



Mary Engle, Associate Director  
Division of Advertising Practices  
Federal Trade Commission  
600 Pennsylvania Avenue, NW  
Washington, DC 20580

April 21, 2011

RE: Complaint regarding advertising of DHA additives in Horizon milk

Dear Ms. Engle,

The Cornucopia Institute urges the Federal Trade Commission (FTC) to investigate Dean Foods' advertising of its Horizon "milk with Omega-3 DHA" products, targeted to pregnant women and children, for false and misleading claims regarding benefits to brain development and the absence of additives, in violation of section 5 of the Federal Trade Commission Act (15 USC 45).

In 2004, your office warned Martek Biosciences Corporation, which makes the DHA supplements used by Dean Foods in its Horizon Organic milk. In your letter to Martek, you stated that "The 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."

You continued to state that "The staff notes, however, that Martek's advertising of the benefits of DHA and ARA for healthy children and adults has been limited," and decided not to take action. We bring to your attention that Dean Foods, using Martek's supplements in its products, has launched a widespread and far-reaching marketing campaign, focused exclusively on claims of improved brain function in children and adults.

The Cornucopia Institute is also aware that the FTC's Division of Advertising Practices investigated another company, Northwest Natural Products, for possible violations of Sections 5 and 12 of the Federal Trade Commission Act related to similar claims regarding omega-3's and brain development. This investigation included concerns regarding Northwest Natural Products' claims that "Gummy Fish boosts, improves, or

promotes brain function, brain development, intelligence, or academic achievement in children.”

The FTC, in February 2010, sent a warning letter to 11 companies. One of the claims that the FTC identified as objectionable includes: “Consuming Product X improves, enhances, or supports brain function, cognitive function, attention span, concentration, and mental focus in children.”

Dean Foods/White Wave makes exactly these claims regarding its Horizon milk with added omega-3 DHA. Cartons state “DHA Omega-3 Supports Brain Health.” Print advertisements proclaim “Milk with DHA Omega-3 isn’t rocket science, but it is genius” and state “DHA Omega-3, a nutrient which supports healthy brain development” and “it’s as delicious as it is smart” (see enclosed advertisement). Another print ad states, “a smart move for growing brains.”

Radio ads announce, “Kids are smart. Continue to help support their brain development with Horizon Organic DHA Omega-3 Milk.” Television ads show a child beating her grandfather at a chess game, and calls the DHA-supplemented milk a “smart move.”

The ads are run on Radio Disney, Disney FamilyFun magazine, disney.com, kaboose.com, disneyfamily.com and familyfun.com. Print ads appear in American Baby, Better Homes and Gardens, Everyday Food, Family Circle, Fitness, Martha Stewart Living, Scholastic Parent and Child and Working Mother.

Moreover, we find the Horizon online promotional materials to be especially objectionable given claims that the products “serve up the natural nourishment of organic dairy without the additives you’d rather avoid.” The type of DHA oil added to Horizon milk is an extract from mutated and fermented algae that have never been part of the human diet. The ingredient is produced by Martek Biosciences Corporation, and scientists have raised concerns regarding the safety of these ingredients. The promotional materials that suggest that Horizon milk with DHA-Omega 3 is simply milk without added ingredients, is simply false.

The online promotional materials are especially misleading given the presence of online videos featuring Dr. Alan Greene, a pediatrician who endorses these products and gives consumers a false and misleading sense that the DHA oil has been medically proven to benefit health. We ask that your investigation focus not only on Dean Foods/White Wave, but also include Dr. Alan Greene and his role in Dean Foods’ false and misleading advertising.

We believe that Dean Foods/White Wave’s promotional materials are not in compliance with the FTC Act, and respectfully request that you immediately investigate this company for violation of the Act, and take effective action to stop this deceptive advertising.

## **False and Misleading Claims**

Dean Foods' objectionable claims are listed below, followed by Cornucopia's research findings illustrating the claims cannot be substantiated. We have also included screenshots of their website's false and misleading claims and copies of objectionable magazine advertisements.

## **Benefits to Infant and Children's Development**

The Horizon website states: "Infants and Children: DHA provides a nutritional boost for children's growing minds and bodies, supporting brain and eye development and function" (See screenshot).

Dean Foods provides two written references to substantiate this claim:

"Uauy R., et al. *Lipids*, 2001;36(9):885-895  
Birch E. et al., *Early Human Development* (2007) 83, 279-284."

The author of the first study, Dr. Ricardo Uauy of the London School of Hygiene and Tropical Medicine, stated in June 2010, in response to the European Union's consideration of health claims regarding DHA and infant brain development:

*"The evidence for effectiveness of DHA addition to formula for term babies in terms of improved long-term mental development is weak at best ... until stronger data are available I would opt for a view that the effects of DHA on mental development are not sufficiently documented to establish public health policy."*<sup>1</sup>

The Uauy study cited on the Horizon website never mentions results of clinical trials that would suggest benefits exist to infants' or children's cognitive development.

The second cited study, by Eileen Birch and her colleagues, is a clinical trial. This trial indeed found some differences on tests of cognitive development between children given a DHA supplement and a control group. However, this is just one of several dozen clinical trials that have been conducted to determine benefits to cognitive development from DHA supplementation of infant formula. The overwhelming majority of clinical trials found no benefits.<sup>2</sup> No respectable scientist or marketer should make claims based on the results of one clinical trial, especially when dozens of other trials have been conducted, and found opposing results.

Instead, responsible scientists turn to independent reviews of all the data that has been collected to date—taking into account all studies that have been performed, not just the one that provided a desired outcome. Two such meta-analysis studies by independent scientists have been published in recent years, in peer-reviewed journals.

The first meta-analysis, published in 2008 in the *Cochrane Systems Database Review*, looked at more than a dozen scientific studies published to get a sense of the overall data. The scientists conclude:

*“The results of most of the well conducted RCTS have not shown beneficial effects of LCPUFA supplementation of formula milk on the physical, visual and neurodevelopmental outcomes of infants born at term.”*

A second meta-analysis, published in 2010 in the peer-reviewed *Journal of Pediatric Gastroenterology and Nutrition*<sup>3</sup>, combined and analyzed the results of four different clinical trials, and concluded:

*“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 against beneficial effects of LCPUFA [DHA and ARA] supplementation on BSID at 18 months under the conditions of the trials included here (emphasis added).”*

These two meta-analysis studies combined and analyzed the results of 18 clinical trials, and concluded there are no proven benefits to infant development from DHA supplementation in infant formula. It is therefore misleading for Dean Foods to imply on the Horizon website that children’s brain development benefits from consuming their milk with added DHA.

These meta-analysis studies considered clinical trials with infants; none looking at potential benefits to toddlers or older children have been published to date, given the scarcity of published studies that specifically consider the effects on toddlers and older children. Some studies that have been conducted showed no benefits exist. For example, a study by Martek, the corporation that supplies Horizon DHA oil, was published in *Clinical Pediatrics* and concluded: “For each test [of cognitive development], results indicated that changes from baseline to end of treatment were not statistically significantly different between the docosahexaenoic acid group and the placebo group.”<sup>4</sup>

We find the misleading marketing claims on the Horizon website to be especially objectionable given the endorsement of a paid spokesperson with a medical degree, Dr. Alan Greene. The website features short videos with Dr. Greene promoting Horizon products with DHA. This endorsement by Dr. Greene, by virtue of his medical degree, is extremely misleading to consumers who are likely to trust a doctor’s advice. Dr. Greene is a paid spokesperson for Dean Foods and the endorsement of a medical doctor does not change the fact that these statements cannot be backed by sound science.

## **Benefits to Pregnant Women**

We are also very concerned about claims that DHA supplementation of milk benefits pregnant and nursing women. The website claims:

“Leading health authorities recommend that pregnant and nursing women consume adequate DHA.”

The Horizon webpage cites two studies to back up its claim:

“Koletzko B, et al., British Journal of Nutrition (2007) 98: 873-877.  
Mozaffarian D and Rimm EB., 296(15):1885-1899.”

The first citation 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,  $\alpha$ -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 (note that the citation on the Horizon website is incomplete, making it difficult for consumers wishing to verify the marketing claim to find the study) also does not conclude that supplementation of products like milk with algal DHA benefits pregnant women.<sup>5</sup> 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. We agree that benefits exist from eating a wholesome diet of varied foods including fish, and believe that 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 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<sup>6</sup>

*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<sup>7</sup>

Moreover, review studies have also suggested that the benefits of consuming fish oil may be due to high levels of another omega-3 fatty acid (EPA) and less due to DHA. Martek's supplements are not high in EPA, and therefore any benefits found from fish oil supplementation may not be conferred by Martek's DHA supplements.

## **Misleading Use of a Medical Doctor as a Paid Spokesperson**

We request that you include Dr. Alan Greene in your investigation. In particular, he makes false and misleading statements on a video, which seems aimed at scaring parents of young children into buying products with added DHA. In the video, he says:

“My big concerns are during pregnancy when pregnant women aren’t getting enough and the other big time is once they’re weaned. Once the breastmilk and formula have stopped, it’s like the DHA is ripped away while the brain is still developing so quickly, especially in the first three years or so. Toddlers in the US are getting a fraction of the DHA that they need, so that’s the time you need to intentionally choose some way to get DHA into them. One way to do that is start them on seafood, that can be great for them, or omega-3 eggs can be another way to do that, or, I’m very happy about DHA in milk for this age of kid, as a way, since they’re drinking milk anyway, can get the extra DHA they may need.”

Terms such as “my big concerns,” “it’s like the DHA is ripped away” and “you need to intentionally choose some way to get DHA into them” are extremely powerful when spoken by a pediatrician. Parents of young children are generally concerned about their child’s proper development, and these videos seem to be designed to profit from these concerns—to sell unnecessary products to well-meaning parents.

## **False Statements Regarding the Absence of Additives**

Dean Foods/White Wave states on its Horizon homepage: “The less we do to our products, the more your family gets out of them. That’s why we keep it simple, serving up the natural nourishment of organic dairy without the additives you’d rather avoid.” The picture accompanying these words on the screen shows a family in their kitchen, with a carton of milk with DHA Omega-3 on the counter, prominently displayed (see enclosed screenshot).

On a separate webpage, Dean Foods/White Wave states: “We keep out the ingredients your family doesn’t need” (see enclosed screenshot).

It is false to proclaim to offer milk “without additives,” or imply that it is without additives, when selling milk with added DHA Omega-3 oil. The added ingredient is a non-organic oil derived from fermented algae that has never before been part of the human food system, especially for young children, and processed using non-organic methods. On their website’s FAQ page, Dean Foods/White Wave readily admits that its DHA Omega-3 oil is not organic (screenshot attached).

We are especially concerned with this false and misleading advertising given the uncertainty regarding the safety of these ingredients. Reports obtained from the FDA’s Medwatch program appear to show that some infants cannot tolerate these oils, and experience serious side effects such as diarrhea and vomiting. It would not be unreasonable to question whether toddlers, many of whom begin drinking cow’s milk (instead of formula) at the age of 12 months, would also be vulnerable to experiencing the same adverse reactions as those that have been found in infants.

**FDA scientists.** When reviewing scientific data regarding the safety of algal DHA and fungal ARA oil for use in infant formula, FDA scientists proposed convening a panel of independent scientists for an independent review of the oils’ safety. This never happened. The scientists did, however, have the following to say about these additives:

*“Some studies have reported adverse events and other morbidities including diarrhea, flatulence, jaundice, and apnea in infants fed long-chain polyunsaturated fatty acids.”*

- Alan Rulis, Ph.D. and Christine Lewis, Ph.D., R.D.  
FDA Center for Food Safety and Applied Nutrition,  
Response Letter 000041

**FDA Medwatch reports.** More than 100 adverse reaction reports submitted to the FDA’s Medwatch program can confidently be linked specifically to DHA algal oil and ARA fungal oil in infant formula. One example:

*Child was given Enfamil [with DHA and ARA] formula at two different times. Child developed severe diarrhea and constipation for three days, every time. When switched to Enfamil with Iron [without DHA and ARA] did fine. He is now X months old and doing fine.”*

- report #61311, acquired from FDA Medwatch program through a Freedom of Information Act request

**Agency for Healthcare Research and Quality, Department of Health and Human Services.** The AHRQ commissioned a study in 2005 to determine the effects of long-chain polyunsaturated fatty acids, including DHA, on public health. They wrote that adverse events have been reported in studies of omega-3 supplementation:

*“In pregnant women, the adverse events related to the omega-3 fatty acids intake were mild and transient, with nausea and gastrointestinal discomfort being the most commonly reported.”<sup>8</sup>*

*"A variety of adverse events were reported in 71 studies."*

*"The GISSI-Prevention Trial, that had over 11,000 subjects and a follow up duration of 182 weeks, reported the largest number of adverse events. This trial contributed about one-third of the total number of gastrointestinal complaints."*

**Institute of Medicine:** In a report titled "Infant Formula, Assessing the Safety of New Ingredients," the Institute of Medicine's Food and Nutrition Board criticized the inadequacy of pre-market safety tests on algal DHA oil. The scientists wrote:

*"It is not clear whether assessments of body composition, immune response, auditory function, and temperament were conducted. Several of these tests are especially important to determine the safety of long-chain polyunsaturated fatty acids because theoretical concerns exist."*

It is also important to note that post-market surveillance to determine the safety of DHA algal oil has not been shared with the FDA by Martek, the company that markets these oils, or infant formula makers using these oils, despite a clear request by the FDA for post-market surveillance and additional safety studies.

*"It is the continuing responsibility of Martek to ensure that food ingredients that the firm markets are safe...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."*

- Alan Rulis, Ph.D. and Christine Lewis, Ph.D., R.D.  
FDA Center for Food Safety and Applied Nutrition,  
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We realize that it is not within the FTC's purview to determine the safety of these oils; however, we include this evidence of safety problems to point out the grave consequences that Horizon's false advertising may have on young children. **It is false and misleading for Dean Foods/White Wave to include this potentially unsafe and unnecessary ingredient in its milk, as a marketing tool, when it claims that its Horizon products are made "without the additives you don't need."**

## **Request for Immediate and Effective Action**

The Cornucopia Institute asks that you take immediate and effective action against Dean Foods/White Wave to stop this false and misleading advertising, aimed at parents of young children and pregnant women. Our most vulnerable citizens need your protection.



If deemed appropriate by the FTC, the Cornucopia Institute also seeks a permanent injunction pursuant to section 13(b) of the Federal Trade Commission Act (15 USC 53(b)) to prevent the marketing of this product if the claims are false and misleading.

Please feel free to contact us if we can be of further assistance.

Sincerely,



Charlotte Vallaey  
Director, Farm and Food Policy  
The Cornucopia Institute

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<sup>1</sup> Ricardo Uauy, London School of Hygiene and Tropical Medicine.

<sup>2</sup> See two recent meta-analysis studies:

Simmer, K., Patole, S. and Rao, S. (2008) Longchain polyunsaturated fatty acid supplementation in infants born at term. *Cochrane Database Systems Review*. Jan 23;(1):CD000376.

Beyerlein, A, Hadders-Algra M, Kennedy K, Fewtrell M, Singhal A, Rosenfeld E, Lucas A, Bouwstra H, Koletzko B, von Kries R (2010) Infant Formula Supplementation With Long-chain Polyunsaturated Fatty Acids Has No Effect on Bayley Developmental Scores at 18 Months of Age-IPD Meta-analysis of 4 Large Clinical Trials. *Journal of Pediatric Gastroenterology and Nutrition* 50(1): 79-84.

<sup>3</sup> Beyerlein, A, Hadders-Algra M, Kennedy K, Fewtrell M, Singhal A, Rosenfeld E, Lucas A, Bouwstra H, Koletzko B, von Kries R (2010) Infant Formula Supplementation With Long-chain Polyunsaturated Fatty Acids Has No Effect on Bayley Developmental Scores at 18 Months of Age-IPD Meta-analysis of 4 Large Clinical Trials. *Journal of Pediatric Gastroenterology and Nutrition* 50(1): 79-84.

<sup>4</sup> Ryan AS and Nelson EB (2008) Assessing the effect of docosahexaenoic acid on cognitive functions in healthy, preschool children: a randomized, placebo-controlled, double-blind study. *Clinical Pediatrics* 47(4), 355-62

<sup>5</sup> Mozaffarian D and Rimm EB (2006) Fish intake, contaminants, and human health: evaluating the risks and the benefits. *The Journal of the American Medical Association* 296(15): 1885-189.

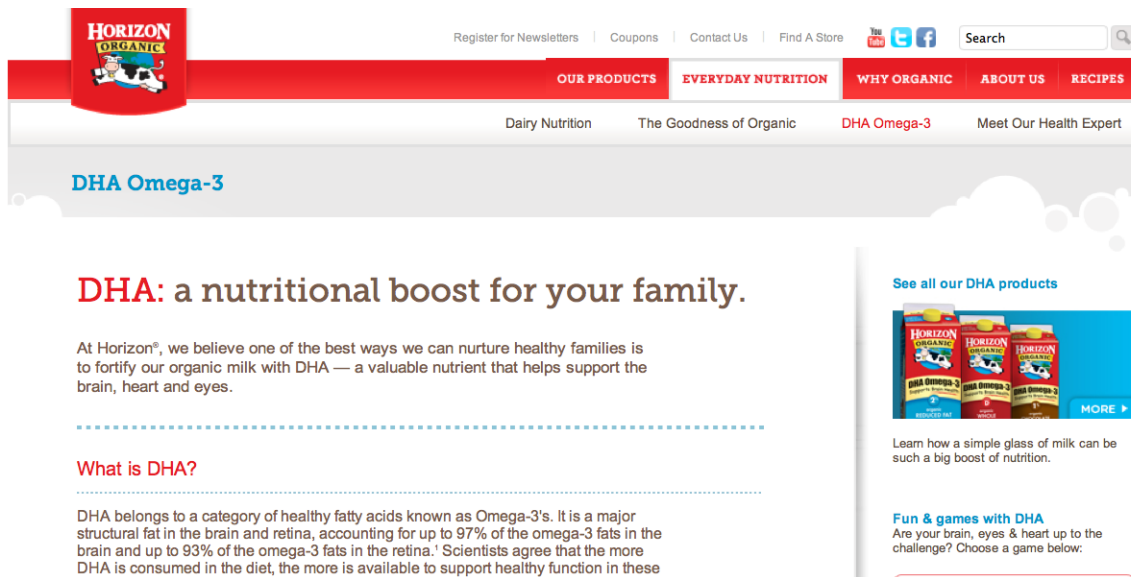
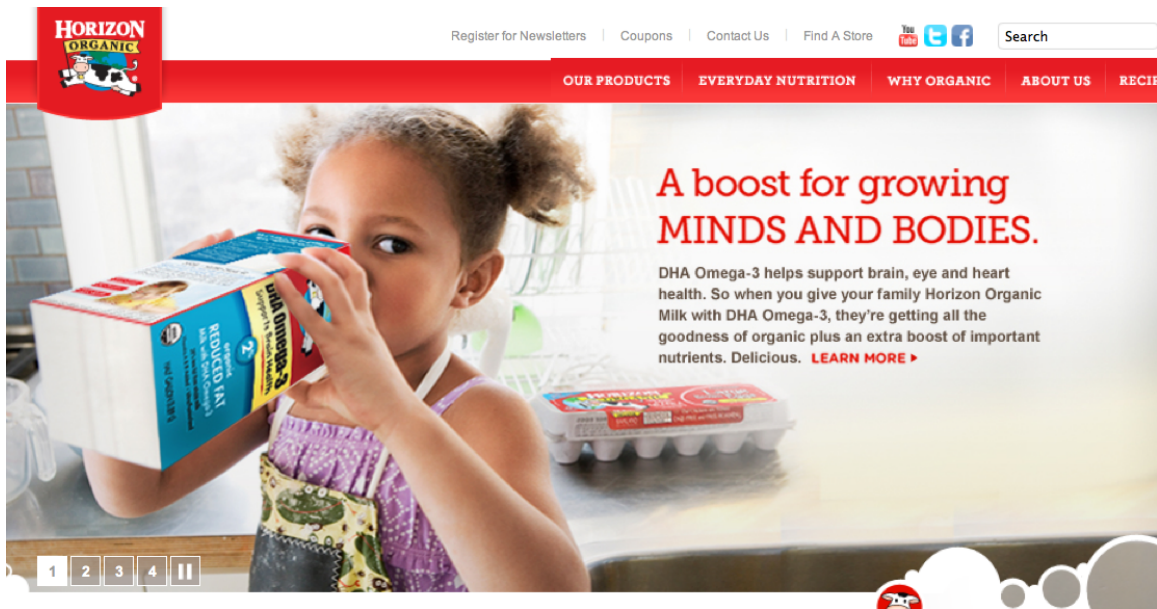
<sup>6</sup> European Food Safety Authority. Scientific substantiation of a health claim related to DHA and support of the visual development of the unborn child and breastfed infant pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Question # 2008-675

<sup>7</sup> European Food Safety Authority. Scientific substantiation of a health claim related to DHA and support of the cognitive development of the unborn child and breastfed infant pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Question #2008-773

<sup>8</sup> Lewin GA, Schachter HM, Yuen D, Merchant P, Mamaladze V, Tsertsvadze A, et al. Effects of Omega-3 Fatty Acids on Child and Maternal Health. Evidence Report/Technology Assessment No. 118. (Prepared by the University of Ottawa

Evidence-based Practice Center, under Contract No. 290-02-0021.) AHRQ Publication No. 05-E025-2. Rockville, MD: Agency for Healthcare Research and Quality. August 2005.

Screenshots from [www.horizondairy.com](http://www.horizondairy.com), April 2011



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## What is DHA?

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DHA belongs to a category of healthy fatty acids known as Omega-3's. It is a major structural fat in the brain and retina, accounting for up to 97% of the omega-3 fats in the brain and up to 93% of the omega-3 fats in the retina.<sup>1</sup> Scientists agree that the more DHA is consumed in the diet, the more is available to support healthy function in these areas. DHA has also been shown to help support heart health.

DHA is especially important to kids, but according to pediatrician Dr. Alan Greene, "Most American kids are not getting the DHA they need. The typical three-year-old needs about 150 mg of DHA a day. On average, they are only getting about 19, mg, a tiny fraction of what they need for optimal brain growth."



While other DHA-fortified milks rely on the addition of fish oil, Horizon<sup>®</sup> uses only pure, plant-based DHA from a sustainable source. And because our DHA is vegetarian, you can be sure your milk has the same deliciously fresh, great taste you expect from Horizon.

## Who needs DHA?

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Most Everyone. DHA may be an important nutrient in all stages of life, yet many American's don't get enough of it from common dietary sources.<sup>1</sup>

## Who needs DHA?

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### Pregnancy & Nursing

Leading health authorities recommend that pregnant and nursing women consume adequate DHA.<sup>2,3</sup> [Dr. Greene on DHA and pregnancy](#)



### Infants & Children

DHA provides a nutritional boost for children's growing minds and bodies, supporting brain and eye development and function.<sup>4,5</sup> [Dr. Greene on DHA and growing brains](#)



### Children & Adults

DHA has been shown to help support heart health in all stages of life.<sup>6</sup> [Dr. Greene on DHA and growing brains](#)



### Senior Years

Studies have investigated DHA for its possible impact on adult eye health and mental acuity.<sup>7</sup>

Learn how a simple glass of milk can be such a big boost of nutrition.

### Fun & games with DHA

Are your brain, eyes & heart up to the challenge? Choose a game below:



**Play the Brain Game** ›



**Play the Eye Game** ›



**Play the Heart Game** ›

### Other Resources

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[Dr.Greene.com](#)

[Organic FAQs](#)

[Top 10 Organic Foods to Eat](#)

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### Senior Years

Studies have investigated DHA for its possible impact on adult eye health and mental acuity.<sup>7</sup>

#### References

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7. Johnson EJ and Schaefer EJ, Am J Clin Nutr 2006;83(suppl):1494S-8S.

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The less we do to our products, the more your family gets out of them. That's why we keep it simple, serving up the natural nourishment of organic dairy without additives you'd rather avoid. [LEARN MORE](#)

