



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

Submitted via www.regulations.gov

TO: Food and Drug Administration, Department of Health and Human Services (HHS)

FROM: Global Organization for EPA and DHA Omega-3s (GOED)

RE: Docket No. FDA–2016–D–2335 Proposed rule - *Food Labeling: Nutrient Content Claims; Definition of Term ‘Healthy’*

DATE: February 16, 2023

GOED, the Global Organization for EPA and DHA Omega-3s, represents the worldwide EPA and DHA omega-3 industry, with a mission to increase consumption of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) around the world. The membership is built on a quality standard unparalleled in the market and members must comply with quality and ethics guidelines that ensure members produce quality products that consumers can trust. Our 170+ members represent the entire supply chain of EPA and DHA omega-3s, from fisheries and crude oil suppliers to refiners, concentrators and finished product brands.

GOED appreciates the opportunity to provide comments on the proposed rule for *Food Labeling: Nutrient Content Claims: Definition of Term ‘Healthy.’* We write to express our support for the eligibility of seafood to be called “healthy” and to request the inclusion of EPA and DHA as nutrients to encourage.

GOED agrees with the FDA’s tentative conclusion that “it is unnecessary to include a limit for dietary cholesterol for the ‘healthy’ claim...,” which previously excluded seafood from being called healthy. By extension, we support the eligibility of seafood to be called healthy.

In response to “We request comment on whether nutrients to encourage should be included in addition to the food group criteria,” GOED supports the addition of nutrients to encourage, specifically EPA and DHA. While this request may present a conundrum due to the absence of dietary reference intakes (DRI) for EPA and DHA, and thus the inability to calculate a daily value (DV), the following are examples in the proposed rule where you acknowledged the importance of EPA and DHA from seafood:

- *Seafood provides important nutrients, such as beneficial fatty acids (e.g., eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)).*
- *The Dietary Guidelines, 2020–2025 further explains that a healthy dietary pattern includes:... Oils, including vegetable oils and oils in food, such as seafood and nuts.*



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GOED agrees that “Because foods provide an array of nutrients and other components that have benefits for health, nutritional needs should be met primarily through foods.”¹ At the same time, we agree with the recognition that “in some cases, fortified foods and dietary supplements are useful when it is not possible otherwise to meet needs for one or more nutrients (e.g., during specific life stages such as pregnancy).” While most Americans fail to consume even 250 mg/day EPA+DHA, research has shown that pregnant women ingesting much more EPA+DHA, particularly DHA, significantly reduce their risk of preterm and early preterm delivery,² thus clearly falling into the Dietary Guidelines for Americans, 2020-2025 exception.

While the Dietary Guidelines for Americans, 2020–2025 correctly noted that almost 90% percent of Americans do not meet the recommendations for seafood consumption, it was the Dietary Guidelines for Americans, 2015-2020 which described the importance of EPA and DHA and their connection to seafood.

Seafood, which includes fish and shellfish, received particular attention in the 2010 Dietary Guidelines because of evidence of health benefits for the general populations as well as for women who are pregnant or breastfeeding. For the general population, consumption of about 8 ounces per week of a variety of seafood, which provide an average consumption of 250 mg per day of EPA and DHA, is associated with reduced cardiac deaths among individuals with and without preexisting CVD. Similarly, consumption by women who are pregnant or breastfeeding of at least 8 ounces per week from seafood choices that are sources of DHA is associated with improved infant health outcomes. The recommendation to consume 8 or more ounces per week (less for young children) of seafood is for the total package of nutrients that seafood provides, including its EPA and DHA content.

It remains unclear why the commentary on EPA and DHA from the Dietary Guidelines for Americans, 2015-2020 was not advanced to the 2020-2025 edition, particularly since the science was even stronger five years later. In fact, during the development of the last Dietary Guidelines for Americans, GOED brought attention to the strength of the evidence when it submitted comments on multiple occasions to the Dietary Guidelines Advisory Committee (DGAC) urging the review of the scientific evidence demonstrating a benefit of omega-3 long-chain polyunsaturated fatty acid interventions during pregnancy for reducing the risk of preterm and early preterm birth. For your reference, a copy of GOED’s comments to the last DGAC detailing the scientific evidence are attached.

In closing, GOED proposes that for individual foods to be eligible to bear the “healthy” claim that they must contain at least 10% of the DV for EPA+DHA. The 10% aligns with the existing

¹ U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at [DietaryGuidelines.gov](https://www.dietaryguidelines.gov).

² Middleton P, Gomersall JC, Gould JF, Shepherd E, Olsen SF, Makrides M. Omega-3 fatty acid addition during pregnancy. *Cochrane Database Syst Rev.* 2018; 15;11:CD003402. <https://pubmed.ncbi.nlm.nih.gov/30480773/>



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definition of “healthy” found in § 101.65(d). Since eight³ to twelve⁴ ounces of commonly consumed seafood per week provides closer to 500, not 250, mg per day of EPA+DHA,⁵ let’s assume the DV for EPA+DHA to be 500 mg. Thus said 10% of the DV is 50 mg.

Thank you in advance for your consideration of our comments.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Harry B. Rice'.

Harry B. Rice, Ph.D.
Vice-President, Regulatory & Scientific Affairs

³ amount of seafood recommended in Dietary Guidelines for Americans, 2015-2020

⁴ amount of seafood recommended in Dietary Guidelines for Americans, 2020-2025

⁵ Cladis DP, Kleiner AC, Freiser HH, Santerre CR. Fatty acid profiles of commercially available finfish fillets in the United States. *Lipids*. 2014 Oct;49(10):1005-18.



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

July 24, 2019

Kristin Koegel
USDA Food and Nutrition Service
Center for Nutrition Policy and Promotion
3101 Park Center Drive, Room 1034
Alexandria, VA 22302

Submitted electronically via www.regulations.gov

RE: Docket No. FNS-2019-0001: Dietary Guidelines Advisory Committee

Dear Dietary Guidelines Advisory Committee:

GOED, the Global Organization for EPA and DHA Omega-3s, is a trade association representing 170+ companies worldwide that are active in the EPA and DHA omega-3 industry. GOED's membership includes all segments of the omega-3 supply chain from fishing and seafood companies to refiners, supplement manufacturers, food and beverage marketers and pharmaceutical companies. GOED's members agree to adhere to product quality and ethical standards that represent the benchmark for quality in the omega-3 market. GOED's mission is to increase global consumption of EPA and DHA and ensure that our members produce quality products that consumers can trust.

GOED thanks the Dietary Guidelines Advisory Committee (DGAC) for the opportunity to provide written comments, which are primarily related to the posted protocols to assess the scientific evidence.

Before that, however, we would like to encourage the DGAC to make use of existing high-quality systematic reviews and meta-analyses conducted by qualified scientists outside of the federal government. While updates to the Dietary Guidelines for Americans should reflect the latest scientific evidence, excluding the use of high-quality, scientifically-sound external systematic reviews and meta-analyses will undoubtedly reduce the efficiency and effectiveness of the DGAC process. In addition, such exclusion introduces an unnecessary bias into the process. In the case of omega-3s (i.e. EPA and DHA), we are happy to provide a list of relevant references once the protocols are finalized.

Regarding the posted protocols, our comments follow:

Pregnancy and Lactation Subcommittee

What is the relationship between omega-3 fatty acids from supplements and/or fortified foods consumed before and during pregnancy and lactation and specific health outcomes?

While the protocol has not been posted, GOED encourages the inclusion of preterm and early preterm birth as outcomes, which are clearly in scope, because this Subcommittee is addressing another question (i.e. What is the relationship between dietary patterns consumed during pregnancy and gestational age at birth?) which



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includes gestational age at birth. Last November, an updated Cochrane Review¹ of 70 randomized controlled trials (RCTs), involving almost 20,000 women, reported that O-3 LCPUFA interventions (supplementation or food additions) during pregnancy reduce the risk of preterm- and early preterm birth by 11% and 42%, respectively. Such risk reductions are of public health relevance, particularly given that the documented benefit of DHA for reducing early preterm birth could save the U.S. healthcare system up to USD 6 billion.²

The intervention/exposure and comparator of omega-3 fatty acids should be further clarified as ALA, EPA and DHA so that studies looking at ALA are not lumped together with studies looking at EPA and DHA.

Birth to 24 Months Subcommittee

For all of the questions listed under *Recommended Duration, Frequency, and Volume of Exclusive Human Milk and/or Infant Formula Feeding*, GOED recommends expanding the topic to include composition (i.e. DHA). The questions listed, including “growth, size, and body composition; food allergies and atopic allergic diseases; long-term health outcomes; and developmental milestones, including neurocognitive development” are relevant/applicable to composition, including DHA. If it’s not desirable to expand the questions to include composition, then all questions listed under *Specific Nutrients from Supplements and/or Fortified Foods* should be expanded to include infant formula. One way or another, the benefits of DHA during this life stage (birth to 24 months) need to be examined.

For all of the questions listed under *Specific Nutrients from Supplements and/or Fortified Foods*, the intervention/exposure and comparator of omega-3 fatty acids should be further clarified as ALA, EPA and DHA so that studies looking at ALA are not lumped together with studies looking at EPA and DHA.

Dietary Fats and Seafood Subcommittee

For all of the questions listed under *Dietary Fats*, the intervention/exposure and comparator of omega-3 fatty acids should be further clarified as ALA, EPA and DHA so that studies looking at ALA are not lumped together with studies looking at EPA and DHA.

Once again, GOED thanks you for the opportunity to provide comments. We look forward to watching the DGAC’s progress on this important work.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Harry B. Rice'.

Harry B. Rice, Ph.D.
Vice-President, Regulatory & Scientific Affairs

¹ Middleton P, Gomersall JC, Gould JF, Shepherd E, Olsen SF, Makrides M. Omega-3 fatty acid addition during pregnancy. *Cochrane Database Syst Rev*. 2018; 15;11:CD003402. <https://www.ncbi.nlm.nih.gov/pubmed/30480773>

² Shireman TI, Kerling EH, Gajewski BJ, Colombo J, Carlson SE. Docosahexaenoic acid supplementation (DHA) and the return on investment for pregnancy outcomes. *Prostaglandins Leukot Essent Fatty Acids*. 2016;111:8-10.



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

October 23, 2019

Kristin Koegel
USDA Food and Nutrition Service
Center for Nutrition Policy and Promotion
3101 Park Center Drive, Room 1034
Alexandria, VA 22302
Submitted electronically via www.regulations.gov

RE: Docket No. FNS-2019-0001: Dietary Guidelines Advisory Committee

Dear Dietary Guidelines Advisory Committee:

GOED, the Global Organization for EPA and DHA Omega-3s, is a trade association representing 170+ companies worldwide that are active in the EPA and DHA omega-3 industry. GOED's membership includes all segments of the omega-3 supply chain from fishing and seafood companies to refiners, supplement manufacturers, food and beverage marketers and pharmaceutical companies. GOED's members agree to adhere to product quality and ethical standards that represent the benchmark for quality in the omega-3 market. GOED's mission is to increase global consumption of EPA and DHA and ensure that our members produce quality products that consumers can trust.

GOED thanks the Dietary Guidelines Advisory Committee (DGAC) for the opportunity to provide written comments, which are specific to the systematic review protocol to be used by the Pregnancy and Lactation Subcommittee to answer the following question: *What is the relationship between omega-3 fatty acids from supplementation and/or fortified foods consumed before and during pregnancy and lactation and specific health outcomes?*

As mentioned previously in our 24 July 2019 comments, GOED encourages the inclusion of preterm and early preterm birth as outcomes, which are clearly in scope, because this Subcommittee is addressing another question (i.e. *What is the relationship between dietary patterns consumed during pregnancy and gestational age at birth?*) which includes gestational age at birth. Last November, an updated Cochrane Review¹ of 70 randomized controlled trials (RCTs), involving almost 20,000 women, reported that O-3 LCPUFA interventions (supplementation or food additions) during pregnancy reduce the risk of preterm- and early preterm birth by 11% and 42%, respectively. Such risk reductions are of public health relevance, particularly given that the documented benefit of DHA for reducing early preterm birth could save the U.S. healthcare system up to USD 6 billion.²

¹ Middleton P, Gomersall JC, Gould JF, Shepherd E, Olsen SF, Makrides M. Omega-3 fatty acid addition during pregnancy. *Cochrane Database Syst Rev.* 2018; 15;11:CD003402. <https://www.ncbi.nlm.nih.gov/pubmed/30480773>

² Shireman TI, Kerling EH, Gajewski BJ, Colombo J, Carlson SE. Docosahexaenoic acid supplementation (DHA) and the return on investment for pregnancy outcomes. *Prostaglandins Leukot Essent Fatty Acids.* 2016;111:8-10.



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For all of the health outcomes, the intervention/exposure and comparator of omega-3 fatty acids should be further clarified as ALA, EPA and DHA so that studies looking at ALA are not lumped together with studies looking at EPA and DHA.

Once again, GOED thanks you for the opportunity to provide comments. We look forward to watching the DGAC's progress on this important work.

Sincerely,

A handwritten signature in blue ink, appearing to read 'H. Rice', is written over a faint, light blue circular watermark or seal.

Harry B. Rice, Ph.D.
Vice-President, Regulatory & Scientific Affairs



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

February 7, 2020

Kristin Koegel
USDA Food and Nutrition Service
Center for Nutrition Policy and Promotion
3101 Park Center Drive, Room 1034
Alexandria, VA 22302
Submitted electronically via www.regulations.gov

RE: Docket No. FNS-2019-0001: Dietary Guidelines Advisory Committee

Dear Dietary Guidelines Advisory Committee:

GOED, the Global Organization for EPA and DHA Omega-3s, is a trade association representing 170+ companies worldwide that are active in the EPA and DHA omega-3 industry. GOED's membership includes all segments of the omega-3 supply chain from fishing and seafood companies to refiners, supplement manufacturers, food and beverage marketers and pharmaceutical companies. GOED's members agree to adhere to product quality and ethical standards that represent the benchmark for quality in the omega-3 market. GOED's mission is to increase global consumption of EPA and DHA and ensure that our members produce quality products that consumers can trust.

GOED thanks the Dietary Guidelines Advisory Committee (DGAC) for its tireless efforts and the opportunity to provide written comments, which are specific to the systematic review protocol to be used by the Pregnancy and Lactation Subcommittee to answer the following question: *What is the relationship between omega-3 fatty acids from supplementation and/or fortified foods consumed before and during pregnancy and lactation and specific health outcomes?*

On January 23-24, 2020, GOED tuned into the webcast of the fourth meeting of the DGAC. While no update was provided on the systematic review to answer the above question, GOED wants to reiterate its July 24, 2019 and October 23, 2019 comments to the DGAC encouraging the inclusion of preterm and early preterm birth as relevant outcomes. These outcomes are clearly in scope, because this Subcommittee is addressing another question (i.e. *What is the relationship between dietary patterns consumed during pregnancy and gestational age at birth?*) which includes gestational age at birth.

In November 2018, an updated Cochrane Review¹ of 70 randomized controlled trials (RCTs), involving almost 20,000 women, reported that O-3 LCPUFA interventions (supplementation or food additions) during pregnancy reduce the risk of preterm and early preterm birth by 11% and

¹Middleton P, Gomersall JC, Gould JF, Shepherd E, Olsen SF, Makrides M. Omega-3 fatty acid addition during pregnancy. Cochrane Database Syst Rev. 2018: 15;11:CD003402. <https://www.ncbi.nlm.nih.gov/pubmed/30480773>



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42%, respectively. On January 29, 2020, during *Nutrition During Pregnancy and Lactation: Exploring New Evidence - A Workshop*², Dr. Maria Makrides, coauthor of this Cochrane Review, provided further substantiation and clarification about the benefits of omega-3s for reducing the risk of preterm and early preterm birth.

With knowledge that pregnant women's omega-3 intakes are low^{3,4}, coupled with an economic impact assessment concluding DHA for reducing early preterm birth could save the U.S. healthcare system up to USD 6 billion⁵, such risk reductions are of public health relevance that cannot be ignored.

Thank you in advance for consideration of our comments.

Sincerely,

A handwritten signature in blue ink, appearing to read "Harry B. Rice". The signature is fluid and cursive, with a long horizontal stroke at the end.

Harry B. Rice, Ph.D.
Vice-President, Regulatory & Scientific Affairs

²<http://www.nationalacademies.org/hmd/Activities/Nutrition/NutritionDuringPregnancyandLactationWorkshop.aspx>

³Zhang Z, Fulgoni VL, Kris-Etherton PM, Mitmesser SH. Dietary Intakes of EPA and DHA Omega-3 Fatty Acids among US Childbearing-Age and Pregnant Women: An Analysis of NHANES 2001-2014. *Nutrients*. 2018 Mar 28;10(4). pii: E416.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5946201/pdf/nutrients-10-00416.pdf>

⁴Thompson M, Hein N, Hanson C, et al. Omega-3 Fatty Acid Intake by Age, Gender, and Pregnancy Status in the United States: National Health and Nutrition Examination Survey 2003-2014. *Nutrients*. 2019 Jan 15;11(1). pii: E177.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6356780/pdf/nutrients-11-00177.pdf>

⁵Shireman TI, Kerling EH, Gajewski BJ, Colombo J, Carlson SE. Docosahexaenoic acid supplementation (DHA) and the return on investment for pregnancy outcomes. *Prostaglandins Leukot Essent Fatty Acids*. 2016;111:8-10. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4978141/pdf/nihms-793254.pdf>