



FEB 7 2001

The Honorable Patrick J. Leahy
United States Senate
Washington, D.C. 20510-4502

Dear Senator Leahy:

Thank you for your letters of August 15, 2000 and January 11, 2001, addressed to Donna E. Shalala, former Secretary of Health and Human Services (Department), co-signed by Senator Tom Harkin, regarding the National Academy of Sciences (NAS) report, *Toxicological Effects of Methylmercury* and the Food and Drug Administration's (FDA or the Agency) reassessment of its consumer guidance and action level for methylmercury in seafood. The department directed FDA to respond to your letters. I apologize for the delay in responding to your letters.

FDA shares your concerns about human exposures to mercury and its compounds and believes that the NAS report represents a significant and important contribution regarding the health effects of methylmercury. The Agency is carefully reviewing this report, as well as other information that continues to emerge from around the world regarding this important environmental issue.

FDA issued a new fish consumption advisory on methylmercury on January 12, 2001, (copy enclosed). As part of the decision-making process, FDA met with interested parties (consumers, industry, health care providers, etc.) to obtain various perspectives on this important issue. A copy of the questions asked of these groups also is enclosed. The Agency also tested different types of messages with consumer focus groups to determine whether these types of messages are clearly understood and how they would be acted upon by consumers. These message tests helped determine the best ways of reaching the public with this important information.

This fiscal year FDA will develop an overall public health strategy for methylmercury in commercial seafood, including a review of the action level. In addition, FDA will need to reconsider the results of any additional studies on methylmercury in fish. This includes the results of the evaluation of the Seychelles Islands cohort study at seven


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years, which is expected to be available in the spring of 2001. This information will allow, for the first time, a side-by-side comparison between the Faroe Islands study, which reported results of evaluation of the children at seven years, and the Seychelles Islands study involving children evaluated at the same age using the same battery of neurologic tests. While methylmercury surveillance data has remained relatively stable for most species, FDA will consider additional steps as part of its overall strategy on methylmercury.

FDA is committed to protecting the public's health and the environment regarding mercury, and will carefully evaluate the NAS report and all other relevant information and take appropriate actions based on that evaluation.

Thank you again for conveying your concerns about this important health issue. A similar letter has been sent to Senator Harkin.

Sincerely,

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Melinda K. Plaisier
Associate Commissioner
for Legislation

2 Enclosures

**Food and Drug Administration's (FDA) Questions to
Interested Parties on Methylmercury**

1. Given the National Academy of Sciences (NAS) report and the emissions standards set by the Environmental Protection Agency, should FDA revise its advisory to consumers (and in particular to vulnerable populations such as pregnant women and women who may become pregnant)? If so, what should the new advisory say?
2. Given the potential nutritional contribution of fish and seafood to a healthful diet, should a consumer advisory be crafted so that it conveys the benefit/risk balance of methylmercury-containing fish? If so, what should be the content of such a message?
3. With additional Seychelles study data expected to be released next spring, what impact, if any, should such new data have on the timing and content of any FDA advisory?
4. What other factors, if any, should impact a decision on whether and how to revise the current consumer guidance?
5. What methods of communication should FDA use to best convey such a consumer advisory?
6. How could FDA measure its success in reaching the consumer audience, including vulnerable populations?



CONSUMER ADVISORY

Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration

January 2001

AN IMPORTANT MESSAGE FOR PREGNANT WOMEN AND WOMEN OF CHILDBEARING AGE WHO MAY BECOME PREGNANT ABOUT THE RISKS OF MERCURY IN FISH

Seafood can be an important part of a balanced diet for pregnant women. It is a good source of high quality protein and other nutrients and is low in fat.

However, some fish contain high levels of a form of mercury called methylmercury that can harm an unborn child's developing nervous system if eaten regularly. By being informed about methylmercury and knowing the kinds of fish that are safe to eat, you can prevent any harm to your unborn child and still enjoy the health benefits of eating seafood.

HOW DOES MERCURY GET INTO FISH?

Mercury occurs naturally in the environment and it can also be released into the air through industrial pollution. Mercury falls from the air and can get into surface water, accumulating in streams and oceans. Bacteria in the water cause chemical changes that transform mercury into methylmercury that can be toxic. Fish absorb methylmercury from water as they feed on aquatic organisms.

HOW CAN I AVOID LEVELS OF MERCURY THAT COULD HARM MY UNBORN CHILD?

Nearly all fish contain trace amounts of methylmercury, which are not harmful to humans. However, long-lived, larger fish that feed on other fish accumulate the highest levels of methylmercury and pose the greatest risk to people who eat them regularly. You can protect your unborn child by not eating these large fish that can contain high levels of methylmercury:

- Shark
- Swordfish
- King mackerel
- Tilefish

While it is true that the primary danger from methylmercury in fish is to the developing nervous system of the unborn child, it is prudent for nursing mothers and young children not to eat these fish as well.

United States Senate

WASHINGTON, DC 20510-4502

August 15, 2000

The Honorable Donna E. Shalala
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Shalala:

In July, the National Academy of Sciences (NAS) issued a long-awaited report requested by Congress and entitled, "Toxicological Effects of Methylmercury." Among other findings, this report concludes that the most scientifically defensible reference dose (RfD) for human consumption of methylmercury is currently 0.1 micrograms per kilogram body weight per day ($\mu\text{g}/\text{kg}/\text{day}$). This is the same reference dose proposed by the Environmental Protection Agency (EPA) in 1998, the year it released its Mercury Report to Congress. In fact, the report indicates that an even lower level would be scientifically supportable.

We are writing to alert you that two of your agencies, the Food and Drug Administration (FDA) and Agency for Toxic Substance and Disease Registry (ATSDR), are now using outdated standards for human methylmercury exposure and should move quickly to consider adoption of the more stringent EPA standard. The FDA "action level," or the level at which the FDA may take legal action to remove a product from the market, is now set at 1.0 part per million methylmercury in fish tissue. When converted to units relevant to human consumption, this value is about 0.5 $\mu\text{g}/\text{kg}/\text{day}$ for methylmercury, or five times less stringent than the NAS-supported EPA level. The ATSDR minimal risk level (or MRL) of 0.3 $\mu\text{g}/\text{kg}/\text{day}$ is three times less stringent than the NAS-supported EPA level. In addition, the NAS report found that selection of studies and choice of uncertainty factors by ATSDR were scientifically-flawed.

The NAS report is the capstone of an already large body of evidence highlighting the need for FDA and ATSDR to update their methylmercury exposure standards and for FDA to resume its suspended tests for methylmercury contamination in domestically-caught fish. We are disappointed that FDA, in particular, has not considered these tasks a high public health priority. The FDA has not tested domestically-caught fish for methylmercury contamination since 1998, even after 1997 tests showed that *three of the four fish* in one sample exceeded FDA action levels. This raises serious questions about FDA's commitment to ensuring seafood safety.

Methylmercury is a dangerous neurotoxin that accumulates in human blood, brain tissue, and organs primarily through the consumption of mercury-contaminated fish. Given the

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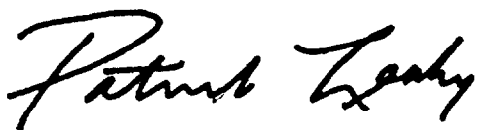
susceptibility of undeveloped neurological systems to methylmercury poisoning, the most at-risk populations in the United States include women of child-bearing age, pregnant women, and small children. According to the NAS study, five percent of U.S. populations that have been studied for methylmercury exposure eat enough fish to exceed the 0.1 $\mu\text{g}/\text{kg}/\text{day}$ EPA level -- this translates into an average of 7% of women and over 60,000 infants at risk each year. In one New Jersey study cited, 21% of women of childbearing age would exceed the EPA reference dose.

It is imperative that, as a nation, we drastically reduce mercury emissions to the atmosphere from coal-fired power plants, municipal trash incinerators, and other industries that emit over 50 tons of mercury each year -- mercury that finds its way into our nation's lakes and streams and, ultimately, fish. We have been working on legislation to do this in the Senate for over a decade and continue to do so. In the meantime, federal health agencies must protect our citizens at the most stringent, and scientifically-justified, levels. For methylmercury exposure, the National Academy of Sciences report suggests this is a level of 0.1 $\mu\text{g}/\text{kg}/\text{day}$ or less.

We hope that you will review this situation and request that (1) both the FDA and ATSDR adopt a scientifically-supported, reference dose for human methylmercury exposure that is consistent with the NAS findings and that adequately protects sensitive populations, and (2) that FDA resume domestically-caught fish monitoring immediately, using statistically-valid sampling methods. With the publication of this report from the nation's premiere scientific advisory panel, there is no longer any justification for interagency discrepancies in the protection of public health from mercury pollution, nor in inaction on the monitoring of fish eaten by our citizens.

We look forward to hearing from you as soon as possible concerning your efforts to address these issues.

Sincerely,



PATRICK J. LEAHY
United States Senator



TOM HARKIN
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WASHINGTON, DC 20510

January 11, 2001

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Dear Secretary Shalala:

We understand the Food and Drug Administration is considering revising its consumer advisory regarding methylmercury contamination in commercial seafood. We strongly support a revision consistent with the conclusions of the recent National Academy of Sciences (NAS) report, one that effectively protects Americans, especially at-risk populations such as pregnant women and young children, from methylmercury exposure. As we have written to you before, this revision is needed as soon as possible to allow Americans to make well-informed diet decisions.

As you know, Congress included report language in the final omnibus budget that calls for FDA to consider "more than one relevant study" to form the basis of any FDA action. We would like to remind you that the July 2000 NAS report included the results of numerous relevant studies. These studies cover the full range of issues, from specific medical effects to dose estimation. A revised FDA advisory based on the findings of the NAS would thus include "the results of more than one relevant study." It is clear that the NAS considered a substantial body of research in preparing its report.

We understand that you have heard concerns that fully informing people about methylmercury could contradict FDA publications advising people to eat more fish. Fish is an important part of a healthy diet. However, a few large species of fish exhibit high levels of methylmercury, and consumer advisories should focus on these species. We have no doubt that FDA can make a distinction between methylmercury-contaminated fish and others in their revised consumer advisory.

Methylmercury is a dangerous neurotoxin that poses a serious health risk to people, especially pregnant women and young children, who consume contaminated fish. After innumerable delays, it is time to protect Americans from this danger. We urge you to instruct FDA to move quickly to revise and promulgate a more comprehensive consumer advisory for methylmercury in seafood and reflect the risks described in the NAS report. This advisory should include all fish species with a danger of high methylmercury levels -- in particular swordfish, shark, and large tuna.

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We also continue to urge you to reconcile the difference in the outdated FDA "action level" for methylmercury in fish tissue and the more current, stricter "reference dose" that is advocated by EPA and supported by the July 2000 NAS report. Conversion of the two numbers shows that the scientifically-supported EPA level is over four times stricter than that of FDA and we strongly believe that this level should be the federal standard to protect public health. We requested that you do this in a previous letter (sent August 15, 2000) and await a formal response.

We appreciate your attention to this important matter.

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cc: FDA Commissioner Jane Henney



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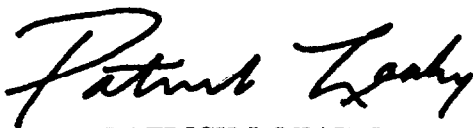
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