CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Publisher of *Nutrition Action Healthletter*

Risk Management Strategies for Methylmercury in Seafood – A Consumer Perspective

Statement of Caroline Smith DeWaal
Center for Science in the Public Interest
FDA Food Advisory Committee Meeting on Methylmercury
July 23, 2002

My name is Caroline Smith DeWaal and I am the food safety director at the Center for Science in the Public Interest (CSPI). CSPI is a non-profit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by the 800,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants. We accept no government or industry funding. Methylmercury in seafood is not a new issue for the Food and Drug Administration, but luckily for the public, it is one that is getting increased attention. I apologize in advance if my talk is somewhat of a history lesson, but this is a topic that I have been working on since the early 1990's.

This Food Advisory Committee is being asked to evaluate whether FDA's consumer advisory on methylmercury is adequate to protect the health of those who follow the advice. To answer this question, the Committee must first be satisfied that FDA's standard, or "action level," is sufficient to protect vulnerable consumers, the same standard that the National Academy of Sciences (NAS) harshly criticized in 1991 with the publication of its report *Seafood Safety*. Second, the Committee should evaluate the appropriateness of placing the entire burden for preventing the adverse consequences of methylmercury in seafood on the consuming public. This Committee should explore the issue of whether FDA should be more proactive in

Tel: (202) 332-9110
Fax: (202) 265-4954
Home Page: www.cspinet.org
E-mail: cspi@cspinet.org

Suite 300
1875 Connecticut Avenue, N.W.
Washington, DC 20009-5728

Michael F. Jacobson, Ph.D.
Executive Director

preventing highly contaminated seafood from reaching the marketplace, especially given the current status of the at-risk population and the failure of FDA's past seafood safety policies addressing methylmercury.

New Information Shows Urgent Need for Action

In 1999, we got the first glimpse of current levels of consumer exposure to methylmercury. The National Health and Nutrition Examination Study (NHANES) showed that one in ten women of childbearing age in the U.S. are at risk of having babies with learning disabilities or other developmental defects because of *in utero* mercury exposure – primarily through fish consumption.[1] These data show that the current risk management strategies have been ineffective in protecting 10% of women of childbearing age from the adverse consequences of methylmercury.

Unfortunately, the structure of the federal food-safety regulatory system is fragmented and ill-equipped to meet this challenge. Two federal regulatory agencies, the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA), as well as a third federal agency, the non-regulatory Agency for Toxic Substances and Disease Registry (ATSDR) all have established standards for human exposure to methylmercury from fish and seafood. None of them agree on what level of mercury represents a threat to consumers.

The FDA has the primary authority for ensuring the safety of seafood consumed by the U.S. public. Using its public-health mandate, FDA has established an "action level" of 1 part per

---

[1] Food and Drug Administration *et al.*, "Blood and Hair Mercury Levels in Young Children and Women of Childbearing Age–United States, 1999," *Morbidity and Mortality Weekly Report*, Vol. 50, No. 8, (Mar. 2, 2001), pp. 140-43. "[A]pproximately 10% of women have Hg levels within one tenth of potentially hazardous levels, indicating a narrow margin of safety for some women and supporting efforts to reduce methylmercury exposure."

million for mercury-tainted commercial seafood. For recreationally caught freshwater fish, however, EPA issued its own methylmercury guideline under water pollution laws.

EPA's water-quality criterion is based on the agency's "reference dose," or RfD, for mercury, which is 0.1 microgram per kilogram of body weight per day. An RfD is defined as an estimate of "daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime."[2] In simpler terms, an RfD represents the daily dose of a substance that would be "acceptably safe," even to sensitive subgroups.[3] So, in the case of mercury, EPA's RfD is designed to account for effects on developing fetuses.

Lest you think that the problems can be solved by getting FDA and EPA to agree on a standard, you should know that a third federal agency, the Agency for Toxic Substances and Disease Registry (ATSDR), has its own risk assessment for methylmercury, which it used to set safety standard for dietary methylmercury of 0.3 micrograms per kilograms per day.

Ironically, EPA–an environmental agency–has a tougher mercury standard than FDA–a public-health agency. FDA's action level of 1 part per million of mercury in fish was calculated only to protect adults, not fetuses. In terms of human exposure, FDA's action level translates to 0.4 micrograms per kilogram of body weight per day–four times higher than EPA's RfD.

Unfortunately for pregnant women and their children, the seafood sold in supermarkets and restaurants is regulated under the weaker FDA standard. Moreover, the FDA's "action level"

---

[2] Institute of Medicine, National Research Council, *Toxicological Effects of Methylmercury*, (Washington, DC: National Academy Press, 2000), p. 342 [hereinafter cited as *2000 NAS Report*].

[3] *2000 NAS Report*, p. 272.

is only an informal enforcement policy. It is not legally binding on the agency or on seafood companies and, more importantly, it does absolutely nothing to prevent heavily contaminated fish from being sold to consumers. FDA's action level on methylmercury is truly a toothless tiger.

FDA's Consumer Advisory is Not Enough

What FDA has done in response to the mounting evidence about the inadequacy of its standard is to issue a consumer advisory, placing the burden firmly on consumers to protect themselves from the risk of this toxic agent in seafood. In January 2001, FDA issued a consumer advisory telling women who are or may become pregnant not to eat shark, swordfish, king mackerel and tilefish due to likely contamination.[4] These women were told it is safe to eat up to 12 ounces per week of other types of cooked fish. No warning was given about tuna. The FDA advisory also states that it would be "prudent" for nursing mothers and young children to follow the same recommendations as women who are or may become pregnant.

FDA's decision to regulate by press release has been highly ineffective, for several reasons: First, there was no major roll-out of this new advisory. There was no public meeting held, nor were any labeling or retail display programs unveiled. Second, many consumers who need to hear the advisory are among those who are least likely to do so. Media outlets often do not reach many target groups because of language barriers. Moreover, half of all pregnancies are unplanned, so to reach the appropriate audience, the message should have been directed to all women of childbearing age.

---

[4] Environmental Protection Agency, Note to Correspondents: FDA and EPA Issue Advisories on Fish, Jan. 12, 2001, <http://www.epa.gov/mercury/fishadv.pdf> [hereinafter cited as *EPA Press Release*]; Food and Drug Administration, Consumer Advisory: An Important Message for Pregnant Women and Women of Childbearing Age Who May Become Pregnant About the Risks of Mercury in Fish, Mar. 2001, <http://www.cfsan.fda.gov/~dms/admehg.html>.

FDA's advice is so incomplete that several other consumer/public health organizations have developed competing advice in order for fill the void. CSPI issued its own advice in *Nutrition Action Healthletter* in September 2001, issuing specific recommendations for young children, an area where FDA has been notably silent.[5]

At the same time that FDA came out with its new consumer advisory, EPA issued a national consumer advisory on recreationally caught freshwater fish. EPA recommended that women who are or may become pregnant and nursing mothers should eat no more than six ounces of cooked freshwater fish per week, and young children should eat no more than two ounces of cooked freshwater fish per week.[6] Although EPA's guidance covered different fish species, for most consumers, they once again heard conflicting messages coming out of different federal agencies.

States, territories and Native American tribes have a fundamental responsibility for protecting their residents from the health risks of eating contaminated recreationally caught fish. To fulfill this duty, states issue consumption advisories that may include recommendations to avoid or limit consumption of certain species from certain bodies of water. The advisories may be directed to sensitive consumers or may extend to the general population. In 2001, there were 1,933 mercury advisories in place in a total of 44 states. Some base their advisories on EPA's standard; others, the FDA action level. Still others follow the World Health Organization

---

[5] Center for Science in the Public Interest, "Throw Back the Fish," *Nutrition Action Healthletter*, vol. 28, no. 7, Sept. 2001.

[6] *EPA Press Release*; Environmental Protection Agency, Consumption Advice Fact Sheet, National Advice on Mercury in Fish Caught by Family and Friends: For Women Who Are Pregnant or May Become Pregnant, Nursing Mothers, and Young Children, Jan. 2001, <http://www.epa.gov/waterscience/fishadvice/factsheet.html>.

guidelines or set their own standards. Coordinated guidance from federal officials would help to resolve these disparities.

What is the consumer response to all of these conflicting messages coming from government? Mistrust and confusion. People don't know what advice to follow. The result is a loss of consumer confidence in the ability of government--both federal and state--to ensure safe food and protect public health. Until FDA puts a stringent, legally enforceable methylmercury standard in place, accompanied by an aggressive sampling program and vigorous enforcement, it can do little to repair the erosion in confidence caused by years of inaction.

FDA Action Level is not Sufficient to Protect Seafood Consumers

The FDA first issued administrative guidelines for mercury in fish in 1969, in response to acute poisoning events in Japan. At that time, the agency set the permissible level of mercury at 0.5 parts per million. FDA converted this standard to an action level in 1974, recognizing that "chronic exposure to fish and shellfish containing methylmercury poses a greater potential for danger to women of childbearing age than to the general population."[7] In later action, FDA ignored this critical public health consideration.

Following litigation challenging its mercury action level, in 1979 FDA relaxed the mercury standard to 1.0 part per million because of new information on consumption and socioeconomic impacts presented by the National Marine Fisheries Service. According to FDA, NMFS concluded that "the higher level would provide a significant economic benefit to those industries most seriously affected by regulatory actions under the 0.5 ppm guideline . . . ."[8] In

---

[7] 39 Fed. Reg. 42,738 (Dec. 6, 1974).

[8] 44 Fed. Reg. 3,992 (Jan. 19, 1979).

1984, FDA revised the 1.0 ppm mercury action level again so that it applied only to methylmercury. In so doing, FDA acknowledged that the revision of the action level might result in increased consumer exposure to methylmercury, but concluded that "this increase in exposure will not be of public health concern."[9]

Despite the recognition by FDA in 1974 that exposure to methylmercury might harm fetuses, no allowance was made in setting the action level to provide protection for pregnant women and children. Later decisions in 1979 and 1984 that increased exposure to mercury never revisited the issue of fetal effects.

It should not be surprising, then, that when the National Academy of Sciences issued its *Seafood Safety* report in 1991, it extensively criticized FDA's methylmercury action level for not adequately protecting pregnant women and children. Most notably, the NAS criticized FDA for basing its standard on the lowest blood level of mercury reported to produce effects on adults, rather than its typical approach, which was to base its analysis on the dietary intake level where no effects are observed.[10] Additionally, NAS pointed out that the FDA standard failed to account for two critical variables: the well-documented differences among individual rates of mercury elimination and among fetal response to mercury exposure.[11] The NAS concluded: "[A]lthough the tenfold safety factor, as applied, appears to offer a reasonable degree of protection for adult effects, projections . . . of the fetal dose-response data suggest the possibility of appreciable risk

---

[9] 49 Fed. Reg. 45,663 (1984).

[10] Institute of Medicine, *Seafood Safety*, (Washington, DC: National Academy Press, 1991), pp. 196-197 [hereinafter cited as *1991 NAS Report*].

[11] *1991 NAS Report*, pp. 196-199, 211.

from methylmercury exposure, even at levels to which many people are exposed via the diet."[12] FDA did nothing in response to this damning report.

Based on the mounting evidence of flaws in FDA's mercury action level, in 1992, I petitioned FDA on behalf of a consumer organization to establish a regulatory limit for methylmercury in seafood that would protect pregnant women and children. There were two significant components to this petition. First, it sought a more stringent standard that would account for fetal effects. Equally important, it asked FDA to set a regulatory limit for methylmercury, rather than just an action level.

An action level identifies the level of contamination above which FDA may bring an enforcement action. At best, an action level is a yellow light for industry, signaling when FDA might consider a food to be adulterated. But each time FDA brings a case based on an action level, it must prove the threat to public health caused by the seafood in question. A regulatory limit, by contrast, is a red light, signaling to industry that it cannot sell seafood exceeding that limit. It is a legally enforceable limit that is binding on the agency and on the industry. It eliminates the need for FDA to justify its action level in each and every case. Unfortunately, the FDA never responded to this petition.

During the 1990's, much of the public debate over mercury centered on EPA's efforts to clamp down on mercury emissions from fossil fuel-burning power plants. The issue of mercury-tainted fish was never far from the spotlight, however, since Congress had asked EPA for a report on the health effects of such emissions, among other things.[13] In its Mercury Study Report

---

[12] *1991 NAS Report*, p. 188.

[13] 42 U.S.C. § 7412(n)(1)(B).

to Congress in 1997, EPA estimated that between one and three percent of women of childbearing age eat sufficient amounts of fish to be at risk from methylmercury exposure.[14] EPA also reaffirmed its RfD of 0.1 µg/kg-bw/day as "protective of brain development in the young child."[15]

EPA's 1997 report was not well-received. So Congress, in EPA's Fiscal Year 1999 funding, instructed EPA to commission a NAS study on the "appropriate" reference dose for methylmercury.[16]

The new NAS report was released in July 2000 and garnered significant media attention. The 2000 NAS committee endorsed EPA's mercury standard of 0.1 microgram per kilogram of body weight per day. NAS said EPA's RfD is "scientifically justifiable for the protection of public health."[17] Of particular note, the NAS estimated that over 60,000 U.S. children are born each year at risk of neurological problems due to *in utero* exposure to methylmercury.[18] What got little attention was the committee's call for harmonization of mercury standards among different agencies.

And, as in the earlier NAS report, several of the panel's recommendations, when applied to the FDA's action level for methylmercury, reveal fatal flaws in the agency's standard-setting process. Specifically, the 2000 NAS panel found the following: First, there is a "strong data

---

[14] Environmental Protection Agency, *Mercury Study Report to Congress*, Vol. I, (1997), p. 3-42, <http://www.epa.gov/ttn/oarpg/t3/reports/volume1.pdf> [hereinafter cited as *1997 EPA Study Report*].

[15] *1997 EPA Study Report*, p. 3-22.

[16] *2000 NAS Report*, pp. 13-14.

[17] *2000 NAS Report*, p. 329.

[18] *2000 NAS Report*, p. 327.

base" of human and animal studies showing neurotoxic effects from in utero exposure to methylmercury and particularly the 1997 Faroe Islands study on the effects of low-level chronic exposure. *By contrast, the FDA action level is based upon a 1971 study of two high-exposure poisoning episodes occurring in the 1960's. Although the FDA conceded in 1994 that long-term exposure to methylmercury in fetuses and infants might have adverse harm, the agency did not reevaluate its action level when the Faroe Islands, Seychelles (1998) or New Zealand (1986, 1989) studies on developmental neurotoxicity were released.*[19]

Second, the NAS said that developmental neurotoxicity should be the end point used in calculating the appropriate regulatory level of methylmercury. *The FDA used overt neurological symptoms in adults as the end point; therefore its action level is set to protect adult men weighing 154 pounds and over.* Third, the NAS panel recommended a benchmark dose limit of 58 parts per billion in cord blood, which corresponds to approximately 12 parts per million in hair.[20] *The FDA action level corresponds to a biomarker of 50 ppm in hair, which is more than 4 times the NAS recommendation.*[21]

This report added to the large body of science showing the adverse effects of low-level methylmercury exposure on developing fetuses. Citing this new study, two years ago CSPI resubmitted the original methylmercury petition to FDA. We urged FDA to immediately adopt EPA's standard for methylmercury as an "action level" and to initiate a rulemaking to adopt a

---

[19] Caroline Smith DeWaal, Letter to FDA Commissioner Jane Henney Re: Petition to Set a Regulatory Limit for Methylmercury in Seafood That Reflects the Risk to Pregnant Women and Children from the Intake of Seafood Containing Methylmercury, July 17, 2000 [hereinafter *CSPI's Re-submission of 1992 petition*].

[20] *2000 NAS Report*, p. 328.

[21] *CSPI's Re-submission of 1992 petition.*

regulatory limit for methylmercury that fully protects the children of women who are or may become pregnant.[22] In addition, CSPI urged that FDA correct the lack of adequate monitoring for methylmercury in commercial seafood.[23]

More than a decade has passed since the first NAS's report criticized FDA's standard for failing to offer adequate protection, especially to the unborn. A full decade has passed since consumer groups first petitioned FDA to address this flaw. Consumers should not have to wait this long -- through the publication of two NAS reports -- for the Food and Drug Administration to take action to protect our health and our children. Now we have a mountain of evidence supporting our call for a more protective standard for methlymercury in seafood. Continued delay in setting and enforcing a public health standard would be unconscionable.

---

[22] *CSPI's Re-submission of 1992 petition.*

[23] In 2000, Michael Bender of the Mercury Policy Project and Jane Williams of California Communities Against Toxics released an important report showing that, in recent years, FDA has drastically cut back its mercury sampling program.

For Immediate Release: December 6, 2005

Government Should Warn About Mercury in Fish, Says CSPI

Groups Say FDA Should Urge States to Require Point-of-Purchase Notices

The Food and Drug Administration (FDA) should urge states to require easy-to-understand advice about mercury in fish right at the seafood counter, according to the nonprofit Center for Science in the Public Interest (CSPI). Such notices would warn high-risk consumers—pregnant women, women who may become pregnant, and young children—not to eat swordfish, shark, king mackerel, and tilefish, and they should limit their consumption of fresh, frozen, and canned white tuna.

California already uses point-of-purchase notices similar to the one CSPI proposed to the FDA, and several major grocers, including Safeway and Wild Oats, post versions of their own. But CSPI says a standardized message would be beneficial to state policymakers, retailers, and consumers alike, many of whom are justifiably confused about the risks posed by mercury in seafood.

"The current advisory on mercury in fish is very complex and was clearly not intended for the general public," said CSPI food safety director Caroline Smith DeWaal. "FDA should ask urge supermarkets to put clear information right at the fish counter, where pregnant women or those serving young children can easily see it. That way, pregnant consumers don't have to avoid the fish counter, but can easily choose alternative seafood that doesn't carry the risk."

DeWaal is speaking on Tuesday at an international conference, Seafood and Health, in Washington, D.C.

In 2003, then-FDA Commissioner McClellan wrote in a letter to CSPI, "One of the key needs for an advisory to be successful is for it to be clear and well-communicated. There are many ways that in which this can be achieved, including the use of printed materials at the point-of-purchase."

Mercury is an environmental pollutant that bioaccumulates in large ocean-dwelling fish, such as swordfish, shark, some types of tuna and king mackerel. Eating seafood is the leading cause of exposure to methylmercury, a reproductive toxin that can cause neurological damage to the developing fetus and young children. Women can avoid the risk by steering clear of fish containing high-levels of mercury for 12 months before becoming pregnant.

In 2001, FDA issued an advisory warning to pregnant women, those planning to become pregnant, nursing mothers and those feeding young children to avoid fish that contain the highest levels of mercury. The advisory was revised in 2004, with the agreement of both the FDA and the Environmental Protection Agency. The revision included advice on limiting consumption of white (albacore) tuna to six ounces per week and to limit overall fish consumption to 12 ounces per week.

CSPI's letter to FDA notes that while California has already implemented a mandatory point-of-purchase advisory, and some chains are adopting them voluntarily, "the size and content of the messages vary. Therefore, FDA would be performing an important service by providing a standard health communication that all fish retailers can use."

The Natural Resources Defense Council, the Mercury Policy Project, and the environmental group Oceana similarly are calling on the FDA to push point-of-purchase advisories on mercury in seafood.

For more information, contact:

Center for Science in the Public Interest
1875 Connecticut Avenue, NW
Washington, DC 20009

phone 202.332.9110
fax 202.265.4954

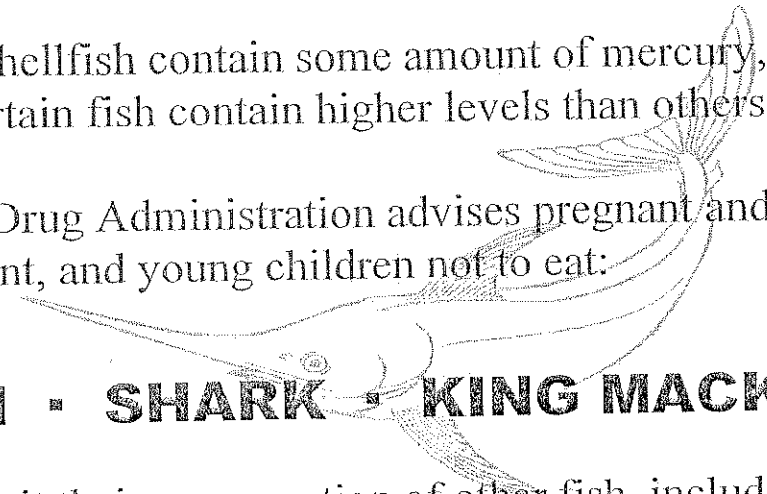
ARE YOU PREGNANT?

OR DO YOU PLAN TO BE IN THE NEXT 12 MONTHS?

OR DO YOU FEED YOUNG CHILDREN?

Nearly all fish and shellfish contain some amount of mercury, which can harm fetuses and young children. Certain fish contain higher levels than others.

The U.S. Food and Drug Administration advises pregnant and nursing women, women who may become pregnant, and young children not to eat:



SWORDFISH · SHARK · KING MACKEREL · TILEFISH

They should also limit their consumption of other fish, including **fresh, frozen and canned white (albacore) tuna.**

Fish and shellfish can be an important source of nutrients. However, the Food and Drug Administration advises pregnant and nursing women, women who may become pregnant, and young children to limit their overall consumption of fish to no more than **12 ounces per week.**

To reduce mercury exposure, eat a variety of fish. Fish that tend to have **little or no mercury** include **salmon (fresh, frozen, or canned), catfish, flounder, shrimp, scallops, and tilapia.** Mercury levels in canned tuna vary. **Light tuna** has the least, 1/3 as much mercury as white (albacore) tuna.

For more information, call the FDA toll-free at **1-888-SAFEFOOD** (1-888-728-3366)