The Organic Watergate—White Paper

Connecting the Dots: Corporate Influence at the USDA's National Organic Program

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Overview

Why do we call it "The Organic Watergate"? Although not a constitutional crisis on par with what happened during the Nixon administration, the USDA's blatant disregard for the requirements laid out in the Organic Foods Production Act of 1990 (OFPA), and the intent of Congress, is illegal and has inappropriately favored

corporate agribusiness over the interests of ethical businesses, farmers and consumers.

We will leave it up to the reader to decide whether the cozy relationship between the USDA and agribusiness lobbyists, in relationship to the documentary evidence we will present, constitutes a "conspiracy" to change the working definition of the organic label.

When Congress passed OFPA, it set up an independent advisory panel, the National Organic Standards Board (NOSB), that, unlike other advisory boards, has statutory authority. Any synthetic input or ingredient used in organic food production must be reviewed and approved by the NOSB to assure that no chemicals that could pose a threat to human health or the environment are used in organic food production.

The NOSB also recommends policy and modifications to the regulations governing organic agriculture and food processing in the United States.

In part to placate concerns about handing over authority of the organic label to the federal government (it was previously a voluntary certification system), Congress specifically earmarked the majority of the 15 seats on the NOSB for organic farmers, consumers, scientists and environmentalists as a way to balance the power of commercial interests involved in organic food manufacturing, marketing and retail sales.

This white paper outlines long-term abuse of congressional intent by the USDA, which has stacked the board with agribusiness representatives, an illegal practice that has stretched over the past three administrations.

The investigation into the “Organic Watergate” was prompted by the approval of highly processed DHA and ARA oils from genetically mutated algae and soil fungus, petitioned by the $12 billion multinational corporation Royal DSM/Martek Biosciences Corporation.

The approval, by a narrow margin, shocked public interest groups that had opposed the petitions. Not a single public interest or consumer organization had favored the approval of Martek’s oils; yet the NOSB Chair, Tracy Miedema, who had aggressively championed Martek’s oils, served in a consumer slot – reserved by law for individuals who represent public interest or consumer organizations.

Miedema never, during her five-year term on the Board, represented a public interest organization. With the approval of Martek’s oils, championed by a “consumer” representative on the Board, it became clear that the corporate stacking of the Board leads to the erosion of the integrity of the organic label, with real repercussions for organic consumers, farmers, and the public interest.

It is not only the corporate stacking of the Board that favors agribusiness, but corporate involvement in technical reviews as well.

Since the NOSB, if properly constituted, represents a diverse cross-section of organic stakeholders, it is not intended to operate as a scientific panel. Therefore, OFPA specified that a technical advisory panel must provide the NOSB with a scientific review of petitioned synthetic materials. It is vitally important that the scientists performing these reviews provide complete and unbiased scientific analyses to the Board, as specified in the NOSB's Policy Manual.

Cornucopia's investigation into past technical reviews was prompted by the inadequacy and biases present in the technical review of Martek's DHA algal oil and ARA fungal oil petition. It led us to question whether past approvals by the Board were also based on faulty, biased and misleading technical reviews. Today, the identity of individuals involved in the technical reviews is secret, not part of the public record – a problem that Cornucopia is urging the Board to remedy.

In the past, technical reviews were generally carried out by multiple individuals who were identified.[1] What we found is that past technical reviews have generally been produced by corporate executives, consultants serving corporate agribusiness or closely aligned academics.

Many of these technical reviews have grossly downplayed health and environmental risks associated with petitioned synthetic materials.

The Fall 2011 meeting's approval of Martek's oils led Cornucopia staff to question whether other ingredients had, similar to the Martek oils, been inappropriately approved for use in organics by a corporate-influenced technical review and a corporate-stacked Board.

Since carrageenan was currently pending a sunset review, Cornucopia staff next examined this ingredient, approved for use in organics in 1995, which has long been controversial due to research showing it causes gastrointestinal inflammation. One type of carrageenan is listed by the World Health Organization's International Agency for Research on Cancer as a "possible human carcinogen."

Who would have thought, when members of the organic community lobbied Congress to set up a system to assure integrity in the organic industry, that we would find the National Organic Standards Board approving a food ingredient classified by the World Health Organization as a "possible carcinogen" in organic food?

[1] Technical reviews are now referred to as "TR's," but were called Technical Advisory Panel (TAP) in the past. OFPA refers to "Technical Advisory Panels."

Not only did the review process break down when carrageenan was first approved by the NOSB in the mid-1990s, it was flawed when it was re-reviewed five years after the organic regulations went into effect, at sunset. 100% of the public comments, at that time, were in support of its continued use in organics. All comments came from corporations producing carrageenan, agribusinesses using the ingredient and the Organic Trade Association.

And now, five years down the road, as carrageenan comes up for its second sunset review, the Handling Committee of the NOSB again unanimously approved it for relisting on the National List of Approved Substances.

This time, the Handling Committee came to the decision to re-approve carrageenan despite a newly created technical review, which did outline concerns with health and environmental impacts (although it should be noted that the TR inappropriately downplayed these concerns).

Cornucopia shared its analysis of research questioning the safety of carrageenan with the Organic Trade Association and with organic food processors currently using carrageenan in its products. We urged the organic industry to stand together in opposing the relisting of carrageenan, and remove carrageenan from organic foods.

Based on the need, The Cornucopia Institute will now become more intimately involved in providing independent oversight and resources to the NOSB, looking at all petitioned materials, past and present, to assure that all ingredients in food production and agricultural inputs are properly and legally reviewed.

Stacking the NOSB with Corporate Representatives

The law's definition of NOSB members

According to the Organic Foods Production Act of 1990, sec. 2119, the NOSB "shall be composed of 15 members, of which –

(1) four shall be individuals who own or operate an organic farming operation;
(2) two shall be individuals who own or operate an organic handling operation;
(3) one shall be an individual who owns or operates a retail establishment with significant trade in organic products;
(4) three shall be individuals with expertise in areas of environmental protection and resource conservation;
(5) three shall be individuals who represent public interest or consumer interest groups;

(6) one shall be an individual with expertise in the fields of toxicology, ecology or biochemistry, and;
(7) one shall be an individual who is a certifying agent as identified under section 2116"

Corporate NOSB appointments

Below are some past and present members of the NOSB who filled environmentalist, scientist, public interest and farmer slots despite not appearing to have the appropriate legally required qualifications to serve in one of those slots. These individuals share one thing in common: they were all employed by (or contracted/consulted with) agribusinesses during their term on the NOSB.

Jean Afterman – environmentalist slot. Afterman worked as vice president and general counsel for PurePak, Inc., a major corporate agribusiness. Afterman has an undergraduate degree in art history and a law degree from the San Francisco School of Law. It is unclear why Afterman was appointed as an environmentalist with no background in environmental science or environmental activism. While at PurePak, Afterman specialized in international market development.

Carmela Beck – farmer slot. Beck is a full-time employee at Driscoll's, which markets both conventional and organic berries. Beck manages the organic certification for Driscoll's farmers and suppliers, and does not own or operate an organic farm.

Gerald Davis – farmer slot. Davis did not own or operate an organic farm at the time of his appointment, but worked as an agronomist at California-based Grimmway Farms, one of the largest carrot producers in the world.

Kristina "Tina" Ellor – environmentalist slot. Ellor was a full-time employee at Phillip's Mushrooms during her term on the NOSB. Phillip's Mushrooms is primarily engaged in conventional mushroom production, with a portion of its business in organics.

William J. Friedman - environmentalist slot. Friedman is currently with the powerful Washington law firm of Covington and Burling. At the time of his appointment, he was a bureaucrat in the New Mexico state government.

Wendy Fulwider – farmer slot. Fulwider is a full-time employee at Organic Valley, a $700 million agribusiness cooperative. At the time of her appointment in 2009, she did not own or operate an organic farm.

Dan Giacomini – consumer/public interest slot. Giacomini did not represent a consumer interest group; rather, he was a nutritionist/feed consultant for the

livestock industry. When on the NOSB as a consumer representative, Giacomini was a feed consultant to Straus Dairy, one of the two prominent opponents of stricter pasture enforcement. Giacomini served as chair of the NOSB.

Katrina Heinze – scientist slot. Heinze, a full-time employee at General Mills, was originally appointed as a consumer/public interest representative. Her name was withdrawn from the consumer slot following public outcry over her appointment, and she was reappointed to a scientist slot.

Tracy Miedema – consumer/public interest slot. In her five years as a consumer representative on the NOSB, Miedema never worked for or represented a public interest organization. She worked for several different companies during her five-year term. According to her Linkedin profile, Miedema worked as an Associate Marketer at General Mills' Small Planet Foods division from 2001-2004, and as a National Sales and Marketing Manager at Stahlbush Island Farm from 2005 to 2010. According to its website, Stahlbush Island Farm grows produce on 5,000 acres, only one third of which is certified organic. She was appointed to a consumer slot in 2006. During her term on the NOSB, in 2010, Miedema became employed at Earthbound Farm, one of the largest organic produce growers and marketers in the country. Earthbound already had an employee on the NOSB, John Foster, so the company had two employees on the NOSB for over a year.

Kevin O'Rell – farmer slot. O'Rell was president of Horizon, a division of the $12 billion Dean Foods. O'Rell's company operated several corporate-owned organic dairies, so he might have technically qualified for one of the four slots reserved for individuals who "own or operate an organic farm" (although we doubt Congress had in mind the president of a vertically-integrated corporate agricultural producer). O'Rell was NOSB Chair in the middle of the debate around more aggressive pasture enforcement at the National Organic Program. At the time, Horizon owned and operated an 8,000-head "organic" dairy operation in Idaho, as well as a second corporate-owned facility with 500-600 cows in Maryland. Horizon was also buying milk from the Case Vander Eyk, Jr. dairy in Pixley, CA, with a capacity of 10,000 milking cows, on a feedlot with no pasture, which Dean Foods/Horizon included in their accounting of their "family farms." While O'Rell was on the Board, Cornucopia had filed legal complaints that were pending with the USDA alleging violation of the law on their dairies.

Disproportionate Corporate Representation

Some companies have had disproportionate representation on the Board. For example, General Mills and its Small Planet Foods division has had four employees serve on the Board.

Two Earthbound Farms employees served on the Board simultaneously (Tracy Miedema as a consumer/public interest representative and John Foster as a handler representative).

The following agribusinesses have had representatives appointed to the Board:

- Earthbound Farm (2 representatives have served, a handler and a consumer representative)
- General Mills (4 representatives have served, three handlers and a scientist)
- Dean Foods (farmer slot)
- Campbell Soup Company (handler slot)
- Grimmway Enterprises, Inc. (farmer slot)
- PurePak, Inc. (environmentalist slot)
- Campbell Soup Company (handler slot)
- Smucker's (handler slot)
- CROPP/Organic Valley (3 representatives, all appointed to a farmer slot)
- Purina Ralcorp (handler slot)
- Driscoll's (farmer slot)
- Phillips Mushrooms (environmentalist slot)

Fixing the NOSB

Congress established the National Organic Standards Board with the clear intention of creating a balanced array of citizens with diverse representations. The Board, according to OFPA, should consist of four farmers, two handlers, three environmentalists, three representatives of the public, a certifier, a retailer representative, and a scientist.

Such diverse representation of the organic community would work well to balance competing interests and corporate power, if the intent of Congress was respected. But since the NOSB's inception, both Republican and Democratic administrations have consistently abused the law and appointed corporate representatives to seats that were clearly intended for independent voices, as described above.

As of the last NOSB meeting, an employee of a $15 billion agribusiness, General Mills, held the scientist's slot. An employee of a $700+ million corporate agribusiness, Organic Valley, held one of the four farmer slots. And recently, USDA Secretary Vilsack appointed another corporate representative, Carmela Beck, to a farmer slot. These appointments, filling slots reserved for scientists and organic farmers with corporate representatives, lead to undue levels of corporate influence on the Board (already holding numerous other NOSB seats), which Congress clearly did not intend.

As a result, consumer organizations cannot count on the public interest representatives on the Board to vote in the public's interest. For example, at the Fall 2011 meeting, two of the three public interest representatives voted in favor of the Martek Biosciences Corporation petitions, despite overwhelming opposition from public interest groups.

Corporate Representatives Advising the NOSB with Technical Reviews

Technical Reviews: Shortcomings with the Martek DHA/ARA Technical Review at the Fall 2011 Meeting

Congress intended the National Organic Standards Board to be a citizen panel representing diverse stakeholders in the organic community, not a scientific expert panel. To ensure that the NOSB – with only one of the fifteen slots filled by a scientist – would base its decisions about synthetic materials on sound science, Congress specified in the Organic Foods Production Act of 1990 (OFPA) that "the Board shall convene technical advisory panels to provide scientific evaluation of the materials considered for inclusion in the National List" (Sec. 2119(k)(3)).

In its Policy Manual, the NOSB outlines the criteria for these technical reviews. The reviews should be free from conjecture, and be based on the best available scientific information.

The understanding, of course, is that the scientists performing the technical reviews should provide an unbiased and complete analysis of the material's appropriateness for use in organics, and should therefore point out any scientific concerns about its potential impacts on human health and the environment. This is based on OFPA, which specifies that materials may be included on the National List of Approved Substances only if they "would not be harmful to human health or the environment" (sec. 2118(c)(1)(A)(i)).

At the Fall 2011 meeting of the NOSB, where the Board approved Martek's DHA algal oil and ARA fungal oil, it became clear that the technical review was fraught with shortcomings and failed to address several important issues related to the legal requirement for materials approved for use in organics. In fact, the writers of the TR often parroted claims made by Martek in its petition, and failed to fact-check several of these claims.

For example, Martek stated that it recycled and reused all n-hexane, a synthetic volatile solvent that is used during processing. The TR failed to check data by the

Environmental Protection Agency that in fact showed thousands of pounds of the air-polluting chemical n-hexane were released by the factory where Martek manufactures its nutritional oils—making them among the top 100 largest emitters of this hazardous air pollutant in the United States.

The TR for Martek's DHA and ARA oils also contained numerous unreferenced claims and conjecture. The TR led the Handling Committee members to believe that Martek's nutritional oils are beneficial to infant development, in part because the TR failed to include the most important meta-analysis studies that had been done on the topic. Important meta-analysis studies such as Simmer et al., 2008 and Beyerlein et al., 2010 were omitted, probably because these studies combined data from numerous clinical trials and concluded that no benefits to infant development exist from DHA supplementation.

The Policy Manual states that the TR should be based on the "best available information." In terms of scientific research, the best available information was left out, presumably because it showed only corporate profits stood to gain from the NOSB's approval.

Instead, the TR relied very heavily on information from a website with information about DHA, run by the Linus Pauling Institute at Oregon State University. During public comment at the NOSB meeting in Savannah, Bob Durst, a consultant for the organic industry commented in favor of the Martek petitions, without disclosing his client. Durst, in addition to working as a paid consultant for the organic industry, is employed at Oregon State University as a research assistant. He was also involved in numerous technical reviews in the mid-1990s.

Since the TR for Martek's oils was certainly not based on the best available scientific information, and may have been created with the assistance of individuals with conflicts of interest, it led Cornucopia staff to question the adequacy of past TRs, and whether any materials were approved by the Board based on a biased or inadequate TR. Indeed, this happened in 1995, when three scientists failed to identify scientific research raising serious concerns with carrageenan.

Bias and Inadequacy of Past Technical Reviews – Carrageenan

Carrageenan was reviewed in 1995 by three scientists with professional relationships to corporate agribusiness, and only one pointed out the potential human health impacts of degraded carrageenan. This is especially outrageous since the scientific community had known for decades, based on an abundance of peer-reviewed published literature, that degraded carrageenan is an inflammatory agent and carcinogenic in lab animals. Degraded carrageenan was listed as a "possible human carcinogen" by the World Health Organization's International Agency for Research on Cancer in 1983 – more than a decade before the 1995 TAP review.

There has been a long-time controversy over the inflammatory and carcinogenic properties of degraded carrageenan. But concerns with food-grade carrageenan date back as far as the late 1970s. In 1980, British scientists R. Marcus and James Watt published a letter in *The Lancet* titled "Potential Hazards of Carrageenan," which sparked an open debate in *The Lancet*.

It was inexcusable for the three TAP reviewers in 1995 to fail to mention the concerns with carrageenan that were so openly and publicly debated in the scientific community.

Carrageenan

In order to better understand the problems with corporate stacking of the NOSB (especially the Handling Committee) and corporate scientists performing the technical reviews, it is important to better understand the history of carrageenan, as an example/case study, which was approved for use in organics in 1995 and re-approved in 2008.

Carrageenan is derived from red seaweed, and is used as an ingredient in foods such as dairy, dairy alternatives (such as soy-based beverages and desserts), and deli meats as a thickening agent, stabilizer and/or emulsifier.

Carrageenan can be classified as low molecular weight, "degraded" carrageenan, or high molecular weight, or "undegraded" carrageenan.

Degraded, low molecular weight carrageenan is recognized as a carcinogen in lab animals, and is therefore classified as a "possible human carcinogen" by the International Agency for Research on Cancer.[i]

Degraded carrageenan also causes inflammation in the colon in rodents, which resembles ulcerative colitis, an inflammatory bowel disease.[ii] This inflammatory property of degraded carrageenan is not in dispute, especially since the medical research community has used degraded carrageenan for decades to induce acute inflammation in experimental trials conducted with lab animals, to test anti-inflammation drugs.[iii] [iv] [v] [vi] [vii]

Carrageenan processors tend to portray the difference between degraded and undegraded carrageenan as a simple, black-and-white distinction. They claim that food-grade carrageenan sold to food processors falls entirely in the undegraded category.

However, studies (including industry-funded studies) show that food-grade carrageenan is also linked to colon inflammation and colon cancer in animals.

Studies have reported that high molecular weight carrageenan can degrade in the gastrointestinal tract to low molecular weight carrageenan.[viii, ix]

Moreover, when the industry tested its food-grade carrageenan for the presence of degraded carrageenan, results showed that every sample had at least some degraded carrageenan, with some test results of food-grade carrageenan showing as much as 25% degraded carrageenan.

Carrageenan timeline

1960s - present: Starting in 1961, animal studies consistently show that degraded carrageenan is carcinogenic.[x xi xii xiii xiv]

1969: Researchers find that degraded carrageenan causes ulcerations and inflammation in lab animals that closely resemble ulcerative colitis, a human inflammatory bowel disease.[xv]

1969 - present: Researchers testing treatments for ulcerative colitis use degraded carrageenan to induce the disease in laboratory animals.[xvi xvii xviii xix]

1973: A study shows that degraded carrageenan induces inflammation in the digestive system of monkeys. This shows that degraded carrageenan affects the gastrointestinal system of primates as well as rodents.[xx]

1975: A study with rhesus monkeys finds adverse effects in the intestinal tract when the animals were given low levels (1% solution) of **undegraded** carrageenan in their drinking water.[xxi]

1978: A study published in *Cancer Research* finds that rats fed a diet containing **undegraded** carrageenan had higher rates of cancer than rats fed a control diet without carrageenan. The authors conclude: "**The undegraded carrageenan in the diet had an enhancing effect in colorectal carcinogenesis in rats**."[xxii]

1980-1981: Leading carrageenan researchers R. Marcus and James Watt publish two letters in *The Lancet*, titled "Danger of Carrageenan in Foods" and "Potential Hazards of Carrageenan," pointing out health concerns with the consumption of carrageenan, **including undegraded carrageenan**.

They note that the harmful effects of undegraded carrageenan in animals "are almost certainly associated with its degradation during passage through the gastrointestinal tract."[xxiii]

1983: With adequate scientific data showing the carcinogenicity of degraded carrageenan in lab animals, the International Agency for Research on Cancer (IARC)

classifies **degraded** carrageenan as Group 2B, "*Possibly carcinogenic to humans*."[xxiv] The Agency determines that there is **not enough evidence to classify undegraded carrageenan** as a possible human carcinogen.

1986: A study finds that exposure of rats to 6% **undegraded** carrageenan in the diet for 24 weeks, with weekly injections of the carcinogenic substance 1,2-dimethylhydrazine (1,2-DMH), was associated with an **increase in tumors** from 40% to 75% and with the more frequent occurrence of larger and proximal tumors.[xxv]

1995: Three scientists perform the Technical Advisory Panel (TAP) review[xxvi] for the National Organic Standards Board, to determine whether carrageenan is an ingredient appropriate for use in organic foods. None of the three reviewers mentions the carcinogenicity in animal studies of degraded carrageenan, or the "possibly carcinogenic to humans" classification by the IARC. None mentions the studies suggesting possible adverse health effects of undegraded carrageenan.

One reviewer, Richard Theuer, downplays the potential human health effects of carrageenan by writing: "Carrageenan has a high molecular weight and must be distinguished from lower molecular weight 'degraded' carrageenan which may have adverse health effects."

The reviewers doing the 1995 TAP review do not include more recent studies (widely available in 1995) pointing to potential human health problems, such as the 1992 study by Wilcox et al., with Proctor and Gamble, that finds an association between epithelial cell loss and the consumption of both undegraded and degraded carrageenan.[xxvii]

1996: The National Research Council of the National Academy of Science adopts the IARC classification for degraded carrageenan (possible human carcinogen).[xxviii]

2001: A study finds higher levels of tumors in rats given food-grade carrageenan, yet reports that the difference is not statistically significant. This study, partially funded by the food industry, publishes its findings with the conclusive and misleading title and conclusion that food-grade, "undegraded" carrageenan is safe (despite its findings of higher cancer rates). Marinalg, the industry trade group for carrageenan processors, uses the study to reassure its customers that carrageenan is safe.[xxix]

June 2001: A Joint FAO/WHO Expert Committee on Food Additives (JECFA) recommends an Acceptable Daily Intake of "not specified" for carrageenan. Marinalg hails the decision and claims it confirms the safety of carrageenan.[xxx]

September 2001: Joanne Tobacman, MD, then Assistant Professor of Clinical Medicine at the University of Iowa (now Associate Professor of Clinical Medicine at the University of Illinois at Chicago), publishes an article in the academic, peer-

reviewed journal *Environmental Health Perspectives*. Dr. Tobacman conducted an independent review of the scientific literature on carrageenan, and concluded: "Because of the acknowledged carcinogenic properties of degraded carrageenan in animal models **and the cancer-promoting effects of undegraded carrageenan in experimental models**, the widespread use of carrageenan in the Western diet should be reconsidered" (emphasis added).[xxxi]

March 2003: The European Commission's Scientific Committee on Food reviews Tobacman's 2001 article, and reviews recent safety data on carrageenan. The Committee suggests that the amount of degraded carrageenan in food-grade carrageenan be kept to levels below 5%, "in order to ensure that the presence of any degraded carrageenan is kept to a minimum."[xxxii]

The Commission also reaffirms its earlier position that it remains inadvisable to use carrageenan as an ingredient in infant formula.

2005: Marinalg, the industry trade group, convenes a working group to determine the levels of degraded carrageenan in its products.[xxxiii] The working group tests 12 samples of food-grade carrageenan from a variety of suppliers in six different laboratories, to measure the presence of degraded carrageenan and determine if the 5% limit is feasible.

The results from the industry's own test results are cause for serious concern. First, the levels of degraded carrageenan detected in the samples varied considerably depending on the laboratory performing the tests. This suggests that even the industry does not have a reliable way of determining the levels of degraded carrageenan in food-grade carrageenan.[xxxiv] If the carrageenan manufacturers have no reliable way of testing levels of degraded carrageenan in their products, how can they claim their food-grade carrageenan is safe?

Second, the results showed that 8 of the 12 samples of food-grade carrageenan contained higher than 5% degraded carrageenan according to at least one of the laboratories (in many cases, according to multiple laboratories).

Most alarmingly, all samples contained at least some degraded carrageenan according to the majority of laboratories.

Not a single sample could confidently claim to be entirely free of the material that is classified as a "possible human carcinogen."

The highest level of degraded carrageenan found in a sample was 25%.

2002-2012: Industry-sponsored scientists question whether the inflammatory nature of carrageenan is rodent-specific, and whether the results of animal studies can be extrapolated to humans.[xxxv] [xxxvi] Scientists conduct experiments using human

colonic epithelial cells and find that carrageenan, even low levels of food-grade carrageenan, induce inflammation in human colon cells as well.[xxxvii] [xxxviii] [xxxix] [xl]

2008: The National Organic Standards Board considers whether to re-allow carrageenan during the sunset process. No public interest groups or scientists chime in. The NOSB receives ten comments from industry, including carrageenan manufacturers, the Organic Trade Association, and various organic food manufacturers using carrageenan, all claiming carrageenan is safe and essential in organic processing.[xli]

2011: A 2011 technical review prepared for the National Organic Standards Board on carrageenan outlines concerns with human health and environmental impacts.

January 2012: Marinalg reports that, after eight years of planning, experimentation, and analysis (2003 to 2011), the industry has been unable to reliably measure the levels of degraded carrageenan in its products in the laboratories of its members, its customers, or in independent laboratories.[xlii]

February 2012: Despite human health and environmental concerns raised in the technical review, the Handling Committee unanimously votes to relist carrageenan on the National List of Approved Substances.

May 2012: The National Organic Standards Board will again review carrageenan during the sunset process, and will decide whether to continue allowing carrageenan in certified organic foods.

Corporate Executives Providing Scientific Advice to the National Organic Standards Board: Dr. Richard Theuer Performs 45 of 50 Reviews in Two Years

So how did carrageenan get approved in the first place? The initial technical review for carrageenan, from 1995, was performed by three scientists, two of them employed by major agribusiness corporations. One was Steve Harper, food scientist at Small Planet Foods, which is now owned by the multi-billion-dollar corporation General Mills. Another reviewer was Richard Theuer, then an executive and public relations expert at the Beech Nut division of the multi-billion-dollar corporation Ralston Purina.

Theuer had served on the Board as a handler from 1992 to 1995. Immediately upon retiring from the NOSB, he became involved in the review of nearly every synthetic ingredient. Between 1995 and 1996, roughly 50 ingredients were reviewed, and Theuer reviewed 45 of the total. He unconditionally approved 35, and recommended 6 with restrictions.

While Theuer is a food scientist, he worked as a corporate executive when he performed the technical reviews for the NOSB. He started his career with the infant

formula division of Mead Johnson, first developing new powdered infant formulas, then on to marketing infant formula (1965-1980). He then worked for Nestle, where he worked in the infant formula marketing department (1980-1983). Nestle's infant formula marketing has been criticized for decades by breastfeeding advocacy groups around the world. Theuer then joined Beech-Nut/Ralston Purina where he worked in the baby food development, but also their public relations business (1983-1999).

He was with BeechNut when he did the 45 TAP reviews. He became a consultant, including for organic businesses, in 1999. Essentially, he is a PR professional for the baby food and infant formula industry (his CV states that he "prepared a defense of comparative advertising claims that survived competitive challenges").

Not only did Theuer recommend that carrageenan be added to organic food when it was initially reviewed in the mid-1990s, but he continues to defend the ingredient today. Theuer submitted a comment to the NOSB in April 2012, stating that he continues to believe that food-grade carrageenan is safe for use in foods.

In his April 25, 2012 comment to the NOSB, related to the pending sunset review, Theuer suggests an annotation: "I believe that an annotation for carrageenan should state that degraded carrageenan is not included in the allowance of 'carrageenan' as an ingredient in or on food labeled as 'organic,' to make it clear that degraded carrageenan is not an acceptable synthetic carrageenan and should not be used."

For reasons outlined above, such an annotation would be meaningless in terms of its impact on human health. The annotation would be an accommodation to food manufacturers wishing to continue to use food-grade carrageenan, since industry research shows that all food-grade carrageenan is contaminated with degraded carrageenan.

Interestingly, at the end of his letter, he states that he avoids all foods with carrageenan because he experiences what he calls an allergic reaction to carrageenan – yet he continues to defend its approval for organics.

Theuer also publicly defended Martek's DHA algal oil and lobbied for its inclusion on the National List. For example, in his public comment, he suggested that the prohibition against the use of synthetic volatile solvents like hexane applies only to organic handlers, and Martek was therefore exempt from the prohibition against using synthetic solvents.[xliii]

Theuer, as an executive in the infant formula and baby food industry, worked with the same scientists who were funded by Mead Johnson and published studies that became the basis for infant formula advertisements touting benefits of DHA algal oil. Theuer is also a member of the Institute of Food Technologists, a pro-nanotech and pro-GMO group that has lobbied at NOSB meetings for allowing nanotechnology in organic foods.

Theuer has co-authored a report by The Organic Center, which is essentially the nonprofit arm of the Organic Trade Association. The Organic Center's board of directors consists almost exclusively of corporate executives in the food industry.

With so many technical reviews performed by Richard Theuer and others like him, who deemed carrageenan to be a safe ingredient despite overwhelming scientific evidence raising concern about its effects on human health, Cornucopia has requested a new technical review for every material that comes up for sunset review.

However, new technical reviews will not necessarily improve the scientific advice given to the Board on petitioned materials if the USDA continues to rely on agribusiness scientists. Theuer, who has consulted for The Organic Center, could once again become involved in TRs if the USDA moves ahead with its plan, which is to contract with The Organic Center for future technical reviews.

The Fox Guarding the Henhouse: USDA Contracts with The Organic Center for Technical Reviews

Inadequate TRs in the past were in part due to the bias and corporate affiliations of the scientists performing the reviews. Today, rather than moving away from technical reviews with corporate bias, the USDA is partnering with The Organic Center to perform technical reviews.

The Organic Center began as the nonprofit arm of the Organic Trade Association (OTA), an industry lobby group, and is generally controlled and funded by the same giant corporations that run the OTA.

The Organic Center's board chairman is Mark Retzloff, president of Aurora Dairy, a corporation that operates five dairies that the USDA found "willfully" violating 14 tenets of the organic standards in 2008—arguably the largest-scale scandal in the history of organics.

The rest of The Organic Center's leadership represents many corporations involved in organics: UNFI, Dean Foods, Earthbound Farms, Safeway, Organic Valley, and Whole Foods. Four individuals have a financial relationship to Dean Foods alone (WhiteWave Division/Horizon and Silk brands).

Moreover, Richard Theuer, who continues to defend the safety of carrageenan, and testified in favor of Martek's petition, has co-authored a paper for The Organic Center. It is not unreasonable to suspect that individuals like Theuer, involved with the Organic Trade Association and The Organic Center, would once again become involved in technical reviews if the USDA contracts with the Organic Center.

Non-organic and synthetic materials for use in organics are nearly universally petitioned by corporations involved in organics, or strongly supported by these corporations. Many of these corporations have executives sitting on the Board of The Organic Center (some of these same firms also have employees serving on the NOSB). The employees of The Organic Center are therefore not in a position to provide truly independent and credible technical reviews.

Conflicts of Interest and Technical Reviews: Identities of Individuals Performing Technical Reviews are Kept Secret

Currently, the identity of technical reviewers is not publicly available, much less the potential conflicts of interest held by the reviewers.

Contractors who perform technical reviews for the National Organic Program and NOSB should be required to disclose their identity to the public. This will give the public an opportunity to determine whether conflicts of interest exist.

The contractors should also sign a statement stating that no conflicts of interest exist, prior to commencing work on the technical review. If the reviewers are unable or unwilling to sign this statement, the USDA should find a different agency or organization to conduct the technical review.

Moreover, when the technical review is finished, the reviewers should disclose for the public record any individuals, within and outside their organization, that provided assistance. Currently, it is possible that outside consultants with conflicts of interest assist technical reviewers. Just as written documentation must be referenced in the technical review, so should telephone conversations and other types of assistance. This will help the public understand who was involved in the production of the technical review and might have influenced its conclusions, and whether conflicts of interest exist.

As an example, for the technical reviews on Martek's DHA algal oil and ARA fungal oil, much of the information was taken from the Linus Pauling Institute website, which is not a primary source of scientific information (a serious deficiency in terms of what is required according to the NOSB procedure manual). A consultant to the food industry, and author of former technical reviews, Bob Durst, is employed at the Linus Pauling Institute, which raises questions about Mr. Durst's possible, undisclosed, involvement with current technical reviews.

We are not alleging any specific improprieties, but rather pointing out why it is important for any individuals and contractors involved with technical reviews to identify themselves.

This is especially important since individuals involved with the TRs could act as consultants for the petitioner. For example, Mr. Durst presented oral testimony at the NOSB meeting in Savannah in favor of DHA algal oil, without disclosing his client.

The Story of Martek's DHA Algal Oil

Cornucopia's closer look at the process by which synthetic, non-organic ingredients have been approved for use in organics in the past was prompted by the NOSB's approval of Martek's DHA algal oil and ARA fungal oil, at the meeting in Savannah, Georgia in the fall of 2011.

Why we care: babies are experiencing diarrhea and vomiting, and serious complications, from conventional and organic formula with Martek's oils

Karen Jensen, a mother in Ohio, experienced every new mother's nightmare—watching her helpless newborn in constant distress from severe and chronic gastrointestinal pain, not knowing how to help.

When her daughter was a month old, she suddenly stopped breathing and turned blue. Luckily, Karen discovered her in time and rushed her to the hospital, where she recovered. Desperate to find relief for her baby, who was formula-fed and had cried constantly from gastrointestinal pain since switching to formula, Karen decided to give her daughter a special type of infant formula. A friend had given her some free samples to try—and it so happened that this hypoallergenic formula was one of the very few options that did not contain the additives DHA and ARA.

Infant formula makers advertise DHA and ARA, which are added as synthetic nutritional oils to infant formula, as being essential for an infant's brain and eye development, so Karen was hesitant to give her baby formula without them. Although her baby did remarkably better on the day after being given non-DHA/ARA formula, Karen wanted to make sure that her baby received these ingredients. She bought the same brand and type of formula, Neocate, but made sure to buy the kind that contained the highly touted additives.

"Suddenly, it seemed like we were back at square one," says Karen. "She cried nonstop daily, couldn't sleep." As soon as the DHA and ARA additives returned to her baby's formula, so did her gastrointestinal distress.

When Karen accidentally received a can without DHA and ARA from her pharmacy, she went online to search for DHA and ARA supplements that she could add herself. That's when she stumbled across The Cornucopia Institute's original report,

released in 2008, which alerts parents to the possibility of adverse reactions from DHA and ARA, and shares adverse reaction reports with the public.

Karen read the reports from other parents, disseminated by The Cornucopia Institute, whose babies had suffered from the Martek oils. "It sounded just like my baby. So, we went ahead and tried the straight formula without the DHA/ARA in it," Karen remembers. "Within 24 hours, we had a brand new, entirely different baby. She had no abdominal distress, no gas, she smiled and played and for the first time ever we heard her laugh."

Karen was careful to avoid formula with DHA and ARA ever since, and marveled at her baby daughter's transformation.

Karen's awful experience with DHA and ARA additives in infant formula is, unfortunately, not unusual.

Holly Schneider, from Taylor, Michigan, put her infant son to sleep every night hooked up to a breathing monitor, as recommended by his pediatrician, in case his constant vomiting should choke him during sleep.

After trying every type and brand of formula, her son's symptoms stopped almost immediately, at six and a half months of age, after Holly accidentally bought formula without DHA and ARA.

Holly remembers the first months of her son's life: "He had explosive diarrhea, projectile vomiting, dehydration, excessive gas, weight loss, cried all the time and couldn't sleep. At every feeding, he would begin squirming and screaming halfway through the bottle, pulling up his legs, and I could hear his stomach churning." When it was time for her son to feed again, the process would start all over.

Along with hundreds of other mothers and fathers who watched the incredible transformation when they gave their baby formula without DHA and ARA additives, Karen and Holly have alerted the FDA. They believe that Martek's DHA and ARA oils are the cause of their baby's suffering, and have shared their stories with the FDA's Medwatch program, which allows consumers and health professionals to officially send adverse reaction reports to the agency.

Some parents simply state the facts—"Child was given Enfamil with DHA and ARA, developed severe diarrhea. When switched to Enfamil without DHA and ARA, did fine"—states one report.

Other can't help but reveal their anger—"why did FDA allow the formula companies to produce these formulas without long term testing???" writes a parent who reported that her baby was "extremely gassy, fussy, and has terrible gas pains" when given formula with DHA and ARA.

This parent probably never received an answer to her question—why the FDA allowed these novel ingredients in infant formula. Other questions worth asking include how these ingredients are produced, why they are found in infant formula, and why they are now found in everything from breads to peanut butter to candy bars.

But the most important question, for consumers who seek out the organic label as a guarantee that the food is free from questionable, highly processed and potentially dangerous novel ingredients, is why these ingredients are now found in organic foods, and infant formula, as well.

The focus of this compilation of information will be on the organic industry, and how Martek Biosciences Corporation, the maker of these novel DHA and ARA oils, managed to penetrate the organic market, which is supposed to provide an alternative to the chemical concoctions masquerading as food.

Following the story of Martek oils' journey into organic foods – a journey guided by corporate lobbyists and corporate science –sheds light on the Organic Watergate.

Why the corporate science focus on DHA?

In the 1970s, two Danish physicians traveled to Greenland to study the diet of the Inuit. Since the thinking at the time was that fat caused heart disease, the scientists were perplexed by the fact that the Inuit, who eat lots of fat and fatty blubber, had virtually no heart disease.

The scientists hypothesized that the high levels of omega-3 fats in fish and seal blubber were responsible for their lower levels of heart disease.

Since then, there have been many studies linking diets high in fish to lower rates of heart disease. But corporations cannot profit much from dietary pattern changes. They can, however, use reductionist science to isolate a nutrient in fish, in this case, the omega-3 fatty acid docosahexanoic acid (DHA), recreate it in a lab, patent it, and sell it for profit by encouraging processed foods to make associated health claims.

DHA is also one of thousands of naturally occurring nutrients in breast milk, and a structural component of the brain and retina. Since some studies have suggested that breast-fed infants have an advantage in cognitive and visual development over formula-fed infants, reductionist scientists similarly honed in on DHA as the magical nutrient in breast milk that would fix the shortcomings of formula.

Marion Nestle, the respected food scientist at New York University, calls these manufactured nutrients "techno-foods." They are high-tech, quick fix solutions to

dietary problems that ignore the complexity of nutrients in foods, and the complexity of how our bodies use foods.

The hypothesis that DHA specifically can be isolated and added to foods for better heart health in adults and brain health in infants has not panned out.

When the Inuit started eating more Western foods, their heart health declined. Pretty soon, their rates of heart disease were comparable to Danish and American rates. To reductionist science, this was perplexing because the consumption of fish and seal blubber *had not declined*. So here was a population eating as much fish as any population could be expected to consume, and heart health declined with the introduction of Western foods in the diet.

These real-world scenarios force scientists, not associated with profit-making ventures, to abandon the reductionist model: there is more going on than simply the number of milligrams of DHA that a person consumes. As will be explained later, it is about the balance of omega-3s and omega-6s, which is more about dietary patterns, agricultural practices and policies, and complex ways nutrients are used within the body.

Peer-reviewed, published studies, looking at DHA-fortified infant formula, shatter the reductionist myth that simply adding a manufactured, isolated nutrient to a processed food can solve nutritional problems and bring the same advantages of breastfeeding to formula-fed babies.

Studies simply have not found long-term benefits in cognitive development for children given DHA-fortified formula as infants, compared with those given non-fortified formula. In the words of the National Institutes of Health, breastmilk is a complex matrix of nutrients, and it is quite "quixotic" to believe that it can be recreated with manufactured nutrients in a laboratory.

Martek's DHA Algal Oil: Highly Processed, Chemically Extracted from Mutated Algae

There is sound science and there is profit, and the two do not always mesh well. Martek Biosciences Corporation relies on reductionist science to sell oils that are extracted from fermented algae and soil fungus that have been genetically altered to contain higher levels of the fatty acids DHA and ARA.

Martek Biosciences Corporation manufactures its DHA algal oil and ARA fungal oil by fermenting algal and fungal microorganisms in stainless steel tanks containing the microorganisms' "feed," which consists of ethanol and other ingredients that are, because of the widespread adoption of genetically engineered crops in the U.S., almost assuredly derived from genetically engineered corn.

When used in infant formula, the oil from the algae and fungus is then extracted by mixing the microorganisms with hexane, a neurotoxic and highly explosive petroleum-based solvent. Their oils for foods, other than infant formula, are extracted with the use of enzymes and the synthetic petroleum-based solvent isopropyl alcohol.

The extracted oil is then further processed, including bleaching and deodorizing. The algal oils destined for liquid products, such as milk, are mixed with conventional sunflower oil, synthetic stabilizers, preservatives and other ingredients. Numerous additional synthetic ingredients, including sweeteners, are added to the powdered form, which is microencapsulated, before it is added to infant formula or other dry foods like baby cereal.

Martek's Science: Influenced by Corporate Greed

The kind of science used to convince people that Martek's oils are necessary to fix our diet-related health problems is not sound science.

There is science that proves, and science that probes, according to philosopher, organic farmer and former NOSB member Frederick Kirschenmann, PhD.[xliv] Science can either aim to better understand and appreciate the complexity of its subject, or it can ignore complexity and interconnectedness in an effort to simply prove a hypothesis. For scientists like those working for Martek Biosciences Corporation, the underlying goal is not to probe, but to prove the already adopted position necessary for profitably selling its products.

Professor Nestle wrote about the corporate influence on nutrition science in *Food Politics*. Calling functional foods like Martek's DHA algal oil "techno-foods," she points out that "it should be evident that the philosophical rationale for techno-foods is flatly reductionist; the value of a food is reduced to its single functional ingredient."[xlv]

When scientists first discovered that eating fish could be beneficial, the quest was on to isolate the one nutrient in fish responsible for these benefits. Similarly, when children who were breastfed as babies scored higher on IQ tests than children who had been formula-fed, scientists interested in bottling and selling that magical nutrient set out not to explore, but to prove that they had found the answer.

Once a nutrient – in this case, DHA – has been identified in a beneficial food, scientists seek to prove that it confers the same benefits as the real food in which the nutrient naturally occurs. Such studies, when performed or analyzed by scientists working for the very corporation that has manufactured those nutrients, cannot be respected as *sound science*.

At around the same time that nutritional and medical scientists identified the link between the traditional diets containing fish and lower levels of heart disease, scientists in laboratories were experimenting with oil production from single cell microorganisms, including algae. This made logical sense since oily fish, with high naturally-occurring DHA levels, eat algae. According to Colin Ratledge, expert on the production of single cell oils, "it was then a question which, if any, possible market might be exploited by these materials."

In other words, once scientists figured out how to make oil from algae, they sought to establish a market to sell it to health-conscious consumers and cash in on their new technology. They sought a market for oils suitable for human consumption, which commands a higher price premium than oils for livestock, and focused on traits in the oils that were not found in common crops like corn and soy. According to Ratledge, "the work on the nutritional benefits and effects of the very long chain polyunsaturated fatty acids found in fish oil was of major importance."

The algae could produce high levels of the fatty acid DHA, which is found in fish oil. But the scientists ran into a problem: fish oil also contains high levels of another fatty acid, EPA. In a classic example of science that aims to prove rather than probe, the scientists, who had algae producing DHA but not EPA, then locked onto the thesis that "it was DHA and not EPA that was important."[xlvi]

Rather than aim to understand the complexity of fish oil, the scientists concluded that "fish oils were not entirely satisfactory sources because all these oils contained both fatty acids in roughly equal proportions."[xlvii] In a 1999 study to determine the effect of DHA on the development of Alzheimer's Disease, led by Martek founder and scientist David Kyle, the authors wrote that they chose algal oil because "it contains no EPA, which may be contraindicated in otherwise healthy elderly patients."[xlviii]

So in order to put their newly discovered microorganisms to profitable use, the scientists needed to discredit one naturally occurring fatty acid in favor of another, for the sole reason that their microorganisms produced one but not the other.

And to make matters more convoluted, corporate scientists then decided that EPA was not "neutral," but that it interfered with the uptake of DHA and therefore actually *harmful*.

In their quest for "science" that would back up their profitable venture, and contradicting all scientific evidence of the time, Martek scientists concluded that eating fish, the natural food that brought them to DHA, would be less beneficial than taking the supplements of algal oil that they developed.

It would be difficult to find a clearer case in the nutritional world of unsound science, driven solely by corporate greed and characterized by extreme arrogance.

Martek's Claims That Its Oils Provide Benefits Are Not Backed by Sound Science

People who eat traditional diets that include fish are healthier than the average American, especially in terms of heart disease. Through reductionist science, the assumption is that a magical nutrient – in this case, DHA – appears in fish that could be taken as a supplement to confer the same health benefits as eating the traditional diet with fish.

To back up its health claims, and to convince the organic community to accept its manufactured DHA algal oil, Martek scientists refer to studies showing health benefits from fish consumption.

This reductionist science ignores the complexity of the full-spectrum of nutrients in fish and ignores the interactions between nutrients in different foods in the diet. When people increase fish consumption without making other changes to their diet, studies show they do not reap the same benefits, in the same way that the Inuit had higher rates of heart disease when they increased their consumption of Western foods.

This is likely because the typical Western diet is loaded with omega-6 fats, primarily found in seed or grain-based oils and grain-fed animal products. With corn – and corn-based fats – making its way into virtually all processed foods, the American food supply is drowning in omega-6 fats, which cancel out the benefits from what little omega-3s are left. As science writer Susan Allport points out in her book on omega-3s, *The Queen of Fats*, "The problem was that the tissues of Western populations were awash in omega-6s, fats that compete with omega-3s."[xlix]

Such complexity is ignored by corporate reductionist science, which relies on mechanistic thinking. For reductionist scientists, if A leads to B, and A contains C, then C must lead to B. If eating fish leads to health, and fish contains DHA, then taking lots of DHA must lead to health, so goes the reductionist thinking. But studies that take this reductionist view and measure health benefits from taking DHA supplements rarely show the same benefits as those conferred by the traditional diets.

Let's take Horizon's marketing materials as an example to see how they backed up their health claims for milk with DHA algal oil. Horizon, a division of the largest dairy processor in the U.S., Dean Foods, started adding DHA to its organic milk in 2008.

The first citation on the Horizon webpage touting the health benefits of algal oil in its milk is a published "consensus statement" by various groups, including some that include scientists working for the corporations that market DHA supplements. The article mentions the importance of fish intake by pregnant and lactating women, but

does not mention algal DHA or supplementation. Relevant conclusions stated in the article include:

> *Women of childbearing age should aim to consume one to two portions of sea fish per week, including oily fish; intake of the DHA precursor, α-linolenic acid, is far less effective with regard to DHA deposition in fetal brain than preformed DHA; intake of fish or other sources of long-chain n-3 fatty acids results in a slightly longer pregnancy duration.*

The second study also does not conclude that supplementation of products like milk with algal DHA benefits pregnant women.[1] The authors' conclusion is as follows:

> *For major health outcomes among adults, based on both the strength of the evidence and the potential magnitudes of effect, the benefits of fish intake exceed the potential risks. For women of childbearing age, benefits of modest fish intake, excepting a few selected species, also outweigh risks.*

Both studies extol the benefits of eating fish, and do not include algal oil in their analyses. Benefits exist from eating a wholesome diet of varied and traditionally produced foods including fish. But using these studies to support a claim that dairy products such as Horizon milk should be supplemented with algal oil is false and misleading. Numerous reviews that specifically considered supplementation of DHA did not find benefits to pregnant or lactating women:

> *Pregnancy outcomes were either unaffected by omega-3 fatty acid supplementation, or the results were inconclusive.*
>
> - Study commissioned by the Agency for Healthcare Research and Quality, Department of Health and Human Services, 2005

> *The Panel concludes that there is insufficient evidence to establish a cause and effect relationship between the consumption of supplementary DHA during pregnancy and lactation and visual development in unborn children or breastfed infants.*
>
> - Conclusion by the Scientific Committee, European Food Safety Authority, 2009[li]

> *The Panel concludes that there is insufficient evidence to establish a cause and effect relationship between the consumption of supplementary DHA during pregnancy and lactation and cognitive development in unborn children or breastfed infants.*
>
> - Conclusion by the Scientific Committee, European Food Safety Authority, 2009[lii]

Martek's Oils and Misleading Advertising to Parents: Claims About Infant Formula are Not Backed by Sound Science

The most comprehensive meta-analysis done on the topic of DHA supplementation and infant development was performed by a team of scientists led by Dr. Karen Simmer, Ph.D. in Perinatal Nutrition and Professor of Newborn Medicine at the University of Western Australia. The scientists tabulated results from all well-conducted clinical trials available at the time, and arrived at the following conclusion:

"This review found that feeding term infants with milk formula enriched with long-chain polyunsaturated fatty acids [DHA and ARA] ***had no proven benefit*** *regarding vision, cognition, or physical growth."*

If parents listen only to infant formula advertisements, they cannot be faulted for believing outrageous claims such as this one in an Enfamil ad: "Enfamil PREMIUM is clinically proven to result in IQ scores that are similar to those of breastfed infants."

Of course, nothing is "clinically proven" until findings from one clinical trial have been repeated and corroborated by other scientists. Mead Johnson bases its outlandish IQ claims on the results of one clinical trial, conducted by scientists affiliated with the Dallas-based Southwest Retina Foundation.

In a 2007 publication, they shared their results that children who were fed formula with DHA and ARA during the first 17 weeks of life had visual acuity and IQ scores similar to breast-fed infants. This team of scientists is sponsored by Mead Johnson, which has, over the years, supplied not only free formula for the trials, but has granted more than 1 million dollars to support their research.

Nearly every other clinical trial—and close to a dozen exist—comes to the opposite conclusion, that adding DHA and ARA to formula provides no benefit. Even those funded by other formula makers, including Abbott Laboratories which the infant formula brand Similac, have not found differences in mental or visual development between infants fed formula with and without added DHA and ARA.

A more recent meta-analysis study, performed by a team of researchers led by Dr. Beyerlein and published in the January 2010 issue of the *Journal of Pediatric Gastroenterology and Nutrition*[liii], uses a different methodology from Simmer's meta-analysis. The authors note that their meta-analysis method, individual patient data meta-analysis, is regarded as providing "the least biased and most reliable means" to combine results from different studies. After combining and analyzing the results from four different clinical trials, the researchers did not find any statistically significant differences between formula groups in any of the subgroups (e.g. boys, girls, low birthweight, maternal education, etc.). They conclude:

> *"**The absence of any detectable benefit or disadvantage** in Neurodevelopment assessed with BSID at the age of 18 months for all of the children or in any subgroup therefore **provides evidence <u>against</u> beneficial effects** of LCPUFA [DHA and ARA] supplementation on BSID at 18 months under the conditions of the trials included here (emphasis added)."*

Several recent studies come to the same conclusion. A study of 241 children found that "estimated total intake of DHA in milk up to age 6 months was not associated with subsequent IQ or with score on any other test." The authors, published in October 2009 in the journal *Archives of Disease in Childhood*[liv], concluded that "differences in children's intelligence according to type of milk fed in infancy may be due more to confounding by maternal or family characteristics than to the amount of long-chain polyunsaturated fatty acids they receive in milk."

The data sets are clear: results from the vast majority of clinical trials suggest that supplementing formula with added DHA and ARA does not benefit brain and eye development for term infants. Nearly every published study that claims benefits exist is authored by the same team of Mead Johnson-funded scientists.

In infant formula advertisements, only the corporate-funded studies showing benefits are cited. And when the National Organic Standards Board deliberated the appropriateness of Martek's oils in organic foods, ten of fourteen members chose to ignore this scientific evidence presented to them by Cornucopia, and opted instead to approve the Martek oils based on testimony by corporate scientists and lobbyists at the meeting.

Corporate Scientists Disappointed by Finding No Benefits: Twisting Scientific Findings

Scientists are no less affected by their personal beliefs and wishes than the rest of us, and it is clear that many who found no benefits were disappointed by their findings. Their ways of coping with their disappointment have varied from reasonable yet misguided, to outrageous.

A study led by a scientist from Abbott Laboratories—makers of Similac—found no differences, and therefore no benefits to adding DHA and ARA. They nevertheless attempted to put a positive spin on their disappointing results. In an article published in *Pediatrics*, a journal respected and read by many pediatricians, they ended the last line of their abstract as follows: "In conclusion, adding both DHA and ARA when supplementing infant formulas with long-chain polyunsaturated fatty acids supports visual and cognitive development through 39 months."[lv]

The conclusion from this article seems to intentionally mislead readers into believing that the researchers found benefits—statistically significant differences—

from formula with DHA and ARA. They did not. For after 39 months, any advantage in cognitive development reverted back to baseline levels commensurate with non-supplemented formula.

Several pediatricians, having read the study and seeing through the deception, wrote to *Pediatrics'* editors,[lvi] pointing out that they could "not find justification for the last sentence in the abstract" and that "this is quite biased" and "misleading at best."

Another common way for scientists to cope with the disappointment of finding no benefits to adding DHA and ARA to formula is by claiming that they did not add enough of the supplemental oils. If only they had added more, they claim, they would have found statistically significant differences. This may sound like a credible claim, but it does stand the test of available scientific evidence.

Most trials' DHA levels are equal to, or close to, the levels added by the Mead Johnson-sponsored Dallas team. The formula supplied to the Dallas team by Mead Johnson contained 0.36% DHA, which is not that much higher from the 0.35% in the Adelaide trials, the 0.32% in the England trial, and the 0.30% in the Netherlands trial—none of which found differences.

So what could be the real reason for why these clinical trials found no differences? For years, breastfeeding advocates have argued that the benefits of breast milk cannot be reduced to single ingredients. Tens of thousands of years of evolution, they argue, have created the perfect food for infants, with thousands of nutrients that interact with one another, and can even change on a daily basis, depending on the infant's particular needs that day. Breast milk is a matrix of nutrients, and it would be foolish for scientists to presume that they could identify, recreate, and reassemble them in a factory-produced formula.

Scientists to Martek: "We don't buy it"

Martek's reductionist science does not sit well with many scientists.

The advice from scientists and doctors who are not on corporate payrolls is to eat real foods that supply important nutrients like DHA and EPA, and make dietary pattern changes, rather than load up on isolated nutrients. Unfortunately for corporations like Martek Biosciences, only increased sales of supplements, not dietary changes, lead to increased profits.

In a 2009 *US News and World Report* article titled "Fish Oil Supplements, EPA, DHA, and ALA: Does Your Omega-3 Source Matter?," the reporter asked three nutrition experts to comment on omega-3s in the diet.

Marion Nestle, Goddard Professor of Nutrition at NYU, again argued that early humans evolved in an environment – and on a diet – that did not have an abundance of fish, yet they were fit enough to survive. "I think plant sources are highly underrated and that most of the fuss about omega-3s is about marketing, not health," she said.[lvii]

Walter Willett, Professor of Nutrition at Harvard and best-selling author of *Eat, Drink and Be Healthy*, told *US News and World Report* that "gulping down fish-oil supplements after a 16-ounce steak is not the same as eating a moderate-size piece of well-prepared salmon." In other words, loading up on isolated nutrients is pointless if destructive dietary patterns remain unchanged.

The third nutrition expert, Stephen Kopecky, Professor of Medicine at the Mayo Clinic, commented specifically on Martek's algal oil supplements. He pointed out that these algal oils are produced through a fermentation process that generates DHA but not EPA. "And when people get their omega-3s from omega-3 rich plant sources like flax or walnuts," he says, "the body converts [the short-chain omega-3s] into primarily EPA and only a little big of DHA." The implication is that if we trust our bodies to naturally do the right thing, and our bodies seem to prefer EPA over DHA, why should we second guess this and load up on algal oil supplements containing DHA but not EPA?

When Martek launched an advertising campaign suggesting that its DHA supplements improve brain health, another *US News and World Report* article reported that "Medical experts who are unaffiliated with [Martek's] index echoed the importance of taking proactive, preventive steps to protect brain function, but some pointed out that Martek might have a special interest in promoting DHA omega-3."

One of these experts is John Ratey, an Associate Clinical Professor of Psychiatry at Harvard Medical School. "It's curious that they're focusing on DHA," he said, citing studies that suggest another kind of omega-3, EPA, may be more important to brain health than DHA. Yet the only omega-3 that Martek focused on was DHA – surely because that is the only omega-3 Martek sells.[lviii]

The same pushback against Martek's science-cloaked marketing is happening in the field of infant formula.

When asked to comment on Martek's DHA and ARA in infant formula by an Associated Press reporter in 2009, pediatrician Frank Greer said, "The truth of the matter is, they're not essential."[lix] Dr. Greer is a Professor of Pediatrics at the University of Wisconsin-Madison, and chairs the American Academy of Pediatrics Committee on Nutrition.

Greer stressed that he was giving his personal opinion and not speaking on behalf of the AAP as he continued: "Humans can synthesize these. Fatty acids are naturally

present in the diet. And the whole issue becomes, do you make really make people smarter if you put DHA and ARA in everything? Or is this just all marketing hype? Personally, I lean toward the latter."

The AAP has not taken a position on whether DHA and ARA should be added to infant formula, and recently noted that the point is moot since all formula now contains these ingredients.

Greer is not alone in his skepticism of Martek's DHA and ARA in formula. Francesco Branca, MD, Ph.D. is the Director of Nutrition at the World Health Organization. In April 2011 he wrote a letter to members of the European Parliament, who were debating labeling laws for infant formula.

"[The World Health Organization] does not have a recommendation regarding the addition of DHA to formula milk, as to date no solid evidence exists to be able to say that adding DHA to infant formula will have important clinical benefits,"[lx] he wrote.

Three of the most prominent and respected independent scientists in the field of DHA/ARA research, Alan Lucas, Kathy Kennedy and Mary Fewtrell, published an open letter in *Archives of Childhood Disease* (of the *British Medical Journal*) to respond to a Martek scientist, stating the following: "the scientific evidence base for [DHA/ARA's] addition [to infant formula] is recognized by most investigators and Key Opinion Leaders in the field to be weak," and that "this field of research has been driven to an extent by enthusiasm and vested interest."

In the letter, they pointed out that one of the most influential clinical trials driving the addition of Martek's DHA and ARA to infant formula in the U.S. was based on "an incomplete follow up where only 19 subjects remained in the relevant intervention group, providing inadequate power to provide any realistic estimation of the treatment effect." This was the study noted earlier, by the Dallas-based team of scientists that has received over a million dollars in funding from Mead Johnson, the infant formula manufacturer marketing Enfamil.

Martek's Corporate Lobbying Power—Getting Its Novel Ingredients on the Market

Before Martek's oils could be added to organic infant formula, they had to be permitted for conventional formula. While Cornucopia's focus is organics, it is necessary to note that Martek's oils are found primarily in conventional foods. While governmental oversight of the safety of ingredients in conventional foods is much more lenient than in organic foods, it is interesting to note the difficulty experienced by Martek to get their ingredients approved for use even in conventional infant formula, and the serious shortcomings of the FDA's approval process.

The FDA Approval Process—Fraught with Shortcomings

When a company like Martek Biosciences Corporation develops a new ingredient for use in infant formula, the law requires that they first petition the FDA for "Generally Recognized As Safe" status—or "GRAS" for short.

Martek petitioned the FDA for GRAS status for its DHA algal oil and ARA fungal oil in 1999.

Federal regulations specify that the recognition of safety must be based on the "views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food." Since it is the company's responsibility to write the petition, which includes comprehensive scientific reviews, they are responsible for convening this panel of experts.

The FDA, due to budget and time constraints, does not generally convene its own panel of experts to review a petitioned substance. That the experts signing off on the GRAS statement are recruited and compensated by the company, rather than the FDA, to serve on the panel to determine an ingredient's safety should immediately discredit them as being "independent."

Indeed, the scientist chosen to lead the safety review for Martek, Dr. Joseph Borzelleca, has a reputation of disregarding safety concerns with chemicals, including food ingredients.

When the *Chicago Tribune* wrote a story in January 2011 on recent research linking chemical food dyes to hyperactivity/attention deficit disorder in children, Dr. Borzelleca disregarded these concerns and said that "the (synthetic food dyes) used in the U.S. are absolutely safe." Despite the groundbreaking study linking food colors to neurological disorder in children, Dr. Borzelleca added that they are safe because "food colors are among the most thoroughly studied of the food ingredients." This scientist signed off on the Martek petition to the FDA for self-affirmed "Generally Recognized As Safe" status.

Dr. Borzelleca again assisted Martek to gain approval for its oils in organics, by writing a letter to the National Organic Standards Board prior to its Fall 2011 meeting. In the letter, Dr. Borzelleca joined Martek in attacking Cornucopia's research, and wrote, "I have read the Cornucopia Institute's recent newsletter on this subject and can honestly say it is one of the most striking examples of non-scientific doublespeak masquerading as a principled policy argument that I have encountered in my nearly 50 year career."[lxi]

As in this paper, Cornucopia's research and education work on the subject has depended on presenting the preponderance of peer-reviewed research, and meta-analyses on the subject. By attempting to discredit our organization, Dr. Borzelleca is basically rejecting virtually all published research on the issue.

Another problem with convening a panel of "experts qualified to evaluate the safety" of additives is that safety can be understood on many levels. Martek's petition for GRAS status is filled with data on toxicology studies, primarily performed on rats. These tests provide proof that very high doses of DHA and ARA oil, when given to rats, do not kill them. The tests did reveal that DHA and ARA affected liver weight and other organs, but Martek's panel arbitrarily dismissed these results as irrelevant.

What none of these tests can reveal, of course, is whether human infants experience gastrointestinal reactions from the doses of DHA and ARA oils included in formula.

At the time when the panel submitted their review to the FDA, the ingredients had never been on the American market—so no post-market surveillance data, or post-market reports, were available. The panel based their assessment of Martek's DHA and ARA oils on toxicological studies on non-human animals, primarily rats, and on the outcomes of "at least fourteen well-conducted clinical trials involving over 1500 infants." They noted that "no adverse events have been reported" in these clinical trials.

What they do not mention is that these clinical trials were not designed, and therefore not equipped, to detect and analyze adverse reactions to formula. They were meant to answer the question of whether these additives confer any benefits to the infants' brain and eye development. It appears that if adverse reactions did occur, the researchers most likely did not have the correct protocol in place to determine the cause of these adverse reactions in participating infants.

For example, a study by the Mead Johnson-funded scientists reported in 2007 that 79 infants were enrolled in its trial, but only 68 remained at four months of age because many had symptoms "suggestive of lactose or cow milk protein intolerance." That is a 14% attrition rate. Medwatch reports suggest that reactions to Martek's DHA and ARA are similar to reactions to lactose or cow milk protein intolerance, and it is unclear from the published report whether the scientists followed up on these adverse reactions. The infants who reacted negatively to the formula may have been lactose intolerant or allergic to cow milk, but the possibility that they reacted to DHA and ARA remained unexplored by the researchers. Clinical trials conducted prior to 1999, and included in Martek's petition, most likely encountered similar drop-out rates.

In fact, Cornucopia found no data in the scientific literature from researchers who followed through to determine whether withdrawals from clinical trials were related specifically to intolerance to DHA and ARA.

It is clear that, when the panel wrote its 1999 GRAS petition, serious and extensive analyses of adverse reactions to formula during clinical trials simply did not exist. Today, all infant formula contains Martek's ingredients, which means that it is no

longer possible to compare an infant's tolerance of regular formula to tolerance of formula with DHA and ARA. All the adverse reaction reports from parents and healthcare professionals that have been received by the formula manufacturers and the FDA have been dismissed by the agency and by the corporations.

FDA Voices Serious Doubts and Concerns—Martek Fights Back

The FDA officials who received and reviewed Martek's petition in 1999, both with Ph.D. degrees, recognized shortcomings with the petition, and voiced serious concerns about allowing GRAS status for these DHA and ARA additives.

A year after they submitted their petition, lawyers representing Martek requested a meeting with the FDA. The attorney who submitted the petition with the FDA in 1999 was present at the Fall 2011 meeting of the NOSB, to assist Martek in gaining approval for use in organics as well. The lawyers communicated their dissatisfaction with the FDA's slow response; the FDA responded that they were not simply dragging their feet, but genuinely concerned with the safety of the ingredients.

A month after the meeting, the FDA outlined their concerns in a letter to Martek. They described the lack of data supporting the need for DHA and ARA in infant formula, studies reporting unexpected deaths from Sudden Infant Death Syndrome (SIDS), sepsis or necrotizing enterocolitis in infants consuming DHA and ARA, and reports of adverse events and other morbidities including diarrhea, flatulence, jaundice, and apnea in infants fed formula with added DHA and ARA.

Within weeks, Martek responded by largely dismissing the FDA's concerns. Less than two months later, the FDA officials gave in and granted GRAS status to DHA and ARA. The Cornucopia Institute, through a Freedom of Information Act query, requested records of meetings between Martek lobbyists or lawyers and FDA officials, to determine why the FDA would give in so suddenly. FDA responded that records of such meetings, which we know occurred, were unavailable.

All we know, at this point, is that Martek lobbyists met with the FDA officials, behind closed doors, and within months, their novel ingredients were on the market.

However, while the FDA granted GRAS status, they did not do so without officially repeating their serious concerns and stressing that they expect rigorous post-market surveillance and additional safety reports from both Martek and formula manufacturers. Here's what the FDA wrote:

"*It is FDA's view that any evaluation that a use of a food ingredient is safe is a time-dependent judgment that is based on general scientific knowledge as well as specific data and information about the ingredient. For these reasons, FDA would expect any infant formula manufacturer who lawfully markets infant formula containing ARASCO*

and DHASCO to monitor, through scientific studies and rigorous post-market surveillance, infants who consume such a formula. We also would expect regular reports of such studies and post-market surveillance."[lxii]

By expressing that its evaluation of DHA and ARA's safety is a "time-dependent judgment," the FDA officials clearly expected that a change in DHA and ARA's GRAS status would be possible, if further information regarding safety problems should come to light in the future. They also expected "rigorous post-market surveillance" of infants who consume formula with DHA and ARA. Their doubts about DHA and ARA's safety could not be any clearer from this letter.

After learning of the hundreds of reports submitted to the FDA by health care providers and parents of infants who became sick from formula with DHA and ARA, The Cornucopia Institute contacted the formula manufacturers directly. Not only were they unwilling to share any data on safety studies or post-market monitoring, but they even vehemently defended DHA and ARA's safety. Although we know of numerous parents who directly contacted the manufacturers, formula manufacturers deny any knowledge of safety problems with these additives.

Formula Manufacturers Fail to Perform Post-Market Surveillance

Perhaps the formula manufacturers did not take the FDA's warning seriously, because they believe that an expectation expressed in a letter from the FDA bears no legal weight. However, monitoring the safety of infant formula is in fact a legal responsibility outlined in federal law and regulations, which state that any manufacturer of infant formula shall have "provisions for the review of any complaint involving an infant formula and for determining the need for an investigation of the possible existence of a hazard to health" (21 CFR 106.100(k)).

These federal rules also state that "when a complaint shows that a hazard to health possibly exists, the manufacturer shall conduct an investigation into the validity of the complaint" (21 CFR 106.100(k)(2)).

Therefore, the expectation that formula manufacturers should have performed post-market surveillance on formula with DHA and ARA comes not only from the FDA's 2001 letter, but from existing federal regulations as well. It was surprising, then, when Mead Johnson responded to Cornucopia's request for information regarding post-market surveillance reports with a complete denial of any problems associated with DHA and ARA.

When The Cornucopia Institute, through FOIA, asked the FDA in 2009 whether any formula manufacturer had submitted a post-market surveillance report or additional safety study since 2001, the answer was "no." In their own words: "FDA has never received any reports or studies regarding post-market surveillance or

scientific studies monitoring or evaluating the safety of DHASCO and ARASCO (Martek's proprietary name for synthetic DHA and ARA oils) in infant formula."[lxiii]

It would be one thing if, nine years after receiving GRAS status from a hesitant FDA, formula manufacturers diligently performed post-market monitoring and safety studies, and concluded that no safety concerns exist. It's another thing when formula manufacturers fail to follow through on their responsibility for post-market monitoring, and apparently ignore any parent who shares with them a report of an infant suffering from an ingredient in their formula.

Meanwhile, some new scientific studies do suggest there is reason for caution. Results from a long-term clinical trial published in 2010 were that "Girls born preterm and randomized to long-chain polyunsaturated fatty acid-supplemented formula showed increased weight, adiposity and blood pressure at 9–11 years, which might have adverse consequences for later health."[lxiv]

And while the FDA has refused to share important data about adverse reaction reports, the agency did share some data that reveals the incidence of "bloating and distension" reported by parents of formula-fed infants increased from 0% in the year 2000, when Martek's oils were not available in the U.S. market, to nearly 10% in 2009, when nearly all infant formula contains Martek's oils.[lxv]

History of Martek's Oils in Organic Foods

The fight over Martek's oils in organic foods pitted multibillion-dollar corporations and their lobbying power against public interest groups like Cornucopia.

It has raised serious questions about the direction the organic industry is moving in, and also led Cornucopia to question the appropriateness of past approvals by the National Organic Standards Board.

The sole reason that corporations like Dean Foods, which puts Martek's oils in its Horizon milk, initially put Martek's oils in organic products was to join the conventional food industry's lucrative practice of slapping misleading health claims on its packaging.

In the debate over Martek's place in organic foods, which began years ago, Martek and its customers and supporters have argued that Martek's oils and health claims on organic foods help sell more organic foods, which is in itself a noble goal. However, it is based on false assumptions and is a risky move that puts the entire organic industry at risk.

It is based on the false assumption that the organic industry can only continue growing if it surrenders to the same misleading and reductionist health claims as

the conventional food industry. As one Board member commented in a private email to his colleagues on the Board, if the conventional food industry writes on the wall with crayons, the knee jerk reaction of the organic industry should not be to grab some organic crayons and join in. The organic industry should be held to higher standards.

The addition to organic foods of questionable ingredients like Martek's oils puts the entire organic industry at risk, because sooner or later consumers will feel cheated by what they thought was a highly regulated label. The organic standards are strong and meaningful, and they are the best guarantee available to consumers that the food was produced in ways that avoid toxins, promote ecological sustainability, etc. To sacrifice the organic standards by slowly chipping away at them – adding materials like Martek's oils to the list of non-organic ingredients that are allowed – may bring short-term profit spikes to a handful of corporations but is not in the best interest of the organic industry as a whole.

Corporate Lobbying and Corrupt Backroom Deals: Martek's Oils in Organic Foods

An organic infant formula was the first organic processed food to contain the Martek oils. Every infant formula manufacturer produces primarily conventional formula, with the organic product as a separate premium line. This applies even to brands that appear strictly organic, like Vermont Organics and Earth's Best, which are manufactured by PBM/Perrigo, the same giant formula maker that produces Walmart's Parent's Choice brands and all other store-brands sold in the United States.

Organic infant formula is the epitome of the "mirror-image" organic processed food – it contains the same list of ingredients, with certified organic instead of conventional milk powder or soy protein isolate, oils and sweeteners as the basis agricultural ingredients. The remaining ingredients exactly mirror the conventional formula in terms of the synthetic, manufactured vitamins, minerals and other added nutrients. Since synthetic vitamins and minerals are allowed in organic foods, it is likely that the formula manufacturers simply added the Martek DHA and ARA oils to the organic formula, without realizing this was illegal.

But it wasn't long before people noticed. Several separate legal complaints were filed with the USDA's National Organic Program, and each one was dismissed.

When investigating the initial complaint in 2006, National Organic Program officials came to the conclusion that companies were indeed in violation of organic standards by adding Martek's DHA and ARA oils to organic formula.

These NOP officials consulted not only with one another—experts in organic regulations—but with FDA officials as well, who assured them that DHA and ARA

are not essential nutrients, and therefore entirely optional as ingredients in infant formula. The NOP officials then drafted and sent a letter to the certifying agency Quality Assurance International, alerting them of the violations, when Barbara Robinson, the head of the National Organic Program at the time, intervened.

Robinson chastised her staff, ordered them to trash the enforcement letter, and draft a new one. She specified that the Martek oils should be allowed as "vitamins and minerals," based on an obscure and long-forgotten 1995 recommendation by the National Organic Standards Board.

Although Robinson was known to stress to certifying agents that only official standards count when certifying organic foods, and that NOSB recommendations carried no weight under the law until adopted as a final rule in the Code of Federal Regulations, in this case she ordered her staff to do just the opposite.

When ordering her staff not to enforce the organic standards, she told them exactly what a corporate lobbyist, William J. Friedman, had suggested to her. Cornucopia discovered, from documents obtained through the Freedom of Information Act, that the corporate lobbyist Friedman had met with Robinson and brokered a backroom deal with her.

Friedman had found the perfect loophole in the organic standards. In an attempt to restrict organic manufacturers from indiscriminately adding synthetic vitamins and minerals to organic foods, the organic standards annotated the listing for "nutrient vitamin and minerals" with the following: "in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods." 21 CFR 104.20 refers to the FDA's Fortification Policy, which aimed to set a standard for the "rational addition of nutrients to foods."[lxvi]

The FDA's Fortification Policy states that "random fortification of foods could … create nutrient imbalances in the food supply" and that it could "also result in deceptive or misleading claims for certain foods." It also states that the FDA "does not encourage the indiscriminate addition of nutrients to foods" and that the agency does not consider it appropriate to fortify foods including fresh foods and snack foods.

21 CFR 104.20 then lists a number of vitamins and minerals and provides guidance for the levels of fortification with these nutrients.

It was clearly the intent of the USDA, when it wrote the organic standards referring to 21 CFR 104.20, to restrict the vitamins and minerals to those listed by the FDA in its official Fortification Policy. However, there is an additional line in the FDA's regulations that states: "Nutrient(s) may be added to foods as permitted or required by applicable regulations established elsewhere in this chapter." This seemingly inconsequential line in the FDA's regulations, which counters the other sections of the rule as well as its general intent, proved to be the perfect loophole for Friedman,

the corporate lobbyist hired by the infant formula manufacturers to rescind the enforcement letter.

Friedman told Robinson that this allowance in the FDA's Fortification Policy for any nutrient that is "permitted" by the FDA should be taken literally, and out of context of the FDA's Fortification Policy.

According to Friedman's interpretation of the standards, which the USDA ended up accepting as its official regulatory policy, it did not matter that Martek's DHA and ARA oils are lipids, which are distinct from vitamins and minerals. It also did not matter that these nutrients are never mentioned in the FDA's Fortification Policy or other FDA standards as being essential nutrients.

All that mattered to Friedman was that the FDA "permitted" a seemingly endless list of novel nutrients to be added to foods. As long as the material was marketed as a "nutrient" and permitted by the FDA in the conventional food supply, Friedman argued, it should be allowed freely and without question in organic foods as well.

Robinson agreed, and ordered her staff to draft a new enforcement letter. And so began the USDA's policy of allowing any ingredient that claims to be a "nutrient" permitted in conventional foods to also be allowed in organic foods.

While the current administration has admitted that Robinson's interpretation of the standards was "incorrect," the USDA, to this day, continues to allow manufacturers to add Martek's oils to organic foods (the National Organic Program has even allowed new products to be introduced, with the Martek materials, since they have corrected the record). Formulated ingredients, like Martek's oils, which contains numerous other synthetics that are not approved for use in organics, are found in organic foods due to this loophole.

Under this policy, it was not just Martek's oils that were added to organic foods without undergoing the proper review and approval process. Nutrients like choline, nucleotides, lycopene, methionine, and others were added to organic foods as well without the proper approval process that is legally required of all synthetic ingredients.

Cornucopia shared these findings with the *Washington Post*, which confirmed and reported on the fact that the inclusion of Martek's oils in organics foods was the result of insider lobbying. Despite the objections of conscientious employees at the National Organic Program, and without any citizen input, Robinson single-handledly allowed all infant formula manufacturers to put these hexane-extracted oils and other synthetic nutrients in organic formula.

When asked by the *Washington Post* reporter, Dr. Robinson dismissed the DHA/ARA issue as a "ridiculous" regulatory matter. Within months of the *Washington Post*

story revealing the corruption at the USDA, Robinson was replaced as the head of the National Organic Program.

Martek's DHA Expands Beyond Infant Formula: Corporate-Owned Horizon Organic Milk "Sprouts Fishy Health Claims"

Michael Pollan saw it coming. In his 2007 *New York Times* article about the food industry's obsession with isolated nutrients instead of real, whole food, he wrote, "Omega-3 fatty acids are poised to become the oat bran of 2007, as food scientists micro-encapsulate fish oil and algae oil and blast them into such formerly all-terrestrial foods as bread and tortillas, milk and yogurt and cheese, all of which will soon, you can be sure, sprout fishy new health claims."[lxvii]

With the commitment by the USDA's National Organic Program to use Friedman's recommended loophole, other corporations involved in organics realized that they could also add Martek's novel ingredients without facing enforcement action, and profit from the "fishy new health claims."

Since adding Martek's DHA oil to foods opens the door to health claims such as "supports brain health," which sets a product apart from others on store shelves, Dean Foods, the largest dairy agribusiness in the United States, introduced a line of its Horizon organic milk with Martek's DHA in 2007.

Health claims on organic food should reflect the nutritional superiority of the foods by virtue of having been produced in a natural, organic way. For example, grass-fed milk and butter is high in the beneficial fatty acid conjugated linoleic acid (CLA) and omega-3s (including DHA), not because of a corporate deal between the milk processor and a nutraceutical corporation that produces these ingredients, but because nature put them in there.

But rather than put all its cows on pasture to naturally improve the omega-3 profile of its milk, Horizon choose the Martek route (independent research of organic milk brands found that Horizon products tested near the bottom of organic dairy products in the marketplace).

As Michael Pollan points out in his critique of health claims, "it's a lot easier to slap a health claim on a box of sugary cereal than on a potato or carrot, with the perverse result that the most healthful foods in the supermarket sit there quietly in the produce section, silent as stroke victims, while a few aisles over, the Cocoa Puffs and Lucky Charms are screaming about their newfound whole-grain goodness."[lxviii] The same was now happening in the organic dairy aisle, with grass-fed dairy products and their nutritionally superior fatty acid levels sitting silently next to the Horizon products' claims such as "supports brain health."

The first Horizon product to be supplemented with the Martek's DHA oil, a whole milk, was clearly targeted to toddlers and young children. By 2011, Horizon offered whole milk, 2% milk, 1% fat milk and skim milk with Martek's DHA algal oil, all claiming that the milk "supports brain health" on the carton.

Then, in 2011, Horizon launched an extensive marketing campaign centered around its DHA algal oil. Print advertisements appeared in popular magazines, from *Martha Stewart Living* and *Better Homes and Gardens* to parenting magazines such as *American Baby* and *Working Mother*. The ads proclaimed that "Milk with DHA Omega-3 isn't rocket science, but it is genius" and stated, "DHA Omega-3, a nutrient which supports healthy brain development" and "it's as delicious as it is smart." Another print ad states, "a smart move for growing brains."

Radio ads, on stations such as Radio Disney, announced, "Kids are smart. Continue to help support their brain development with Horizon Organic DHA Omega-3 Milk." Television ads showed a child beating her grandfather at a chess game, and called the DHA-supplemented milk a "smart move."

In 2011, The Cornucopia Institute urged the Federal Trade Commission (FTC) to investigate Dean Foods' advertising of its Horizon DHA milk for false and misleading advertising, in violation of section 5 of the Federal Trade Commission Act (15 USC 45).

The Federal Trade Commission, which enforces the Federal Trade Commission Act and is charged with preventing businesses form deceptive advertising to consumers, had already warned Martek in the past.

In 2004, the FTC warned Martek Biosciences Corporation: "The [FTC] staff continues to have concerns about whether Martek possesses adequate substantiation to make claims about the benefits of DHA and ARA supplementation for eye and brain function in older children and adults." While the FTC had noted in 2004 that "Martek' s advertising of the benefits of DHA and ARA for healthy children and adults has been limited," the agency decided not to take action.

The FTC had also investigated another company, Northwest Natural Products, for possible violations of the Federal Trade Commission Act related to similar claims regarding omega-3s and brain development. Northwest Natural Products marketed children's supplements with added omega-3s, and made similar claims that these products improve brain function, brain development, intelligence or academic achievement in children.

The FTC, in February 2010, sent a warning letter to 11 companies, including Northwest Natural Products, identifying these claims as objectionable.[lxix]

When Dean Foods launched its marketing campaign centered around its DHA algal oil, using the exact same language that the FTC had already objected to and warned

other companies about, Cornucopia brought these misleading health claims to the FTC's attention.

In terms of misleading its customers about the health claims, Horizon took it one step further by implying to organic consumers that the Martek oils are pure and free from synthetic ingredients. Online promotional materials claimed that Horizon DHA milk was a product "without the additives you'd rather avoid." Horizon, of course, never disclosed to its customers that the Martek oils are in fact produced with numerous undisclosed additives.

The misleading marketing claims on the Horizon website were especially objectionable given the endorsement of a paid spokesperson with a medical degree, Dr. Alan Greene. The website featured short videos with Greene promoting Horizon products with DHA. Cornucopia found this endorsement by Greene, by virtue of his medical degree, to be extremely misleading to consumers who are likely to trust a doctor's advice.

In January 2012, the FTC closed its investigation of Dean Foods' health claims on its Horizon milk products. Dean Foods/White Wave voluntarily suspended various aspects of the advertising campaign, including pulling the especially egregious online videos with Greene, and replacing them with a toned-down video without these misleading claims.

Up for a Vote: The NOSB Submits to Corporate Lobbying

In April 2010, with Barbara Robinson gone and under a new administration, the USDA admitted its past mistake in allowing these oils to be added without enforcement action. In a memo,[lxx] the National Organic Program wrote that its previous interpretation had been "incorrect," and that companies had to properly petition non-organic and synthetic nutrients like DHA algal oil.

Martek then petitioned its DHA algal oil and ARA fungal oil, in August 2010, more than 4 years after the first infant formula manufacturer put Martek's DHA and ARA in its organic formula.

Nearly a year and a half after Martek filed its petition, the National Organic Standards Board's 14 citizen members heard two days of public testimony – on this issue as well as many others – before voting at its meeting in Savannah, Georgia, in the fall of 2011.

Five votes against the Martek petitions were needed to uphold organic integrity and force manufacturers to take the Martek oils out of organic foods. Ten of the members voted in favor of Martek, and only four against.

In order to gain the ten votes it needed, Martek hired the organic industry's most infamous pro-corporate lobbyist, William J. Friedman. Friedman had experience with Martek's DHA – after all, he had been the one to broker the corrupt backroom deal with Robinson back in 2006. But more importantly, Friedman was the most experienced lobbyist in loosening the organic standards for corporate clients.

Friedman had been involved when the Organic Trade Association successfully lobbied Congress for a rider loosening NOSB oversight, Aurora Dairy's appeal of their proposed decertification, and in seeing several other synthetic ingredients through the NOSB's approval process.

In addition to having secured the industry's most notorious corporate lobbyist, Martek found one of its most ardent supporters in the NOSB's Chair. The Chair of the NOSB was Tracy Miedema, who was serving on the board as a "consumer" representative.

OFPA requires that a consumer representative should "represent public interest groups." Miedema worked for Earthbound Farm, the giant organic vegetable producer and distributor based in California. Not only did she not represent a consumer group, she publicly disparaged the work and positions taken by public interest groups regarding the Martek petitions. She took an overt personal interest in Martek's petition specifically, and became Martek's champion on the Board.

The National Organic Standards Board consists of committees that review petitions prior to the official biannual meeting, and issue their recommendations to the full Board. A petition like Martek's, which seeks approval as an ingredient in organic processed foods, goes first to the Handling Committee.

The majority of Handling Committee members in 2011 were employed by large food corporations, including the Campbell Soup Company, General Mills and Whole Foods. Two of its members, including Miedema, were employed by Earthbound Farms, the giant vegetable producers and distributor. Only two of the Handling Committee members held no corporate ties.

It therefore came as no surprise that the Handling Committee had recommended to approve Martek's petitions, but it was surprising that even the two members without corporate affiliations had voted in favor. The full Board would hear public comment, discuss the petitions, and vote at its meeting in Savannah, but the committee proposal set the tone for the debate.

To issue their proposals, committees fill out decision sheets answering important questions that are based on the official organic standards. For example, committee members determine the answers to questions like "are there negative environmental impacts from the production of the material?" and "is the material essential in organic handling?"

Rather than answer these questions truthfully, Miedema had filled out the questions with the answers she needed to justify recommending the Martek oils for approval.

For the question, "are there negative environmental effects from manufacture of the material?" Miedema answered "no." Martek had never hidden the fact that it uses the petroleum-based solvent hexane to manufacture its oils, and Miedema had heard in previous testimony at NOSB meetings that hexane is considered a "hazardous air pollutant" by the Environmental Protection Agency.

However, Martek had claimed in its petition that it captured and recycled all hexane, therefore implying its factories emitted no hazardous hexane fumes. The technical review that had been compiled for the Martek oils was severely deficient, and had failed to check the EPA's publicly available emissions data, which showed that Martek's oil factory did in fact emit thousands of pounds of the smog-producing hexane into the air annually. Miedema happily took Martek's word and answered "no" to the environmental impacts question.

For the question of whether organic alternatives exist, the Committee never considered that an organic diet of greens, grass-fed meat and milk, pastured eggs, and fish provides the most sensible and sustainable source of omega-3s. Instead, the Committee wrote that "there are no known certified organic sources of algal oil, nor certified organic sources of algal oil DHA."

But perhaps most importantly, the Handling Committee outright ignored one of the most crucial questions on the decision sheet: the question of essentiality. This question is based on a requirement in the law that only essential synthetic ingredients should be allowed in organic foods.

It is therefore a question that every committee needs to answer before issuing a final recommendation, and it clearly posed a problem for Miedema. The correct answer is "no:" there is nothing essential about Martek's oils in terms of organic handling.

While an organic cookie without baking powder would not rise, milk without algal oil has been perfectly acceptable the marketplace. The only reason for including algal and fungal oil in organic foods is to give the company a leg up in terms of advertising and marketing. But rather than answer "no," Miedema ignored the question entirely by checking the "not applicable" box.

What Money Can Buy: At the National Organic Standards Board Meeting in Savannah, Georgia

At the meeting in Savannah, the odds were stacked heavily in Martek's favor and against the public interest groups like Cornucopia , the National Organic Coalition

and the Organic Consumers Association that had urged the Board to reject the petitions.

With Dean Foods as Martek's largest organic customer to profit from the misleading health claims on the cartons of its Horizon milk products, Martek had another powerful corporation on its side. Together, the two $12-billion corporations hired lobbyists and flew in their own scientists and executives to convince the Board to approve the oils. They even arranged for farmers, supplying the Horizon milk brand, and corporate spokesperson Dr. Alan Greene to come to their rescue and support the Martek petitions in emotional public testimony, giving the appearance that even many in the organic community at large supported their petitions.

At the NOSB meeting in Savannah, two days were set aside for public testimony. While every citizen who signs up to speak is entitled to five minutes according to the NOSB's policy manual, Miedema had cut down on public participation, during her tenure, by decreeing, as the Board Chair, that every individual would only get three minutes. That handicapped public interest groups that, unlike corporate participants, lack the budget to stack the deck with numerous appearances they could underwrite.

On top of cutting down everybody's speaking time from five to three minutes, Miedema also restricted every individual's time slot to either their own or a proxy's statement. In the past, an individual had always had the opportunity to speak twice – once on their own behalf and a second time on behalf of an individual unable to attend the meeting in person. Cornucopia staff members had always taken this opportunity to comment on behalf of either a member-farmer unable to attend, or on behalf of a Cornucopia Board member unable to attend.

As a result, a staff member from an organization like Cornucopia that speaks on behalf of thousands of family farmer-members would no longer have ten minutes, but three. Presenting years' worth of research, and a variety of arguments for rejecting the Martek petitions, had to fit into three minutes (not to mention other important issues that were up for a vote before the NOSB).

In Savannah, Cornucopia had three of its staff members present, but also had to present on other issues of vital importance to the organic community, like animal welfare and a proposal to add synthetic preservatives in wine. Only one of Cornucopia's three staff members was able to devote all three minutes to commenting on the Martek petitions.

Likewise, the National Organic Coalition (NOC) had two staff members at the meeting, but multiple issues to comment on as well. Only one NOC staff member was able to comment on Martek's oils, and for mere seconds. Finally, the Organic Consumers Association sent one person to the meeting, and used all three minutes to comment on the Martek petitions.

Meanwhile, Martek and Dean Foods/WhiteWave had one issue to focus on, and an unlimited budget for paying lobbyists and airfare and hotel costs for its own employees. Seven corporate executives or corporate lawyers for Martek and Dean Foods/WhiteWave appeared at the podium. Three lobbyists, three corporate scientists, one professional corporate spokesperson masquerading as an independent pediatrician, and four farmers shipping milk to WhiteWave appeared at the podium to testify in favor of the Martek petitions.

With each individual getting three minutes, public interest groups in opposition to the petitions were able to present for approximately six minutes. One organic business, Nature's One, which makes organic toddler formula without Martek's oils, presented for three minutes. Corporate representatives in favor of Martek's petitions presented for 54 minutes – nearly an hour all told.

And that's not to mention that, because Martek was the petitioner, representatives of the company were afforded a liberal amount of time to, appropriately, answer extensive questions from board members.

Cornucopia did have hand-signed proxy letters from organic farmers and consumers – upwards of 15,000 of them. While corporate representatives were testifying downstairs in the hotel meeting room, the Cornucopia codirectors' hotel room was transformed into a bustling hub of local volunteers opening mail and processing letters from organic farmers and consumers who had signed their name to a letter opposing the Martek petitions.

On the first day of public comment, Cornucopia Codirector Mark Kastel had to borrow an industrial dolly from the hotel's engineering staff to deliver boxes with 14,300 letters. On the last day of public comment, Cornucopia's other co-director, Will Fantle, presented another 1,200 letters to the Board members, bringing the total to 15,500 citizens – organic farmers and organic consumers – opposing the Martek oils in organic foods.

But most Board members only glanced at the boxes of letters, and likely never bothered to consider the meaning of more than 15,000 individually signed and mailed letters. These were not organic stakeholders who merely click on an icon to sign an online petition. These were hard copies of letters, many customized with heartfelt messages for the Board. Yet they obviously did not carry the weight of a handful of lobbyists from Martek and Dean Foods.

NOSB members were listening to the people in the room. With every citizen getting but three minutes, it helps to have the resources to fly in lots of bodies, and create an impression that the public interest groups like Cornucopia and the National Organic Coalition are merely on the fringe, representing a "purist" minority.

Moreover, some of the farmers acting as spokespersons for Dean Foods deliberately created the impression that they were speaking on behalf of the National Organic

Coalition, which opposed the Martek petitions. Mr. Perry Clutts, an organic dairy farmer from Ohio, said that "In addition to being a dairy farmer I'm also a proud member of NODPA, which is the Northeast Organic Dairy Producers Association, which is also a member of NOC, the National Organic Coalition." Another dairy farmer, Mr. Ed Zimba, used the same tactic. While the National Organic Coalition opposed the Martek petitions, Clutts and Zimba followed these affiliation statements with their passionate comments attempting to discredit the work of The Cornucopia Institute and urging the Board to approve the Martek oils.

Arranging for these farmers to present at the meeting was a smart move by Dean Foods. The WhiteWave executives (WhiteWave is a division of Dean Foods) gave these farmers a message to pound home during their public testimony: that Martek's DHA oil is non-GMO, non-hexane-extracted, and non-synthetic, and should be approved.

It didn't matter to the Dean Foods/WhiteWave executives that this was an extremely misleading statement, since the Board was voting also on the hexane-extracted oils that go into infant formula, or that questions about the genetically engineered status of the oils, including the microorganisms' feed and the other corn-based ingredients in the final powdered form of the oils, were still unanswered.

When asked questions by Board members, the farmers clearly did not understand the complexity of the materials and the petitions. For example, Board member Jay Feldman asked dairy farmer Zimba, who had stated that algal oil was non-hexane-extracted, whether he knew that the Board would be voting also on the hexane-extracted Martek oils. Feldman asked Zimba if that piece of information would change his opinion. Zimba answered, "I don't understand that part of it," and was clearly confused by the question.

Zimba seemed completely unaware that hexane-extracted algal oil was part of the Martek petition. In his testimony, he had also derided Cornucopia and suggested that Cornucopia's opposition to the petition was based on false information. He had stated that Cornucopia's action alert on the issue was "irresponsible, exploiting the public," and called it "unscientific attacks." This was a clear example of corporate executives at WhiteWave taking advantage of passionate farmers like Mr. Zimba, who had not read or understood Cornucopia's materials and were therefore unaware of the complexity of the issue.

Moreover, with Miedema as the Board Chair, Zimba was allowed to continue his disparaging remarks against Cornucopia without interruption. The NOSB Policy Manual specifically prohibits disparaging remarks against other individuals or organizations during public testimony. Board Chairs, including Miedema, have always taken seriously their responsibility to gavel down anybody who violates this important rule. Miedema allowed Zimba to continue unabated in his diatribe against Cornucopia.

By arranging for the presence of farmers at the meeting, Dean Foods/WhiteWave succeeded in shifting the attention away from the multibillion-dollar corporate nature of the petitioners, and created the impression that organic family farmers like Zimba and Clutts desperately needed the approval of the petition to stay in the organic business.

Meanwhile, thousands of organic farmers and consumers had sent letters to the NOSB, urging them to reject the Martek petitions. But, without a corporation to pay their airfare to Savannah, these farmers and consumers did not appear in person and could only hope that their letters, along with thousands of others, could sway the Board. They obviously didn't.

Corporate Science at the NOSB Meeting

Every scientist who testified at the NOSB meeting had a financial interest in the outcome of the vote. Their presentation of science at the meeting had only one goal: to convince the Board members that their manufactured algal and fungal oils are beneficial and essential. This is not a sound use of science.

In her book *Food Politics*, Dr. Marion Nestle suggests that science by the food industry is often used to defend a position, rather than make new discoveries. Agrarian philosopher Dr. Frederick Kirschenmann agrees that sound science should aim to probe, not prove.

The point that the scientists at the NOSB meeting aimed to prove is best articulated in the words of those scientists. Troy Akan, with the Hain Celestial Group that markets Earth's Best infant formula (containing Martek's DHA algal oil), said that "we also have a responsibility to provide the best possible nutrition for babies and therefore based on the most credible scientific evidence."

Yet in presenting the science regarding the benefits of DHA algal oil and ARA fungal oil, not a single Martek or other corporate scientist included the most credible scientific evidence: the only two meta-analysis studies that have reviewed all the available scientific studies on this topic and concluded that no cognitive benefits exist from adding DHA and ARA to infant formula.

Although he was writing primarily about agricultural science, Kirschenmann's essay on sound science applies to nutritional science as well. Kirschenmann suggests that sound science should be practiced as dialogue, not monologue. The scientific debate surrounding the Martek oils at the NOSB meeting was purely monologue by the Martek scientists. Their goal was not to present the complexity of the science and appreciate unanswered questions about these nutrients, but rather to assert that their profitable oils are "proven" beneficial and essential. Rather than present all

scientific data, most of which would not support their position, they set out to prove their already adopted assertion.

Kirschenmann writes that "any science claiming validity that has not been scrutinized by a community of independent scientists exploring similar data cannot be considered good science." The two meta-analysis studies are as close to a review of the science by a community of independent scientists as we'll likely ever get, and their conclusions were squarely in conflict with the Martek scientist conclusions.

Yet the Martek scientists claimed the high ground, and repeatedly spoke of their presentations as "sound science" while referring to the science presented by Cornucopia (anchored by the two published, peer-reviewed meta-analyses) as "misinformation."

Board Chair Miedema supported the idea that the corporate scientists were presenting real science while the studies presented by public interest groups are too tainted by "personal opinion" to qualify as "science." "We have a statutory responsibility to use science. We have a statutory responsibility to leave those personal opinions behind," Miedema told the Board during the meeting.

Of course, the idea that the Martek scientists have no "personal opinion" is preposterous. Philosopher Karl Polanyi has pointed out that there is no such thing as objective science, because every individual is shaped by past experiences, personal biases and the context in which the individual lives. To assume that one can be free of personal opinion in science is dangerous, precisely because it marginalizes those who use science more responsibly – to continue exploring and seeking a deeper understanding of the studied subject matter.

In the 1990s, a scientist specializing in omega-3s at the National Institutes of Health tested eggs from hens that ranged freely and ate their natural diet of insects, worms and greens. The results showed that the eggs from the free-ranging hens contained twenty times more omega-3 fatty acids than standard supermarket eggs, which would of course be from hens raised mostly on corn and soybeans.

The free-range eggs had a ratio of omega-6 to omega-3 fatty acids of 1:1, which is better than ideal, while the supermarket eggs had a dangerously lopsided ratio of 20:1. This scientist was Norman Salem. In 2008, Salem left the National Institutes of Health to join Martek Biosciences Corporation as its Chief Scientific Officer. He was at the meeting, and testified under the pretense of "sound science," creating the impression that Martek's oils are desperately needed to fix our nation's omega-3 problem. Obviously, switching the way our livestock are raised, as he had previously concluded, would be more cost-effective and efficacious, and certainly more consistent with federal organic standards.

Corporate Spokespeople at the National Organic Standards Board Meeting

For the meeting, Dean Foods/WhiteWave had arranged for its celebrity spokesperson, Dr. Alan Greene, to testify in favor of the oils. Cornucopia had in the past initiated a dialogue with Greene about Martek's DHA oils, but it soon became clear that he had made up his mind about the benefits of Martek's oils for organic foods. Perhaps the generous pay from Dean Foods/WhiteWave – he is reported to receive $100,000 yearly – is more powerful than the strength of the scientific findings.

When Greene appeared in Savannah, Cornucopia Codirector Mark Kastel worried that Greene would represent himself as an independent expert in child nutrition, rather than the generously compensated professional corporate spokesperson that he is.

During a break in the meetings, Kastel spoke with Greene in the hotel lobby, and urged him to disclose his financial ties with Horizon during his testimony. Kastel then told Greene that if he did not disclose his relationship, Cornucopia would devote considerable resources to "outing" him as a corporate mercenary.

Since Greene made his living, almost exclusively, through selling books, a proprietary umbrella that includes a popular website, corporate endorsements and media appearances, it was assumed that he would be concerned with preserving his "independent" reputation.

During his subsequent public testimony, Greene seized on the opportunity to further discredit Cornucopia's work and shift public opinion in favor of the Martek oils.

He said in his three-minute public testimony: "Mr. Kastel from the Cornucopia Institute pulled me aside in the hallway outside this room and warned me point blank that if I testify in favor of the petition on DHA that he would devote considerable resources (his words) to a public campaign to ruin my reputation and destroy my career."

He went on to state that "When Horizon was considering adding DHA to their milk they asked my opinion, which I gave. My views are mine, not theirs. The only person who has used economic incentive to try to change my opinion is Mr. Kastel."

Finally, after sharing his story of his wife's breast cancer diagnosis while nursing their son, he stated that "DHA was the issue that led me to my passion for good food as central to good health and to organics as our best hope."

He then stated, "After weighing his statements this week, I've concluded that the value of my 3 minute testimony in advancing children's health would not be worth

the risk to myself, my wife and my children, so I will not comment on the DHA petition before the board."

Greene spun Kastel's comments to turn the tide of public opinion against Cornucopia's campaign to challenge the Martek petition. Kastel never threatened Greene's livelihood. Rather, he declared his intention to expose Greene's financial relationship with the corporation that stood to gain most from the approval of DHA algal oil and that is, not coincidentally, handsomely compensating him—a financial relationship Greene should have disclosed himself if he were to act with integrity as a spokesperson on behalf of Martek's additives.

If Greene felt threatened – which he clearly did – it was only because he realized that his public persona, as an honorable, independent, pro-organic practicing pediatrician, could soon be shattered by the research and subsequent public outreach of a group like Cornucopia.

Although he publicly acknowledged that he was working as a "consultant" answering questions about DHA for Dean Foods, he failed to reveal that he had also produced numerous promotional videos, including encouraging viewers to get their DHA from Horizon brand milk, that appeared on Dean's Horizon website.

Greene says he is pro-breastfeeding, but in the past decade, there has been no action in the U.S. worse, in terms of undoing the progress by breastfeeding advocates, than the marketing by Mead Johnson/Enfamil concerning their addition of Martek's DHA and ARA to infant formula (Enfamil does not have an organic option).

In his testimony, Greene also did not reveal the fact that he had been intimately involved in promoting DHA, in conventional infant formula, for one of the nation's largest pharmaceutical companies.

Mead Johnson hired Greene in 2002 to travel around the country, giving talks to pediatricians and parents, to "educate" them about the benefits of DHA and ARA. He still appears on the Enfamil website advocating for the DHA and ARA oils.

The breastfeeding community, both in the U.S. and Europe, was outraged at the Mead Johnson campaign touting DHA and ARA as now making infant formula "as close as ever to breast milk" because they contain "nutrients naturally found in breast milk" which have set back their progress considerably.

Government statistics show the rates of breastfeeding ***falling*** in the U.S. in the year following the introduction of DHA/ARA infant formula – which was combined with aggressive product marketing. Greene was a professional advertising spokesperson for Mead Johnson, while at the same time claiming to be pro-breastfeeding, and was criticized on Internet sites, by breast-feeding advocates, for his duplicity.

Greene also failed to inform the NOSB that he has also been a spokesperson for a supplement maker that uses the Martek oils. His face and name appear on the front panel of DHA supplements marketed by the nutraceutical corporation Twinlab, where his face appears side-by-side the Martek "Life'sDHA" logo for a DHA supplement for toddlers. Dr. Greene was financially compensated for this, with Twinlab listed as a "sponsor" of his Drgreene.com website (alongside the Horizon logo).

Dr. Greene has also been a spokesperson for Novartis and other, lesser-well-known, pharmaceutical companies, in addition to The Hain Celestial Group.

Yet the only past financial relationships that he chose to disclose to the NOSB during his public testimony were his past association with two large organic companies that have no involvement with the Martek DHA issue, Organic Valley and Stonyfield — no doubt to win the hearts of the NOSB members before beginning his attack on Mark Kastel. He made no mention of other corporate relationships—most poignantly leaving out all professional involvement promoting Martek DHA products—when DHA was the topic of his 3-minute talk.

Every other commenter for Martek and Dean Foods fully disclosed his or her relevant affiliations. William J. Friedman was listed on the agenda as working for Martek. The Martek scientists were listed as working for Martek. The Horizon farmers were honest about disclosing their relationship with Horizon. **Nobody needed to tell those individuals that they needed to disclose their financial relationship with these corporations, because they did so voluntarily.** The content of their testimony may not, in many cases, have been accurate, but at least their disclosure of their affiliation was honest.

Dr. Greene registered himself as a "citizen" for the meeting (registered before his conversation with Cornucopia's Kastel). Without Kastel's request, Greene would likely have gone to the podium and introduced himself as a "pediatrician with Stanford Medical School," and would likely have sold himself as an independent expert on DHA.

His unethical behavior, and that of his benefactors, was reminiscent of testimony in front of federal panels, during the 1960s and 70s, when physicians hired by tobacco companies commonly challenged the preponderance of peer-reviewed science illustrating deleterious health effects from smoking, and the more recent history of scientists working for oil companies challenging the science of climate change.

Board Chair Tracy Miedema: Corporate Representative Serving in a "Consumer" Slot Champions Marteks' Oils

Miedema had taken the responsibility for writing the Handling Committee's proposal for the Martek petitions, and therefore took the opportunity to speak at

length when introducing the petitions to the full Board during the public session on December 1, 2011.

Martek had found in Miedema the perfectly unquestioning and willing Board member to take up its cause.

Miedema, even though she served as a public interest representative on the Board, all but ignored the issues that had been raised by public interest groups like Cornucopia, the Organic Consumers Association and the National Organic Coalition. In her talk on Tuesday, she referred to information that had been distributed by these groups as propaganda and misinformation, and called on her colleagues on the Board to "leave [their] personal opinions at the door."

She questioned the accuracy of non-profit organization's research and claims. Finally, she referred to a FDA letter responding to Cornucopia's concerns, refuting reports of gastrointestinal symptoms in infants.

She referred to the FDA – the agency that claims genetically engineered foods, aspartame and MSG are safe – as the "world's preeminent food safety authority." Based on the FDA's letter, which disregarded numerous adverse reaction reports, Miedema cast doubt on all the information supplied by public interest groups like Cornucopia: "There's no sort of moral high ground granted to one opinion. I would ask you please simply because of an organization's tax status, we've already heard many of the facts that were propagated refuted. And in fact, for years we had people stand at this podium talking about this GI issue with this material, and how horrible this was for babies. This was a waste of our time."

Miedema was referring to stories of gastrointestinal symptoms in babies that had been shared in public testimony at previous meetings. For example, at the NOSB meeting in Madison, Wisconsin, the previous year, Cornucopia had shared the story of Suzanne Stock, a mother whose 8-month old daughter suffered reactions when given organic formula with DHA and ARA.

Stock's daughter had recovered almost immediately when switched to an organic toddler formula that does not contain the Martek oils, and Stock had given Cornucopia's Director of Farm and Food Policy, Charlotte Vallaeys, permission to share her story during her testimony to the NOSB. This story, and others like it that had been presented during previous public testimony, is what Miedema referred to when she spoke of "a waste of our time."

NOTE: First-hand accounts of parents and healthcare providers can be found in the Cornucopia report, *Replacing Mother-Imitating Human Breast Milk in the Laboratory* and in a video that can be found in the video gallery of the Cornucopia website.

Miedema's motivation for championing Martek's oils has never been clear. She works for Earthbound Farms, which is one of the largest players in the organic

industry, but does not market any products with the Martek oils (interestingly, Dr. Alan Greene disclosed on a website that requires a conflict of interest statement, that he had contracted with Earthbound Farms—which the company later disputed).

The only written public comment from an organic consumer that was supportive of the Martek petitions (thousands of letters were submitted from organic farmers and consumers) was from a close relative of Miedema.

The Voice of the Organic Consumer and Public Interest Groups: Ignored

Miedema based her support of the Martek oils, in part, on the fact that organic consumers had been buying Horizon milk with DHA, and other organic foods with the added Martek oils. "Who are we to second guess three million Americans?" she asked during her talk, referring to the three million Americans who, according to data supplied to Miedema, had bought organic foods with Martek's oils.

Her assumption that organic consumers had bought these because they wanted Martek's oils in their organic foods was shattered by the results of a survey conducted by PCC Natural Markets in Seattle, which was also presented to Miedema, but ignored.

PCC Natural Markets, the largest consumer-owned natural foods grocer in the United States, with 40,000 members, surveyed nearly 1,500 organic shoppers to determine their awareness and concerns regarding the source and regulation of natural and synthetic nutrients added to organic foods. Below are excerpts of some of their findings:

PCC shoppers prefer, by an overwhelming margin, that added omega-3s be made from naturally occurring sources, compared to synthetically-derived omega-3s.

Six of 10 shoppers who are aware of how many certified organic foods they purchase would not purchase products to which omega-3s made from synthetic sources have been added. If responses of "less inclined" and "would not purchase" are combined, an obvious conclusion is that the majority of even "less organic" shoppers (those whose grocery purchases are less than 50% organic) **do not want** added, synthetically-derived omega-3s in their food.

PCC Natural Markets found that the vast majority of their organic consumers shoppers reject hexane-extraction in their foods, including in added sources of omega-3 DHA. The PCC survey shows that only 0.3% of organic shoppers would be "more inclined to purchase" foods with added DHA if it is hexane-extracted, and 88.6% "would not purchase."

These results suggest that organic consumers, upon seeing the ingredient "algal oil" listed on the package or carton of an organic product, had assumed this meant the algal oil was "natural" and produced in accordance with the organic standards.

If the overwhelming majority of organic consumers filling out the PCC survey said they would reject nutrient ingredients made with the use of hexane, non-organic oils, and synthetic stabilizers, it could only mean that the vast majority of the three million organic consumers who have purchased organic foods with "algal oil" were misled and simply did not know that these oils were in fact produced with synthetic solvents, non-organic oils and synthetic ingredients.

While this data shattered Miedema's only legitimate argument, no representative from PCC Markets, which is located in Seattle, on the other corner of the country from the meeting in Savannah, was able to attend the meeting to present the survey results. The survey results were never discussed, and only briefly mentioned by Cornucopia's Charlotte Vallaeys in testimony during the Q&A of her 3-minute public testimony (although the findings of the study were submitted in writing in advance for NOSB members to review).

Corporate Lobbyists Successful Ploy

While the Dean Foods/WhiteWave farmers, the Dr. Greene emotional performance, and Martek's corporate scientists played a role, the lobbyists, in concert with Board Chair Miedema, were ultimately responsible for elbowing the oils into organic foods.

Friedman was not the only lobbyist. Dean Foods/WhiteWave hired Martin Hahn, who had overseen Martek's petition to the FDA for GRAS status in 2001, and was therefore experienced in gaining regulatory approval for Martek's oils specifically. Another lobbyist, Bob Durst, did not disclose a relationship with Martek or any of its customers, but did devote his 3-minute testimony to the Martek petitions. He had this to say:

> "What has really disappointed me in the last few days is the rhetoric, distorted truths, and outright falsehoods that are being thrown around in opposition of these petitions. The inflammatory scare tactics being touted as a search for the truth are as bad as the fanatical political squabbling that is hamstringing our country at present."

Issues Not Addressed by the NOSB: "Other ingredients"

Martek's algal oils or algal oil powders are not merely comprised of the mutated or hexane-extracted algae. Numerous other ingredients – some non-organic agricultural products and others purely synthetic – are also inserted in the oils or

powders before being added to infant formula, milk or other foods. These non-organic and synthetic ingredients are used as preservatives, stabilizers, fillers and sweeteners. Some were disclosed in the Martek petition, but many were not.

In the spring of 2011, Cornucopia filed a legal complaint against Nurture, Inc., which markets Happybellies cereal for babies. The certified organic product contains Martek's DHA algal oil powder, and disclosed on the ingredients list that it contains glucose syrup solids, modified starch, mannitol, sodium ascorbate, sodium polyphosphate and high oleic sunflower oil. None of these ingredients have been approved for use in organics nor have they been individually petitioned for review by the NOSB.

Rather than take enforcement action on the Cornucopia complaint, the USDA sent a memo to the NOSB just weeks before the meeting to request clarification. In his memo, NOP administrator Miles McEvoy pointed out that the rule for synthetics in organic crop and livestock production are very clear: "synthetic substances are prohibited for use in organic production unless specifically allowed."

But the NOP recognized that certifiers had been allowing synthetic substances as stabilizers, fillers, and "other ingredients" in formulated ingredients like the Martek oils. According to the NOP, this had to be clarified and fixed. McEvoy wrote: "From this point forward, the NOP is requesting that the NOSB consider the presence of any "other ingredients" as part of their review process"[lxxi]

Miedema was not happy. "So, you know, pretty 11th hour to tell you the truth," she said during the NOSB meeting about the NOP's November 15 memo. But she led the effort to come up with criteria for "other ingredients" in the Martek products, and made the criteria as broad as legally possible. However, one of the criteria was that any ingredient that was not disclosed on the petition would be disallowed. The glucose syrup solids, mannitol, modified starch, sodium polyphosphate and sodium ascorbate present in the Happybellies organic baby cereal were not disclosed in the Martek petition.

During public testimony, Cornucopia's Charlotte Vallaeys had brought a can of the Happybellies cereal containing the algal oil powder to the podium and passed it around the Board members to see the ingredients list for themselves. Some Board members were clearly concerned, and wanted to clarify whether they would be voting on the powdered form of algal oil that is found in this product. When Board member Nick Maravell asked the question to a Martek executive, their lobbyist, Friedman, waltzed up to the podium and responded that he could answer the question, saying, "That is not the petitioned material."

Miedema then repeated: "So for the record, the material that was passed around to the Board yesterday is not anything – it's not part of the pending matters of this Board or any of our proceedings."

Yet the official Martek petition had stated that it petitioned *all* DHA products that "had been authorized previously" by the USDA, meaning any Martek DHA ingredient currently in certified organic products. Clearly, the algal oil powder in the Happybellies product *was* part of the official petition.

Furthermore, the Martek petition clearly stated that powdered and liquid forms of their products were both being presented for approval.

Since Friedman clearly misled the Board members, Cornucopia filed an ethics compliant with the DC Bar Association against Friedman. The complaint is currently being adjudicated.

Several weeks after the NOSB's vote of approval for the Martek petitions, the USDA sent a letter to Cornucopia dismissing the official complaint against Nurture, Inc's use of algal oil powder containing the long list of unapproved synthetic substances. Cornucopia staff has now submitted additional information and asked the USDA to reconsider their initial decision. If this powdered material was not indeed included in the petition, it was added illegally and unlike the liquid form there is no current pathway for legal approval.

Arguments ignored

Cornucopia had submitted comprehensive written comments to the Board during the public comments period, weeks before the meeting. This comment pointed out the environmental impacts of the use of hexane, and raised questions regarding genetic engineering, essentiality, natural alternatives, synthetic "other" ingredients, etc. Cornucopia's public testimonies focused on the fact that these oils are not essential for organic handling, and that natural and organic alternative sources of DHA are available.

In written comments, Cornucopia had also pointed out that developing organic algal oil was entirely feasible, and that adding Martek's oil to the National List now would immediately bring an end to any innovation in this field

Cornucopia shared with the Board that it had been in dialogue with one European company in the process of developing an organic algal oil – grown in organic substrates, extracted using organic methods, and stabilized with organic ingredients. Approving Martek's non-organic algal oil, Cornucopia pointed out, would immediately squander any hopes of ever seeing truly organic algal oil on the market.

But the pressure to add Martek's oils was too high. The night before the vote, Martek's lobbyist Friedman met with the Handling Committee to broker a deal,

again behind closed doors. The proposal was to accept the Martek oils with the following annotation: "not hexane-extracted, with organic agricultural materials"

Without the presence of public interest groups like Cornucopia to provide balance, the Handling Committee members accepted the annotation written by Friedman. The petitions would be approved in a vote, with ten NOSB members voting "yes" and 4 voting "no," with this annotation the following day.

Remaining concerns

The Board voted to allow algal oil and fungal oil with an annotation that it be "not hexane-extracted." This allows for algal and fungal oils to be extracted with volatile synthetic solvents other than hexane, such as acetone or isopropyl alcohol.

A compromise using the term "not hexane-extracted" was a deliberate ploy offered by the Martek and Dean Foods lobbyists because algal oil for products other than infant formula is extracted with other synthetic solvents, including isopropyl alcohol, which is also a petroleum-based volatile synthetic solvent and therefore prohibited in organics.

It should be noted that all synthetic solvents are specifically prohibited in organic production and handling.

Although the regulations prohibit all synthetic solvents, in the year running up to the NOSB meeting, and the subsequent approval of Martek oils, hexane use had been a hot button public issue and debated extensively in the media.

At least one board member challenged the agreement, before their vote, stating that a simple "not hexane extracted" annotation would leave the door open to other synthetic solvents, some potentially even more harmful than hexane. "We're opening up the barn door," said NOSB member Jay Feldman, "when we have an open-ended list [of synthetic solvents] with acetone, chloroform and, Steve says hundreds of others that could be used."

But the corporate Board members were eager to vote with a restriction on hexane only, and the annotation as proposed by the lobbyist remained unchanged.

Cornucopia believes that the annotation for algal oil and fungal oil should be consistent with the organic standards, which prohibit any and all "volatile synthetic solvents," that does not single out hexane as the only prohibited synthetic solvent.

The second part of the annotation, which states that agricultural ingredients in the oils must be organic, is problematic as well, since it focuses only on agricultural

materials and remains silent on all other synthetic stabilizers, sweeteners and preservatives.

Other issues remaining unaddressed

Many issues and concerns that were raised by Cornucopia before the meeting remain unaddressed. These concerns include:

1. **Genetic Modification:** The organic standards prohibit genetic modification, and specifically state that techniques of genetic modification are not restricted to recombinant DNA techniques but include "a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions" (see 7 CFR 205.105(e)).

   Serious questions remain regarding the techniques used by Martek Biosciences to develop the specific strains of algae and fungus used to produce its oils. The NOSB should not rely solely on an assertion by Martek executives and lobbyists, with questionable scientific knowledge regarding the genetic modification techniques used, that the oils are "non-GMO" and accepted in the EU.

   The NOSB should demand documentary evidence and detailed descriptions of the process by which these organisms were developed. The unquestioned acceptance of a verbal assertion by Martek executives during public comment sets an unacceptable precedent – materials should not be voted onto the National List based on incomplete information regarding important questions such as genetic engineering.

   Martek developed its DHA algal strain through classical mutagenesis, which subjects the algae to harsh chemicals or radiation to induce changes in the DNA sequence that would not occur naturally. Even if no techniques other than mutagenesis were used, the strains should be rejected from organics because mutagenesis is a technique of genetic modification that cannot occur under natural conditions and is not compatible with organic production.

   And finally, the only documentary evidence available from Martek includes patents with provisions for their products be developed through recombinant genetic engineering. A verbal assurance, from an executive not under oath, should not be the sole buffer between the American public, trusting the organic label to be free from genetic engineering, and biotechnology companies and agribusinesses on a quest to maximize profit or grow market share.

   Because these specific varieties of algae and fungus have been developed years ago, and passed through numerous owners (including Monsanto), Martek executives and lobbyists testifying at the last NOSB meeting likely have no

firsthand knowledge of the genesis of these products. Cornucopia has urged the Board should demand a full documentary explanation of their development.

2. **Synthetic or non-synthetic**: The Board voted to list the oils as "non-synthetic," but Cornucopia believes they should be classified as "synthetic." Based on past precedent, materials that are heavily processed could be classified as "synthetic." For example, unbleached lecithin is listed as an agricultural ingredient, whereas bleached lecithin – because it is bleached – is listed as a synthetic. Martek's oils are not only bleached, but extracted with synthetics, stabilized with synthetics, and deodorized and winterized.

   The Board should not have solely depended on a substandard technical review, which primarily relied upon materials submitted by the petitioner, in making their determination that patented Martek oils are "natural." If in fact they were "natural," they most likely could not be patented in the first place.

3. **The use of genetically engineered corn as a fermentation medium:** The algae and fungus are fermented in a medium that includes corn derivatives, which Martek has stated is derived from conventional corn.

   Organic eggs, meat and poultry could not be produced, legally, from animals that consume conventional feed. Logically, microorganisms used in organic processed foods should be prohibited if they are raised on conventional feedstuffs. Consumers turn to organics to assure that their diets are "clean" and free of genetically modified organisms and agrichemical residues.

4. **Microencapsulation:** The organic standards specifically prohibit microencapsulation (7 CFR 205.105(e))) – and see definition of "excluded methods" in 7 CFR 205.2 "Terms Defined")

   In its petition for algal oil, Martek states that the petition encompasses all products marketed by Martek under the trade name "Life'sDHA," which includes powdered algal oil that is currently found in infant formula and organic baby foods. In its petition, Martek states that the powdered algal oil is manufactured using microencapsulation.

   NOSB members were misled by Martek's lobbyist, William J. Friedman, who stated on the record that the DHA algal oil powder used in a particular brand of organic baby food was not part of the petition. The official petition that was the subject of the NOSB vote states that all "Life'sDHA" products, which includes the powdered form, are part of the petition.

   Furthermore, and this is a glaring deficiency, the Martek petitions also did not disclose the ingredient(s) that the oil particles are microencapsulated in.

5. **Nanotechnology:** When the oil particles are microencapsulated for use in infant formula, baby cereal and other powdered foods, what is the size of the particles? Would these classify as nanoparticles? Other food products currently microencapsulated would be made up of small enough particles to be categorized as produced with nanotechnology. These questions should have been resolved before a board vote.

Cornucopia sent a letter to the Board members asking to put the petitions back on the agenda for the Spring 2012 meeting, and revote.

At the Spring 2012 NOSB meeting, numerous other synthetic nutrients that have already been added to organic foods without being petitioned first are on the agenda for potential approval.

Connecting the Dots: The Organic Watergate

The approval of Martek's DHA algal oil and ARA fungal oil for use in organics, at the Fall 2011 NOSB meeting, was a watershed event for Cornucopia. It became clear that Martek Biosciences Corporation managed to gain approval not only due to its unlimited budget for lobbying, but that the system had broken down within the NOSB as well.

The technical review was severely deficient and misleading, in favor of the addition of Martek's oils to organics. The identity of the individuals involved with the creation of the TR remained secret, but the TR relied heavily on information from an organization that also employs a corporate consultant, Bob Durst, who was present at the meeting to speak on behalf of Martek, without disclosing his client.

On the Board, the most ardent and outspoken champion of the Martek petitions was its chairperson, Tracy Miedema, who served in a slot reserved for representatives of public interest organizations. Not only did Miedema never work for a public interest organization in her five years on the Board, she was employed by several corporate agribusinesses during her term.

Despite overwhelming opposition to the Martek petitions from public interest organizations, and thousands of citizens who submitted proxy letters, Miedema, as a public interest representative, took the lead in championing the Martek oils. It became clear that the stacking of the Board with corporate representatives has real repercussions for the integrity of the organic label, and the actions that the Board takes.

Meanwhile, the seat on the Board reserved, by law, for an independent scientist, was held by Katrina Heinze, an employee of General Mills, one of the largest food

corporations in the world. General Mills and Martek Biosciences Corporation entered into a licensing agreement for the microencapsulation of Martek's oils.

This potential conflict of interest was never disclosed by Heinze, despite a policy that Board members with conflicts of interest recuse themselves from voting.

Again, the corporate affiliations of Board members, in seats reserved for consumers, scientists and farmers, are clearly not without consequence.

Both in written public comment and oral public presentations, the Board members heard from individuals who serve as consultants to the organic industry, and testified in favor of adding the Martek oils to the National List of Approved Substances. These individuals, including Bob Durst and Richard Theuer, did not disclose whether they were paid, and by whom, to submit this testimony. More alarmingly for Cornucopia staff, however, is the fact that these individuals have been involved in technical reviews for past petitions.

The fiasco with the Martek oils led Cornucopia to question whether similarly problematic ingredients had been approved in the past, with the same undue corporate influence of Board members and technical reviews. This led to our comprehensive examination of carrageenan and how it was initially approved for use in organics, and the process to have it relisted which is currently before the NOSB.

Similar stacking of the Board with corporate representatives, holding seats reserved for public interest representatives, environmentalists, scientists and farmers has indeed been happening since the first Board convened in 1992. At its last appointment of new Board members, Secretary Vilsack again passed over real organic farmers who had applied, and gave the farmer seat to a corporate employee who does not in fact own or operate an organic farm.

Moreover, the Handling Committee of the National Organic Standards Board continues to act solely in the interest of corporate agribusiness, as its recommendation for the relisting of carrageenan makes clear. Carrageenan, an ingredient that serves no nutritional purpose in foods but is added as a stabilizer and thickening agent, was approved in 1995 based on a severely deficient technical review by three scientists with corporate ties.

One of the scientists worked for Small Planet Foods, which is today a division of General Mills. Another scientist, Richard Theuer, was a corporate executive at the time of the carrageenan technical review. He is still active today as a consultant to the organic industry, and recently reaffirmed his view that carrageenan is a safe ingredient, despite overwhelming and convincing scientific evidence that carrageenan is an inflammatory agent and contains a substance that is classified as a "possible human carcinogen."

Appendix A: Comments submitted by Cornucopia to the NOSB regarding Martek's petitions for DHA algal oil and ARA fungal oil

The following arguments by Cornucopia opposing the legality of Martek's oils in organic foods were submitted to the Board prior to its Fall 2011 meeting. In addition to submitting these comments through www.regulations.org, the official web vehicle for accepting public input, Cornucopia also sent, via Federal Express, copies of its testimony directly to board members. There is no excuse for not being aware of the creditable science we presented.

Mutated Algae Oil

GMOs are explicitly prohibited in organics, and are not eligible for consideration on the National List (7CFR205.105(e)).

Martek Biosciences Corporation is a biotechnology company that genetically engineers algal and fungal microorganisms for high DHA and ARA production. In patents filed as far back as 1991, Martek Biosciences Corporation references that it wanted its patents to cover genetically engineered algae (recombinant DNA as well as mutations, see US Patent 5,397,591). The company, now owned by the multi-billion dollar, multinational corporation DSM (based in The Netherlands), is currently using recombinant DNA technologies on organisms in an attempt to make algae produce EPA, another long-chain omega-3 fatty acid found in fish oil, in addition to DHA (see US Patent 7,973,149).

The strain of algae that Martek currently uses to produce one type of its DHA Algal Oils was developed in Monsanto's laboratories through "classical mutagenesis," which entails blasting algal microorganisms with chemicals or radiation to artificially induce genetic mutations, and screening the organisms until one with a favorable genetic mutation – in this case, high DHA production – is identified.

Consumer Acceptance of Martek's Oils*:* According to a consumer poll by PCC Natural Markets, which surveyed nearly 1,500 organic consumers, 76.4% "would not purchase" organic products supplemented with genetically engineered algae, and 12% would be "less inclined to purchase" these products. Only 2.3% of organic shoppers would be "more inclined" to purchase organic products with genetically modified algae.

These findings indicate that many organic consumers who are currently purchasing products with Martek's algal oil would not have made these purchases if they knew the full story behind the algal oil. Current sales of organic products with Martek's oils are likely the result of misled consumers, who believed they were purchasing a truly organic product containing only organic and approved ingredients.

***Organic standards prohibit Martek's oils**:* The organic standards prohibit genetic modification of organisms. 7CFR205.105(e) states that "To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of: (e) excluded methods," which refers to genetic modification.

The standards clearly state that "excluded methods" are not restricted to recombinant DNA technology, but include other methods that "genetically modify organisms or influence their growth and development by means that are not possible under natural conditions" (7CFR205.105(e)).

"Classical mutagenesis" is not specifically listed as an excluded method, but mutations through harsh chemicals or radiation do not occur "under natural conditions" and should therefore be prohibited from organics.

***Incomplete Technical Review**:* The technical review, which was deficient in several respects, failed to include this information. The Handling Committee's recommendation was therefore based on incomplete information.

Since Genetically Modified Organisms (GMOs) (the definition is not limited to genetically modified organisms using recombinant DNA technology) are not eligible for consideration on the National List, the Board should vote to reject the Martek DHA Algal Oil petition.

Hexane

The Handling Committee answered "No" to the question, "Are there adverse effects on environment from manufacture, use, or disposal?" The answer should be "Yes."

EPA data, which the technical review failed to consult, show that the Martek Biosciences plant in South Carolina released 8,400 pounds of n-hexane into the air in 2010. Martek Biosciences Corporation is one of the top 100 polluters of n-hexane in the country.

The EPA considers n-hexane a **hazardous air pollutant** because it reacts with nitrous oxide to form ground-level ozone, also known as "smog."

The EPA also lists n-hexane as a **neurotoxin**, which poses a danger to the health of workers who come in contact with the chemical.

N-hexane is also an **occupational hazard**, as it is a Class I flammable liquid and has caused explosions (in some cases leading to worker deaths and serious injuries, including burns) in oil extraction plants around the world. Martek Biosciences Corporation's factory caused an explosion in 2003 at a nearby wastewater treatment plant. The Office of the Kentucky State Fire Marshal concluded that the release of n-hexane from the Martek Biosciences Corporation plant into the local sanitary sewer system caused the explosion.

Organic standards prohibit the use of n-hexane: The standards state that "(c) 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: Except, That, nonorganic ingredients in products labeled "made with organic (specified ingredients or food group(s))" are not subject to this requirement" (7CFR205.270(c)(2)).

7CFR205.207(2) is restricted to "agricultural products," and Martek is petitioning its oils as non-agricultural products. However, the intent of the organic rule is clearly to avoid neurotoxic and polluting solvents like hexane, especially when alternatives exist (egg phospholipids are water-extracted, and fish oil is cooked and pressed).

***Consumer Acceptance of Martek's Oils**:* 88.6% of organic consumers "would not purchase" organic foods with hexane-extracted oil, according to the PCC consumer survey, and 4.5% would be "less inclined" to purchase organic products with hexane-extracted DHA oil. Only 0.3% would be "more inclined to purchase" organic products with hexane-extracted DHA oil, and 0% of very committed organic shoppers (referring to shoppers whose grocery purchases are 75-100% organic).

Incomplete Technical Review: Once again, the technical review failed to fact-check Martek Biosciences Corporation's claims and relied exclusively on information provided by the petitioner. Martek claims that all n-hexane used during manufacture of its DHA and ARA oils is recycled and reused, and the TR simply repeated this claim without verifying.

Given the adverse effects on the environment from the manufacture of Martek's oils, especially the release of n-hexane into the air, as well as human health impacts and occupational safety concerns, the Board should reject the Martek petitions.

Synthetic ingredients

Martek's oils and powders contain numerous synthetic and non-organic ingredients that have not been approved for use in organics.

Synthetics that were in fact identified in the Martek petition were not analyzed in the TR. Moreover, Martek uses non-organic sunflower oil in its oils, and neither the TR nor the Handling Committee has raised the specific question of whether this oil is hexane-extracted, how much is present in the final product, and the general question of why Martek would be allowed to use non-organic agricultural ingredients that are not listed on 205.606.

More troubling is Martek's failure to disclose numerous synthetics used in its production of "Life'sDHA" products. For example, "DHA Algal Oil Powder" in HappyBellies™ certified organic baby cereal contains mannitol (an unapproved sugar alcohol), sodium polyphosphate (an unapproved synthetic), modified starch (unapproved non-agricultural product, possibly from GMO corn) and glucose syrup solids (unapproved non-agricultural product, possibly from GMO corn).

Without a clear understanding of the full spectrum of synthetics used in its formulated products, and without the commitment by Martek to use organic agricultural products in its oils, the Martek petitions should be rejected.

Natural alternatives exist

In determining whether Martek's oils are *essential* in organic handling, Board members cannot ignore the fact that organic manufacturers, who wished to avoid Martek's unapproved oils, have turned to fish oil and egg phospholipids as sources of DHA.

Fish oil has been added to certified organic milk (Organic Valley), yogurt (Stonyfield) and baby food (Gerber) as a source of DHA. A blind taste test of milk with fish oil revealed that no taster was able to identify a "fishy" flavor. Fish oil, which is not hexane-extracted, has appeared on the National List since 2007, with the important annotation that only organic stabilizers, or stabilizers on the National List, may be used.

In baby formula, a certified organic manufacturer has added egg phospholipids as a source of DHA and ARA – offering organic parents an alternative to formula with Martek's hexane-extracted algae and fungus.

Not essential in organic handling

Martek's oils are not essential in organic handling. Organic products can be made without these oils, and organic and natural alternatives exist. Moreover, if an organic consumer wishes to supplement with DHA, they can buy supplements. Supplements are available for every segment of the population, from the general adult population (in the form of pills) to pregnant and nursing mothers (in the form of prenatal supplements) to children (in the form of "chewables") to infants (in the form of a liquid that can be added to formula or milk). Supplements derived from fish oil and from Martek's algal oil are available, offering consumers a wide range of DHA supplements.

The Handling Committee answered "N/A" to the question of essentiality in organic handling. The "N/A" category is for questions that do not apply to the material; for example, "Are there detrimental physiological effects on soil organisms, crops, or livestock?" is not relevant for the Martek oils, and "N/A" is an appropriate answer. But for the question, "is the substance essential for handling?" the question must be answered and cannot be ignored. The correct answer is "no," DHA algal oil is <u>not</u> essential for handling.

Organic consumers reject Martek's oils

According to a poll of nearly 1,500 organic consumers, conducted by PCC Natural Markets, the largest food cooperative in the United States with 9 stores in the Seattle area, the overwhelming majority of shoppers would reject organic products with Martek's oils if they knew the details of the sourcing of the microorganisms and processing methods used by Martek.

76.4% of shoppers polled in the PCC survey would not purchase organic products with DHA from genetically modified algae, and 88.6% would not purchase organic products with hexane-extracted DHA oil. If consumers knew that Martek's oils are stabilized with synthetic ingredients, the PCC poll suggests that 78.3% of consumers

would not purchase the products (current ingredient lists simply state “DHA Algal Oil” without disclosing the ingredients in the oil, which includes synthetics).

Meanwhile, 56.2% of consumers would be more inclined to purchase organic products if they contained DHA from wild fish, and 51.6% would be more inclined to purchase organic products if they contained DHA from organic algae.

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