September 7, 2021

John P. Connelly
President
National Fisheries Institute
7918 Jones Branch Drive
Suite 700
McLean, Virginia 22102

Sent Electronically

Dear Mr. Connelly,

This letter is in response to your Information Quality Act (IQA) Request for Correction (Request) dated January 8, 2020. Your Request concerns the U.S. Food and Drug Administration's (FDA or we) advisory[1] entitled, "Advice about Eating Fish for Women Who Are or Might Become Pregnant, Breastfeeding Mothers, and Young Children,"[2] (2019 Fish Advice) which published on July 2, 2019. While acknowledging that the consumption chart of the 2019 Fish Advice is based only on the U.S. Environmental Protection Agency's (EPA) methylmercury reference dose (RfD), your Request asks that FDA change the chart to take into account nutrition science, as well. Your Request seeks (a) changing the categorization of some of the fish, resulting in a consumption chart with a different purpose – one focused on mercury content *and* potential neurocognitive or other nutritional benefits of seafood consumption for four types of fish (out of over 60 types in a table pertaining solely to mercury content), and (b) updating the advice to account for the information that would be displayed in this new chart, using an approach consistent with FDA's 2014 quantitative assessment of the net effects on fetal neurodevelopment from eating commercial fish (the 2014 Net Effects Assessment).

We respectfully decline your request to create a new consumption chart. Regarding changing the categorization of certain fish and, therefore, creating a new consumption chart, FDA and EPA

[1] While your Request refers to this document as a "guidance," FDA considers it to be health advice and will refer to it as such.
[2] U.S. Food and Drug Administration. Advice about Eating Fish for Women Who Are or Might Become Pregnant, Breastfeeding Mothers, and Young Children. July 2, 2019. Available at https://www.fda.gov/media/102331/download.

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made a health-protective policy decision to use the RfD to develop the consumption chart. Both FDA and EPA have been transparent about the data-driven, scientific approach for dividing types of seafood between categories based on their methylmercury levels. As a matter of public health policy, we believe that it is appropriate to provide consumption advice that emphasizes the health benefits of eating fish and the nutritional value of fish, while also ensuring that the target population limits exposure to methylmercury. To the extent that your IQA Request seeks to change our policies, we decline to do so. Such matters are not appropriately addressed through IQA channels, and we will not address that portion of your Request further.[3]

After careful review and consideration of the technical, scientific aspect of your Request, we respectfully decline to modify the 2019 Fish Advice using an approach consistent with the 2014 Net Effects Assessment, for the reasons described below.

I. The Request

The Request alleges that FDA failed to meet the quality requirements set forth by the IQA when we issued the 2019 Fish Advice, as it "ignore[s] the Net Effects Report's specific conclusions as to over 3/4 of the fish named in the consumption chart" (Request at p. 15). You state that "FDA…ignored the IQA, Office of Management and Budget ("OMB") IQA requirements, and [U.S. Department of Health and Human Services (HHS)] guidance regarding information quality" by relying "exclusively on the EPA environmental science – the mercury RfD – for the consumption chart and ignor[ing] its own nutrition science that balances risks with nutritional benefits – the Net Effects Report" (Request at pp. 3 and 5).

The Request contends that our reliance on EPA's RfD and the exclusion of our own research contravenes the IQA. You argue that the 2019 Fish Advice "do[es] not rest on the best available science…and ignore[s] nutrition science used by other federal agencies in developing nutrition guidance documents" (Request at p. 4). Specifically, you point to the *Dietary Guidelines for Americans* and note that HHS and the U.S. Department of Agriculture (USDA) have not relied on the RfD in developing or updating the *Dietary Guidelines for Americans* (Request at pp. 5-7). You argue "FDA…ignor[ed] the emergence of significant research documenting that pregnant and nursing women run risks of eating *too little* seafood" (Request at p. 7).

Your Request also states that we ignored the Food and Agriculture Organization of the United Nations and the World Health Organization's (FAO/WHO) joint report on the risks and benefits of seafood consumption, as well as FDA's Net Effects Assessments. You argue that "[t]here is no relevant, large-scale scientific research, concluded after the Net Effects Report was finalized in May 2014, that calls into question the principal conclusions of the Net Effects Report or the FAO/WHO study – and that therefore would necessitate FDA's abandonment of the agency's own research" (Request at p. 16).

II. FDA's Response to the Request

[3] Office of Management and Budget M-19-15, "Improving Implementation of the Information Quality Act," Implementation update 4.3. Available at https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf.

The 2019 Fish Advice encourages women who are pregnant or might become pregnant, breastfeeding mothers, and children over 2 years to consume 8 to 12 ounces (less for young children) of a variety of fish per week, from choices that are lower in mercury. It reflects the agencies' best effort to communicate to the public about how to gain the nutritional benefits of eating fish while minimizing the risk of exposure to methylmercury, which is found in all fish in at least trace amounts. Methylmercury can be harmful to the brain and nervous system if a person is exposed to too much of it over time.

The 2019 Fish Advice consists of two components. The first component encourages fish consumption by emphasizing the health benefits of eating fish and the nutritional value of fish. Specifically, it includes a statement that eating fish while pregnant or breastfeeding can provide health benefits and that fish and other protein-rich foods have nutrients that can help children's growth and development. The 2019 Fish Advice revised the 2017 advice entitled, "Advice About Eating Fish" (82 FR 6571), by adding a discussion of the nutritional value of fish, as outlined in the *2015-2020 Dietary Guidelines for Americans*, and reflecting the recommendation of the *Dietary Guidelines* that Americans eat seafood as part of a healthy eating pattern because there are benefits in doing so.[4] Based on information in the *2015-2020 Dietary Guidelines for Americans*, the revised 2019 advice states prominently at the top of the document that fish are part of a healthy eating pattern and provide protein; healthy omega-3 fats; more vitamin B12 and vitamin D than any other type of food; iron; and other minerals like selenium, zinc, and iodine.

The second component consists of a consumption chart, which presents over 60 types of fish in three different categories based on their mercury levels and is intended to help women who are or might become pregnant, breastfeeding mothers, and caregivers of children over 2 years of age make informed choices among types of fish and their mercury levels. As we describe in the questions and answers that accompany the advice,[5] the categorization of fish is based on how many servings the average pregnant woman could eat in a week using information on mercury content of each fish type from FDA's database for commercial fish and other sources. FDA and EPA decided which category each seafood species belonged to by calculating the average amount of mercury that could be in a species when a four-ounce serving is eaten one, two, or three times a week without going over the maximum acceptable mercury intake amount for an average body weight for a woman who is pregnant. The chart can help the target audience choose types of fish from the "Best Choices" category, from which we recommend eating two to three servings a week (8 to 12 ounces), or the "Good Choices" category, from which we recommend eating one serving a week (4 ounces). The chart also presents "Choices to Avoid."

Overall, the 2019 Fish Advice supports the recommendations of the *2015-2020 Dietary Guidelines for Americans*, developed for people 2 years and older, which reflects the current

[4] This revision occurred in accordance with the directive in section 773 of Public Law 116-6 that the advice be updated "in a manner that is consistent with nutrition science recognized by FDA on the net effects of seafood consumption."

[5] See Questions & Answers from the FDA/EPA Advice about Eating Fish for Women Who Are or Might Become Pregnant, Breastfeeding Mothers, and Young Children. Available at https://www.fda.gov/food/consumers/questions-answers-fdaepa-advice-about-eating-fish-women-who-are-or-might-become-pregnant.

science on nutrition to improve public health.[6,7] FDA's goal in publishing the 2019 Fish Advice was to encourage everyone to eat more seafood than currently consumed and to encourage women who are pregnant or considering becoming pregnant, women who are breastfeeding, and young children to eat more seafood from choices lower in methylmercury.

NFI recommends that FDA rely on the Net Effects Assessment

The 2014 Net Effects Assessment is based on a mathematical construct to estimate outcomes based on various scenarios that consider the risks from mercury in the diet and the potential benefits of seafood consumption. As discussed in Groth's 2017 review of evidence on the scientific foundations of fish consumption advice for pregnant women, disparate conclusions from published risk-benefit models and recent epidemiological evidence have called into question the results of the 2014 Net Effects Assessment.[8] Beginning with estimating the benefits of all fish as identical packages, the modeling of benefits in the 2014 Net Effects Assessment was based on only one study,[9] rather than using a totality of evidence approach to model benefits. Also, new data published after the 2014 Net Effects Assessment calls into question the potential benefits of omega-3 fatty acids, which was a nutrient used to estimate benefits in some of the model scenarios in that assessment. For example, HHS's Agency for Healthcare Research and Quality's 2016 systematic review concluded that, with the exception of small increases in birth weight and length of gestation, omega-3 fatty acid supplementation or fortification had no consistent evidence of beneficial effects on peripartum maternal or infant health outcomes.[10]

In light of the scientific information that became available after the 2014 Net Effects Assessment was completed, FDA declines the NFI recommendation that FDA rely on the 2014 Net Effects Assessment.

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[6] The *Dietary Guidelines for Americans* establishes Federal, evidence-based policy on diet and health. The *Dietary Guidelines* focus on dietary patterns and the effects of food and nutrient characteristics on health, and Public Law 101-445 requires that they be based on the preponderance of current scientific and medical knowledge. See U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015-2020 Dietary Guidelines for Americans*. 8th Edition. December 2015. Available at https://health.gov/our-work/food-and-nutrition/2015-2020-dietary-guidelines/.

[7] In December 2020, USDA and HHS released the *Dietary Guidelines for Americans, 2020-2025*. We are currently reviewing these guidelines to determine what updates to the 2019 Fish Advice may be needed. See 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.

[8] Groth E.3rd. Scientific foundations of fish-consumption advice for pregnant women: Epidemiological evidence, benefit-risk modeling, and an integrated approach. *Environmental Research*. 2017;152:386-406. doi:10.1016/j.envres.2016.07.022

[9] Avon Longitudinal Study of Parents and Children (ALSPAC), available at http://www.bristol.ac.uk/alspac/. Both Hibbeln et al. (2007) and Daniels et al. (2004) relied on data from the ALSPAC study. Daniels, J.L., et al. Fish Intake During Pregnancy and Early Cognitive Development of Offspring. *Epidemiology*, 2004;15:394-402; Hibbeln, J.R., et al. Maternal seafood consumption in pregnancy and neurodevelopmental outcomes in childhood (ALSPAC study): an observational cohort study. *Lancet*, 2007;369:578-85.

[10] Newberry, S.J., Chung, M., Booth, M. et al. Omega-3 Fatty Acids and Maternal and Child Health: An Updated Systematic Review. Evidence Report/Technology Assessment No. 224. (Prepared by the RAND Southern California Evidence-based Practice Center under Contract No. 290-2012-00006-I.) AHRQ Publication No. 16(17)-E003-EF. Rockville, MD: Agency for Healthcare Research and Quality. October 2016. Available at https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/omega-3-maternity_research.pdf.

NFI recommends that FDA rely on nutrition science

We disagree with your assertion that we ignored research documenting the risks of eating too little seafood. One of the primary goals of the 2019 Fish Advice, in addition to encouraging consumers to eat seafood as part of a healthy diet, has been to empower specific consumer groups – including pregnant women, women who might become pregnant, women who are breastfeeding, and caregivers feeding young children – to reassure them and build confidence surrounding seafood consumption at these important life stages. By expressing the advice in terms of recommendations for one's weekly intake of seafood based on the RfD, FDA and EPA aim to reassure consumers about seafood consumption while helping them reduce exposure to mercury, as is recommended in the Dietary Guidelines for women who are pregnant and breastfeeding. To provide the potential health benefits of consuming seafood, the consumption chart allows for 8 to 12 ounces of seafood per week from the "Best Choices" category, thereby incorporating the recommendations of the Dietary Guidelines that women who are pregnant, or breastfeeding eat 8 to 12 ounces per week of seafood lower in mercury.

Beyond the consumption chart, the 2019 Fish Advice, as a whole, highlights the recommendations of the *2015-2020 Dietary Guidelines for Americans*, the nutritional value of seafood, and the potential health benefits of eating seafood to help women who are or might become pregnant, breastfeeding mothers, and caregivers of children over 2 years of age make informed choices about seafood that is nutritious while reducing avoidable exposure to mercury. We relied on the complete available body of scientific evidence, which included the science-supported nutrition advice described in the *2015-2020 Dietary Guidelines for Americans*, to add a discussion about the nutritional value of fish consumption to the first component of the 2019 Fish Advice. Nutrition science reflected in the *2015-2020 Dietary Guidelines for Americans* is based on scientific analysis that considered evidence regarding the net effects of seafood consumption.[11] Although we did not use either the FAO/WHO or the FDA net effects models to determine the categorization of types of fish in the consumption chart component of the 2019 Fish Advice, we did consider the results of these reports in developing the overall advice.

III. Conclusion

Thank you for your interest in the quality of information disseminated by HHS. If you do not agree with FDA's decision on your Request, you may send a Request for Reconsideration within 30 days of receipt of this decision. Your Request for Reconsideration should be designated as an "Information Quality Appeal," should state the reasons why you believe the response is inadequate and should include a copy of your original Request as well as this decision. The request may be sent to the following address:

[11] See Dietary Guidelines Advisory Committee. *Scientific Report of the 2015 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture*. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC. 2015. Available at https://health.gov/sites/default/files/2019-09/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf.

Food and Drug Administration
Office of the Ombudsman
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WO Building 1, Room 4208
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We will respond to all requests for appeals within the time frame specified in the procedure you use. Where a procedure does not specify a time frame for a response to your appeal, we will respond in a timely manner, in accordance with the OMB and HHS Guidelines.

Sincerely,

Mark A. Moorman, Ph.D.
Director, Office of Food Safety
Center for Food Safety
and Applied Nutrition