



NATIONAL
FISHERIES
INSTITUTE

INFORMATION QUALITY ACT REQUEST FOR CORRECTION

January 8, 2020

Office of the Ombudsman
Food and Drug Administration
10903 New Hampshire Avenue
WO Building 32, Room 4260
Silver Spring, Maryland 20993

Submitted Via Electronic Mail & Registered United States Mail.

Re: Request for Corrections in connection with federal seafood guidance entitled, “Advice about Eating Fish for Women Who Are or Might Become Pregnant, Breastfeeding Mothers, and Young Children” (84 Federal Register 32747-32749 (July 9, 2019)).

To Whom It May Concern:

Millions of American mothers, caregivers, and their health care providers turn to the federal government for accurate, science-based information about the seemingly endless string of important decisions to be made regarding food and nutrition during pregnancy, nursing, and early childhood. Guidance documents issued by the Food and Drug Administration (“FDA”) directed specifically at pregnant and nursing women and their babies must “improve maternal and child health.”¹ This straightforward goal should guide both FDA research and the nutrition policy and guidance documents that arise out of that research.

¹ OFFICE OF ASSISTANT SEC’Y FOR PLG. & EVAL., *HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public*, U.S. DEP’T OF HEALTH & HUMAN SERV. at 7 (Oct. 1, 2002), <https://aspe.hhs.gov/report/hhs-guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information-disseminated-public> [hereinafter *HHS IQA Guidelines*]. Similarly, guidance issued by the federal government must rest on high quality information that helps to “ensure a safe and healthy America.” *Id.*

To make certain that information developed and utilized in such a fashion advances and does not frustrate this objective, the Information Quality Act (“IQA”) sets forth requirements applicable to information developed and relied upon by FDA and other Executive Branch agencies in official documents, including non-regulatory guidance documents. According to the White House Office of Management and Budget (“OMB”), “prudent decision making depends on reliable, high-quality information.”² In the case of FDA, agency documents issued in adherence to IQA standards are more likely to contribute to improved public health outcomes for the target audiences than documents issued in violation of such standards.

Regrettably, FDA, in collaboration with the Environmental Protection Agency (“EPA”) recently discarded this principle in connection with two of the nation’s most vulnerable populations – pregnant and nursing women and their growing babies. On July 9, FDA issued “Advice about Eating Fish for Women Who Are or Might Become Pregnant, Breastfeeding Mothers, and Young Children,” (collectively, the “July 9 Seafood Advice”).³ The July 9 Seafood Advice – along with its predecessor which was rushed to publication on January 19, 2017 prior to a change in Administration – ignores the “Net Effects Report,”⁴ FDA’s own comprehensive, peer-reviewed research on the neurocognitive risks and benefits of regular maternal seafood consumption, and the science underlying it. Specifically, the consumption chart contained in the January 19 document – and then reproduced unchanged in the bottom half of the July 9 Seafood Advice – instead relies *entirely* on EPA environmental data calculated using that agency’s mercury reference dose (the “mercury RfD”).

Thus the July 9 Seafood Advice erroneously classifies multiple seafood products as so hazardous to babies that pregnant and nursing women can safely eat only a small amount of those products, even though the Net Effects Report and ample additional research concludes that the neurocognitive benefits to babies of eating significantly more fish far outweigh the risks arising from methylmercury.

The document also ignores the will of Congress, which in fiscal year 2019 FDA appropriations legislation expressly directed FDA to issued revised seafood advice “in a manner that is consistent with nutrition science recognized by the Food and Drug Administration on the net effects of seafood consumption.” It is clear that Congress does not believe the July 9 Seafood

² EXEC. OFFICE OF THE PRESIDENT OFFICE OF MGMT. & BUDGET, M-19-15, Memorandum for the Heads of Executive Departments and Agencies from Acting Director Russell T. Vought, *Improving Implementation of the Information Quality Act* at 1 (Apr. 24, 2019), <https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf> [hereinafter *OMB Guidance*].

³ 84 Fed. Reg. 32,747 (July 9, 2019) [hereinafter July 9 Seafood Advice], <https://www.govinfo.gov/content/pkg/FR-2019-07-09/pdf/2019-14524.pdf>.

⁴ U.S. FOOD & DRUG ADMIN., A QUANTITATIVE ASSESSMENT OF THE NET EFFECTS ON FETAL NEURODEVELOPMENT FROM EATING COMMERCIAL FISH (AS MEASURED BY IQ AND ALSO BY EARLY AGE VERBAL DEVELOPMENT IN CHILDREN) (May 2014), <https://www.fda.gov/media/88491/download> (fully incorporated herein) [hereinafter cited as the *Net Effects Report*].

Advice fulfilled this statutory directive, because in legislation enacted in December 2019, Congress reprised the exact same mandate, directing the agency again to issue advice consistent with its own nutrition science.

To justify their departure from the detailed conclusions of the Net Effects Report and the science underlying it, FDA and EPA in late 2016 engaged in a limited peer review process conducted by an environmental consulting company, producing several months later (in January 2017) a guidance document that relies exclusively on the EPA mercury RfD. FDA's own webpage posting the final guidance includes a hyperlink to the FDA Net Effects Report and a full peer review of the Net Effects Report under a headline of "Resources & Supporting Scientific Documents."⁵ The consumption chart in the final guidance, however, is inconsistent with the Net Effects Report's conclusions. Final advice to pregnant women based on outdated EPA environmental science, instead of FDA nutrition science, plainly fails to meet the OMB Guidance requirement to "make decisions using the best data reasonably available."⁶

As discussed below, in issuing the July 9 Seafood Advice and in issuing its January 19, 2017 predecessor, FDA and EPA ignored the IQA, Office of Management and Budget ("OMB") IQA requirements, and HHS guidance regarding information quality. As a result, pregnant and nursing women and their health care providers across the United States are today drawing conclusions about maternal seafood consumption that rest on incomplete and outdated scientific foundations. This should be and can be corrected with comparative ease by adjusting the consumption chart accompanying the July 9 Seafood Advice to reflect the wide body of research that the agency relied upon in issuing draft Seafood Advice in 2014.

Applying FDA's own nutrition science to this guidance, seafood items that the July 9 Seafood Advice restricts to four ounces of weekly consumption – but that the Net Effects Report concludes can be eaten in abundance – should be shifted from the confusing "Good Choices" category to the "Best Choices" category. To meet IQA standards, widely consumed albacore and yellowfin tuna, halibut, and rockfish should be moved from "Good Choices" to "Best Choices."

NFI submits this Request for Corrections, seeking these modifications of the consumption chart in the final Seafood Advice in alignment with specific information contained in the preponderance of published science, including FDA's own Net Effects Report, but also scores of large-sample, peer-reviewed studies from independent scholars around the world. Reliance on information that meets IQA standards will improve the quality of this and other nutrition guidance disseminated to the public, thus fulfilling a core IQA objective. NFI submits this Request pursuant to the following authorities, without limitation: (i) the Information Quality Act; (ii) the HHS IQA Guidelines; (iii) OMB Guidance; and (iv) FDA good guidance policy at 21 CFR 10.115.

⁵ See *Advice about Eating Fish*, U.S. FOOD & DRUG ADMIN. (July 2, 2019), <https://www.fda.gov/food/consumers/advice-about-eating-fish>.

⁶ *OMB Guidance*, *supra* note 2, at 1.

The materials in question in this Request include:

1. The Net Effects Report final version (May 2014);
2. Proposed revision to the Seafood Advice (June 6, 2014);
3. Final revision to the Seafood Advice (Jan. 19, 2017);
4. Further revision to the Seafood Advice (July 9, 2019); and
5. EPA Inspector General Report No. 17-P-0174 (Apr. 12, 2017).⁷

Two fundamental points emerge from review of these materials. First, the two recent revisions to the Seafood Advice do not rest on the best available science, as they must to pass IQA muster, because these revisions contain a consumption chart derived solely from the EPA environmental mercury RfD and ignore nutrition science used by other federal agencies in developing nutrition guidance documents. Second, even if the mercury RfD were properly utilized as the *exclusive* source of information for the Seafood Advice – and it was not – the current mercury RfD evaluates risk only and is not an appropriate scientific basis to guide nutrition advice on seafood consumption. By EPA’s own admission, the mercury RfD is not meant to be used to fashion national seafood advice. Basing nutrition guidance solely on this flawed and outdated risk-based construct ignores the overall net benefits demonstrated to arise from seafood consumption in pregnant women, nursing mothers and young children.⁸

These two points lead inexorably to the need to correct the July 9 Seafood Advice to align it in certain respects with widely-available research that balances the benefits and risks to developing babies of maternal seafood consumption. If FDA responds to this request for correction by appropriately revising the consumption chart for albacore and yellowfin tuna, halibut, and rockfish to be consistent with the best available nutrition science, pregnant women, nursing mothers and young children will receive the best advice to make informed decisions to improve public health outcomes. If FDA does nothing, the federal agency with responsibility over seafood nutrition will continue advising pregnant women with a consumption chart based on outdated environmental science that was never intended to serve as the basis for national seafood advice. The nation will experience worse public health outcomes because pregnant women, nursing mothers, and young children will be discouraged from consuming seafood that the best available nutrition science has concluded is essential to their health and development.

⁷ OFFICE OF INSPECTOR GENERAL, 17-P-0174, EPA NEEDS TO PROVIDE LEADERSHIP AND BETTER GUIDANCE TO IMPROVE FISH ADVISORY RISK COMMUNICATIONS, U.S. ENVTL. PROT. AGENCY at 3 (Apr. 12, 2017), https://www.epa.gov/sites/production/files/2017-04/documents/epa_oig_20170412-17-p-0174.pdf [hereinafter EPA OIG REPORT]. The latter four documents are attached as Attachments A-D.

⁸ U.S. ENVTL. PROT. AGENCY, MATERIALS SUBMITTED TO THE NATIONAL RESEARCH COUNCIL PART I: STATUS OF IMPLEMENTATION OF RECOMMENDATIONS at 2 (Jan. 30, 2013), https://www.epa.gov/sites/production/files/201406/documents/iris_program_materials_to_nrc_part_1.pdf.

**A. FDA Reliance On The EPA Mercury RfD,
To The Exclusion Of FDA’s Own Research, Contravenes The IQA.**

**1. The EPA Mercury RfD Cannot Possibly Be Reckoned As
The “Best Available Science” For Nutrition Policy Guidance.**

The touchstone of any IQA analysis is whether the agency used the “best available science” in formulating the guidance document at issue. In this case, FDA relied exclusively on the EPA environmental science – the mercury RfD – for the consumption chart and ignored its own nutrition science that balances risks with nutritional benefits – the Net Effects Report. This failure has generated two documents that did not and do not rest on the best available science, in plain violation of the IQA.

To begin, the mercury RfD is simply not, and was not designed to be, a tool for developing nutrition guidance documents for public utilization. Like other EPA reference doses, the mercury RfD measures toxicity from a given substance. The mercury RfD takes no account of the nutritional benefits of fish or any other food to any population. Fish contain a complex bundle of beneficial nutrients, including some, such as selenium, that have direct synergistic effects with mercury. Advice about eating any one part of seafood – beneficial or not – in isolation is incomplete and inaccurate. Though the mercury RfD may be appropriate for local fish advisories issued by EPA, EPA’s own Office of Inspector General concluded that the agency “does not have regulatory responsibility for nationally issued fish advisories. This responsibility falls under the purview of the U.S. Food and Drug Administration (FDA),” as discussed below.⁹

It is therefore not surprising that the Departments of Health and Human Services and Agriculture have *never* relied on the mercury RfD in developing the principal nutrition guidance document of the federal government, the Dietary Guidelines for Americans (the “Dietary Guidelines” or “DGAs”). According to the Administration, the Dietary Guidelines “are the cornerstone of Federal nutrition policy and nutrition education activities, providing food-based recommendations to promote health, help prevent diet-related disease, and meet nutrient needs.”¹⁰ Further, the DGAs

serve as a central source of guidance that nutrition programs within the government can use to inform their food and nutrition programs and initiatives while tailoring their efforts for their specific audiences, like women and children. The Dietary Guidelines also support the development of science-based nutrition education messages and consumer materials for the general public, as well as for special

⁹ EPA OIG REPORT, *supra* note 7, at 8.

¹⁰ *Most Popular Questions*, DIETARY GUIDELINES FOR AMERICANS, <https://www.dietaryguidelines.gov/most-popular-questions> (last visited Jan. 7, 2020).

audiences. Additionally, outside organizations and companies use the Dietary Guidelines in the private sector.¹¹

Federal law requires HHS and USDA to issue updated DGAs every five years, “based on the preponderance of the scientific and medical knowledge which is current at the time the report is prepared.”¹² The DGAs and the MyPlate icon – not unlike the EPA-FDA Seafood Advice – are intended to supply guidance on eating fish as a whole food, and therefore must be based on science that looks at the effects of eating fish as a whole food.

To NFI’s knowledge, *the Dietary Guidelines have never utilized the EPA mercury RfD in developing food-based recommendations.* The Dietary Guidelines Advisory Committee (the “DGAC” or the “Committee”) in 2010 began exploring the effects of eating seafood during pregnancy. In the intervening decade, the DGAC has never included the EPA mercury RfD in its systemic review of applicable science, despite the lengthy process for developing the DGAs and the voluminous record of materials developed for each iteration of the Dietary Guidelines that result. The Committee’s disinterest in the mercury RfD in formulating the DGAs is, again, not surprising since it is not nutrition science.

This is consistent with the DGAC’s longstanding insistence on considering only directly applicable nutrition science. For instance, the DGAC has consistently excluded omega-3 supplement studies that do not evaluate consumption of actual fish. Indeed, the DGAC itself has urged *FDA* to change the Seafood Advice to reflect the best available nutrition science, not vice versa. In the Scientific Report of the 2015 Dietary Guidelines for Americans, the Committee concluded the following:

Based on the most current evidence on mercury levels in albacore tuna provided in the Report of the Joint United Nations Food and Agriculture Organization/World Health Organization Expert Consultation on the Risks and Benefits of Fish Consumption, 2010, the DGAC recommends that the Environmental Protection Agency and FDA re-evaluate their current recommendations for women who are pregnant (or for women who may become pregnant) or breastfeeding to limit white albacore tuna to not more than 6 ounces a week.¹³

¹¹ *Id.*

¹² 7 U.S.C. § 5341(a)(1-2) (2018).

¹³ U.S. DEP’T OF AGRIC., SCIENTIFIC REPORT OF THE 2015 DIETARY GUIDELINES ADVISORY COMMITTEE at 296 (Feb. 2015), <https://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf>. Not only does the July 9 Seafood Advice fail to implement this recommendation, it further restricts the albacore tuna recommendation to four ounces per week.

Recent DGAC focus on the central issue the Seafood Advice purports to address – namely, the comparative benefits and risks associated with regular maternal seafood consumption – means that the Dietary Guidelines contributors have had every opportunity to apply the EPA mercury RfD to their work. Yet there is no evidence of that happening. If the EPA mercury RfD has had any impact on any iteration of the Dietary Guidelines, there is no trace of it on the public record.

2. In Relying Exclusively On The Mercury RfD, EPA And FDA Ignored Substantial Recent Science That Takes Account Of Both Risks And Benefits Of Seafood Consumption.

In preparing the two recent revisions to the Seafood Advice, FDA nevertheless relied heavily upon the mercury RfD, while ignoring the emergence of significant research documenting that pregnant and nursing women run risks in eating *too little* seafood. Understanding this point requires brief review of the history of the FDA-EPA seafood advice and the science underlying its various revisions.

In 2006, the Institute of Medicine concluded in a report on the benefits and risks of seafood that a “better way is needed to characterize the risks combined with the benefits analysis” of seafood consumption.¹⁴ Also in 2006, FDA began work on an exhaustive review and analysis of the seafood science. FDA researchers reviewed the benefits and risks of seafood consumption in one quantitative equation, which introduced the concept of a net effects approach. FDA explained that “the methodology used for this quantitative assessment is novel for FDA in that, rather than attempting to quantify the risk resulting from the presence of a particular hazard in a food, it seeks to balance that risk and the benefit from consumption of the food in the same quantitative analysis.”¹⁵

Then, in 2010, the United Nations Food & Agriculture Organization and World Health Organization jointly issued a report on the risks and benefits of seafood consumption. After exhaustive review of the science, a panel of 17 doctors, toxicologists, and nutritionists concluded

¹⁴ Malden C. Nesheim & Ann L. Yaktine (eds.), *Seafood Choices: Balancing Benefits and Risks*, INST. OF MED. OF NAT'L ACADEMIES (Oct. 13, 2006). The Institute of Medicine is now known as the National Academy of Medicine. The Academy’s “foundational goal is to be the most reliable source for credible scientific and policy advice on matters concerning human health.” *See About the National Academy of Medicine*, <https://nam.edu/about-the-nam/> (last visited Dec. 5, 2019).

¹⁵ U.S. FOOD & DRUG ADMIN., *Report of Quantitative Risk and Benefit Assessment of Commercial Fish Consumption, Focusing on Fetal Neurodevelopmental Effects (Measured by Verbal Development in Children) and on Coronary Heart Disease and Stroke in the General Population, and Summary of Published Research on the Beneficial Effects of Fish Consumption and Omega-3 Fatty Acids for Certain Neurodevelopmental and Cardiovascular Endpoints*, 74 Fed. Reg. 3615, 3616 (Jan. 21, 2009).

that governments should emphasize not only the benefits of eating fish for heart health in adults and brain development in babies, but also the risks of avoiding fish for these groups.¹⁶

Senior FDA researchers finalized the Net Effects Report in 2014. The Report reviewed 120 studies, most of them large-sample, mother-child studies measuring outcomes attributable to maternal seafood consumption over the course of several decades of childhood development. From this science, the Net Effects authors generated a risk-benefit crossover point for each of 47 selected finfish and shellfish species. The risk-benefit crossover point identified the weekly limit of consumption of a given fish at which the neurodevelopmental benefits to the baby – especially via the brain-building benefits of omega-3 fatty acids and in particular the omega-3 fatty acid DHA – are exceeded by risks attributable to methylmercury.¹⁷ At or below this crossover point, FDA researchers concluded, eating a given seafood item would have net beneficial effects on a child’s developing brain, as measured through the age of nine. To guard against any possibility of neonatal or maternal harm, the Net Effects authors calculated a second series of crossover points, assuming that “each fish contained 20 percent more methylmercury on average than the concentrations recorded in the FDA database.”¹⁸ The Report then estimated the maximum benefits to children of regular maternal consumption of that seafood item – typically 8-9 ounces – in the form of IQ points.¹⁹

The Report was peer-reviewed, offered for public comment, peer-reviewed again, modified, shared with OMB and subjected to interagency review, and then finalized in May 2014.²⁰

¹⁶ FOOD & AGRIC. ORG. OF THE UNITED NATIONS & WORLD HEALTH ORG., FIPM/R978, REPORT OF THE JOINT FAO/WHO EXPERT CONSULTATION ON THE RISKS AND BENEFITS OF FISH CONSUMPTION (2011), <http://www.fao.org/docrep/014/ba0136e/ba0136e00.pdf>.

¹⁷ The Net Effects Report measured only neurological benefits, excluding well-established cardiovascular, obesity-related, and ocular benefits. In this respect, the Report’s comparative analysis tilts more *towards* risks than would have been the case had it factored in these other, widely acknowledged nutritional benefits from seafood consumption. Even so, the fact that the Report balances risks versus benefits is what distinguishes the Report and scholarship it summarizes from the risk-only EPA mercury RfD. *Net Effects Report*, *supra* note 4.

¹⁸ *Id.* at 111, Table V-10.

¹⁹ There is no evidence that FDA sampling of mercury levels in commercial seafood is or has been under-calculated or understated, nor do the Net Effects Report’s authors claim as much. Their caution in that respect was, according to the Report itself, intended to provide policymakers with an extra safety buffer for decisions affecting these vulnerable populations. Indeed, the Report assumes that “the methylmercury concentrations recorded in the FDA fish database (FDA 2010) (e.g., the mean concentration for each species and the high-low range of concentrations for each species) are an accurate reflection of fish in commerce.” *Id.* at 109.

²⁰ *Id.* at 23.

FDA researchers concluded overall that:

- “In studies published since 2004, beneficial net effects on neurodevelopment appear to have been the most likely consequence of fish consumption in the populations studied, including populations in the United States.”
- “The past decade has witnessed the accumulation of substantial evidence that fish consumption can benefit fetal neurodevelopment... Fish provide a source of easily digestible protein, high levels of the amino acids taurine, arginine and glutamine, micronutrients including vitamins A and D, and minerals such as iodine and selenium. Many fish also provide a uniquely rich source of omega-3 fatty acids, most notably docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA). DHA has been shown to be essential for development of the central nervous system. Also, a number of research studies have reported associations between omega-3 fatty acids and reduced risk of cardiovascular events such as heart attack and stroke.”
- “Substantial evidence has emerged within the past decade that fish consumption during pregnancy can benefit the developing nervous system even though fish contain methylmercury.”
- On a population basis, average neurodevelopment in the U.S. is estimated to benefit by nearly 0.7 of an IQ point from maternal consumption of commercial fish. If all pregnant women ate 12 ounces of a variety of fish per week, children would receive a brain boost of 2.63 IQ points.
- Because net benefits to growing babies “do not begin until some minimal amount of fish is consumed, *e.g.*, over three ounces per week,” extremely low maternal seafood consumption – which FDA sampling demonstrates is the case for most American women – has little benefit.²¹

FDA in June 2014 issued a proposed revision of the preceding, 2004 guidance document on the subject. The June 2014 proposed revision incorporated the benefits of seafood consumption. In unveiling this new proposed Seafood Advice, the then-Chief Medical Officer of FDA, Dr. Stephen Ostroff, stated: “For years many women have limited or avoided eating fish during pregnancy or feeding fish to their young children. But emerging science now tells us that limiting or avoiding fish during pregnancy and early childhood can mean missing out on important

²¹ *Id.* at 9, 10, 117, 156 (internal citations omitted).

nutrients that can have a positive impact on growth and development as well as on general health.”²²

Subsequently, in litigation concerning a citizen petition submitted to FDA, the agency in a sworn Declaration before the United States District Court asserted that the Net Effects Report formed an important part of the scientific basis for issuing the June 2014 proposed revision. Relying on this statement, the Court found that:

At the time Plaintiffs petitioned FDA, it was in the process of evaluating its approach to mercury in seafood. According to the Administration, since publishing the 2004 Advisory, substantial evidence has emerged that fish consumption by pregnant women and young children can improve neurodevelopment even though fish contain mercury. See Def. Mot. & Opp., Declaration of Michael Landa, ¶ 12.

To address this issue, starting in approximately 2006, FDA began developing a methodology for assessing the net effects of fish consumption on neurodevelopment, and in January 2009, after obtaining peer review, issued the draft recommendations for public comment. *Id.*, ¶¶ 13, 18, 19.

The Draft Advisory represents FDA’s proposed position on how to maximize the benefits of seafood consumption for the Target Group and was influenced by the Final Assessment [the Net Effects Report]. See *id.*, ¶ 25.

That project [the Net Effects Report] has now drawn to a close, and, as a result, FDA and EPA are currently drafting new recommendations to replace those currently posted online.²³

The 2014 proposed Seafood Advice captured the emerging science to which Dr. Ostroff referred and was clearly based, in substantial part, on the Net Effects Report. The 2014 proposed revision, however, was never finalized. Instead, FDA and EPA on January 19, 2017 issued a final version of the Seafood Advice that ignores the Net Effects Report. The January 19 version instead was based on the EPA mercury RfD. Using values calculated from an algorithm that incorporates the mercury RfD, the document for the first time divided fish into different categories – Best,

²² Julia Q. Ortiz, News Release, *FDA and EPA issue updated draft advice for fish consumption / Advice encourages pregnant women and breastfeeding mothers to eat more fish that are lower in mercury*, U.S. ENVTL. PROT. AGENCY (June 9, 2014).

https://archive.epa.gov/epapages/newsroom_archive/newsreleases/b8edc480d8cfe29b85257cf20065f826.html (quoting Dr. Stephen Ostroff). Dr. Ostroff subsequently served as Deputy Commissioner and Acting Commissioner in this Administration.

²³ *Ctr. for Sci. in the Pub. Interest v. U.S. Food & Drug Admin.*, Civ. No. 14-375 (JEB), 2014 WL 6612146 at 1, 4-5 (D.D.C. Nov. 21, 2014).

Good, and Fish to Avoid. The document categorized fish entirely on their mercury levels, without reference to nutritional benefits from omega-3 acids or other nutrients.

EPA and FDA purported to base their January 19, 2017 Seafood Advice on a limited peer review process conducted by an environmental consulting company in October 2016. The FDA webpage posting the final guidance includes a hyperlink to the FDA Net Effects Report and a full peer review of the Net Effects Report under a headline of “Resources & Supporting Scientific Documents.”²⁴ In contrast to the June 2014 proposal, the January 19 document was never subjected to interagency review or public comment, was never (to NFI’s knowledge) shared with OMB by either of the two responsible agencies, and (again, to NFI’s knowledge) was issued in violation of 7 U.S.C. 5431(b). There was no legitimate reason to issue the January 19, 2017 Seafood when and how it was issued.

The July 9 Seafood Advice reprints without change the seafood consumption chart based exclusively on the EPA mercury RfD. However, the July 9 Seafood Advice adds a new section that cites the Dietary Guidelines for Americans and emphasizes the varied nutritional benefits seafood supplies, especially to pregnant and nursing women. As a result, the one document incorporates two opposing scientific approaches – the new top section that speaks to the effects of eating fish as a whole food and the old consumption chart that considers only the effects of mercury and restricts weekly consumption of multiple species to four ounces. Indeed, the July 9 Seafood Advice advises women to use the chart it contains to “choose which fish to eat, and how often to eat them, *based on their mercury levels.*”

Ignoring as it does the research described above, the July 9 Seafood Advice cannot possibly be characterized as resting on the best available science. For this reason, it violates the IQA.²⁵

²⁴ *Advice about Eating Fish*, *supra* note 5.

²⁵ Nor does the July 9 Seafood Advice meet the will of Congress. In February 2019, in fiscal year 2019 spending legislation, Congress directed FDA to revise the January 19 Seafood Advice “in a manner that is consistent with nutrition science recognized by the Food and Drug Administration on the net effects of seafood consumption.” Consolidated Appropriations Act, 2019, Pub. L. No. 116-6, § 773 (Feb. 15, 2019), <https://www.congress.gov/116/plaws/publ6/PLAW-116publ6.pdf>. Congress does not view the July 9 Seafood Advice as having met the intent of Section 773, because in its fiscal year 2020 spending legislation Congress repeated the exact same mandate. See Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94 § 751 (2019) (again directing FDA to revise the underlying guidance “in a manner that is consistent with nutrition science recognized by the Food and Drug Administration on the net effects of seafood consumption.”), <https://www.congress.gov/116/bills/hr1865/BILLS-116hr1865enr.pdf>.

B. The Mercury RfD In Its Present Form Is Badly Outmoded, And EPA Admits That The Process For Revision Of Such Standards Is Itself In Need Of Reform.

Even if the mercury RfD as a conceptual matter could properly be applied to nutrition guidance about commercial seafood – and for the reasons discussed above, it cannot – the current EPA mercury RfD is based on a badly flawed risk assessment tool for at least three reasons. First, the data EPA used to develop the current mercury RfD is outdated, and the mercury RfD has been on EPA’s high priority list for updating since 2012. Second, significant deficiencies in the Integrated Risk Information System (“IRIS”) process used to develop the mercury RfD have been identified since 2001 but remain unaddressed as applied to mercury. Third, IRIS human health assessments are not comprehensive risk assessments and, according to EPA, are not meant to be considered in a vacuum that disregards appropriate cost/benefit analysis.

First, the current mercury RfD was developed nearly two decades ago. In 2012, EPA listed an update to the methylmercury RfD on its list of agency priorities for IRIS assessments.²⁶ EPA failed to move forward on updating the mercury RfD but again listed it as a high priority in 2015.²⁷ After EPA again failed to update the mercury RfD, the EPA Office of Inspector General (“OIG”) published a report in 2017 critical of the current mercury RfD. That report stated that “since the EPA established the current mercury RfD 15 years ago, several new scientific studies relating to the impacts of methylmercury on human health have emerged and added new information to the scientific literature.”²⁸ The OIG report stated:

The EPA’s 2001 oral reference dose (RfD) for methylmercury has not been assessed as proposed in its published agendas. Based on its Integrated Risk Information System, the EPA included methylmercury on its 2012 agenda for assessment, and on its 2015 agenda as a priority for assessment. However, to date, the agency has not started the assessment. The mercury RfD must be accurate and based on the best available science to support development of protective fish advisories. Without effectively developed and communicated fish advisories, consumers may be exposed to unsafe levels of methylmercury through the consumption of fish.

In its recommendations to EPA, the OIG stated that EPA’s Assistant Administrator for Research and Development should “[c]onduct an assessment for methylmercury to determine

²⁶ U.S. ENVTL. PROT. AGENCY, *Integrated Risk Information System (IRIS); Announcement of 2012 Program*, 77 Fed. Reg. 88, 26,751 (May 7, 2012).

²⁷ U.S. ENVTL. PROT. AGENCY, IRIS MULTI-YEAR AGENDA (Dec. 2015), https://www.epa.gov/sites/production/files/2018-12/documents/iris_multiyear_agenda_12-2015.pdf.

²⁸ EPA OIG REPORT, *supra* note 7, at 8.

whether the reference dose requires updating, as indicated by the Integrated Risk Information System, and as proposed in the system's 2012 and 2015 IRIS agendas."²⁹

Second, beyond simply being outdated with respect to mercury, the scientific process used to develop the 2001 methylmercury RfD has been identified as deficient by the National Academies of Science and Congress. EPA published its current methylmercury RfD utilizing, at the time, EPA's recommended method for developing the reference dose. In 2011, however, at the behest of Congress, the National Academies of Science's National Research Council ("NRC") published a seminal report addressing an RfD developed for formaldehyde.³⁰ This report identified a slew of insufficiencies in the general IRIS draft assessment development process and made several dozen specific recommendations to EPA to amend the IRIS process as a whole. The recommended changes affect a number of steps in IRIS review, including selection of studies for derivation of toxicity values, calculation of toxicity values, evidence evaluation, and weight-of-evidence evaluation. EPA agreed with the NRC's recommendations and committed to implement the NRC recommendations on a rolling basis.

Despite EPA's professed desire to move forward with implementing the NRC's recommendations, EPA has not revised the mercury RfD. Congress has expressed concerns about the existing mercury RfD, directing EPA to update its IRIS assessments after the NRC report. Language accompanying the FY 2012 EPA appropriations legislation implied that assessments made without taking EPA's recommendations into consideration were not "based firmly on the principles of modern scientific methods" and expressly barred the EPA from taking any administrative action based on any draft or final assessment in which the NRC recommendations were not documented:

In order to ensure that any action taken by EPA as a result of ongoing and new assessments is based firmly on the principles of modern scientific methods and commonly accepted practices, no funds shall be used to take any administrative action based on any draft or final assessment that does not incorporate the recommendations in Chapter 7 of the National Research Council's Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde as part of the assessment process.

²⁹ *Id.* at 17.

³⁰ NATL. RESEARCH COUNCIL, *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde*, NAT'L ACADEMIES OF SCI. ENG. & MED. (2011).

Additionally, no funds shall be used to take any administrative action based on any draft or final assessment which has not fully documented the implementation of the National Academy of Science's (NAS) recommendations.³¹

Language encouraging the Agency to fully implement the NAS's recommendations in updated RfDs have appeared in reports accompanying the annual appropriations bills to this day. EPA in April 2019 began its initial scoping of the methylmercury RfD update – step one in the IRIS process – but the process typically takes years to complete from start to finish.

Third, IRIS human health assessments are not comprehensive risk assessments, and EPA itself uses and advises using additional data, including cost/benefit information, to make judgments on public health risks. In its response to the NRC report referenced above, EPA stated the following:

IRIS human health assessments contain information that can be used to support the first two steps (hazard identification and dose-response analysis) of the risk assessment paradigm.... This information is used by EPA, together with other considerations (e.g. statutory and legal requirements, cost/benefit information, technological feasibility, and economic factors), to characterize the public health risks of environmental chemicals and make risk management decisions, including regulations, to protect public health.³²

Thus, *by EPA's own admission*, the current EPA mercury RfD should be revised as soon as possible, and the process by which it must be revised is itself deficient and in pressing need of reform. Moreover, EPA policy explicitly counsels against relying solely on a human health assessment such as the mercury RfD to characterize public health risks, without considering a series of additional factors. Yet EPA and its co-author, FDA, insist that the July 9 Seafood Advice can rest solely on the reference dose in its current form and without consideration of any nutrition science.

³¹ H. Rept. 112-151, United States Department of the Interior, Environment, and Related Agencies Appropriation Bill, 2012, *Report together with Dissenting Views [to accompany H.R. 2584]*, 112th Cong. (July 19, 2011).

³² U.S. ENVTL. PROT. AGENCY, MATERIALS SUBMITTED TO THE NATIONAL RESEARCH COUNCIL PART I: STATUS OF IMPLEMENTATION OF RECOMMENDATIONS, *supra* note 8, at 2.

**C. The Information At Issue In This Request
Does Not Meet Applicable OMB, HHS, And
FDA Guidelines For Multiple Reasons.**

This state of affairs disserves nursing mothers and their children and plainly violates IQA requirements. There is no question that the IQA applies here. FDA states that the IQA and the HHS Guidelines govern seafood nutrition guidance for pregnant and nursing women.³³ The IQA commits the federal government to “ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies.” The law directs federal agencies to issue guidelines in support of this goal and to establish mechanisms “allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency” that violates that guidance.³⁴

As demonstrated above, the information relied on in generating both the January 19, 2017 and July 9 Seafood Advice does not meet OMB or HHS requirements for information quality. “Quality” encompasses utility, objectivity, and integrity,³⁵ and the current Seafood Advice meets neither the utility nor the objectivity mandates. In developing agency risk assessments, FDA must use “the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer reviewed science and supporting studies when available.” Further, “in the dissemination of public information about risks, the Agency will ensure that the presentation of information about risk effects is comprehensive, informative, and understandable.”³⁶

EPA and FDA cannot maintain that the agency relied on the “best available science and supporting studies” when it used the EPA environmental science in the form of the mercury RfD to develop either the January 19, 2017 or the July 9, 2019 consumption charts. Those determinations rest solely on the formula contained in the January 19, 2017 Seafood Advice, which incorporates the mercury RfD. At the same time, these two documents ignore the Net Effects Report’s specific conclusions as to over 3/4 of the fish named in the consumption chart. The Net Effects Report concludes that pregnant and nursing women benefit from consuming virtually all commercially-available seafood each week, but the Seafood Advice limits these women to one four-ounce weekly serving *from all fish in that category cumulatively*. Here are three specific examples, among many others:³⁷

³³ *HHS IQA Guidelines*, *supra* note 1, at 17 (listing the original 2001 FDA-EPA seafood advice for pregnant and nursing women as an illustration of agency information disseminated to the public).

³⁴ Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, §§ 515(a) & 515(b)(2)(A), (B) (2000).

³⁵ *HHS IQA Guidelines*, *supra* note 1, at 4.

³⁶ *Id.* at 33.

³⁷ For the values of all 47 species studied, *see Net Effects Report*, *supra* note 4, at 104, Table V-7 & at 111, Table V-10.

	Crossover Risk-Benefit Weekly Consumption	Crossover Risk-Benefit Weekly Consumption Using 20 Percent MeHg Concentration <i>above</i> FDA Sampling Results	<i>Cumulative</i> Amount Pregnant And Nursing Women May Consume Safely, According to July 2, 2019 Seafood Advice	Size of Maximum Benefit Expressed As a Number of IQ Points, When Mothers Eat 8-9 Ounces Weekly
Tuna, Albacore Canned	67 ounces	56 ounces	4 ounces	2.8
Halibut	95 ounces	88 ounces	4 ounces	2.9-3.0
Perch (ocean), Rockfish, Mullet	157 ounces	131 ounces	4 ounces	3.0-3.1

There 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.

To the contrary, recent research suggests that the Net Effects Report may have *understated* the neurocognitive benefits seafood provides for developing babies. Applying the nutrition evidence systematic review already utilized by the DGAC, a group of widely recognized nutrition science experts examined dozens of post-2000 studies assessing various health outcomes of maternal seafood consumption on children. The authors measured benefits to neurocognition from omega-3 fats and other nutrients critical to optimal neurological development, but they also integrated “any adverse effects from neurotoxins” in their analysis. The authors conclude that: (i) “no adverse effects of seafood consumption on neurocognition were found in 44 publications reporting on 102,944 mother-offspring pairs and 25,031 children”; and (ii) benefits to child neurocognitive development “began at the lowest amounts of seafood consumed in pregnancy (~4 oz/wk) and up to >100 oz/wk, with benefits to age appropriate measures of neurocognitive development including *an average increase of 7.7 IQ points.*”³⁸

³⁸ Joseph R. Hibbeln et al., *Relationships between Seafood Consumption During Pregnancy and Childhood and Neurocognitive Development: Two Systematic Reviews*, 151 PROSTAGLANDINS, LEUKOTRIENES & ESSENTIAL FATTY ACIDS (PLEFA) 14 (Oct. 2019) (emphasis added).

According to OMB, “Congress has long recognized that federal agencies should make decisions using the best data reasonably available.”³⁹ Recognizing that the FDA Net Effects report reflects the best available data, Congress specifically directed FDA in its FY 2019 appropriations bill to utilize its own nutrition science considering the net effects of seafood consumption in finalizing the Seafood Advice by July 1, 2019.⁴⁰ Though the agency adhered to part of its statutory obligation in finalizing the 2019 Seafood Advice, FDA deliberately ignored the law’s direction to finalize the advice consistent with the scientific basis in the Net Effects Report.

Indeed, in this case, not only was the Net Effects Report developed by FDA and easily accessible to FDA policymakers, but according to FDA itself, as demonstrated above, the Report was undertaken, reviewed, and finalized for the purpose of informing a badly needed revision to the 2004 Seafood Advice. Moreover, recent research has validated the core findings of the agency’s research. No such claims can be made with respect to the mercury RfD. In the context of agency risk communication concerning food for human consumption, then, which is closer to being the “best available, peer-reviewed science [supported by] studies conducted in accordance with sound and objective scientific practices”: the Net Effects Report and the scholarly research that supports and validates its conclusions, or the EPA mercury RfD? The answer is clear.

D. Specific Recommendations For Correcting The Information.

As flawed as the consumption chart is accompanying the July 9 Seafood Advice is, addressing its IQA-related flaws to ensure the most accurate advice reaches pregnant and nursing women can be achieved rather easily. To align with the evidence, seafood items that the consumption chart accompanying the July 9 Seafood Advice restricts to four ounces of weekly consumption – but that the Net Effects Report concludes can be eaten in abundance – should be shifted from the confusing “Good Choices” category to the “Best Choices” category. This would mean moving widely consumed albacore and yellowfin tuna, halibut, and rockfish from “Good Choices” to “Best Choices.”⁴¹ It would not involve making any changes to the “Choices to Avoid” category of fish, nor would it entail any changes to the top half of the document.

³⁹ *OMB Guidance*, *supra* note 2, at 1.

⁴⁰ Pub. L. No. 116-6, § 773 (2019).

⁴¹ Ocean perch, which is grouped with rockfish in consumption data, is already in the “Best Choices” category.

These fish are among the most widely consumed species in the “Good Choices” category, as demonstrated by recent per capita consumption numbers:

▪ Albacore tuna	.25 lbs per capita
▪ Yellowfin tuna ⁴²	.12 lbs per capita
▪ Ocean perch/rockfish	.14 lbs per capita
▪ Halibut	.05 lbs per capita

Making these simple changes, at a minimum, would be amply justified by the unrebutted, directly applicable science FDA developed for the purpose of informing revised seafood guidance for pregnant and nursing women in the first place. It would empower women to maximize the neurodevelopmental benefits to growing babies of regular seafood consumption, thus ensuring that these babies do not miss out on the IQ points widely acknowledged science argues are available in all these fish. And it would make it easier for the federal government to deliver a clear, effective message to pregnant and nursing women about the overall benefits and risks of regular maternal seafood consumption – something FDA claims to welcome.

**E. NFI And Its Member Companies Are Directly Affected
By The Information Errors The July 9 Seafood Advice Contains,
But, Even More Importantly, Pregnant And Nursing Women And Their
Children Stand To Lose Out If The Agencies Do Not Correct This Advice.**

In disseminating IQA-covered information, agencies must consider the uses of the information “not only from the perspective of the agency but also from the perspective of the public.”⁴³ NFI’s mission is to ensure the media, consumers and regulators have the facts about seafood and support sound public policy and nutrition information based on science. In support of that mission, NFI is routinely compelled to address incorrect and non-scientific claims about the need to deprive pregnant mothers and children from the nutritional benefits of seafood. These reports nearly always cite to the January 19, 2017 or the July 9 revisions to the FDA-EPA Seafood

⁴² Although the Net Effects Report did not assess yellowfin tuna, well over a decade of FDA sampling demonstrates that yellowfin tuna has mercury levels below those of albacore tuna. See *Mercury Levels in Commercial Fish and Shellfish (1990-2012)*, U.S. FOOD & DRUG ADMIN. (Oct. 25, 2017), <https://www.fda.gov/food/metals/mercury-levels-commercial-fish-and-shellfish-1990-2012>. FDA’s sampling has shown the mean mercury concentration for yellowfin tuna is 0.354 ppm, lower than the 0.358 for albacore. The median mercury concentration for yellowfin tuna is 0.311 ppm, lower than the 0.360 for albacore. Thus, the same logic that applies to shifting the albacore tuna classification applies to shifting the yellowfin tuna classification as well.

⁴³ *HHS IQA Guidelines*, *supra* note 1, at 4.

Advice.⁴⁴ Such reports make it more difficult for consumers – including men and grown children who often take their cues from mothers about healthy eating – to make informed dietary choices about an entire category of nutrient-rich proteins whose health benefits extend from infant development throughout life. This for a food that the federal government in other publications urges Americans – including American mothers – to eat in larger amounts than they currently do.

Ultimately, of course, it is pregnant and nursing women and their growing babies who matter most in this calculus. Government information disseminated to them about critically important choices must be accurate, science-based, and updated. That cannot be said of the July 9 Seafood Advice or its January 19, 2017 predecessor. Thus, it is incumbent on FDA to correct that document, both to meet the agency’s IQA obligations and to ensure, finally, that this vulnerable group of Americans and their healthcare providers receive the best nutrition guidance.

Conclusion

For the foregoing reasons, NFI respectfully requests review of this Request for Corrections in accordance with applicable OMB, HHS, and FDA requirements and the corrections described above.

Respectfully submitted,



John P. Connelly
President

⁴⁴ Recent instances of high-profile media outlets and health care providers erroneously counselling pregnant and nursing women to restrict their seafood intake include: Rhys McKay, *How Many Calories in a Can of Tuna?*, BETTER HOMES & GARDENS (Oct. 2, 2019), <https://www.bhg.com.au/how-many-calories-in-a-can-of-tuna> (citing the July 9 Seafood Advice and then concluding that “if you’re pregnant or breastfeeding, it’s recommended that you avoid canned tuna.”); and *Eating Smart When You’re Pregnant*, ST. ELIZABETH HEALTHCARE HEALTHY HEADLINES BLOG (July 23, 2019) <https://www.stelizabeth.com/healthyheadlines/eating-smart-when-youre-pregnant/> (inaccurately stating that fish “with high mercury like tuna, swordfish, shark and tilefish should be avoided during pregnancy.”). HHS itself issued a summary of the January 19, 2017 Seafood Advice interpreting that document to encourage seafood consumption “starting at age 2.” OFFICE OF DISEASE PREVENTION & HEALTH PROMOTION, *Five Strategies for Encouraging Seafood Consumption: What Health Professionals Need to Know*, HEALTH.GOV (Mar. 20, 2017) <https://health.gov/news/blog/2017/03/five-strategies-for-encouraging-seafood-consumption-what-health-professionals-need-to-know/>.

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Advice about Eating Fish for Women Who Are or Might
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Fish and Seafood: What Pregnant Women and Parents of Young Children Should Know, Advice from FDA and EPA

Updated Advice by FDA and EPA / June 2014

Key Message	Increase the amount of fish and seafood you eat to at least 2 or 3 servings (8-12 ounces) of a variety of fish and seafood each week. Eating fish and seafood during pregnancy and breastfeeding can help improve your baby's brain development. That is because fish and seafood are full of nutrients including healthy oils called omega-3s. Omega-3s are needed for the brain to grow and work properly. Omega-3s are also good for your heart.
Who Should Know	Follow these simple tips during pregnancy and breastfeeding as well as when feeding fish and seafood to young children to make sure you and your family are getting plenty fish and seafood.
Why This Advice Is Important	Many people do not currently eat the recommended amount of fish and seafood. When you do not eat enough fish and seafood, you and your children may miss out brain and heart health benefits.
What to Do	<ol style="list-style-type: none"> 1. Increase the amount of fish and seafood you eat to at least 2 or 3 servings (8-12 ounces) of a variety of fish and seafood each week. <ul style="list-style-type: none"> • The average pregnant woman in the U.S. eats about half a serving (2 ounces) of seafood per week. So you should likely eat four-times the amount of seafood you currently eat each week. • For young children, give them 2 or 3 servings of fish and seafood a week in child-sized portions. 2. Choose a variety of cooked seafood to help you meet your omega-3 needs. <ul style="list-style-type: none"> • Eat at least 2-3 servings (8-12 ounces) of a variety of seafood each week, including some higher omega-3 types like salmon, canned white (albacore) tuna, mackerel, sardines, trout, and anchovies. 3. During pregnancy and breastfeeding avoid only four types of fish that are higher in mercury: tilefish from the Gulf of Mexico, shark, swordfish, and king mackerel. <ul style="list-style-type: none"> • Most people in the U.S. already do not eat these four types of fish to avoid, which have mercury levels close to or over 1 part per million. • Overall, the types of fish we eat in the U.S. are low in mercury, with levels well below 1 part per million. • If you are not pregnant or breastfeeding, there are no types of commercial seafood to avoid. 4. When adding more fish and seafood to your diet, be sure to stay within your calorie needs. <ul style="list-style-type: none"> • Choose fish and seafood in place of some meat and poultry.

Sources

This updated advice is based on several reviews of science conducted in the last five years about the health effects of eating seafood, including the following:

- U.S Food and Drug Administration, 2014. "A Quantitative Assessment of the Net Effects on Fetal Neurodevelopment From Eating Commercial Fish (As Measured by IQ and also by Early Age Verbal Development in Children)."
- Food and Agriculture Organization of the United Nations/World Health Organization, 2011. "Report of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption,"
- U.S. Departments of Agriculture and Health and Human Services, 2010. Dietary Guidelines for Americans 2010, chapter 4, "Foods and Nutrients to Increase"

Questions & Answers

1. Why we are issuing this advice now?

We (the Food and Drug Administration and the Environmental Protection Agency) are issuing this advice to encourage women to eat recommended amounts and types of fish. Recent reports show many pregnant women in the United States are not consuming fish in amounts recommended by the [Dietary Guidelines for Americans 2010](#). This advice is being issued now to encourage women who are pregnant (or may become pregnant) or breastfeeding and young children to eat more fish and to eat a variety of fish from choices that are lower in mercury. The [Dietary Guidelines for Americans 2010](#), the federal government's evidence-based nutritional guidance to promote healthy eating, now recommends that "women who are pregnant or breastfeeding consume at least 8 and up to 12 ounces of a variety of seafood per week, from choices lower in methyl mercury."

There is longstanding evidence of the nutritional value of fish in the diet. Fish contain high quality protein, many vitamins and minerals, omega-3 fatty acids, are mostly low in saturated fat, and some fish even contain vitamin D. The nutritional value of fish is especially important during growth and development before birth, in early infancy for breastfed infants, and in childhood.

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2. Can you provide me with a list of different types of fish and how much mercury and omega-3 fatty acids they contain? The following table provides a list of common fish that can be bought in stores and restaurants.

Common Varieties	Milligrams of Omega-3 Fatty Acids (Eicosapentaenoic (EPA) and Docosahexaenoic (DHA) Per 4 Ounces of Cooked Fish	Micrograms of Mercury Per 4 Ounces of Cooked Fish
Salmon: Atlantic, Chinook, Coho	1,200 – 2,400	2
Anchovies, Herring, and Shad	2,300 – 2,400	5 - 10
Mackerel: Atlantic & Pacific (not King)	1,350 – 2,100	8 - 13

Common Varieties	Milligrams of Omega-3 Fatty Acids (Eicosapentaenoic (EPA) and Docosahexaenoic (DHA) Per 4 Ounces of Cooked Fish	Micrograms of Mercury Per 4 Ounces of Cooked Fish
Tuna: Bluefin & Albacore	1,700	54-58
Sardines: Atlantic & Pacific	1,100 – 1,600	2
Oysters: Pacific	1,550	2
Trout: Freshwater	1,000 – 1,100	11
Tuna: White (Albacore) canned	1,000	40
Mussels: Blue	900	NA*
Salmon: Pink & Sockeye	700 – 900	2
Squid	750	11
Pollock: Atlantic & Walleye	600	6
Marlin	250 – 1030**	69

Common Varieties	Milligrams of Omega-3 Fatty Acids (Eicosapentaenoic (EPA) and Docosahexaenoic (DHA) Per 4 Ounces of Cooked Fish	Micrograms of Mercury Per 4 Ounces of Cooked Fish
Crab: Blue, King, Snow, Queen, & Dungeness	200 – 550	9
Tuna: Skipjack & Yellowfin	150 – 350	31 – 49
Flounder, Plaice, & Sole (Flatfish)	350	7
Clams	200 – 300	<1***
Tuna: Light canned	150 – 300	13
Catfish	100 – 250	7
Cod: Atlantic & Pacific	200	14
Scallops: Bay & Sea	200	8
Haddock & Hake	200	2 – 5
Lobster: American	200	47

Common Varieties	Milligrams of Omega-3 Fatty Acids (Eicosapentaenoic (EPA) and Docosahexaenoic (DHA) Per 4 Ounces of Cooked Fish	Micrograms of Mercury Per 4 Ounces of Cooked Fish
Crayfish	200	5
Tilapia	150	2
Shrimp	100	<1***
Orange Roughy	42	80
Varieties That Should Not be Consumed by Women Who Are Pregnant or Breastfeeding or by Young Children		
Shark	1,250	151
Tilefish: Gulf of Mexico	1,000	219
Swordfish	1,000	147
Mackerel: King	450	110

*Not available. It is likely to be comparable to the levels in oysters and clams.

**250 is the value for blue marlin and 1030 is the value for striped marlin.

***Less than one.

This table can be found in Appendix 11 in the [Dietary Guidelines for Americans 2010](#). We have modified it to change “zero” to “less than one” for clams and shrimp since they do contain very small amounts of mercury. We have also added orange roughy and marlin to the table because we are seeking public comment on whether to recommend that pregnant and breastfeeding women and young children avoid these fish.

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3. What are mercury and methylmercury?

Mercury occurs naturally in the environment and can also be released to the environment through many types of human activity. Mercury can collect in streams, lakes, and oceans and is turned into methylmercury in the water. It is this type of mercury that is present in fish. Methylmercury is a neurotoxin that can be harmful to the brain and nervous system if a person is exposed to too much of it.

4. Is there methylmercury in all fish?

Nearly all fish contain at least traces of methylmercury. As they feed, fish absorb methylmercury. Methylmercury tends to build up more in some types of fish than others, especially in larger fish with longer life spans.

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5. What fish should I avoid?

You should avoid these four types of fish that are highest in mercury*

- Tilefish from the Gulf of Mexico
- Shark
- Swordfish
- King mackerel

As you can see from the above table, those fish are notably higher in mercury on average than the other listed fish.

*Mercury concentration data come from the FDA database located at <http://www.fda.gov/Food/FoodborneIllnessContaminants/metals/ucm115644.htm>.

6. How many servings of fish should I eat every week in order to eat 8-12 ounces?

If you eat 2-3 servings per week it is likely that you will eat 8-12 ounces. That would be 4-6 ounces per serving.

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7. Is it true that pregnant women and young children should avoid raw fish?

Yes. The [Dietary Guidelines for Americans 2010](#) and FDA recommend that pregnant women and young children should only eat foods with fish, meat, poultry, or eggs that have been cooked to safe temperatures to protect against microbes that might be in those foods. Pregnant women and young children often lack strong immune systems and are more at risk for foodborne illnesses.

8. How should I eat 8-12 ounces of fish every week within my calorie needs?

If you have to eat more fish than you usually do in order to eat 8-12 ounces per week, you should be mindful not to exceed what would be a good number of calories for you. [The Dietary Guidelines for Americans 2010](#) recommend increasing the amount and variety of fish you eat by choosing fish in place of other protein sources. This may mean eating less of other things in order to stay within your calorie needs. It may also mean paying attention to how the fish are prepared. Broiled fish, for example, typically contain fewer calories than fried fish and can be healthier in other ways as well. If you are uncertain about what the right number of calories is for you, useful information is available at www.choosemyplate.gov (specific information available at <http://www.choosemyplate.gov/weight-management-calories/weight-management/better-choices/amount-calories.html>). If you wish further information, we recommend that you consult a nutritionist or your physician.

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9. It is hard to imagine a young child eating 8-12 ounces of fish every week. Would it be OK to serve less?

Yes. We recommend serving fish to young children 2-3 times per week but the portion sizes should be smaller than adult portions and right for your child's age and appetite. The USDA Food Patterns, which provide examples of the types and amounts of foods to consume for health, suggest that children ages 2-8 years eat about 3-6 ounces of fish per week, depending on calorie needs. For children under the age of six, the USDA Food Patterns suggest an amount of 3-5 ounces per week. For children ages 6-8, the total for the week should be about 4-6 ounces. Appropriate amounts of fish for older children would increase up to the adult recommendation of at least 8 ounces per week as their calorie needs increase. As an additional matter, parents should feed fish to young children only after 6 months of age. Because fish, and particularly shellfish, are regarded as major allergens, parents feeding fish to their children for the first time should monitor for signs of an allergic reaction before feeding a second time.

The recommendation to limit consumption of albacore tuna to 6 ounces per week should similarly be adjusted for age and portion size. And, of course, the recommendation to avoid the fish highest in mercury (tilefish from the Gulf of Mexico, king mackerel, shark, and swordfish) applies to young children as well as to pregnant women and breastfeeding mothers. The recommendation for fish that you or others catch in rivers, streams, and lakes and for which no advice is available is that children under the age of six should limit their consumption of these fish to 1 – 2 ounces per week and children ages 6 – 12 should limit their consumption to 2 – 3 ounces per week. In neither case should children eat other fish that week.

10. Should I be concerned if I eat one serving of the four fish you recommend against eating?

While it is unlikely that a single serving could have any health impact, these fish should not be part of your regular diet. We recommend that you avoid these fish while pregnant, if you plan to get pregnant, or while breastfeeding, and that you avoid serving these fish to young children.

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11. I eat a lot of tuna, especially canned light tuna because it is particularly affordable. Is it alright to eat mostly canned light tuna?

Canned light tuna is fine to eat because it is not high in methylmercury, but we recommend that you eat a variety of fish, including at least some fish that are even lower in mercury. You may wish to try other affordable fish lower in mercury such as other types of canned fish, frozen fish, or fresh fish that are on sale.

12. I eat a lot of tuna, but prefer to eat albacore tuna. Should I continue to eat mostly albacore tuna?

White tuna (albacore) contains much less mercury on average than the fish we recommend avoiding, but it does typically contain three times as much methylmercury on average as canned light tuna. As recommended in the [Dietary Guidelines for Americans 2010](#), you should limit white tuna (albacore) to six ounces per week. When serving albacore to children, we suggest reducing by roughly one-half the amounts recommended by the [Dietary Guidelines for Americans 2010](#) described above in the answer to Question 9 (e.g., 1-4 ounces).

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13. What happens if I eat less than eight or more than 12 ounces of fish (including shellfish) in a week?

Our advice is provided as a general guideline for how much fish to eat weekly. If you eat more or less than the recommended amount one week, simply try to eat the recommended amount in the following weeks.

14. Why should I follow the recommendations for eating fish?

Fish are a good source of many nutrients, including protein and minerals such as iron, and most of them are low in saturated fats. Fish also contain varying amounts of omega-3 fatty acids and some fish contain vitamin D. Fish consumption, as part of a healthy eating pattern and when consumed within caloric needs, is associated with overall health. The nutritional value of fish lower in mercury is especially important during growth and development before birth, in early infancy (for breastfed infants), and in childhood.

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15. Should I avoid all fish during pregnancy in order to avoid mercury?

You do not need to avoid fish during pregnancy. In fact, primary research studies with pregnant women have consistently found that the nutritional value of fish is important during growth and development before birth, even though nearly all fish contain at least traces of mercury. This has been especially the case when the fish has been lower in mercury. The [Dietary Guidelines for Americans 2010](#) include fish as a food to increase, both generally and during pregnancy, because most people eat below the recommended amounts. Avoiding fish during pregnancy in favor of omega-3 supplements means that you would be missing out on many other important nutrients contained in fish that are required for overall health.

16. Why does this advice include a recommendation for recreationally caught fish from local waters?

There are local waters where there may have been little or no monitoring and, therefore, the extent of potential methylmercury contamination is unknown. Local fresh water fish may also differ in their nutritional composition. That's why it is important for those who fish to pay attention to local advisories. If there is no local fish advisory, you should eat no more than 6 ounces per week and do not eat any other fish that week. Children under the age of six should limit their consumption of these fish to 1 – 2 ounces per week and children ages 6 – 12 should limit their consumption to 2 – 3 ounces per week. In neither case should children eat other fish that week.

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17. Where do I get information about the safety of fish caught by family or friends?

Check the applicable fishing regulations booklet or website for information about recreationally caught fish. Local health departments also have information about advisories in their jurisdiction.

18. Can I clean or prepare (e.g., cook) my fish to reduce the amount of methylmercury that might be present?

Methylmercury is found throughout the tissue in fish, so cleaning or cooking will not reduce the amount of methylmercury in a fish meal. However, it's always a good idea to remove skin, belly fat, and internal organs (where other harmful pollutants may accumulate) before you cook fish. This is particularly true for locally caught fish

References

[Dietary Guidelines for Americans 2010](#), Chapter 4: Foods and Nutrients to Increase, Chapter 5: Building Healthy Eating Patterns, Appendix 6, Appendix 7, and Appendix 11, available at <http://health.gov/dietaryguidelines/2010.asp>.

Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010 to the Secretary of Agriculture and the Secretary of Health and Human Services, pages 239-241, available at <http://www.cnpp.usda.gov/DGAs2010-DGACReport.htm>.



Eating Fish: What Pregnant Women and Parents Should Know

January 2017

FDA and EPA have issued advice regarding eating fish. This advice is geared toward helping women who are pregnant or may become pregnant - as well as breastfeeding mothers and parents of young children - make informed choices when it comes to fish that is healthy and safe to eat.

The advice includes a **chart** that makes it easier than ever to choose dozens of healthy and safe options, and a set of **frequently asked questions & answers**.

To learn more and download materials, visit us at www.fda.gov/fishadvice and www.epa.gov/fishadvice.

Chart

Advice About Eating Fish

What Pregnant Women & Parents Should Know

Fish and other protein-rich foods have nutrients that can help your child's growth and development.

For women of childbearing age (about 16-49 years old), especially pregnant and breastfeeding women, and for parents and caregivers of young children.

- Eat 2 to 3 servings of fish a week from the "Best Choices" list OR 1 serving from the "Good Choices" list.
- Eat a variety of fish.
- Serve 1 to 2 servings of fish a week to children, starting at age 2.
- If you eat fish caught by family or friends, check for fish advisories. If there is no advisory, eat only one serving and no other fish that week.*

Use this chart!

You can use this chart to help you choose which fish to eat, and how often to eat them, based on their mercury levels. The "Best Choices" have the lowest levels of mercury.

What is a serving?



For an adult
4 ounces



For children,
ages 4 to 7
2 ounces

To find out, use the palm of your hand!

Best Choices EAT 2 TO 3 SERVINGS A WEEK			OR	Good Choices EAT 1 SERVING A WEEK		
Anchovy	Herring	Scallop		Bluefish	Monkfish	Tilefish (Atlantic Ocean)
Atlantic croaker	Lobster, American and spiny	Shad		Buffalofish	Rockfish	Tuna, albacore/white tuna, canned and fresh/frozen
Atlantic mackerel	Mullet	Shrimp		Carp	Sablefish	Tuna, yellowfin
Black sea bass	Oyster	Skate		Chilean sea bass/Patagonian toothfish	Sheepshead	Weakfish/seatrout
Butterfish	Pacific chub mackerel	Smelt		Grouper	Snapper	White croaker/Pacific croaker
Catfish	Perch, freshwater and ocean	Sole		Halibut	Spanish mackerel	
Clam	Pickorel	Squid		Mahi mahi/dolphinfish	Striped bass (ocean)	
Cod	Plaice	Tilapia				
Crab	Pollock	Trout, freshwater				
Crawfish	Salmon	Tuna, canned light (includes skipjack)				
Flounder	Sardine	Whitefish				
Haddock		Whiting				
Hake						
Choices to Avoid HIGHEST MERCURY LEVELS						
				King mackerel	Shark	Tilefish (Gulf of Mexico)
				Marlin	Swordfish	Tuna, bigeye
				Orange roughy		

*Some fish caught by family and friends, such as larger carp, catfish, trout and perch, are more likely to have fish advisories due to mercury or other contaminants. State advisories will tell you how often you can safely eat those fish.

www.FDA.gov/fishadvice
www.EPA.gov/fishadvice



Questions & Answers

I. USING THE CHART

1. How do I use the chart?

Fish are a high quality protein source, and lower mercury fish are a good choice for everyone. This advice is specifically for women who are pregnant, might become pregnant or are breastfeeding, and for young children, but everyone can follow this advice.

Use the chart to help you choose which fish to eat each week. Eating a variety of fish is better for you and your child than eating the same type every time.

You can eat 2 to 3 servings a week of fish in the “Best Choices” category, based on a serving size of four ounces, in the context of a total healthy diet.

You can eat 1 serving a week of fish in the “Good Choices” category.

You should not eat fish in the “Choices to Avoid” category or feed them to young children. However, if you do, eat fish with lower mercury levels in the following weeks.

2. How did you decide which fish went in each category?

We took a cautious and highly protective approach in determining which fish belonged in each category. We calculated 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. If she could eat that fish at least three times a week, then we listed it in the “Best Choices” category. If she could eat that fish only once a week, or twice but not three times a week, then we listed it in the “Good Choices” category. If she could not eat a serving of that fish once a week, then we listed the fish in the “Choices to Avoid” category.

For more information, please see our [technical page](#).

3. How can some fish be in more than one category?

There are different types (or species) of tuna, such as albacore, bigeye, and yellowfin. Some types of tuna that are bigger or live longer tend to have higher mercury levels, and that is why they are in different categories. So, canned light tuna is in the “Best Choices” category. Albacore (or white) tuna and yellowfin tuna are in the “Good Choices” category, and bigeye tuna is in the “Choices to Avoid.” In addition, fish of the same species that are caught in different geographic locations can vary in mercury content. For example, tilefish are in two categories because tilefish in the Gulf of Mexico have higher mercury levels than those in the Atlantic Ocean.

4. Why are some fish not on the chart?

If you are looking for a species of fish that is not on the chart, such as mussels, that means we did not have enough reliable mercury data to include it. We plan to update the website as we get more data.

5. How can I find out more details on the mercury levels in fish?

Go to our more detailed, sortable [table](#) that shows the average mercury levels in commercial fish.

II. SERVINGS

1. What is a serving?

For adults, a typical serving is 4 ounces of fish, measured before cooking. Our advice is to eat 2 to 3 servings of a variety of cooked fish, or about 8 to 12 ounces, in a week.

2. How can I tell how much 4 ounces is?

Four ounces is about the size and thickness of an adult's palm.



For an adult
4 ounces



For children,
ages 4 to 7
2 ounces

3. What happens if I eat less fish than the 2 to 3 servings a week you recommend?

You could miss out on the high quality protein, minerals and vitamins present in fish that are beneficial to overall health. Simply try to eat the recommended amount from a variety of fish in the following weeks. Our advice is provided as a general guideline for how much fish to eat weekly.

4. What happens if I eat more than 3 servings of fish in a week?

Try to vary the fish you eat. If you eat more than 3 servings in a week and some include fish with higher mercury levels, try to eat fish with lower mercury levels in the following weeks.

5. Should I make any changes to the advice based on my weight?

The advice provided here is intended as a general guideline. Women who weigh less than the average (165 pounds) may wish to eat smaller portions or to eat two servings of fish a week instead of three.

III. CHILDREN

1. Should children eat fish and if so, how much?

Yes, fish, like other protein-rich foods, is good for a child's growth and development. We recommend serving fish to children 1 to 2 times per week from a variety of fish, but the portion sizes should be smaller than adult portions and right for your child's age and total calorie needs. On average, a serving size is about 1 ounce for children ages 2-3 years, 2 ounces for children ages 4-7 years, 3 ounces for children ages 8-10 years and 4 ounces for children 11 years and older. For more information, please see our [technical page](#). Also read Q&A VI.2 and Q&A VII.1 for information on children and tuna and fish caught by family and friends.

2. At what age can I start giving my child fish?

Parents can feed fish to young children, but should not feed fish to children younger than 6 months of age. Because fish, and particularly shellfish, are regarded as major potential allergens, parents feeding fish to their children for the first time should monitor for signs of an [allergic reaction](#) before feeding a second time.

IV. NUTRIENTS IN FISH

1. What nutrients are in fish and why are they good for you?

Most fish are an excellent source of high quality protein. Fish are also important sources of selenium, zinc, iodine, iron, and other minerals needed by the body. Fish are natural sources of many B vitamins, and oily fish provide vitamins A and D. Studies with pregnant women have found that the nutritional benefits of fish, like other protein-rich foods, are important for their children's growth and development during pregnancy and childhood. Most fish are low in fat, and most of the fat that is present in fish is healthy polyunsaturated fat. The polyunsaturated omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) are also present in many types of fish. Research is still underway to determine the health benefits of omega-3 fatty acids.

2. Can I get the same benefits from omega-3 supplements than from eating fish?

Omega-3 supplements do not provide protein, vitamins, or minerals. Taking omega-3 supplements instead of eating fish means that you would be missing out on the high quality protein, minerals, and vitamins present in fish that are beneficial to overall health. The research is still underway on the [health benefits of omega-3 supplements](#).

V. CONTAMINANTS IN FISH

1. What are mercury and methylmercury?

Mercury is an element that occurs naturally in the environment and is also released to the environment through many types of human activity. It can collect in streams, lakes, and oceans and is turned into methylmercury in the water or sediment. It is this type of mercury that is present in fish. Methylmercury can be harmful to the brain and nervous system if a person is exposed to too much of it over time.

2. Is there methylmercury in all fish?

Nearly all fish contain at least traces of methylmercury. Fish absorb methylmercury from the food they eat. It tends to build up more in some types of fish than others, especially in larger fish that eat other fish and those fish that live longer.

3. Should I not eat fish during pregnancy in order to avoid mercury?

No, fish can contribute to a healthy diet before and during pregnancy and while breastfeeding. Studies with pregnant women have found that the nutritional benefits of fish, like other protein-rich foods, are important for their child's growth and development during pregnancy and childhood. This is especially true when the fish is lower in mercury. Most people eat less than the recommended amount of fish, both in general and during pregnancy. A [2005 FDA survey](#) found pregnant women typically ate only 2 ounces of fish a week. The chart in this advice shows which fish are the best choices for women who are pregnant, might become pregnant, or are breastfeeding, or for young children.

4. Can cleaning or preparing (e.g., cooking) my fish reduce the amount of mercury that might be present?

No. Mercury is found throughout the tissue in fish, so cleaning or cooking will not reduce the amount of mercury. The way to reduce the amount of mercury is to eat the fish shown on the chart identified as the "Best Choices."

For fish purchased whole in stores please see additional information in the response to Question V.6.

5. Should I be concerned if I eat one serving of the fish listed in the “Choices to Avoid” category?

No, but going forward, choose from fish from the “Best Choices” or “Good Choices” categories. Just try to avoid eating the “Choices to Avoid” fish or feeding them to children. We recommend you eat a variety of fish from the “Best Choices” and “Good Choices” categories on the chart.

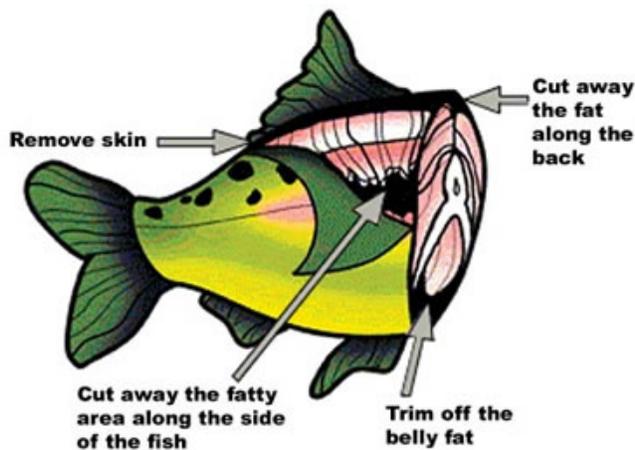
6. Are there other contaminants in fish?

Yes, however, FDA has found that the levels of other contaminants in commercial fish generally do not raise human health concerns. For many years, FDA has sampled and tested commercial seafood for pesticides and industrial chemicals as well as other heavy metals besides mercury and the results are available on FDA’s website:

- [Pesticide Program Residue Monitoring](#)
- [Total Diet Study Analytical Results](#)

Levels of other contaminants vary by location and fish species. State and local health departments or fish and game agencies provide advice on other contaminants, such as polychlorinated biphenyls (PCBs) in fish from particular bodies of water. People who catch their own fish for recreation or as a source of protein in their diets should check for fish advisories for both fresh and marine waters.

It is a good idea to remove skin, fat, and internal organs where other types of harmful pollutants may accumulate for fish you and your friends catch before you cook these fish. This is particularly true because fish from some local waters may be more likely to contain other contaminants.



And remember - eat a variety of fish, not just the same type every time you eat fish. There are plenty of fish shown on the chart to choose from, so there are fish for every taste.

VI. WHAT ABOUT TUNA?

1. What is the difference between albacore (white) tuna and canned light tuna?

Albacore, or white tuna, is larger and lives longer than the fish generally used in canned light tuna. Meanwhile, canned light tuna can be a mix of a variety of generally smaller tuna species, most often skipjack.

2. I eat a lot of tuna, especially canned light tuna because it is particularly affordable. Is this okay?

Yes. Canned light tuna is in the “Best Choices” category and it is fine to eat 2 to 3 servings per week. We recommend that you eat a variety of fish. You may wish to try other affordable fish in the “Best

Choices” category such as canned salmon or sardines, frozen fish, or fresh fish that are at a reduced price.

3. I eat a lot of tuna, but prefer to eat albacore tuna. Is this okay?

Albacore tuna, also known as white tuna, typically contains three times more mercury than canned light tuna. You can eat albacore or any of the other fish from the “Good Choices” category once a week.

VII. FISH CAUGHT BY FAMILY AND FRIENDS

1. What if I eat fish caught by family and friends?

When eating fish you or others have caught, pay attention to fish advisories on those water bodies. There are waters where there may have been little or no monitoring and, therefore, the extent of potential mercury contamination is unknown. If advice isn’t available, you should limit your consumption of that fish to one serving per week and not eat any other fish that week. Adults should eat no more than 6 ounces that week, children under the age of six should limit their consumption of these fish to 1 to 2 ounces per week, and older children (ages six to twelve) should limit their consumption to 2 to 3 ounces per week. Again, neither adults nor children should eat other fish that week.

2. Where do I get information about the safety of fish caught by family or friends?

Check the applicable fishing regulations booklet or website for information about recreationally caught fish. Local, state, and tribal health departments and fish and game agencies also have information about advisories for consuming fish in their jurisdiction. Also see [EPA’s website for fish consumption advisories](#).

VIII. ADDITIONAL TIPS FOR EATING FISH

1. How does eating 2 to 3 servings of fish a week fit within a healthy eating pattern?

The [2015-2020 Dietary Guidelines for Americans](#) recommend increasing the amount of fish, and to choose a variety of fish lower in mercury. Fish should be eaten in place of other protein sources, such as some meat and poultry. This may also mean paying attention to how the fish are prepared. Broiled fish, for example, typically contain fewer calories than fried fish and can be healthier in other ways as well. Sodium and cholesterol content from the fish or from the cooking process should also be considered as with other aspects of healthy eating. If you are uncertain about what the right number of calories is for you, please visit www.choosemyplate.gov for information regarding appropriate caloric intake (specific information available at [My Weight Manager](#)). If you want more information, we recommend that you consult a nutritionist or your physician.

2. Is it true that pregnant women and young children should avoid raw fish?

Yes. The [2015-2020 Dietary Guidelines for Americans](#) and FDA recommend that pregnant women and young children should only eat foods with fish, meat, poultry, or eggs that have been cooked to safe internal temperatures to protect against microbes that might be in those foods. This includes raw fish served as part of sushi or sashimi (Japanese-style foods) that are available in many restaurants and food stores. Pregnant women and young children often have weaker immune systems and are more at risk for foodborne illnesses.

3. What if I cannot or do not eat fish? Will my baby be okay?

Fish is one source of high quality protein, minerals and vitamins that are beneficial to overall health. You can have a healthy baby even if you don’t eat fish.

4. I'm a woman who could have children but I'm not pregnant. Why should I follow this advice?

If you could become pregnant in the next year, we encourage you to begin following this advice now. Eating 2 to 3 servings of a variety of fish a week along with other protein-rich foods can help your child's growth and development, and following the recommendations for how often to eat the various fish types is also important. That's because mercury in fish can accumulate in your body over time. While mercury is removed from the body naturally, the process can take several months. So, following this advice before pregnancy can benefit the developing child, especially during the important first trimester.

5. What advice do you have about eating fish for people who are not pregnant, will not become pregnant, or are not breastfeeding?

Fish are a high quality protein source, and lower mercury fish are a good choice for everyone. This advice is specifically for women who are pregnant, might become pregnant or are breastfeeding, and for young children, but everyone can follow this advice.

6. Does this advice consider fishery sustainability issues?

No. This advice focuses on the benefits of fish consumption and the number of fish meals per week that could be eaten based on mercury levels in fish. This advice does not reflect concerns about fishery sustainability issues. For more information, see the National Oceanic and Atmospheric Administration's website at <http://www.fishwatch.gov>.

IX. REFERENCES

2015-2020 [Dietary Guidelines for Americans](https://health.gov/dietaryguidelines/2015/guidelines/), available at <https://health.gov/dietaryguidelines/2015/guidelines/>

Questions & Answers from the FDA/EPA Advice about Eating Fish for Women Who Are or Might Become Pregnant, Breastfeeding Mothers, and Young Children

Advice Main Page (</food/consumers/eating-fish-what-pregnant-women-and-parents-should-know>)

FDA and EPA have issued advice regarding eating fish. This advice can help women who are pregnant or may become pregnant - as well as breastfeeding mothers and parents and caregivers feeding children 2 years and older - make informed choices when it comes to fish that are nutritious and safe to eat. This advice supports the recommendations of the *2015-2020 Dietary Guidelines for Americans*, (<https://health.gov/dietaryguidelines/2015/guidelines/>) developed for people 2 years and older. For advice about feeding children under 2 years of age, you can consult the American Academy of Pediatrics (<https://healthychildren.org/English/ages-stages/baby/feeding-nutrition/Pages/Starting-Solid-Foods.aspx>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>).

The advice features a chart (</media/102331/download>) that makes it easier than ever to choose dozens of healthy and safe options and includes information about the nutritional value of fish. A set of **frequently asked questions & answers** (below) provides more information on how to use the chart and additional tips for eating fish.

I. USING THE CHART

II. SERVINGS

III. CHILDREN

IV. NUTRIENTS IN FISH

V. CONTAMINANTS IN FISH

VI. WHAT ABOUT TUNA?

VII. FISH CAUGHT BY FAMILY AND FRIENDS

VIII. ADDITIONAL TIPS FOR EATING FISH

IX. REFERENCES

I. USING THE CHART (/media/102331/download)

The Advice Chart



[Enlarge in PDF \(472KB\) \(/media/102331/download\)](#)

1. How do I use the chart (/media/102331/download)?

Fish are a high quality protein source, and lower mercury fish are a good choice for everyone. This advice is specifically for women who are or might become pregnant, breastfeeding mothers, and children over 2 years but everyone can follow this advice.

Use the chart (/media/102331/download) to help you choose which fish to eat each week. Eating a variety of fish is better for you and your child than eating the same type every time.

You can eat 2 to 3 servings a week of fish in the “Best Choices” category, based on a serving size of four ounces, in the context of a total healthy diet.

You can eat 1 serving a week of fish in the “Good Choices” category, but no other fish that week.

You should not eat fish in the “Choices to Avoid” category or feed them to young children. However, if you do, eat fish with lower mercury levels in the following weeks.

2. How did you decide which fish went in each category?

We took a cautious and highly protective approach in determining which fish belonged in each category. We calculated 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. If she could eat that fish at least three times a week, then we listed it in

the “Best Choices” category. If she could eat that fish only once a week, or twice but not three times a week, then we listed it in the “Good Choices” category. If she could not eat a serving of that fish once a week, then we listed the fish in the “Choices to Avoid” category.

For more information, please see our technical page (</food/metals/technical-information-development-fish-consumption-advice-fdaepa-advice-what-pregnant-women-and>).

3. How can some fish be in more than one category?

There are different types (or species) of tuna, such as albacore, bigeye, and yellowfin. Some types of tuna that are bigger or live longer tend to have higher mercury levels, and that is why they are in different categories. So, canned light tuna is in the “Best Choices” category. Albacore (or white) tuna and yellowfin tuna are in the “Good Choices” category, and bigeye tuna is in the “Choices to Avoid.” In addition, fish of the same species that are caught in different geographic locations can vary in mercury content. For example, tilefish are in two categories because tilefish in the Gulf of Mexico have higher mercury levels than those in the Atlantic Ocean.

4. Why are some fish not on the chart (</media/102331/download>)?

If you are looking for a species of fish that is not on the chart (</media/102331/download>), such as mussels, that means we did not have enough reliable mercury data to include it. We plan to update the website as we get more data.

5. How can I find out more details on the mercury levels in fish?

Go to our more detailed, table that shows the average mercury levels in commercial fish (</food/metals/technical-information-development-fish-consumption-advice-fdaepa-advice-what-pregnant-women-and#table>).

II. SERVINGS

1. What is a serving?

For adults, a typical serving is 4 ounces of fish, measured before cooking. Our advice is to eat 2 to 3 servings of a variety of cooked fish, or about 8 to 12 ounces, in a week.

2. How can I tell how much 4 ounces is?

Four ounces is about the size and thickness of an adult’s palm.



**For an adult
4 ounces**

3. What happens if I eat less fish than the 2 to 3 servings a week you recommend?

You could miss out on the high quality protein, minerals and vitamins present in fish that are beneficial to overall health. Simply try to eat the recommended amount from a variety of fish in the following weeks. Our advice is provided as a general guideline for how much fish to eat weekly based on mercury levels.

4. What happens if I eat more than 3 servings of fish in a week?

Try to vary the fish you eat. If you eat more than 3 servings in a week, eat fish in the “Best Choices” category. If some choices are fish with higher mercury levels, try to eat fish with lower mercury levels in the following weeks.

5. Should I make any changes to the advice based on my weight?

The advice provided here is intended as a general guideline. Women who weigh less than the average (165 pounds) may wish to eat smaller portions or to eat two servings of fish a week instead of three.

6. How much fish does the *Dietary Guidelines for Americans* recommend?

The *Dietary Guidelines for Americans*

(<https://health.gov/dietaryguidelines/2015/guidelines/chapter-1/a-closer-look-inside-healthy-eating-patterns/#callout-seafood>) recommends at least 8 ounces of seafood per week (based on a 2,000 calorie diet) and less for young children. Women who are pregnant or breastfeeding should eat between 8 and 12 ounces of a variety of seafood per week, from choices that are lower in mercury.

III. CHILDREN

1. Should children eat fish and if so, how much?

Yes, fish, like other protein-rich foods, have nutrients that can help your child’s growth and development. Our advice is developed for people 2 years and older. (For advice about feeding children under 2 years of age, you can consult the American Academy of Pediatrics)

(<https://healthychildren.org/English/ages-stages/baby/feeding-nutrition/Pages/Starting-Solid-Foods.aspx>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>.) We recommend serving fish to children 1-2 times per week from a variety of fish, but the portion sizes should be smaller than adult portions and right for your child's age and total calorie needs. On average, a serving size is about 1 ounce for children ages 2-3 years, 2 ounces for children ages 4-7 years, 3 ounces for children ages 8-10 years and 4 ounces for children 11 years and older. For more information, please see our technical page (</food/metals/technical-information-development-fish-consumption-advice-fdaepa-advice-what-pregnant-women-and>). Also read Q&A VI.2 and Q&A VII.1 for information on children and tuna and fish caught by family and friends.

2. When can I start giving my child fish?

According to the American Academy of Pediatrics (<https://healthychildren.org/English/ages-stages/baby/feeding-nutrition/Pages/Starting-Solid-Foods.aspx>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>), fish can be added to your child's diet when your baby has been introduced to and accepted solid foods with the goal of achieving a wide variety of foods from all food groups.

3. How should I start giving my child fish?

As fish is a common food allergy, introduce fish or shellfish while watching for signs of an allergy (</food/food-allergens/frequently-asked-questions-about-food-allergies>) for several days before feeding a second time. If there is a history of food allergy in the family or your child develops any signs of food allergy, consult with your child's doctor or nurse.

IV. NUTRIENTS IN FISH

1. What nutrients are in fish and why are they good for you?

Most fish are an excellent source of high quality protein (<https://medlineplus.gov/ency/article/002467.htm>). Most fish are low in fat, and most of the fat that is present in fish is healthy polyunsaturated fat. The polyunsaturated omega-3 fatty acids (<https://ods.od.nih.gov/pdf/factsheets/Omega3FattyAcids-Consumer.pdf>) eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) are also present in many types of fish. Research is still underway to determine the health benefits of omega-3 fatty acids. Fish are also important sources of selenium (<https://ods.od.nih.gov/factsheets/Selenium-Consumer/>), zinc (<https://ods.od.nih.gov/factsheets/Zinc-Consumer/>), iodine (<https://ods.od.nih.gov/factsheets/Iodine-Consumer/>), iron (<https://ods.od.nih.gov/factsheets/Iron-Consumer/>), and other minerals needed by the body. Fish are natural sources of many B vitamins, like vitamin B12, (<https://ods.od.nih.gov/factsheets/VitaminB12-Consumer/>) and oily fish provide vitamins A (<https://ods.od.nih.gov/factsheets/VitaminA-Consumer/>) and D

(<https://ods.od.nih.gov/factsheets/VitaminD-Consumer/>). Studies with pregnant women have found that the nutritional benefits of fish, like other protein-rich foods, are important for their children's growth and development during pregnancy and childhood. As part of a healthy eating pattern, eating fish may also offer heart health benefits and lower the risk of obesity.

2. Why does the *Dietary Guidelines for Americans*

(<https://health.gov/dietaryguidelines/2015/guidelines/chapter-1/a-closer-look-inside-healthy-eating-patterns/#callout-seafood>) recommend fish as part of a healthy eating pattern?

Eating fish can provide heart health benefits. As part of a healthy eating pattern, eating fish may also lower the risk of obesity. Among women who are pregnant or breastfeeding, eating the recommended amount of fish from choices that include the omega-3 fatty acid DHA has been related to better health for the baby.

3. Can I get the same benefits from omega-3 supplements than from eating fish?

Omega-3 supplements do not provide protein, vitamins, or minerals. Taking omega-3 supplements instead of eating fish means that you would be missing out on the high quality protein, minerals, and vitamins present in fish that are beneficial to overall health. The research is still underway on the health benefits of omega-3 supplements.

V. CONTAMINANTS IN FISH

1. What are mercury and methylmercury?

Mercury is an element that occurs naturally in the environment and is also released to the environment through many types of human activity. It can collect in streams, lakes, and oceans, and is turned into methylmercury in the water or sediment. It is this type of mercury that is present in fish. Methylmercury can be harmful to the brain and nervous system if a person is exposed to too much of it over time.

2. Is there methylmercury in all fish?

Nearly all fish contain at least traces of methylmercury. Fish absorb methylmercury from the food they eat. It tends to build up more in some types of fish than others, especially in larger fish that eat other fish and those fish that live longer.

3. Should I not eat fish during pregnancy in order to avoid mercury?

No, fish can contribute to a healthy diet before and during pregnancy and while breastfeeding. Studies with pregnant women have found that the nutritional benefits of fish, like other protein-rich foods, are important for their child's growth and development during pregnancy and childhood. While it is important to limit mercury in the diets of women who are pregnant and

breastfeeding and young children, many types of fish are both nutritious and lower in mercury. Most people eat less than the recommended amount of fish, both in general and during pregnancy. A 2005 FDA survey

(<http://www.sciencedirect.com/science/article/pii/S0013935112001168>) 

(<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) found pregnant women typically ate only 2 ounces of fish a week. The chart (</media/102331/download>) in this advice shows which fish are the best choices for women who are pregnant, might become pregnant, or are breastfeeding, or for children over 2 years of age. (For advice about feeding children under 2 years of age, you can consult the American Academy of Pediatrics

(<https://healthychildren.org/English/ages-stages/baby/feeding-nutrition/Pages/Starting-Solid-Foods.aspx>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>).

4. Can cleaning or preparing (e.g., cooking) my fish reduce the amount of mercury that might be present?

No. Mercury is found throughout the tissue in fish, so cleaning or cooking will not reduce the amount of mercury. The way to reduce the amount of mercury is to eat the fish shown on the chart (</media/102331/download>) identified as the “Best Choices.”

For fish purchased whole in stores please see additional information in the response to Question V.6.

5. Should I be concerned if I eat one serving of the fish listed in the “Choices to Avoid” category?

No, but going forward, choose from fish from the “Best Choices” or “Good Choices” categories. Just try to avoid eating the “Choices to Avoid” fish or feeding them to children. We recommend you eat a variety of fish from the “Best Choices” and “Good Choices” categories on the chart (</media/102331/download>).

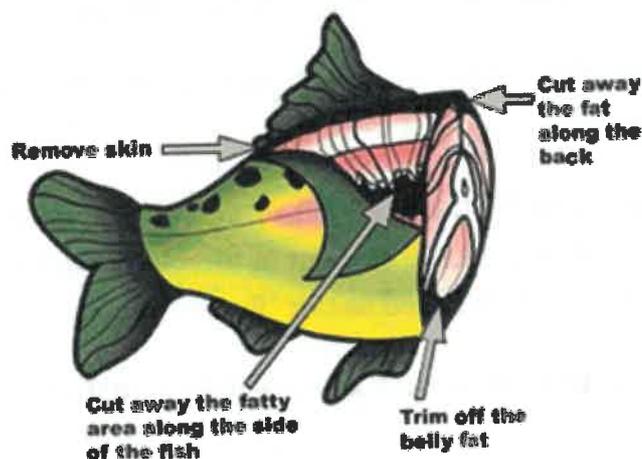
6. Are there other contaminants in fish?

Yes, however, FDA has found that the levels of other contaminants in commercial fish generally do not raise human health concerns. For many years, FDA has sampled and tested commercial seafood for pesticides and industrial chemicals as well as other heavy metals besides mercury and the results are available on FDA’s website:

- Pesticide Program Residue Monitoring (</food/pesticides/pesticide-residue-monitoring-program>)
- Total Diet Study Analytical Results (</food/total-diet-study/analytical-results-total-diet-study>)

Levels of other contaminants vary by location and fish species. State and local health departments or fish and game agencies provide advice on other contaminants, such as polychlorinated biphenyls (PCBs) in fish from particular bodies of water. People who catch their own fish for recreation or as a source of protein in their diets should check for fish advisories for both fresh and marine waters.

It is a good idea to remove skin, fat, and internal organs where other types of harmful pollutants may accumulate for fish you and your friends catch before you cook these fish. This is particularly true because fish from some local waters may be more likely to contain other contaminants.



And remember - eat a variety of fish, not just the same type every time you eat fish. There are plenty of fish shown on the chart (/media/102331/download) to choose from, so there are fish for every taste.

VI. WHAT ABOUT TUNA?

1. What is the difference between albacore (white) tuna and canned light tuna?

Albacore, or white tuna, is larger and lives longer than the fish generally used in canned light tuna. Meanwhile, canned light tuna can be a mix of a variety of generally smaller tuna species, most often skipjack.

2. I eat a lot of tuna, especially canned light tuna because it is particularly affordable. Is this okay?

Yes. Canned light tuna is in the "Best Choices" category and it is fine to eat 2 to 3 servings per week. We recommend that you eat a variety of fish. You may wish to try other affordable fish in the "Best Choices" category such as canned salmon or sardines, frozen fish, or fresh fish that are at a reduced price.

3. I eat a lot of tuna, but prefer to eat albacore tuna. Is this okay?

Albacore tuna, also known as white tuna, typically contains three times more mercury than canned light tuna. When you eat albacore or any of the other fish from the “Good Choices” category, have only 1 serving and no other fish that week.

VII. FISH CAUGHT BY FAMILY AND FRIENDS

1. What if I eat fish caught by family and friends?

When eating fish you or others have caught, pay attention to fish advisories on those water bodies. There are waters where there may have been little or no monitoring and, therefore, the extent of potential mercury contamination is unknown. If advice isn't available, you should limit your consumption of that fish to one serving per week and not eat any other fish that week. Adults should eat no more than 6 ounces that week, children under the age of six should limit their consumption of these fish to 1 to 2 ounces per week, and older children (ages six to twelve) should limit their consumption to 2 to 3 ounces per week. Again, neither adults nor children should eat other fish that week.

2. Where do I get information about the safety of fish caught by family or friends?

Check the applicable fishing regulations booklet or website for information about recreationally caught fish. Local, state, and tribal health departments and fish and game agencies also have information about advisories for consuming fish in their jurisdiction. Also see EPA's website for fish consumption advisories. (<http://www2.epa.gov/choose-fish-and-shellfish-wisely>)

VIII. ADDITIONAL TIPS FOR EATING FISH

1. How does eating 2 to 3 servings of fish a week fit within a healthy eating pattern?

The 2015-2020 Dietary Guidelines for Americans

(<https://health.gov/dietaryguidelines/2015/guidelines/chapter-1/a-closer-look-inside-healthy-eating-patterns/#callout-seafood>) recommends women who are pregnant or breastfeeding to eat 8 to 12 ounces (2 to 3 servings) per week of a variety of fish lower in mercury.

Fish should be eaten in place of other protein sources, such as some meat and poultry. This may also mean paying attention to how the fish are prepared. Broiled fish, for example, typically contain fewer calories than fried fish and can be healthier in other ways as well.

Sodium and cholesterol content from the fish or from the cooking process should also be considered as with other aspects of healthy eating. If you are uncertain about what the right number of calories is for you, please visit www.choosemyplate.gov

(<http://www.choosemyplate.gov/>) for information regarding appropriate caloric intake (specific information available at MyPlate Plan (<https://www.choosemyplate.gov/MyPlatePlan>)). If you want more information, we recommend that you consult a nutritionist or your physician.

(<http://www2.epa.gov/choose-fish-and-shellfish-wisely>)

(<http://www2.epa.gov/choose-fish-and-shellfish-wisely>)

(<http://www2.epa.gov/choose-fish-and-shellfish-wisely>)

(<http://www2.epa.gov/choose-fish-and-shellfish-wisely>)

2. Is it true that pregnant women and young children should avoid raw fish?

Yes. The *2015-2020 Dietary Guidelines for Americans*

(<https://health.gov/dietaryguidelines/2015/guidelines/appendix-14/>) and FDA recommend that pregnant women and young children should only eat foods with fish, meat, poultry, or eggs that have been cooked to safe internal temperatures to protect against microbes that might be in those foods. This includes not eating raw fish served as part of sushi or sashimi (Japanese-style foods) that are available in many restaurants and food stores. Pregnant women and young children often have weaker immune systems and are more at risk for foodborne illnesses.

3. What if I cannot or do not eat fish? Will my baby be okay?

Fish is one source of high quality protein, minerals and vitamins that are beneficial to overall health. You can have a healthy baby even if you don't eat fish.

4. I'm a woman who might have children in the future but I'm not pregnant. Why should I follow this advice?

If you might become pregnant in the next year, we encourage you to begin following this advice now. Eating 2 to 3 servings a week of a variety of fish lower in mercury, along with other protein-rich foods, can help your child's growth and development, and following the recommendations for how often to eat the various fish types is also important. That's because mercury in fish can accumulate in your body over time. While mercury is removed from the body naturally, the process can take several months. So, following this advice before pregnancy can benefit the developing child, especially during the important first trimester.

5. What advice do you have about eating fish for people who are not pregnant, will not become pregnant, or are not breastfeeding?

Fish are a high quality protein source, and lower mercury fish are a good choice for everyone. This advice is specifically for women who are or might become pregnant, breastfeeding mothers, and children over 2 years, but everyone can follow this advice. The *Dietary Guidelines for Americans* (<https://health.gov/dietaryguidelines/2015/guidelines/chapter-1/a-closer-look-inside-healthy-eating-patterns/#callout-seafood>) recommends at least 8 ounces of seafood per week (based on a 2,000 calorie diet) for adults. Eating fish can provide heart health benefits. As part of a healthy eating pattern, eating fish may also lower the risk of obesity.

6. Does this advice consider fishery sustainability issues?

No. This advice focuses on the benefits of fish consumption and the number of fish servings per week that could be eaten based on mercury levels in fish. This advice does not reflect concerns about fishery sustainability issues. For more information, see the National Oceanic and Atmospheric Administration's website at <http://www.fishwatch.gov> (<http://www.fishwatch.gov/>).

IX. REFERENCES

2015-2020 Dietary Guidelines for Americans, available at
<https://health.gov/dietaryguidelines/2015/guidelines/>
(<https://health.gov/dietaryguidelines/2015/guidelines/>)



U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF INSPECTOR GENERAL

Water Quality

EPA Needs to Provide Leadership and Better Guidance to Improve Fish Advisory Risk Communications

Report No. 17-P-0174

April 12, 2017



Report Contributors:

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Abbreviations

AWQC	Ambient Water Quality Criterion
CFR	Code of Federal Regulations
CWA	Clean Water Act
EPA	U.S. Environmental Protection Agency
FDA	U.S. Food and Drug Administration
IRIS	Integrated Risk Information System
OIG	Office of Inspector General
ppm	parts per million
RfD	Oral Reference Dose
WQC	Water Quality Criteria
WQS	Water Quality Standards

Cover photo: Fish advisory sign. (EPA photo)

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At a Glance

Why We Did This Review

The U.S. Environmental Protection Agency (EPA), Office of Inspector General (OIG), conducted this review to evaluate the extent the EPA ensures that federal, state and tribal risk communication efforts protect the public from mercury contamination through the consumption of fish. We focused our evaluation on determining how effectively fish consumption advisory information reached consumers so that they could make healthy consumption choices.

Research shows that consuming fish contaminated by mercury can lead to negative health impacts in humans. The Clean Water Act (CWA) establishes a goal of "water quality which provides for the protection and propagation of fish, shellfish and wildlife." The EPA interprets this CWA goal as supporting water quality that provides for the protection of human health related to the consumption of fish.

This report addresses the following EPA goal or cross-agency strategy:

- *Protecting America's waters.*

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EPA Needs to Provide Leadership and Better Guidance to Improve Fish Advisory Risk Communications

What We Found

Some subsistence fishers, tribes, sport fishers and other groups consume large amounts of contaminated fish without health warnings. Although most states and some tribes have fish advisories in place, this information is often confusing,

Without EPA guidance and assistance, subsistence fishers, including tribes, will continue to consume unhealthy amounts of contaminated fish.

complex and does not effectively reach those segments of the population. Fish advisories differ from state to state, between states and tribes, and across state and tribal borders, which in some cases leads to multiple advisories with conflicting advice for a single waterbody. In addition, although the EPA's risk communication guidance recommends evaluations of fish advisories, we found that less than half of states, and no tribes, have evaluated the effectiveness of their fish advisories. Under the CWA, the EPA can take a stronger leadership role in working with states and tribes to ensure that effective fish advisory information reaches all such segments of the population.

We also found that the EPA has not assessed methylmercury as proposed in the agency's published Integrated Risk Information System (IRIS) agendas. The EPA included methylmercury on its 2012 IRIS agenda for assessment, and on its 2015 IRIS agenda as a priority for assessment. However, to date, the agency has not commenced the assessment. Currently, the EPA's 2001 reference dose for methylmercury is an agency-supported value that the EPA continues to accept for decision-making. Because of its importance in developing water quality standards, and ultimately fish advisories, the RfD should be accurate to ensure that effective fish advisory information is communicated.

Recommendations and Planned Agency Corrective Actions

We recommend that the EPA's Office of Water provide updated fish advisory guidance to states and tribes, work with states and tribes to develop best practices to evaluate the effectiveness of fish advisories, and develop and implement methods to ensure tribal members receive current fish advisory information. We recommend that the EPA's Office of Research and Development conduct an assessment for methylmercury to determine whether the reference dose requires updating as proposed in the 2012 and 2015 IRIS agendas. After receiving responses to our draft report from the two EPA offices, we met to discuss their comments and our recommendations. Based on the follow-up discussion and supplemental information provided by both offices, we found that their corrective actions and milestone dates meet the intent of our recommendations (Appendix C). All recommendations are resolved.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE INSPECTOR GENERAL

April 12, 2017

MEMORANDUM

SUBJECT: EPA Needs to Provide Leadership and Better Guidance to Improve
Fish Advisory Risk Communications
Report No. 17-P-0174

FROM: Arthur A. Elkins Jr.

A handwritten signature in black ink, appearing to read "Arthur A. Elkins Jr.", is written over the printed name.

TO: Michael H. Shapiro, Acting Assistant Administrator
Office of Water

Robert Kavlock, Acting Assistant Administrator
Office of Research and Development

This report on the evaluation of existing public protections for mercury contamination in fish was conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). The project number for this evaluation was OPE-FY15-0061. This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

Action Required

You are not required to provide a written response to this final report because you provided agreed-to corrective actions and planned completion dates for the report's recommendations. Should you choose to provide a final response, we will post your response on the OIG's public website, along with our memorandum commenting on your response. Your response should be provided as an Adobe PDF file that complies with the accessibility requirements of Section 508 of the Rehabilitation Act of 1973, as amended. The final response should not contain data that you do not want to be released to the public; if your response contains such data, you should identify the data for redaction or removal along with corresponding justification.

We will post this report to our website at www.epa.gov/oig.

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Introduction

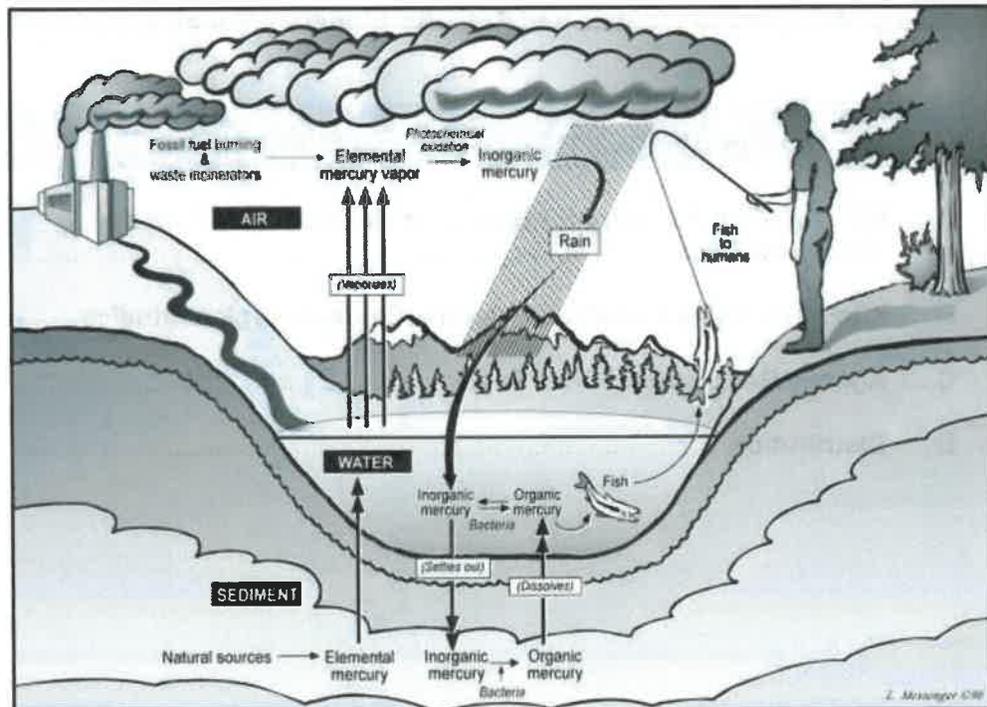
Why We Did This Review

The Office of Inspector General (OIG) for the U.S. Environmental Protection Agency (EPA) conducted this evaluation to determine the extent the EPA ensures that federal, state and tribal risk communication efforts protect the public from mercury contamination through the consumption of fish.

Background

About 80 percent of all fish advisories in the United States focus on mercury contamination. Mercury cycles in the environment as a result of natural and human activities like coal burning and other industrial and manufacturing processes. Most released mercury circulates in the atmosphere and travels thousands of miles from sources of emission. As it cycles between the atmosphere, land and water, mercury transforms into methylmercury and enters the aquatic food web through microscopic plants and animals (Figure 1). This allows methylmercury to accumulate in the food web, becoming most

Figure 1: How mercury cycles through the ecosystem



Source: Utah Department of Environmental Quality.

concentrated in predatory fish (Figure 2). Predatory organisms at the top of the food web (e.g., swordfish, king mackerel, or tuna) generally have higher methylmercury concentrations.

Figure 2: Methylmercury bioaccumulation through the aquatic food web



Source: OIG modification of EPA figure.

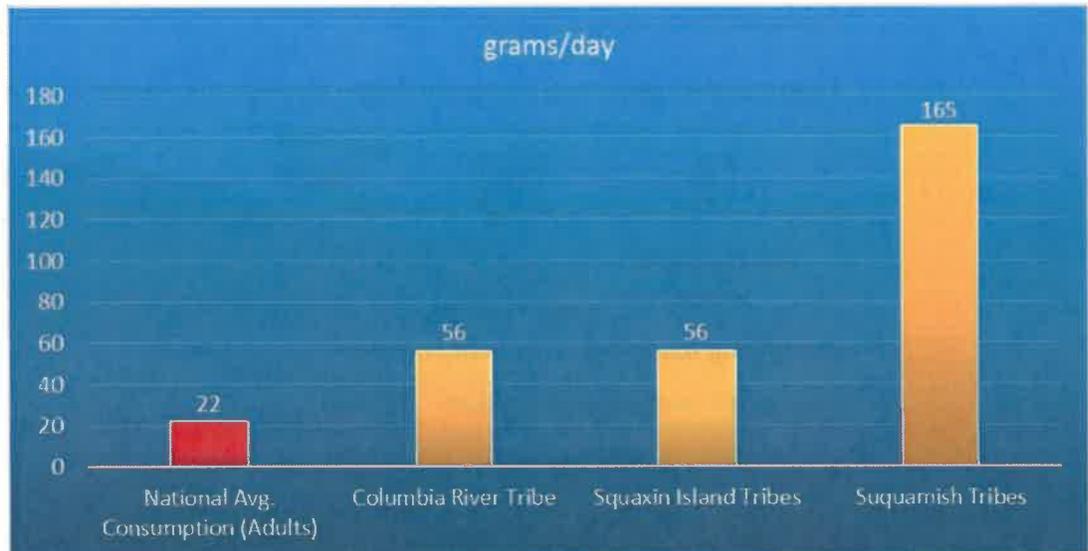
Human Health Effects From Mercury

According to an EPA 2001 fact sheet, titled “Water Quality Criterion for the Protection of Human Health: Methylmercury,” humans are exposed to methylmercury primarily through the consumption of contaminated fish. Methylmercury causes a number of adverse health effects in humans and animals. In pregnant women, methylmercury passes through the placenta to the fetus and fetal brain. Research has shown that high-dose exposure to methylmercury in humans results in mental retardation, cerebral palsy, deafness, blindness, and dysarthria in utero; and in sensory and motor impairment in adults. Recent research has uncovered cardiovascular and immunological effects providing more evidence of toxicity from low-dose methylmercury exposure.

Eating fish from restaurants and grocery stores generally does not expose the average consumer to harmful levels of methylmercury from fish. The most frequently consumed commercial fish contain low levels of methylmercury. However, some types of commercially sold fish contain high levels of mercury and should be avoided by women of childbearing age and children. In addition, wild-caught fish from lakes, rivers or other water bodies may contain high levels of methylmercury, depending on the location, species and size of the fish. Further, subsistence fishers who routinely consume wild-caught fish are exposed to higher levels of methylmercury because of their consumption habits. These fishers may consume fish on a daily basis, not only for subsistence, but as a cultural way of life. For example, Figure 3 shows that the Suquamish Tribe consumes more than eight times more fish than the average population on a daily basis.

As a protective measure, federal agencies, states and tribes issue fish consumption advisories that provide information on segments of the population most at risk; what fish to avoid; what fish can be consumed; and the amount and frequency of contaminated fish that should be eaten.

Figure 3: Comparison of daily average U.S. fish consumption rates for three Indian tribes in grams per day



Source: OIG-developed chart based on data from the U.S. Food and Drug Administration and Polissar et al. (2012).

EPA's Role in Developing Fish Advisories

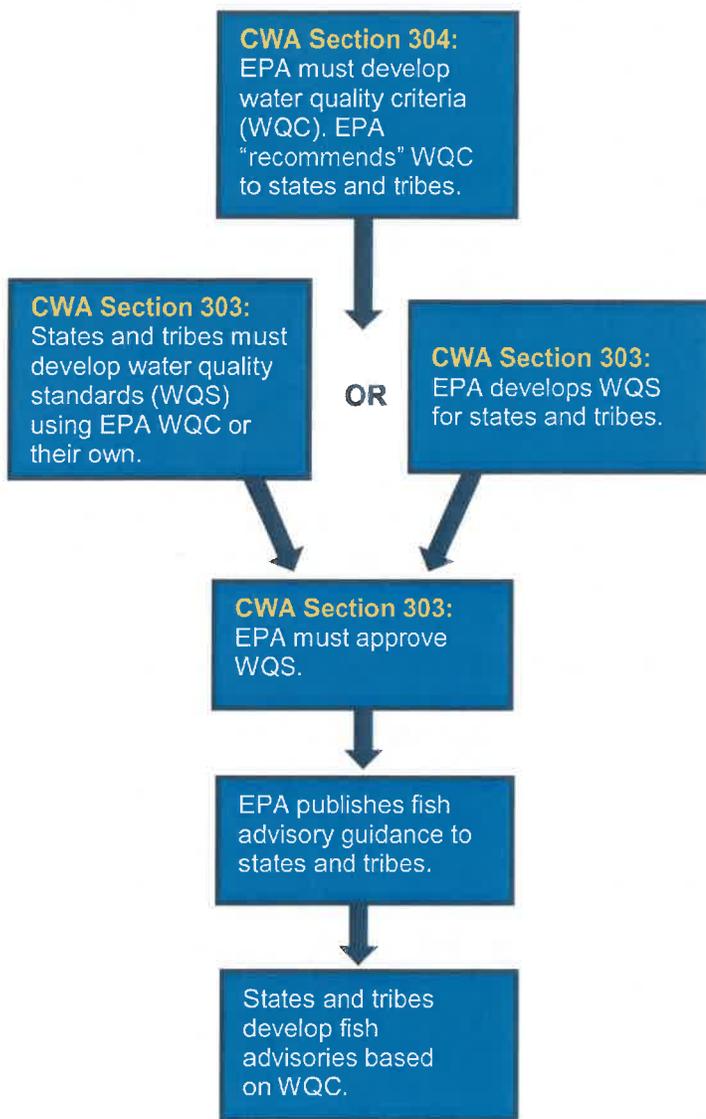
Fish consumption advisories are issued on a national level for commercially marketed fish; and on a local level for fish caught directly from lakes, rivers and other water bodies by individual fishers. The EPA does not have regulatory responsibility for nationally issued fish advisories. This responsibility falls under the purview of the U.S. Food and Drug Administration (FDA). The FDA does, however, collaborate with the EPA when developing national fish advisories.

For locally issued advisories for lakes, rivers and other waterbodies, the EPA, under the Clean Water Act (CWA), shares responsibility and works collectively with states and tribes to establish water quality criteria and standards that lead to fish advisories when warranted. The EPA is responsible for establishing water quality criteria and contaminant toxicity values that states and tribes use to develop fish advisories. The agency also provides national leadership to states and tribes by issuing risk communication and fish advisory guidance. Under the CWA, states and tribes also have certain responsibilities as shown in Figure 4.

Clean Water Act

The CWA defines EPA, state and tribe responsibilities in the development of water quality criteria and water quality standards that lead to fish consumption advisories. One goal of the CWA, as interpreted by the EPA, is "fishable, swimmable" waters. The EPA interprets "fishable" uses to include, at a minimum, designated uses providing for the protection of aquatic communities and human health related to consumption of fish and shellfish.

Figure 4: Clean Water Act requirements leading to fish advisories



Source: OIG analysis of Clean Water Act sections.

CWA Section 304(a) requires the EPA to develop water quality criteria (WQC) for states and tribes to use to develop water quality standards (WQS). EPA regulations found in 40 CFR Part 131.11(a) (1) provide that WQC must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect a waterbody’s designated use—such as fishable.

CWA Section 303(c) directs states and tribes to adopt WQS for their waters subject to EPA approval. CWA Section 303(c)(2)(A), and the EPA’s implementing regulations at 40 CFR Part 131, require that state and tribe WQS specify appropriate designated uses of the waters (in this case fishable uses), and that WQC protect those uses. Along with other factors, the WQS dictate the need for, and the content of, fish advisories that define the amount and rate of consumption of fish containing methylmercury.

The EPA published a national WQC for methylmercury in 2001. This criterion described the concentration of methylmercury in freshwater and estuarine fish and shellfish tissue that would protect consumers of fish and shellfish among the general population. Because of methylmercury’s unique bioaccumulation process in fish tissue, this is the first time the EPA established water quality criterion based on a contaminant in fish tissue rather than the amount of a contaminant in the water column.

Once WQC and WQS are established, states and tribes may use these measures to develop fish consumption advisories. The EPA does not develop and publish fish advisories. Local fish advisories for lakes, rivers and other water bodies are developed and published by states and tribes. However, the EPA does maintain a searchable database of all fish advisories that the public can access through the EPA’s internet site.

EPA Responsibilities Under Federal Indian Policy

The U.S. recognizes tribes as sovereign nations. Tribal sovereignty is recognized through the government-to-government relationship that tribes have with the federal government. Like other treaty obligations of the U.S., Indian treaties are considered to be the supreme law of the land, and they are the foundation upon which the federal Indian trust relationship is based. The federal Indian trust responsibility involves a legal obligation under which the U.S. has charged itself with moral obligations of the highest responsibility and trust toward Indian tribes. The trust responsibility establishes the federal government's legal fiduciary obligations to tribes, including the protection of treaty-reserved fishing rights. Although tribes are sovereign nations, the U.S. has a trust responsibility to protect tribal resources and treaty right.

Based on the EPA's Federal Indian Policy published in November 1984, the EPA must recognize tribal governments as sovereign entities with primary authority and responsibility for the reservation populace; retain responsibility for managing programs for reservations until tribal governments are willing and able to assume full responsibility for delegable programs; and encourage communication and cooperation among tribes, states and local governments.

Many tribes have members who are unique subsistence fishers. They consume large amounts of contaminated fish. They also have treaty rights that give them considerable latitude to fish on and off the reservation, and to take large amounts of fish without restrictions. These fishing rights can be exercised irrespective of state-owned/controlled land or state borders.

According to EPA's policy, some treaties explicitly name protected rights and resources. For example, a treaty may reserve or protect the right to hunt, fish or gather a particular animal or plant in specific areas. Similarly, the policy notes that an explicit treaty right to hunt, fish or gather may include an implied right to a certain level of environmental quality to maintain the activity or a guarantee of access to the activity site.

EPA Supports States and Tribes That Develop Fish Advisories

The EPA assists states and tribes by issuing risk communication and fish advisory guidance, and by providing leadership in meeting the challenges of fish contamination. For example, the EPA developed guidance to assist states and tribes with communicating fish consumption advisories in 1995. This fish advisory guidance walks users through a five-part process to develop a robust risk communication program: (1) problem analysis and developing objectives; (2) audience identification and needs; (3) communication strategy design; (4) communication strategy implementation; and (5) evaluation. The EPA also supports state and tribal fish advisory efforts through the periodic National Forum on Contaminants in Fish.

Responsible Offices

The EPA's Office of Water, Office of Science and Technology, develops guidance and conducts advisory and outreach programs designed to assist states and tribes with fish advisory programs. The Office of International and Tribal Affairs leads and coordinates agencywide efforts to strengthen public health and environmental protection in Indian country, with a special emphasis on helping tribes administer their own environmental programs. The EPA's Office of Research and Development supports the agency's mission to protect human health by identifying and characterizing the health hazards of chemicals found in the environment through its Integrated Risk Information System.

Noteworthy Achievements

The EPA hosts the National Forum on Contaminants in Fish to present and discuss the latest science and public health policies pertaining to the health risks and benefits of fish consumption. The EPA has hosted the forum 12 times since 1990. Our review identified the forum as a beneficial gathering that enables state and tribal representatives to learn about new science, exchange best practices, and make contacts for the future. The EPA also maintains a series of web-based advisory and technical resources to further support state and tribal risk communication efforts. These resources include scientific data, a clearinghouse of fish tissue data and fish consumption advisories from states, a list of contacts and partners, and access to past forum proceedings.

Many stakeholders that we interviewed applauded the EPA for hosting the fish forum and stated that they would like to see the EPA continue to host the forum in the future. We found that the forum is effective for communicating the risk of consuming fish contaminated by mercury, and (if possible) we suggest the EPA continue to conduct the forum on a regular basis in the future.

Scope and Methodology

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the evaluation to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our evaluation objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our evaluation objective. We conducted this evaluation from September 2015 to December 12, 2016.

Our evaluation focused on EPA activities that develop a protective WQC, and support state and tribal fish advisories for methylmercury contaminated fish. We

did not evaluate fish consumption advisories for chemicals other than mercury. To answer our objective question, we conducted a literature review on issues relating to the hazards of methylmercury, fish consumption rates, and the issuance and efficacy of state and tribal fish advisories. Based on our literature review, we focused on the authorities and/or activities used by the EPA, states and tribes to implement and manage risk communication to the public. We focused on locations throughout the country that had large or numerous waterbodies used for subsistence, recreational or sport fishing. We also focused on subpopulations or groups most vulnerable to methylmercury in fish because of their greater-than-average fish consumption rates.

We interviewed staff from the EPA and five states regarding their risk communication efforts to inform the public about the hazards of methylmercury, fish consumption rates, and fish advisories. Staff we interviewed at EPA headquarters were from the Office of Water, the Office of Research and Development, and the Office of Tribal and International Affairs. Staff in EPA Regions 4, 5 and 10 were interviewed as well. We also interviewed staff from environmental protection and health departments in Florida, Wisconsin, Oregon, Minnesota and Washington.

In addition, we interviewed members and representatives from the Miccosukee Tribe of Indians, Seminole Tribe of Florida, Squaxin Island Tribe, Confederated Tribes of the Grand Ronde Community of Oregon, and Eastern Band of Cherokee Indians. Subject-matter experts from academia and other stakeholders, such as the Great Lakes Indian Fish and Wildlife Commission, and the Columbia River Inter-Tribal Fish Commission, were also interviewed.

The scope of our work did not include an evaluation of the national fish advisory because it falls under the purview of the FDA, not the EPA. We also did not evaluate the consumption of fish-eating mammals.

Results

Fish advisory information does not effectively reach many subsistence fishers, including tribes and other groups that consume large amounts of wild-caught fish on a regular basis. Risk communication efforts are ineffective in many instances because fish advisory information is conflicting, confusing, too complex and often not followed. In addition, individual states publish different advisory information for the same waterbody, and state fish advisory information does not regularly reach tribes that routinely fish state waters. Consequently, subsistence fishers consume large amounts of contaminated fish without adequate health warnings. Further, the EPA, states and tribes may not be aware of the effectiveness of existing fish advisories, since less than half of states and no tribes have adequately evaluated the effectiveness of fish advisories as outlined in the EPA's 1995 risk communication guidance.

The EPA's 2001 oral reference dose (RfD) for methylmercury has not been assessed as proposed in its published agendas. Based on its Integrated Risk Information System, the EPA included methylmercury on its 2012 agenda for assessment, and on its 2015 agenda as a priority for assessment. However, to date, the agency has not started the assessment. The RfD must be accurate and based on the best available science to support development of protective fish advisories. Without effectively developed and communicated fish advisories, consumers may be exposed to unsafe levels of methylmercury through the consumption of fish.

Advisory Information Does Not Reach Many Subsistence Fishers

Fish advisory information does not reach some groups, such as subsistence fishers (including tribes), sport fishers, and others that consume higher amounts of fish than the average population. For example, the San Francisco Department of Health Services surveyed subsistence fishers in the Bay area and found that 90 percent of the people interviewed ate what they caught, but 42 percent did not have knowledge of active fish advisories for those waters, even though many had fished the same waters for more than 10 years.



Local fisherman at a Florida canal. (EPA OIG photo)

Although research shows that one of the most effective ways to provide fish advisory information to these groups is to post the advisory information at the site where fish are caught, we did not observe any fish advisory information posted at fishing sites we visited. We also found instances where state fish advisory information did not reach tribal members who routinely fish state waters adjacent to the reservations.

Fish Advisory Information Is Not Posted

We visited three reservoirs in North Carolina, a lake in Georgia, three public boat ramps in Florida, and several Columbia River treaty fishing access sites in Oregon and Washington.¹ All of these waterbodies have state-published fish consumption advisories; however, we did not find any fish advisory information at these locations.



Information board at a fishing reservoir has no fish advisory information. (EPA OIG photo)

Research shows that posting fish advisory information at the site where fishers enter the waterbody or where fish are caught are some of the most effective ways to provide fish advisory information to fishers.

For example, in 2010, the EPA conducted a survey on the awareness and effectiveness of the Mississippi Delta fish consumption advisory. The agency found that the majority of survey respondents obtained advisory information from signs posted at the affected waterbody as opposed to other methods of communication, including television news, talk shows or radio.

In a similar report on contaminated fish in San Francisco Bay, fishers stated that one of the best methods for getting fish advisory information to fishers was through posted signs. By posting fish advisory information at the source location where fish are caught, states and tribes can more effectively provide advisory information.

In addition, we identified the use of social media as another promising method for informing subsistence fishers. An organization that develops its social media outreach can issue advisories through Facebook and Twitter. Organizations can then confirm the reach of these posts through analytical tools built into social media platforms.

Some Tribes Do Not Receive State Advisory Information

During an on-site interview, a tribal representative said tribe members routinely take fish from state reservoirs adjacent to the reservation, but many tribe members do not know about state fish advisories for those reservoirs. The tribal representative said the tribe (because of its sovereignty) does not have a governance arrangement with the state, wherein fish advisory information would

¹ We visited the Hiawassee, Santeetlah, and Fontana reservoirs in North Carolina; Lake Allatoona in Georgia; public boat ramps along the Tamiami Trail East in Florida; and the North Bonneville, Cooks, Underwood, and White Salmon treaty fishing access sites along the Columbia River in Washington and Oregon.

be shared, and the tribe does not issue its own advisories for those reservoirs. Tribal leaders said they would welcome the EPA or state officials providing relevant fish advisory information to their chief or community leader, who would then ensure that the information is passed on to every member of the tribe.

In another state, tribal representatives said tribe members routinely consume certain fish species as a traditional food source and cultural norm. However, for most waterbodies, the statewide fish consumption advisory recommends that no

Dilemma Between Two Governments

Treaties grant tribal nations unlimited access to hunt, fish and gather on lands ceded to the U.S. However, fish advisories place a limit on the amount of fish to be consumed and frequency of consumption to avoid adverse health effects. Some tribes we visited expressed a concern that fish advisories limit their treaty rights because the tribes cannot safely consume unlimited amounts of fish.

Tribes suggested that the EPA has a constitutional obligation to honor tribal rights by protecting fish resources granted by treaty. However, the U.S. government cannot control all sources of mercury entering the atmosphere that cycles through the environment and ultimately into fish. Consequently, fish advisories are needed to provide useful health information about the amount and frequency that fish should be consumed.

one eat *any* of this particular fish species. For example, members of one Florida tribe eat fish contaminated with methylmercury at much higher rates than most Americans. While Florida has issued fish advisories for many of the waters on and near the tribe's reservation, tribe members have not received this advice, and the tribe has not communicated its own fish advisory information to tribe members.

The EPA does provide fish advisory guidance and supporting data for advisories. Through its risk communication and fish advisory guidance, the EPA can help states and tribes identify and address conflicting fish advisories across borders to ensure that clear and meaningful advisory information is provided to fish consumers.

In situations where state fish consumption information is not reaching tribes, the EPA can take a leadership role and ensure that vital fish advisory information is provided to affected tribes. Moreover, the EPA can better protect the health of subsistence fishers and other groups by identifying the areas where fish consumption is high and fish advisory information is nonexistent.

Advisories Provide Conflicting, Confusing and Complex Advice

Fish consumption advisories sometimes provide conflicting and confusing advisory information from the federal government, and from states that share common waterbodies. Without clear information, consumers may not know which fish they should avoid, how much fish they may safely consume, and whether advisories apply to them specifically or to other groups (e.g., women of child-

bearing age, adolescents, adults, etc.). Because the information that advisories are based on may vary nationally, among states, and between states and tribes, the EPA can take a leadership role by promoting consistency to help reduce confusion.

Conflicting and Confusing Advisory Information

Federal agencies publish fish advisories, dietary guidelines for fish consumption, and varying toxicity levels for safe consumption of fish contaminated with mercury. These agencies serve different missions and deliver different messages to their audiences, but these differing messages create confusion for fish consumers. For example, the FDA issues a national fish advisory; but the advisory only applies to commercially marketed fish, and only addresses pregnant and breastfeeding women, those who might become pregnant, and young children. This national fish advisory is different from local fish advisories issued by states and tribes.

The FDA action level and EPA screening values serve different purposes, but they are often interpreted by the public as the same advice. This leads to confusion. The FDA established an enforcement action level at 1.0 parts per million (ppm) for mercury in fish. The FDA can remove any fish with mercury readings above 1.0 ppm from commercial store shelves. The EPA has developed a screening value of 0.049 ppm for those individuals who eat a great deal of fish—commonly referred to as subsistence fishers. In addition, the EPA has determined that 0.4 ppm is a safe upper limit for mercury in fish when consumption and other sources of exposure are limited. At levels above 0.4 ppm the EPA recommends consumption restrictions.

Comments we received from a scientist, a dietician, and an analyst reflect the confusion they see with advisories that target the fish-consuming public.

- A leading Harvard mercury researcher said: “I feel like confusion is reigning. The federal fish advisories need clarity and conflict avoiding messaging.”
- A nationally known dietician said: “I think there is a lot of misinformation out there. I think when it comes to mercury in fish, people simply don’t know where to go for information.”
- A Senior Analyst with the Environmental Advocacy Group said, “The agency needs to focus on separating out the risks and the benefits of eating fish.”

The U.S. Department of Health and Human Services, and the U.S. Department of Agriculture jointly publish the “Dietary Guidelines” that advocate for fish and shellfish consumption because of the health benefits for the general population, and for women who are pregnant or breastfeeding. The Dietary Guidelines encourage choosing fish higher in essential nutrients—such as Omega-3s—but lower in methylmercury.

In 2002, the state of Alabama used the FDA’s action level of 1.0 ppm for mercury to establish its fish consumption advisory instead of the EPA’s recommended maximum level of 0.29 ppm. This meant the state’s fish consumption advisory could allow methylmercury levels three times higher than the maximum levels recommended by the EPA. Under the CWA, Alabama should have used the EPA’s value of 0.29 ppm or developed their own water quality standard for its fish advisories. Currently, all EPA Region 4 states, including Alabama, use the EPA’s methylmercury consumption limits when developing fish advisories.

State-to-State Advisories Conflict

Fish advisories across state lines can conflict and lead to unclear advice. A single waterbody common to different states may have different fish advisories. For example, the fish advisories for polychlorinated biphenyls (PCBs) from Maryland to Virginia urge fishers to limit their consumption of the region’s most popular catch—striped bass—because its flesh may contain traces of toxic substances acquired from other fish and the waters in which the fish swim.

Recommendations vary from “do not eat” for striped bass caught in the Washington, D.C., portion of the Chesapeake Bay’s tidal rivers, to as many as three servings per month for the same fish caught in the Maryland portion of the Bay. Meanwhile, Virginia advises fishers to eat no more than two servings per month of striped bass caught in that state’s end of the Chesapeake Bay. For Washington, D.C., Maryland and Virginia, the difference in consumption advice reflects the testing methods they use. (Figure 5).

Figure 5: Conflicting fish advisories in Maryland, Washington, D.C., and Virginia



Source: OIG developed, and based on the review of selected state and Washington, D.C., fish advisories.

Some Fish Advisories Are Complex and Difficult to Understand

States and tribes publish local fish advisories, but those advisories can be complex and difficult to understand. For example, in the Great Lakes region where 35 federally recognized tribes exist, the Bad River Advisory illustrates the challenge of creating a simple, easy-to-follow guide for fish consumption (Appendix A). The Bad River Advisory contains complicated information that a consumer would need to study and analyze. The advisory includes the following information:

- Two different maps and two different sets of instructions (one for high-risk and the other for low-risk segments of the populations).
- Different advisories for different lakes (dozens in total).
- Lake-by-lake recommendations on the maximum number of walleye meals to consume per month.

- A warning to adjust the number of walleye meals per month, depending on the size of portions consumed.
- A suggestion to bag and label walleye according to portion size and lake of origin before freezing the fish.
- A recommendation to avoid certain other fish species altogether.

For tribes that consume large quantities of self-caught fish, avoiding methylmercury overexposure requires navigating a myriad of complex advisory information. Through its leadership, the EPA can guide states and tribes to examples of clearly communicated fish advisories.

Minimal Information on Advisory Effectiveness



Fisherman preparing his line at the Santeetlah Reservoir in North Carolina. (EPA OIG photo)

The EPA, states and tribes have not consistently evaluated the effectiveness of fish advisory information that reaches targeted audiences. The EPA's 1995 *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories* recommends that states and tribes establish an evaluation component to help them determine whether their fish advisories succeed.² This guidance says that states and tribes can use evaluations to help (1) ensure that a health advisory communication program is designed to meet the needs of the target audiences and the objectives of the agency; (2) monitor whether the communication program is being implemented as intended; and (3) assess the extent to which audience needs and agency objectives have been met.

However, the majority of states and tribes do not have an evaluation system in place. Since the EPA issued its initial fish advisory guidance to states and tribes in 1995, the agency found that 24 states and no tribes have evaluated the effectiveness of their advisories on the public's awareness of the hazards associated with consuming fish contaminated by methylmercury.

Evaluations can identify areas where people do not receive the advisories, where advisory information is unclear, or where other factors may be essential to operating an effective risk communication program. Through its leadership and guidance, the EPA should continue to encourage state and tribe evaluation efforts,

² The EPA's Office of Water, Office of Science and Technology. *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories*, Volume 4: Risk Communication. February 1995.

and provide examples or templates that can be used to establish and operate effective evaluation programs.

Ensuring That Consumption Advice Uses Up-to-Date Science

The EPA's 2001 reference dose for methylmercury is an agency-supported value that remains accepted by EPA for decision-making. However, the current reference dose does not include recent epidemiological studies on mercury health effects. Since the EPA established the current RfD 15 years ago, several new scientific studies relating to the impacts of methylmercury on human health have emerged and added new information to the scientific literature.

We interviewed the research scientist whose work contributed to the EPA's original RfD. He stated that although the present RfD was acceptable because it was based on the best available science in 2001, the RfD is in need of an assessment because additional scientific research has been completed. We also interviewed another research scientist who made several contributions to the EPA's National Fish Forum in 2014. He also indicated the RfD was in need of an assessment and identified 22 additional epidemiological studies related to the impacts of methylmercury on human health—studies that were conducted between 2001 and 2015 (Appendix B). According to these scientists, the studies present up-to-date scientific research on the impacts of methylmercury and may provide relevant information for the development of a revised RfD. Figure 6 illustrates how the RfD is used to calculate the ambient water quality criterion (AWQC).

Based on its Integrated Risk Information System, the EPA included methylmercury on its 2012 agenda for assessment to begin in fiscal year 2014, and on its 2015 agenda as a priority for assessment. However, to date, the agency has not started the assessment.

Because the RfD serves as a primary scientific risk assessment factor for deriving the AWQC, and ultimately determining the content of fish advisories, if the RfD is too high, the resulting water quality standards and fish advisory information may not be protective. On the other hand, if the RfD is too restrictive, limiting fish consumption may also limit the nutritional benefits of fish consumption. Moreover, the EPA's RfD is used by other federal agencies, states, local health departments, tribes and other local entities to determine human health impacts; determine waterbody impairments; and develop local water quality criteria.

Figure 6: Formula that the EPA, states and tribes use to develop ambient water quality criterion

The generalized equations for deriving AWQC based on noncancer effects are:

$$AWQC = RfD \cdot RSC \cdot \left(\frac{BW}{DI + \sum_{i=2}^4 (FI_i \cdot BAF_i)} \right)$$

AWQC = Ambient Water Quality Criterion (mg/L, or milligrams/Liter)

RfD = Reference dose for noncancer effects (mg/kg-day, or milligram/kilogram-day)

RSC = Relative source contribution factor to account for non-water sources of exposure

BW = Human body weight (default = 70 kg for adults)

DI = Drinking water intake (default = 2 L/day for adults)

FI = Fish intake (defaults = 0.0175 kg/day for general population and sport anglers, and 0.142 kg/day for subsistence fishers)

BAF = Bioaccumulation factor, lipid normalized (L/kg)

Source: EPA Methodology for Deriving Ambient Water Quality Criterion for the Protection of Human Health (2000).

Without effectively developed and communicated fish advisories, consumers may be exposed to unsafe levels of methylmercury through the consumption of fish. The EPA shares the responsibility of protecting public health and the environment from methylmercury contamination with states and tribes. The criteria and standards that the EPA develops and approves should ensure that the CWA's goal of "fishable" waters is obtained, and that fish advisories are based on the best available science and are routinely evaluated to determine their effectiveness.

Conclusion

Based on its mission to protect human health, and its responsibilities under the CWA and EPA's Indian Policy, the EPA should take a leadership role in guiding and working with states and tribes to develop and distribute fish advisories that provide meaningful information that reaches all segments of the public. The EPA can act as a bridge connecting federal agencies, states and tribes to ensure that risk communication efforts are effective in providing the public with relevant information to help make healthy fish consumption choices.

Recommendations

We recommend that the Assistant Administrator for Water:

1. Provide updated guidance to states and tribes on clear and effective risk communication methods for fish advisories, especially for high-risk groups. This guidance could recommend posting fish advisory information at locations where fish are caught; and using up-to-date communication methods that include social media, webinars, emails, newsletters, etc.
2. Working with states and tribes, develop and disseminate best practices they can use to evaluate the effectiveness of fish advisories in providing risk information to subpopulations, such as subsistence fishers, tribes and other high fish-consuming groups.
3. Develop and implement methods to ensure that tribal members receive current fish advisory information.

We recommend that the Assistant Administrator for Research and Development:

4. Conduct an assessment for methylmercury to determine whether the reference dose requires updating, as indicated by the Integrated Risk Information System, and as proposed in the system's 2012 and 2015 agendas.

Agency Response and OIG Evaluation

The EPA provided a consolidated response from Acting Assistant Administrators for the Office of Water, and the Office of Research and Development. We met with agency staff to discuss their comments, and we made changes to the report as appropriate.

The agency agreed with all final report recommendations, and provided acceptable corrective actions and projected completion dates. The full agency response can be found in Appendix C. All recommendations are resolved with corrective actions pending.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS

Rec. No.	Page No.	Subject	Status ¹	Action Official	Planned Completion Date	Potential Monetary Benefits (in \$000s)
1	17	Provide updated guidance to states and tribes on clear and effective risk communication methods for fish advisories, especially for high-risk groups. This guidance could recommend posting fish advisory information at locations where fish are caught; and using up-to-date communication methods that include social media, webinars, emails, newsletters, etc.	R	Assistant Administrator for Water	Draft 9/30/2018 Final 3/31/2020	
2	17	Working with states and tribes, develop and disseminate best practices they can use to evaluate the effectiveness of fish advisories in providing risk information to subpopulations, such as subsistence fishers, tribes and other high fish-consuming groups.	R	Assistant Administrator for Water	Draft 9/30/2018 Final 3/30/2020	
3	17	Develop and implement methods to ensure that tribal members receive current fish advisory information.	R	Assistant Administrator for Water	09/30/2017	
4	17	Conduct an assessment for methylmercury to determine whether the reference dose requires updating, as indicated by the Integrated Risk Information System, and as proposed in the system's 2012 and 2015 agendas.	R	Assistant Administrator for Research and Development	12/31/2018	

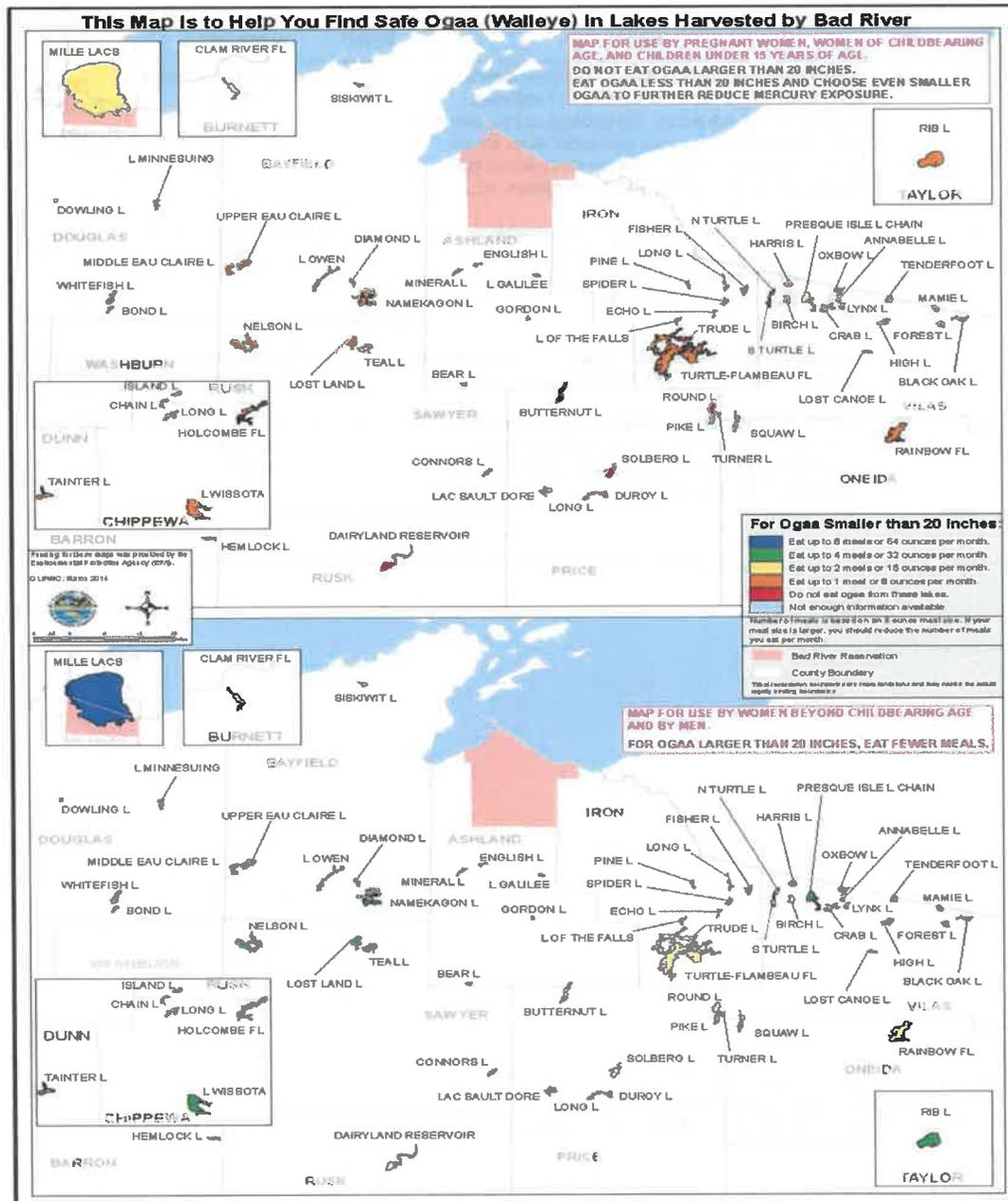
¹ C = Corrective action completed.

R = Recommendation resolved with corrective action pending.

U = Recommendation unresolved with resolution efforts in progress.

Mercury Fish Advisory for Bad River Band of Lake Superior Chippewa Tribe

Page 1 of 2



Recommended Maximum Number of Ogaal Meals per Month for Lakes Harvested by Bad River

SORTING AND LABELING OGAAL PRIOR TO FREEZING

When Cleaning Ogaal:

- Put ogaal under 20 inches in bags labeled "under 20 inches."
- Put ogaal over 20 inches in bags labeled "over 20 inches."
- Label bags with the lake name.
- Follow the advice below for maximum number of meals per month.

USING THIS CHART TO FIND SAFER GIIGOOH

MAXIMUM NUMBER OF MEALS PER MONTH

Advice is for all lakes combined. For example, if you eat four meals in a month from green lakes you should not eat any other meals of ogaal in that month.

MEAL SIZE

Meal size is based on 8 ounces. An average 19 inch ogaal will have 8 ounces of meat. If your meal size is larger you should eat fewer meals of ogaal. If it is smaller you can eat more meals of ogaal.

OTHER GIIGOOH

Ogiiooh such as muskellunge, largemouth bass, smallmouth bass, and northern pike will have more mercury than giigoooh such as lake whitefish, herring, bluegill, sunfish, crappie or perch. Try to choose safer giigoooh.

LAKE	COUNTY	Women of childbearing age and children less than 15 Maximum number of meals per month	Women beyond childbearing years and men 15 and older Maximum number of meals per month
ANNABELLE L	VILAS	2	2
BEAR L	ASHLAND	2	2
BIRCH L	VILAS	2	2
BLACK OAK L	VILAS	2	2
BOND L	DOUGLAS	2	2
BUTTERNUT L	PRICE	2	2
CHAIN L	RUSK	2	2
CLAM R FL	BURNETT	Not Enough Information	2
CONNORS L	SAWYER	2	2
CRAB L	VILAS	2	2
DAIRYLAND RESERVOIR	RUSK	2	2
DIAMOND L	BAYFIELD	2	2
DOWLING L	DOUGLAS	2	2
DUROY L	PRICE	2	2
ECHO L	IRON	2	2
ENGLISH L	ASHLAND	2	2
FISHER L	IRON	Not Enough Information	2
FOREST L	VILAS	2	2
GORDON L	ASHLAND	Not Enough Information	2
HARRIS L	VILAS	2	2
HEMLOCK L	BARRON	Not Enough Information	2
HIGH L	VILAS	2	2
HOLCOMBE FL	CHIPPEWA	2	2
ISLAND L	RUSK	2	2
L GALILEE	ASHLAND	2	2
L MINNESUING	DOUGLAS	2	2
L OF THE FALLS	IRON	Not Enough Information	2
L OWEN	BAYFIELD	2	2
L WISSOTA	CHIPPEWA	2	2
LAC SAULT DORE	PRICE	2	2
LONG L	CHIPPEWA	2	2
LONG L	IRON	2	2

LAKE	COUNTY	Women of childbearing age and children less than 15 Maximum number of meals per month	Women beyond childbearing years and men 15 and older Maximum number of meals per month
LONG L	PRICE	2	2
LOST CANOE L	VILAS	Not Enough Information	2
LOST LAND L	SAWYER	2	2
LYNX L	VILAS	2	2
MAMIE L	VILAS	2	2
MIDDLE EAU CLAIRE L	BAYFIELD	2	2
MILLE LACS	MILLE LACS	2	2
MINERAL L	ASHLAND	2	2
N TURTLE L	VILAS	2	2
NAMEKAGON L	BAYFIELD	2	2
NELSON L	SAWYER	2	2
OXBOW L	VILAS	2	2
PIKE L	PRICE	2	2
PINE L	IRON	2	2
PRESQUE ISLE L CHAIN	VILAS	2	2
RAINBOW FL	ONEIDA	2	2
RIB L	TAYLOR	2	2
ROUND L	PRICE	2	2
S TURTLE L	VILAS	2	2
SISKWIT L	BAYFIELD	2	2
SOLBERG L	PRICE	2	2
SPIDER L	IRON	2	2
SQUAW L	VILAS	2	2
TANTER L	DUNN	2	2
TEAL L	SAWYER	2	2
TENDERFOOT L	VILAS	2	2
TRUDEL	IRON	2	2
TURNER L	PRICE	2	2
TURTLE-FLAMBEAU FL	IRON	2	2
UPPER EAU CLAIRE L	BAYFIELD	2	2
WHITEFISH L	DOUGLAS	2	2

For many native people, giigoooh are part of a traditional and healthy diet. If you rely on giigoooh, choose safer giigoooh with lower levels of mercury by following the advice on this map.

RISKS AND BENEFITS

Risk: Mercury can damage the nervous system, especially the brain. Fetuses and babies are the most at risk because their nervous systems are rapidly developing. Children exposed to unsafe levels while in the womb have been found to experience delayed development in walking and talking, even though the mother was not affected. Mercury cannot be removed by trimming or cooking.

Benefit: Eating even as few as two to three meals of giigoooh a month may reduce your risk of death due to heart disease.



If you have questions about finding safer ogaal, call GLIFWC at 1-715-632-6619. To learn more about mercury in ogaal, visit GLIFWC's website at www.glifwc.org/Mercury/mercury.html

Source: Supreme Court, Brief of *Amici Curiae* National Congress of American Indians, federally recognized Indian Tribes, and Inter-Tribal Fish Commissions in Support of Respondents.

Literature Review of Methylmercury Epidemiological Studies

We reviewed reports from health and environmental publications for information about potential public health and environmental impacts. Many additional studies have been conducted on the effects of eating fish contaminated with mercury since the EPA's methylmercury RfD dose was issued in 2001. Some of these studies are listed below.

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Received on February 28, 2017

Agency Response to Draft Report

MEMORANDUM

SUBJECT: Response to Office of Inspector General Draft Report No. OPE-FY15-0061 — EPA Needs to Provide Leadership and Better Guidance to Improve Fish Advisory Risk Communications, dated December 2016

FROM: Michael Shapiro
Acting Assistant Administrator
Office of Water

Robert Kavlock
Acting Assistant Administrator
Office of Research and Development

TO: Carolyn Copper
Assistant Inspector General
Office of Inspector General

Thank you for the opportunity to respond to the issues and recommendations in the subject audit report. Following is a summary of the agency's overall position, along with its position on each of the report recommendations. We have provided high-level intended corrective actions and estimated completion dates to the extent we can. For your consideration, we have included a Technical Comments Attachment to supplement this response.

AGENCY'S OVERALL POSITION

EPA appreciates being provided with the opportunity to share the most current information on fish advisories and efforts to reevaluate the oral reference dose (RfD) for methylmercury. This response includes comments from the Office of Water (Headquarters; Regions 4, 5, 6, and 10; and the Great Lakes National Program Office) and the Office of Research and Development.

EPA generally agrees with the findings in this report, pending suggested changes noted in this memo and in a Technical Comments Attachment that corrects some errors we found during our review and suggests some clarifications. We have concerns with some of the OIG's recommendations and conclusions and believe modifications are needed to improve clarity and avoid a misrepresentation of both the fish advisory and IRIS processes. Adjusting the second, third and fourth recommendations as suggested will result in more meaningful corrective actions and ultimately, better public health protection for those who eat fish.

EPA would like to alert you to an example of recent leadership regarding fish advisory communications. EPA and FDA released their joint national-level fish advisory on January 18, 2017. This easy-to-understand advisory provides information for the high-risk groups of women of child-bearing age and children, and it is consistent with other federal messages, such as those found in the *2015-20 Dietary Guidelines for Americans*. We also appreciate your support for our leadership of the National Forum on Contaminants in Fish and our web-based advisory and technical resources which are included in the “Noteworthy Achievement” section of the report.

We request that you include the entirety of this response as an appendix to the OIG final report.

AGENCY’S RESPONSE TO REPORT RECOMMENDATIONS

Agreements

Recommendation 1: “Provide updated guidance to states and tribes on clear and effective risk communication methods for fish advisories, especially for high-risk groups. This guidance could recommend posting fish advisory information at locations where fish are caught; and using up-to-date communication methods that include social media, webinars, emails, newsletters, etc.”

Response: Develop a draft updated version of *Volume 4: Risk Communication* of the *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories*.

Recommendation 2: “Working with states and tribes, develop and disseminate best practices they can use to measure the effectiveness of fish advisories in providing risk information to subpopulations, such as subsistence fishers, tribes and other high fish-consuming groups.”

Response: EPA concurs with the end goal of the recommendation – making sure high-risk subpopulations receive information on risks of eating certain fish. EPA understands the benefits of evaluating the effectiveness of fish advisory programs and agrees that working with the states and tribes in that area would benefit the fish advisory programs as well as the fishing population.

Recommendation 3: “Develop and implement methods to ensure that tribal members receive current fish advisory information.”

Response: EPA agrees with the goal of tribes receiving fish advisory information and thinks EPA can facilitate that communication.

Recommendation 4: “Conduct an assessment for methylmercury to determine whether the reference dose requires updating, as indicated by the Integrated Risk Information System, and as proposed in the system’s 2012 and 2015 agendas.”

Response: Following discussion with OIG, we have come to an understanding of OIG’s use of the term “assessment” as presented in the existing recommendation. ORD generally concurs with the recommendation pending clarifications to the report language, including OIG conclusions as noted below and in the Technical Comments Attachment.

EPA disagrees with the OIG's conclusion that the EPA's oral RfD for methylmercury is overdue for an update because methylmercury was included as a priority in the 2012 and 2015 multi-year agendas. The OIG correctly reports that methylmercury was included in the 2015 multi-year agenda and was among the 6 chemicals listed as highest priority for evaluation. However, inclusion of a chemical on the multi-year agenda does not indicate a determination of whether any specific toxicity value, such as the RfD, requires updating. Importantly, IRIS has not yet determined that the RfD for methylmercury requires updating. Updating or reassessing a toxicity value within the IRIS assessment development process can be made after scoping (to identify Agency partner needs) and problem formulation (to frame scientific questions in the assessment) are conducted. Only then can a determination be made that the methylmercury RfD should be reassessed to update the reference dose (among other toxicity values).

In addition, EPA does not agree with the OIG determination that since the current RfD for methylmercury does not include recent epidemiological studies on mercury health effects, it is therefore overdue for reassessment. This presumption incorrectly focuses on making a determination whether the RfD requires updating based on the identification of selected scientific literature that post-dates the 2001 IRIS methylmercury RfD. We recognize that the publication of epidemiological studies on mercury health effects has added information to the scientific literature. However, the existence of new literature does not automatically trigger a need for a reassessment, nor does it necessarily discredit an existing IRIS value. Determination of whether new literature provides information that warrants reassessment of the RfD can be made after scoping and problem formulation are conducted.

Accordingly, ORD respectfully requests the OIG conclusions be clarified, as well as state that the IRIS Program has not yet made a determination on whether the RfD requires updating.

Actions and Timeframes to Respond to OIG Recommendations

No.	Recommendation (including proposed revision)	EPA Office	High-Level Intended Corrective Action(s)	Estimated Completion by Quarter and FY
1	Provide updated guidance to states and tribes on clear and effective risk communication methods for fish advisories, especially for high-risk groups. This guidance could recommend posting fish advisory information at locations where fish are caught; and using up-to-date communication methods that include social media, webinars, emails, newsletters, etc.	OW	Develop a draft updated version of <i>Volume 4: Risk Communication of the Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories</i> . Release final version.	Draft: 4 th Q FY2018 Final: 2 nd Q FY2020
2	Working with states and tribes, develop and disseminate best practices they can use to measure the effectiveness of fish	OW	Develop draft guidance that identifies best practices to measure the	Draft: 4 th Q FY2018

No.	Recommendation (including proposed revision)	EPA Office	High-Level Intended Corrective Action(s)	Estimated Completion by Quarter and FY
	advisories in providing risk information to subpopulations, such as subsistence fishers, tribes and other high fish-consuming groups.		effectiveness of fish advisories. Release final version.	Final: 2 nd Q FY2020
3	Develop and implement methods to ensure that tribal members receive current fish advisory information.	OW	Send EPA's fish advisory program newsletter to tribes. Work with Regions and OITA to share current fish advisory information with tribes.	3 rd Q FY 2017 4 th Q FY 2017
4	Conduct an assessment for methylmercury to determine whether the reference dose requires updating, as indicated by the Integrated Risk Information System, and as proposed in the system's 2012 and 2015 agendas.	ORD	Within the broader IRIS assessment development process, identification of whether a specific toxicity value (such as the reference dose) requires updating is accomplished following scoping and problem formulation. The IRIS Program will complete scoping and problem formulation for methylmercury and determine whether the reference dose needs to be updated.	1 st Q FY 2019

CONTACT INFORMATION

If you have any questions regarding this response, please contact Laura Drummond, Audit Follow-up Coordinator of the Office of Water at 202-564-6561 or Drummond.laura@epa.gov or Maureen Hingeley, Audit Follow-up Coordinator of the Office of Research and Development at (202) 564-1306 or Hingeley.maureen@epa.gov.

Attachment

Technical Comments

CC: Arthur Elkins
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Benita Best-Wong
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Technical Comments Attachment

EPA Comments on the Draft December 2016 OIG Report: *EPA Needs to Provide Leadership and Better Guidance to Improve Fish Advisory Risk Communications*

The following table compiles errors and areas needing clarification found during the Office of Water's review of the draft report. Suggestions provided by the Office of Research and Development follow the table.

Page	Suggestion type	Suggestion and Rationale
2	Clarification	In the first sentence in the first paragraph of the <i>Human Health Effects From Mercury</i> section, you may want to specify that the 2001 criterion is for methylmercury. EPA has more than 100 water quality criteria just to protect human health, with 60 more to protect aquatic life.
2	Clarification	In the second paragraph of the <i>Human Health Effects From Mercury</i> section, it discusses that the most frequently consumed commercial fish contain low levels of methylmercury, which is true. However, you may want to mention that 7 types of commercially available fish contain high levels of methylmercury, and women of childbearing age and young children should avoid eating them. It is not just wild-caught fish that have high levels of mercury.
2	Clarification	In the second paragraph of the <i>Human Health Effects From Mercury</i> section, please clarify that wild-caught fish may contain high levels of methylmercury depending on location, species, and size of the fish since methylmercury tends to be higher in older, larger, predatory species.
2	Correction	We suggest using an EPA source for average fish consumption rates in Figure 3. If that source is used, the Suquamish Tribe consumes 7.5 times more fish than the average population on a daily basis.
3	Correction	In Figure 3, we suggest using an EPA source for average fish consumption rates: <i>Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003-2010)</i> , which can be found at https://www.epa.gov/fish-tech/estimated-fish-consumption-rates-reports . EPA has used a fish consumption rate of 22 grams per day, found in that document and is the freshwater and estuarine (or nearshore) 90th percentile rate for all consumers, in its human health criteria recommendations since 2015.
3	Correction	Non-national advisories are done at both the state and local levels, not just local. It is not uncommon to have state-wide advisories.
3	Correction	Neither EPA nor FDA has a statutory or regulatory requirement to issue a national-level fish advisory. The joint collaboration is a voluntary effort.
3	Clarification	The report indicates that EPA is responsible for local fish advisories. Fish consumption advisories are generally produced by state health departments, which are not the state environmental agencies EPA usually interacts with.
3	Correction	Water quality criteria, whether developed by EPA or the states, are not used to develop fish advisories. Instead, states and tribe use the reference dose for non-carcinogenic compounds like mercury and the cancer potency factor and the maximum acceptable risk level for carcinogenic compounds. The reference dose is used in an equation that calculates maximum allowable consumption

Page	Suggestion type	Suggestion and Rationale
		rates. Please see chapter 3 of <i>Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories: Volume 2 - Risk Assessment and Fish Consumption Limits, Third Edition</i> for more information.
3-4	Correction	EPA establishes water quality criteria <i>recommendations</i> . States and tribes are not required to adopt EPA's recommendations; they can submit criteria for approval that they developed. Because criteria are not used in developing fish advisories, we recommend removing all text referring to water quality criteria and water quality standards, including Figure 4.
3	Correction	EPA's Office of Research and Development derives the contaminant toxicity values in IRIS that are used in fish advisories. Those toxicity values are not developed under the purview of the Clean Water Act.
3	Clarification	We recommend including a citation to CWA § 101(a)(2) when you first mention the goal of "fishable, swimmable" waters.
4	Correction	In Figure 4, EPA develops water quality standards for states and tribes only where the Administrator determines they are necessary.
4	Correction	Water quality standards do not dictate the content of or need for fish advisories. While fish advisories and water quality criteria use similar risk assessment tools, a water quality criterion or standard does not trigger a fish advisory. An advisory is the amount of fish that can be safely consumed for a given contaminant level found in fish tissue from a particular waterbody. A water quality criterion is a regulatory value that specifies acceptable levels of a chemical in the nation's waters.
4	Typographic	"Protest" should be "protect."
4	Clarification	While states and tribes may use water quality criteria and water quality standards to develop fish consumption advisories, they are not obligated to and they often identify other action levels to use instead. In addition, water quality criteria are based on exposure from multiple sources whereas fish advisories focus solely on exposure from eating fish.
4	Clarification	EPA has not updated its searchable database of fish advisories since 2011.
5	Clarification	<p>The topic of tribal treaty rights and fish consumption is a little more nuanced than as expressed in the third paragraph in the "EPA Responsibilities Under Federal Indian Policy" section. EPA suggests something like: "Many tribes consume higher amounts of fish and shellfish than the general population. Some tribes hold reserved rights to take fish for subsistence, ceremonial, religious, and commercial purposes, including in waters under state jurisdiction. Their consumption habits may or may not be affected by health warnings about contaminated fish."</p> <p>In addition to contamination, suppression may play a role in impeding treaty rights regarding fish. As noted by the National Environmental Justice Advisory Council in the 2002 publication <i>Fish Consumption and Environmental Justice</i>, "a suppression effect may arise when fish upon which humans rely are no longer available in historical quantities (and kinds), such that humans are unable to catch and consume as much fish as they had or would. Such depleted</p>

Page	Suggestion type	Suggestion and Rationale
		fisheries may result from a variety of affronts, including an aquatic environment that is contaminated, altered (due, among other things, to the presence of dams), overdrawn, and/or overfished. Were the fish not depleted, these people would consume fish at more robust baseline levels. . . . In the Pacific Northwest, for example, compromised aquatic ecosystems mean that fish are no longer available for tribal members to take, as they are entitled to do in exercise of their treaty rights.”
5	Correction	EPA does not have data to back up the statement that tribes “consume large amounts of contaminated fish.” The levels of fish contamination vary by location, species of fish, age of the fish, size of the fish, and where it exists on the food chain. Cultural norms may influence consumption of fish species that are typically low in mercury. Tribal consumption of fish may be low because of lifestyle changes from a historical fishing-dependent lifestyle, restrictions to accessing waterways, and other factors that may reduce tribal fish consumption rates.
7	Typographic	The sentence at the top of the page needs a period.
7	Correction	The last paragraph should be corrected to reflect that neither FDA nor EPA have regulatory requirements to conduct the national fish advisory.
7	Typographic	The sentence at the bottom of the page needs a period. In addition, it restates the assertion that the OIG did not evaluate contaminants other than methylmercury, which was stated two paragraphs earlier.
8	Correction	Like the comment on a similar sentence on page 5, EPA does not have data to back up the statement that “subsistence fishers consume large amounts of contaminated fish without health warnings.”
8	Clarification	In the first paragraph in the “Results” section, it would be clearer to state that only about half have adequately evaluated the effectiveness of their advisories. We would like the OIG to provide a listing of these states as an appendix to the report.
8	Clarification	While the RfD is important in developing water quality standards, because standards are not used to develop fish advisories, it would be less confusing if the statement “Because of its importance in developing water quality standards” was deleted.
8	Clarification	Is the fisher in the photo truly a subsistence fisher or just a recreational one?
8	Typographic	In the last paragraph, “group” needs an “s”.
8-9	Clarification	It would be helpful to identify specific situations where tribes do not receive advisory information. In some areas of the country (e.g., the Pacific Northwest), all of the tribes are very aware of contaminants in the water. However, some tribal members may decide that spiritual, cultural, and economic reasons for eating fish outweigh the risk any contaminants pose.
9	Typographic	In the third paragraph, “effected” should be “affected.”
10	Clarification	In the “Tribes Do Not Receive State Advisory Information” section, it would be helpful and more balanced to mention that EPA describes new and revised advisories that are posted by states in its monthly <i>Fish and Shellfish Program Newsletter</i> . Currently about one dozen tribes receive the newsletter.

Page	Suggestion type	Suggestion and Rationale
10-12	Clarification	In the “Advisories Provide Conflicting . . . Advice” section, it is entirely appropriate that fish advisories for specific fish and waterbodies should differ from advice regarding consumption of fish on a national scale. Contaminant levels within particular waterbodies differ, and these differences result in different advisories.
11	Clarification	While technically the national-level effort by FDA and EPA is an advisory, the agencies refer to it as “advice” to reduce its likelihood to scare the general public.
11	Correction	The joint FDA-EPA advice is not exclusive to commercial fish. It also mentions locally caught fish and tells people to look for local advisories and what to do if they can’t find advisory information.
11	Correction	EPA disagrees that the federal agencies publishing the fish advice, dietary guidelines, and toxicity levels deliver conflicting information. The reason FDA and EPA issue the fish advice jointly is to eliminate potential confusion by the public from potentially conflicting information from agencies with different missions. When USDA and HHS were developing the <i>Dietary Guidelines 2015-20</i> , they were in touch with FDA and EPA to make sure that the information in the Dietary Guidelines did not conflict with the joint fish advice and that both products were delivering a consistent message. See https://www.epa.gov/fish-tech/epa-fda-advice-about-eating-fish-and-shellfish .
11	Clarification	EPA does not see the importance of the point regarding FDA’s action level and EPA’s screening values as it is unlikely the general public knows about these values. More importantly, the public has access to and will easily understand the updated joint FDA-EPA fish advice, of which the most recent version is clear and easy to understand.
11	Correction	There is no federal statute or regulation that requires consumption restrictions for the average consumer if mercury concentrations in fish exceed a certain level.
11	Correction	There is a fundamental misunderstanding about the methylmercury criterion (0.3 ppm) and fish advisories. The report falsely equates the methylmercury criterion with the fish tissue concentration that would generate an advisory. The 2010 implementation guidance for methylmercury explains how and why the criterion differs from a recommended screening value for a fish advisory limit for mercury in sections 5.4.3 and 5.4.4. In section 5.4.2 it states that someone eating fish at the average rate of consumption (17.5 g/d at the time) would not exceed the RfD for methylmercury if the fish tissue concentration were 0.4 mg/kg, not 0.3 ppm as stated in the report.
11	Clarification	A criterion is a regulatory value that does not balance risks and benefits; it is only concerned with preventing unacceptable risk. An advisory may consider benefits and risks when providing consumption advice.
11	Clarification	A screening value is the concentration of a contaminant in fish tissue that is of public health concern and is used as a threshold value against which tissue residue levels can be compared (p. 1-5, <i>Vol. 2: Risk Assessment and fish Consumption Limits</i>). The calculation of consumption limits is based upon

Page	Suggestion type	Suggestion and Rationale
		multiple factors – reference dose, body weight, meal size, time period, and contaminant concentration in fish tissue. The table of monthly consumption limits based on methylmercury (p. 4-5, Vol 2) shows that fish with concentrations of 0.049 ppm (a potential screening value for subsistence fishers) can be eaten 16 times per month, or approximately 4 times per week.
12	Correction	The Alabama example is incorrect – according to Region 4, the number should be 0.29 ppm (not 0.029), resulting in a level 3 times higher, not 30. In any case, the example is confusing. According to our guidance, a mercury level of 1 ppm should result in an advisory of 0.5 meals/month or one meal every other month and 0.029 ppm is appropriate for unlimited consumption. Without knowing what consumption limit Alabama set for that 1 ppm concentration, it is difficult to determine if it were inappropriate. In addition, it is unclear why the example is included since states can set their own risk levels and the last sentence implies that Alabama changed their consumption limits and is now consistent with all the other states in EPA Region 4.
12	Clarification	As stated in Section 5.4.2 of the implementation guidance for the methylmercury criterion, “Advisory limits can differ from one state or tribe to another. This inconsistency is due to a host of reasons, some of which speak to the flexibility states and authorized tribes have to use different assumptions (chemical concentrations, exposure scenarios and assumptions) to determine the necessity for issuing an advisory. The nonregulatory nature of fish advisories allows such agencies to choose the risk level deemed appropriate to more accurately reflect local fishing habits or to safely protect certain subpopulations (e.g., subsistence fishers).” Given the range of feasible policy choices that government agencies can make, it would not be surprising to find instances where state advisories differ.
12	Correction	The consumption restriction in Maryland and Virginia for striped bass is due to PCB contamination. The report repeatedly stresses it is focused solely on methylmercury, so EPA questions the inclusion of this example.
12	Correction	The Chesapeake Bay is not a homogeneous body of water and as such is not a good example to use for “conflicting” advisories. Contamination occurs in “hot spots” and different rivers (with differing mercury concentration levels) feed into different sections of the bay, so it would not be unusual to have different consumption rate recommendations in different parts of the bay as shown in Figure 5.
13	Correction	The Florida example is not one where tribe and state advisories disagree; from the way it is written it sounds like it is an example of a tribe not getting fish advisory information. Please consider including a better or clearer example.
13	Clarification	The Florida example is confusing for another reason. An advisory identifies the amount of fish that can be safely consumed given a particular level of contamination. The advisory is not affected by the consumption patterns of different groups that may consume fish from the waterbody. If one group eats fish at a rate higher than the advisory, it has unacceptable risk. If another group

Page	Suggestion type	Suggestion and Rationale
		eats fish at a lower rate than the advisory, then its risks is acceptable. The advisory does not change based on potential audiences.
15	Correction	24 evaluations, almost half of U.S. states, is not “few states or tribes.” As stated earlier, EPA requests a list of those states in an appendix to the final report.
15	Clarification	EPA regions and program offices actively engage and collaborate with state and tribal fish advisory programs. For example, the Great Lakes National Program Office has funded activities that assess the efficiency of fish consumption messaging to different populations within the Great Lakes basin. In addition, GLNPO is funding a “point in time” survey which will assess knowledge and understanding of fish advisories across the basin. Region 10 has some success stories where effective advisories have and are being developed, for example at the Palos Verdes Superfund site (http://journals.sagepub.com/doi/abs/10.1080/15245000903528381) and the lower Duwamish Waterway (http://www.kingcounty.gov/depts/dnrp/newsroom/newsreleases/2014/September/09-30-Duwamish-Fisher-Survey.aspx).
15	Clarification	As a result of the EPA 2008-9 survey on the effectiveness of the Mississippi Delta fish advisory, which may be what the IG report is referring to in “EPA examined this question in 2010”, Mississippi used the survey results to improve their outreach campaigns in the Delta.
15-16	Correction	As noted previously, the water quality criterion for methylmercury is not used in developing fish advisories, so suggest removing Figure 6 and the sentence referencing it on page 15. Similarly, please remove “ultimately” in the paragraph after Figure 6 to unlink the AWQC and fish advisories. To reduce confusion, you could delete all references to water quality criteria and standards in that paragraph.
16	Correction	Because fish advisories do not rely on water quality criteria, it would be more relevant to the report to include the equations used in fish advisories. See Equation 3-3 in EPA’s <i>Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories: Volume 2 - Risk Assessment and Fish Consumption Limits, Third Edition</i> .
16	Clarification	If a health department wishes to balance the benefits of fish consumption with risk, it may do so as a risk management decision so any perceived leniency or restrictiveness of the RfD could be compensated for in the advisory.

Technical Comments from the Office of Research and Development

At A Glance

“We also found that the EPA’s 2001 oral reference dose (RfD) for methylmercury is overdue for review. Through its Integrated Risk Information System (IRIS), the EPA has recognized the need to revise its 2001 RfD for methylmercury, and the agency proposed a revision in 2012 and again in 2015.” (What We Found)

These sentences are not accurate. Addition of a chemical to the IRIS agenda does not constitute starting the assessment. Projected start dates are subject to change depending on Agency resources and priorities, and should not be used to determine whether an assessment has begun development, or if an assessment is overdue. Inclusion of a chemical on the agenda does not indicate whether any specific toxicity value has been identified as needed to be revised.

Suggested Revision: ORD suggests replacing these two sentences with: “EPA included methylmercury on its 2012 and 2015 agendas for the Integrated Risk Information System (IRIS) Program. Although the EPA’s 2001 RfD for methylmercury is an agency-supported value that remains accepted by EPA for decision-making...”

“We recommend that the EPA's Office of Research and Development conduct an assessment for methylmercury to determine whether the reference dose requires updating as proposed in the 2012 and 2015 IRIS agendas.” (Recommendations)

As discussed earlier in the memorandum, the recommendation should be clarified to indicate when in the assessment development process the determination is made whether a specific toxicity value (in this case, the RfD) may be impacted by new literature and a reassessment is warranted.

Suggested Revision: ORD suggests replacing this sentence with “We recommend that the EPA's Office of Research and Development conduct scoping and problem formulation to determine whether a reassessment to update the reference dose is required, consistent with methylmercury’s inclusion in the IRIS Program’s 2012 and 2015 agendas.”

Report

Page 7: The Scope and Methodology section should be clarified to indicate that it did not include an evaluation of the IRIS assessment development process, or the process for developing the IRIS 2015 multi-year agenda, which was developed with extensive involvement of the program and regional offices to reflect their priority needs.

Suggested Revision: ORD suggests adding language to Scope and Methodology section that includes: “the scope of our work did not include an evaluation of the IRIS assessment development process, or the process for developing the IRIS 2015 multi-year agenda.”

Page 8: The report states: “The EPA’s 2001 oral reference dose (RfD) for methylmercury is overdue for review. Through its Integrated Risk Information System (IRIS) process, the EPA has recognized that a revision of the methylmercury RfD is due, but to date the revision process has not started.” As noted earlier, the IRIS assessment for methylmercury is not overdue. Addition of a chemical to the IRIS agenda does not constitute starting the assessment. Projected start dates are subject to change depending on Agency resources and priorities, and should not be used to determine whether an assessment has begun development, or if an assessment is overdue. Inclusion of a chemical on the agenda does not indicate whether any specific toxicity value has been identified as needed to be revised.

Suggested Revision: ORD suggests replacing these two sentences with: “The publication of epidemiological studies on mercury health effects has added information to the scientific literature. ORD should determine whether this and other new literature would warrant a reassessment to update the 2001 oral reference dose (RfD) for methylmercury.”

Page 15: The report includes a section titled “*Consumption Advice Is Not Based on Up-to-Date Science*” which is misleading and could be interpreted as undermining the current RfD. The availability of new literature published after the 2001 RfD does not indicate that the value or the science is outdated, nor does it automatically trigger a need for a reassessment or discredit an existing IRIS value. This misrepresents the scientific approaches used to develop toxicity values such as RfDs. Determination of whether new literature provides information that warrants reassessment of the RfD can be made after scoping and problem formulation are conducted.

Suggested Revision: ORD suggests revising this title as follows: “Ensuring Up-to-Date Science for Consumption Advice.”

Page 15: The OIG evaluation’s scope including OIG interviews with two scientists did not include a comprehensive evaluation of the methylmercury literature. As noted in the report, the scientists indicate their studies “*may [emphasis added] provide relevant information for the development of a revised RfD.*” The existence of new literature does not automatically trigger a need for a reassessment, nor does it discredit an existing IRIS value.

Suggested Revision: ORD requests that additional text be included that clarifies the limitations and uncertainties in the analysis of selected references for methylmercury.

Page 15: In the report, OIG states, “*Through its IRIS process, the EPA recognized that a revision of the methylmercury RfD is due. In 2012, the EPA included methylmercury on its IRIS agenda for revision by the end of fiscal year 2014, but this did not occur.*” As noted previously, inclusion of a chemical on the IRIS agenda does not constitute a determination that a specific toxicity value need to be updated. Additionally, projected start dates are subject to change depending on the Agency’s resources and priorities, and should not be used to determine whether an assessment has begun development, or if an assessment is overdue.

Suggested Revision: ORD suggests revising these sentences as follows: “Through its IRIS process, EPA prioritized initiating a number of assessments, including methylmercury, as indicated by the IRIS 2015 agenda.”

Page 21: Bullet 1 is an incomplete citation.

Suggested Revision: Boucher O, Jacobson SW, Plusquellec P, Dewailly É, Ayotte P, Forget-Dubois N, Jacobson JL, Muckle G. 2012. Prenatal Methylmercury, Postnatal Lead Exposure, and Evidence of Attention Deficit/Hyperactivity Disorder among Inuit Children in Arctic Québec. *Environ Health Perspect* 120:1456–1461; <http://dx.doi.org/10.1289/ehp.1204976>

Page 21: Bullet 3 is a citation for a conference presentation. Presentations and posters are not peer reviewed, and would not inform the development of an IRIS assessment.

Suggested Revision: Please remove citation.

Page 21: Bullet 6 is an incomplete citation.

Suggested Revision: Jedrychowski W, Jankowski J, Flak E, Skarupa A, Mroz E, Sochacka-Tatara E, Lisowska-Miszczuk I, Szpanowska-Wohn A, Rauh V, Skolicki Z, Kaim I, Perera F. 2006. Effects of prenatal exposure to mercury on cognitive and psychomotor function in one-year-old infants: epidemiologic cohort study in Poland. *Ann Epidemiol.* 16(6): 439-47.

Page 21: Bullet 8 includes two references, one incomplete.

Suggested Revision: Tai F. Fok, Hugh S. Lam, Pak C. Ng, Alexander S.K. Yip, Ngai C. Sin, Iris H.S. Chan, Goldie J.S. Gu, Hung K. So, Eric M.C. Wong, Christopher W.K. Lam. 2007. Fetal methylmercury exposure as measured by cord blood mercury concentrations in a mother–infant cohort in Hong Kong. *Environ. Int.* 33(1) 84-92.

Page 21: Bullet 9 is an incomplete citation.

Suggested Revision: Lederman, S. A., Jones, R. L., Caldwell, K. L., Rauh, V., Sheets, S. E., Tang, D., ... Perera, F. P. (2008). Relation between Cord Blood Mercury Levels and Early Child Development in a World Trade Center Cohort. *Environmental Health Perspectives*, 116(8), 1085–1091. <http://doi.org/10.1289/ehp.10831>.

Page 22: Bullet 1 is an incomplete citation.

Suggested Revision: Katsuyuki Murata, Pál Weihe, Esben Budtz-Jørgensen, Poul J Jørgensen, Philippe Grandjean. 2004. Delayed brainstem auditory evoked potential latencies in 14-year-old children exposed to methylmercury. *J. Pediatrics.* 144(2) 177-183.

Page 22: Bullet 3 is an incomplete citation.

Suggested Revision: Oken, E., Guthrie, L. B., Bloomingdale, A., Platek, D. N., Price, S., Haines, J., ... Wright, R. O. (2013). A pilot randomized controlled trial to promote healthful fish consumption during pregnancy: The Food for Thought Study. *Nutrition Journal*, 12, 33. <http://doi.org/10.1186/1475-2891-12-33>.

Page 22: Bullet 4 is an incomplete citation.

Suggested Revision: Oken, E., Radesky, J. S., Wright, R. O., Bellinger, D. C., Amarasiriwardena, C. J., Kleinman, K. P., ... Gillman, M. W. (2008). Maternal fish intake during pregnancy, blood mercury, and child cognition at age 3 years in a US cohort. *American Journal of Epidemiology*, 167(10), 1171–1181. <http://doi.org/10.1093/aje/kwn034>.

Page 22: Bullet 5 is an incomplete citation.

Suggested Revision: Oken, E., Wright, R. O., Kleinman, K. P., Bellinger, D., Amarasiriwardena, C. J., Hu, H., ... Gillman, M. W. (2005). Maternal Fish Consumption, Hair Mercury, and Infant

Cognition in a U.S. Cohort. *Environmental Health Perspectives*, 113(10), 1376–1380.
<http://doi.org/10.1289/ehp.8041>.

Page 22: Bullet 6 is an incomplete citation.

Suggested Revision: Orenstein ST, Thurston SW, Bellinger DC, Schwartz JD, Amarasiriwardena CJ, Altshul LM, Korrick SA. 2014. Prenatal organochlorine and methylmercury exposure and memory and learning in school-age children in communities near the New Bedford Harbor Superfund Site, Massachusetts. *Environ Health Perspect* 122:1253–1259; <http://dx.doi.org/10.1289/ehp.1307804>.

Page 22: Bullet 7 is an incomplete citation.

Suggested Revision: Sagiv, S. K., Thurston, S. W., Bellinger, D. C., Amarasiriwardena, C., & Korrick, S. A. (2012). Prenatal exposure to mercury and fish consumption during pregnancy and ADHD-related behavior in children. *Archives of Pediatrics & Adolescent Medicine*, 166(12), 1123–1131. <http://doi.org/10.1001/archpediatrics.2012.1286>.

Page 22: Bullet 9 is an incomplete citation. Only the authors are listed and not the data source.

Suggested Revision: Identify the appropriate source.

Page 22: Bullet 10 has a typo.

Suggested Revision: Should be “93-99,” not “93e99.”

Distribution

The Administrator
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Associate Administrator for Congressional and Intergovernmental Relations
Associate Administrator for Public Affairs
Principal Deputy Assistant Administrator, Office of Water
Associate Director for Science, Office of Research and Development
Principal Deputy Assistant Administrator, Office of International and Tribal Affairs
Deputy Assistant Administrator for Management, Office of Research and Development
Deputy Regional Administrator, Region 4
Deputy Regional Administrator, Region 5
Deputy Regional Administrator, Region 10
Audit Follow-Up Coordinator, Office of the Administrator
Audit Follow-Up Coordinator, Office of Water
Audit Follow-Up Coordinator, Office of Research and Development
Audit Follow-Up Coordinator, Office of International and Tribal Affairs
Audit Follow-Up Coordinator, Region 4
Audit Follow-Up Coordinator, Region 5
Audit Follow-Up Coordinator, Region 10

