



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 6

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JUL 11 2008

Ms. L'Oreal W. Stepney, P.E., Director
Water Quality Division
Texas Commission on Environmental Quality
P.O. Box 13087
Austin, TX 78711-3087

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TCEQ
WATER QUALITY DIV.

Re: EPA's Comments on Draft Revisions to Texas' Human Health Criteria for Mercury

Dear Ms. Stepney:

We appreciate receiving the Texas Commission on Environmental Quality's (TCEQ) letter dated April 23, 2008, which included the State's rationale for revisions to the human health criteria for mercury. In its letter, TCEQ asked the Environmental Protection Agency (EPA) to express its potential objections to a methylmercury fish tissue criterion of 0.7 mg/kg for the protection of human health. EPA Region 6 and Headquarters offices have reviewed the State's information and offer comments on the proposed methylmercury criterion. It should be noted that the positions described below are preliminary in nature and should not be construed as final agency decisions under §303(c) of the Clean Water Act (CWA). EPA's approval/disapproval decision will be made following final adoption of new/revised water quality standards by TCEQ and submittal to EPA. Approval/disapproval decisions will be made considering all pertinent information available to the Agency.

The draft revisions to the *Texas Surface Water Quality Standards* include numerous changes to Table 2, one of which is removing the water column human health criteria for mercury. A methylmercury fish tissue criterion of 0.7 mg/kg is proposed to replace the existing human health water column criteria for consumption of water and fish and consumption of fish only. The 0.7 mg/kg value is less stringent than EPA's 2001 §304(a) recommended criterion of 0.3 mg/kg.¹

While we are very supportive of TCEQ's desire to better regulate mercury, we have concerns with TCEQ's approach to deriving a state-specific criterion for methylmercury. EPA's regulation requires that water quality criteria must protect designated uses, and must be scientifically defensible. As explained in more detail below, EPA will have difficulty in accepting the scientific basis for TCEQ's approach.

¹ USEPA. 2001. *Water quality criterion for the protection of human health: Methylmercury*. EPA-823-R-01-001. U.S. Environmental Protection Agency, Office of Water, Washington, D.C.
<http://www.epa.gov/waterscience/criteria/methylmercury/document.html>

Minimum Risk Level

EPA applies its 2000 Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health in deriving criteria.² This methodology entails the use of a scientifically defensible reference dose (RfD). TCEQ's draft criterion of 0.7 mg/kg is the same value used by the Texas Department of State Health Services (DSHS) for issuing fish consumption advisories. The DSHS derived their fish consumption advisory value based on a Minimum Risk Level (MRL) of 0.0003 mg/kg/day used by the Agency of Toxic Substances and Disease Registry (ATSDR). MRLs are similar, but not identical, to RfDs. MRLs are health guidance values established by ATSDR and are intended for use by public health officials as screening tools when determining whether further evaluation of potential human exposure at hazardous waste sites is warranted. ATSDR states that MRLs are not intended for use in determining clean-up levels or for other regulatory purposes.³ EPA's 2001 recommended methylmercury criterion is based on an RfD of 0.0001 mg/kg/day, which is more stringent than ATSDR's MRL. We previously provided brief information to your staff in August 2007 on the development of the RfD in EPA's 2001 criteria document and how this compares to ATSDR's MRL.

Prior to completing EPA's 2001 criteria document, the Agency was directed by Congress to contract with the U.S. National Academy of Sciences, National Research Council (NRC) to review the body of information available on the health effects of mercury.⁴ The NRC was critical of the MRL used by ATSDR. The NRC recommended that given three studies of equally acceptable quality, EPA should base its risk assessment on those with findings demonstrating a correlation between health effects and exposure to mercury.⁵ The NRC (2000) made the following statements in its report to EPA⁶:

"... because there is a large body of scientific evidence showing adverse neurodevelopmental effects, including well-designed epidemiological studies, the committee concludes that an RfD should not be derived from a study, such as the Seychelles study, that did not observe any associations with MeHg." (p.6)

"It would not be appropriate to base risk-assessment decisions on the Seychelles study because it did not find an association between MeHg and adverse neurodevelopment effects. That finding is not consistent with the weight of evidence demonstrating such an association in the Faroe Islands and New Zealand studies." (p. 299)

In calculating its MRL, ATSDR used data only from the Seychelles study. EPA, following the advice of the NRC and another independent peer review panel, calculated RfDs from multiple endpoints from the Faroe Island and New Zealand studies as well as a bounding estimate from the Seychelles study. The published RfD of 0.0001 mg/kg/day considered all of these calculations.⁷

² USEPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. EPA-822-B-00-004. U.S. Environmental Protection Agency. Washington D.C.
<http://www.epa.gov/waterscience/criteria/humanhealth/method/index.html>.

³ ATSDR Background: Toxicological Profile for Mercury; April 1999.

⁴ See Section 4.1.5 in EPA's Methylmercury Fish Tissue Criterion document.

⁵ See Section 4.1.5 in EPA's Methylmercury Fish Tissue Criterion document.

⁶ Committee on the Toxicological Effects of Methylmercury, Board on Environmental Studies and Toxicology, National Research Council: *Toxicological Effects of Methylmercury*. 2000.

⁷ See Section 4.6 in EPA's Methylmercury Fish Tissue Criterion document.

Blood Mercury Levels

TCEQ staff previously provided EPA with documentation related to the proposed criterion of 0.7 mg/kg, including a report published by DSHS and ATSDR on an investigation of consumption of fish with elevated mercury levels from Caddo Lake.⁸ The Caddo Lake study is an exposure study rather than an epidemiology study or other measure of health endpoints. These exposure data, while of scientific interest, are not relevant to determining a criterion. For example, the study provides no information about any health effects in the sampled population.

TCEQ noted that none of the Caddo Lake study participants had blood levels above the "benchmark dose lower limit" of 58 µg/L found in EPA's 2001 methylmercury criteria document. EPA has serious concerns regarding the defensibility of using the benchmark dose lower limit as a means to justify a fish tissue criterion. The benchmark dose lower limit of 58 µg/L is not a "no effect" level. Rather, it is an effect level for a percentage of the population. Section 4.3.1 of EPA's methylmercury criteria document summarizes the differences between using a NOAEL and using a benchmark dose to calculate RfDs. Also, blood level of mercury is a biomarker of exposure, rather than a biological effect.

As a separate issue, care must be taken in comparing exposure data with a health risk dose-response estimate, such as an RfD. The National Health and Nutrition Examination Surveys (NHANES) conducted by the Centers for Disease Control are representative of the U.S. population because of the study design and large number of subjects. The Caddo Lake study may be representative of that particular population, but the sample size is very small. It is not appropriate to extrapolate from the Caddo Lake study to larger regional or state populations.

Suggested Approach

We have considered TCEQ's perspectives and our own criterion and would like to propose an approach that would be both scientifically acceptable and environmentally protective. We recommend that TCEQ consider a dual implementation approach for mercury:

- Adopt a water quality criterion of 0.3 mg/kg in the WQS for implementation in regulatory actions, such as wastewater permitting.
- Use a non-regulatory screening level (e.g., 0.7 mg/kg) to trigger a definitive risk assessment for determining the need for fish consumption advisories and bans. Once adequate data have been collected and the risk assessment completed, appropriate decisions on advisories and bans can be made. This is consistent with the existing approach that the State uses for issuing advisories.

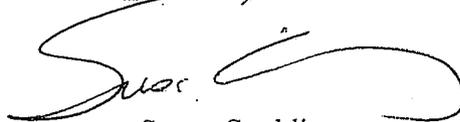
⁸ DSHS. 2005. *Health Consultation: Mercury Exposure Investigation Caddo Lake Area-Harrison County Texas*. Agency for Toxic Substances and Disease Registry.
http://www.tceq.state.tx.us/assets/public/comm_exec/pubs/sfr/085.pdf

We also recommend that TCEQ develop an assessment protocol with the adoption of any new criterion. An assessment protocol might incorporate fish consumption advisories and bans with analysis of fish tissue data.

In conclusion, EPA would have difficulty in finding Texas' proposed criterion of 0.7 mg/kg scientifically defensible, based on its reliance on an MRL which EPA explicitly chose not to use as the sole basis for the 2001 §304(a) nationally recommended water quality criterion. Although TCEQ may choose to adopt a criterion different from EPA's national recommendation, we must be able to find the State's criterion scientifically defensible. Based on current information from TCEQ, the use of the MRL and exposure studies as described by TCEQ, in place of the EPA-recommended RfD derived from epidemiological studies, does not appear to be a scientifically defensible method for deriving human health criteria.

We hope these comments are helpful to TCEQ for its rulemaking process. We appreciate the efforts of the Water Quality Division and the Chief Engineer's Office to address issues of concern to EPA. We've discussed your proposal with EPA's national experts, but for the reasons outlined above, we would have difficulty accepting the revision you are considering. Hopefully, once we have had an opportunity to work with you and your staff to resolve these issues, the State will be able to adopt a methylmercury criterion that EPA can fully support. If there are questions concerning our comments, please have your staff contact Diane Evans of my staff at (214) 665-6677 or call Philip Crocker at (214) 665-6644.

Sincerely,



Susan Spalding
Acting Chief
Ecosystems Protection Branch (6WQ-E)

cc: Ms. Debbie Miller, TCEQ - Water Quality Assessment Section (MC-150)
Dr. Tracie Phillips, TCEQ - Toxicology Section (MC-168)