GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

August 13, 2020

Secretary Sonny Perdue
U.S. Department of Agriculture
1400 Jefferson Drive SW
Washington, DC 20201

Secretary Alex M. Azar
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20024

Submitted electronically via www.regulations.gov

RE: Docket No. FNS-2020-0015; Scientific Report of the 2020 DGAC

Dear Secretaries Perdue and Azar:

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 fish oil 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 United States Departments of Agriculture (USDA) and Health and Human Services (HHS) for the opportunity to provide written comments on the 2020 Dietary Guidelines Advisory Committee's (DGAC) Scientific Report.[1]

As a general recommendation, GOED would like to see the Dietary Guidelines for Americans (DGA) highlight nutrient needs at each life stage and include strategies to meet nutrient intake targets that incorporate dietary supplements, particularly when food does not provide recommended intakes of under-consumed nutrients, especially for those of public health concern.

As you consider the DGAC's Scientific Report and develop the DGA, GOED highlights EPA/DHA-related issues for your consideration.

Women who are pregnant or breastfeeding "should consume at least 8 and up to 12 ounces of a variety of seafood per week from choices that are lower in methlymercury and higher in omega-3 fatty acids."
GOED is pleased with the DGAC's recommendation that women who are pregnant or breastfeeding should consume at least 8 ounces of a variety of seafood high in omega-3 fatty

[1]Dietary Guidelines Advisory Committee. 2020. Scientific Report of the 2020 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Agriculture and the Secretary of Health and Human Services. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC.

acids, but GOED also recommends the inclusion of an EPA/DHA supplementation recommendation for the large number of women who fall short of the seafood recommendation due to any number of reasons, including, but not limited to, accessibility, expense, knowledge, etc… In the absence of a supplementation recommendation for EPA/DHA, offspring of women consuming a low amount of seafood may fall short in their neurocognitive development compared to offspring of higher fish-consuming women.

GOED is concerned about qualifying the recommendation with "from choices that are lower in methylmercury" and "up to 12 ounces." Rather than repeat what has been expressed so well by others, we refer you to the attached comments dated August 1.

EPA/DHA supplementation recommendation for reducing risk of preterm and early preterm birth
An EPA/DHA supplementation recommendation is also warranted for reducing the risk of preterm and early preterm birth. The DGAC's recommendation for the next Committee to "examine a question on the relationship between omega-3 fatty acid supplements consumed before and during pregnancy and pregnancy outcomes," falls short of addressing a public health crisis – preterm birth – which should not wait for another DGAC cycle.

The Committee noted that it "did not assess the effect of omega-3 fatty acid supplements consumed before or during pregnancy and pregnancy outcomes. However, seafood emerged as a component that was higher in dietary patterns associated with a reduced risk of, among other things, preterm birth. Although seafood contains nutrients other than omega-3 fatty acids, systematic reviews have associated omega-3 supplements with preventing early or any preterm delivery. "

For your reference, the relevant scientific support can be found in a November 2018 Cochrane Review[2] of 70 randomized controlled trials (RCTs), involving almost 20,000 women, which 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. In January 2020, during the National Academies' *Nutrition During Pregnancy and Lactation: Exploring New Evidence - A Workshop*[3,4], Dr. Maria Makrides, coauthor of the Cochrane Review, provided further substantiation and clarification about the benefits of omega-3s for reducing the risk of preterm and early preterm birth.

[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://www.ncbi.nlm.nih.gov/pubmed/30480773
[3]http://www.nationalacademies.org/hmd/Activities/Nutrition/NutritionDuringPregnancyandLactationWorkshop.aspx
[4]National Academies of Sciences, Engineering, and Medicine 2020. Nutrition During Pregnancy and Lactation: Exploring New Evidence: Proceedings of a Workshop. Washington, DC: The National Academies Press. https://doi.org/10.17226/25841.

With the knowledge that pregnant women's omega-3 intakes are low[5,6], coupled with a compelling economic impact assessment concluding DHA for reducing early preterm birth could save the U.S. healthcare system up to $6 billion/year[7], such risk reductions are of public health relevance and cannot be ignored.

"Provide good sources of omega-3 and omega-6 fatty acids, such as seafood, beginning at ages 6 to 12 months."
GOED assumes the omega-3 recommendation is specific to EPA and DHA since seafood is cited as the only example. If this is true, GOED recommends calling out EPA and DHA in parentheses after "omega-3." If alpha linolenic acid is included in the omega-3 recommendation, then GOED recommends including another food example.

Focus Areas for Future Committees
GOED recognizes the need for the Committee, like past Committees, to prioritize questions, nutrients and outcomes to complete its work by a given deadline. GOED asks the Departments to direct the next DGAC to prioritize uncompleted work including the following (listed by subcommittee):

> Pregnancy and Lactation Subcommittee, Specific Nutrients from Supplements and/or Fortified Foods
> Question: 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?
> - Despite GOED's multiple requests (i.e. July 24, 2019, October 23, 2019 and February 7, 2020) to include preterm and early preterm birth as outcomes of interest, they were never added. Technically, this is not uncompleted work, but, as discussed above, they are very important outcomes to address for pregnant women.
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> Birth to 24 Months Subcommittee, Specific Nutrients from Supplements and/or Fortified Foods
> The protocols associated with all three questions and dated July 2, 2019 included omega-3s as a comparator. Unfortunately, the subcommittee determined in order for it to

[5]Zhang 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
[6]Thompson 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
[7]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.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4978141/pdf/nihms-793254.pdf

complete its work on time it needed to decrease the number of comparators. GOED suggests the next DGAC address the benefits of omega-3s for this age group.

Dietary Fats and Seafood Subcommittee, Dietary Fats

When the DGAC commenced its work, four questions were proposed, including:

1. What is the relationship between types of dietary fat consumed and neurocognitive development (birth to 18 years) or neurocognitive health (for those 18 years and older)?
2. What is the relationship between types of dietary fat consumed and risk of cardiovascular disease?
3. What is the relationship between types of dietary fat consumed and risk of certain types of cancer?
4. What is the relationship between types of dietary fat consumed and all-cause mortality?

The July 2, 2019 protocols associated with all four questions included omega-3s as a comparator. Unfortunately, there was only enough time for the second question to be addressed. GOED suggests the next DGAC address the remaining three questions with consideration of omega-3s as a comparator. In the fourth question, given the strength of the evidence supporting a role for EPA/DHA in reducing the risk of death from other causes (i.e. coronary heart disease and cardiovascular disease)[8], the cause of death should be expanded beyond all-cause mortality.

Thank you for considering our comments.

Sincerely,

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

[8]Hu Y, Hu FB, Manson JE. Marine Omega-3 Supplementation and Cardiovascular Disease: An Updated Meta-Analysis of 13 Randomized Controlled Trials Involving 127 477 Participants. J Am Heart Assoc. 2019 Oct;8(19):e013543. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6806028/

Docket FNS-2020-0015 August 1, 2020

Comment to the U.S. Departments of Agriculture and Health and Human Services on the Scientific Report of the 2020 Dietary Guidelines Advisory Committee Relating to Seafood Consumption During Pregnancy

We are academics, scientists, and former public health officials with subject matter expertise on seafood consumption, polyunsaturated fatty acids, neuroscience, and methylmercury exposure. We are submitting these comments on how the state of the science informs the advice from the 2020 Dietary Guidelines Advisory Committee (2020 DGAC) on following question:

> *"What is the relationship between seafood consumption during pregnancy and the neurocognitive development of the infant?"*

Our comments also address how the 2020 Dietary Guidelines for Americans (DGA) should respond to that question.

Our comments focus on cognitive development, a category of neurodevelopment in the DGAC's scientific report of July 15, 2020. As described in that report, cognitive development includes milestone development and IQ among other measures. We are not commenting on the DGAC's advice relating to the other categories of neurodevelopment in the scientific report.

The DGAC's advice is based on the results from published research involving consumption of seafood by pregnant women and its relationship to cognitive development in their children. Our comments derive from our own reading of these studies. Seafood in these studies consisted primarily of commercially available species. Whether the same outcomes would be associated with the consumption of non-commercial species, e.g., local freshwater catch, has not been well studied.

The weight of evidence accumulated over the last two decades shows that prudent public health policy should encourage pregnant women to consume at least 8 ounces per week of a variety of commercial seafood to support the cognitive development of their children as well as their own health. Well intentioned advisories to limit seafood consumption to avoid an implied risk from methylmercury in seafood are likely to have done more harm than good to the cognitive development of American children, and may still be doing so. The current state of the evidence now indicates that the 2020 DGA should reconsider that aspect of previous DGA recommendations.

SUMMARY OF OUR COMMENTS

Our reading of the seafood consumption studies leads us to offer the following comments. The scientific justification for each comment is provided in the body of this document.

- We agree with the 2020 DGAC that scientific evidence supports the existence of benefits to cognitive development in young children from seafood eaten by their mothers during pregnancy. The 2020 DGA should so advise the public.

- The 2020 DGA should consider pointing out that seafood appears to be unique in that respect. The 2020 DGAC scientific report does not make that point.
- We agree with the 2020 DGAC that the evidence supports the existence of benefits to "young children," but we recommend that the 2020 DGA define this term as meaning children through 9 years of age.
- We agree with the 2020 DGAC that pregnant women should eat at least 8 ounces per week of a variety of seafood for their children's cognitive development. The evidence supports the likelihood that at least 8 ounces per week can impart greater benefits to cognitive development than a lesser amount. We recommend that the 2020 DGA explain this.
- The 2020 DGA should further encourage pregnant women to eat at least some seafood each week for their children's cognitive development if they are unable to eat at least 8 ounces per week. The 2020 DGAC scientific report does not mention this.
- We agree with the 2020 DGAC that pregnant women should eat seafood higher in the polyunsaturated fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). The 2020 DGA should include such a recommendation.
- We disagree with the 2020 DGAC's advice that pregnant women not exceed 12 ounces per week and eat only seafood "lower in methylmercury" if these recommendations are offered for the purpose of avoiding harm to cognitive development. The scientific evidence does not support a likelihood of harm that these recommendations would resolve while benefits to cognitive development have been repeatedly associated with consumption considerably above 12 ounces per week. We recommend that the 2020 DGA not repeat these recommendations from the previous two DGAs.

BACKGROUND

The relationship between seafood consumption during pregnancy and cognitive development was addressed directly in the 2010 DGA and implicitly in the 2015 DGA DGAs build on one another as scientific information accumulates and we anticipate that the 2020 DGA will do likewise. Evidence from numerous seafood consumption studies enables the 2020 DGA to provide an answer that is more informed and robust than was the case in 2010 and 2015. Here we briefly review the conclusions and recommendations in the 2010 and 2015 DGAs.

<u>The 2010 DGA</u>:

The 2010 DGA took into account results from seafood consumption studies that compared amounts eaten by pregnant women (the exposure) against results on tests of neurocognition by their children (the outcome). All such studies have been observational in nature. As a general rule, the highest rating possible that the DGA gives to evidence from observational studies is "moderate."[1]

[1] "Moderate" evidence can be compelling. The evidence that smoking causes cancer is "moderate" under this standard. The evidence that "binge drinking (consuming 5 or more drinks for men or 4 or more drinks for women during a drinking occasion) is associated with increased risk of all-cause mortality, and that more frequent binge drinking is associated with increased all-cause mortality risk compared with less frequent or no binge drinking among those who drink" is "moderate" in the 2020 DGA scientific report of July 15 **(Part D, Chapter 11, p.11)**.

The 2010 DGA concluded that:

- "Moderate evidence indicates that intake of omega-3 fatty acids, in particular DHA [docosahexaenoic acid] from *at least* 8 ounces of seafood per week for women who are pregnant or breastfeeding is associated with improved infant health outcomes, such as visual and cognitive development" **[Ref. 1, p. 39]**. This evidence included four observational studies cited by the 2010 DGAC that reported beneficial associations between seafood eaten during pregnancy and aspects of neurocognitive development in children **[Ref. 2, p. 239]**.
- Pregnant women should eat "...at least 8 and up to 12 ounces of a variety of seafood per week, from choices that are lower in mercury" to obtain those benefits **[Ref. 1, p. 39]**.

The 2015 DGA:

The 2015 DGAC reiterated that "moderate evidence" supported "improved cognitive ability in infants" **[Ref. 3, p. 206]**. This evidence included the four prospective cohort studies that were cited in 2010.

The 2015 DGA concluded that:

- Pregnant women should eat "...at least 8 and up to 12 ounces of a variety of seafood per week, from choices that are lower in mercury" **[Ref. 4, p. 24]**.
- "Some seafood choices with higher amounts of EPA and DHA [omega-3 fatty acids in seafood] should be included" **[Ref. 4, p. 24]**.
- The reason for including at least some seafood higher in omega-3 fatty acids was that "...at least 8 ounces per week from seafood choices that are sources of DHA is associated with improved infant health outcomes" **[Ref. 4, p. 24].**

The "improved infant health outcomes" in this last sentence did not include the examples of visual and cognitive development that were contained in the 2010 DGA. The Food and Drug Administration (FDA) subsequently used the absence of these examples to support its assertion that benefits to cognitive development are unlikely to exist **[Ref. 5, p. 5]**. FDA's current advice to pregnant women, issued jointly with the Environmental Protection Agency (EPA) (hereinafter "the FDA/EPA advice") does not mention cognitive development as a reason for eating seafood **[Ref. 6]**. Correcting this omission will have significant implications for consumption advice to pregnant women.

KEY FEATURES OF THE 2020 DGAC SCIENTIFIC REPORT OF JULY 15, 2020

The report concluded that:

- "Moderate evidence indicates that seafood intake during pregnancy is associated favorably with measures of cognitive development in young children" **(Part D, Chapter 2, p.32)**. This statement appears to be among the cores of the 2020 DGAC's recommended answer to the question that has been assigned to the 2020 DGA.

- Pregnant women should be encouraged to eat "...at least 8 and up to 12 ounces of a variety of seafood per week, from choices that are lower in methyl mercury and higher in omega-3 fatty acids" **(Part D, Chapter 2, p. 66)**.
- Pregnant women should do so "...in accordance with recommendations by the *2015-2020 Dietary Guidelines for Americans*, the Food and Drug Administration, and the Environmental Protection Agency" **(Part D, Chapter 2, p. 66)**. We urge the drafters of the 2020 DGA to interpret the evidence independently based on the current state of the science and not assume that previous conclusions or omissions still have an adequate basis.

THE SCIENTIFIC BASIS FOR OUR RECOMMENDATIONS

The Evidence for Eating at Least 8 Ounces Per Week During Pregnancy

Benefits to Cognitive Development: Per our reading of them, 15 of the seafood consumption studies identified by the 2020 DGAC reported beneficial associations with one or more measures of children's cognitive development **[Refs. 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21]**. Four of them included improvements to either full scale IQ or at least one component of IQ **[Refs. 10, 11, 11, 21]**. These studies represent a dramatic increase in available research support for the "moderate" grade assigned by the 2010 and 2015 DGAs.

The evidence supports the 2020 DGAC's conclusion that seafood eaten during pregnancy is associated favorably with cognitive development. We therefore recommend that the 2020 DGA emphasize that "improved health outcomes" include cognitive development in accordance with that conclusion. Saying so would answer the question assigned to the 2020 DGA and clarify the issue for public health authorities and the public.

Although the 2020 DGAC does not mention this, we also recommend that the 2020 DGA point out that seafood appears to be the only food for which such evidence for cognitive development exists when eaten during pregnancy. We are not aware of studies that have generated such evidence for any other food.

Eating At Least 8 Ounces Per Week: Benefits to cognitive development tended to increase initially as consumption increased. Three studies reported that the most benefits in their cohorts were associated with eating at least 8 ounces per week **([Refs. 21, 13, 14]**. Three other studies reported that the most benefits in their cohorts were associated with eating at least 12 ounces per week **[Refs. 10, 11, 19]**.

The evidence supports the 2020 DGAC's advice that pregnant women should eat *at least* 8 ounces per week of a variety of seafood. We recommend that the 2020 DGA that at least 8 ounces per week represents a threshold amount that has been associated with the most benefits to cognitive development that seafood could provide. We are unable to identify any other scientific basis for recommending that particular amount of seafood as a minimum for cognitive development.

Seven studies reported beneficial associations with eating less than 8 ounces per week **[Refs. 7, 8, 9, 11, 14, 18, 21]**. Pregnant women typically eat slightly less than two ounces per week **[Ref. 22]**.

Although the 2020 DGAC does not mention this, we recommend that the 2020 DGA further encourage pregnant women to eat at least some seafood weekly if they are unable to eat 8 ounces per week. It would be unfortunate if a recommendation to eat at least 8 ounces per week were perceived as meaning that eating less than 8 ounces per week would not benefit cognitive development.

Cognitive Development in Young Children: Both the 2010 and 2015 DGAs stated that "moderate evidence" linked at least 8 ounces of seafood per week to "...improved *infant* [emphasis added] health outcomes." The 2020 DGAC advises that the evidence now extends to "young children" **(Part D, Chapter 2, p.32)**. Our reading of the studies is that beneficial associations occurred in children through 9 years of age.

The evidence supports the 2020 DGAC's conclusion that the evidence links improved cognitive development to "young children." We recommend that the 2020 DGA further define "young children" as meaning at least through 9 years of age.

Including Some Seafood Choices with Higher Amounts of EPA and DHA: As stated above, the 2015 DGA made this recommendation and the 2020 DGAC is now making it. Few seafood consumption studies have attempted to distinguish between neurocognitive outcomes from seafood with higher versus lower amounts of the polyunsaturated fatty acids EPA and DHA. For the small number that have, the results have been ambiguous. It is challenging to try to segment an observational cohort into those who eat seafood high in omega-3 fatty acids and those who eat seafood low in omega-3 fatty acids. Nonetheless, the science still supports the importance of EPA and DHA in seafood, as follows.

- These fatty acids are needed for brain development **[Ref. 23]**, as pointed out by the 2020 DGAC in its scientific report **(Part D Chapter 2, p. 51)**.
- Seafood is the primary dietary source of these fatty acids **[Ref 24]** as pointed out by the 2020 DGAC in its scientific report **(Part D, Chapter 2, p. 51)**[2].
- Seafood has been linked to benefits to cognitive development.

We agree with the 2020 DGAC that pregnant women should include seafood higher in the polyunsaturated fatty acids EPA and DHA. Strong circumstantial evidence supports it and it is consistent with the recommendation to eat a variety of seafood. We recommend that the 2020 DGA include such a recommendation.

The Evidence for Not Eating More than 12 Ounces Per Week During Pregnancy

The recommendation not to eat more than 12 ounces per week during pregnancy in the 2010 and 2015 DGAs was intended to reduce or avoid risk of harm from methylmercury in seafood. At

[2] As an additional matter, eating more than 8 ounces per week may be needed to reach the 1,750 mg. of omega-3 fatty acids EPA and DHA as recommended in the 2010 DGA for the general population **[Ref. 2, p. 86]**.

very high levels methylmercury is indisputably a neurotoxicant, so out of an abundance of caution its presence in seafood in lesser amounts has at least the potential to affect cognitive development in young children. The immediate question is whether the seafood consumption studies support a 12 ounce per week cap to protect cognitive development.

The existing 12 ounce per week cap is an artifact from a precautionary-type policy decision by FDA in 2001 unrelated to any evidence from seafood consumption studies, as recalled by two former FDA officials who signed this comment.[3] Neither the previous two DGAs nor any of the DGACs have claimed that "moderate evidence" exists for harm to cognitive development immediately above 12 ounces of seafood per week. "Moderate evidence" has only referred to benefits to cognitive development from eating seafood.

Eating More Than 12 Ounces Per Week: At least 12 of the studies involving cognitive development reported effects from consumption above 12 ounces per week.[4] Nine of these studies reported beneficial associations with amounts well above 12 ounces per week.[5] Four of them reported associations that were essentially null with amounts well beyond 12 ounces per week.[6] Harm above 12 ounces per week or at any level of consumption was expressly considered but no study found it. As stated by the 2020 DGAC scientific report, "Few detrimental associations between seafood intake during pregnancy and measures of child cognitive or language development were found" **(Part D Chapter 2 p. 33-4)**. The 2020 DGAC also pointed out that most studies that measured maternal mercury exposure "found that controlling for mercury exposure strengthened or had little impact on the association between seafood intake during pregnancy and developmental outcomes" **(Part D Chapter 2, p. 34).** We do not know how to reconcile these factually accurate statements by the 2020 DGAC with its

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[3] In 2001 FDA decided to issue seafood consumption advice that would recommend a numerical cap on consumption by pregnant women to protect against risk of harm to neurocognition from methylmercury. However, FDA lacked a body of evidence or an analytical basis that would enable it to calculate such a cap. FDA selected a cap of two servings per week so as not to recommend eating less than the two servings per week then being recommended by the American Heart Association for heart health. In its 2001 seafood consumption advice, FDA translated 2 servings per week to 12 ounces per week and has retained this amount in subsequent iterations of its advice. (Recollections of P. Spiller and P.M. Bolger, two signers to this comment who participated in FDA's decision.) The 2010 and 2015 DGAs adopted FDA's 12 ounce per week cap out of apparent deference to FDA.

[4] Some studies reported on consumption above 8 ounces per week that may have extended beyond 12 ounces per week but we do not include them here.

[5] Hibbeln et al. (2007): benefits above 12 ounces per week **[Ref. 7]**;
Gale et al. (2008): benefits associated with amounts above 12 ounces per week **[Ref. 8]**;
Oken et al. (2008): benefits associated with amounts through 30 ounces per week **[Ref. 12]**;
Julvez et al. (2016): benefits associated with amounts through 30.2 ounces per week **[Ref. 13]**;
Daniels et al. (2004): benefits associated with amounts above 18 ounces per week **[Ref. 15]**;
Oken at al. (2005); benefits associated with amounts through 22 ounces per week **[Ref. 16]**;
Oken et al. (2008a): benefits associated with amounts through 121 ounces per week **[Ref. 20]**;
Valent et al. (2013): benefits associated with amounts through 44 ounces per week **[Ref. 21].**

[6] Mendez et al. (2009): beneficial up to 12 ounces per week; null beyond 12 ounces per week **[Ref. 11]**;
Davidson et al. (2008): null through a mean of 36 ounces per week **[Ref. 22]**;
Oken et al. (2016): null through 48 ounces per week **[Ref. 23]**;
Steenweg-de Graaff et al. (2016): null through 21.2 ounces per week**[Ref. 24]**.

advice to continue the 12 ounce per week limitation on consumption. The abundance of caution approach of 20 years ago should be superseded by the evidence indicating that eating a variety of seafood, even in amounts two times or more higher than 12 ounces per week, can enhance cognitive development without causing harm. The concentrations of methylmercury in seafood have therefore been empirically established as well below hypothetical levels of concern from the turn of the millennium.

We do not agree with the 2020 DGAC that it is necessary for pregnant women to limit themselves to no more than 12 ounces per week in order to avoid harm to cognitive development. Considerable evidence now indicates that if followed, this cap blocks benefits associated with consumption above 12 ounces per week without protecting against harm. It can also frighten some pregnant women from consuming even minimal seafood. By contrast, the recommendation to consume at least 8 ounces of a variety of seafood per week is evidence-based. We therefore recommend that the 2020 DGA not carry forward the 12 ounce per week cap from the previous two DGAs.

Conversely, if the 2020 DGA were to retain the 12 ounce per week cap for safety, it should at least explain why it is doing so notwithstanding the evidence of no harm above 12 ounces per week as acknowledged by the 2020 DGAC in its scientific report.

Exposure to Mercury Above the Reference Dose: We have also considered whether the seafood consumption studies support a 12 ounce cap on consumption to keep exposures from exceeding EPA's RfD for mercury. The FDA/EPA advice groups individual fish into consumption categories for the purpose of keeping exposure below the EPA RfD **([Ref. 6]**. Recall that the 2020 DGAC scientific report references this advice.

The RfD is a level of exposure to a toxic substance that is deemed to be without appreciable risk over a lifetime of exposure **[Ref. 25]**. The RfD for methylmercury can be expressed as circa 1.1 parts per million (ppm) mercury measured in hair. At least eight of the seafood consumption studies reported exposures significantly above 1.1 ppm.[7] These ranged from 1.78 ppm in hair to 13.52 ppm in hair[8]. Six of these studies showed beneficial associations **[Refs. 9, 14, 17, 30, 31, 32]**, none were adverse, and two were null.

Benefits and no harm when exposures exceed the RfD corroborate that the RfD is what it was designed to be, i.e., a level of exposure without appreciable risk. The seafood consumption

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[7] Oken et al. (2005): 2.38 ppm **[Ref. 9]**
Oken et al. (2008): 2.3 ppm **[Ref. 14]**
Valent et al (2013): 13.52 ppm **[Ref. 17]**
Davidson et al. (2008): 8.5 ppm **[Ref. 25]**
Deroma et al. (2008): 8.03 ppm **[Ref. 29]**
Sagiv et al. (2012): 5.14 ppm **[Ref. 30]**
Xu et al. (2016): 1.78 ppm **[Ref. 31]**
Vajrup et al. (2018): 3.8 ppm **[Ref. 32]**

[8] Not all studies that measured exposure to mercury calculated exposure in terms of ppm in hair. For those that calculated exposure in terms of concentrations in blood, these were converted to ppm in hair where possible in a systematic review of the evidence relating to seafood consumption and neurocognition published in Prostaglandins, Leukotrienes and Essential Fatty Acids, 151 (2019) 14-36. We draw on those values here.

results also confirm that the RfD is not a dividing line between safe and unsafe. Beneficial associations above the RfD raise questions about whether a 12 ounce per week cap on seafood consumption for the purpose of keeping exposures below the RfD would be in the public interest.

We emphasize the importance of seafood consumption to this conclusion. There is evidence that methylmercury can have different effects on cognition depending on whether it comes from seafood eaten during pregnancy or from some other source. In the Faroe Islands, prenatal exposure to methylmercury had adverse associations with neurocognitive outcomes in children when exposure was primarily from pilot whale **[Ref. 33]**. Pilot whale contains other toxicants and is not included in the DGAC's definition of "seafood" **(Part D. Chapter 2, p. 33)**. Roughly the same or slightly higher prenatal exposures to methylmercury from seafood but not pilot whale in the Seychelles Islands had no such associations **[Ref. 34]**. In the United Kingdom, associations between prenatal exposure to methylmercury and IQ were beneficial when mothers ate seafood, but trended adverse when mothers ate no seafood even though the prenatal exposures were the same for both groups **[Ref. 35]**. These are just two examples of different outcomes when seafood is the independent variable as compared to when total mercury or methylmercury is the independent variable. The EPA RfD was derived largely from exposures to methylmercury from pilot whale independent of seafood. .

We have no opinion, however, on the public health utility of the RfD when exposures are other than from seafood, e.g., from local freshwater fish taken recreationally or for subsistence purposes. Unlike commercial seafood, these fish have not been well studied for their relationship to cognitive development. Likewise, we have no opinion on the utility of the RfD to exposures from other foods, which are now known to occur **[Refs. 36, 37]**.

We do not agree that a 12 ounce per week cap should exist in order to keep exposure to methylmercury below EPA's RfD of 1.1 ppm as measured in hair. Considerable evidence now indicates that a 1.1 ppm cap on exposure would block benefits associated with higher exposures without protecting against harm. This evidence does not negate the possibility that a scientifically based exposure limit could be determined, but considerable evidence indicates that it would be above the apparently benign exposures reported in the seafood studies, many of which were well above 1.1 ppm. We therefore recommend that the 2020 DGA not retain the 12 ounce per week cap for the purpose of establishing a 1.1 ppm exposure limit.

Selecting From Choices That Are Lower in Methylmercury: The 2020 DGAC is advising that the 2020 DGA retain this recommendation from the 2010 and 2015 DGAs. We know from our own reading that the seafood consumption studies provide no evidence that different methylmercury concentrations affect cognitive outcomes differently. The studies did not address that question. We do know that the pregnant women in these studies made choices based on their own preferences without reported harm to their children, as the 2020 DGAC acknowledged (see above). The 2020 DGAC's recommendation that pregnant women select from choices lower in methylmercury is not supported by the seafood consumption evidence if it is being made for the purpose of protecting against harm to cognitive development, as is apparently the case here.

We do agree, however, with the 2020 DGAC that "Evaluating seafood consumption is inherently a 'net effects' evaluation that implicitly reflect[s] the sum of benefits and risks from all the constituents in fish" **(Part D Chapter 2 p. 51),** like any other natural food. Two efforts to model these "net effects," one by the FDA **[Ref. 38]** and by the Food and Agriculture Organization together with the World Health Organization (FAO/WHO) **[Ref. 39]**, calculated that seafood containing less methylmercury can be more beneficial than seafood containing more methylmercury. Selecting seafood "lower in methylmercury" with that in mind should not require much thought for most consumers since nearly all the top 20 mot popular commercial species in the United States have below average concentrations of methylmercury **[Ref. 38, p. 29].** On the other hand, if most selections by most people are likely to be lower in methylmercury anyway-- especially if a variety of seafood is eaten -- this raises a question of whether recommending seafood "lower in methylmercury" is worth it. Doing so risks an adverse psychological effect that could cause women to reduce their seafood intake unnecessarily.

We disagree with the 2020 DGAC's advice that pregnant women should only eat seafood "lower in mercury" if the purpose for doing so is to protect against harm to cognitive development. There is no evidence from the seafood consumption studies that that the amounts of methylmercury in the seafood caused harm to cognitive development. On the other hand, there is evidence from modeling efforts by FDA and the FAO/WHO that seafood lower in methylmercury could provide greater benefits than seafood higher in methylmercury. We recommend that the 2020 DGA give careful thought about whether to say "lower in methylmercury" and how to say it so as not to frighten pregnant women unnecessarily.

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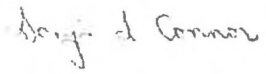

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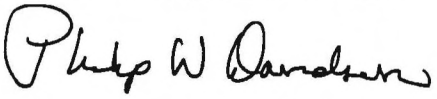

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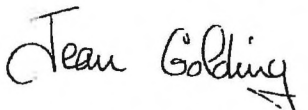

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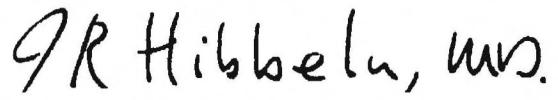

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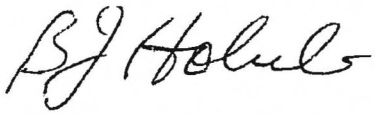

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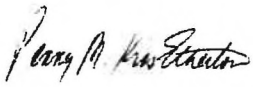

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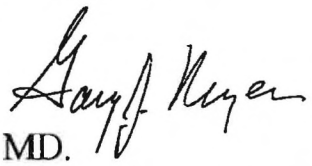

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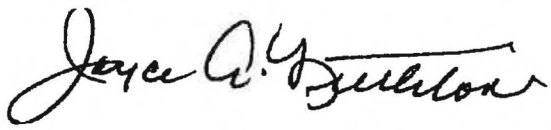

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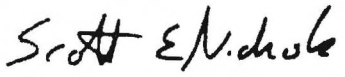

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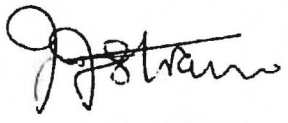

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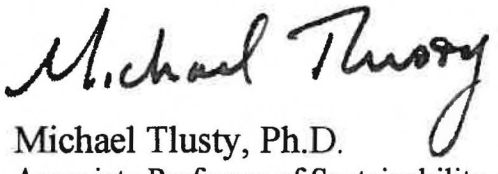

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