



CORNUCOPIA
I N S T I T U T E

January 23, 2012

Dear members of the National Organic Standards Board (including incoming members),

We respectfully request that you reconsider the Board's approval of Martek Biosciences Corporation's DHA algal oil and ARA fungal oil for use in organic foods.

There was only one reason to approve Martek's petitions, and that reason was to increase market share for a handful of organic brands wishing to compete with the marketing claims of conventional foods. By reading below you will, we hope, concur that the risks to the reputation of organics, and the questionable legality of the approval process, will compel you to act in the interest of maintaining organic integrity.

Serious questions regarding the source, processing, and other ingredients used in Martek's materials were either not addressed or were hidden from the board by Martek, Dean Foods and others supporting the petition.

The concerns that were never fully addressed before the Board voted on the Martek petitions include:

1. **Disclosed and undisclosed synthetic ingredients:** Martek's algal and fungal oils are formulated products containing numerous "other ingredients" that are synthetic and not approved for use in organics. These are legally required to be reviewed by the NOSB. This was not done.

Some of the synthetic ingredients that were not disclosed in the petition but are listed on the ingredient panel of an organic product containing DHA algal oil include mannitol (an unapproved sugar alcohol), modified starch (unapproved non-agricultural product, possibly from GMO corn) and glucose syrup solids (an unapproved non-agricultural product, possibly from GMO corn).

In addition, at least one synthetic ingredients that was disclosed by Martek has never been separately petitioned, reviewed and recommended for inclusion on the National List: ascorbyl palmitate.

There are likely numerous other ingredients that are used to manufacture the DHA algal oil that were not disclosed. The only reason we know about mannitol, modified

starch and glucose syrup solids is that one of Martek's customers listed them on their ingredients list. Martek never disclosed them in its petition.

Non-organic baby foods containing Martek's powdered algal oil have disclosed additional ingredients such as sodium caseinate, soy protein and tetrasodium diphosphate, in addition to the aforementioned ingredients. We simply have no idea whether these "other ingredients" are used in other organic foods as well, since many manufacturers (including all infant formula manufacturers) do not disclose these ingredients.

Furthermore, the powdered formulation used in infant formula and baby cereal is microencapsulated, and the medium used to microencapsulate the powdered form is not disclosed.

These ingredients are currently in organic baby foods (and might very well be included in some other organic products). The full spectrum of synthetics used by Martek in its oils and powders is still unclear. The NOSB needs to demand a full accounting of all ingredients and materials used in Martek oils.

The annotation for Martek's oils states that agricultural ingredients must be organic, but says nothing of the synthetic stabilizers, sweeteners and preservatives. This means that Martek's algal oil is held to a lesser and different standard than the natural source of DHA, fish oil, for which the annotation states that all stabilizers must be either organic or on the National List.

This double standard, competitively disadvantaging other ingredient manufacturers in the organic marketplace, could certainly be the subject of a legal challenge.

2. **Volatile Synthetic Solvents:** 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.

A compromise using the term "not hexane-extracted" was a deliberate ploy offered by the Martek/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.

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

3. **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. Mutagenesis would be an illegal process under the regulations, whether or not some minute percentage of agricultural crops developed through mutagenesis have made it through the regulatory system and are now being marketed as organic.

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. The Board should demand a full documentary explanation of their development.

4. **Synthetic or non-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.

5. **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.

6. **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.

7. **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.
8. **Misleading statement by Martek lobbyist:** When asked whether the powdered form of algal oil was included in the petition, the Martek lobbyist, William J. Friedman, clearly stated to the Board that it was not. This was a misleading answer

apparently designed to alleviate some of the Board member's concerns about undisclosed synthetic ingredients in algal oil powder currently in organic baby food.

However, this statement directly contradicts Martek's official petition, which clearly states that it includes all Martek products under the trade name "Life'sDHA" and all products "authorized previously" by the USDA. Some Board members may have taken the lobbyist's misleading answer as the actual truth and assumed they were voting only on Martek products containing disclosed synthetic ingredients.

- 9. Deficiencies in Technical Review:** The majority of the NOSB members are not scientists and need to depend on independent and unbiased USDA-provided technical reviews, the parameters of which are laid out in the NOSB procedure manual. The review prepared on Martek's petition was deficient in several important areas, including exhibiting scientific bias and failing to include a variety of sources.

The incomplete Technical Review led the NOSB members to believe that manufactured DHA from algal oil is equally beneficial to human health as naturally-occurring omega-3s from natural sources such as grass-fed meat and milk, green vegetables, flax and nuts, wild fish or breast milk.

The vast majority of peer-reviewed studies have concluded that the consumption of manufactured DHA **does not** confer the same benefits as consuming a diet high in omega-3s with a favorable omega-6 to omega-3 ratio. These studies, for some reason, were not included in the Technical Review. Instead, the Technical Review relied heavily on sources supplied by the petitioner, Martek.

Martek's petition is referenced 16 times and David Kyle is referenced 15 times. Kyle is one of the founders of Martek Biosciences Corporation, a previous Vice-President of Martek, and a patent holder for several of the DHA algal oils.

- 10. Outstanding Health and Safety Concerns:** Although the outgoing NOSB chairperson made an impassioned appeal for board members to defer to the FDA's determination that the adverse action reports by parents and healthcare professionals were without merit, we feel the board needs to take the FDA statements, and that of the Board chairperson, into context.

First, despite reservations articulated by the independent scientific panel set up by the National Institute of Medicine to evaluate the safety of new ingredients in infant formula, including the Martek oils, the FDA continued to allow new ingredients in infant formula without doing any of its own independent safety testing.

The FDA gave the green light to the Martek oils only after aggressive industry lobbying to overcome concerns raised by FDA scientists. The FDA clearly articulated that they expected the infant formula manufacturers to formally track adverse

reactions. Based on inquiries to the companies involved, and FOIA requests to the FDA, this obligation was not fulfilled.

Instead, formula companies have made it virtually impossible to determine whether the cause of an infant's problems is the DHA/ARA oils, because they no longer market formula without these novel ingredients.

When Martek's oils were first included in a select number of premium-priced formula products, there was a flurry of adverse reaction reports submitted to the FDA.

Reported gastrointestinal problems included diarrhea, flatulence, vomiting, and in some cases led to the failure to thrive, dehydration, invasive diagnostic procedures and hospitalization.

Since formula without Martek's DHA and ARA oils was still readily available at that time, parents easily noticed that children who became seriously ill on formula with Martek's oils recovered almost immediately when given equivalent formula (many times the exact same brand) without the Martek oils.

Unfortunately, since all conventional and organic formula, with the exception of one organic brand, are now formulated with Martek oils (and the industry has succeeded in greatly increasing the cost of the products) parents and caregivers can no longer link serious health ailments to the Martek oils. Enclosed, please find one of the rare current complaints that was forwarded to us.

A 4-minute video, including three first-hand testimonials from parents can be found on The Cornucopia Institute website:

<http://www.cornucopia.org/2011/04/infant-health-at-risk-corporations-polluting-organic-food/>

Finally, in terms of the former chairperson's blanket endorsement to trust the FDA as the worldwide preeminent food safety authority, Cornucopia and many organic stakeholders would have to disagree. One of the reasons many people come to organics, looking for pure, unadulterated and natural food, is they don't trust the FDA. This is the same federal agency that just assumes all GMOs are safe, without requiring human testing, and has blessed materials like sodium saccharine, aspartame, MSG, artificial food colors, and many other questionable novel ingredients. The NOSB needs to do its own scrutiny and hold all synthetic and non-organic materials in organics to a much higher standard.

The approval of the amended petition represents a serious gamble with the trust of organic consumers, who seek wholesome, non-genetically modified, non-synthetic, non-bleached, non-volatile-solvent-extracted, non-artificially-sweetened and non-artificially-preserved nutrition. Martek's oils, as petitioned, fail on all these counts.

Rather than focus on educating consumers that healthy balances of omega-3 and omega-6 fatty acids can be achieved by choosing a well-rounded organic diet that includes

grass-fed meat and dairy, pastured eggs, leafy green vegetables and/or sustainable fish like sardines and anchovies (and reducing consumption of grain-fed livestock products and processed foods with grain-based oils and additives), some companies have apparently chosen to “educate” consumers about DHA – just one of numerous healthy fatty acids – on the front panel of their packaging where they can now make highly profitable, though scientifically unsubstantiated, health claims.

Furthermore, supplements readily exist on store shelves for consumers who want to supplement their diet with DHA, including DHA for toddlers and children.

The range of troubling issues raised in this document demands a careful and complete analysis and accounting. We urge you, as custodians of organic integrity, to reconsider the Martek petitions, by voting to place the issue back on the NOSB agenda for the Spring 2012 meeting in Albuquerque.

Any one of the documented problems, or serious questions outlined in this letter, should be enough to err on the side of caution and formally reconsider the prior NOSB vote on these materials.

If these profitable and patented substances can be approved, despite the lack of definitive scientific documentation regarding their efficacy and essentiality, in addition to outstanding questions concerning safety and incompatibility with the OFPA and organic regulations, it would seem that the barriers for use in organics have been reset so low that consumers will soon no longer feel that they are protecting their families by choosing organics.

Thank you for your consideration,

Will Fantle
Mark A. Kastel
Charlotte Vallaeyes
The policy team at The Cornucopia Institute

From: [Please contact Cornucopia for name and email address]

Sent: Saturday, January 14, 2012 11:40 PM

To: cultivate@cornucopia.org

Subject:

My baby is having horrible reactions to DHA / ARA. She is 2 months old and we tried several formulas, but nothing was working for her. She was extremely fussy. Screamed and cried as if she was in horrible pain. She had diarrhea. She was puking everywhere. She was choking and gasping for air and her face would turn red as acid came up her throat. She could not be consoled and would not sleep longer than a couple minutes at a time and would make little sounds like she was in pain while sleeping then would wake up screaming and crying. Kicking her legs and waving her arms frantically. After trying simlilac advance, alimentum and then isomil...her doctor put her on EleCare. We noticed a change in her instantly. She was a completely different baby. No more puking. No more crying for hours and hours on end. No more diarrhea. No more sleepless nights. Infact, she started sleeping up to 8 hours at night. Even her reflux got better. We were getting samples of the EleCare from her doctor

and originally, the cans they gave us did not contain DHA /ARA. They ran out of those and got the newer ones that contained DHA /ARA. When I gave her the formula containing that...all of her issues started back up instantly. I thought maybe the formula stopped working for her. It didn't even cross my mind that it could be the dha. We got more samples from a friend. She actually gave us 9 cans of EleCare that did not contain DHA. My baby was PERFECT during the time she was on that formula. No issues other than some mild reflux. Well...again...we ran out. So, we got more samples from her doctor. The same day I started giving it to her...her symptoms came back again. It was then that I started suspecting that maybe it was the DHA / ARA that was causing them. So I looked online and found several stories similar to mine. I got on a facebook group with mothers who give their children elecare and asked them if they were having issues with the dha and their stories were the same as mine. Our insurance is now paying for our elecare, so I asked the place that was bringing it to us if that had any non dha ara elecare left. They had a few cans and brought them out yesterday morning. My baby instantly improved as soon as I gave her the formula and has been fine since. I called Abbott and unfortunately, this stuff is in all of their formula now. My husband and I looked online and we were able to find an organic formula available at whole foods that does not contain DHA /ARA. We are going to give it a shot as this is our last resort. If it doesn't work, I honestly don't know what we will do. Our baby can NOT handle dha ara. I don't know who to go to or where to turn. I feel so completely helpless because I'm sure this is a battle that can not be won...but there HAS to be another option for these babies who react horribly to this stuff. Please let me know what to do. I am begging whoever is reading this to please tell me what I can do. Who all can I report this to? Why is this stuff being put in formula when it is clearly hurting babies??