

**NLWJC - Kagan**

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Seafood**

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ENCLOSURES FILED OVERSIZE ATTACHMENTS

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14359

ENCLOSURES FILED OVERSIZE ATTACHMENTS

NARA 11672

August 30, 1999

MEMORANDUM FOR: ANNA RICHTER

FROM:

TERRY GOOD    
OFFICE OF RECORDS MANAGEMENT

RE: ELENA KAGAN FILES

This Elena Kagan box (# 14358) is charged to you.

Please call me when you no longer need it.

I would recommend that you copy those documents you wish to use and return as soon as possible the originals to their file folder.

Please do not permanently remove or add any documents.

Cms pr - food safety - seafood

# OSTP

**Office of Science and Technology Policy  
Executive Office of the President  
Washington, D.C. 20502**

## FAX TRANSMITTAL SHEET

Date: December 19, 1997

TO: Elena Kagen

FAX #: 6-2878

FROM: Fran Sharples

Environment Division

PHONE: 202 456-6079 FAX: 202-456-6025

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NUMBER OF PAGES INCLUDING COVER PAGE: 4

MESSAGE: OSTP prepared these for McCurry with input from FDA. Thought you might like to see them.

**Q & As for Release of EPA's Mercury Study Report to Congress**

**Q:** What are the basic findings of EPA's Report?

**A:** The Report says that mercury cycles in the environment as a result of both natural factors and human activities. Combustion of coal and incineration of wastes, among other things, release mercury vapor to the atmosphere. Some of this mercury is deposited on land and in water bodies. From there it can be taken up by plants and animals in the form of methylmercury, which can be concentrated in the food chain. Human exposures to mercury in the United States occur mainly via the consumption of fish.

**Q:** Doesn't EPA's report say that mercury exposures, especially through seafood, are more dangerous than previously thought?

**A:** EPA's report identifies environmental mercury pollution as a problem that we should be concerned about. It summarizes a lot of information about mercury, but nothing about the health effects of mercury that hasn't been known for many years. Both EPA and the Food and Drug Administration, the federal agency with regulatory responsibility for the safety of seafood, emphasize that commercial seafood purchased in grocery stores and at restaurants is safe.

**Q:** So EPA's report isn't advising people not to eat fish?

**A:** No, EPA is not advising people to stop eating fish. Fish and shellfish are excellent foods, and eating fish has many health benefits. Fish that are purchased in a grocery store or eaten at a restaurant do not pose health risks. Detailed dietary advice on commercially purchased fish is available from FDA and concerned individuals should contact FDA for more information at 202-205-4144. There are some concerns about fish that people catch themselves if they come from water bodies that are contaminated with mercury.

**Q:** How do people know if the fish they catch are safe to eat?

**A:** Thirty-nine states have mercury advisories for certain lakes and rivers. People who intend to eat fish from these lakes and rivers should check with their state health department to find out if there are any consumption limitations they should be aware of.

**Q:** Is it safe for pregnant women to eat fish?

**A:** Because methylmercury is toxic to the human nervous system, and because the nervous system of the developing fetus is very sensitive to methylmercury, pregnant women should avoid high exposures to mercury. Certain large predatory fish, such as shark and swordfish, may

contain more mercury than other marine fish, so pregnant women should limit their consumption of these species to once a month, according to FDA. Again, detailed dietary advice for pregnant women or women who intend to become pregnant is available from FDA.

**Q:** What about children?

**A:** At this time, we do not know whether children have the same sensitivity to mercury as adults or if their sensitivity is greater due to the fact that some nervous system development continues in young children. FDA's dietary advice suggests that children benefit from eating a variety of fish, as do adults. Levels of mercury in commercially purchased fish and shellfish are generally low, and do not represent a significant source of exposure to harmful levels of mercury for children. Consult FDA for more detailed advice on such concerns.

**Q:** But shouldn't children and pregnant women limit their consumption of tuna, just to be on the safe side?

**A:** Seafood is an important part of a healthy, balanced diet for everyone. Except for FDA's advice that pregnant women and women of childbearing age should limit consumption of shark and swordfish to once a month, the federal government's advice is that consumption of commercial seafood is safe --and that includes tuna.

**Q:** EPA's report seems to indicate that EPA and FDA disagree about mercury risks and that EPA is being more protective of people, especially children, than FDA. Is that true?

**A:** EPA and FDA agree on the fundamental message to consumers of commercial seafood that it is safe to eat. For any complicated scientific issue where there are data gaps, some disagreement among scientists is to be expected. There are few studies of people exposed to low levels of mercury through fish in their diets. In the absence of such studies, both EPA and FDA have had to base their risk evaluations on past incidents (that occurred in Japan and Iraq) in which people ingested extremely high amounts of mercury. While these situations taught scientists a great deal about the effects of very high levels of exposure, they didn't provide much information about the risks of very low level exposures comparable to what the U.S. population experiences. It is in the complexities of extrapolating from extremely high exposures to very low exposures that there is some disagreement. Two new studies--which neither agency has fully reviewed yet--may help resolve some of the uncertainties in the near future. EPA, FDA and other federal agencies plan to conduct an interagency review of all the available data in the near future to help decide whether changing current evaluations of mercury's risks is warranted.

**Q:** Why doesn't EPA do something to stop mercury pollution?

**A:** EPA has already developed rules to limit mercury emissions to the air from incineration of municipal and medical waste. These rules are expected to result in a 50% reduction of air emissions of mercury over the next few years. They are also evaluating what other actions make sense, and will continue to study the problem.



Cms Pro - food safety -  
mercury report

## 1. THE MERCURY STUDY REPORT TO CONGRESS

The Clean Air Act Amendments of 1990 (CAA) established section 112(n)(1)(B) which requires the United States Environmental Protection Agency (U.S. EPA) to study the impacts of mercury air pollution. In particular, section 112(n)(B) specifies the following:

The Administrator shall conduct, and transmit to the Congress not later than 4 years after the date of enactment of the Clean Air Act Amendments of 1990, a study of mercury emissions from electric utility steam generating units, municipal waste combustion units, and other sources, including area sources. Such study shall consider the rate and mass of such emissions, the health and environmental effects of such emissions, technologies which are available to control such emissions, and the costs of such technologies.

The U.S. EPA designed the Mercury Study to address many different (but linked) types of information:

- data on type, sources, and trends in emissions;
- evaluation of the atmospheric transport of mercury to locations distant from emission sources;
- assessment of potential impacts of mercury emissions close to the source;
- identification of major pathways of exposure to humans and non-human biota;
- identification of the types of human health consequences of mercury exposure and the amount of exposure likely to result in adverse effects;
- evaluation of mercury exposure consequences for ecosystems and for non-human species;
- identification of populations especially at risk from mercury exposure due to innate sensitivity or high exposure; and
- estimates of control technology efficiencies and costs.

The Report used the above types of information to assess the impact of emissions to air of mercury from a variety of sources. This assessment included judgments as to the potential hazard to humans and wildlife of methylmercury exposure which (as is described in succeeding sections) is largely through the consumption of contaminated fish.

There was no attempt in this Report to do a comparative risk/benefit analysis of fish as an important source of protein and calories in the diet of U.S. populations. Such an analysis would be beyond the scope of the CAA mandate. As emphasized in succeeding sections, the typical U.S. consumer of fish is not in danger of consuming harmful levels of methylmercury and is not being advised to reduce fish consumption.

## OVERVIEW

This Mercury Study is a Report to Congress prepared by the U.S. Environmental Protection Agency. It fulfills the requirements of section 112(n)(1)(B) of the Clean Air Act, as amended in 1990. The Report provides an assessment of the magnitude of U.S. mercury emissions by source, the health and environmental implications of those emissions, and the availability and cost of control technologies. As the state-of-the-science for mercury is continuously and rapidly evolving, this report should be viewed as a "snapshot" of current mercury.

Mercury cycles in the environment as a result of natural and human (anthropogenic) activities. The amount of mercury mobilized and released into the biosphere has increased since the beginning of the industrial age. Most of the mercury in the atmosphere is elemental mercury vapor, which circulates in the atmosphere for up to a year, and hence can be widely dispersed and transported thousands of miles from likely sources of emission. Most of the mercury in water, soil, sediments, or plants and animals is in the form of inorganic mercury salts and organic forms of mercury (e.g., methylmercury). The inorganic form of mercury, when either bound to airborne particles or in a gaseous form, is readily removed from the atmosphere by precipitation and is also dry deposited. Wet deposition is the primary mechanism for transporting mercury from the atmosphere to surface waters and land. Even after it deposits, mercury commonly is emitted back to the atmosphere either as a gas or associated with particles, to be re-deposited elsewhere. As it cycles between the atmosphere, land, and water, mercury undergoes a series of complex chemical and physical transformations, many of which are not completely understood.

Mercury accumulates most efficiently in the aquatic food web. Predatory organisms at the top of the food web generally have higher mercury concentrations. Nearly all of the mercury that accumulates in fish tissue is methylmercury. Inorganic mercury, which is less efficiently absorbed and more readily eliminated from the body than methylmercury, does not tend to bioaccumulate.

### *Mercury Emissions and Deposition in the U.S.*

The best point estimate of annual anthropogenic U.S. emissions of mercury in 1994-1995 is 158 tons. Roughly 87 percent of these emissions are from combustion sources, including waste and fossil fuel combustion. Contemporary anthropogenic emissions are only one part of the mercury cycle. Releases from human activities today are adding to the mercury reservoirs that already exist in land, water, and air, both naturally and as a result of previous human activities. The flux of mercury from the atmosphere to land or water at any one location is comprised of contributions from the natural global cycle including re-emissions from the oceans, regional sources, and local sources. Local sources could also include direct water discharges in addition to air emissions. Past uses of mercury, such as fungicide application to crops are also a component of the present mercury burden in the environment. One estimate of the total annual global input to the atmosphere from all sources including natural, anthropogenic, and oceanic emissions is 5,500 tons. Based on this, United States sources are estimated to have contributed about 3 percent of the 5,500 tons in 1995.

A computer simulation of long-range transport of mercury suggests that about one-third (~ 52 tons) of U.S. anthropogenic emissions are deposited, through wet and dry deposition, within the lower 48 States. The remaining approximate two-thirds (~ 107 tons) is transported outside of U.S. borders where it diffuses into the global reservoir. In addition, the computer simulation suggests that another 35 tons of mercury from the global reservoir is deposited for a total deposition of roughly 87 tons. Although this type of modeling is uncertain, the simulation suggests that about three times as much mercury is being added to the global reservoir from U.S. sources as is being deposited from it.

The highest deposition rates from anthropogenic and global contributions for mercury are predicted to occur in the southern Great Lakes and Ohio River valley, the Northeast and scattered areas in the South, with the most elevated deposition in the Miami and Tampa areas. The location of sources, the chemical species of mercury emitted and the climate and meteorology are key factors in mercury deposition. Humid locations have higher deposition than arid locations.

#### *Public Health Impacts*

Epidemics of mercury poisoning following high-dose exposures to methylmercury in Japan and Iraq demonstrated that neurotoxicity is the health effect of greatest concern when methylmercury exposure occurs to the developing fetus during pregnancy. Neurotoxicity of methylmercury is the health endpoint of greatest concern. Developing fetuses are the subpopulation of greatest interest. Dietary methylmercury is almost completely absorbed into the blood and distributed to all tissues including the brain; it also readily passes through the placenta to the fetus and fetal brain. The Reference Dose (RfD) is an amount of methylmercury, which when ingested daily over a lifetime is anticipated to be without adverse health effects to humans, including sensitive subpopulations. At the RfD or below, exposures are expected to be safe. The risk following exposures above the RfD is uncertain, but risk increases as exposures to methylmercury increase.

Extrapolating from the high-dose exposures that occurred in the Iraq incident, the U.S. EPA derived a RfD for methylmercury. However, while the U.S. EPA has been advised by scientific reviewers to employ this RfD for this analysis, new data are emerging. Currently ongoing are two large epidemiology studies in the Seychelle Islands and in the Faroe Islands that were designed to evaluate childhood development and neurotoxicity in relation to fetal exposures to methylmercury in fish-consuming populations. Because of various limitations and uncertainties in the Iraqi data set, the U.S. EPA and other federal agencies intend to participate in an interagency review of all the human data on methylmercury, including the more comprehensive studies from the Seychelle Islands and the Faroe Islands. The purpose of this review is to reduce the level of uncertainty attending current estimates of the level of exposure to mercury associated with subtle neurological endpoints. After this process, the U.S. EPA will re-assess its RfD for methylmercury to determine if change is warranted.

Fish consumption dominates the pathway for human and wildlife exposure to methylmercury. This study supports a plausible link between anthropogenic release of mercury from industrial and combustion sources in the United States and mercury in fish. However, these

fish mercury concentrations also result from existing background concentrations of mercury (which may consist of mercury from natural sources, as well as mercury which has been re-emitted from the oceans or soils) and deposition from the global reservoir (which includes mercury emitted by other countries). The current scientific understanding of the environmental fate and transport of this element, it is not possible to quantify how much of the methylmercury in seafood and freshwater fish consumed by the U.S. population is contributed by U.S. emissions relative to other sources of mercury (such as natural sources and re-emissions from the global pool).

Critical elements in estimating methylmercury exposure and risk from fish consumption include the species of fish consumed, the concentrations of methylmercury in the fish, the quantity of fish consumed, and how frequently fish is consumed. The typical U.S. consumer eating fish from restaurants and grocery stores is not in danger of consuming harmful levels of mercury from fish and are not advised to limit fish consumption. The levels of mercury found in the most frequently consumed commercial fish are low, especially compared to levels that might be found in some non-commercial fish from fresh water bodies that have been affected by mercury pollution. While most U.S. consumers need not be concerned about their exposure to mercury, some exposures may be of concern. Those who regularly and frequently consume large amounts of fish -- either marine species that typically have much higher levels of mercury than the rest of seafood, or freshwater fish that have been affected by mercury pollution -- are more highly exposed. Because the developing fetus may be the most sensitive to the effects of mercury in fish, women of child-bearing age are regarded as the population of greatest interest. In this report, an analysis of dietary surveys led the U.S. EPA to conclude that between 1 and 3 percent of women of child-bearing age (i.e., between the ages of 15 and 44) eat sufficient amount of fish to be at risk from mercury exposure depending on the mercury concentrations in the fish. These consumers should be aware of the Food and Drug Administration and State fish advisories that suggest limiting the consumption of contaminated fish. Advisories in the United States have been issued in 39 states, warning against consumption of certain species of fish contaminated with mercury.

To the extent that concern is focused on high-end fish and seafood consumers, research is needed on the actual consumption patterns and estimated methylmercury exposure of this subpopulation. In addition, the findings from such research should be validated by analysis of hair samples from a representative sample of members of this subpopulation.

### *Environmental Impacts*

The pattern of mercury deposition nationwide influences which eco-regions and eco-systems will be more highly exposed. Piscivorous (fish-eating) birds and mammals are more highly exposed to mercury than any other known component of aquatic ecosystems. Adverse effects of mercury on fish, birds and mammals include death, reduced reproductive success, impaired growth and development, and behavioral abnormalities.

Mercury contamination has been documented in the endangered Florida panther and the wood stork, as well as populations of loons, eagles, and furbearers such as mink and otter. These

species are at high risk of mercury exposure and effects because they either are piscivores or eat piscivores. Concentrations of mercury in the tissues of wildlife species have been reported at levels associated with adverse health effects in laboratory studies with the same species. However, field data are insufficient to conclude whether piscivorous wading birds or mammals have suffered adverse effects due to airborne mercury emissions. Modeling analyses conducted for this report suggest that it is probable that individuals of some highly exposed wildlife subpopulations are experiencing adverse effects due to airborne mercury emissions.

### *Mercury Control Technologies*

Mercury is widely used in industry because of its diverse properties and serves as a process or product ingredient in several industrial sectors, however, industrial demand for mercury has declined by about 75 percent between 1988 and 1996, due largely to the elimination of mercury additives in paints and pesticides and the reduction of mercury in batteries. Most of the emissions of mercury are produced when waste or fuel containing mercury is burned. The U.S. EPA has already finalized emission limits for municipal waste combustors and medical waste incinerators. As a result, by the year 2000, emissions from these categories will decline at least 90 percent from 1995 levels. In addition, mercury emission limits have been proposed for hazardous waste incinerators.

The largest remaining identified source of mercury emissions are coal-fired utility boilers. Although a number of mercury control technologies are being evaluated for utility boilers, most are still in the research stages, making it difficult to predict final cost-effectiveness as well as the time required to scale-up and commercialize the technologies. Because the chemical species of mercury emitted from boilers varies from plant to plant, there is no single control technology that removes all forms of mercury. There remains a wide variation in the end costs of control measures for utilities and the possible impact of such costs on utilities. Preliminary estimates of national control costs for utility boilers (based on pilot scale data) are in the billions of dollars per year. Ongoing research, as well as research needs related to mercury controls for utilities, are described in the document.

Cost-effective opportunities to deal with mercury during the product life-cycle, rather than just at the point of disposal, need to be pursued. A balanced strategy which integrates end-of-pipe control technologies with material substitution and separation, design-for-environment, and fundamental process change approaches is needed. In addition, international efforts to reduce mercury emissions as well as greenhouse gases will play an important role in reducing inputs to the global reservoir of mercury.

As noted above, because of the current, limited scientific understanding of the environmental fate and transport of this pollutant, it is not possible to quantify the contribution of U.S. anthropogenic emissions relative to other sources of mercury, including natural sources and re-emissions from the global pool, on methylmercury levels in seafood and freshwater fish consumed by the U.S. population. Consequently, the U.S. EPA is unable to predict at this time how much, and over what time period, methylmercury concentrations in fish would decline as a result of actions to control U.S. anthropogenic emissions. This is an area of ongoing study.

Cous pro - food safety - seafood



U.S. FOOD AND DRUG ADMINISTRATION  
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Date: 12/5/97

To: ELENA KAGAN

Fax Number:

From: **Bill Hubbard**

Pages (w/o cover):

Comments:

I understand Jim O'Hara raised this mercury issue with you. The attached is a brief explanation of a contentious issue that we fear must be handled very carefully or result in possible public anxiety about seafood safety.

Of course, this reflects FDA's view of things.

## MERCURY REPORT TO CONGRESS

Mercury is a neurotoxic metal to which the human fetus is especially sensitive. Although it is naturally found in the environment, it is also a pollutant resulting from industrial processes. The Clean Air Amendments of 1990 required EPA to study and report on mercury air pollution. EPA's draft report reviews, among other things, human exposures and health effects. FDA's concerns focus on the sections of the report that address health effects from the consumption of seafood, the primary route of human exposure to mercury.

Beginning last summer, a review process began that was to be coordinated by OSTP; in addition, an OMB review was to take place before the court-ordered release date of the report (December 19). Although the OSTP review process has resolved some issues among the various agencies involved, there are still substantial concerns remaining at this late date. (The agencies include EPA, FDA, CDC, National Marine Fisheries Service, & Energy.) Whether OMB will conduct its own review is unclear.

The concerns about the report involve some highly technical scientific analyses and interpretations. However, here's a simplistic summary of some of the major issues: Both FDA and EPA have established versions of Allowable Daily Intakes (ADI) for mercury intended to provide a reasonable margin of safety. FDA, based on its ADI set, set a regulatory "action level" for mercury of 1 part-per-million for all seafood. EPA's analogous level is a "Reference Dose" (RfD) for mercury that is 4 times lower than FDA's. The discrepancy is that EPA has based its RfD on data from a study of a poisoning event in Iraq, while FDA has long felt that this study contains significant uncertainties that make it inappropriate for setting regulatory limits (e.g., sample size of only 4 mother-infant pairs).

In its draft report, EPA defines an RfD as an estimate of daily exposure to humans that is likely to be without appreciable risk during a lifetime. The report highlights the RfD in a way that suggests that the RfD can provide a basis for estimating the size of the U.S. population at risk from mercury in seafood. The implication is that there is a linkage between exceeding the RfD and risk of adverse health effects. Consequently, FDA is concerned that the public will perceive the RfD as presented in the EPA report as a dividing line between safe and unsafe.

One way in which the report highlights the RfD is by pointing out that up to 25 percent of American children are exposed to mercury above the EPA RfD. And since seafood is the predominant source of mercury exposure, the public may draw the conclusion (that FDA believes is erroneous) that many children may be in danger from consuming commercial seafood. FDA's concern is that such a misperception would seriously and needlessly erode public confidence in the safety of seafood. Indeed, FDA's longstanding scientific conclusion is that children are not at risk from commercial seafood and do not need to alter their intake of such food.