

Additional information concerning the Science Advisory Board, its structure, function, and composition, may be found on the SAB Website (<http://www.epa.gov/sab>) and in The FY2000 Annual Report of the Staff Director which is available from the SAB Publications Staff at (202) 564-4533 or via fax at (202) 501-0256.

Individuals requiring special accommodation at this meeting, including wheelchair access, should contact Mr. Flaak at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: December 28, 2000.

**Donald G. Barnes,**

*Staff Director, Science Advisory Board.*

[FR Doc. 01-465 Filed 1-5-01; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-6924-8]

### Water Quality Criteria: Notice of Availability of Water Quality Criterion for the Protection of Human Health: Methylmercury

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of availability of water quality criterion for the protection of human health: methylmercury.

**SUMMARY:** Pursuant to the Clean Water Act (CWA) section 304(a), EPA is announcing the availability of its recommended water quality criterion for methylmercury. This water quality criterion describes the concentration of methylmercury in freshwater and estuarine fish and shellfish tissue that should not be exceeded to protect consumers of fish and shellfish among the general population. EPA expects the criterion recommendation to be used as guidance by States, authorized Tribes, and EPA in establishing or updating water quality standards for waters of the United States and in issuing fish and shellfish consumption advisories. This is the first time EPA has issued a water quality criterion expressed as a fish and shellfish tissue value rather than as a water column value. This approach is a direct consequence of the scientific consensus that consumption of contaminated fish and shellfish is the primary human route of exposure to methylmercury. EPA recognizes that this approach differs from traditional water column criteria, and will pose implementation challenges. In this notice, EPA is providing suggested approaches for relating the fish and

shellfish tissue criterion to concentrations of methylmercury in the water column. EPA also plans to develop more detailed guidance to assist States and Tribes with implementation of the methylmercury criterion in water quality standards and related programs. EPA believes that flexibility will be needed when designing control programs to meet this water quality criterion because mercury is highly persistent in the environment and because air deposition is the primary source of mercury for many waterbodies.

**ADDRESSES:** Copies of the complete document, titled *Water Quality Criterion for the Protection of Human Health: Methylmercury* can be obtained from EPA's National Service Center for Environmental Publications (NSCEP), telephone number 1-800-490-9198. Alternatively, the document and related fact sheet can be obtained from EPA's web site at <http://www.epa.gov/waterscience/standards/methylmercury/> on the Internet. Copies of the draft EPA internal report *National Bioaccumulation Factors for Methylmercury*, the peer review report on the draft bioaccumulation factors, responses to public comments on the notice of intent to develop a methylmercury water quality criterion, and responses to peer review comments on the methylmercury reference dose are in Water Docket W-00-20 methylmercury. These materials are available for inspection at the Water Docket Room EB 57, 401 M Street SW, Washington, DC 20460, open between 9 am and 3:30 pm EST. Appointments to review the material may be made by calling 202-260-3027.

**FOR FURTHER INFORMATION CONTACT:** For general questions regarding the methylmercury water quality criterion guidance, contact Mary Manibusan, USEPA, Health and Ecological Criteria Division (4304), Office of Science and Technology, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; or call (202) 260-3688; fax (202) 260-1036; or e-mail [manibusan.mary@epa.gov](mailto:manibusan.mary@epa.gov). For specific issues regarding mercury bioaccumulation, contact Erik Winchester, USEPA, Health and Ecological Criteria Division (4304), Office of Science and Technology, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; or call (202) 260-6107. For questions about implementation of the water quality criterion, contact William Morrow, USEPA, Standards and Health Protection Division, Office of Science and Technology, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; or call (202) 260-3657.

**SUPPLEMENTARY INFORMATION:** This Supplementary Information Section is organized as follows:

- I. Introduction
- II. Background Information
  - A. What are human health ambient water quality criteria?
  - B. How is the 2000 Human Health Methodology used?
  - C. How does EPA use its recommended section 304(a) water quality criteria?
  - D. What water quality criteria must a State or authorized Tribe adopt into its water quality standards?
  - E. May States and authorized Tribes adopt water quality criteria based on local conditions?
  - F. How does 40 CFR 131.21 affect water quality standards adopted by States and authorized Tribes?
- III. Mercury Sources, Environmental Fate, and Implications for Water Quality Criterion Derivation
  - A. What are the mercury emissions and deposition sources in the United States?
  - B. How does mercury cycle in the environment?
  - C. Does methylmercury bioaccumulate?
  - D. Why is the section 303(a) human health water quality criterion for methylmercury expressed as a fish tissue residue value?
- IV. Current Activities to Address Mercury Pollution
  - A. Fish consumption advisory activities
  - B. Water quality standards
  - C. Total maximum daily load
  - D. Pollution minimization activities
  - E. National air emissions regulations
- V. Derivation of the Methylmercury Fish Tissue Residue Water Quality Criterion
  - A. What is the health risk assessment for methylmercury?
  - B. How are mercury exposure and relative source contribution assessed?
  - C. How is the methylmercury water quality criterion calculated?
- VI. How Can the Fish Tissue Residue Water Quality Criterion Be Related to a Mercury Concentration in Water?
- VII. What is the Relationship Between Fish Advisories and the Fish Tissue Residue Water Quality Criterion?
- VIII. How Does EPA Suggest Implementing the Methylmercury Water Quality Criterion?
- IX. Literature Cited

## I. Introduction

Pursuant to section 304(a)(1) of the Clean Water Act (CWA), the Environmental Protection Agency is announcing the availability of EPA's recommended section 304(a) human health water quality criterion for methylmercury. Section 304(a) human health ambient water quality criteria are numeric guidance values considered to be protective of human health for pollutant concentrations in aquatic media, such as ambient waters and edible tissues of aquatic organisms. EPA's recommended section 304(a) water quality criteria provide guidance

for States and authorized Tribes to use in establishing water quality standards and, when adopted into water quality standards and approved for CWA purposes, may form a basis for controlling discharges or releases of pollutants. Section 304(a) water quality criteria also provide guidance to EPA when promulgating Federal regulations under CWA section 303(c) when such actions are necessary. Under the CWA and its implementing regulations, States and authorized Tribes are to adopt water quality criteria to protect designated uses. EPA's recommended human health water quality criteria do not substitute for the Act or regulations, nor are they regulations themselves. Thus, EPA's recommended section 304(a) water quality criteria do not impose legally binding requirements. States and authorized Tribes retain the discretion to adopt, where appropriate, other scientifically defensible water quality standards that differ from these recommendations. EPA may change the section 304(a) water quality criteria in the future.

Mercury is a complex multi-media pollutant that requires a more unique approach to source management, pollution reduction and control, and development of a water quality criterion than is typically required for a less complex pollutant. In the United States, humans are exposed primarily to methylmercury rather than to inorganic mercury. The dominant exposure pathway is through consumption of contaminated fish and shellfish rather than from ambient water. The water quality criterion published in this notice is for methylmercury, and it is expressed as a fish tissue (including shellfish) residue criterion rather than a water column criterion. Henceforth, EPA will refer to today's methylmercury water quality criterion as a fish tissue residue criterion, which should be understood to include shellfish as well. The Agency's basis for expressing the methylmercury water quality criterion in this format is discussed later in this notice and in more detail in the water quality criterion document titled *Water Quality Criterion for the Protection of Human Health: Methylmercury* (USEPA, 2001), which is available today.

EPA recognizes that a fish tissue residue water quality criterion is new to States and authorized Tribes and will pose implementation challenges for traditional water quality standards programs. Water quality standards, water quality-based effluent limits, total maximum daily loads, and other activities generally employ a water column value. In this notice, EPA suggests approaches for relating the fish

tissue residue water quality criterion to concentrations of methylmercury in water. EPA also plans to develop guidance to assist States and Tribes to implement this methylmercury water quality criterion in their water quality programs. EPA believes that the range of implementation issues would be addressed best through broad national implementation guidance, and will work to develop such guidance with input from the public. Mercury is highly persistent in the environment and reductions in environmental concentrations are likely to occur over years or decades. For many waterbodies the primary source of mercury pollution is through air deposition and not point source discharge, EPA believes that flexibility may be appropriate as water quality standards based on this methylmercury water quality criterion are implemented. Flexible approaches will enable environmental protection to be achieved efficiently given the resource constraints that exist for both regulators and the regulated community.

This notice also discusses the unique aspects of mercury and methylmercury as an environmental pollutant; announces EPA's intention to publish methylmercury water quality criterion implementation guidance, which will support prevention and reduction of mercury contamination of surface water and fish; and invites the public to provide information and their views on approaches to prevent or reduce mercury pollution and to implement water quality standards for methylmercury.

This document has been approved for publication by the Office of Water, United States Environmental Protection Agency. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

## II. Background Information

### A. What Are Human Health Ambient Water Quality Criteria?

Human health ambient water quality criteria (AWQC) are numeric values considered to be protective of human health for pollutant concentrations in aquatic media, such as ambient waters and edible tissues of organisms. Under section 304(a) of the Clean Water Act (CWA), water quality criteria are based solely on data and scientific judgments about the relationship between pollutant concentrations and environmental and human health effects. Protective assumptions are made regarding potential human exposure intakes. Water quality criteria do not reflect consideration of economic

impacts or the technological feasibility of meeting the pollutant concentrations in ambient water. Section 304(a)(1) of the CWA requires EPA to develop and publish, and from time to time revise, criteria for water quality accurately reflecting the latest scientific knowledge. EPA's recommended section 304(a) water quality criteria may serve as guidance for States and authorized Tribes in establishing water quality standards. The resulting standards may ultimately may provide a basis for controlling discharges or releases of pollutants. Section 304(a) water quality criteria also provide guidance to EPA when promulgating Federal regulations under CWA Section 303(c) when such actions are necessary.

### B. How Is the 2000 Human Health Methodology Used?

In November 2000, EPA published the revised *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (2000) (hereafter the 2000 Human Health Methodology (USEPA, 2000a). See 65 FR 66444 (November 3, 2000). Previous to this, recommended human health ambient water quality criteria were developed using the 1980 *Ambient Water Quality Criteria National Guidelines* (hereafter the 1980 Methodology; USEPA 1980). The 2000 Human Health Methodology incorporates significant scientific advances that have occurred over the last two decades, particularly in the areas of cancer and noncancer risk assessments (using new information, procedures, and published Agency Guidelines), exposure assessments (using new studies on human intake and exposure patterns, and new Agency Guidelines) and methodologies to estimate bioaccumulation in fish.

EPA intends to use the 2000 Human Health Methodology to develop new section 304(a) water quality criteria for additional pollutants and to revise existing section 304(a) water quality criteria. The 2000 Human Health Methodology is an important component of EPA's efforts to improve the quality of the Nation's waters and enhance the overall scientific basis of water quality criteria. Furthermore, the 2000 Human Health Methodology should help States and authorized Tribes address their unique water quality issues and make risk management decisions to protect human health consistent with section 303(c). It will also afford them greater flexibility in developing their water quality programs. The 2000 Human Health provides the detailed means for developing water quality criteria,

including systematic procedures for evaluating cancer risk, noncancer health effects, human exposure, and bioaccumulation potential in fish.

One particular area of new science is in developing the Reference Dose (RfD) value. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of daily exposure to the human population (including sensitive subgroups) that is likely to be protective without an appreciable risk of deleterious health effects during a lifetime. For noncarcinogenic pollutants, the process for deriving a level of exposure considered to be without appreciable risk of effect has evolved over time. EPA has developed guidance on assessing noncarcinogenic effects of chemicals and for the RfD derivation. The 2000 Human Health Methodology recommends consideration of other issues related to the RfD process including integrating reproductive and developmental, immunotoxicity, and neurotoxicity data into the calculation. In the 2000 Human Health Methodology, EPA recommends using quantitative dose-response modeling for the derivation of RfDs when the available data support its use. EPA has provided additional guidance (in its Risk Assessment Technical Support Document (USEPA, 2000b)) to States and authorized Tribes on conducting their own risk assessments.

For exposure assessment, States and authorized Tribes are encouraged to use local studies on human fish and shellfish consumption that better reflect local intake patterns and choices. In the absence of local data, EPA recommends separate default fish consumption values for the general population, recreational fishers and subsistence fishers. A factor to account for other sources of exposure, such as other fish, non-fish food, and air, is included when deriving AWQC for noncarcinogens and for carcinogens based on a nonlinear low-dose extrapolation. In other words, consumption of contaminated water and fish (including shellfish) are not the only exposures considered.

The 2000 Human Health Methodology places greater emphasis on the use of bioaccumulation factors (BAFs) for estimating potential human exposure to contaminants via the consumption of contaminated fish and shellfish than did the 1980 Methodology. BAFs reflect the accumulation of chemicals by aquatic organisms from all surrounding media (includes water, food, and sediment). Compared with bioconcentration factors, which reflect chemical accumulation by aquatic organisms from water only, BAFs are considered to be better predictors of chemical

accumulation by fish and shellfish for chemicals where exposure from food and sediment is important (e.g., highly persistent, hydrophobic chemicals). EPA prefers to use high quality field data (e.g., water and fish data collected in the waterbody of interest) to derive BAFs over laboratory or model-derived estimates of BAFs. This preference is because field data best reflect site-specific factors that can affect the extent of bioaccumulation (e.g., chemical metabolism, food web structure).

#### *C. How Does EPA Use Its Recommended Section 304(a) Water Quality Criteria?*

Water quality standards consist of designated uses, water quality criteria to protect those uses, a policy for antidegradation, and general policies for application and implementation. As part of the water quality standards triennial review process defined in section 303(c)(1) of the CWA, States and authorized Tribes are responsible for maintaining and revising water quality standards. Section 303(c)(1) requires States and authorized Tribes to review, and modify if appropriate, their water quality standards at least once every three years.

EPA's recommended section 304(a) water quality criteria form the basis for Agency decisions, both regulatory and nonregulatory, until superseded by EPA publication of new or revised section 304(a) water quality criteria. These recommended water quality criteria are used in the following ways: (1) As guidance to States and authorized Tribes in adopting water quality standards; (2) as guidance to EPA in promulgating Federal water quality standards; (3) to interpret a State's narrative water quality standard (in the absence of a State adopted numeric standard) in order to establish National Pollutant Discharge Elimination System (NPDES) water quality-based permit limits; and (4) for all other purposes of section 304(a) under the Act. It is important to emphasize the two distinct purposes that are served by the section 304(a) water quality criteria. The first is as guidance to the States and authorized Tribes in the development and adoption of water quality criteria that will protect designated uses (e.g., aquatic life, primary contact recreation). The second is as the basis for promulgation of Federal water quality criteria for States or authorized Tribes when such action is necessary.

#### *D. What Water Quality Criteria Must a State or Authorized Tribe Adopt Into Its Water Quality Standards?*

States and authorized Tribes must adopt water quality criteria that protect

designated uses. See CWA section 303(c)(2)(A). Water quality criteria must be based on a sound scientific rationale and must contain sufficient parameters or components to protect the designated uses. See 40 CFR 131.11(a). Water quality criteria may be expressed in either narrative or numeric format. States and authorized Tribes may employ one of four approaches when adopting water quality criteria: (1) Establish numerical values based on section 304(a) recommended water quality criteria; (2) modify the section 304(a) recommended water quality criteria to reflect site-specific conditions; (3) use other scientifically defensible methods to derive protective water quality criteria; and (4) establish narrative water quality criteria where numeric criteria cannot be determined or to supplement numeric water quality criteria. See 40 CFR 131.11(b).

EPA encourages States and authorized Tribes to use EPA's CWA section 304(a) water quality criteria as guidance in adopting water quality standards consistent with section 303(c) of the CWA and the implementing Federal regulations at 40 CFR Part 131. These water quality criteria are contained in EPA's last compilation of National Recommended Water Quality Criteria. See 63 FR 68354, December 10, 1998; correction in 64 FR 19781, April 22, 1999. In the future, EPA will be publishing new and revised section 304(a) water quality criteria guidance for pollutants of high priority and national importance based upon the 2000 Human Health Methodology. Because this process will take time, EPA encourages States and authorized Tribes, prior to publication of a revised section 304(a) water quality criterion, to make appropriate changes when necessary to their water quality standards to reflect the guidance in the 2000 Human Health Methodology. EPA expects that it would promptly consider for approval any new or revised water quality criterion submitted by a State or authorized Tribe that is based on the 2000 Human Health Methodology.

Once EPA publishes new or revised section 304(a) water quality criteria guidance that reflects the 2000 Human Health Methodology, EPA expects States and authorized Tribes to reassess their water quality standards and, where necessary, establish new or revised water quality criteria consistent with one of the four approaches described above. With today's publication of this section 304(a) human health water quality criterion for methylmercury, EPA is withdrawing the previous ambient human health water quality criteria for mercury (see 63 FR 68354,

December 10, 1998; correction in 64 FR 19781, April 22, 1999) as the recommended section 304(a) water quality criteria for States and authorized Tribes to use as guidance in adopting water quality standards. Implementation issues for this criterion are discussed in Section VIII of today's Notice.

*E. May States and Authorized Tribes Adopt Water Quality Criteria Based on Local Conditions?*

EPA encourages States and authorized Tribes to develop and adopt water quality criteria to reflect local and regional conditions. In the 2000 Human Health Methodology, EPA published default values for risk level, fish intake, drinking water intake, and body weight for use by EPA or States in deriving human health water quality criteria. EPA also intends to publish default bioaccumulation factors and relative source contribution (RSC) factors as chemical-specific water quality criteria are developed or revised. EPA believes these default values result in water quality criteria protective of the general population. States and authorized Tribes may also use these default values when deriving their own water quality criteria, or they may use other values more representative of local conditions if data have been collected supporting the alternative values. However, when establishing a numeric value based on a section 304(a) water quality criterion modified to reflect site-specific conditions, or water quality criteria based on other scientifically defensible methods, EPA strongly cautions States and authorized Tribes not to selectively apply data in order to ensure water quality criteria less stringent than EPA's section 304(a) water quality criteria. Such an approach would inaccurately characterize risk.

*F. How Does 40 CFR 131.21 Affect Water Quality Criteria Adopted by States and Authorized Tribes?*

On April 27, 2000, EPA published new regulations addressing its review and approval of water quality standards adopted by States and authorized Tribes. See 65 FR 24642 April 27, 2000. Under the new regulations, which are codified at 40 CFR 131.21(c)–(f), State or authorized Tribal water quality standards that were adopted, in effect, and submitted to EPA prior to May 30, 2000, are in effect for CWA purposes unless superseded by replacement Federal water quality standards. See 40 CFR 131.21(c). However, under the new regulation, State or authorized Tribal water quality criteria adopted and in effect after May 30, 2000, are in effect for CWA purposes only after EPA

approval of any new or revised water quality standards. Therefore, any new or revised water quality criterion for methylmercury adopted by States or authorized Tribes would not take effect for CWA purposes until after EPA approves such standards.

**III. Mercury Sources, Environmental Fate, and Implications for Water Quality Criterion Derivation**

The 1997 *Mercury Study Report to Congress* (The Mercury Study) (USEPA, 1997a) describes mercury emission sources, fate and transport, exposure to humans and wildlife, human health and ecological impacts of mercury exposure, and control technologies for air emissions. The most recent data and reviews on human health impacts are described and updated in the *Water Quality Criterion for the Protection of Human Health: Methylmercury* (USEPA, 2001), that we are announcing the availability of today.

*A. What Are the Mercury Emissions and Deposition Sources in the United States?*

Based on the EPA's National Toxics Inventory, the highest emitters of mercury to the air include coal-burning electric utilities, municipal waste combustors, medical waste incinerators, chlor-alkali plants, hazardous waste combustors, and cement manufacturers. The Mercury Study estimated that the annual anthropogenic United States emissions of mercury in 1994–1995 was 158 tons. Roughly 87 percent of these emissions were 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 deposition of mercury from the atmosphere to land or water at any location comes from: (1) The natural global cycle (including re-emissions from the oceans); (2) regional sources; and (3) local sources. Local sources can include direct water discharges in addition to mercury from air emissions. Past uses of mercury, such as fungicide application to crops, are also a component of the present mercury burden in the environment. The Mercury Study estimated that, for 1995, the United States sources contributed approximately 3 percent (or 165 tons) of the total global mercury emissions (5,500 tons). The Mercury Study further estimated that, of United States anthropogenic mercury emissions, approximately one-third (52 tons) are

deposited through wet and dry deposition within the lower 48 States. The remaining two-thirds (approximately 107 tons) of anthropogenically emitted mercury is transported outside of the United States' borders where it enters the global reservoir. In addition to mercury deposited from United States sources, approximately another 35 tons of mercury from the global reservoir is deposited for a total deposition of roughly 87 tons within the lower 48 States. In the United States, 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 Miami and Tampa areas having the most elevated levels in the South. The location of sources, the chemical species of mercury emitted, and the climate and meteorology are key factors in where and how rapidly mercury deposition occurs.

*B. How Does Mercury Cycle in the Environment?*

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 can circulate in the atmosphere for up to a year (USEPA, 1997a). Mercury in the atmosphere can be widely dispersed and transported thousands of miles from likely sources of emission (USEPA, 1997a). Inorganic mercury in the atmosphere, when either bound to airborne particles or in a gaseous form, is deposited to soils and waterbodies through wet and dry deposition events. Wet deposition as precipitation is the primary mechanism for transporting mercury from the atmosphere to surface waters and land. After it deposits, mercury can be emitted back to the atmosphere, either as a gas or associated with particles, to be re-deposited elsewhere. As it cycles among the atmosphere, land, and water, mercury undergoes a series of complex chemical and physical transformations, many of which are not completely understood. Most of the mercury that ends up in water, soil, sediments, and plants and animals is in the form of inorganic mercury salts and organic forms of mercury, such as methylmercury. Detailed discussions of mercury chemistry can be found in Nriagu (1979) and Mason et al. (1994).

Mercury from air emissions can be deposited to watershed soils, where a

portion of it can be methylated through soil microbial activity. Mercury in soils can be washed from the watershed into wetlands, lakes, streams, and rivers where microbial activity in sediments converts inorganic mercury to methylmercury. In particular, wetlands appear to be key environments for microbially enhanced conversion of mercury into methylmercury. Once in aquatic systems, mercury can exist in dissolved or particulate forms and can undergo a number of chemical transformations. Contaminated sediments at the bottom of surface waters can serve as an important mercury reservoir, with sediment-bound mercury recycling back into the aquatic ecosystem for decades or longer. Mercury also has a long retention time in soils; as a result, mercury that has accumulated in soils may continue to be released to surface waters and other media for long periods of time, possibly hundreds of years.

#### C. Does Methylmercury Bioaccumulate?

Methylmercury is highly bioaccumulative and is the form of mercury that bioaccumulates most efficiently in the aquatic food web. Methylation of mercury is a key step in the entrance of mercury into food chains. The biotransformation of inorganic mercury species to methylated organic species in water bodies can occur in the sediment and the water column. Inorganic mercury can be absorbed by aquatic organisms but is generally taken up at a slower rate and with lower efficiency than is methylmercury. Methylmercury continues to accumulate in fish as they age. Predatory organisms at the top of aquatic and terrestrial food webs generally have higher methylmercury concentrations because methylmercury is typically not completely eliminated by organisms and is transferred up the food chain when predators feed on prey; for example, when a largemouth bass feeds on a bluegill sunfish, which fed on aquatic insects and smaller fish, all of which could contain some amount of methylmercury that gets transferred to the predator. Nearly 100 percent of the mercury that bioaccumulates in upper trophic level fish (predator) tissue is methylmercury (Bloom, 1992; Akagi, 1995; Kim, 1995; Becker and Bigham, 1995). Methylmercury BAFs for upper trophic level freshwater and estuarine fish and shellfish typically consumed by humans generally range between 500,000 and 10,000,000 (Glass *et al.*, 1999; Lores *et al.*, 1998; Miles and Fink, 1998; Monson and Brezonik, 1998; Watras *et al.*, 1998; Mason and Sullivan, 1997).

Numerous factors can influence the bioaccumulation of mercury in aquatic biota. These include, but are not limited to, the acidity (pH) of the water, length of the aquatic food chain, temperature, and dissolved organic material. Physical and chemical characteristics of a watershed, such as soil type and erosion or proportion of area that is wetlands, affect the amount of mercury that is transported from soils to water bodies. Interrelationships among these factors are poorly understood and are likely to be site-specific. No single factor (including pH) has been correlated with extent of mercury bioaccumulation in all cases examined. Two lakes that are similar biologically, physically, and chemically can have different methylmercury concentrations in water, fish, and other aquatic organisms (Cope *et al.*, 1990; Grieb *et al.*, 1990; Jackson, 1991; Lange *et al.*, 1993). For more indepth discussions about the chemical, physical, and biological interactions affecting methylmercury bioaccumulation in aquatic organism see the compilation of papers in *Mercury Pollution: Integration and Synthesis* (Watras and Huckabee, 1994).

Because mercury methylation and entrance of methylmercury at the base of the food web is critical to the overall bioaccumulation process and magnitude of biomagnification, it is EPA's belief that reductions in the available pool of total mercury will ultimately lead to reduced concentrations in fish and shellfish typically consumed by humans. The extent to which concentrations of methylmercury will be reduced in fish and shellfish as a result of reduced pools of total mercury in the environment will be location specific and depend on the unique chemical, physical, and biological interactions that occur in a given system.

#### D. Why Is the 304(a) Human Health Water Quality Criterion for Methylmercury Expressed as a Fish Tissue Residue Value?

To derive section 304(a) water quality criteria for the protection of human health, EPA needs to conduct a human health risk assessment on the pollutant in question and gather information on the target population's exposure to the pollutant. Traditionally, EPA has expressed its section 304(a) water quality criteria guidance to protect human health in the form of pollutant concentrations in ambient surface water. To account for human exposure through the aquatic food pathway when deriving a water column-based water quality criterion, EPA uses national BAFs (USEPA, 2000a). A BAF is a ratio (in L/

kg) that relates the concentration of a chemical in water to its expected concentration in commonly consumed aquatic organisms in a specified trophic level (USEPA, 2000a). A national BAF is meant to be broadly applicable to all waters in the United States, whereas a site-specific BAF is based on local data and integrates local spatial and temporal factors that can influence bioaccumulation. Some pollutants not only bioaccumulate, but also biomagnify in aquatic food webs. Biomagnification is a process whereby chemical concentrations increase in aquatic organisms of each successively higher trophic level due to increasing dietary exposures (e.g., increasing concentrations from algae, to zooplankton, to forage fish, to predator fish). For pollutants that biomagnify, EPA's preferred approach for deriving national BAFs for use in deriving section 304(a) water quality criteria is to use empirical field data collected in the natural environment. With this preference in mind, EPA explored the feasibility of developing field-derived national methylmercury BAFs for each trophic level of the aquatic food chain consumed by humans (*i.e.*, trophic levels 2–4). Using Agency guidance on BAFs contained in the 2000 Human Health Methodology and procedures outlined in Volume III, Appendix D of the peer reviewed Mercury Study, EPA empirically derived draft national methylmercury BAFs for each trophic level of the aquatic food chain. The draft national BAFs were single value trophic level-specific BAFs calculated as the geometric mean of field data collected across the United States and reported in the open literature as well as other publically available reports. These draft methylmercury BAFs were compiled in a draft internal report and submitted to a panel of external scientific experts for peer review. The methylmercury water quality criterion document presents a summary of the draft internal BAF report as well as a summary of the peer review comments. The entire internal draft methylmercury BAF report and peer review report can be obtained from the Water Docket. See the **ADDRESSES** section of today's Notice to obtain a copy of the BAF peer report from the Water Docket.

Within any given trophic level, the individual empirically derived draft methylmercury BAFs generally ranged up to two orders of magnitude. This range in BAFs reflects the various biotic factors (such as food chain interactions and fish age/size) and abiotic factors (such as pH and dissolved organic carbon). The large range in the

individual empirically derived draft methylmercury BAFs results in uncertainty as to the ability of single trophic level-specific national methylmercury BAFs to accurately predict bioaccumulation of methylmercury in general across the waters of the United States. Presently, it is EPA's understanding that the mechanisms that underlie many of the influencing factors are not well understood and cannot be accurately predicted. As the science of methylmercury improves, in the future it may be possible to predict or model these processes and use such information to more accurately predict bioaccumulation. Until such time, EPA is unable to improve the predictive power of the methylmercury BAFs by universally accounting for influencing factors. This is not the case for other highly bioaccumulative pollutants, for example polychlorinated biphenyls (PCBs). For such pollutants, EPA has methods that improve the predictive capability of empirically derived or model predicted BAFs (*e.g.*, normalizing fish tissue concentrations to lipid and normalizing ambient water concentrations to dissolved and particulate organic carbon). EPA is actively involved in, and will continue to support, various types of research aimed at better understanding the fate of mercury in the environment and the processes that underlie methylmercury bioaccumulation. EPA hopes that results of new research will enable EPA to make better predictions about methylmercury bioaccumulation.

The BAF peer reviewers recognized the need for methylmercury BAFs and were supportive of most aspects of the methodology used to derive the draft national methylmercury BAFs. The peer reviewers did have issues with certain data used to derive the methylmercury BAFs and certain assumptions about food chain relationships. Overall, most of the peer reviewers believed that derivation of single-value trophic level-specific national BAFs for methylmercury that would be generally applicable to all waters of the United States under all conditions is difficult at best. This opinion was based on consideration of the highly site-specific nature of methylmercury bioaccumulation in aquatic environments and the large range in the empirically derived draft methylmercury BAFs. These peer reviewers recommended developing methylmercury BAFs on a more local or regional scale, if not on a site-specific basis. See the Addresses section of

today's Notice to obtain a copy of the BAF peer report from the Water Docket.

After considering the various issues about mercury fate in the environment, the recent report by the National Academy of Sciences' National Research Council (NRC, 2000) on the toxicological effects of mercury (see Section V.A. of this Notice), and the methylmercury BAF peer review comments, EPA concluded that it is more appropriate at this time to derive a fish tissue (including shellfish) residue water quality criterion for methylmercury rather than a water column-based water quality criterion. EPA believes a fish tissue residue water quality criterion for methylmercury is appropriate for many reasons. A fish tissue residue water quality criterion integrates spatial and temporal complexity that occurs in aquatic systems and that affect methylmercury bioaccumulation. A fish tissue residue water quality criterion in this instance is more closely tied to the CWA goal of protecting the public health because it is based directly on the dominant human exposure route for methylmercury. The concentration of methylmercury is also generally easier to quantify in fish tissue than in water and is less variable in fish and shellfish tissue over the time periods in which water quality standards are typically implemented in water quality-based controls, such as NPDES permits. Thus, the data used in permitting activities can be based on a more consistent and measurable endpoint. Finally, this approach is consistent with how fish advisories are issued. Fish advisories for mercury are also based on the amount of methylmercury in fish tissue that is considered acceptable, although such advisories are usually issued for a certain fish or shellfish species in terms of a meal size. A fish tissue residue water quality criterion should enhance harmonization between these two approaches for protecting the public health.

Because EPA did not use national, empirically derived methylmercury BAFs to establish today's section 304(a) recommended methylmercury water quality criterion, EPA has deferred further efforts to derive national BAFs for methylmercury at this time. EPA notes, however, that there may be adequate field data for some waterbodies or geographical regions to derive, accurate predictive, site-specific methylmercury BAFs. EPA may reconsider developing national methylmercury BAFs in the future once more field data is available for a broader range of species and aquatic ecosystems, or once more information is available

describing the mechanisms that affect bioaccumulation. Such information could enable EPA to more accurately predict methylmercury bioaccumulation on a broader scale given a certain total mercury concentration in water.

#### **IV. Current Activities To Address Mercury Pollution**

EPA is very aware of the multimedia character of mercury as an environmental contaminant. As has been discussed, releases of mercury are largely into the air, but releases directly into water and onto the land can also be significant. Moreover, statutory authority over mercury releases into various media are under the purview of all of EPA's statutes. To coordinate its various activities dealing with mercury, EPA issued a draft Mercury Action Plan for public comment in 1998 and expects to issue a revised Plan shortly. The Plan lays out a comprehensive program to address all aspects of the mercury problem from all sources and into all media, using all of the Agency's tools, and includes the issuance and implementation of this human health water-quality criterion. Some of the approaches currently employed to inform the public of the human health risks of mercury, and to manage, control, and reduce its release to the environment are briefly discussed below.

##### *A. Fish Consumption Advisory Activities*

States and authorized Tribes have primary responsibility for protecting residents from the health risks of consuming contaminated noncommercially caught fish and wildlife. They do this by issuing fish consumption advisories for the general population, recreational and subsistence fishers, as well as for sensitive subpopulations (such as pregnant women, nursing mothers, and children). These advisories inform the public that unacceptable concentrations of chemical contaminants (*e.g.*, methylmercury and dioxins) have been found in local fish and wildlife. The advisories include recommendations to limit or avoid consumption of certain fish and wildlife species from specific waterbodies or, in some cases, from specific waterbody types (*e.g.*, all lakes). States typically issue five major types of advisories and bans to protect both the general population and specific subpopulations. When levels of chemical contamination pose a health risk to the general public, States may issue a no consumption advisory for the general population. When contaminant levels pose a health risk to sensitive

subpopulations, States may issue a no consumption advisory for the sensitive subpopulation. In waterbodies where chemical contamination is less severe, States may issue an advisory recommending that either the general population or a sensitive subpopulation restrict their consumption of the specific species for which the advisory is issued. A commercial fishing ban can be issued, that prohibits the commercial harvest and sale of fish, shellfish, and/or wildlife species from a designated waterbody and, by inference, the consumption of all species identified in the fishing ban from that waterbody.

EPA has published guidance for States and Tribes to use in deriving their recommended fish consumption limits. See *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories, Volume 2* (USEPA, 2000e). That guidance addresses chemical contaminants with carcinogenic and/or noncarcinogenic effects, calculating consumption limits for a single contaminant in a multiple species diet or for multiple contaminants causing the same chronic health effects endpoints. The guidance recommends expressing species-specific consumption limits as fish meals per month, calculated at various fish tissue concentrations for both noncancer and cancer endpoints. Developing fish consumption limits requires making assumptions about the edible portions of fish because most chemical contaminants are not evenly distributed throughout the fish. The fish advisory guidance also recommends that human exposure via sources of contaminants other than consumption of recreationally or subsistence caught fish should be quantified.

#### B. Mercury Water Quality Standards

As discussed above, once EPA publishes new or revised section 304(a) water quality criteria guidance that reflects the 2000 Human Health Methodology, EPA expects States and authorized Tribes to reassess their water quality standards and, where necessary, establish new or revised water quality criteria consistent with one of the four approaches described above.

EPA has published numerous recommended water quality criteria for mercury throughout the years, reflecting changes in the best available scientific information. Consistent with CWA Section 303(c)(2)(B), States and authorized Tribes have adopted a numeric criterion, or an appropriate narrative translator, for mercury. Some States have adopted a previously recommended AWQC for aquatic life of 0.12 ng/L total mercury (USEPA, 1984).

This value is based on a tissue residue value and bioconcentration factor and was derived using an aquatic life criteria methodology that was superseded by the 1985 aquatic life guidelines (Stephen *et al.*, 1985). EPA's promulgation of the National Toxics Rule in 1992 (see 40 CFR 131.36) included this value with an additional footnote directing States to measure methylmercury in the edible portion of aquatic species of concern, and initiate a revision of its criterion in water quality standards to protect designated uses, if the ambient water concentration exceeds 12 ng/L more than once in a three year period.

More recently, many States have adopted EPA's 1997 criteria recommendations of 50 ng/L total mercury for human health protection from the consumption water and organisms and 51 ng/L total mercury for human health protection from the consumption of organisms only. See 62 FR 42160. These values were derived using toxicological and exposure input values current at the time of its publication, including a bioconcentration factor. The criterion published today reflects EPA's 2000 Human Health Methodology, reflects the best available science, and supercedes all previous section 304(a) human health mercury criteria recommendations published by EPA, except for the waters of the Great Lakes System as discussed below. EPA encourages States and authorized Tribes to adopt the methylmercury criterion published today in their water quality standards to protect human health. States and authorized Tribes may alternatively develop data which indicates a site-specific water quality criteria for a particular pollutant is appropriate and take action to adopt such a criteria into their water quality standards. Site-specific criteria are allowed by regulation and are subject to EPA review and approval.

In 1995, EPA promulgated the *Final Water Quality Guidance for the Great Lakes System*. See 60 FR 15366, 40 CFR 132). This rule established a numeric criterion, based in part on bioaccumulation factors (BAFs) and a factor to account for other exposure sources, of 3.1 ng/L for total mercury in ambient waters of the Great Lakes System for human health protection. EPA continues to view this criterion as appropriately protective for these waters. Great Lakes States and authorized Tribes are also encouraged to adopt today's criterion for methylmercury in fish tissue in addition to the ambient water criterion for mercury contained in 40 CFR 132.

As discussed above, water quality standards consist of designated uses, water quality criteria to protect designated uses, an antidegradation policy, and general policies for application and implementation. States and authorized Tribes have considerable discretion in designating uses, and may find that changes in use designations are warranted. EPA reviews any new or revised use designation, including refinement of a designated use, adopted by States and authorized Tribes to determine if the standards meet the requirements of the CWA and implementing regulations. Under 40 CFR 131.10(j), a use attainability analysis (UAA) must be conducted whenever a State or authorized Tribe designates or has designated uses that do not include the uses specified in Section 101(a)(2) of the CWA (*i.e.*, suitable for fishing and swimming), or when the State wishes to remove a designated use that is specified in section 101(a)(2) of the Act, or adopt subcategories of uses that require less stringent criteria. Uses are considered by EPA to be attainable, at a minimum, if the uses can be achieved (1) when effluent limitations under Section 301(b)(1)(A) and (B) and Section 306 are imposed on point source dischargers, and (2) when cost effective and reasonable best management practices are imposed on nonpoint source dischargers. 40 CFR 131.10 lists grounds upon which to base a finding that attaining the designated use is not feasible, as long as the designated use is not an existing use.

States and authorized Tribes may also adopt water quality standards variances. EPA believes variances are particularly suitable when the cause of nonattainment is discharger-specific and/or it appears that the designated use in question will eventually be attainable. EPA has approved the granting of water quality standards variances by States in circumstances which would otherwise justify changing a use designation on grounds of nonattainability (*i.e.*, the six circumstances contained in 40 CFR 131.10(g)). In contrast to a change in standards which removes a use designation for a water body, a water quality standards variance can apply only to the discharger to whom it is granted and only to the pollutant parameter(s) upon which the finding of nonattainability was based; the underlying standard remains in effect for all other purposes.

The essential elements of a variance are: a variance should be granted only where there is a demonstration that one of the use removal factors (see 40 CFR



131.10(g)) has been satisfied; a variance is granted to an individual discharger for a specific pollutant(s) and does not otherwise modify the standards; a variance identifies and justifies the numerical criteria that will apply during the existence of the variance; a variance is established as close to the underlying numerical criteria as is possible; a variance is reviewed every three years, at a minimum, and extended only where the conditions for granting the variance still apply; upon expiration of the variance, the underlying numerical criteria have full regulatory effect; a variance does not exempt the discharger from compliance with applicable technology or other water quality-based limits; and, a variance does not affect effluent limitations for other dischargers.

In 1995, EPA and the Great Lakes states agreed to a comprehensive plan to restore the health of the Great Lakes. Using the *Final Water Quality Guidance for the Great Lakes System* (see 40 CFR 132), Great Lakes States and authorized Tribes established water quality criteria, methodologies, policies and procedures to establish consistent, enforceable, long term protection for fish and shellfish in the Great Lakes and their tributaries, as well as the people and wildlife who consume them. Under 40 CFR 132, the State of Ohio adopted, and EPA approved, a statewide variance specifically for mercury.

The basis for this mercury variance was the adverse social and economic impacts of end of pipe treatment to attain effluent limits for mercury of less than 12 ng/L total mercury. Ohio determined a cost of \$10 million per pound for mercury removal from NPDES permitted discharges. Ohio also specified implementation procedures whereby the discharger requests coverage under the mercury variance; describes the mercury control measures taken to date; provides a plan of study intended to identify and control sources of mercury (including documenting current influent and effluent concentrations, identifying known sources, describing how known sources will be reduced or eliminated, identifying other potential sources, and providing a schedule for evaluating sources and control methods); and, provides an explanation of the permittee's basis for concluding that there are no readily available means of complying without resorting to end of pipe treatment. Where the discharger demonstration is inadequate (including an inadequate demonstration that end of pipe treatment is the only readily available option for complying), Ohio denies the applicability of the mercury

variance to the individual discharge. In this case, each variance is also submitted to EPA for review and action.

It is important to note that Ohio's mercury variance relieves individual dischargers of the responsibility to demonstrate social and economic impacts of complying with the mercury criteria. Individual dischargers must still demonstrate that end of pipe treatment is the only viable compliance option. In addition, in this case EPA retains review and approval authority over individual variance decisions, but EPA's review is limited to the technical merits of the alternatives analysis (e.g., are there options other than end of pipe treatment).

#### C. Total Maximum Daily Load

Section 303(d) of the CWA requires States and authorized Tribes to identify and establish a priority ranking for waters for which existing pollution controls are not stringent enough to attain and maintain applicable water quality standards; to establish total maximum daily loads (TMDLs) for those waters; and to submit from time to time the list of waters and TMDLs to EPA. Section 303(d) of the CWA requires EPA to review and approve or disapprove lists and TMDLs within 30 days of the date they are submitted. If EPA disapproves a State's or Tribe's identification of waters or a TMDL, EPA must establish the list or a TMDL for the State or authorized Tribe.

TMDLs specify the amount of a particular pollutant that may be present in the water and still allow the waterbody to meet applicable water quality standards, including a margin of safety and after considering seasonal variability. TMDLs allocate the allowable pollutant loads among point and nonpoint sources of pollution. TMDLs also provide the basis for attaining or maintaining applicable water quality standards through implementation of pollutant reductions in the NPDES permit program and in nonpoint source controls programs.

On the 1998 lists of impaired waterbodies, 33 States reported at least one waterbody as being impaired due to mercury contamination. Over 1,000 individual waterbody segments were identified by the States as specifically having mercury contamination. In addition, over 3,900 waterbody segments were identified as impaired due to contamination by metals, which may include mercury.

In many cases, as described earlier in this document, atmospheric deposition can be a significant source of mercury to waterbodies. On the 1998 lists of impaired waters, atmospheric

deposition of mercury was identified as a source of impairment in over 600 waterbody segments. As States are not required to identify atmospheric deposition as a source of impairment, this is likely to be an underestimate.

EPA is currently conducting pilot studies to assist States in developing TMDLs for waterbodies impaired by mercury from atmospheric deposition. One goal of the pilot studies is to evaluate modeling approaches, such as techniques for identifying the relative contribution of various types of mercury sources to a waterbody. Another goal of the studies is to examine how TMDLs can incorporate ongoing efforts to address sources of mercury, pollution including programs under the Clean Air Act and water-related pollution prevention activities.

#### D. Pollution Minimization Activities

The CWA prohibits the discharge of any pollutant (other than dredged of fill material) from a point source into waters of the United States except in compliance with an NPDES permit. See section 301(a) and section 402 of the CWA. NPDES permits are issued by EPA or by States and Tribes that are authorized to administer the NPDES program. These permits commonly contain numerical limits on the amounts of specified pollutants that may be discharged. In place of or in addition to numerical limits, permits may contain best management practices (BMPs) (e.g., practices or procedures that a facility installs or follows that result in a reduction of pollutants to waters of the United States). These "effluent limitations" implement both technology-based and water quality-based requirements of the Act. Technology-based effluent limitations represent the degree of control that can be achieved by point sources using various levels of pollution control technology. See sections 301, 304, and 306 of the CWA. For a publicly owned treatment works (POTW), section 301(b)(1)(B) of the CWA specifies the applicable technology-based control standard as "secondary treatment." See CWA sections 301(b)(1)(B).

As discussed above, the CWA directs the States to establish water quality standards. See CWA section 303(c). If necessary to achieve applicable water quality standards, NPDES permits must contain water quality-based limitations (WQBELs) more stringent than the applicable technology-based requirements. See CWA section 301(b)(1)(C). The need for a WQBEL is based on a determination that pollutants in a discharger's effluent will cause, have the reasonable potential to cause,



or contribute to a violation of the applicable water quality standards. See 40 CFR 122.44(d)(1).

Many point source dischargers of mercury have either technology-based limits or water quality-based limits for mercury in their NPDES permits. Many point source dischargers install treatment technologies that will treat their effluent, resulting in lower quantities of mercury in their discharged effluent. In addition, point sources that discharge mercury to the Great Lakes System are required to develop a pollutant minimization program (PMP) for mercury whenever their WQBELs for mercury are calculated to be less than the quantification level of the applicable analytical method. See 40 CFR 132, Appendix F, Procedure 8.D. Implementation of PMPs should be viewed as an iterative process as new and improved methods to reduce or eliminate mercury become available, including a control strategy which identifies control measures to be implemented that become enforceable requirements in their NPDES permit. These PMPs are subject to revision as the implementation of PMPs is viewed as an iterative process recognizing that there will be new and improved methods to reduce or eliminate mercury that are not currently available.

Some pollution prevention strategies focus on changing existing processes or replacing uses of mercury in production activities with alternative substances as a way of achieving water quality-based effluent limitations. Also, some facilities with mercury do not discharge mercury to waters of the United States, but rather transport the waste to hazardous waste disposal facilities or incinerate it. EPA expects mercury dischargers to use one or a combination of these approaches to reduce or eliminate discharges of mercury to the environment. Pollution prevention, however, is the preferred approach because it reduces mercury releases to the environment in general.

#### *E. National Air Emissions Regulations*

Most of the mercury currently entering the United States environment is the result of air emissions of mercury that are deposited on land or water. In addition to publishing mercury water quality criteria guidance under the Clean Water Act, under the Clean Air Act EPA has issued a number of regulations to reduce mercury pollution through air emissions. The following summarize the key regulations pertaining to air sources of mercury.

—Municipal waste combustors emitted about 20 percent of total national mercury emissions into the air

in 1990. EPA issued final regulations for municipal waste combustors in 1995. These regulations are predicted to reduce mercury emissions from these facilities by about 90 percent from 1990 emission levels.

—Medical waste incinerators emitted about 24 percent of total national mercury emissions into the air in 1990. EPA issued emission standards for medical waste incinerators in 1997. When fully implemented, the final rule is expected to reduce mercury emissions from medical waste incinerators by about 94 percent from 1990 emission levels.

—Hazardous waste combustors emitted about 2.5 percent of total national mercury emissions in 1990. In February 1999, EPA issued emission standards for these facilities, which include incinerators, cement kilns, and light weight aggregate kilns that burn hazardous waste. When fully implemented, these standards are predicted to reduce mercury emissions from hazardous waste combustors by more than 50 percent from 1990 emission levels.

In addition to the above regulations, EPA is developing a regulation that will limit mercury emissions from chlorine production plants. Proposed and final rules are scheduled for late 2000 and 2001, respectively. Under the Integrated Urban Air Toxics Strategy, which was published in 1999, EPA is developing emissions standards for categories of smaller sources of air toxics, including mercury, that pose the greatest risk to human health in urban areas. These standards are expected to be issued by 2004.

Also, on December 14, 2000 EPA announced that it intends to develop a regulation to limit mercury emissions from coal-fired power plants. A proposal is expected in late 2003 and a final regulation at the end of 2004. These plants are the largest source of mercury emissions in the United States of mercury emissions from coal-fired power plants will be a significant next step in this ongoing effort to address mercury emissions.

#### **V. Derivation of the Methylmercury Fish Tissue Water Quality Criterion**

##### *A. What Is the Health Risk Assessment for Methylmercury?*

Methylmercury is highly toxic to mammalian species and causes a number of adverse effects. There are no data to indicate that it is carcinogenic in humans, and it induces tumors in animals only at highly toxic doses. The quantitative health risk assessment for a non-carcinogen is a reference dose

(RfD). This is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious health effects during a lifetime. EPA has revised the current RfD for methylmercury. The value of the RfD has not changed from 0.1  $\mu\text{g}/\text{kg}/\text{day}$ , but the basis for the RfD has been updated using the most current data and analyses. This RfD is protective of all populations in the United States, including sensitive subpopulations. It is applied to lifetime daily exposure as are other RfDs. The basis for the RfD update is discussed below.

EPA previously published two RfDs for methylmercury representing the Agency's views at the time. An RfD of 0.3  $\mu\text{g}/\text{kg}/\text{day}$  was established in 1985 and published on EPA's Integrated Risk Information System (IRIS) in 1986. The critical effects were multiple central nervous system (CNS) effects, including ataxia (problems with muscle coordination) and paresthesia (changes in the sense of touch) in Iraqi adults who had eaten methylmercury-contaminated grain (summarized by Clarkson *et al.*, 1976; Nordberg and Strangert, 1976; and WHO, 1976).

An RfD of 0.1  $\mu\text{g}/\text{kg}/\text{day}$  was established as the Agency consensus estimate in 1995. It was published in IRIS in 1996 and in extended form in 1997 in the Mercury Study (which included a state-of-the-science evaluation of the health effects of methylmercury). Prior to the 1997 Mercury Study, many scientists and other concerned parties had questioned whether the 1985 RfD based on effects in exposed adults was protective against developmental effects. The 1995 RfD was thus set on clinical neurological signs and symptoms in 81 Iraqi children who had been exposed when their mothers ate methylmercury-contaminated grain while pregnant. Maternal hair mercury was the indication of exposure. EPA used a mathematical procedure, calculation of a benchmark dose (BMD), to estimate the functional equivalent of a no adverse effect level from the data. A one compartment pharmacokinetic model was used to determine an amount of daily methylmercury ingestion which would result in the BMD. An uncertainty factor of 10 was applied to deal with the following areas of uncertainty and variability: Wide variation in half-life of methylmercury in the body and the variation that occurs in the hair-to-blood ratio for mercury; lack of a two-generation reproductive study; and lack of data on possible

chronic manifestations of the adult effects.

Since 1997 there has been continuing discussion in the scientific community as to regarding the level of human exposure to methylmercury that is likely to present no appreciable risk of adverse health effects. Congress directed EPA through the House Appropriations Report for FY99 to contract with the National Research Council (NRC) to evaluate the data on the health effects of methylmercury, with emphasis on data available after the 1997 Mercury Study. NRC was to provide recommendations on issues relevant to the derivation of an appropriate RfD for methylmercury. EPA received the NRC report *Toxicological Effects of Methylmercury* in July, 2000 (NRC, 2000). EPA has thoroughly reviewed this document and generally concurs with the NRC findings and recommendations. Based on the NRC report, EPA has revised the RfD for methylmercury. A draft EPA RfD document was submitted for external scientific review in late October 2000; at the same time it was circulated for comment to other Federal Agencies through the Committee on Environment and Natural Resources (CENR) and Office of Science and Technology Policy (OSTP). See the **ADDRESSES** section of this Notice to obtain a copy of the RfD peer review report from the Water Docket. A public scientific review meeting was held November 15, 2000; the final peer review report was delivered to EPA on December 7, 2000. See the **ADDRESSES** section of today's Notice to inspect the peer review report in the Water Docket. The draft RfD document was revised to reflect the scientific critique received from the peer review, and it is now available as the risk assessment chapter in the water quality criterion document for methylmercury.

The revised RfD was derived to be protective of the population (including sensitive subgroups) against the many adverse health effects associated with methylmercury exposure. Most data are on neurotoxicity, particularly in developing organisms; there is a substantial amount of data on effects of methylmercury on human development. The brain is considered to be the most sensitive target organ for which there are data suitable for derivation of an RfD.

The NRC report and EPA's review considered human epidemiological, longitudinal developmental studies from the Seychelles Islands, the Faroe Islands, and New Zealand in assessing the quantitative risk from mercury exposure. These are all studies wherein effects were measured in children of

mothers exposed to methylmercury through consumption of fish and seafood. The Seychelles study showed no evidence of impairment related to methylmercury exposure, while both the Faroe Islands and New Zealand studies found dose-related adverse effects on a number of neuropsychological endpoints. The Faroe Islands study is the larger of the latter two studies and has been extensively peer reviewed. EPA has used the Faroe Islands study for derivation of the RfD. A BMD was chosen as the most appropriate method of quantifying the dose-effect relationship. The BMD EPA used is the lower limit (BMDL) on a 5% effect level obtained by applying a K power model ( $K \geq 1$ ) to dose-response data based on mercury measured in cord blood.

There are several endpoints which are sensitive measures of methylmercury effects in the Faroese children. EPA considered the recommendations of the NRC and our external peer review panel in coming to a decision as to the appropriate endpoint. The NRC recommended the use of a BMDL of 58 ppb mercury in cord blood from the Boston Naming Test (BNT). This is a test in which the subject is shown drawings and is asked to name what they depict. The BNT score is related to language ability, assessing word formulation and word retrieval. NRC considered the score from the whole cohort to be the most sensitive, reliable endpoint. The NRC noted that the scores for the Continuous Performance Test (CPT) gave a lower BMDL, 46 ppb mercury in cord blood, but that these results were from a smaller number of children (there had been test administration problems in one year of the study).

The external peer panel disagreed with the NRC choice. They felt that the BNT scores showed an effect of concomitant PCB exposure in some analyses. They preferred a PCB-adjusted BMDL of 71 ppb mercury in cord blood for the BNT. A difficulty with this choice is that this BMDL is based on scores from only about one-half of the total cohort.

EPA prepared a comparison of the NRC and peer reviewer recommended approaches; this analysis also includes BMDLs from mercury-associated Faroese endpoint, results of the NRC integrated analysis and geometric means of four scores from the Faroes. The table of comparisons can be found in the methylmercury water quality criterion document. When one completes the dose conversion and applies an uncertainty factor (see paragraphs below), the calculated RfD values converge at the same point: 0.1  $\mu\text{g/kg/}$

day. Rather than choosing a single measure for the RfD critical endpoint, EPA considers that this RfD is based on several scores. These test scores are all indications of neuropsychological processes which are involved with the ability of a child to learn and process information. In the *Water Quality Criterion for the Protection of Human Health: Methylmercury*, EPA uses the NRC recommended BMDL of 58 ppb mercury in cord blood as an example in the dose conversion and RfD calculation.

The BMDL of 58 ppb mercury in cord blood was converted to an ingested daily dose using a one-compartment pharmacokinetic model similar to that used in the Mercury Study. The ingested daily dose at the benchmark dose is 1  $\mu\text{g/kg}$  per day.

In the water quality criterion guidance for methylmercury, EPA discusses several sources of variability and uncertainty in its estimate and chose an uncertainty factor of 10. This was based on a factor of 3 for pharmacokinetic inter-individual variability (particularly methylmercury half-life and uncertainty concerning the relationship between cord and maternal blood mercury concentrations). An additional factor of 3 was applied for pharmacodynamic variability and uncertainty. EPA also describes additional areas of concern including inability to quantify long-term sequelae; concern for effects that may be observed at exposures below the BMDL; and lack of a two-generation reproductive effects assay. Given the over all robustness of the data base for methylmercury, EPA considered that a composite uncertainty factor of 10 was sufficient; this conclusion was affirmed by the external peer review panel.

The resulting RfD for methylmercury is, thus, 0.1  $\mu\text{g/kg}$  per day. This RfD is applied to lifetime daily exposure for all populations in the United States, including sensitive subpopulations.

#### *B. How Are Mercury Exposure and Relative Source Contribution Assessed?*

The exposure assessment and estimate of the relative source contribution (RSC) for methylmercury follows the recently published 2000 Human Health Methodology. When an AWQC is based on noncarcinogenic effects, anticipated exposures from sources other than drinking water and freshwater/estuarine fish and shellfish ingestion are taken into account so that the entire RfD is not apportioned to drinking water and freshwater/estuarine fish and shellfish consumption alone. The amount of exposure attributed to each source compared to total exposure is referred to as the RSC. The RSC is

used to adjust the RfD to ensure that the water quality criterion is protective enough, given the other anticipated sources of exposure. Detailed discussion of the RSC method is described in the 2000 Human Health Methodology.

The method of determining the RSC differs depending on several factors: (1) The magnitude of total exposure compared with the RfD; (2) the adequacy of data available; (3) whether more than one criterion is to be set for methylmercury; and (4) whether there is more than one significant exposure source for the chemical and population of concern. The population of concern, sources of methylmercury exposure, and estimates of exposure and the RSC for the identified population are discussed in detail in the 2001 methylmercury water quality criterion document.

The population basis for the exposure estimate are adults in the general population. The health risk measure, the RfD, is intended to be protective of the whole population, including sensitive subpopulations. This is not a developmental RfD *per se*; even though the critical endpoint was neurotoxic effects observed in children, application of the RfD is not restricted to pregnancy only, or to developmental periods only.

The exposure assessment section of the 2001 methylmercury water quality criterion document characterizes the sources of methylmercury exposure in environmental media, provides available information on levels of occurrence, and provides estimates of intake from the relevant sources. Specifically, the evaluation includes estimates of methylmercury in ambient surface water, drinking water, fish, non-fish foods, air, soil and sediment.

As discussed in the 2000 Human Health Methodology, the Agency's RSC policy approach allows for use of a subtraction method to account for other exposures when one health-based water quality criterion is relevant for the chemical in question. In this circumstance, other sources of exposure can be considered "background" and can be subtracted from the RfD. Such is the case with methylmercury; that is, there are no health-based criteria, pesticide tolerances, or other regulatory activities to apportion with the alternate percentage approach (see discussion in the 2000 Human Health Methodology).

The assessment of human exposure in the methylmercury water quality criterion document includes estimates from multiple media sources. Based on available data, human exposures to methylmercury from all media sources except freshwater/estuarine and marine fish are negligible, both in comparison to exposures from fish and compared to

the RfD. Estimated exposure from ambient water, drinking water, non-fish dietary foods, air, and soil are all, on average, at least several orders of magnitude less than those from freshwater/estuarine fish and shellfish intakes. In units of  $\mu\text{g}/\text{kg}\cdot\text{day}$ , non-fish sources of intake are in the range of  $10^{-5}$  to  $10^{-9}$   $\mu\text{g}/\text{kg}\cdot\text{day}$  for adults in the general population (USEPA, 2001). The combined methylmercury exposure intakes from water ingestion, non-fish diet, air, and soil represent approximately 0.07 percent of total estimated exposure to methylmercury (less than  $\frac{1}{100}$  of one percent of the RfD). Therefore, these exposures were not factored into the RSC.

Ingestion of marine fish is a significant contributor to total methylmercury exposure. This intake has been accounted for in the derivation of the fish tissue water quality criterion value. The estimate of marine fish methylmercury exposure is based on data available primarily from the National Marine Fisheries Survey. See the exposure section of the 2001 methylmercury water quality criterion document. Species-specific mean concentrations of methylmercury in marine fish and shellfish were used to estimate daily exposure from methylmercury. A consumption-weighted mean concentration of methylmercury for all marine fish and shellfish was then calculated by EPA (USEPA 2001) based on the mean consumption rates from the *United States Department of Agriculture's Continuing Survey of Food Intake by Individuals (CSFII) 1994-1996* (USDA 1998). The CSFII 1994-1996 consumption rates are also the source of EPA's recommended intake rates for freshwater/estuarine fish. Detailed discussion of this procedure is included in the methylmercury water quality criterion document (USEPA, 2001). Following the Mercury Study (USEPA, 1997a), 100 percent of the mercury in marine fish was assumed to be present as methylmercury. The estimated weighted-average methylmercury concentrations in marine fish is 0.157 mg methylmercury/kg fish tissue, and the estimated average exposure to methylmercury from marine fish is  $2.7 \times 10^{-5}$  mg methylmercury/kg fish tissue-day. This exposure represents almost 30 percent of the RfD.

As indicated above, the RSC from marine fish has been calculated with an assumed average intake of 12.46 gm/day of marine fish based on the CSFII, for all respondents aged 18 and over. The Mercury Study (USEPA, 1997a) indicates that in the general population of fish consumers, those that consume

freshwater/estuarine species of fish are also consumers of marine species of fish and shellfish. EPA has, therefore, made the same assumption in the derivation of the methylmercury fish tissue residue water quality criterion. EPA's recommended default fish intake rate to protect the general population of consumers of freshwater/estuarine fish is 17.5 grams/day. This value is the 90th percentile from the CSFII 94-96 survey (USEPA, 2000f). As described in the 2000 Human Health Methodology, the Agency selected this default intake rate as protective of a majority of the population. The recommended body weight for the general adult population used in this estimate is 70 kg (USEPA, 2000a). While EPA acknowledges that consumers of freshwater/estuarine fish are also typically consumers of marine fish, EPA does not believe that the high-end consumer of freshwater/estuarine fish is also a high-end consumer of marine fish. EPA believes that it is more appropriate, and a reasonably conservative assumption, to use a central tendency intake rate (approximately 12.5 grams/day) for the marine fish component of the RSC estimate.

For deriving the fish tissue water quality criterion for methylmercury, the mean daily exposure estimate from ingestion of marine fish for adult consumers in the general population (which is also protective of the developmental endpoint),  $2.7 \times 10^{-5}$  mg/kg-day, is used for the RSC in the subtraction approach to calculate the methylmercury fish tissue water quality criterion.

#### C. How Is the Methylmercury Water Quality Criterion Calculated?

The derivation of a methylmercury water quality criterion requires a human health risk assessment (e.g., an RfD), exposure data (e.g., the amount of pollutant ingested or inhaled per day), and data about the target population to be protected. The equation for calculating the methylmercury fish tissue residue water quality criterion for the protection of human health is:

$$\text{TRC} = \frac{\text{BW} \times (\text{RfD} - \text{RSC})}{\sum_{i=2}^4 \text{FI}_i}$$

Where:

TRC = Fish tissue residue criterion (mg methylmercury/kg fish tissue) for freshwater and estuarine fish and shellfish

RfD = Reference Dose (based on noncancer human health effects).

For methylmercury it is 0.0001 mg/kg BW-day (0.1  $\mu\text{g}/\text{kg BW}\cdot\text{day}$ )

RSC = Relative source contribution (subtracted from the RfD to account for marine fish consumption) estimated to be  $2.7 \times 10^{-5}$  mg/kg BW-day

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

FI = Fish intake at trophic level (TL)  $i$  ( $i = 2, 3, 4$ ); total default intake is 0.0175 kg fish/day for general adult population. Trophic level breakouts for the general population are: TL2 = 0.0038 kg fish/day; TL3 = 0.0080 kg fish/day; and TL4 = 0.0057 kg fish/day.

This equation is the same equation used in the 2000 Human Health Methodology to calculate a water quality criterion for a noncarcinogenic pollutant, but is rearranged to solve for a protective concentration in fish tissue rather than in water. Thus, it does not include a BAF or drinking water intake value (as discussed above, exposure from drinking water is negligible). When all of the numeric values are put into the generalized equation, the Tissue Residue Criterion = 0.3 mg methylmercury/kg fish (rounded to one significant digit from 0.292 mg methylmercury/kg fish tissue). This is the concentration in fish tissue that should not be exceeded based on a total fish and shellfish consumption-weighted rate of 0.0175 kg fish/day (17.5 g/day). On a site-specific or local level, States and authorized Tribes can choose to apportion all of the 0.0175 kg fish/day to the highest trophic level consumed for their population or modify it based on local or regional consumption patterns. EPA strongly encourages States and authorized Tribes to develop a water quality criterion for methylmercury using local or regional data over the default values if they believe that such a water quality criterion would be more appropriate for their target population.

#### VI. How Can the Fish Tissue Residue Water Quality Criterion Be Related to a Mercury Concentration in Water?

EPA recognizes that a State's water quality criterion in the form of a fish tissue residue value may pose implementation challenges under traditional water quality based control programs. Under a water quality-based approach to controlling pollutants, NPDES permit compliance with water quality standards is usually determined by comparing the allowable concentration of a pollutant in the water column to the actual pollutant concentration measured in the water column over some specific period of time. Mechanisms to control pollutants in waterbodies usually involve

determining the allowable discharge load to a waterbody by conducting TMDL and waste load allocation (WLA) calculations. The traditional approach for monitoring, measuring compliance, and ultimately controlling the discharge of a pollutant is based on the concentration of the pollutant in water; thus, a mechanism is needed to relate concentrations of methylmercury in fish tissue to concentrations in water. EPA has provided three recommended approaches in order to relate the methylmercury fish tissue water quality criterion to concentrations of mercury in water. Each approach has its own advantages, limitations, and uncertainties as discussed below.

EPA's preferred approach for relating a concentration of methylmercury in fish tissue to a concentration of mercury in ambient water is to derive site-specific BAFs based on water and fish collected in the waterbody of concern. This recommendation is consistent with EPA's bioaccumulation guidance contained in the 2000 Human Health Methodology. Furthermore, this recommendation is consistent with the views expressed by the methylmercury BAF peer reviewers. See the Addresses section of today's Notice to obtain peer review responses from the Water Docket. EPA prefers the use of site-specific BAFs because they inherently incorporate the net effects of the biotic and abiotic factors at a particular location that can affect bioaccumulation in the aquatic food chain, and thus provide an accurate accounting of the uptake of methylmercury. When sampling fish and water to derive a site-specific BAF, one needs to consider how best to sample so that issues such as seasonal variability in fish exposure to methylmercury, spacial variability, and fish size are taken into account. These issues and others should also be assessed in relation to the fish consumption patterns of the exposed human population. EPA expects to publish specific guidance for deriving field-measured site-specific BAFs in late 2001. However, until then the recently published procedures in the 2000 Human Health Methodology for deriving BAFs can be used as a general guide. In addition, the *Bioaccumulation Technical Support Document* (TSD) for the 2000 Human Health Methodology (expected to be published in late 2001) will provide additional information and guidance on deriving site-specific BAFs.

Another approach for deriving methylmercury BAFs is to use a bioaccumulation model. Most bioaccumulation models are generally process-based or mechanistic type mathematical models that are meant to

represent what occurs in nature. At this time, the general science of bioaccumulation modeling, especially for mercury, is not advanced to the stage where models are readily available and applicable to all types of pollutants and aquatic systems. Three examples of mechanistic-type bioaccumulation models are: the Mercury Cycling Model (Tetra Tech, 1999); EPA's aquatic food chain model AQUATOX (USEPA, 2000g); and the Quantitative Environmental Analysis food chain model QEA (QEA, 2000). There are only a few models that might be used to predict methylmercury bioaccumulation. Such models generally have not been widely used and have only been applied to mercury in a few aquatic ecosystems under specific environmental conditions. Of the examples listed above, only the Mercury Cycling Model was developed solely for mercury. The others have been generally developed for nonionic organic chemicals that bioaccumulate. They might be applied to mercury with substantial modifications. Most bioaccumulation models are based upon a chemical mass balance approach for fish or other aquatic organisms, which requires considerable understanding of mercury loadings to the environment and how mercury moves through the environment. Each model results in a BAF with some level of uncertainty. None of the example models can predict bioaccumulation without considerable site-specific information and at least some degree of calibration to the waterbody of interest, and in some cases considerable modification of the model. The amount and quality of data required for proper model application may equal or exceed that necessary to develop a site-specific methylmercury BAF. Other types of models could also be used if they are scientifically defensible. Regardless of the type of model, if a model is chosen, the issues discussed in the bioaccumulation guidance contained in the 2000 Human Health Methodology should be carefully considered. The derivation of site-specific parameters used in the model should also be documented, and some indication given of the uncertainty surrounding the BAFs predicted by the model.

EPA acknowledges that derivation of site-specific field-measured BAFs may not be feasible in all situations. Therefore, in the absence of site-specific methylmercury bioaccumulation data, a possible third approach is to use EPA's empirically derived draft methylmercury BAFs. As previously discussed, as part of initial efforts to

derive a water column-based section 304(a) water quality criterion, EPA used the Agency's BAF guidance in the 2000 Human Health Methodology and BAF

methods in Volume III, Appendix D of the Mercury Study to develop draft empirically derived BAFs from field data collected across the United States

and reported in the open literature. The empirically derived BAFs are listed by trophic level in Table 1.

TABLE 1.—EMPIRICALLY DERIVED BAFs FOR METHYLMERCURY

	BAF trophic level 2	BAF trophic level 3	BAF trophic level 4
BAF .....	160,000	680,000	2,700,000

The BAF peer reviewers expressed concerns about the predictive capability of these draft BAFs and about using them to derive a section 304(a) water quality criterion for methylmercury that would be accurately protective for waterbodies across the nation. However, EPA believes that the methylmercury BAFs in Table 1 are sufficiently predictive of bioaccumulation to be used in implementing a fish tissue based methylmercury water quality criterion in a State's or authorized Tribe's water quality standards in the absence of any other site-specific bioaccumulation data. Thus, EPA will consider water quality standards implementation approaches that use these empirically derived BAFs. EPA recognizes that these methylmercury BAF values are not entirely representative of the methylmercury bioaccumulation potential in all waterbodies across the United States, and they may over- or underestimate site-specific bioaccumulation potential. There is uncertainty in using these BAFs as they collapse a very complex nonlinear process into a simplistic and linear approach to predicting bioaccumulation and assume that the biotic and abiotic process affecting mercury fate and bioaccumulation are similar across different waterbodies. The decision to publish these empirically derived BAFs is an Agency

risk management decision made based on the need for a mechanism to relate a fish tissue concentration of methylmercury to a water column concentration. EPA has selected the geometric mean of the field-measured BAFs obtained from the open literature as the empirically derived BAFs for each trophic level. EPA believes the geometric mean is the central tendency value that best represents the wide range of environmental and biological conditions present in the waters of the United States. Choosing a value near the extremes of the distribution (e.g., 10th or 90th percentile) may introduce an unacceptable level of uncertainty into the CWA goal of protecting public health. Furthermore, EPA believes a geometric mean is most appropriate because the underlying processes of methylmercury bioaccumulation are more likely multiplicative than additive.

Other empirical, modeling, or newly developed bioaccumulation prediction approaches may be used to relate concentrations of methylmercury in fish tissue to concentrations of methylmercury in water, provided the approach is scientifically defensible and adequately documented.

In addition to using BAFs to relate concentrations of methylmercury in fish tissue to methylmercury concentrations in water, a factor is needed to translate methylmercury in water to its total mercury equivalent. NPDES permits and

other water quality-based pollution control activities are traditionally based on the total concentration of the inorganic metal form, not the dissolved organic form. Many of the issues surrounding the uncertainty in predictability and transferability of methylmercury BAFs across different waterbodies also pertain to relating methylmercury in water to a given total mercury concentration. As with BAFs, EPA's preferred approach for translating between total and methylmercury is for States and authorized Tribes to measure total mercury and methylmercury and in the waterbody of interest. However, EPA will consider standards implemented with empirically derived translators. As part of exercise to develop draft methylmercury BAFs, EPA derived methylmercury-to-total mercury translator factors for rivers/streams and lakes. Like the BAFs, the methylmercury-to-total mercury translators were empirically derived based on water data collected in the field from a variety of locations across the United States. Depending on the available mercury water data, more than one translation may be necessary to translate to the total concentration of mercury in ambient waters. Table 2 lists the translator factors that could be used to translate between methylmercury and mercury in ambient surface waters in the absence of any site-specific data.

TABLE 2.—SUMMARY OF MERCURY TRANSLATORS

Translation	Lakes and reservoirs <sup>1</sup>	Rivers and streams <sup>1</sup>
Fraction of total mercury that is dissolved .....	0.60	0.37
Fraction of total mercury that is dissolved methylmercury .....	0.032	0.014
Fraction of total methylmercury that is dissolved methylmercury .....	0.61	0.49

<sup>1</sup> Values are from Section II, Table 15, of the EPA internal draft report *National Bioaccumulation Factors for Methylmercury*, available from the Water Docket.

## VII. What Is the Relationship Between Fish Advisories and the Fish Tissue Residue Water Quality Criterion?

A majority of States and authorized Tribes with fish advisory programs have adopted a risk-based approach to

developing fish advisories that is similar to the approach recommended in EPA's *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories* (EPA 2000 e, h). However, due to variations in State and Tribal fish advisory programs, some States and

Tribes may not be adequately warning the public of health risks. A small number of States continue to use fish consumption advisory approaches that are considered by EPA to be inadequate for protecting public health. The use of these approaches may lead to significant

increased health risks for people consuming fish harvested from contaminated local waters. Such approaches include the inappropriate use of Action Levels and Tolerances developed by EPA and the Food and Drug Administration. These are appropriate for use in the commercial market place, but are considered to be inappropriate for establishing local advisory needs and should not be used for that purpose.

Both today's section 304(a) human health water quality criterion guidance for methylmercury and EPA's recommended fish consumption limit for mercury (which EPA encourages States and authorized Tribes to use as guidance in setting fish advisories) are meant to protect humans from consumption of mercury-contaminated fish. The procedures for deriving these two values are consistent with each other, but in deriving the section 304(a) methylmercury water quality criterion, EPA used an RSC of  $2.7 \cdot 10^{-5}$  mg/kg-day to account for exposure from non-freshwater and non-estuarine fish. See section IV.B of today's Notice. The guidance for setting fish consumption limits (USEPA, 2000e) also discusses using an RSC to account for exposures other than noncommercially caught fish, but does not specifically require this to be done. The RSC guidance in the 2000 Human Health Methodology provides more detail and specific quantitative procedures to account for other exposure pathways. EPA recommends that States and authorized Tribes consider using an RSC to account other sources of mercury exposure when deriving a fish consumption limit and setting a fish advisory for mercury.

#### **VIII. How Does EPA Suggest Implementing the Methylmercury Water Quality Criterion?**

EPA encourages States and authorized Tribes to adopt the fish tissue residue water quality criterion for methylmercury outlined in this notice into their water quality standards to protect CWA section 101(a) designated uses related to human consumption of fish. This recommended water quality criterion reflects the most current and best science. EPA recognizes and emphasizes that States and authorized Tribes will need additional, specific procedures and water quality program guidance in order to implement water quality criteria they adopt based on this guidance. These procedures include, but are not necessarily limited to: (1) An analytical method for detecting and measuring concentrations in fish and water; (2) a field sampling plan for collecting fish and protocols for

laboratory analysis and data interpretation; (3) a procedure for translating methylmercury concentrations in fish to total mercury concentrations in ambient surface water or effluent; (4) data quality objectives and associated procedures for determining attainment of the water quality criterion and status of designated use impairment based on fish residue data; (5) harmonization with fish consumption advisory programs; (6) procedures for determining the need for a water quality-based effluent limit (WQBEL) in NPDES permits for point source discharges of mercury; (7) procedures for developing and implementing WQBELs for NPDES permits; and, (8) procedures for developing targets for TMDL load and waste load allocations.

To help States and authorized Tribes adopt the recommended section 304(a) water quality criterion for methylmercury as part of their standards, and to implement those standards, EPA plans to begin development implementation procedures and guidance documents by the end of 2001. These will be part of a broad national implementation policy for this water quality criterion. The implementation policy will be developed with consideration of the draft Mercury Action Plan submitted for public comment in 1998 and expected to be revised soon. EPA expects States and authorized Tribes to adopt new or revised human health mercury water quality criteria and to use the procedures and guidance contained in the forthcoming implementation policy to adopt their water quality criteria within five years from today's publication. EPA generally believes that five years from the date of EPA's publication of new or revised section 304(a) water quality criteria guidance is a reasonable time by which States and Tribes should take action to adopt new or revised water quality criteria necessary to protect the designated uses of their waters. See 63 FR 68353.

EPA recently published a new analytical method (method 1631) for detecting and measuring total and dissolved mercury in water and fish samples (USEPA, 1999b). This method is approximately 400 times more sensitive than EPA's previously recommended analytical method and is capable of measuring mercury concentrations well into the ranges identified in this notice for fish concentrations as well as those anticipated for associated water concentrations (detection limit of 0.2 ng/L in water). This method determines the amount of total mercury, not

methylmercury, in water and fish. This will likely result in a substantial increase in the number of point source discharges of mercury needing WQBELs in their NPDES permits.

Among the many issues associated with implementation, State and Tribal water quality managers will need to identify which species to target for sampling, determine sample compositing procedures and frequency of sampling, and relate sampling and analysis procedures to the consumption patterns intended for protection by the water quality criterion. The Agency has published guidance on field sampling and analysis as part of the package of guidance to States and Tribes for issuing fish consumption advisories. EPA anticipates that this guidance will also be useful for implementing State or Tribal water quality criterion for methylmercury based on today's criterion guidance.

Three translations are necessary to relate the methylmercury water quality criterion for fish tissue expressed in this notice to a total mercury concentration in ambient water or effluent, for NPDES or TMDL purposes. The first translation is to determine the fraction of measured mercury in fish that is methylmercury. Although this can vary in practice, the methylmercury fraction is typically very high in freshwater and estuarine fish, and approaches 100 percent for higher trophic level organisms. The second translation is from methylmercury in fish to methylmercury in water. As discussed in detail above, the best means of determining this relationship is through site-specific analysis of bioaccumulation patterns. The third translation is from methylmercury in water to total mercury in water. As with the BAFs, the preferred method to do this translation is to measure the concentrations of methylmercury and total mercury in ambient water.

As mentioned, EPA believes an implementation policy is necessary that addresses recommendations for establishing sampling protocols and determining attainment of State or Tribal methylmercury water quality criterion, NPDES permitting and TMDL development, and source management and control strategies. For example, the water quality standards portion of this policy would address issues such as how the water quality standards variance and use attainability analysis processes could be used to address legacy contaminants. Also, EPA expects that, as a result of this revised methylmercury water quality criterion, together with the more sensitive method for detecting mercury, there will be an increase in the number of waterbodies

reported on State 303(d) lists as impaired due to mercury contamination. Thus, the policy would also discuss approaches for managing the development of TMDLs for waterbodies impaired by mercury. This would include approaches for addressing waterbodies where much of the mercury is from atmospheric sources, and how TMDLs can take into account ongoing efforts to address sources of mercury, such as programs under the Clean Air Act and pollution prevention activities.

The policy would also address numerous issues associated with point source discharges of mercury such as determining the need for a WQBEL in NPDES permits and, where needed, developing and implementing those limits. EPA intends to take the following factors or assumptions into account when it addresses these issues: the unique properties of mercury; EPA's expectation that there will likely be a substantial increase in the number of point source discharges needing WQBELs as a result of the new more sensitive method; and, in most cases, the relatively small contribution from point source discharges to the total loadings of mercury to a waterbody.

Given the ongoing atmospheric sources of mercury and the long-term cycling of mercury in the environment, the most effective means of protecting public health for the next few decades will continue to be the issuance of fish consumption advisories by State and Tribal authorities, to ensure the public knows what level of fish consumption from specific waters is safe. EPA also emphasizes that the science underlying today's recommended section 304(a) water quality criterion is sound and recommends that States and authorized Tribes consider using an appropriate RSC in establishing and issuing fish consumption advisories as described in the fish advisory guidance (USEPA, 2000e). However, effective source control and management programs need to be initiated and developed in the coming few years to begin the long-term process of recovery from the widespread mercury contamination evident in our aquatic environments, with the goal of reducing mercury contamination so that fish consumption advisories can be removed.

EPA believes that flexibility may be appropriate as water quality standards based on today's methylmercury water quality criterion are implemented. Today's notice serves as an initiation of dialogue with stakeholders on recommended approaches for using today's section 304(a) water quality criterion guidance and managing mercury contamination in the aquatic

environment. EPA is interested in obtaining information, views, suggestions, and innovative approaches from the public. EPA is particularly interested in specific examples or model approaches for management of mercury contamination at the Federal, State, Tribal, and local level. EPA anticipates this dialogue will be facilitated by a variety of means, which may include public meetings, meetings with stakeholders, and written correspondence and responses.

#### IX. Literature Cited

- Akagi, H., O. Malm, Y. Kinjo, M. Harada, F.J.P. Branches, W.C. Pfeiffer and H. Kato (1995). Methylmercury pollution in the Amazon, Brazil. *Sci. Total Environ.* 175:85-95.
- Becker, D. S. and G.N. Bigham. 1995. Distribution of Mercury in the Aquatic Food Web of Onondaga Lake, New York. *Water Air Soil Pollu.* 80:563-571.
- Bloom, N.S. 1992. On the chemical form of mercury in edible fish and marine invertebrate tissue. *Can. J. Fish. Aquat. Sci.* 49:1010-1017.
- Cope, W.G., J.G. Wiener and R.G. Rada. 1990. Mercury accumulation in yellow perch in Wisconsin seepage lakes: Relation to lake characteristics. *Environ. Toxicol. Chem.* 9:931-940.
- Clarkson, T. W., L. Amin-Zaki, and S. Al-Tikriti. 1976. An outbreak of methylmercury poisoning due to consumption of contaminated grain. *Fed. Proc.* 35: 2395-2399.
- Davidson, P., G. Myers, C. Cox, C. Shamlaye, D. Marsh, M. Tanner, M. Berlin, J. Sloane-Reeves, E. Cernichiari, O. Choisy, A. Choi, and T. Clarkson. 1995. Longitudinal neurodevelopmental study of Seychellois children following in utero exposure to methylmercury from maternal fish ingestion: outcomes at 19 and 29 months. *Neurotoxicology* 16:677-688.
- Glass, G., J.A. Sorenson, and G.R. Rapp, Jr. 1999. Mercury deposition and lake quality trends. Final report Project: I-11/I-15, Legislative Commission on Minnesota Resources, St Paul, MN.
- Grieb, T.M., C.T. Driscoll, S.P. Gloss, C.L. Schofield, G.L. Bowie and D.B. Porcella. 1990. Factors affecting mercury accumulation in fish in the upper Michigan peninsula. *Environ. Toxicol. Chem.* 9:919-930.
- Jackson, T.A. 1991. Biological and environmental control of mercury accumulation by fish in lakes and reservoirs of northern Manitoba, Canada. *Can. J. Fish. Aquat. Sci.* 48:2449-2470.
- Kim, J.P. 1995. Methylmercury in rainbow trout (*Oncorhynchus mykiss*) from Lakes Okareka, Okaro, Rotmahana, Rotorua and Tarawera, North Island, New Zealand. *Sci. Total Environ.* 164:209-219.
- Lange, T.R., H.E. Royals and L.L. Connor. 1993. Influence of water chemistry on mercury concentration in largemouth bass from Florida lakes. *Trans. Am. Fish. Soc.* 122:74-84.
- Lores, E.M., J. Macauley, L.R. Goodman, R.G. Smith and D.M. Wells. 1998. Factors affecting bioavailability of methylmercury in Florida Bay. *Soc. Environ. Toxicol. Chem.* 19th Annual Meeting. Charlotte, NC. Abstr. No. 468. p. 101.
- Mason, R.P., W.F. Fitzgerald and F.M.M. Morel. 1994. The Biogeochemical Cycling of Elemental Mercury: Anthropogenic Influences. *Geochimica et Cosmochimica Acta.* 58(15):3191-3198.
- Mason, R.P. and K.A. Sullivan. 1997. Mercury in Lake Michigan. *Environ. Sci. Technol.* 31:942-947.
- Miles, C.J. and L.E. Fink. 1998. Monitoring and mass budget for mercury in the Everglades nutrient removal project. *Arch. Environ. Contam. Toxicol.* 35:549-557.
- Monson, B.A. and P.L. Brezonik. 1998. Seasonal patterns of mercury species in water and plankton from softwater lakes in Northeastern Minnesota. *Biogeochem.* 40:147-162.
- Nordberg, G. F. and P. Strangert. 1976. Estimations of a dose-response curve for long-term exposure to methylmercuric compounds in human being taking into account availability of critical organ concentration and biological half-time: A preliminary communication. In: Effects and Dose-Response Relationships of Toxic Metals, G.F. Nordberg, Ed. Elsevier, Amsterdam. p. 273-282.
- NRC (National Research Council). 2000. Toxicological Effects of Methylmercury. Committee on the Toxicological Effects of Methylmercury, National Academy Press, Washington, D.C. July. ??pp.
- Nriagu, J. O. 1979. The Biogeochemistry of Mercury in the Environment. Elsevier/North Holland. Biomedical Press: New York.
- QEA (Quantitative Environmental Analysis, LLC). 2000. Bioaccumulation Model QUAFDCHN v1.0. Montvale, NJ. September.
- Stephan, C.E., D.I. Mount, D.J. Hansen, J.H. Gentile, G.A. Chapman and W.A. Brungs. 1985. Guidelines for deriving numerical national water quality criteria for the protection of aquatic organisms and their uses. NTIS Publication No.: PB85-227049.
- Tetra Tech.. 1999. Dynamic Mercury Cycling Model for Windows 95/NT. A Model for Mercury Cycling in Lakes. D-MCM Version 1.0. Users Guide and Technical Reference. Prepared by Tetra Tech Inc. for EPRI. Lafayette, CA. April.
- USDA (U.S. Department of Agriculture). 1998. 1994-1996 Continuing Survey of Food Intakes by Individuals and 1994-1996 Diet and Health Knowledge Survey. Agricultural Research Service, USDA. NTIS CD-ROM, accession number PB98-500457.
- USEPA (U.S. Environmental Protection Agency). 1980. Guidelines and methodology used in the preparation of health effect assessment chapters of the consent decree water criteria documents. **Federal Register** 45:79347, Appendix C.
- USEPA (U.S. Environmental Protection Agency). 1984. Ambient Water Quality Criteria for Mercury 1984. Office of Water, Washington, DC EPA440/5-84-026. January 1985.
- USEPA (U.S. Environmental Protection Agency). 1995. Final Water Quality



- Guidance for the Great Lakes System. **Federal Register** 60:15366.
- USEPA (U.S. Environmental Protection Agency). 1997a. Mercury Study Report to Congress. U.S. Washington, DC December.
- USEPA (U.S. Environmental Protection Agency). 1997b. Final Rule for Hazardous Air Pollutants for Hospital/Medical/ Infectious Waste Incinerators. **Federal Register** 62:48379.
- USEPA (U.S. Environmental Protection Agency). 1998. National recommended water quality criteria; Notice; Republication. **Federal Register** 63:68354, December 10, 1998.
- USEPA (U.S. Environmental Protection Agency). 1999a. National Recommended Water Quality Criteria—Correction. **Federal Register** 64:19781, April 22, 1999. Office of Water. Washington, DC EPA–822–Z–99–001. April.
- USEPA (U.S. Environmental Protection Agency). 1999b. Method 1631, Revision B: Mercury in Water by Oxidation, Purge and Trap, and Cold Vapor Atomic Fluorescence Spectrometry. Office of Water. Washington, DC EPA–821–R–99–005. May.
- USEPA (U.S. Environmental Protection Agency). 2000a. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). Office of Water. Washington DC EPA–822–B–00–004. October.
- USEPA (U.S. Environmental Protection Agency). 2000b. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). Technical Support Document. Volume 1: Risk Assessment. Office of Water. EPA–822–B–00–005. October.
- USEPA (U.S. Environmental Protection Agency). 2000c. Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). **Federal Register** 65:66444, November 3, 2000.
- USEPA (U.S. Environmental Protection Agency). 2000d. Review and approval of State and Tribal water quality standards. **Federal Register** 65:24642.
- USEPA (U.S. Environmental Protection Agency). 2000e. Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories. Volume 2: Risk Assessment and Fish Consumption Limits. Office of Water. Washington, DC EPA–823–B–00–008.
- USEPA (U.S. Environmental Protection Agency). 2000f. Estimated Per Capita Fish Consumption in the United States: Based on Data Collected by the United States Department of Agriculture's 1994–1996 Continuing Survey of Food Intake by Individuals. Office of Science and Technology, Office of Water, Washington, DC March.
- USEPA (U.S. Environmental Protection Agency). 2000g. AQUATOX. EPA Release 1. File Version 1.69. Office of Water. Washington, DC EPA–823–C–00–001. September.
- USEPA (U.S. Environmental Protection Agency). 2000h. Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories. Volume 1: Fish Sampling and Analysis. Office of Water. Washington, DC EPA–823–B–00–007.
- USEPA (U.S. Environmental Protection Agency). 2001. Water Quality Criterion for the Protection of Human Health: Methylmercury. Office of Water. Washington, DC EPA–823–R–01–001. January.
- Watras, C.J. and J.W. Huckabee, Eds. (1994). Mercury pollution: Integration and Synthesis. Lewis Publishers, New York, NY., 727pp.
- Watras, C.J., R.C. Back, S. Halvorsen. R.J.M. Hudson, K.A. Morrison and S.P. Wentz. 1998. Bioaccumulation of mercury in pelagic freshwater food webs. *Sci. Total Environ.* 219:183–208.
- WHO (World Health Organization). 1976. Environmental Health Criteria: Mercury. World Health Organization, Geneva, Switzerland, 121.
- Dated: December 21, 2000.
- J. Charles Fox,**  
Assistant Administrator for Water.  
[FR Doc. 01–217 Filed 1–5–01; 8:45 am]
- BILLING CODE 6560–50–P**

## FEDERAL DEPOSIT INSURANCE CORPORATION

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Federal Deposit Insurance Corporation (FDIC).

**ACTION:** Notice and request for comment.

**SUMMARY:** The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). Currently, the FDIC is soliciting comments concerning an information collection titled “Occasional Qualitative Surveys.”

**DATES:** Comments must be submitted on or before March 9, 2001.

**ADDRESSES:** Interested parties are invited to submit written comments to Tamara R. Manly, Management Analyst (Regulatory Analysis), (202) 898–7453, Office of the Executive Secretary, Room F–4058, Attention: Comments/OES, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429. All comments should refer to “Occasional Qualitative Surveys.” Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7 a.m. and 5 p.m. [FAX number (202) 898–3838; Internet address: [comments@fdic.gov](mailto:comments@fdic.gov)]. Comments may also be submitted to the OMB desk officer for the FDIC:

Alexander Hunt, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503.

### FOR FURTHER INFORMATION CONTACT:

Tamara R. Manly, at the address identified above.

### SUPPLEMENTARY INFORMATION:

Proposal to renew the following currently approved collection of information:

*Title:* Occasional Qualitative Surveys.

*OMB Number:* 3064–0127.

*Frequency of Response:* On occasion.

*Affected Public:* All financial institutions.

*Estimated Number of Respondents:* 5,000.

*Estimated Time per Response:* 1 hour.

*Estimated Total Annual Burden:* 5,000 hours.

*General Description of Collection:* The collection involves the occasional use of qualitative surveys to gather anecdotal information about regulatory burden, problems or successes in the bank supervisory process (including both safety-and-soundness and consumer-related exams), and similar concerns.

### Request for Comment

*Comments are invited on:* (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the collection should be modified prior to submission to OMB for review and approval. Comments submitted in response to this notice also will be summarized or included in the FDIC's requests to OMB for renewal of this collection. All comments will become a matter of public record.

Dated at Washington, DC, this 2nd day of January, 2001.

Federal Deposit Insurance Corporation  
**Robert E. Feldman,**  
Executive Secretary.

[FR Doc. 01–437 Filed 1–5–01; 8:45 am]

**BILLING CODE 6714–01–P**