

June 21, 2007

Dr. Kathleen Ellwood
Director, Nutrition Program and Labeling Staff
(HFS-830)
Office of Nutritional Products, Labeling and
Dietary Supplements
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Dr. Ellwood:

The Center for Science in the Public Interest (CSPI) is filing this complaint to request that the Food and Drug Administration (FDA) take enforcement action to halt false and misleading claims about omega-3 fatty acids and a reduced risk of coronary heart disease. Such claims – as well as other deceptive and inaccurate statements not addressed in this letter – appear in the labeling of at least seven brands of fresh eggs purchased in the Washington, D.C. area. Those products are misbranded under sections 403(a), 403(r)(1)(A) and 403(r)(1)(B) of the Federal Food, Drug and Cosmetic Act (FDCA). CSPI is requesting that FDA issue warning letters to the seven companies named in this letter, as well as an Industry Letter and/or Guidance reminding manufacturers of the eligibility requirements for making health and nutrient content claims for omega-3 fatty acids.

More generally, the marketplace abuses of these companies reveal the ramifications of permitting qualified health claims for food. The FDA's authorization of a preliminary health claim for omega-3 fatty acids and a reduced risk of coronary heart disease helped make "omega-3s" a household word and helped spur the use of statements such as "100 mg omega-3s" on products not eligible to make the actual disease risk reduction claim. When such statements prominently appear on banners, sunbursts, or distinctive type on product labels, they constitute "implied nutrient content claims" and are not permitted under FDA regulations.²

Research shows that when consumers become aware that a product contains an ingredient that is the subject of a health or implied nutrient content claim, they are more likely to buy a product containing that ingredient because they are predisposed to associate a health benefit with it. When consumers read claims that implicitly characterize the level of omega-3

¹ Many other types of products also make omega-3 claims, but eggs are the only food specifically prohibited from making the qualified health claim. Letter Regarding Eggs with Enhanced Omega-3 Fatty Acid Content and a Balanced 1:1 Ratio of Omega-3/Omega-6 Fatty Acids and Reduced Risk of Heart Disease and Sudden Fatal Heart Attack (Belovo Petition) (Docket No. 2004Q-0072)(Apr. 5, 2005) [hereinafter *Belovo Response*] at 15. http://www.cfsan.fda.gov/~dms/qhceggs.html (Accessed June 6, 2007).

² 21 C.F.R. § 101.13(i)(3).

fatty acids in the product (as a good or excellent source), many infer that the food is useful in reducing the risk of heart disease.³ It is, no doubt, one of the reasons that the American Egg Board states that it "is committed to research to increase the omega-3 content of egg and egg products" even though eggs contain too much saturated fat and cholesterol to bear the qualified health claim for omega-3s.⁴ The Agency should, therefore, reevaluate its practices to prevent such abuses in the future. (Of course, FDA's ill-conceived and illegal qualified health claims policy facilitates such deceptive labeling.)

I. Background

The addition of omega-3 fatty acids to foods is currently the "hottest fortified food trend," and there are predictions that it will remain so for years to come. Part of this trend was fueled by a widely publicized 2004 letter by FDA announcing that it would exercise its enforcement discretion and permit a qualified health claim for two kinds of omega-3 fatty acids – eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Foods eligible to make the qualified claims are limited to those that are "low in saturated fat," i.e., contain 1 gram or less, and "low in cholesterol," i.e., contain 20 mg or less. In addition, foods are required to declare the number of grams of EPA and DHA as part of the claim.

FDA expressly forbade nutrient content claims characterizing the level of omega-3s in the product (e.g., good or excellent source) because there is insufficient evidence on which to

E-Mail from Alan S. Levy, Chief, Consumer Studies Branch, CFSAN, FDA to Ilene Ringel Heller, Senior Staff Attorney, CSPI (June 13, 2007, 4:05 PM EDT)(on file with CSPI).

³ Alan S. Levy, Chief of the Center for Food Safety and Applied Nutrition (CFSAN) Consumer Studies Branch summarized the results of his research on whether consumers are influenced by a relevant content claim for a dietary ingredient specified in a qualified health claim as follows:

^{... [}C]onsumers will tend to become more responsive to relevant content claims as they become more familiar with the diet/disease relationship being invoked by the QHC [qualified health claim], but the speed and magnitude of the response is likely contingent on the amount and successfulness of marketing efforts to popularize the diet/disease relationships. As a practical matter, an approved QHC from FDA probably helps these marketing efforts, which is the practical value to the company of getting a QHC.

⁴ http://www.aeb.org/Assets/PDF/AmericanEggBoard Nov.06.pdf, at1. (Accessed June 6, 2007).

⁵ Packaged Facts, http://www.digital50.com/news/items/PR/2007/02/22/NYTH157/omega-3-infused-food-and-beverage-sales-skyrocketing-to-7-billion-by-2011/print (Accessed June 6, 2007).

⁶ Letter Responding to Health Claim Petition dated November 3, 2003 (Martek Petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease (Docket No. 2003Q-0401). [Hereinafter *Martek Response*] Available at http://www.cfsan.fda.gov/~dms/ds-ltr37.html.

⁷ 21 C.F.R. § 101.62 (c)(2).

⁸ 21 C.F.R. § 101.62 (d)(2).

⁹ Martek Response, supra at 13-15.

base a Daily Value (DV). 10 Nutrient content claims are tied to the percent of the DV a product supplies.

The following year, FDA rejected a petition filed on behalf of an egg producer, Belovo, Inc., to permit a qualified health claim for omega-3s in the eggs of specially fed hens. Over 80% of the omega-3 fatty acids in those eggs consisted of alpha-linolenic acid (ALA). The remainder consisted of EPA, DHA and docosapentaenoic acid (DPA) fatty acids. ¹¹ FDA concluded that:

Given the significant cholesterol and saturated fat content of Belovo eggs and the well-established association between increased intake of these lipids and higher CHD [coronary heart disease] risk, FDA is not convinced that public health considerations would warrant exercising enforcement discretion [i.e., allowing the claim] with respect to the disqualifying level for cholesterol even if there were credible evidence for a relationship between Belovo PUFA-enriched [polyunsaturated fatty acid] eggs and CHD risk reduction. 12

Despite the fact that FDA (1) limited the omega-3 qualified health claims to EPA and DHA fatty acids; (2) expressly prohibited qualified health claims for ALA, DHA, and EPA omega-3 on egg labels; and (3) forbade the use of nutrient content claims for DHA and EPA omega-3 fatty acids, ¹³ numerous producers are, nevertheless, marketing eggs on the basis of those statements. ¹⁴ It is particularly disturbing that the American Egg Board tells its members that "more food marketers are making use of FDA's qualified health claim suggesting a reduced risk of coronary heart disease with consuming conventional foods containing EPA and DHA." ¹⁵ But it fails to warn that the FDA specifically prohibited omega-3 claims for eggs.

II. Product-Specific Violations

A. Land O Lakes (Attachment A)

The principal display panel of the label specifically states "Contains 350 mg of OMEGA-3 fatty acids per serving." This constitutes an illegal nutrient content claim because the word

10. at 17.

¹⁰ "[T]he scientific evidence for this relationship is not conclusive and does not support the establishment of a recommended daily dietary intake level or even a possible level of effect for the general U.S. population." *Id.* at 22.

¹¹ Belovo Response, supra at 5. http://www.cfsan.fda.gov/~dms/qhceggs.html (Accessed June 6, 2007).

¹² *Id.* at 14.

¹³ Under 21 C.F.R. § 101.13 (b), claims that characterize the level of a nutrient may not be made unless FDA has issued a regulation defining the parameters. Thus, ALA claims are also impermissible.

¹⁴ As one marketer stated, "There are more and more new products containing omega-3s on the market every day. It can be very confusing to decide what to choose because all omega-3s are not created equal." Chart, "Not All Omega-3 Eggs are Created Equal," www.goldcirclefarms.com (Accessed May 17, 2007). (*See* Attachment C).

¹⁵ http://www.aeb.org/Assets/PDF/AmericanEggBoard_Nov.06.pdf, at1. (Accessed June 6, 2007).

"contains" implies that there is a significant amount of the nutrient in the product. ¹⁶ That implication is bolstered by the huge print on the front label stating "OMEGA 3 EGGS." Nutrient content claims cannot be made unless their parameters have been specifically defined by FDA pursuant to a regulation. ¹⁷ Not only has FDA not issued a nutrient content claim for omega-3 fatty acids, but, as noted above, it has expressly prohibited them for DHA and EPA omega-3 fatty acids. ¹⁸

The information panel inside the carton explains that Omega 3 All-Natural Eggs are a "good source of heart-healthy nutrition." "Good source" may only be used for products that contain 10% of the Daily Value for a nutrient. Since there is no established DV for omega-3s, such a claim constitutes an illegal nutrient content claim. The use of the term "healthy" is also an impermissible nutrient content claim because the eggs contain too much saturated fat and cholesterol to comply with FDA's definition of "healthy."

The information panel further states "Omega 3 All-Natural Eggs contain 350 mg of Omega 3 fatty acids per serving – an essential nutrient that may lessen the risk of heart disease." That constitutes an unapproved qualified health claim. FDA specifically rejected a petition by Belovo, Inc., for a similar qualified health claim in April 2005 stating: "FDA does not believe that a qualified health claim about these eggs and reduced risk of CHD would assist consumers in maintaining healthy dietary practices, given the amount of cholesterol and saturated fat found in the eggs." ²¹

Furthermore, the claims on the front label and inside information panel that each egg contains "350 mg of OMEGA-3s" are deceptive. Land O Lakes' claims imply that the omega-3s in the product are the apparently beneficial DHA and EPA omega-3 fatty acids. But tests by an independent laboratory hired by CSPI found that less than half of the claimed amount comes from DHA and EPA. ²² The inclusion of less important omega-3s with EPA and DHA deceives consumers. Many consumers believe that omega-3s are beneficial because of publicity about preliminary studies suggesting their effectiveness in preventing or treating a variety of

¹⁶ Letter from Barbara O. Schneeman, Director, Office of Nutritional Products, Labeling and Dietary Supplements, FDA to Michael E. [sic] Jacobson, Ph.D, Executive Director, CSPI. (Apr. 14, 2006) (The use of descriptive words, such as "only" or "contains," would implicitly characterize the level of the nutrient . . . A claim that expressly or implicitly characterizes the level of a nutrient may not be made on the label or in the labeling of food unless the claim is made in accordance with those regulations)(on file with CSPI).

¹⁷ 21 C.F.R. § 101.13 (b).

¹⁸ See n. 10 supra, and accompanying text.

¹⁹ 21 C.F.R. § 101.54 (c).

²⁰ 21 C.F.R. § 101.65 (d).

²¹ Belovo Response, supra at 15.

²² The Land O Lakes eggs were tested by Eurofins Scientific, Inc., Des Moines, Iowa in February 2007. The tests showed that Land O Lakes contained a total of 338 mg omega-3 fatty acids, a bit less than the 350 mg claimed on the label. Of that amount, 95 mg per egg are EPA and 58 mg are DHA, or a total of 153 mg of the most valuable omega-3s.

conditions, ranging from heart disease to Attention Deficit Hyperactivity Disorder (ADHD), as well as publicity about FDA's qualified health claim.²³ But many consumers have no idea that the extent of the benefits is dependent upon the exact types of omega-3s that are found in a product.²⁴

Land O Lakes also makes an illegal health claim on its Web site, the URL of which is stated on its information panel:

Omega-3 fatty acids have been linked with reduced risk of heart disease, and can only be acquired through diet. Land O Lakes All-Natural Eggs with omega-3 are produced by hens fed our specially formulated all-natural diet.²⁵

FDA has concluded that a reference on the product label to additional material on a company's Web site causes the Internet material to be "labeling" subject to FDA's jurisdiction.²⁶

²³ For example, in 2005, cartons of the The Country Hen eggs contained an insert utilizing the qualified health claim for omega-3 fatty acids, even though it was not eligible to make such claims. (*See* Attachment E) Under the heading "The FDA Speaks," The Country Hen says:

The Food and Drug Administration has given all of us good news. We just learned through the FDA website we can now make a "Qualified Health Claim" for Omega-3 Fatty Acids. It reads as follows: "Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of two Country Hen eggs provides .3 grams of EPA and DHA omega-3 fatty acids." [Emphasis omitted]

²⁴ An industry publication explains that foods with added flax, a source of ALA omega-3s, benefits from consumers' generalized knowledge of omega-3, rather than of the specific information about the various kinds. "Although the 2004 health claim on omega-3 oils EPA and DHA was exclusively for fish oil-derived omega-3s, the consumer cache [sic?] of 'omega-3s' is stronger than the cumbersome FDA-minted health claim, and so food fortification with flax-derived omega-3s continues apace." *Annual Ingredients Market Overview*, Functional Foods & Nutraceuticals (Oct. 6, 2006). http://www.ffnmag.com/ASP/articleDisplay.asp?strArticleId=1112&strSite=FFNSite (Accessed June 6, 2007). If FDA determines that statements such as "100 mg omega-3" as used on the packages cited in this complaint are not implied nutrient content claims, manufacturers, at a minimum, should be required to indicate the amounts of DHA and EPA in the product. No claims based on ALA content should be permitted.

²⁵ Land O Lakes Web site. Land O Lakes All-Natural Eggs. http://www.moarkllc.com/pagefiles/1.html. (Accessed June 15, 2007).

²⁶ Warning letter to Robert Hawthorne, President, Ocean Spray Cranberries from Gail T. Costello, District Director New England District Office, FDA (Jan. 19, 2001).

²⁷ E.g., Letter from Barbara O. Schneeman, Director, Office of Nutritional Products, Labeling and Dietary Supplements, FDA, to Michael E.[sic] Jacobson, Ph.D., Executive Director CSPI. (Apr. 14, 2006) In explaining why FDA permits factual statements about trans fat such as "0 g trans fat" when the Agency considers whether to permit nutrient content claims, Dr. Schneeman explained that statements of amount "are appropriate when, in fact, the Nutrition Facts Panel represents the same amount." This is consistent with the examples of permissible statements of fact used in the nutrient content claims regulation: "100 calories" or "5 grams of fat." 21 C.F.R. § 101.13(i)(3). The quantitative amounts of both of those nutrients are required to be listed on the Nutrition Facts panel. (on file with CSPI)

B. Safeway (Attachment B)

The Principal Display Panel (PDP) of the Specialty 3 egg carton conspicuously promotes the amounts of vitamin E, lutein, and omega-3. Only vitamin E has a DV. The large print referencing amounts of omega-3s on the product carton constitutes an implied nutrient content claim under 21 C.F.R. § 101.13(i)(3). Given the fact that the use of the term "omega-3" is associated with the "hottest" marketing trend and that the presence of "omega-3" is material to the purchasing decision, manufacturers should not be permitted to pretend that they are "making a factual statement" permitted by 21 C.F.R. § 101.13(i)(3). In the past, when FDA has permitted statements about the amount of nutrients in a product, that nutrient was listed in the Nutrition Facts panel, along with a DV.²⁷ In the absence of a DV, consumers have no way of knowing whether the amount of the omega-3s in the product makes a significant contribution to the diet.

The inside panel of the carton states that the hens are fed a special diet of nutritious grains and are not fed animal fats or by-products, and that the principal fat in the hen's diet is linolenic acid. Thus, unless the hens were fed algae, ²⁸ it would appear that the primary omega-3 is ALA rather than DHA or EPA. ALA omega-3 fatty acids are not as protective against heart disease as EPA and DHA likely are. ²⁹ Many consumers, however, are unaware of the different types of omega-3s, and, because of this deception, the sales of products with ALA omega-3 fatty acids from flax have also risen. ³⁰

C. Gold Circle Farms (Attachment C)

The front label indicates that two eggs provide 450 mg of Omega-3 and that "2 eggs provide 300 mg of the nutrient DHA Omega-3." The sunburst and the large print promoting the omega-3s constitute an implied nutrient content claim under 21 C.F.R. § 101.13(i)(3). Again, manufacturers should not be permitted to pretend that they are simply "making a factual statement" permitted by 21 C.F.R. § 101.13(i)(3). As explained above, when FDA has permitted statements about the amount of nutrients in a product, that nutrient was listed in the Nutrition Facts panel, along with a DV. ³¹

ALA and the long chain omega-3 PUFAs serve different metabolic functions which are not interchangeable. The metabolic role of EPA is as the precursor for formation of hormone-like substances . . . which are involved in a large number of cellular functions. [citations omitted] DHA is thought to be important for brain development and functioning. The only known metabolic function of ALA is as a precursor for EPA and DHA. [citations omitted]. However, the rate of ALA to EPA/DHA conversion in humans occurs slowly and the extent to which the conversion occurs in humans is unclear [citations omitted].

Belovo Response at 5. See n. 11, supra.

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²⁸ Safeway declined to tell CSPI (a) whether the hens' diet does, in fact, contain DHA or EPA omega-3 fatty acids and (b) the amount of DHA, EPA and ALA omega-3 fatty acids per egg.

²⁹ In its letter denying a petition for a qualified health claim for omega-3 eggs, FDA explained:

³⁰ See n. 24, supra and accompanying text.

³¹ See n. 27, supra.

In addition, the package is misleading because it bases the amount of omega-3s on the consumption of two eggs.³² But the reference amount customarily consumed (RACC) for eggs is one egg, and nutrition information is required to be presented on a per-serving basis.

Additionally, the Web site illegally claims that the product will reduce the risk of heart disease and provide other health benefits. ("Evidence shows DHA, an Omega-3 Fatty acid, is an essential nutrient that reduces the risk of heart disease.") Because the carton states the company's Web site on the information panel, the Web site constitutes "labeling" and misbrands the product.³³

D. Eggland's Best (Attachment D)

The Web site for Eggland's Best, which is referenced on the rear of the package, states that "Omega 3 essential fatty acids may play an important role in the prevention of coronary heart disease." That is an unapproved health claim for eggs that misbrands the product. 35

The inside cover of the egg carton states that the eggs are "high in Vitamin E, and contains 25% less saturated fat than ordinary eggs, as well as 100 mg of Omega-3, and 185 mcg of Lutein," (emphasis added). Both the omega-3 and lutein claims are unapproved nutrient content claims because descriptive terms such as "contains" are expressly prohibited in the absence of a nutrient content claim regulation. 37

The 25% less saturated fat claim is misleading (even assuming the claim is accurate, which it might not be). The "25% less" reduction is, in fact, *de minimis* – only 0.39 grams.

³² Without a crackdown by FDA, both consumers and other egg producers are injured. The average shopper is unlikely to notice that the amount of omega-3s in The Country Hen product is higher than other brands because the "serving size" has been doubled. Producers who appropriately declare amounts on a per-serving basis suffer from an unlevel playing field.

³³ See n. 26, supra and accompanying text.

³⁴ Eggland's Best Web site. http://www.egglandsbest.com/why_eggland/whyegg.asp?pg=nutritional_benefits (Accessed June 15, 2007).

³⁵ See n. 26, supra and accompanying text.

³⁶ An independent test conducted for CSPI by Eurofins Scientific, Inc. found that Eggland's have 132 mg of DHA and EPA omega-3 fatty acids. The consumer has no way of knowing that the omega-3s in this product are superior to ALA fatty acids in other products.

³⁷ See n. 16, supra and accompanying text.

³⁸ Although the label states that the product has 1 gram of saturated fat, a test conducted for CSPI by Eurofins Scientific, Inc., Des Moines, Iowa, in Feb. 2007 found that the eggs actually contained 1.59 grams. USDA states that a large egg has 1.55 grams of saturated fat. USDA National Nutrient Database for Standard Reference, Release 19, *available at* http://www.nal.usda.gov/fnic/foodcomp/search. (Accessed June 6, 2007).

Indeed, if a product contains only 0.39 grams of saturated fat, FDA considers it to be "0" for purposes of nutrition labeling.³⁹

E. The Country Hen (Attachment E)

The prominent placement of the statement "600 mg omega-3s per 2 eggs" in a sunburst on the principal display panel constitutes an unauthorized implied nutrient content claim. ⁴⁰ The inside cover refers to the eggs as "healthy." But as explained above, the nutrient content claim "healthy" should not be used because the product contains too much saturated fat and cholesterol. ⁴¹

In addition, the package is misleading because it bases the amount of omega-3s found in the product on two eggs. As explained above, the RACC for eggs is one egg, and the company lists the quantities of selenium, lutein + zea[xanthin], and choline on a per egg basis. The Country Hen tries to mislead consumers by stating the omega-3 content based on two eggs so that the amount of omega-3 seems to be significantly higher than that of other brands of eggs.

F. Giving Nature (Attachment F)

The principal display panel highlights that the product has 75 mg of DHA and 225 mg of Omega 3 per egg, which constitutes an illegal nutrient content claim.⁴² The inside label explains that: "For years flax seed (the purple flowering plant on our label) has been known to hold high levels of DHA Omega 3." But, according to the Flax Council of Canada and others, DHA and EPA are not found in plants.⁴³ Therefore, the label is false and misleading.

G. Full Spectrum Farms (Attachment G)

The large print reference to omega-3s followed by the statement "Provides 30 mg of Omega 3 fatty acids per serving" on the principal display panel is an illegal implied nutrient content claim. ⁴⁴ Furthermore, that claim is particularly misleading and illustrates how easy it is to deceive consumers in the absence of a DV. According to USDA, a large egg (50g) contains approximately 37 mg of omega-3s including 18 mg DHA, 2 mg EPA and 17 mg ALA and other

³⁹ E.g., FDA regulations provide that if a serving of a product contains less than 0.5 grams saturated fat, the content shall be expressed as zero. 21 C.F.R. § 101.9 (c)(2)(i). FDA should specifically forbid "less saturated fat" claims if the reduction is less than 1 gram per serving.

⁴⁰ 21 C.F.R. §101.13(i)(3).

⁴¹ See n. 20 supra, and accompanying text.

⁴² 21 C.F.R. § 101.13(i)(3).

⁴³ http://www.flaxcouncil.ca/english/pdf/FFtsheet Fish Flax R2.pdf. (Accessed June 6, 2007).

⁴⁴ 21 C.F.R. § 101.13(i)(3).

omega-3 fatty acids.⁴⁵ But based on the product label, a consumer would be led to believe that this brand of eggs has a higher amount of omega-3s than typical eggs.⁴⁶ The carton also claims to have 25% less saturated fat, which, even if true and as explained above, represents a trivial reduction and further misleads consumers.⁴⁷

III. Conclusion

We urge the Agency to take prompt action to ensure that eggs, as well as other products making omega-3 claims, are no longer marketed with unauthorized health claims, unauthorized nutrient content claims, and other false or misleading statements pertaining to omega-3 fatty acids. Moreover, because the marketplace abuses of these companies highlight the pitfalls of permitting qualified health claims for food, we urge the FDA to reevaluate its policy on qualified health claims, which increase the likelihood of deceptive and illegal claims, such as the ones that many egg producers are making.

Sincerely,

Ilene Ringel Heller Senior Staff Attorney

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Michael F. Jacobson, Ph.D. Executive Director

Michael F. Jacobson

Bruce Silverglade Director of Legal Affairs

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Attachments

⁴⁵ USDA National Nutrient Database for Standard Reference, Release 19, *available at* http://www.ars.usda.gov/main/site_main.htm?modecode=12354500. (Accessed June 6, 2007).

⁴⁶ The American Egg Board states: "A standard egg (50 grams) contains 34 mg of DHA, with very little EPA (<5 mg)." Available at http://www.aeb.org/Assets/PDF/AmericanEggBoard Nov.06.pdf (Accessed June 5, 2007).

⁴⁷ See n. 39, supra and accompanying text.



NET WT. 24 oz. (1 lb. 8 oz.) 681g SAFE HANDLING INSTRUCTIONS:

To prevent illness from bacteria: Keep eggs
retitgerated, cook eggs until yolks are frim,
and cook foods containing eggs thoroughly.

We share your concern about the environment. We use recycled plastic packaging. Please recycle.



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Vegetarian feed contains no animal fat, animal by-products, preservatives or antibiotics





A GRADE

OMEGA 3 EGGS ALL-NATURAL LARGE GRADE A BROWN

OMEGA 3 EGGS
ALL-NATURAL



FRESH LARGE GRADE A BROWN

ONE DOZEN

Keep Refrigerated at or below 45°F.

BEST BEFORE

OMEGA 3 ALL-NATURAL EGGS



Where simple goodness begins™.

Introducing LAND O LAKES™ Omega 3 All-Natural Eggs. Produced by hens fed an all-natural, whole grain diet, LAND O LAKES™ Omega 3 All-Natural Eggs contain 350 mg of Omega 3 fatty acids per serving – an essential nutrient that may lessen the risk of heart disease.

The result? An egg that's both naturally delicious and a good source of heart-healthy nutrition.

So add a little simple goodness to your family's table with LAND O LAKES™ Omega 3 All-Natural Eggs.

For more than 80 years, it's what you have come to trust and expect from the LAND O LAKES brand.

Nutrition Fa Serving Size 1 egg (50g) Servings 12	icts
Amount Per Serving	
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% Dai	ly Value*
Total Fat 4.5 g	7%
Saturated Fat 1.5 g	8%
Trans Fat 0 g	
Cholesterol 215 mg	71%
Sodium 65 mg	3%
Total Carbohydrate 1	g 0 %
Protein 6 g	10%
Vitamin A 6% • Vitam	in C 0%
Calcium 2% •	Iron 4%
Not a significant source of Dietary Fibe	er or Sugars.

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs: Calories 2.000 Total Fat Less than 65g 80g 25a Sat Fat Less than 20a 300ma Cholesterol Less than 300mg Less than 2.400mg 2.400mg 375g

 Cholesterol
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 Dietary Fiber
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 Fat 9 • Carbohydrate 4 • Protein 4

LARGE EGGS

5275-0656-1

For more information and great-tasting recipes, visit our website at www.landolakes.com

omega Page 1 of 1



LAND O LAKES™All-Natural Eggs with Omega-3

Omega-3 fatty acids have been linked with reduced risk of heart disease, and can only be acquired through diet. LAND O LAKESTM All-Natural Eggs with Omega-3 are produced by hens fed our specially formulated all-natural diet, enhanced with flax-seed oil, and other natural sources of heart-healthy Omega-3 fatty acids. As a result, each delicious egg contains 350mg of this valuable nutrient.

Color: Brown-shelled, White-shelled

Package Size: 12-count

Egg Size: Large

All LAND O LAKESTM Eggs are United Egg Producers Certified. For more information, please \underline{visit} www.uepcertified.com.

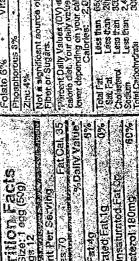


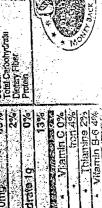
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Attachment A

ONE DOZEN GRADE A-LARGE EGGS PERISHABLE KEEP REFRIGERATED ◆ SELL BY SEE INSIDE LID FOR IN ON NUTRIENTS AND (

Attachment B





nutritious grains with nauxal-source Viamin E in addition to natural planta that enflance the golder. color of the york. The hens are fed no animal tets of animal by products. Cancia oil, which is low th saturated fat and a source of innoterio acid, is added as the principal for in the heri's diet Comparison of a Referrary Statest Specially 3 Egg in a Regular Egg

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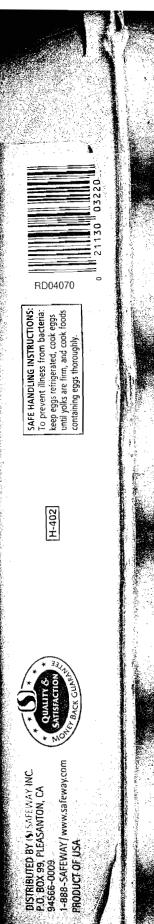
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"Comparison based on one large whole egg (20g)
"Regular egg nutrient values from USDA Mutrient L. tabase for Standard Reference.

Release 11, (Sept. 1636).

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Attachment B





Not Just Any Omega-3. CAGE FREE DHA OMEGA-

2 eggs provide 300 mg of the nutrient DHA Omega-3

One Dozen

DHA is vital for a healthy heart and for brain and eye development and function. GRADE A LARGE EGG

SUPPORTS A HEALTHY PREGNANCY

Keep Refrigerated at 45°F

Net Wt. 24 oz. (1 lb. 8 oz.) 680g

SAFE HANDLING INSTRUCTIONS: TO PREVENT ILLNESS FROM



2 eggs provide 300 mg of the nutrient



Not All Omega-3 Eggs Are Created Equal

Source Matters-Know What You're Getting





There are more and more new products containing omega-3's on the market everyday. It can be very confusing to decide what to choose because all omega-3's are not created equal. The following chart lists several sources of omega-3's and how they differ. Consider this when choosing your source of omega-3.

MOST IMPORTANTLY, when it comes to health benefits, all Omega-3's are not created equal. The three main Omega-3's are DHA, EPA, and LNA.

		SOURCE	
	Marine Microalgae	Fish/ Fish Oil	Flaxseed/ Flax Oil
Type of Omega-3	DHA	DHA/EPA	LNA
Health Benefits			
Heart	Yes	Yes	Yes, but limited
Brain	Yes	Yes, but limited	No 1
Eye	Yes	Yes, but limited	No 1
DHA Concentration ²	20%	9%	0%
Additional Nutrients Provided	Vitamin B. carotenoids, Vitamin E. protein		
Taste	Neutral Flavor	Fish-like flavor	Grass-like flavor or fish if rancid
Environmental Pollutants	None - Pure	May contain environmental contaminants (PCB,DDT)	Presence of environmental contaminants not investigated
Environmentally Friendly	Yes	No ³	Yes

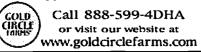
If the product you are evaluating contains cholesterol (like eggs), remember ALL whole eggs contain cholesterol regardless of DHA Omega-3 content.

Gold Circle Farms DHA Omega-3 Eggs Are Guaranteed Better!

As a responsible grocer, you always provide your customers with the very best products and brands. Gold Circle Farms eggs are the Omega-3 brand to feature in your egg case because each egg is fortified with 150 mg of DHA and 6 times more Vitamin E than regular eggs. Most other brands' of Omega-3 eggs have little DHA.

Evidence shows **DHA**, an Omega-3 fatty acid, is an essential nutrient that reduces the risk of heart disease; improves infant brain and eye development, and heart functions; is linked to lower rates of postpartum depression; and increases birth weight, promoting full-term pregnancies.

Gold Circle Farms hens are fed an all-natural, vegetarian feed that is rich in a marine microalgae (similar to cold-water fish), nature's original source of DHA. Through an exclusive, patented process, the "fishy" taste that plagues other brands is eliminated, and the egg's natural flavor is enhanced. No other egg company can make this claim.



Your Store's Egg Case Should Feature Nothing Less Than The Best!

The country's leading brand of DHA Omega-3 eggs

Attachment C

I Very little of the LNA we consumer is converted to DHA. The main health benefit of LNA is associated with skin integrity

² By weight 3 Production of fish oil strips toes of fish from the ocean thus disrupting nature's balance

Figh in Vitamin E 100mg of Companier Eggs 25% Less Saturated Fat than Regular Eggs 25% Less Saturated Fat than Regular

VEGETARIAN FED HENS

Attachment D

FARM FRESH

ALL ARADE A EGGS
NATURAL LARGE

WATURAL LARGE

WATU

Eggland's Best®...America's Best Tasting Egg

We are proud and excited to announce that Egg-land's Best has recently been judged America's Best Tasting Egg by the professional chefs of the American Culinary Institute. Egg-land's Best eggs won the top honors based on superior taste, texture and appearance.

Of course, in addition to being America's Best Tasting Egg, Egg-land's Best is high in Vilamin E, and contains 25% less saturated fat than ordinary eggs, as well as 100 mig of Omera 3, and 185 mcg of Lutein.

How can an egg that has such great taste be so good for you? We only feed our hens a patented all-natural, all-vegetarian diet with no animal fat or animal by-products to bring you the best tasting, most nutritious egg we possibly can. Also, laying hen diets contain no added hormones. Egg-land's Best never uses antibiotics of any kind.

Now, as you try to eat healthier, you can still enjoy one of your favorite foods, Egg-land's Best!

Recommended American Diabetes Association/American Dietetic Association dietary exchange: 1 Egg*land's Best egg for 1 Medium Fat meat.

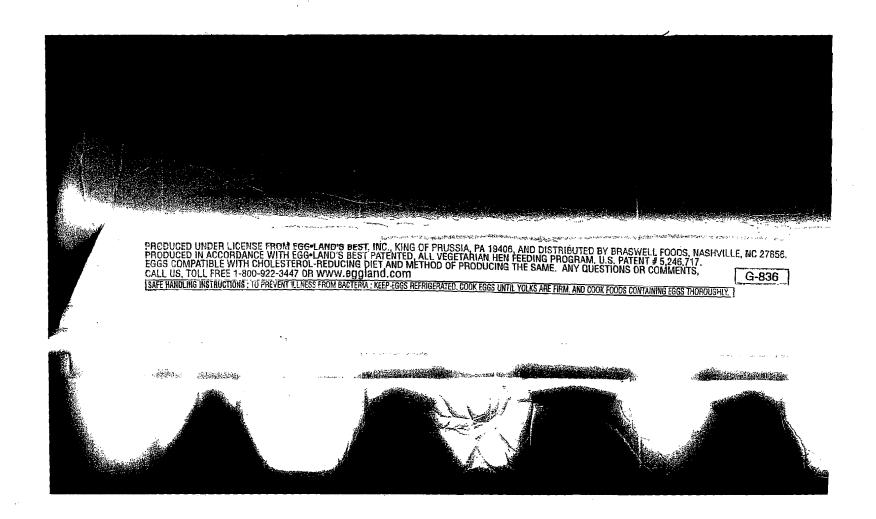


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Total Fat 4g	5%
Saturated Fat 1g	5 %
Trans Fat Og	
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Sedium 65mg	2%
Total Carbehydra	te Og 9%
Protein 6g	13%
Vitamin A 6%	• Vitamin C 0%
Calcium 2%	• Iron 4%
Vitamin E 25%	Thiamine 2%
Riboflavin 15%	 Vitamin B-6 4%
Folate 6% •	Vitamin B-12 8%

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ł	<u>Calories</u>	2,000	2.500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	30Dng
Socium	Less then	2,400mg	2,400mg
Total Carbohyd	rate	300g	375g
Diatary Fiber		25g	30g
Protein		50α	650

Saturated Fat 25% less than ordinary eggs: 1 g vs. 1.5g (quantities rounded). Total fat 4 g., cholesterol 180 mg.

If you are concerned about cholesterol, follow a diet lower in saturated fat and cholesterol and ask your doctor about Egg-Land's Best Clinical studies.



Nutritional Benefits Page 1 of 2



BETTER TASTE, BETTER NUTRITION, BETTER EGGS.

Why Eggland's?

EB Recipes

EB News

Store Locator

Contact Us

Why Eggland's? **⊙**

- ► About Eggland's Best
- Quality
- ▶ Great Taste
- ▶ Nutritional Facts
- ► Nutritional Benefits
- ▶ Diet & Health
- ► EB FAQs & Tips

Nutritional Benefits



LEARN WHY EGGLAND'S BEST EGGS ARE THE MOST NUTRITIOUS EGGS FOR YOU AND YOUR FAMILY.

DISTINCTIVE QUALITIES OF AN EGGLAND'S BEST EGG

In addition to the great taste, Eggland's Best eggs are nutritionally superior to ordinary eggs:

- 180mg of <u>cholesterol</u> compared to 213mg of cholesterol in an ordinary egg. <u>Clinical tests</u> demonstrated that people on a low-fat diet ate 12 Eggland's Best eggs a week without increasing their serum cholesterol level.
- Higher in <u>Vitamin E</u>, at least 10 times more than in an ordinary egg. One Eggland's Best egg
 provides 25% of a person's recommended daily allowance of Vitamin E. Vitamin E is an
 antioxidant that may help reduce the risk of some health problems, such as heart disease,
 cancer, lung disease, and arthritis.
- 25% less <u>saturated fat</u> than in an ordinary egg. Cutting back on saturated fat is an effective way
 to help lower blood cholesterol and improve heart health.
- 4 grams of total fat compared to 4.5 grams in an ordinary egg.
- 100mg of Omega 3, three times the amount in an ordinary egg. Omega 3 fatty acids are termed
 "essential" and are believed to be beneficial for heart health, hypertension, brain and eye
 function, and infant development.
- 200mcg of <u>Lutein</u> which is 25% more Lutein than ordinary eggs. Lutein is an important
 antioxidant that helps to maintain healthy vision and may reduce the risk of cataracts and
 macular degeneration in the elderly and people with diabetes. It may also reduce a person's risk
 of developing some cancers.
- Higher in lodine. 40% of the Daily Value of lodine compared to 15% in an ordinary egg. lodine is an essential element for thyroid function, necessary for the normal growth, development, and functioning of the brain and body.
- A "complete <u>protein</u>". A single egg supplies about 10% of the protein you need daily, along with vitamins A, D, and B12. Eggs are an economical, convenient, and easy-to prepare source of high-quality protein.

Cholesterol

Our quality assurance laboratory randomly tests our eggs from each of our farmers across the country to ensure that Eggland's Best eggs have a lower level of cholesterol.

Vitamin E

Through normal bodily processes and external sources, such as air pollution, we are exposed to highly reactive, oxygen-containing chemicals called "free radicals." Free radicals can damage our cells and tissues; in fact, scientists have begun to establish links between oxidative, free-radical damage to the body's cells and chronic diseases, such as arthritis, atherosclerosis, cancer, cataracts, heart disease, and lung ailments.

Nutritional scientists are studying the roles of various dietary factors against such diseases. There are substances called "antioxidants" that can help curb these damaging oxidative reactions. Among the nutrients most frequently being studied are antioxidants, such as Vitamin E, which are capable of neutralizing free radicals and other reactive chemicals. It is thought that the antioxidant vitamin terminates these harmful chemical reactions, thereby helping to protect body cells.

Attachment D

Nutritional Benefits Page 2 of 2

> There are other good sources of Vitamin E, but most of these sources contain higher levels of total fat and calories than an Eggland's Best egg.

Vitamin E Source	Size/Amount	Vitamin E	Total Fat	Calories
Eggland's Best Egg	1 Large Egg	5.0mg	4.0g	70
Generic Egg	1 Large Egg	0.7mg	4.5g	75
* Wheat Germ	1/4 c	5.0mg	3.0g	109
* Hazelnuts	1/4 c	8.0mg	21.0g	213
* Sunflower Seeds	1/4 c	18.0mg	18.0g	205
* Peanut Butter	2 Tbsp	3.0mg	16.0g	188

Saturated Fat

Saturated fat is believed to be the single most detrimental factor in raising blood cholesterol levels. Reducing one's intake of saturated fat may be the most effective strategy to reduce blood cholesterol levels. A reduction of blood cholesterol may result in a lower risk for developing coronary heart disease.

Eggland's Best eggs have reduced saturated fat because the principal source of fat in the Eggland's Best high-quality hen diet is canola oil, which is the lowest saturated fat oil and contains appreciable levels of linolenic acid.

Omega 3

Research indicates that Omega 3 essential fatty acids may play an important role in the prevention of coronary heart disease by lowering serum cholesterol, triglyceride, and low density lipoprotein levels. They are also beneficial for brain and eye function, infant development, and a healthy immune system. The Omega 3 in Eggland's Best eggs comes from the hens' special feed.

Lutein

A powerful antioxidant, Lutein has been shown to protect against macular degeneration, a debilitating eye disorder among the elderly. Researchers are studying Lutein consumption and the role it may play in maintaining the health of eyes, heart and skin, as well as women's breasts and cervixes, along with the possible role of Lutein in preventing heart disease and aiding in immune system health.

Lutein is not made in the body and must be obtained from food or vitamin supplements. Major sources of Lutein are found in egg yolks, corn, spinach, and other green leafy vegetables. The extra Lutein in Eggland's Best eggs comes from the hens' special feed.

lodine

lodine is an essential element for thyroid function, necessary for the normal growth, development, and functioning of the brain and body. Because thyroid hormones are essential to life, the body must have proper levels of thyroid hormone to work well.

Our bodies do not produce lodine, therefore, we must get lodine through our food. The chart below shows the lodine content of Eggland's Best compared to some other known sources of lodine.

Food	lodine
Table salt, iodized (1/4 teaspoon)	100 mg
Cod, cooked (3 ounces)	87 mg
Eggland`s Best egg (1 large)	60 mg
Potato, cooked (1 medium)	7 mg
Spinach, cooked (1/2 cup)	5 mg
Almonds (1 ounce)	4 mg

Protein is a part of every body cell and is needed to repair body cells as they wear out. Protein is also critical to the process of making new body tissue during times of growth, infancy, childhood, adolescence, and pregnancy. Protein also helps regulate body processes. As enzymes and hormones, proteins are important to make various chemical reactions happen in the body. As antibodies, proteins protect you from disease-carrying bacteria and viruses.

Protein is often referred to as a single nutrient. Yet proteins in foods and in your body cells are made up of 20 amino acids. Nine of these amino acids are considered essential, which means your food choices must supply them.

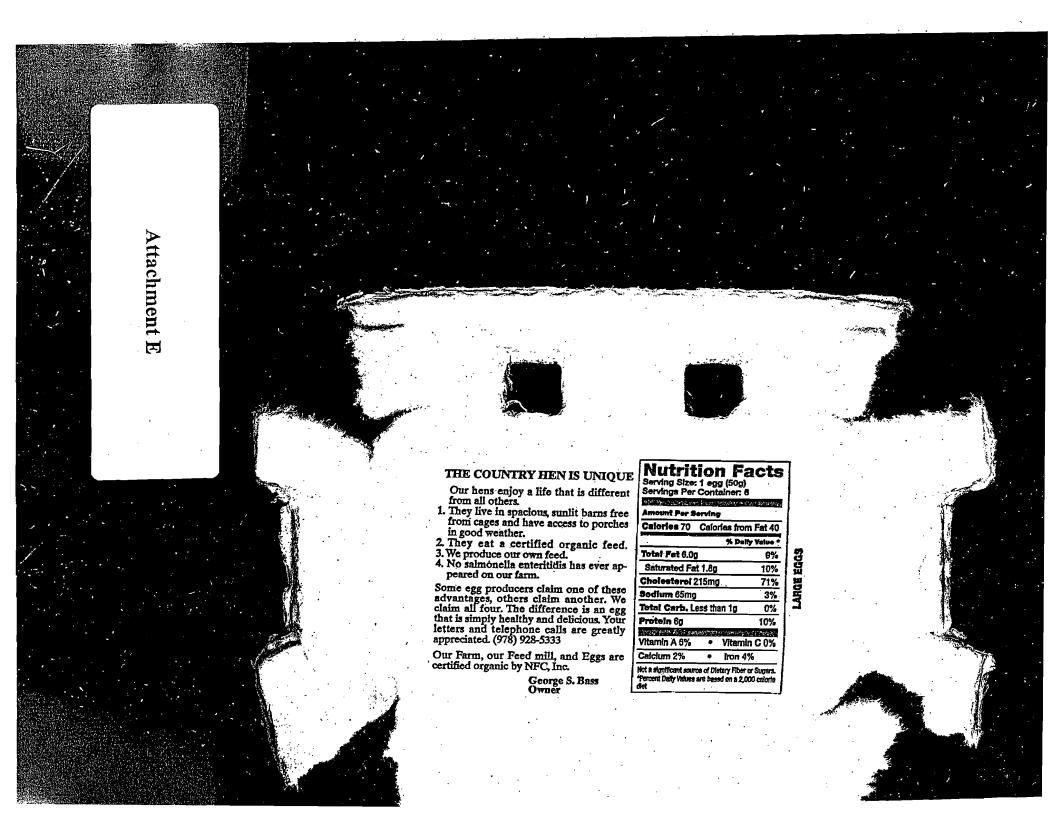
All proteins are not alike. The protein found in eggs is considered a "complete protein," or of a composition which can supply all the body's requirements (all the essential amino acids). In fact, many experts believe eggs are the best source of high-quality protein.

Attachment D



Eggcyclopedia, American Egg Board, Rev. 4/94
 Reference: Becker, Gail L., The Antioxidant Pocket Counter, Times Books, New York, 1993





The Country Hen



Hubbardston, MA 01452

2005

Dear Egg Buyer,

WINTER IS HERE

On the first day of winter the temperature was 0 degrees on our pole. Before I came to work I went to Barn 6 to see if the water might have frozen. If the water freezes in any of the barns, it may take half a day to thaw the pipes with blowtorches and space heaters. Fortunately, Barn 6 was ok.

THE FDA SPEAKS

The Food and Drug Administration has given all of us good news. We just learned through the FDA website we can now make a "Qualified Health Claim" for Omega-3 Fatty Acids. It reads as follows:

"Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of two Country Hen eggs provides .3 grams of EPA and DHA omega-3 fatty acids."

THE REST OF THE STORY

The Country Hen egg also contains two other omega-3 fatty acids: one is a major constituent, lenolenic acid, and the other is a minor omega-3

labeled 22:5w3. Lenolenic acid is also important in health, but is not contained in the FDA health claim. Lenolenic acid and "its smaller brother" 22:5w3 make up another .3 grams in a serving of two eggs. The total omega-3's contained in two of our eggs amount to .6 grams of omega-3 fatty acids.

THANK YOU FDA

We are happy that the FDA recognizes the possible benefits of EPA and DHA in coronary heart disease. We are the only egg company to our knowledge that has an egg, organic or otherwise, that is enriched with both EPA and DHA. All the rest are merely LNA enriched. LNA is not as potent a health agent as EPA and DHA. Furthermore, the one egg that does claim DHA is produced by hens in cages. Ugh!

OUR ONLY CLAIM

Our only claim is that we produce THE WORLD'S BEST EGG. The shells are tough, the yolks are deep yellow and stand tall, and the whites don't run. And the taste is just as good as any barn yard bird you that could find anywhere. We are a family farm and not part of any megacorp. Come and see us when spring breaks through and visit with some of our 67,000 happy employees most of whom wear feathers. And thanks for being our customer.



VING NATURE.

ORGANIC EGGS

Tree Positing Here

RTIFIED at MANE

Meets the Humano Farm Animal Caro organ standards, which incline tritious diet without antibonics, or irmones, animals raised with shelter, sting areas, sufficient space and the

USDA URGANIC

Attachment F

- La Library



For years flax seed (the purple flowering plant on our label) has been known to hold high levels of DHA Omega 3. Our certified organic, vegetarian, whole grain feed formula creates a 225mg level of Omega 3 and a 75 mg level of DHA per one large egg. DHA Omega-3 in our diets is necessary for optimum development and function of human tissue such as the brain, eyes and heart through out life, including pragnancy.

"Get Real, Get Certified!"

We also ensure against a Fox watching the Hen House by having all of our hens inspected and certified by Certified Humane® and USDA accredited Organic Certifiers oversee our organic laying hens.

For more information, go to our web site at www.givingnaturefoods.com



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Amount Per Serving	<u> </u>
Calories 80 Fat Cal. 45	
	%DV*
Total Fat 5g	8%
Saturated Fat 1.5g	8%
Trans Fat 0g	
Cholesterol 240mg	79%
Sodium 70mg	3%
Total Carbohydrate 1g	0%
Protein 7g	15%
Vitamin A 8% · Vitamin	C 0%

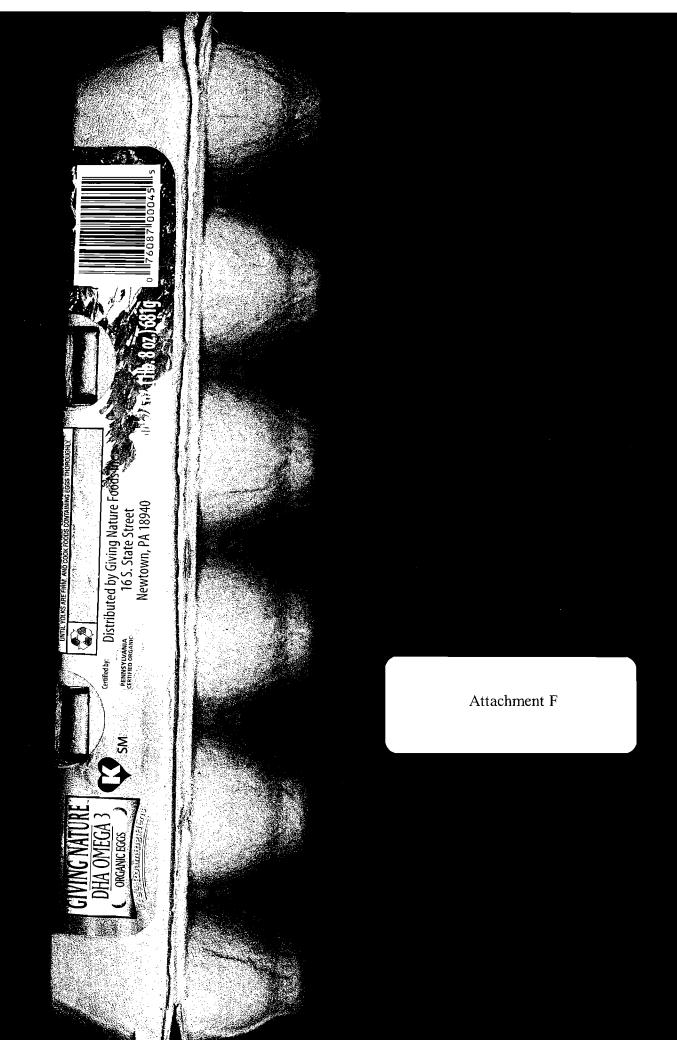
Calcium 2% · Iron 4%

Not a significant source of Dietary. Fiber or Sugars.

*Percent Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

	Catories:	2,000	2,500
Total Fat Sat. Fat	Less than	659 200	80g 25g
Cholesterol	Less than	300mg 2,400mg	300mg 2,400mg
Total Carbony		300g	375g
Dietary Fiber Protein		25g 50g	30g 65g
Calories po Fat 9 Ca	r gram: rbohydrate	4 • Pro	lein 4

EXTRA LARGE EGG





Full Spectrum.

SERVING SIZE ONE LARGE EGG

ONE DOZEN

GRADE A EGGS LARGE

KEEP REFRIGERATED

MAY BE SOLD UNTIL DATE STAMPED ON END.
PACKED FOR FULL SPECTRUM FARMS, INC., LANCASTER, PA 17601
200-P2 NET WEIGHT 1 lb. 8 oz. (680g)



- 25% less saturated fat than a regular 50 g large egg.
- See underlid for nutrition information on cholesterol and other nutrients.

NO ANTIBIOTICS

 All flocks fed NO antibiotics in either the feed or water.

OMEGA 3

 Provides 30 mg of Omega 3 fatty acids per serving.