TO: 2015 Dietary Guidelines Advisory Committee (DGAC)

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

DATE: March 7, 2014

The Global Organization for EPA and DHA Omega-3s (GOED) is an association of processors, refiners, manufacturers, distributors, marketers, retailers and supporters of products containing eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) omega-3 fatty acids. GOED’s membership represents a broad range of businesses, from small entrepreneurs to multinational food companies. The Organization’s objectives are to educate consumers about the health benefits of EPA & DHA and to collaborate with government groups, the healthcare community and the industry on issues related to omega-3s, while setting high standards for our business sector. As such, our members have a profound interest in ensuring that valuable information regarding EPA & DHA is communicated to consumers in a meaningful and timely way. GOED appreciates the opportunity to provide comments to the 2015 Dietary Guidelines Advisory Committee (DGAC). Our comments will focus on the following areas: 1) seafood sustainability 2) EPA + DHA benefits 3) long-chain omega-3 rich supplements and 4) food safety-risks associated with EPA+DHA/seafood consumption.

Seafood Sustainability
GOED supports the creation of “sustainable dietary guidelines” which promote health and reduce chronic disease, while increasing sustainability. While it’s appropriate for any potential impact of consumption on food availability to be considered in the Dietary Guidelines, the reality is that Americans fall very short of meeting the recommendation to consume two servings (4 oz per serving) of seafood per week providing an average of 250 milligrams per day of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).1,2

To believe that publishing dietary guidance will result in a mass extinction of fish is unfounded. Since the publication of the 2010 Dietary Guidelines for Americans, emphasizing increased seafood consumption for the general population, actual annual fish consumption per capita in the U.S. has declined from 15.8 lbs to 14.4 lbs.3 In 2005, per capita consumption was 16.2 lbs. The unfortunate reality is that fish consumption in the U.S. is the lowest it has been since the early 1980s, suggesting the elimination of thirty years of public health gains. Should we be fortunate enough to see a reversal of this trend to the extent that there’s a real sustainability issue, then novel sources of EPA & DHA, like single cell algal oils and genetically modified (GM) vegetable crops, can serve to satisfy

nutritional demands without having an impact on fish stocks. In the U.S., infant formula is fortified with DHA sourced almost exclusively from algae.

The seafood trade is a global industry, so it is short-sighted to assess achieving the maximum potential impact of the Dietary Guidelines on the sustainability of fisheries by only looking at U.S.-based fisheries. A more appropriate approach is to examine the sustainability status of the individual fisheries around the world from which Americans are supplied their seafood and supplementary EPA+DHA. If the U.S. is largely sourcing its seafood and EPA+DHA needs from responsible fisheries, then it serves as a positive example to other countries and also supports continued advice that consumers get enough seafood in their diet.

While overfishing is a worldwide concern, those species that are most notoriously over-exploited (e.g. Bluefin tuna, Chilean sea bass, sharks) contribute only a small part of the overall consumption of Americans. The American market is dominated by species that are farmed (tilapia, catfish) and/or whose fisheries are, for the most part, managed responsibly (pollock, salmon).

The Sustainable Fisheries Partnership (SFP), an independent group, collects and analyzes publically available data to evaluate the sustainability of different wild fish stocks. According to GOED’s analysis, 78% of the seafood volume consumed in the U.S. is either farmed or wild-caught from a stock that the SFP assessed as healthy with no anticipated changes in the foreseeable future. Similarly, 80% of all omega-3 rich oils used in the U.S. come from healthy stocks. Results from this analysis (see below figure) provide an aggregation of the total catch or oil volumes from stocks rated as red (if overfished), yellow (not overfished, but likely to become so unless changes are implemented), green (properly managed to avoid overfishing) or unknown (where data is insufficient, or the catch comes from a large number of small stocks).
The previous analysis identified the total volume of seafood and omega-3-rich oils consumed in the U.S. that originate from sustainable stocks, but many of the benefits of seafood consumption are derived from their EPA and DHA content; therefore, it makes sense to look at what percentage of these nutrients comes from fisheries that are managed sustainably. According to our analysis (results depicted in the below figure), a majority (88%) of the EPA and DHA from seafood in the American diet is obtained from healthy fisheries. Similarly, 80% of EPA and DHA from omega-3-rich oils consumed in the U.S. are currently obtained from sustainably managed sources.

**EPA + DHA Benefits**
There is a wealth of scientific evidence supporting the benefits of EPA and DHA for the risk reduction of cardiovascular disease in the general, healthy population. Globally, in 2010, the attributable burden of a diet low in seafood (rich source of EPA & DHA) was 1.1% of global disability-adjusted life-years (DALYs; 95% CI 0.8–1.5), with 22% of ischaemic heart disease DALYs attributable to low seafood intake.4,5 In the United States, low EPA+DHA intake accounts for 72,000-96,000 deaths per year from

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CVD. In addition, EPA+DHA have been shown to be associated with a lower total mortality, translating into living an extra 2+ years.

GOED encourages the DGAC to consider the scientific evidence supporting the need for additional intake of EPA & DHA for the prevention of cardiovascular disease in a general, healthy population. Recently, GOED commissioned a meta-analysis of randomized controlled trials to examine the effect of EPA+DHA on blood pressure, a FDA-recognized biomarker of coronary heart disease (CHD). The available evidence (i.e. 70 randomized clinical trials) indicates that provision of EPA+DHA reduces blood pressure. This meta-analysis serves as the basis for GOED’s very recent authorized health claim petition to the Food and Drug Administration (FDA). In addition, a manuscript of the meta-analysis has recently been published.

Several recent randomized trials and meta-analyses have questioned the value of n-3 LCPUFA supplementation in cardiovascular disease risk reduction, but it’s important to put these findings into proper perspective. Instead of rehashing what others have expressed so eloquently, GOED refers the DGAC to published papers from Harris, as well as Hu and Manson. While some publications have generated controversy about the cardiovascular benefits of EPA + DHA, it is now well-established that EPA + DHA reduce triglycerides, blood pressure and even highly critical meta-analyses have demonstrated a 9% risk reduction of cardiac death.

**Long-Chain Omega-3 Rich Supplements**

As mentioned previously, annual U.S. per capita fish consumption continues to decline - from 16.2 lbs in 2005 to 15.8 lbs in 2010 to 14.4 lbs today. According to “What We Eat In America, NHANES 2001-2004” as presented in the 2010 Dietary Guidelines for Americans, the usual intake of fish/seafood for adults in the U.S. is only 0.5 ounce per day, which falls short of the weekly recommendation of eight ounces. Thus said, GOED urges the 2015 DGAC to consider extending the advice found in the 2010 Dietary Guidelines for Americans by recommending EPA & DHA dietary

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8 Miller PE, Van Elswyk M, Alexander DD (Epub ahead of print March 7, 2014). Long-Chain Omega-3 Fatty Acids Eicosapentaenoic Acid and Docosahexaenoic Acid and Blood Pressure: A Meta-Analysis of Randomized Controlled Trials. *Am J Hypertens.* [http://m.ajh.oxfordjournals.org/content/early/2014/03/06/ajh.hpu024.full.pdf](http://m.ajh.oxfordjournals.org/content/early/2014/03/06/ajh.hpu024.full.pdf)
supplements and fortified foods, in addition to fatty fish, in an effort to ensure that consumers can practically meet the daily goal of 250 mg EPA+DHA which translates to eight ounces of seafood per week.

Optimally, Americans would achieve nutrient adequacy through a total diet. While theoretically possible, the unfortunate reality is that Americans do not consume sufficient quantities of fatty fish to obtain enough EPA & DHA. While public health campaigns and other efforts may increase EPA & DHA intake via increasing fish intake, there are likely to be many individuals who still fall short of the “optimal” intake due to accessibility, expense, knowledge/understanding, cultural issues, and other factors such as dislike of the taste of fish.

The 2010 Dietary Guidelines for Americans\textsuperscript{13} noted that “In certain cases, fortified foods and dietary supplements may be useful in providing one or more nutrients that otherwise might be consumed in less than recommended amounts.” In addition, the first sentence of the section entitled “Nutrients of Concern” is “Because consumption of vegetables, fruits, whole grains, milk and milk products, and seafood is lower than recommended, intake by Americans of some nutrients is low enough to be of public health concern.” While the second sentence listed the majority of the nutrients associated with those foods, EPA & DHA were not listed. Provided the 2015 Dietary Guidelines for Americans include “Nutrients of Concern”, GOED recommends the inclusion of EPA & DHA based on the gap between current and recommended levels of consumption.

**Food Safety - Risks Associated with EPA+DHA/Seafood Consumption**

**Contaminants**

The 2010 Dietary Guidelines Advisory Committee concluded that “Moderate, consistent evidence shows that health benefits derived from the consumption of a variety of cooked seafood in the U.S. in amounts recommended by the Committee outweigh the risks associated with methyl mercury (MeHg) and persistent organic pollutants (POPs) exposure, even among women who may become or who are pregnant, nursing mothers, and children ages 12 and younger.”\textsuperscript{14}

In 2010, the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO) convened a Joint Expert Consultation on the Risks and Benefits of Fish Consumption “to review data on levels of nutrients (long-chain omega-3 fatty acids) and specific chemical contaminants (methylmercury and dioxins) in a range of fish species and to compare the


health benefits of fish consumption and nutrient intake with the health risks associated with contaminants present in fish.”15 The Expert Consultation concluded the following:

- **Among the general adult population, consumption of fish, particularly fatty fish, lowers the risk of mortality from coronary heart disease. There is an absence of probable or convincing evidence of risk of coronary heart disease associated with methylmercury. Potential cancer risks associated with dioxins are well below established coronary heart disease benefits from fish consumption.**
- **When comparing the benefits of LCn3PUFAs with the risks of methylmercury among women of childbearing age, maternal fish consumption lowers the risk of suboptimal neurodevelopment in their offspring compared with the offspring of women not eating fish in most circumstances evaluated.**
- **At levels of maternal exposure to dioxins (from fish and other dietary sources) that do not exceed the provisional tolerable monthly intake (PTMI) of 70 pg/kg body weight established by JECFA (for PCDDs, PCDFs and coplanar PCBs), neurodevelopmental risk for the fetus is negligible. At levels of maternal exposure to dioxins (from fish and other dietary sources) that exceed the PTMI, neurodevelopmental risk for the fetus may no longer be negligible.**
- **Among infants, young children and adolescents, the available data are currently insufficient to derive a quantitative framework of the health risks and health benefits of eating fish. However, healthy dietary patterns that include fish consumption and are established early in life influence dietary habits and health during adult life.**

Cancer

Last July, data on the association between plasma phospholipid fatty acids and prostate cancer risk were published.16 The authors concluded that their findings suggested that EPA & DHA are involved in prostate tumorigenesis. Even though the study did not evaluate O-3 intake, the authors also concluded that recommendations to increase O-3 intake should consider its potential risks. Based on the available scientific literature, the association of prostate cancer outcomes with dietary intake of O-3s appears to be different from the association with plasma phospholipid levels of these fatty acids. This is described in a recent editorial.17

Following the publication by Brasky et al., GOED commissioned a meta-analysis to estimate the potential association between LCω-3PUFA consumption and status and prostate cancer. The results do not support an association between LCω-3PUFAs and prostate cancer. The meta-analysis has been submitted for publication and we will provide the DGAC a copy once it is published.