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**

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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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U.S. Environmental Protection Agency
Office of Inspector General

17-P-0174
April 12, 2017

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

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

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, 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.

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

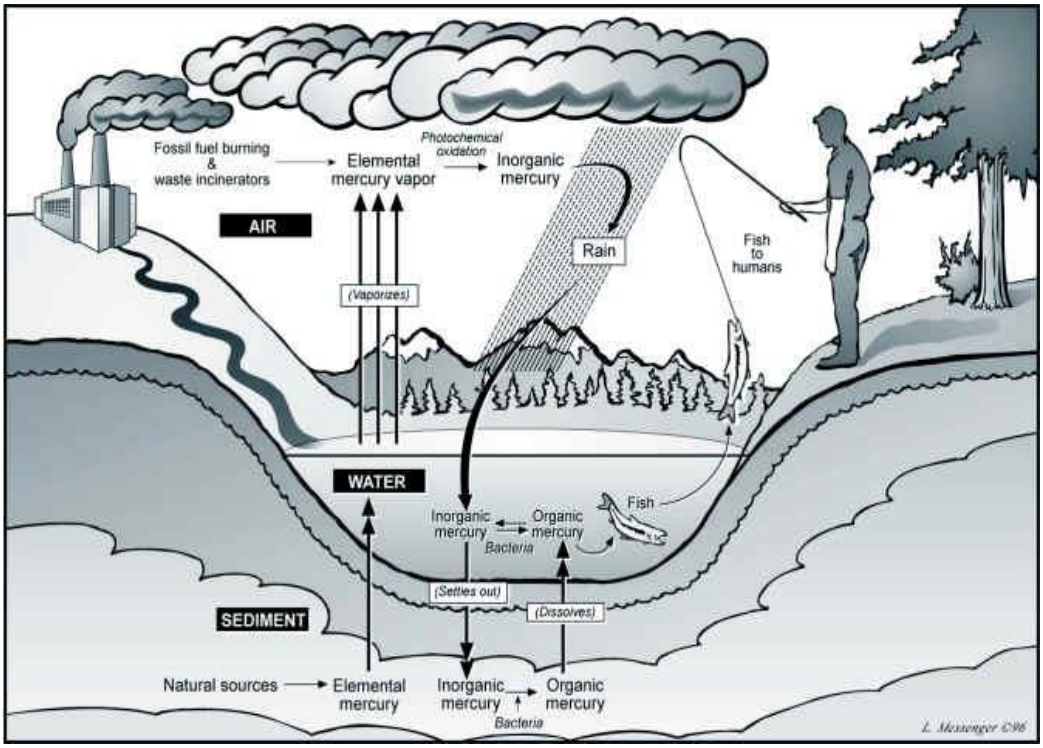
Why We Did This Review

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

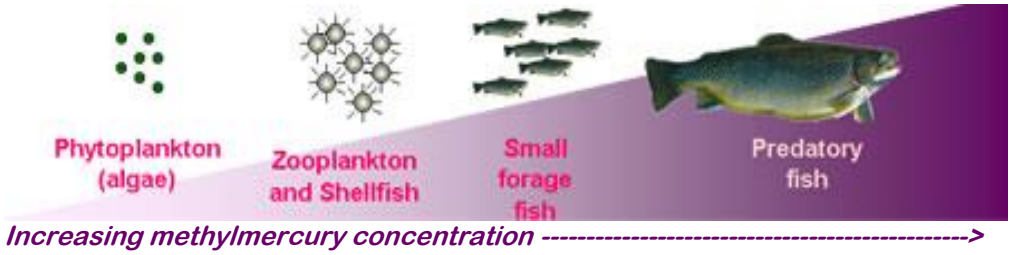
Figure 1: How mercury cycles through the ecosystem



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.

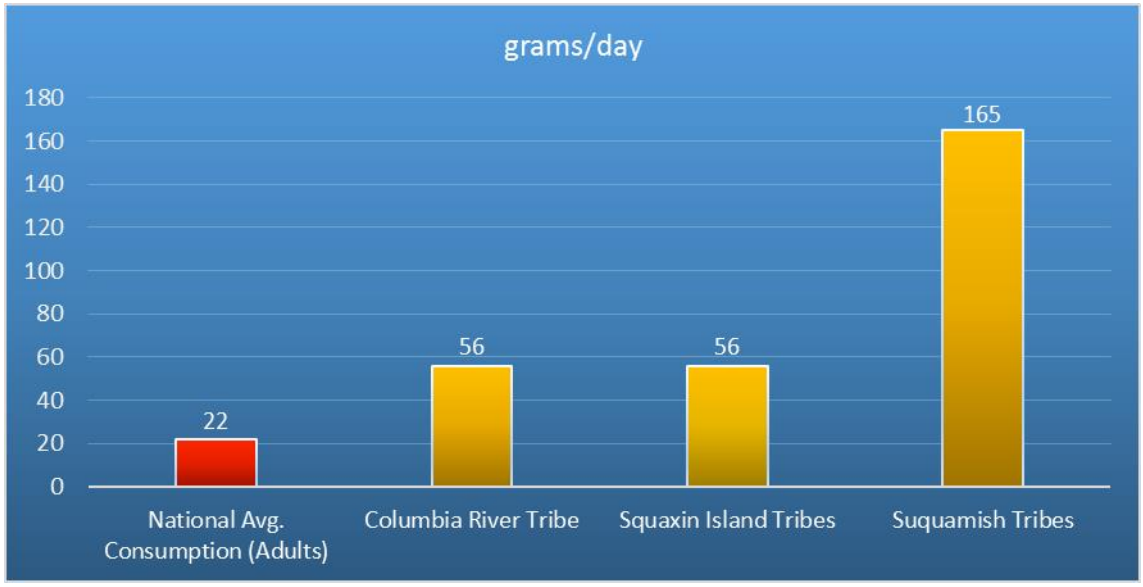
Human Health Effects From Mercury

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

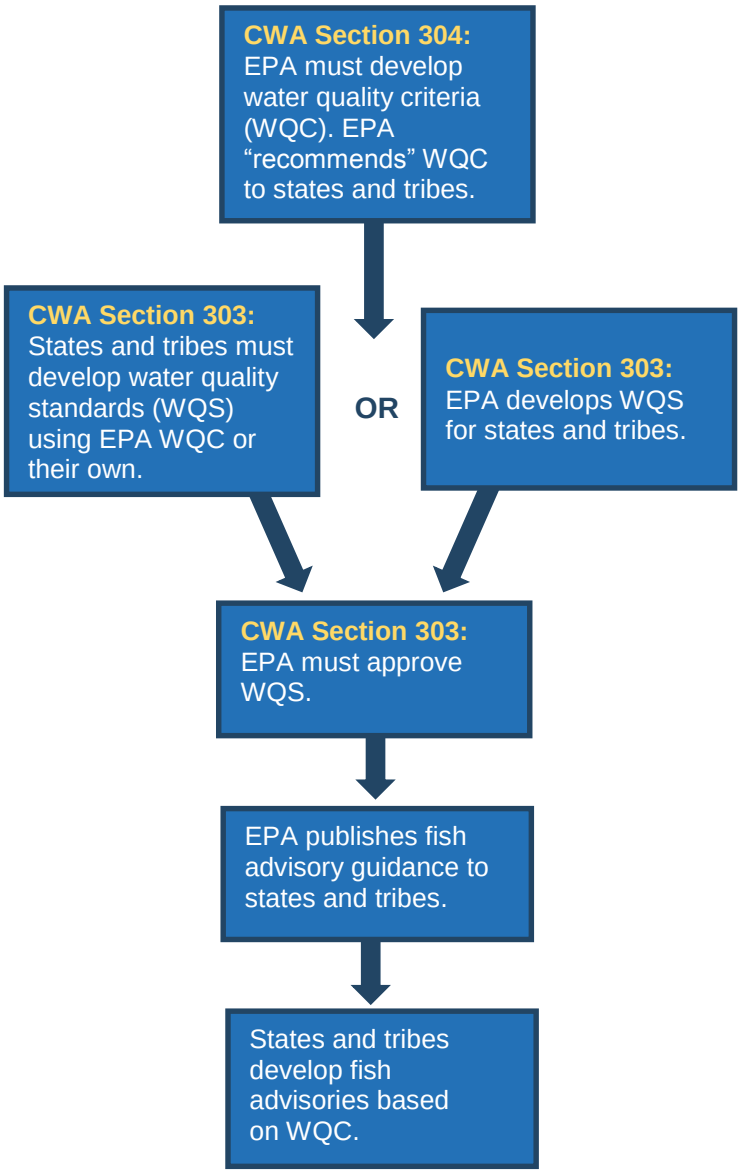
Fish consumption advisories are issued on a national level for commercially marketed fish; and on a local level for fish caught directly from lakes, rivers and other water bodies by individual fishers. The EPA does not have regulatory responsibility for nationally issued fish advisories. This responsibility 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 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.

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.

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.

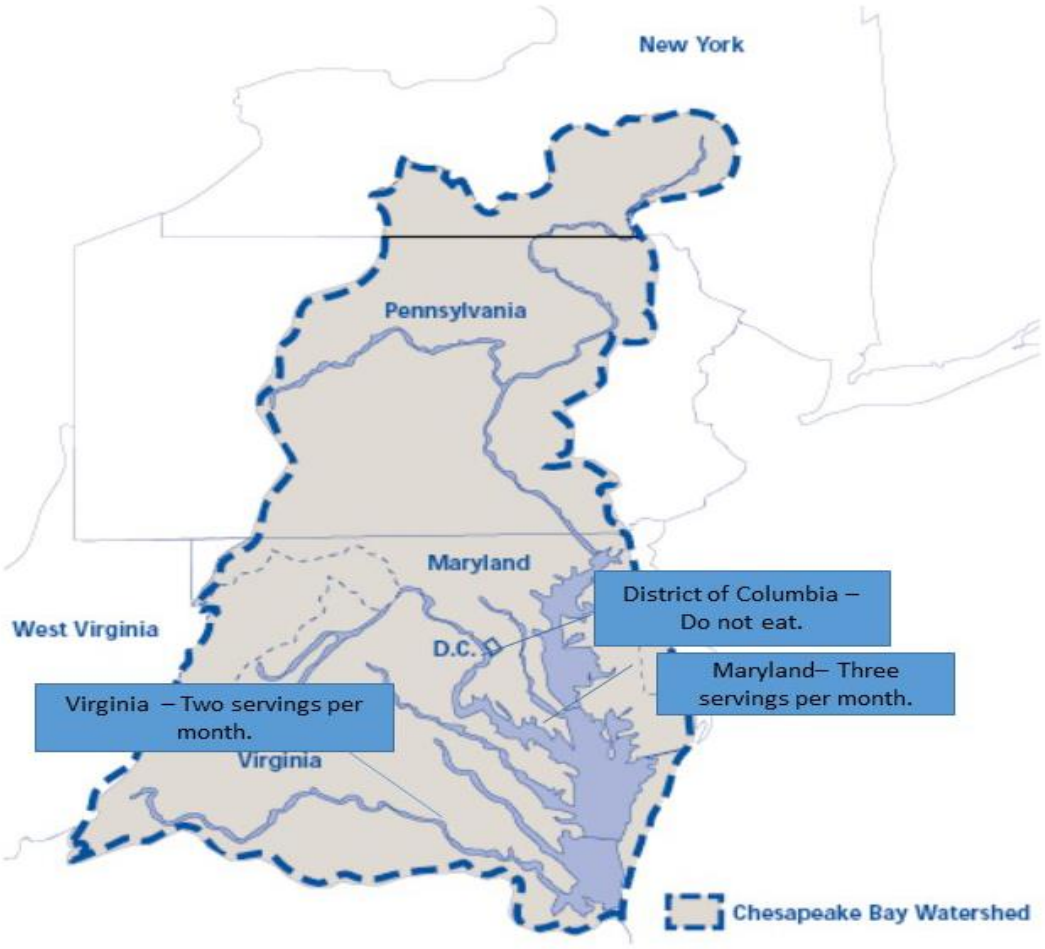
In 2002, the state of Alabama used the FDA's action level of 1.0 ppm for mercury to establish its fish consumption advisory instead of the EPA's recommended maximum level of 0.29 ppm. This meant the state's fish consumption advisory could allow methylmercury levels three times higher than the maximum 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

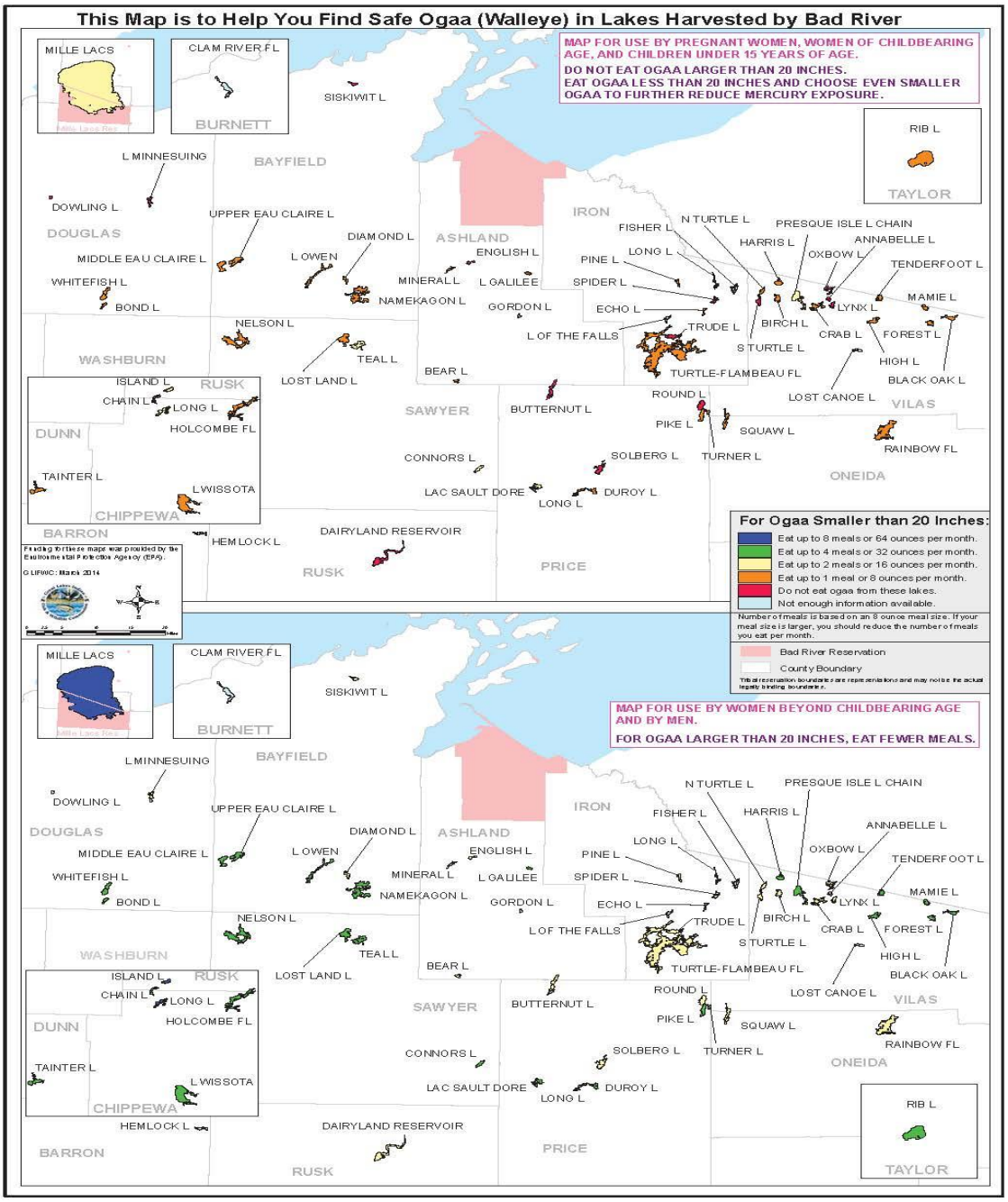
Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Potential Monetary Benefits (in $000s)
1	17	Provide updated guidance to states and tribes on clear and effective risk communication methods for fish advisories, especially for high-risk groups. This guidance could recommend posting 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.

Appendix A

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

Page 1 of 2



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

SORTING AND LABELING *OGAA* PRIOR TO FREEZING

When Cleaning *Ogaa*:

- Put *ogaa* under 20 inches in bags labeled "under 20 inches."
- Put *ogaa* 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 *GIIGOONH*

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 *ogaa* in that month.

MEAL SIZE

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

OTHER *GIIGOONH*

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

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	0	2
BEAR L	ASHLAND	1	2
BIRCH L	VILAS	1	2
BLACK OAK L	VILAS	1	4
BOND L	DOUGLAS	1	4
BUTTERNUT L	PRICE	0	2
CHAIN L	RUSK	1	4
CLAM R FL	BURNETT	Not Enough Information	
CONNORS L	SAWYER	2	4
CRAB L	VILAS	1	2
DAIRYLAND RESERVOIR	RUSK	0	2
DIAMOND L	BAYFIELD	1	2
DOWLING L	DOUGLAS	0	2
DUROY L	PRICE	1	4
ECHO L	IRON	1	4
ENGLISH L	ASHLAND	0	2
FISHER L	IRON	Not Enough Information	
FOREST L	VILAS	1	4
GORDON L	ASHLAND	Not Enough Information	
HARRIS L	VILAS	1	4
HEMLOCK L	BARRON	Not Enough Information	
HIGH L	VILAS	1	4
HOLCOMBE FL	CHIPPEWA	1	4
ISLAND L	RUSK	2	8
L GALILEE	ASHLAND	1	4
L MINNESUING	DOUGLAS	0	2
L OF THE FALLS	IRON	Not Enough Information	
L OWEN	BAYFIELD	1	4
L WISSOTA	CHIPPEWA	1	4
LAC SAULT DORE	PRICE	2	4
LONG L	CHIPPEWA	2	8
LONG L	IRON	0	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	1	4
LOST CANOE L	VILAS	Not Enough Information	
LOST LAND L	SAWYER	1	4
LYNX L	VILAS	0	2
MAMIE L	VILAS	1	4
MIDDLE EAU CLAIRE L	BAYFIELD	1	4
MILLE LACS	MILLE LACS	2	8
MINERAL L	ASHLAND	1	2
N TURTLE L	VILAS	1	2
NAMEKAGON L	BAYFIELD	1	4
NELSON L	SAWYER	1	4
OXBOW L	VILAS	0	2
PIKE L	PRICE	1	4
PINE L	IRON	1	2
PRESQUE ISLE L CHAIN	VILAS	2	4
RAINBOW FL	ONEIDA	1	2
RIB L	TAYLOR	1	4
ROUND L	PRICE	0	2
S TURTLE L	VILAS	0	2
SISKIWIT L	BAYFIELD	0	2
SOLBERG L	PRICE	0	2
SPIDER L	IRON	0	2
SQUAW L	VILAS	1	2
TAINTER L	DUNN	1	4
TEAL L	SAWYER	2	4
TENDERFOOT L	VILAS	1	4
TRUDE L	IRON	0	2
TURNER L	PRICE	1	4
TURTLE-FLAMBEAU FL	IRON	1	2
UPPER EAU CLAIRE L	BAYFIELD	1	4
WHITEFISH L	DOUGLAS	1	4

For many native people, *giigoonh* are part of a traditional and healthy diet. If you rely on *giigoonh*, choose safer *giigoonh* 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 *giigoonh* a month may reduce your risk of death due to heart disease.

If you have questions about finding safer ogaa, call GLIFWC at 1-715-682-6619.
To learn more about mercury in ogaa, 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.

Appendix B

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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- 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.

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- 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.
- 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.
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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 *Volume 4: Risk Communication* of the *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories*. Release final version.	Draft: 4th Q FY2018 Final: 2nd 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: 4th 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: 2nd 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.	3rd Q FY 2017 4th 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.	1st 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
Charles Sheehan
Benita Best-Wong
Tim Fontaine
Sharon Vazquez
Laura Drummond
Tina Bahadori
Louis D'Amico
Heather Cursio
Maureen Hingeley

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 *Human Health Effects From Mercury* 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 *Human Health Effects From Mercury* 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 *Human Health Effects From Mercury* 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: *Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003-2010)*, 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 *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories: Volume 2 - Risk Assessment and Fish Consumption Limits, Third Edition* for more information.
3-4	Correction	EPA establishes water quality criteria *recommendations*. 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 Administer 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	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." 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 *Fish Consumption and Environmental Justice*, ''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

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 *Fish and Shellfish Program Newsletter*. 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 *Dietary Guidelines 2015-20*, 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, *Vol. 2: Risk Assessment and fish Consumption Limits*). 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 *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories: Volume 2 - Risk Assessment and Fish Consumption Limits, Third Edition*.
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-Miszczyk 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."

Appendix D

Distribution

The Administrator
Assistant Administrator for Water
Assistant Administrator for Research and Development
Assistant Administrator for International and Tribal Affairs
Regional Administrator, Region 4
Regional Administrator, Region 5
Regional Administrator, Region 10
Agency Follow-Up Official (the CFO)
Agency Follow-Up Coordinator
General Counsel
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
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Audit Follow-Up Coordinator, Region 4
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