sunflower oil, organic coconut oil, organic soy oil, and less than 1% of each of the following: soy lecithin, **vitamins:** (vitamin a palmitate, vitamin D3, dl-alpha-tocopherol, phytonadione, thiamin hydrochloride, riboflavin, pyridoxine hydrochloride, vitamin B-12, niacinamide, folic acid, calcium pantothenate, biotin, sodium ascorbate, ascorbic acid, ascorbyl palmitate, choline chloride, inositol), **minerals:** (calcium phosphate, calcium citrate, magnesium chloride, ferrous sulfate, zinc sulfate, cupric sulfate, potassium iodide, potassium citrate, potassium chloride, potassium phosphate, sodium chloride, sodium hydroxide, sodium selenite), l-carnitine, taurine, methionine, **lipids:** DHA (docosahexaenoic acid), ARA (arachidonic acid).

Ultra Bright Beginnings Organic Infant Formula (Manufactured by PBM Nutritionals)

Ingredients: organic lactose, organic vegetable oils (palm or palm olein, high oleic (safflower or sunflower), coconut, soy), organic nonfat milk, organic whey protein concentrate, **and less than 1%:** mortierella alpina oil*, crypthecodinium cohnii oil**, soy lecithin, **vitamins:** ascorbic acid, ascorbyl palmitate, beta-carotene, biotin, calcium pantothenate, choline chloride, cyanocobalamin, folic acid, inositol, mixed tocopherol concentrate, niacinamide, pyridoxine hydrochloride, riboflavin, thiamine hydrochloride, vitamin A palmitate, vitamin D (cholecalciferol), vitamin E (dl-alpha tocopheryl acetate), vitamin K (phytonadione), **minerals:** (calcium chloride, calcium hydroxide, cupric sulfate, ferrous sulfate, magnesium chloride, manganese sulfate, potassium bicarbonate, potassium hydroxide, potassium iodide, potassium phosphate, sodium citrate, sodium selenite, zinc sulfate, taurine), nucleotides (adenosine-5'-monophosphate, cytidine-5'-monophosphate, disodium guanosine-5'-monophosphate, disodium inosine-5'-monophosphate, disodium uridine-5'-monophosphate).

* A source of ARA.

** A source of DHA.

Appendix C: Martek Uses Hexane to Extract Oils

1. Martek's petition for GRAS status for DHASCO and ARASCO with the FDA provides a description of the processing procedures to obtain DHASCO and ARASCO¹⁷³:

Page 37:

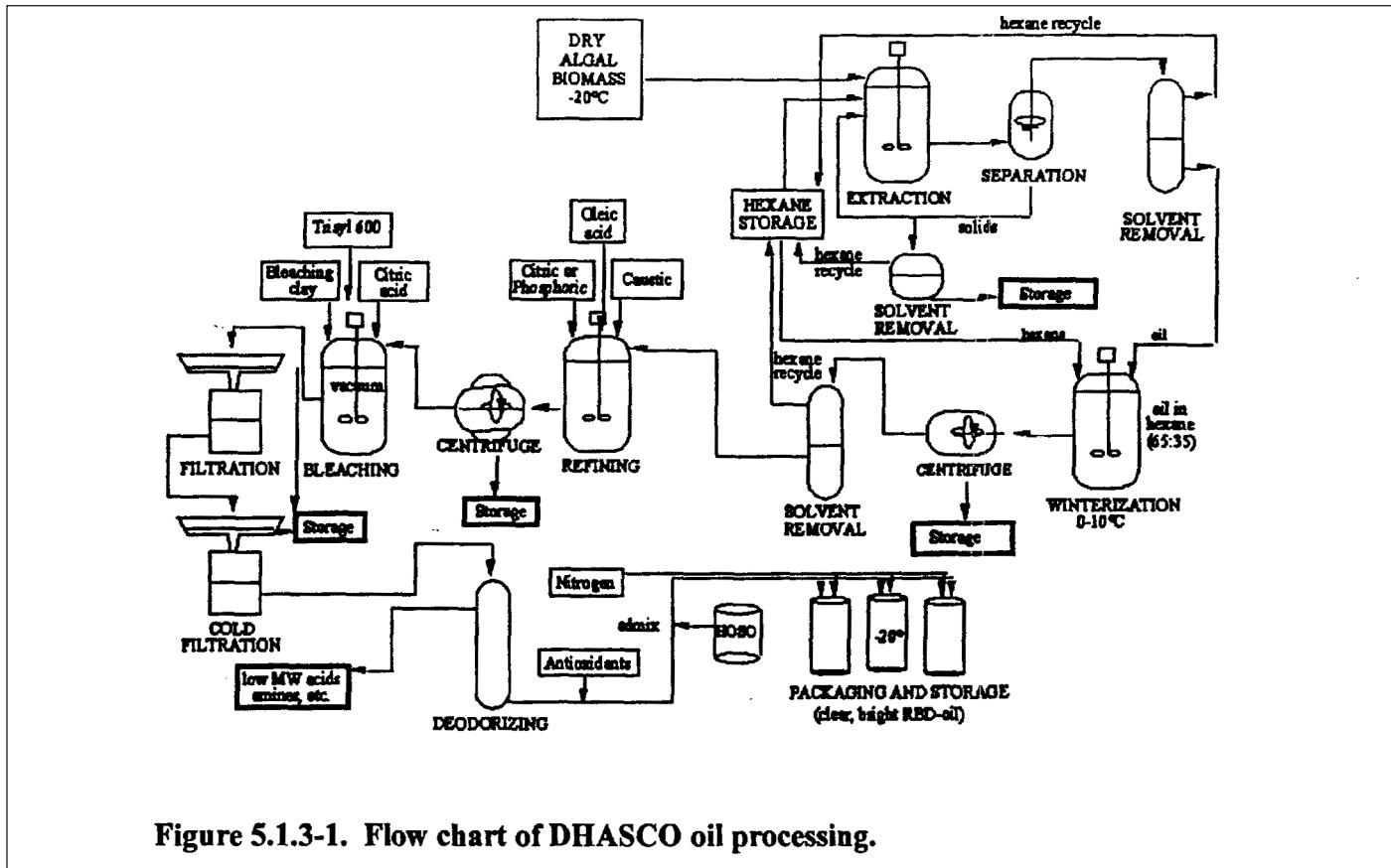


Figure 5.1.3-1. Flow chart of DHASCO oil processing.

Page 42:

The diagram in Figure 5.2.3-1 pictorially describes the ARASCO oil processing procedure. The oil is first extracted by blending the dried biomass with hexane in a continuous extraction process. The miscella (hexane:oil mixture) is separated from the de-oiled solids, filtered, and desolvanted under vacuum to reduce the volatiles. The crude ARASCO is then refined to remove free fatty acids, phospholipids and other impurities.

2. Martek Biosciences Corporation 2006 Annual Report (available online, <http://library.corporate-ir.net/library/11/116/116214/items/232799/AnnualReport2006.pdf>):

As large scale manufacturing facilities, our plants in Winchester, Kentucky and Kingstree, South Carolina are required to abide by applicable federal and state environmental and safety laws, including regulations established by the Environmental Protection Agency ('U.S. EPA') and the Occupational Safety and Health Administration ('OSHA'). In addition, *our solvent extraction processes include the use of hexane*, which is extremely flammable and subject to emission requirements [emphasis added]. Ongoing compliance with environmental and safety laws is monitored by periodic inspections by the U.S. EPA and OSHA. If we fail to abide by these laws we could receive fines, or if the violations were serious enough, our operations could be shut down until the problems are fixed. Such penalties could have a material adverse effect on our ability to manufacture our nutritional oils, and

our financial results could be negatively impacted. While the costs of our compliance with environmental laws and regulations cannot be predicted with certainty, such costs are not expected to have a material adverse effect on our earnings or financial or competitive position. See Item 3 of Part I of our Form 10-K for the year ended October 31, 2006 for further discussion.

3. Press Release, “Martek Updates Wastewater Treatment Plant Issue” (2003, available online at <http://www.secinfo.com/dsvRq.2178.d.htm>):

Columbia, MD, April 8, 2003 – Martek Biosciences Corporation (Nasdaq: MATK), today announced that it has received a report from the Office of the Kentucky State Fire Marshal that concluded that the explosion that occurred in March, 2003 at a wastewater pretreatment facility in Winchester, KY resulted from the introduction of *n*-hexane, a class I flammable liquid, into the local sanitary sewer system. The Fire Marshal’s report did not rule out other possible contributors to the explosion.

Martek utilizes *n*-hexane in its production process at the Company’s plant in Winchester, KY, and the Fire Marshal has concluded that inadvertent discharges of hexane from Martek’s plant had resulted in elevated levels of *n*-hexane in the sewer system. Martek has taken measures to insure that no further *n*-hexane is emitted into the sewer system. Production at the facility has not been negatively affected by these events.

Martek is in the process of evaluating the Fire Marshal’s conclusions and, as previously disclosed, continues to believe that the ultimate outcome of this matter will not have a material adverse effect on the Company’s financial condition or results of operations.

Martek Biosciences Corporation develops, manufactures and sells products from microalgae. The Company’s products include: (1) specialty, nutritional oils for infant formula that aid in the development of the eyes and central nervous system in newborns; (2) nutritional supplements and food ingredients that may play a beneficial role in promoting mental and cardiovascular health throughout life; and (3) new, powerful fluorescent markers for diagnostics, rapid miniaturized screening, and gene and protein detection.

This press release contains statements relating to the Company’s production process and compliance with regulatory agencies. Such statements involve risks and uncertainties that could cause future actual results to differ due to a variety of risk factors, including without limitation those factors set forth in Martek’s filings with the SEC.

4. Commonwealth of Kentucky Division for Air Quality Permit Application Summary Form (2004, available online, <http://www.air.ky.gov/NR/rdonlyres/6A62DFAC-0AB7-426B-A6743CE69C286023/0/V06051Summary.pdf>):

The Martek Biosciences facility in Winchester produces two single cell oils, each of which is enriched in a specific fatty acid. One is a triglyceride oil enriched in DHA (docosahexaenoic acid) derived from a marine microalgae (DHASCO®) and the second is a triglyceride oil enriched in ARA (arachidonic acid) derived from a common soil organism (ARASCO®). The process begins when a biomass is produced through cultivation of a starter seed culture, particular to the oil to be produced, in a series of increasingly larger fermentors. After the final fermentation, in the case of the marine algae, the biomass is spray dried. The ARASCO® biomass must be dried through other means at a toll processing facility. *The oil is extracted from the dried biomass using a hexane extraction process* [emphasis added]. The oil is winterized, refined, bleached, and deodorized to produce the final product.

5. Opinion Expert Panel, submitted to FDA to acquire Generally Recognized As Safe Status for DHASCO and ARASCO (2000, available online: <http://www.fda.gov/ohrms/dockets/dailys/00/mar00/030900/rpt0003.pdf>):

Section 5.1.3 Extraction and Purification of DHASCO: The DHASCO oil is extracted from the algal biomass and processed using methods and procedures that have been well established in the edible oils industry. ... The oil is first extracted by blending the dried biomass with hexane in a continuous extraction process [emphasis added].

Appendix D: Legal Complaint Letter to USDA

January 24, 2008

TO: David Trykowski, Office of Compliance, National Organic Program

RE: Complaint concerning multiple possible violations of the National Organic Program's regulatory standards by Hain Celestial, Abbott Laboratories, PBM Nutritionals, Nurture/HappyBaby, Dean Foods/Horizon Organic, Stremicks Heritage Foods, and NuGo Nutrition.

Dear Mr. Trykowski,

The Cornucopia Institute is filing this complaint with your office concerning possible multiple violations of National Organic Program (NOP) regulatory standards. Several manufacturers are currently selling organic infant formula, organic dairy products, and organic nutrition bars containing DHASCO and ARASCO produced by Martek Biosciences. DHASCO and ARASCO are not on the National List of Approved and Prohibited Substances.

While microorganisms are on the National List of Approved and Prohibited Substances, by-products of microorganisms are not. Martek's DHASCO and ARASCO are by-products of an alga and fungus, respectively. In addition, The Cornucopia Institute has reason to believe that these oils are solvent extracted and therefore also illegal in organic foods. Furthermore, The Cornucopia Institute has reason to believe that Martek Biosciences is genetically engineering the microorganisms used to produce DHASCO and ARASCO.

Handlers that are adding Martek's DHASCO and/or ARASCO to organic foods include:

- The Hain Celestial Group (Earth's Best Soy Infant Formula)
- 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)
- Nurture, Inc. (Happy Baby Organic baby food with DHA)
- Horizon Organic (fluid milk with DHA)
- Stremicks Heritage Foods (fluid milk with DHA)
- NuGo Nutrition (NuGo Nutrition Bars)

DHASCO and ARASCO are not on the National List: Martek's algal DHASCO and fungal ARASCO do not appear on the National List of Approved and Prohibited Substances. Therefore, the use of these substances in organic food is a violation of section 205.105(c), which prohibits the use of synthetic and non-synthetic substances, not on the National List, in the processing of organic foods.

Some certifiers have apparently argued that the rules prohibit the use of synthetic solvent extraction only for organic ingredients, but not for nonorganic ingredients in organic foods. However, the rule seems to clearly prohibit the use of hexane extraction for nonorganic ingredients in foods that are labeled "organic," but not for nonorganic ingredients in foods that are labeled "made with organic ingredients." This exception is articulated in section 205.270(c)(2): "*Except*, that, non-organic ingredients in products labeled 'made with organic (specified ingredients or food group(s))' are not subject to this requirement." It does not say that nonorganic ingredients in products labeled "organic" are not subject to this requirement. Infant formula, milk and nutrition bars with Martek's DHASCO and ARASCO are all labeled "organic," not "made with organic ingredients"; therefore, hexane extracted ingredients should not be allowed.

Hexane extraction: According to Martek's Generally Recognized as Safe (GRAS) petition to the FDA, which was necessary to gain approval for adding these oils to infant formula, hexane is used to extract DHASCO and ARASCO from fermented algae and fungus (see attachment, pages 37 and 42). Hexane is a chemical by-product of gasoline refinement, a toxic air pollutant regulated by EPA, an occupational hazard according to OSHA, and a highly explosive solvent. In addition, patent documents filed with the U.S. government also indicate that hexane is a part of the processing protocol for DHASCO and ARASCO.

As we understand the organic regulations, solvent-extracted ingredients are not allowed in organic products. Section 205.270 (Organic Handling Requirements) states that a "handler of an organic handling operations must not use in or on agricultural products intended to be sold, labeled or represented as ... 'organic' ... (2) a volatile synthetic solvent or other synthetic processing aid not allowed under §205.605."

A synthetic solvent may be allowed if it is listed under §205.605. Hexane is not listed in section 205.605.

There are exceptions to this rule. Section 205.605(b) allows "nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods." **However, DHASCO and ARASCO are not covered under these exceptions, since they are oils containing fatty acids, not vitamins or minerals.** The National Organic Standards Board did advise that "accessory nutrients" also be included under the exemptions of Section 205.605(b). DHASCO and ARASCO may qualify as accessory nutrients, but the NOSB's recommendations were not adopted in the regulations.

Given Martek's description of the processing procedure to obtain DHASCO and ARASCO, we have reason to believe that hexane-extracted ingredients are added to organic foods. We ask that you investigate whether these manufacturers are adding hexane-extracted DHASCO and ARASCO to organic foods. We point out that these novel ingredients should have been scrutinized by the certifier, Quality Assurance International, and we ask you to also investigate the conduct of QAI and their qualifications to have performed a proper analysis of these products prior to certification.

Genetically engineered microorganisms: We would also request the USDA to investigate whether ARASCO comes from genetically engineered fungus. According to the patent application for ARASCO¹⁷⁴ (patent 6,749,849), newly identified strains of the fungus *Mortierella sect. schmuckeri* can be used to produce ARASCO with high productivity; these strains can be "obtained by genetically-engineering microorganisms to produce increased amounts of arachidonic acid."

The patent application shows that genetic engineering is performed on fungus for the production of ARASCO. The application specifically states, "A 'mutated microorganism' is a mutated parental microorganism in which the nucleotide composition of such microorganism has been modified by mutation(s) that occur naturally, that are the result of exposure to a mutagen, or that are the result of genetic engineering." While Martek's web site states that its ARASCO come from non-genetically engineered sources, we would like the USDA to investigate so as to ensure consumers that no genetically engineered organisms are used to produce oils for organic infant formula and other organic food products.

Additionally, we request that the USDA investigate the possibility that algae and fungus used to extract DHASCO and ARASCO are cultivated with the use of growth media that contain genetically engineered material. As described in the patent application, the growth medium for algae varies but must contain a carbon source, which may come in the form of "molasses, high fructose corn syrup, hydrolyzed starch or any other low cost conventional carbon source used in fermentation processes."¹⁷⁵

Given the widespread availability and low cost of high fructose corn syrup, we suspect that this may be a regularly used growth medium for the oils. For fungus to produce ARASCO, the patent application states that "suitable complex nitrogen sources include, for example, corn steep liquor, protein hydrolysates, microbial biomass hydrolysates, soy tone, soy meal, fish meal, meat meal, meat extract, peptone, tryptone, yeast extract, yeast and whey."

Since most corn and soybeans in the United States are genetically engineered, we ask the USDA to investigate whether the algae and fungus used to extract oils for organic foods are grown in genetically engineered media, which would violate the NOP regulations. Again, it is important to note that the certifier should have performed this scrutiny.

If the USDA finds violations of the organic standards: The Cornucopia Institute asks that the USDA take appropriate action if violations are found. We request that the USDA notify all manufacturers of infant formula containing Martek's DHASCO/ARASCO that are labeled "certified organic" and all foods containing Martek's DHASCO that are labeled as "certified organic," with two requests.

First, all such products should be immediately removed from store shelves.

Second, these manufacturers should be prohibited from adding Martek's DHASCO/ARASCO or DHASCO to products with the organic label.

Cornucopia requests that the USDA weigh the following in assessing the need for penalties. According to §205.100(c)(1), any operation that "knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty

of not more than \$10,000 per violation."

Furthermore, §205.100(c)(2) states that making "a false statement under the Act to the Secretary, a governing State official, or an accredited certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code."

The Cornucopia Institute is concerned that this specific possible violation of the organic standards may be a symptom of a deeper underlying problem, which is that certain certifiers are either knowingly allowing nonapproved substances in organic foods, or that certifiers are not qualified nor possess the necessary scientific expertise to determine the status of specific new ingredients, like DHASCO and ARASCO.

Certifiers should know that Martek's DHASCO and ARASCO are not on the National List of Approved and Prohibited Substances. "Byproducts of microorganisms" are also not on the List, *despite a petition by Martek to add this category*. Concerning the use of hexane, certifiers should research the production methods of new ingredients to discover the use of synthetic organic solvents, or other prohibited substances—research that may or may not have been done by QAI when it determined that infant formula with DHASCO and ARASCO and milk with DHASCO could carry the "organic" label.

The organic standards specify that the USDA must ensure that certifiers are qualified. According to 7 CFR 205.501(a), "a private or governmental entity accredited as a certifying agent under this Subpart must:

"Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned." 7 CFR 205.501(a)(5)

"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." 7 CFR 205.501(a)(1)

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 possibly hexane-extracted and genetically engineered.

The Cornucopia Institute requests that the USDA's Office of Compliance 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. We take this matter very seriously.

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,

Will Fantle

Research Director

The Cornucopia Institute

Appendix E: Petition to the Federal Trade Commission

January 24, 2008

The Honorable Deborah Platt Majoras
Chairman
Federal Trade Commission
600 Pennsylvania Ave, N.W.
Washington, D.C. 20580

Dear Chair Majoras,

The Cornucopia Institute and the National Alliance for Breastfeeding Advocacy request the Federal Trade Commission to investigate possible violations of the law (15 USC 45) and to take immediate and effective action against the offending parties.

Several infant formula manufacturers, including Ross Products (Abbott Laboratories), Mead Johnson (Bristol-Myers-Squibb), PBM Nutritionals, Nestle, and Earth's Best (the Hain Celestial Group) are in possible violation of Section 5 of the Federal Trade Commission Act by misleadingly advertising infant formula containing the additives docosahexaenoic single cell oil (DHASCO) and arachidonic single cell oil (ARASCO), which are manufactured sources of the fatty acids DHA and ARA.

Presently, infant formula manufacturers are claiming in their advertisements that formula with DHASCO and ARASCO is "closer than ever to breast milk." They use different variations of this claim, as well as the claim that formula with DHASCO and ARASCO will improve brain and eye development in formula-fed infants. These claims are likely to mislead consumers acting reasonably under the circumstances into believing that infant formula is equivalent, or near-equivalent, to human milk, and its use will result in superior cognitive, developmental, vision, and immune system outcomes. These claims have caused mothers to contact health care providers stating the following:

- "I want the breastmilk formula."
- "I want the formula with breast milk in it."
- "Whose breast milk is in the formula?"

We can supply additional backup and documentation upon request.

See the different advertisement claims:

Similac Advance helps support both brain development like breast milk and the developing immune system.
(Kisses, hugs, and silly songs are up to you.)

Only Similac Advance with DHA and ARA has both:
A patented blend of special breast milk nutrients called nucleotides, which has been clinically shown to help support development of a baby's immune system.
Published long-term clinical research showing brain development like breast milk!
So much like breast milk in so many ways!

SEE HOW ENFAMIL LIPIL[®] MAKES A DIFFERENCE

- 20/41 Vision - 20/28 Vision

WITHOUT LIPIL[®] WITH LIPIL[®]

Enfamil LIPIL[®] with Iron
Our Closest Formula to Breast Milk
Milk-Based Formula

These claims are misleading for several reasons.

First, the scientific data to support these claims is inconclusive. A thorough review of peer-reviewed, academic journals shows that the benefits of adding DHASCO and ARASCO to infant formula are uncertain and inconclusive. For example, a pediatrician and researcher at the University of Louisville writes in the June 2007 issue of the *Journal of Perinatology* that “the addition of long-chain polyunsaturated fatty acids and nucleotides to formula are intended to promote visual, neuro and immune development. Studies in both preterm and term infants have not consistently demonstrated efficacy with long-chain polyunsaturated fatty acids supplementation of infant formula.”¹⁷⁶ This is one of many such articles by respected scientists, who have published articles with similar conclusions—that there is insufficient evidence showing benefits of DHASCO and ARASCO in infant formula—in the *American Journal of Clinical Nutrition*, the *Annual Review of Nutrition*, *Pediatrics*, and the *Journal of Pediatric Gastroenterology and Nutrition*, to name just a few. Review articles demonstrate the same inconclusive evidence¹⁷⁷ with no published scientific studies showing long-term benefits of DHASCO and ARASCO to brain development and IQ in formula-fed infants.

Second, breast milk offers innumerable health benefits to infants that formula cannot provide. To claim that formula is “as close as ever to breast milk” is misleading, given the scientific evidence showing breast milk to be immeasurably superior to formula in terms of infant nutrition and quite dissimilar in composition. The American Academy of Pediatrics writes that the advantages of breastfeeding include “health, nutritional, immunologic, developmental, psychologic, social, economic, and environmental benefits.” The Academy’s position is that breast milk is superior to formula.¹⁷⁸

The American Academy of Pediatrics writes that benefits of breast milk include a decrease 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 and urinary tract infection. Breastfeeding decreases the rates of sudden infant death syndrome in the first year of life. Long-term health benefits of breastfeeding include decreased likelihood of developing—as older children and adults—lymphoma, leukemia and Hodgkin’s disease, hypercholesterolemia and asthma, as well as the likelihood of becoming overweight or obese. Post neonatal infant mortality rates in the United States are reduced by 21% in breastfed infants.¹⁷⁹ Promoting breastfeeding has the potential to prevent or delay 720 infant deaths in the United States every year, mostly by preventing infectious disease and sudden infant death syndrome.¹⁸⁰

Breastfeeding could potentially reduce annual health care costs by \$3.6 billion in the United States and would lead to decreased costs for public health programs such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC).¹⁸¹

There is a grave likelihood that consumers will rely on misleading claims about DHA/ARA formula when making important decisions about feeding their infants. These advertisements are harming infants by undermining efforts at promoting breastfeeding and resulting in an increased incidence of acute and chronic diseases and conditions.

We have reason to believe that these misleading claims have already affected infant health in real ways. Results from a survey conducted by the U.S. Department of Human and Health Services¹⁸² shows a significant rise in the percentage of Americans who believe that breastfeeding and infant formula are equally good ways to feed an infant—this rise occurred at the same time that infant formula manufacturers began marketing their DHA/ARA formula as “closer than ever to breast milk.” In 2003, 12% of respondents thought that breastfeeding and formula are equally good ways to feed an infant; one year later, this number shot up to 24%. The timing of this jump coincides with the timing of the DHA/ARA advertisements. Even following the national advertisement campaign to promote breastfeeding by the Department of Human and Health Services, this figure did not return to its 2003 status; by 2005, still 15% of respondents thought infant formula is as good as breast milk.

Despite efforts to promote breastfeeding by health care professionals, public interest groups, and government agencies, breastfeeding rates are declining in the United States. While there are many factors contributing to a mother’s decision to formula feed her infant, the impact of advertisement cannot be dismissed, especially when these advertisements are misleadingly suggesting that formula is an equally good way of feeding an infant.¹⁸³ We also have anecdotal evidence from health care professionals who find it more difficult to convince women to breastfeed when they have seen advertisements claiming that DHA/ARA formula is “as close as ever to breast milk.”

The Federal Trade Commission is under a legal duty to end misleading advertisements, under Section 5 of the Federal Trade Commission Act, 15 USC 45. 15 USC 45 (a)(1) states that “deceptive acts or practices in or affecting commerce are hereby declared unlawful,” and 15 USC 45 (a)(2) empowers and directs the Federal Trade Commission to prevent corporations from using deceptive acts in or affecting commerce.

The Federal Trade Commission has described a misleading advertisement as a representation, omission or practice that is likely to mislead the consumer.⁴ The FTC has also written that “the basic question is whether the act or practice is likely to affect the consumer’s conduct or decision with regard to a product or service. If so, the practice is material, and consumer injury is likely, because consumers are likely to have chosen differently but for the deception.”¹⁸⁴

In the case of DHA/ARA formula, infant formula advertisements are likely to mislead parents into believing that formula offers benefits to their infant’s development, when scientific research shows that this is an unproven conclusion. This deception in the advertisements causes serious injury not only to the consumer (the mother) but to the most vulnerable segment of our population—infants—by falsely claiming that infant formula is an equally good way of feeding an infant. In addition, there is a growing body of scientific literature indicating that discouraging women from breastfeeding could be deleterious to their health.

Thus, we urge you, the FTC, to thoroughly investigate this matter pursuant to your statutory authority, including but not limited to the issuance of a civil investigative demand. If deemed appropriate by the FTC, the Cornucopia Institute and the National Alliance for Breastfeeding Advocacy also seeks a permanent injunction pursuant to section 13(b) of the Federal Trade Commission Act (15 USC 53(b)) to prevent the marketing of this product if the claims are false and misleading.

Respectfully yours,

Will Fantle
Research Director
The Cornucopia Institute

Marsha Walker, RN, IBCLC
Executive Director
National Alliance for Breastfeeding Advocacy

Appendix F: Petition to the FDA to Add a Warning Label

January 24, 2008

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852.

Preliminary Statement

The Cornucopia Institute and The National Alliance for Breast Feeding Advocacy submit this petition under section 4(d) of the Administrative Procedure Act (5 U.S.C. § 553(e)¹⁸⁵) and sections 201(n)¹⁸⁶, 402(a)(1)¹⁸⁷, 402(f)(1)(B)¹⁸⁸, 403(a)(1)¹⁸⁹, and 701(a)¹⁹⁰ of the federal Food, Drug, and Cosmetic Act (FFDCA), (21 U.S.C. §§ 342(a)(1), 342(a)(2)(A), 342(f)(1)(B) and 371(a)) to request the Commissioner of Food and Drugs to revise the labeling requirements for infant formulas that contain DHA and ARA from algal and fungal sources, respectively. We specifically request a notice on the label of infant formula with DHA- and ARA-containing oils to warn parents of the possibility of adverse reactions to these novel ingredients.

Incidences of infants experiencing adverse reactions, including diarrhea, vomiting, bloating, and gastrointestinal distress, have been reported to the FDA's MedWatch system. These reports suggest that a subset of the population reacts adversely to the DHA and ARA oils that have been added to infant formula since 2002. Cornucopia and NABA request that the FDA conduct an investigation of adverse reactions in infants to DHA and ARA oils in infant formula, including a thorough investigation of any postmarket surveillance performed by formula manufacturers. If, as a result of such investigations, the FDA finds that a subset of the infant population does indeed react adversely to infant formula with DHA and ARA oils, Cornucopia and NABA request a regulatory change in labeling requirements for infant formula to warn parents of the possibility of adverse reactions.

Action Requested

Cornucopia and NABA request that the FDA take regulatory action to revise the existing regulation by requiring a label notice for all infant food products containing DHA and ARA oils. The proposed regulation should prescribe the following (or similar) language: "NOTICE: This product contains DHA oil from algal microorganisms and ARA oil from fungal microorganisms, which have been linked to diarrhea, bloating, vomiting, and other gastrointestinal problems in some infants. Discontinue usage and seek medical help if your infant reacts adversely to this formula and symptoms do not immediately resolve upon switching to an alternative formula without DHA/ARA oils."

Factual Grounds for Action

Since 2002, infant formula manufacturers have produced formula with DHA/ARA by adding the novel ingredients DHASCO and ARASCO to formula. DHASCO stands for docosahexaenoic acid single cell oil and ARASCO stands for arachidonic acid single cell oil. These oils are produced and marketed by Martek Biosciences Corporation.

Docosahexaenoic acid (DHA) and arachidonic acid (ARA) are naturally present in human breast milk—a breastfeeding mother acquires these fatty acids from sources such as fatty fish or synthesizes them from other omega-3 fatty acid sources like walnuts, flaxseed, and eggs. Given their presence in breast milk, DHA and ARA are believed to be highly beneficial to an infant's development.

Martek's DHASCO and ARASCO are novel foods. They are extracted with the use of a solvent (hexane) from fermented algae and soil fungus. Moreover, DHASCO and ARASCO contain DHA and ARA triglycerides that are not identical to those found in human milk. These structural differences should be investigated as a possible cause of the gastrointestinal distress that some infants experience after ingesting formula supplemented with DHASCO and ARASCO.

Scientists have conducted numerous studies that question long-term benefits to an infant's development from adding DHA and ARA to infant formula. Overall, research results are inconsistent and inconclusive. The scientific community does not agree that DHA and ARA added to formula confer proven benefits to an infant's development and well-being.

DHASCO and ARASCO are considered Generally Recognized as Safe (GRAS), although FDA officials reviewing the GRAS notice by Martek never affirmed the safety of DHASCO and ARASCO. In their letter to Martek, FDA officials wrote:

"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."¹⁹¹ [emphasis added]

Parents of infants reacting adversely to formula supplemented with DHASCO and ARASCO oils have reported adverse reactions to the FDA. *These reports, along with anecdotal evidence from health care professionals, reveal that a subset of the population experiences pain and distress from consuming DHA/ARA formula.* Premarket safety tests did not reveal these adverse reactions, which could be due to the fact that ethical guidelines require the withdrawal of infants reacting negatively, or due to the fact that rare adverse reactions are only revealed once hundreds of infants consume the formula. If that is the case, then adverse reactions would come to light only after the product reaches the market.

A total of 98 adverse reaction reports submitted to the FDA's MedWatch program could reasonably be linked to the DHA and ARA oils in infant formula. While 98 adverse reaction reports may seem like a low number, we feel the need to point out that this does not justify a dismissal of the severity of the problem. First, parents are currently left in the dark about the possibility that DHA and ARA oils in formula could be the cause of their infant's diarrhea or other adverse reactions. Physicians and other healthcare providers might assume that the widely marketed brands of infant formula are not the root cause when examining patients or consulting with worried parents over the phone.

It is precisely for this reason that we request a warning label on formula. Formula labels and manufacturers' websites or advertisements do not currently point to any possibility that an infant's diarrhea or other problems may be caused by the DHA and ARA oils in formula. As a result, parents and health providers are unlikely to identify DHA and ARA oils as a possible cause of their infant's problems, and these adverse reactions will go unreported. Second, parents whose infants react adversely may not be aware of the FDA's MedWatch program, which contributes to possible underreporting of this problem.

Legal Grounds for Action

Our petition is submitted based on sections 201(n), 402(a)(1), 402(f)(1)(B), 403(a)(1) and 701(a) of the Federal Food, Drug and Cosmetics Act. Section 402(a)(1) determines that a food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health. To at least a subset of the infant population, Martek's DHASCO and ARASCO in infant formula appear to be injurious to health by causing adverse reactions such as diarrhea, vomiting, and gastrointestinal distress.

In addition, according to section 402(f)(1)(B) a food shall be deemed to be adulterated if it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. FDA's GRAS Notice 000041 states that the agency has not made its own determination regarding the GRAS status of the subject use of ARASCO and DHASCO. We believe that inadequate information regarding the safety of DHASCO and ARASCO was available when DHA/ARA-supplemented formula came on the market, and that reports of adverse reactions demonstrate a lack of reasonable assurance that these ingredients do not present an unreasonable risk of illness or injury to infants.

Under section 201(n), FDA determines whether labeling is misleading by examining, among other things, the extent to which the labeling *fails to reveal facts* material as to consequences that may result from use of the product under conditions of use prescribed in the labeling or under customary or usual conditions of use. We believe that the lack of information regarding the possibility of adverse reactions in infants from the consumption of DHA/ARA-supplemented formula constitutes misleading labeling.

Section 403(a)(1) states that a food is misbranded if its labeling is false or misleading in any particular. Section 701(a) generally authorizes FDA to issue regulations for the efficient enforcement of the FFDCA. FDA has relied upon its authority under those

sections of the FFDCA to require label notices that alert consumers to the potential health hazards posed by certain foods and food ingredients.¹⁹²

Environmental Impact

This petition is categorically excluded from the requirement for an environmental assessment under 21 C.F.R. § 25.30(k), because it requests the "[e]stablishment or repeal by regulation of labeling requirements for marketed articles" for which "there will be no increase in the existing levels of use or change in the intended uses of the product or its substitutes." In any event, and NABA do not believe that the actions requested in this petition would have any environmental impact.

Conclusion

The lack of labeling of infant formula with DHA- and ARA-containing oils does not adequately protect the health and well being of infants who experience adverse reactions, such as diarrhea, bloating, vomiting, and gastrointestinal distress from the consumption of formula with DHA and ARA oils. Currently, no labeling or warning is required, and formula manufacturers are not voluntarily warning parents of the possibility of adverse reactions. Parents are unaware that the simple switch to a non-DHA/ARA-supplemented formula may relieve their infant's pain and suffering from adverse reactions to Martek's DHASCO and ARASCO. Taking the action urged by Cornucopia and NABA would alert parents and caregivers of formula-fed infants to the possibility of adverse reactions caused by algal DHA and fungal ARA, providing them with knowledge that may help them end their infants' pain and distress.

Cornucopia and NABA request that the FDA determine whether such a warning label is warranted. We especially urge the FDA to undergo an investigation of the adequacy and results of post-market surveillance by formula manufacturers. If deemed necessary, the FDA should revise its existing regulations to require a label notice alerting parents to the possibility of adverse reactions.

Certification

The undersigned certify, that, to our best knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petition which are unfavorable to the petition.

Respectfully submitted,

Will Fantle
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The Cornucopia Institute

Marsha Walker, RN, IBCLC
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Sources

Adamkin, D.H. (2007) Controversies in neonatal nutrition: docosahexanoic acid (DHA) and nucleotides. *Journal of Perinatology* 27, Suppl 1: S79–82.

Agency for Healthcare Research and Quality, (2004) Health effects of omega-3 fatty acids on cardiovascular disease. Structured abstract. March 2004. Rockville, MD. Available online <http://www.ahrq.gov/clinic/tp/o3cardtp.htm>. Last accessed on October 12, 2007.

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

Associated Press, Worldstream. Explosion claims second life in South Africa. July 12, 1999. Available on Lexis-Nexis. Accessed on June 13, 2007.

Associated Press, Malvern, Pennsylvania. Tanker truck explosion and fire critically injures two men. July 20, 2001. Available on Lexis-Nexis. Accessed on June 13, 2007.

Associated Press. Investigation into Sioux City plant explosion inconclusive. December 6, 2003. BC Cycle. Available on Lexis-Nexis. Accessed on June 13, 2007.

Associated Press. Release of solvent caused explosion, report says. April 9, 2003. Available on Lexis-Nexis. Accessed on June 13, 2007.

Associated Press, International. Four dead in Italian olive oil factory blast. November 25, 2006. Available on Lexis-Nexis. Accessed on June 13, 2007.

Auestad, N., Halter, R., Hall, R.T., Blatter, M., Bogle, M.L., Burks, W., Erickson, J.R., Fitzgerald, K.M., Dobson, V., Innis, S.M., Singer, L.T., Montaldo, M.B., Jacobs, J.R., Qiu, W., Bornstein, M.H. (2001) Growth and development in term infants fed long-chain polyunsaturated fatty acids: a double-masked, randomized, parallel, prospective, multivariate study. *Pediatrics* 108, 2: 372–381.

Auestad, N., Scott, D.T., Janowsky, J.S., Jacobsen, C., Carroll, R.E., Montaldo, M.B., Halter, R., Qiu, W., Jacobs, J.R., Connor, W.E., Connor, S.L., Taylor, J.A., Neuringer, M., Fitzgerald, K.M., Hall, R.T. (2003) Visual, cognitive, and language assessments at 39 months: a follow-up study of children fed formulas containing long-chain polyunsaturated fatty acids to 1 year of age. *Pediatrics* 112, 3Pt1: 177–183.

Australia New Zealand Food Authority. P93 Review of infant formula. Supplementary final assessment report. March 13, 2002. Available online at [http://www.foodstandards.gov.au/_srcfiles/P93_completeFinalAssRep\(supplement\).pdf#search=%22Crypthec%20odinium%20%22](http://www.foodstandards.gov.au/_srcfiles/P93_completeFinalAssRep(supplement).pdf#search=%22Crypthec%20odinium%20%22). Last accessed on July 17, 2007.

Birch, E.E., Garfield, S., Castañeda, Y., Hughbanks-Wheaton, D., Uauy, R. and Hoffman, D. (2007) Visual acuity and cognitive outcomes at 4 years of age in a double-blind, randomized trial of long-chain polyunsaturated fatty acid-supplemented infant formula. *Early Human Development* 83, 5: 279–284.

Blanchard, D.S. (2006) Omega-3 fatty acid supplementation in perinatal settings. *American Journal of Maternal Child Nursing* 31, 4: 250–256.

Bondía-Martínez, E., López-Sabater, M.C., Castellote-Bargalló, A.I., Rodríguez-Palmero, M., González-Corbella, M.J., Rivero-Urgell, M., Campoy-Folgoso, C., Bayés-García, R. (1998) Fatty acid composition of plasma and erythrocytes in term infants fed human milk and formulae with and without docosahexaenoic and arachidonic acids from egg yolk lecithin. *Early Human Development* 53: S109–119.

Brady, M. Protecting a mother's right to independent information on infant feeding. Presented at NHS Wales/SureStart event in Cardiff for National Breastfeeding Awareness Week, 2007. Available online at <http://www.babymilkaction.org/resources/nbaw07.html>. Last accessed on July 23, 2007.

British Broadcasting Corporation. Organic Produce "Better for You" October 29, 2007. Available online <http://news.bbc.co.uk/2/hi/health/7067100.stm>. Last accessed on October 31, 2007.

Butnik, S.M., Oster, G.D., Gabel, S. (1986) Understanding psychological testing in children: a guide for health professionals. Springer Publishing.

Canadian Broadcasting Corporation Marketplace. Genius in a bottle. February 10, 2004. Available online at <http://www.cbc.ca/consumers/market/files/heath/babyformula/>. Last accessed on July 17, 2007.

Carelli, V., Franceschini, F., Venturi, S., Barboni, P., Savini, G., Barbieri, G., Pirro, E., La Morgia, C., Valentino, M.L., Zanardi, F., Violante, F.S. and Mattioli, S. (2007) Grand Rounds: could occupational exposure to n-hexane and other solvents precipitate visual failure in Leber hereditary optic neuropathy? (Environmental Medicine). Environmental Health Perspectives 115, 1: 113-116.

Carlson S.E., Ford, A.J., Werkman, S.H., Peeples, J.M., Koo, W.W. (1996) Visual acuity and fatty acid status of term infants fed human milk and formulas with and without docosahexaenoate and arachidonate from egg yolk lecithin. Pediatric Research 39, 5: 882-888. Committee on the Evaluation of Addition of Ingredients New to Infant Formula (2004) Infant formula: evaluating the safety of new ingredients. National Academies Press. Available online at <http://www.nap.edu/books/0309091500/html/>. Last accessed on July 17, 2007.

Cornucopia Institute, The. Organic dairy scorecard. Available online at http://cornucopia.org/dairysurvey/FarmID_139.html. Last accessed on July 17, 2007.

Couvreur, S., Hurtaud, C., Lopez, C., Delaby, L. and Peyraud J. L. (2006) The linear relationship between the proportion of fresh grass in the cow diet, milk fatty acid composition, and butter properties. Journal of Dairy Science 89, 6: 1956-1969.

Couvreur, S., Hurtaud, C., Marnet, P. G., Faverdin, P., Peyraud J. L. (2007) Composition of milk fat from cows selected for milk fat globule size and offered either fresh pasture or a corn silage-based diet. Journal of Dairy Science 90, 1: 392-403.

Cunnane, S. (2007) Docosahexaenoic acid and human brain evolution: missing the forest for the trees. Comments by Cunnane. British Journal of Nutrition 97: 1021-1022.

Epstein, S. (1996) Unlabeled milk from cows treated with biosynthetic growth hormones: a case of regulatory abdication. International Journal of Health Services 26, 1: 173-185.

Fewtrell, M.S., Morley, R., Abbott, R.A., Singhal, A., Isaacs, E.B., Stephenson, T., MacFadyen, U., Lucas, A. (2002) Double-blind, randomized trial of long-chain polyunsaturated fatty acid supplementation in formula fed to preterm infants. Pediatrics 110, 1Pt1: 73-82.

Follett, J., Ishii, K.D., Heinig, M.J. (2003) The role of long-chain fatty acids in infant health: helping families make informed decisions about DHA. Davis, CA: University of California Davis Human Lactation Center.

Gibson, R.A., Makrides, M. (2001) Long-chain polyunsaturated fatty acids in breast milk: are they essential? Advances in Experimental Medicine and Biology 501: 375-383.

Harris, W.S., Poston, W.C., Haddock, C.K. (2007) Tissue n-3 and n-6 fatty acids and risk for coronary heart disease events. Atherosclerosis 193, 1: 1-10.

Hautfenne A., Pocklington W.D., Wolfe J.P. (1987) Determination of hexane residues in oils: results of a collaborative study and the standardised method. Pure and Applied Chemistry 59, 11: 1561-1570.

Heird, W.C. (2001) The role of polyunsaturated fatty acids in term and preterm infants and breastfeeding mothers. Pediatric Clinics of North America 48, 1: 173-188.

Heird, W.C., Lapillonne, A. (2005) The role of essential fatty acids in development. Annual Review of Nutrition 25: 549-571.

Hoffman, D.R., Theuer, R.C., Castañeda, Y.S., Wheaton, D.H., Bosworth, R.G., O'Connor, A.R., Morale, S.E., Wiedemann, L.E., and Birch, E.E. (2004) Maturation of visual acuity is accelerated in breast-fed term infants fed baby food containing DHA-enriched egg yolk. Journal of Nutrition 134: 2307-2313

Hooper, L., Thompson, R.L., Harrison, R.A., Summerbell, C.D., Ness, A.R., Moore, H.J., Worthington, H.V., Higgins, J.P.T., Durrington, P.L., Capps, N.E., Riemersma, R.A., Ebrahim, S.B.J., Smith, G.D. (2006) Risks and benefits of omega 3 fats for mortality, cardiovascular disease, and cancer: systematic review. *British Medical Journal* 332,7544: 752-756.

Hørby, J.M., Hølmer, G., Lund, P., Hernell, O., Michaelsen, K.F. (1998) Effect of formula supplemented with docosahexaenoic acid and gamma-linolenic acid on fatty acid status and visual acuity in term infants. *Journal of Pediatric Gastroenterology and Nutrition* 26, 4: 412–421.

Innis, S. (2003) Perinatal biochemistry and physiology of long-chain polyunsaturated fatty acids. *Journal of Pediatrics* 143, 4: S1-S8.

Infact Canada. Action alert: Similac Advance. June 21, 2004. Available online: http://www.infactcanada.ca/action_alert_June_21_2004.htm. Last accessed on July 17, 2007.

Infact Canada. Fatty acids in infant development. Summer 1998 Newsletter. Available online at http://www.infactcanada.ca/fatty_acids_in_infant_developmen.htm. Last accessed on July 17, 2007.

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.

International Baby Food Action Network, “What is the International Code?” Available online at http://www.ibfan.org/site2005/Pages/article.php?art_id=51&iui=1. Last accessed on July 17, 2007.

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.l

Lapillonne, A., Picaud, J.C., Chirouze, V., Goudable, J., Reygobellet, B., Claris, O., Salle, B.L. (2000) The use of low-EPA fish oil for long-chain polyunsaturated fatty acid supplementation of preterm infants. *Pediatric Research* 48, 6: 835–841.

Lucas, A., Morley, R. 1999. Efficacy and safety of long-chain polyunsaturated fatty acid supplementation of infant-formula milk: a randomised trial. *Lancet* 354: 1948–1954.

Marlowe, I.T., Giddings, T.J., Richardson, S.J., Stentiford, A. (1991) U.K. industry and ozone pollution from volatile organic compound emissions. II. Update to October 1991. Warres Spring Laboratory. The Environmental Technology Executive Agency of the Department of Trade and Industry, London. Report 878 (PA).

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. Available online at <http://www.fda.gov/ohrms/dockets/dailys/00/mar00/030900/rpt0003.pdf>. Last accessed on July 17, 2007.

Martek Biosciences Corporation. Martek and Dean Foods Company team up to expand products available with DHA. Press release, March 9, 2007. Available online at <http://investors.martek.com/phoenix.zhtml?c=116214&p=irol-newsArticle&ID=972456&highlight=>. Last accessed on January 16, 2008.

Martek Biosciences Corporation. Martek's life'sDHA(TM) featured in Stremicks Heritage Foods(TM) organic milk enriched with omega-3 DHA. Press release, June 20, 2007. Available online at http://newsroom.martek.com/index.php?s=press_releases&item=245&printable. Last accessed on July 17, 2007.

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.

McNamara, R.K., Chang-Gyu, H., Jandacek, R., Rider, T., Tso, P., Stanford, K.E., Richtand, N.M. (2007) Selective deficits in the omega-3 fatty acid docosahexaenoic acid in the postmortem orbitofrontal cortex of patients with major depressive disorder. *Biological Psychiatry* 62, 1: 17–24.

MacLean, C.H., Issa, A.M., Newberry, S.J., Mojica, W.A., Morton, S.C., Garland, R.H., Hilton, L.G., Traina, S.B., Shekelle, P.G. (2005) Effects of omega-3 fatty acids on cognitive function with aging, dementia, and neurological diseases. Agency for Healthcare Research and Quality, Evidence Report no. 114. Available online at <http://www.ahrq.gov/clinic/epcsums/o3cognsum.htm>. Last accessed on November 2, 2007.

Medeiros, D.M., Hampton, M., Kurtzer, K., Parelman, M., Al-Tamimi, E., Drouillard, J.S. (2007) Feeding enriched omega-3 fatty acid beef to rats increases omega-3 fatty acid content of heart and liver membranes and decreases serum vascular cell adhesion molecule-1 and cholesterol levels. *Nutrition Research* 27, 5: 295–299.

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. Available online at <http://www.epa.gov/ttn/chief/ap42/ch09/final/c9s11-1.pdf>. Last accessed on July 17, 2007.

Mitchell, A.E., Hong, Y-J., Koh, E., Barrett, D.M., Bryant, D.E. Denison, R. F. and Kaffka, S. (2007) Ten-year comparison of the influences of organic and conventional crop management practices on the content of flavonoids in tomatoes. *Journal of Food and Agricultural Chemistry*, 55, 15: 6154-6159.

Monterey Bay Aquarium Seafood Watch Program. Available online at http://www.montereybayaquarium.org/cr/SeafoodWatch/web/sfw_search.aspx. Last accessed on September 27, 2007.

Muskiet, F.A.J., Fokkema, M.R., Schaafsma, A., Boersma, E.R., Crawford, M.A. (2004) Is docosahexaenoic acid (DHA) Essential? Lessons from DHA status regulation, our ancient diet, epidemiology and randomized controlled trials. *American Society for Nutritional Sciences* 134: 183–186.

National Research Council (1993) Pesticides in the diets of infants and children. National Academies Press. Executive summary available online http://www.nap.edu/openbook.php?record_id=2126&page=R1. Last accessed on October 31, 2007.

Natural Resources Defense Council. Mercury contamination in fish: a guide to staying healthy and fighting back. Available online at <http://www.nrdc.org/health/effects/mercury/guide.asp>. Last accessed on September 27, 2007.

O'Connor, D.L., Hall, R., Adamkin, D., Auestad, N., Castillo, M., Connor, W.E., Connor, S.L., Fitzgerald, K., Groh-Wargo, S., Hartmann, E.E., Jacobs, J., Janowsky, J., Lucas, A., Margeson, D., Mena, P., Neuringer, M., Nesin, M., Singer, L., Stephenson, T., Szabo, J., Zemon, V. (2001) Growth and development in preterm infants fed long-chain polyunsaturated fatty acids: a prospective, randomized controlled trial. *Pediatrics* 108, 2: 359–371.

Oken, E., Yi, N., Rifas-Shiman, S.L., Rich-Edwards, J.W., Olsen, S.F., Gillman, M.W. (2007) Diet during pregnancy and risk of preeclampsia or gestational hypertension. *Annals of Epidemiology*, in press, corrected proof. Available online 23 May 2007. Last accessed on July 17, 2007.

Oleskey, C., McCalley, M. A guide to biomonitoring of industrial chemicals. Center for Children's Health and the Environment. Available online at <http://www.childrenenvironment.org/pdfs/bmguide.pdf>. Last accessed on July 17, 2007.

Oskarsson, A., Palminger Hallén, I., Sundberg, J., Petersson Grawé, K. (1998) Risk assessment in relation to neonatal metal exposure. *Analyst* 123, 1: 19–23.

Parent's Choice Organic web site. Organic baby formula with lipids. Available online at <http://www.parentschoiceformula.com/?deptid=274>. Last accessed on July 17, 2007.

Rabinowitz, M., Leviton, A., Needleman, H. (1985) Lead in milk and infant blood: a dose-response model. *Archives of Environmental Health* 40, 5: 283–286.

Rapisarda, P., Calabretta, M.L., Romano, G., Intrigliolo, F. (2005) Nitrogen Metabolism Components as a Tool to Discriminate between Organic and Conventional Citrus Fruits. *Journal of Agricultural and Food Chemistry* 53, 7: 2664–2669.

Reynolds, A. (2001) Brain development and breastfeeding. *Pediatric Clinics of North America* 48, 1: 159–171.

Rosenthal, A., Pyle, D.L., Nirajan, K. (1996) Aqueous and enzymatic processes for edible oil extraction. *Enzyme and Microbial Technology* 19: 402–420.

- Salem N. J., H.-Y.K., 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.
- Schaefer, E.J., Bongard, V., Beiser, A.S., Lamon-Fava, S., Robins, S.R., Au, R., Tucker, K.L., Kyle, D.J., Wilson, P.W.F., Wolf, P.A. (2006) Plasma phosphatidylcholine docosahexaenoic acid content and risk of dementia and Alzheimers disease: the Framingham Study. *Archives of Neurology* 63: 1545–1550.
- Schroeder, F., Delahoy, J.E., Vidaurreta, I., Bargo, F., Gagliostro, G.A., Muller, L.D. (2003) Milk fatty acid composition of cows fed a total mixed ration or pasture plus concentrates replacing corn with fat. *Journal of Dairy Science* 86: 3237–3248.
- Scott, D.T., Janowsky, J.S., Carroll, R.E., Taylor, J.A., Auestad, N., Montalto, M.B. (1998) Formula supplementation with long-chain polyunsaturated fatty acids: are there developmental benefits? *Pediatrics* 102, 5: E59.
- Smithers, R. (2007) Organic milk may help babies beat allergies. The Guardian, November 9, 2007. Available online at <http://www.guardian.co.uk/society/2007/nov/09/health.children>. Last accessed on November 9, 2007.
- Simmer, K. (2000) Longchain polyunsaturated fatty acid supplementation in preterm infants. Cochrane Database Systems Review CD000375.
- Staten, C. EmergencyNet News Service. (1992) Explosions rip Mexican city, 200 dead, 600 injured. Available on Lexis-Nexis. Accessed on June 13, 2007.
- Theobald, H.E., Goodall, A.H., Sattar, N., Talbot, D.C.S., Chowienczyk, P.J., Sanders, T.A.B. (2007) Low-dose docosahexaenoic acid lowers diastolic blood pressure in middle-aged men and women. *Journal of Nutrition* 137: 973–978.
- Uauy, R., Mena, P., Wegher, B., Nieto, S., Salem, N., Jr. (2000) Long chain polyunsaturated fatty acid formation in neonates: effect of gestational age and intrauterine growth. *Pediatric Research* 47: 127–135.
- Uauy, R., Hoffman, D.R., Mena, P., Llanos, A., Birch, E.E. (2003) Term infant studies of DHA and ARA supplementation on neurodevelopment: results of randomized controlled trials. *The Journal of Pediatrics* 143, 4: S17-S25.
- 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. Last accessed on July 17, 2007.
- United States Department of Agriculture, Agricultural Research Service, Nutrient Data Laboratory web site. Available online at <http://www.nal.usda.gov/fnic/foodcomp/search/>. Last accessed on September 27, 2007.
- United States Department of Health and Human Services. Agency for Toxic Substances and Disease Registry. Available online at <http://www.atsdr.cdc.gov/tfacts113.html>. Last accessed on July 17, 2007.
- United States Department of Health and Human Services, Centers for Disease Control and Prevention. Breastfeeding practices—results from the national immunization survey. Available online at http://www.cdc.gov/breastfeeding/data/NIS_data/data_2004.htm. Last accessed on September 27, 2007.
- United States Environmental Protection Agency, Technology Transfers web site, Air Toxics web site. Hazard summary, hexane. Created April 1992, revised 2000. Available online at <http://www.epa.gov/ttn/atw/hlthef/hexane.html>. Last accessed on July 17, 2007.
- United States Environmental Protection Agency, Technology Transfers web site, Air Toxics web site. The original list of hazardous air pollutants. Available online at <http://www.epa.gov/ttn/atw/orig189.html>. Last accessed on July 17, 2007.
- United States Environmental Protection Agency. Fact sheet: final air toxics rule for solvent extraction in vegetable oil production. April 3, 2001. Available online at: http://www.epa.gov/ttn/oarpg/t3/fact_sheets/vegoil_fs.pdf. Last accessed on July 17, 2007.
- United States Food and Drug Administration. GRAS Notice 000041. Available online at <http://www.cfsan.fda.gov/~rdb/opa-g041.html>. Last accessed on July 17, 2007.

United States Food and Drug Administration, Center for Food Safety and Applied Nutrition. Infant formula. Available online at <http://www.cfsan.fda.gov/~dms/inf-toc.html>. Last accessed on July 17, 2007.

United States Food and Drug Administration, CFSAN Office of Nutritional Products, Labeling and Dietary Supplements. What is the evidence that addition of DHA and ARA is beneficial? July 2002. Available online at <http://www.cfsan.fda.gov/%7Edms/qa-inf17.html>. Last accessed on July 17, 2007.

United States Occupational Safety and Hazards Office. Occupational safety and health guideline for n-hexane. Available online at <http://www.osha.gov/SLTC/healthguidelines/n-hexane/recognition.html>. Last accessed on July 17, 2007.

United States Patent Office. Patent 5,374,657, David J. Kyle, Martek Biosciences Corporation.

Walker M. 2001. Selling out mothers and babies: marketing of breast milk substitutes in the USA. Weston-Price Foundation, Weston, MA.

World Health Organization and Food and Agriculture Organization of the United Nations (2004) Enterobacter sakazakii and other microorganisms in powdered infant formula. Microbiological Risk Assessment Series 6. Available online at <http://www.fao.org/docrep/007/y5502e/y5502e00.HTM>. Last accessed on October 22, 2007.

Ziegler, E.E. (2006) Growth of breast-fed and formula-fed infants. Nestle Nutrition Workshop Series, Paediatric Programme 58: 51–9; discussion 59–63.

Endnotes

1 Quoted in 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. Source of the quote: Martek Biosciences Corporation, Investment Thesis 1996.

2 Haynes, Suzanne (2005) National Breastfeeding Awareness Campaign results: Babies were born to be breastfed! Available online at http://www.4women.gov/breastfeeding/campaign_results.pdf. Last accessed on September 6, 2007.

3 For references for the outcomes mentioned, see American Academy of Pediatrics (2005) Breastfeeding and the use of human milk. *Pediatrics* 115, 2: 496–506.

4 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. Agency for Healthcare Research and Quality, Rockville, MD.

5 Under sections 201(s) and 409 of the Federal Food, Drug and Cosmetic Act, and FDA's implementing 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. Available online at <http://www.cfsan.fda.gov/~dms/grasguid.html>. Last accessed on July 17, 2007.

6 United States Food and Drug Administration. GRAS Notice 000041. Available online at <http://www.cfsan.fda.gov/~rdb/opa-g041.html>. Last accessed on July 17, 2007.

7 Vitamins and minerals qualify for use in organic foods under the 205.605(b)(19) allowance of nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods.

8 7 CFR Part 205 National Organic Program Final Rule, Section 205.270(c)(2).

9 United States Food and Drug Administration. GRAS Notice 000041. Available online at <http://www.cfsan.fda.gov/~rdb/opa-g041.html>. Last accessed on July 17, 2007.

10 Associated Press, Release of solvent caused explosion, report says. April 9, 2003. Available on Lexis-Nexis. Accessed on June 13, 2007.

11 United States Environmental Protection Agency, Technology Transfers web site, Air Toxics web site. The original list of hazardous air pollutants. Available online at <http://www.epa.gov/ttn/atw/orig189.html>. Last accessed on July 17, 2007. Note: EPA is required to control 188 hazardous air pollutants.

12 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>. Last accessed on July 17, 2007.

13 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>. Last accessed on July 17, 2007.

14 Salem N. J., H.-Y.K, 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.

15 Reynolds, A. (2001) Brain development and breastfeeding. *Pediatric Clinics of North America* 48, 1: 159–171.

- 16 Innis, S. (2003) Perinatal biochemistry and physiology of long-chain polyunsaturated fatty acids. *The Journal of Pediatrics* 143, 4: S1–S8
- 17 Cunnane, S. (2007) Docosahexaenoic acid and human brain evolution: missing the forest for the trees. Comments by Cunnane. *British Journal of Nutrition* 97: 1021–1022. See also Muskiet, F.A.J., Fokkema, M.R., Schaafsma, A., Boersma, E.R., Crawford, M.A. (2004) Is docosahexaenoic acid (DHA) essential? Lessons from DHA status regulation, our ancient diet, epidemiology and randomized controlled trials. *American Society for Nutritional Sciences* 134: 183–186.
- 18 Scientists write: “We conclude that supplementing preterm infants with low-eicosapentaenoic fish oil is effective in improving DHA status, but results in worsening of n-6 fatty acid status. We speculate that preterm infants may require a dietary supply of arachidonic acid as well as DHA if the same fatty acid status as that of breast-fed infants is to be achieved.” Lapillonne, A., Picaud, J.C., Chirouze, V., Goudable, J., Reygrobelle, B., Claris, O., Salle, B.L. (2000) The use of low-EPA fish oil for long-chain polyunsaturated fatty acid supplementation of preterm infants. *Pediatric Research* 48, 6: 835–841.
- 19 Innis, S. (2003) Perinatal biochemistry and physiology of long-chain polyunsaturated fatty acids. *Journal of Pediatrics* 143, 4: S1–S8.
- 20 One hypothesis is that algal sources of DHA are not carried the same way on the triglyceride molecule as the DHA found in human milk, and therefore do not confer the same benefits as DHA from breast milk. See Follett, J., Ishii, K.D., Heinig, M.J. 2003. The role of long-chain fatty acids in infant health. Helping families make informed decisions about DHA. University of California, Davis, Human Lactation Center, Davis, CA.
- 21 U.S. Patent Office. Patent 5,374,657 by David J. Kyle, Martek Biosciences Corporation.
- 22 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. Section 5.1.3. Available online at <http://www.fda.gov/ohrms/dockets/dailys/00/mar00/030900/rpt0003.pdf>. Last accessed on July 17, 2007.
- 23 Martek has patented the process for obtaining DHASCO and ARASCO from algae and fungus. They described the process in both their patent application, which is now on file with the U.S. Patent Office, and in their petition to the FDA for Generally Recognized As Safe Status, which is now available from the FDA web site. Both documents list the use of hexane as the method for extraction. See U.S. Patent Office. Patent 5,374,657 by David J. Kyle, Martek Biosciences Corporation, and 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. Section 5.1.3. Available online at <http://www.fda.gov/ohrms/dockets/dailys/00/mar00/030900/rpt0003.pdf>. Last accessed on July 17, 2007.
- 24 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. Section 5.1.3. Available online at <http://www.fda.gov/ohrms/dockets/dailys/00/mar00/030900/rpt0003.pdf>. Last accessed on July 17, 2007.
- 25 U.S. Patent Office. Patent 5,374,657 by David J. Kyle, Martek Biosciences Corporation.
- 26 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. Section 5.1.3. Available online at <http://www.fda.gov/ohrms/dockets/dailys/00/mar00/030900/rpt0003.pdf>. Last accessed on July 17, 2007.
- 27 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. Available online at <http://www.fda.gov/ohrms/dockets/dailys/00/mar00/030900/rpt0003.pdf>. Last accessed on July 17, 2007.
- 28 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.

29 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. Available online at <http://www.fda.gov/ohrms/dockets/dailys/00/mar00/030900/rpt0003.pdf>. Last accessed on July 17, 2007.

30 In detailed descriptions of several of their DHA patents, Martek writes that “any microorganism which produces enhanced levels of oil containing DHA is considered to be within the scope of this invention,” including any specific type of microorganism, such as “wild strains, mutants or recombinant_types” (Patent # 5,492,938 and patent 5,407,957). “Recombinant types” refers to genetically engineered microorganisms. At least three patents mention genetically engineered microorganisms for the production of DHA oils (U.S. Patent Office, patents #5,492,938, #5,407,957, and #5,374,657). These patent descriptions all suggest that Martek either has succeeded in genetically engineering the microorganisms or is actively pursuing it.

Patents also suggest that Martek is genetically engineering fungus for the increased production of ARA. Martek writes that newly identified strains of the fungus *Mortierella sect. schmuckeri* can be used to produce ARA with high productivity; these strains can be “obtained by genetically-engineering microorganisms to produce increased amounts of arachidonic acid” (U.S. Patent Office. Patent 6,749,849. William R. Barclay. June 15, 2004).

31 Martek Biosciences Corporation web site: <http://consumer.martek.com/aboutdha/aboutlifesdha/>.

32 Quoted in 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. Source of the quote: Martek Biosciences Corporation, Investment Thesis 1996.

33 Lucas A., Morley, R. 1999. Efficacy and safety of long-chain polyunsaturated fatty acid supplementation of infant-formula milk: a randomised trial. *Lancet* 354: 1948–1954.

34 United States Food and Drug Administration. GRAS Notice 000041. Available online at <http://www.cfsan.fda.gov/~rdb/opa-g041.html>. Last accessed on July 17, 2007.

35 Enfamil Lipil advertisement. See Appendix A.

36 Infact Canada. Action Alert: Similac Advance. June 21, 2004. Available online at http://www.infactcanada.ca/action_alert_June_21_2004.htm. Last accessed on July 17, 2007.

37 Enfamil Lipil advertisement. See Appendix A.

38 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, May 2004. Available online at <http://www.ibfan.org/english/pdfs/btr04.pdf>. Last accessed on July 17, 2007.

39 International Baby Food Action Network. What is the International Code? Available online at http://www.ibfan.org/site2005/Pages/article.php?art_id=51&iui=1. Last accessed on July 17, 2007.

40 Cited in 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. Page 37. Available online at <http://www.ibfan.org/english/pdfs/btr04.pdf>. Last accessed on July 17, 2007.

41 Walker, M. (2001) *Selling out mothers and babies: marketing of breast milk substitutes in the USA*. Weston-Price Foundation, Weston, MA.

42 Haynes, S. (2005) National Breastfeeding Awareness Campaign results: babies were born to be breastfed! Available online at http://www.4women.gov/breastfeeding/campaign_results.pdf. Last accessed on September 6, 2007.

- 43 Government Accountability Office. (2006) Breastfeeding: Some strategies used to market infant formula may discourage breastfeeding; state contracts should better protect against misuse of WIC name. GAO 06-282.
- 44 Kaufman, M., Lee, C. HHS toned down breastfeeding ads. *Washington Post*, August 31, 2007.
- 45 Kaufman, M., Lee, C. HHS toned down breastfeeding ads. *Washington Post*, August 31, 2007.
- 46 Nestle, M. (2006) What to eat. North Point Press. Page 452.
- 47 Committee on the Evaluation of Addition of Ingredients New to Infant Formula (2004) *Infant formula: evaluating the safety of new ingredients*. National Academies Press. Page 44.
- 48 Scott, D.T., Janowsky, J.S., Carroll, R.E., Taylor, J.A., Auestad, N., Montalto, M.B. (1998) Formula supplementation with long-chain polyunsaturated fatty acids: are there developmental benefits? *Pediatrics* 102, 5: E59.
- 49 Scott, D.T., Janowsky, J.S., Carroll, R.E., Taylor, J.A., Auestad, N., Montalto, M.B. (1998) Formula supplementation with long-chain polyunsaturated fatty acids: are there developmental benefits? *Pediatrics* 102, 5: E59. There were no statistically significant differences for either the Bayley Mental Scale or the Bayley Motor Scale, neither when the analysis was restricted to the three randomized formula groups nor when the analysis included all four groups. (The Bayley Scales of Infant Development are a well-standardized measure of development in infants and young children from 2 months to 30 months. They are considered to be the best measure in terms of reliability, validity, and general usefulness and provide valuable data regarding early mental and motor development. Butnik, S.M., Oster, G.D., Gabel, S. (1986) *Understanding psychological testing in children: a guide for health professionals*. Springer.)

However, the DHA formula group had significantly lower scores on two of the MacArthur scales: the DHA group scored lower than the nonrandomized human milk comparison group on the Vocabulary Comprehension Scale, and the DHA group scored lower than the randomized control formula group on the Vocabulary Production Scale. (The MacArthur Scale is a “parent-report instrument that evaluates early word production, language comprehension, and gestural communication.” [Scott et al. 1998]).

Moreover, additional analyses both in the formula groups and in the human milk comparison group “found significant negative correlations between DHA levels and vocabulary outcomes.”

- 50 Scott, D.T., Janowsky, J.S., Carroll, R.E., Taylor, J.A., Auestad, N., Montalto, M.B. (1998) Formula supplementation with long-chain polyunsaturated fatty acids: are there developmental benefits? *Pediatrics* 102, 5: E59.

- 51 Personal communication, Dr. Jimi Francis, Allie M. Lee Laboratory, University of Nevada–Reno.

- 52 Quoted in 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.

- 53 Chen, A., Rogan, W.J. (2004) Breastfeeding and the risk of postneonatal death in the United States. *Pediatrics* 113: 435–439.

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

- 55 For references for the outcomes mentioned, see American Academy of Pediatrics (2005) Breastfeeding and the use of human milk. *Pediatrics* 115, 2: 496–506.

- 56 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. Agency for Healthcare Research and Quality, Rockville, MD.

57 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. Agency for Healthcare Research and Quality, Rockville, MD.

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

59 The Centers for Disease Control and Prevention, Department of Health and Human Services. Breastfeeding practices: results from the National Immunization Survey." Available online at http://www.cdc.gov/breastfeeding/data/NIS_data/2004.htm. Last accessed on September 27, 2007.

60 Ethical concerns regarding testing of infant formula are beyond the scope of this report, but important to mention as well. Infants who are selected to receive infant formula with novel ingredients may be put at unnecessary risk. They consume novel ingredients in quantities that are very large in proportion to their body weight. Moreover, they are unable to give consent. As members of one of the most vulnerable segments of our population, they should be given greater consideration when it comes to testing foods.

61 Infact Canada. Fatty acids in infant development. Summer 1998 Newsletter. Available online at http://www.infact-canada.ca/fatty_acids_in_infant_developmen.htm. Last accessed on July 17, 2007.

62 Under sections 201(s) and 409 of the Federal Food, Drug and Cosmetic Act, and FDA's implementing 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. Available online at <http://www.cfsan.fda.gov/~dms/grasguid.html>. Last accessed on July 17, 2007.

63 United States Food and Drug Administration, Center for Food Safety and Applied Nutrition. Available online at <http://www.cfsan.fda.gov/~dms/inf-toc.html>. Last accessed on July 17, 2007.

64 United States Food and Drug Administration. GRAS Notice 000041. Available online at <http://www.cfsan.fda.gov/~rdb/opa-g041.html>. Last accessed on July 17, 2007.

65 United States Food and Drug Administration. GRAS Notice 000041. Available online at <http://www.cfsan.fda.gov/~rdb/opa-g041.html>. Last accessed on July 17, 2007.

66 United States Food and Drug Administration. GRAS Notice 000041. Available online at <http://www.cfsan.fda.gov/~rdb/opa-g041.html>. Last accessed on July 17, 2007.

67 United States Food and Drug Administration. GRAS Notice 000041. Available online at <http://www.cfsan.fda.gov/~rdb/opa-g041.html>. Last accessed on July 17, 2007.

68 United States Food and Drug Administration, CFSAN Office of Nutritional Products, Labeling and Dietary Supplements. (2002) What is the evidence that addition of DHA and ARA is beneficial? Available online at <http://www.cfsan.fda.gov/~/Edms/qa-inf17.html>. Last accessed on July 17, 2007.

69 Canadian Broadcasting Corporation. The secret life of Dr. Chandra." From *The National*, January 30, 2006. Reported by Chris O'Neill-Yates and produced by Lynn Burgess. Available online at <http://www.cbc.ca/national/news/chandra/>. Last accessed on January 16, 2008.

70 "Nonhuman primate studies of polyunsaturated fatty acids, including DHA, are limited." Committee on the Evaluation of Addition of Ingredients New to Infant Formula (2004) *Infant Formula: Evaluating the Safety of New Ingredients*. National Academies Press. Page 80. Available online at <http://www.nap.edu/books/0309091500/html/>. Last accessed on July 17, 2007.

71 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. Section 7.5.9. Available online at <http://www.fda.gov/ohrms/dockets/dailys/00/mar00/030900/rpt0003.pdf>. Last accessed on January 16, 2008.

72 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. Section 7.5.9. Available online at <http://www.fda.gov/ohrms/docs/dailys/00/mar00/030900/rpt0003.pdf>. Last accessed on January 16, 2008.

73 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. Section 7.5.9. Available online at <http://www.fda.gov/ohrms/docs/dailys/00/mar00/030900/rpt0003.pdf>. Last accessed on January 16, 2008.

74 Australia New Zealand Food Authority. P93 Review of Infant Formula. Supplementary Final Assessment Report. March 13, 2002. Available online at [http://www.foodstandards.gov.au/_srcfiles/P93_completeFinalAssRep\(supplement\).pdf#search=%20Crypthecodinium%20%22](http://www.foodstandards.gov.au/_srcfiles/P93_completeFinalAssRep(supplement).pdf#search=%20Crypthecodinium%20%22). Last accessed on July 17, 2007.

75 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. Section 7.5.9. Available online at <http://www.fda.gov/ohrms/docs/dailys/00/mar00/030900/rpt0003.pdf>. Last accessed on January 16, 2008.

76 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. Section 7.5.9. Available online at <http://www.fda.gov/ohrms/docs/dailys/00/mar00/030900/rpt0003.pdf>. Last accessed on January 16, 2008.

77 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. Section 7.5.9. Available online at <http://www.fda.gov/ohrms/docs/dailys/00/mar00/030900/rpt0003.pdf>. Last accessed on January 16, 2008.

78 Committee on the Evaluation of Addition of Ingredients New to Infant Formula (2004) *Infant Formula: Evaluating the Safety of New Ingredients*. National Academies Press.

page 80. Available online at <http://www.nap.edu/books/0309091500/html/>. Last accessed on July 17, 2007.

79 Personal communication, Marsha Walker.

80 Personal communication, Dr. Jimi Francis.

81 Committee on the Evaluation of Addition of Ingredients New to Infant Formula (2004) *Infant formula: evaluating the safety of new ingredients*. National Academies Press. Page 92. Available online at <http://www.nap.edu/books/0309091500/html/>. Last accessed on July 17, 2007.

82 Martek Biosciences Corporation. Life'sDHA frequently asked questions. <http://consumer.martek.com/infants/faqs/>. Last accessed on January 16, 2008.

83 Personal Communication, Dr. Jimi Francis, November 1, 2007.

84 Committee on the Evaluation of Addition of Ingredients New to Infant Formula (2004) *infant formula: evaluating the safety of new ingredients*. National Academies Press.

page 13. Available online at <http://www.nap.edu/books/0309091500/html/>. Last accessed on July 17, 2007.

85 Committee on the Evaluation of Addition of Ingredients New to Infant Formula (2004) *Infant formula: evaluating the safety of new ingredients*. National Academies Press.

page 13. Available online at <http://www.nap.edu/books/0309091500/html/>. Last accessed on July 17, 2007.

86 Parent's Choice Organic web site. Organic baby formula with lipids. Available online at <http://www.parentschoiceformula.com/?deptid=274>. Last accessed on July 17, 2007.

- 87 Mead Johnson. Available online at <http://www.enfamil.com/app/iwp/FormulaFinder.do?dm=enf&id=-8798>. Last accessed on January 16, 2008.
- 88 Similac web site for Similac Alimentum Hypoallergenic formula. Available online at <http://welcomeaddition.com/product8.aspx>. Last accessed on January 16, 2008.
- 89 As quoted in Brady, M. Protecting a mother's right to independent information on infant feeding. Presented at NHS Wales/SureStart event in Cardiff for National Breastfeeding Awareness Week, 2007. Available online at <http://www.babymilkaction.org/resources/nbaw07.html>. Last accessed on July 23, 2007.
- 90 Adamkin, D.H. (2007) Controversies in neonatal nutrition: docosahexanoic acid (DHA) and nucleotides. *Journal of Perinatology* 27, Suppl 1: S79–82.
- 91 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.
- 92 Committee on the Evaluation of Addition of Ingredients New to Infant Formula (2004) *Infant formula: evaluating the safety of new ingredients*. National Academies Press. Page 49. Available online at <http://www.nap.edu/books/0309091500/html/>. Last accessed on July 17, 2007.
- 93 McCann and Ames point out that possible explanations include “inadequate supplementation of DHA in formulas, poor study quality, the ability of term infants fed unsupplemented formulas to synthesize their own DHA, an absence of cognitive deficits when differences in brain concentrations of DHA are small due to brain plasticity (i.e., the ability of the brain to adapt), or the inability of performance tests to detect subtle differences in performance that result from relatively small differences in brain concentrations of DHA.” 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.
- 94 Hotz, R.L. Most science studies appear to be tainted by sloppy analysis. *Wall Street Journal*, September 14, 2007.
- 95 Heird, W.C., Lapillonne, A. (2005) The role of essential fatty acids in development. *Annual Review of Nutrition* 25: 549–571.
- 96 Simmer, K. (2000) Longchain polyunsaturated fatty acid supplementation in preterm infants. *Cochrane Database Systems Review* CD000375.
- 97 As cited in Simmer, K. (2000) Longchain polyunsaturated fatty acid supplementation in preterm infants. *Cochrane Database Systems Review* CD000375: Uauy et al. 1990, Birch et al. 1992, Hoffman and Uauy 1992, Uauy et al. 1994.
- 98 As cited in Simmer, K. (2004) Longchain polyunsaturated fatty acid supplementation in preterm infants. *Cochrane Database Systems Review* CD000375: Carlson et al. 1991, Carlson et al. 1992, Carlson et al. 1993, Werkman and Carlson 1996.
- 99 As cited in Simmer, K. (2000) Longchain polyunsaturated fatty acid supplementation in preterm infants. *Cochrane Database Systems Review* CD000375: the Mead Johnson study, Hansen et al. 1997.
- 100 As cited in Simmer, K. (2000) Longchain polyunsaturated fatty acid supplementation in preterm infants. *Cochrane Database Systems Review* CD000375: Clandinin et al. 1997.
- 101 As cited in Simmer, K. (2000) Longchain polyunsaturated fatty acid supplementation in preterm infants. *Cochrane Database Systems Review* CD000375: Vanderhoof et al. 1997.
- 102 Simmer, K. (2000) Longchain polyunsaturated fatty acid supplementation for preterm infants. *Cochrane Systems Database Review* CD000375.

- 103 Auestad, N., Halter, R., Hall, R.T., Blatter, M., Bogle, M.L., Burks, W., Erickson, J.R., Fitzgerald, K.M., Dobson, V., Innis, S.M., Singer, L.T., Montalto, M.B., Jacobs, J.R., Qiu, W., Bornstein, M.H. (2001) Growth and development in term infants fed long-chain polyunsaturated fatty acids: a double-masked, randomized, parallel, prospective, multivariate study. *Pediatrics* 108, 2: 372–881.
- 104 Gibson, R.A., Makrides, M. (2001) Long-chain polyunsaturated fatty acids in breast milk: are they essential? *Advances in Experimental Medicine and Biology* 501: 375–383.
- 105 Auestad, N., Scott, D.T., Janowsky, J.S., Jacobsen, C., Carroll, R.E., Montalto, M.B., Halter, R., Qiu, W., Jacobs, J.R., Connor, W.E., Connor, S.L., Taylor, J.A., Neuringer, M., Fitzgerald, K.M., Hall, R.T. (2003) Visual, cognitive, and language assessments at 39 months: a follow-up study of children fed formulas containing long-chain polyunsaturated fatty acids to 1 year of age. *Pediatrics* 112, 3Pt1: 177–183.
- 106 (0.3 wt%)
- 107 (0.3 wt%)
- 108 Hørby, J.M., Hølmer, G., Lund, P., Hernell, O., Michaelsen, K.F. (1998) Effect of formula supplemented with docosahexaenoic acid and gamma-linolenic acid on fatty acid status and visual acuity in term infants. *Journal of Pediatric Gastroenterology and Nutrition* 26, 4: 412–421.
- 109 Fewtrell, M.S., Morley, R., Abbott, R.A., Singhal, A., Isaacs, E.B., Stephenson, T., MacFadyen, U., Lucas, A. (2002) Double-blind, randomized trial of long-chain polyunsaturated fatty acid supplementation in formula fed to preterm infants. *Pediatrics* 110, 1Pt1: 73–82.
- 110 Birch, E.E., Garfield, S., Castañeda, Y., Hughbanks-Wheaton, D., Uauy, R., Hoffman, D. (2007) Visual acuity and cognitive outcomes at 4 years of age in a double-blind, randomized trial of long-chain polyunsaturated fatty acid-supplemented infant formula. *Early Human Development* 83, 5: 279–284.
- 111 Nutrient data from the Nutrient Data Laboratory, Agricultural Research Service, United States Department of Agriculture. Available online at <http://www.nal.usda.gov/fnic/foodcomp/search/index.html>. Last accessed on September 27, 2007.
- Mercury contamination level data from Natural Resources Defense Council. Mercury contamination in fish: a guide to staying healthy and fighting back. Available online at <http://www.nrdc.org/health/effects/mercury/guide.asp>. Last accessed on September 27, 2007.
- Overfishing data from the Monterey Bay Aquarium Seafood Watch program. Available online at http://www.montereybayaquarium.org/cr/SeafoodWatch/web/swf_search.aspx. Last accessed on September 27, 2007.
- 112 Brown, Craig. Take omega-3 during pregnancy, EU says. *The Scotsman*, August 29, 2007.
- 113 Collected by Marsha Walker. From <http://www.naba-breastfeeding.org/images/Recalls.pdf>.
- 114 World Health Organization and Food and Agriculture Organization of the United Nations (2004) *Enterobacter sakazakii and other microorganisms in powdered infant formula*. Microbiological Risk Assessment Series 6. Available online at <http://www.fao.org/docrep/007/y5502e/y5502e00.HTM>. Last accessed on October 22, 2007.
- 115 van Acker et al. (2001) Outbreak of necrotizing enterocolitis associated with *Enterobacter sakazakii* in powdered milk formula. *Journal of Clinical Microbiology* 39: 293–297.
- 116 Taylor, C. (2002) Health professionals letter on *Enterobacter sakazakii* infections associated with use of powdered (dry) infant formulas in neonatal intensive care units. Available online at <http://www.cfsan.fda.gov/~dms/inf-ltr3.html>, Last accessed on January 16, 2008.

- 117 Environmental Working Group. (2007) Toxic plastics chemical in infant formula. Available online at <http://www.ewg.org/reports/bpaformula>. Last accessed on January 16, 2008.
- 118 Oskarsson, A., Palminger Hallén, I., Sundberg, J., Petersson Grawé, K. (1998) Risk assessment in relation to neonatal metal exposure. *Analyst* 123, 1: 19–23.
- 119 Natural Resources Defense Council (2001) Healthy milk, healthy baby. Available online at <http://www.nrdc.org/breast-milk/chem13.asp#note#note>. Last accessed on August 23, 2007.
- 120 Rabinowitz, M., Leviton, A., Needleman, H. (1985) Lead in milk and infant blood: a dose-response model. *Archives of Environmental Health* 40, 5: 283–286.
- 121 Damgaard, I.N., Skakkebaek, N.E., Toppari, J., Virtanen, H.E., Shen HeQing Schramm, K.W., Petersen, J.H., Jensen, T.K., Main, K.M. (2006) Persistent pesticides in human breast milk and cryptorchidism. *Environmental Health Perspectives* 114, 7: 1133–1138.
- 122 Food and Drug Administration (2003) Pesticide Program residue monitoring 2003. Available online at <http://www.cfsan.fda.gov/~dms/pes03rep.html>. Last accessed on August 23, 2007.
- 123 Department of Human and Health Services, Agency for Toxic Substances and Disease Registry. ToxFAQs for malathion. September 2003. Available online at <http://www.atsdr.cdc.gov/tfacts154.html>. Last accessed on August 24, 2007.
- 124 Food and Drug Administration (2003) Pesticide Program residue monitoring 2003. Available online at <http://www.cfsan.fda.gov/~dms/pes03rep.html>. Last accessed on August 23, 2007.
- 125 Rist, L., Mueller, A., Barthel, C., Snijders, B., Jansen, M., Simoes-Wust, A.P., Huber, M., Kummeling, I., von Mandach, U., Steinhart H., Thijss, C. (2007) Influence of organic diet on the amount of conjugated linoleic acids in breast milk of lactating women in the Netherlands. *British Journal of Nutrition* 97, 4: 735–743.
- 126 As cited in Smither, R. (2007) Organic milk may help babies beat allergies. *The Guardian*, November 9, 2007. Available online <http://www.guardian.co.uk/society/2007/nov/09/health.children>. Last accessed on November 9, 2007.
- 127 Numerous studies have been published on this topic. Two examples:
- Rapisarda, P., Calabretta, M.L., Romano, G., Intrigliolo, F. (2005) Nitrogen metabolism components as a tool to discriminate between organic and conventional citrus fruits. *Journal of Agricultural and Food Chemistry* 53, 7: 2664–2669.
- Mitchell, A.E., Hong, Y.-J., Koh, E., Barrett, D.M., Bryant, D.E. Denison, R.F., Kaffka, S. (2007) Ten-year comparison of the influences of organic and conventional crop management practices on the content of flavonoids in tomatoes. *Journal of Food and Agricultural Chemistry*, published online June 23, 2007.
- 128 British Broadcasting Corporation. Organic Produce “Better for you.” October 29, 2007. Available online at <http://news.bbc.co.uk/2/hi/health/7067100.stm>. Last accessed on October 31, 2007.
- 129 National Research Council (1993) Pesticides in the diets of infants and children. National Academies Press. Executive summary available online http://www.nap.edu/openbook.php?record_id=2126&page=R1. Last accessed on October 31, 2007.
- 130 The Organic Center. FAQs on pesticides in milk. Available online http://www.organic-center.org/science.pest.php?action=view&report_id=79. Last accessed on October 31, 2007.
- 131 Epstein, S. (1996) Unlabeled milk from cows treated with biosynthetic growth hormones: a case of regulatory abdication. *International Journal of Health Services* 26, 1: 173–185.
- 132 Ziegler, E.E. (2006) Growth of breast-fed and formula-fed infants. *Nestle Nutrition Workshop Series, Paediatric Programme*. 58: 51–59; discussion 59–63.

- 133 Hautfenne A., Pocklington W.D., Wolfe J.P. (1987) Determination of hexane residues in oils: results of a collaborative study and the standardised method. *Pure and Applied Chemistry* 59, 11: 1561–1570.
- 134 United States Food and Drug Administration. GRAS Notice 000041. Available online at <http://www.cfsan.fda.gov/~rdb/opa-g041.html>. Last accessed on July 17, 2007.
- 135 Private correspondence, letter dated April 3, 2007, from William Bent, Compliance Officer, United States Department of Agriculture to David Cox of Lane, Alton and Horst, LLC.
- 136 Martek Biosciences Corporation. Form 10-K/A, filed with the Securities and Exchange Commission on May 8, 2007. Available online at <http://sec.edgar-online.com/2007/05/08/0000950133-07-002165/Section2.asp>. Last accessed on August 9, 2007.
- 137 For example, a review of 25 scientific studies, published in *Atherosclerosis* in July 2007, revealed that people experiencing coronary heart disease consistently had lower levels of long-chain omega-3 fatty acids, especially DHA, in their tissue. The authors of the review article conclude that long-chain omega-3 fatty acids are cardioprotective. Harris, W.S., Poston, W.C., Haddock, C.K. (2007) Tissue n-3 and n-6 fatty acids and risk for coronary heart disease events. *Atherosclerosis* 193, 1: 1–10. See also *Health effects of omega-3 fatty acids on cardiovascular disease*. Structured abstract. March 2004. Agency for Healthcare Research and Quality, Rockville, MD. Available online at <http://www.ahrq.gov/clinic/tp/o3cardtp.htm>. Last accessed on January 16, 2008.
- 138 Theobald, H.E., Goodall, A.H., Sattar, N., Talbot, D.C.S., Chowienczyk, P.J., Sanders, T.A.B. (2007) Low-dose docosahexaenoic acid lowers diastolic blood pressure in middle-aged men and women. *Journal of Nutrition* 137: 973–978.
- 139 MacLean, C.H., Issa, A.M., Newberry, S.J., Mojica, W.A., Morton, S.C., Garland, R.H., Hilton, L.G., Traina, S.B. and Shekelle, P.G. (2005) Effects of omega-3 fatty acids on cognitive function with aging, dementia, and neurological diseases. Agency for Healthcare Research and Quality, Evidence Report no. 114. Available online at <http://www.ahrq.gov/clinic/epcsums/o3cognsum.htm>. Last accessed on November 2, 2007.
- 140 American Heart Association. Available online.
- 141 Martek Biosciences Corporation. Press release, June 20, 2007. Martek's Life'sDHA(TM) featured in Stremicks Heritage Foods(TM) organic milk enriched with omega-3 DHA. Available online at http://newsroom.martek.com/index.php?s=press_releases&item=245&printable. Last accessed on July 17, 2007.
- 142 Horizon Organic web site; Martek Biosciences Corporation. Press release, June 20, 2007. Martek's Life'sDHA featured in Stremicks Heritage Foods organic milk enriched with omega-3 DHA. Available online at http://newsroom.martek.com/index.php?s=press_releases&item=245&printable. Last accessed on July 17, 2007.
- 143 United States Department of Agriculture, Agricultural Research Service, Nutrient Data Laboratory web site. Available online at <http://www.nal.usda.gov/fnic/foodcomp/search/>. Last accessed on July 17, 2007. A non-omega-3 egg contains 1.9 mg of DHA, a 100 gram piece of tilapia contains 13 mg, 100 grams of canned tuna contains 22 mg of DHA.
- 144 Ellis, K.A., Innocent, G., Grove-White, D., Cripps, P., McLean, W.G., Howard, C.V., Mihm, M. (2006) Comparing the fatty acid composition of organic and conventional milk. *Journal of Dairy Science* 89: 1938–1950.
- 145 Schroeder, F., Delahoy, J.E., Vidaurreta, I., Bargo, F., Gagliostro, G.A., Muller, L.D. (2003) Milk fatty acid composition of cows fed a total mixed ration or pasture plus concentrates replacing corn with fat. *Journal of Dairy Science* 86: 3237–3248.
- 146 Couvreur, S. Hurtaud, C. Lopez, C. Delaby, L., Peyraud J. L. (2006) The linear relationship between the proportion of fresh grass in the cow diet, milk fatty acid composition, and butter properties. *Journal of Dairy Science* 89, 6: 1956–1969.
- 147 A 2007 study compared the fatty acid content of milk from cows fed a corn-based silage diet with the milk from cows grazed on pasture, and results showed that milk from the pastured cows contained higher levels of monounsaturated and polyun-

saturated fatty acids. Couvreur, S., Hurtaud, C., Marnet, P. G., Faverdin, P., Peyraud J. L. (2007) Composition of milk fat from cows selected for milk fat globule size and offered either fresh pasture or a corn silage-based diet. *Journal of Dairy Science* 90, 1: 392–403.

148 Couvreur, S. Hurtaud, C. Lopez, C. Delaby, L., Peyraud J. L. (2006) The linear relationship between the proportion of fresh grass in the cow diet, milk fatty acid composition, and butter properties. *Journal of Dairy Science* 89, 6: 1956–1969.

149 United States Environmental Protection Agency, Technology Transfers web site, Air Toxics web site. Hazard summary, hexane. Created April 1992, revised 2000. Available online at <http://www.epa.gov/ttn/atw/hlthef/hexane.html>. Last accessed on July 17, 2007.

150 United States Environmental Protection Agency, Office of Air Quality Planning and Standards Emission Factor and Inventory Group. Vegetable oil processing, final report. Emission Factor Documentation for AP-42, Section 9.11.1. November 1995.

151 Joint campaign Basel city (specialist laboratory) and Basel country. Vegetable oils / fatty acid composition, hexane residues, declaration, pesticides (organic culinary oils only). 2004. Available online at <http://www.labor.bs.ch/files/berichte/Report0424.pdf>. Last accessed on October 22, 2007.

152 United States Department of Human and Health Services, Agency for Toxic Substances and Disease Registry. ToxFAQs for *n*-hexane. Available online at <http://www.atsdr.cdc.gov/tfacts113.html>. Last accessed on July 17, 2007.

153 Oleskey, C., McCalley, M. A guide to biomonitoring of industrial chemicals. Center for Children's Health and the Environment. Available online at <http://www.childrenenvironment.org/pdfs/bmguide.pdf>. Last accessed on July 17, 2007.

154 Oleskey, C., McCalley, M. A guide to biomonitoring of industrial chemicals. Center for Children's Health and the Environment. Available online at <http://www.childrenenvironment.org/pdfs/bmguide.pdf>. Last accessed on July 17, 2007.

155 Oleskey, C., McCalley, M. A guide to biomonitoring of industrial chemicals. Center for Children's Health and the Environment. Available online at <http://www.childrenenvironment.org/pdfs/bmguide.pdf>. Last accessed on July 17, 2007.

156 United States Occupational Safety and Hazards Office. Occupational safety and health guideline for *n*-hexane. Available online at <http://www.osha.gov/SLTC/healthguidelines/n-hexane/recognition.html>. Last accessed on July 24, 2007.

157 United States Occupational Safety and Hazards Office. Occupational safety and health guideline for n-hexane. Available online at <http://www.osha.gov/SLTC/healthguidelines/n-hexane/recognition.html>. Last accessed on July 24, 2007.

158 Carelli, V., Franceschini, F., Venturi, S., Barboni, P., Savini, G., Barbieri, G., Pirro, E., La Morgia, C., Valentino, M. L., Zanardi, F., Violante, F.S., Mattioli, S. (2007) Grand Rounds: could occupational exposure to *n*-hexane and other solvents precipitate visual failure in Leber hereditary optic neuropathy? (Environmental Medicine). *Environmental Health Perspectives* 115, 1: 113–116.

159 United States Occupational Safety and Hazards Office. Occupational safety and health guideline for *n*-hexane. Available online at <http://www.osha.gov/SLTC/healthguidelines/n-hexane/recognition.html>. Last accessed on July 24, 2007.

160 Associated Press. Investigation into Sioux City plant explosion inconclusive Investigation into Sioux City plant explosion inconclusive. December 6, 2003. BC Cycle. Available on Lexis-Nexis.

161 Associated Press, Worldstream. Explosion claims second life in South Africa. July 12, 1999. Available on Lexis-Nexis.

162 Associated Press, International. Four dead in Italian olive oil factory blast. November 25, 2006. Available on Lexis-Nexis.

163 Staten, Clark. EmergencyNet News Service. Explosions rip Mexican city, 200 dead, 600 injured. 1992. Available on

Lexis-Nexis.

164 Associated Press, Malvern, Pennsylvania. Tanker truck explosion and fire critically injures two men. July 20, 2001. Available on Lexis-Nexis.

165 Associated Press. Release of solvent caused explosion, report says. April 9, 2003. Available on Lexis-Nexis. Last accessed on June 13, 2007.

166 United States Environmental Protection Agency, Technology Transfers web site, Air Toxics web site. The original list of hazardous air pollutants." Available online at <http://www.epa.gov/ttn/atw/orig189.html>. Last accessed on July 17, 2007. Note: EPA is required to control 188 hazardous air pollutants.

167 Marlowe, I.T., Giddings, T.J., Richardson, S.J., Stentiford, A. (1991) U.K. industry and ozone pollution from volatile organic compound emissions. II. Update to October 1991. Warres Spring Laboratory, The Environmental Technology Executive Agency of the Department of Trade and Industry, London. Report 878 (PA). Quoted in: Rosenthal, A., Pyle, D.L., Niranjan, K. (1996) Aqueous and enzymatic processes for edible oil extraction. *Enzyme and Microbial Technology* 19: 402–420.

168 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. Available online at <http://www.epa.gov/ttn/chief/ap42/ch09/final/c9s11-1.pdf>. Last accessed on July 17, 2007.

169 Associated Press. Release of solvent caused explosion, report says. April 9, 2003. Available on Lexis-Nexis. Accessed on June 13, 2007.

170 Private correspondence, letter dated February 14, 2007, from Jake van den Akker, Quality Assurance and International Program Specialist, Quality Assurance International to David Cox of Lane, Alton, and Horst, LLC.

171 Parents' Choice Gentle Infant Formula with Lipids. Available online at <http://www.parentschoiceformula.com/gentle-milk-formula.aspx>.

172 United States Environmental Protection Agency, Technology Transfers web site, Air Toxics web site. Hazard summary, hexane." Created April 1992, Revised 2000. Available online at <http://www.epa.gov/ttn/atw/hlthef/hexane.html>. Last accessed on July 17, 2007.

173 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. Section 7.5.9. Available online at <http://www.fda.gov/ohrms/dockets/dailys/00/mar00/030900/rpt0003.pdf>. Last accessed on July 17, 2007.

174 U.S. Patent Office. Patent 6,749,849. William R. Barclay. June 15, 2004.

175 Patent Application 5,374,657, December 1994. David J. Kyle, Martek Corporation.

176 Adamkin, D.H. (2007) Controversies in neonatal nutrition: docosahexaenoic acid (DHA) and nucleotides. *Journal of Perinatology* 27, Suppl 1: S79–82.

177 Simmer, K. (2001) Longchain polyunsaturated fatty acid supplementation in infants born at term. *Cochrane Database Systems Review* CD000375.

Wright, K., Coverston, C., Tiedman, M., Abegglen, J.A. (2006) Formula supplemented with docosahexaenoic acid (DHA) and arachidonic acid (ARA): a critical review of the research. *Journal for Specialists in Pediatric Nursing* 11: 100–112.

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

- 179 American Academy of Pediatrics (2005) Breastfeeding and the use of human milk. *Pediatrics* 115, 2: 496–506.
- 180 Chen, A., Rogan, W.J. (2004) Breastfeeding and the risk of postneonatal death in the United States. *Pediatrics* 113: 435–439.
- 181 American Academy of Pediatrics (2005) Breastfeeding and the use of human milk. *Pediatrics* 115, 2: 496–506.
- 182 Haynes, S. National Breastfeeding Awareness campaign results. Office on Women's Health of the U.S. Department of Human and Health Services. Available online at http://www.4women.gov/breastfeeding/campaign_results.pdf.
- 183 According to the Government Accountability Office, formula companies spent \$50 million on advertisements for infant formula, an increase of \$20 million from 2000.
- 184 FTC policy statement on deception. Appended to Clifffdale Associates, Inc., 103 FTC 11, 174 (1984).
- 185 Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.
- 186 201(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.
- 187 SEC. 402. [21 U.S.C. 342] A food shall be deemed to be adulterated— 1 (a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.
- 188 A food shall be deemed to be adulterated if it is a dietary supplement or contains a dietary ingredient that is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury
- 189 Sec 403. A food shall be deemed to be misbranded (a) False or misleading label. If (1) its labeling is false or misleading in any particular.
- 190 The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.
- 191 United States Food and Drug Administration. GRAS Notice 000041. Available online at <http://www.cfsan.fda.gov/~rdp/opa-g041.html>.
- 192 U.S. Department of Health and Human Services, Food and Drug Administration. Food labeling; warning and notice statements; labeling of juice products; proposed rule. *Federal Register*, Vol. 63, No. 79, 1998, p. 20487.

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