UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NATIONAL CENTER FOR ENVIRONMENTAL RESEARCH
WASHINGTON, DC 20460

OFFICE OF
RESEARCH AND DEVELOPMENT

December 5, 2008

MEMORANDUM

SUBJECT: Comments from the National Center for Environmental Assessment on the draft FDA report, "*An Evaluation of Risk to U.S. Consumers from Methylmercury in Commercial Fish Products, Including a Quantitative Assessment of Risk and Beneficial Health Effects from Fish.*"

FROM: Peter W. Preuss, Ph.D., Director
National Center for Environmental Assessment
Office of Research and Development

THROUGH: Fred Hauchman
Office of Science Policy
Office of Research and Development

TO: Ephraim King, Director
Office of Science and Technology
Office of Water

During the month of November, the National Center for Environmental Assessment (NCEA) was asked to provide comments on a draft document from the U.S. Food and Drug Administration (FDA) entitled "An Evaluation of Risk to U.S. Consumers from Methylmercury in Commercial Fish Products, Including a Quantitative Assessment of Risk and Beneficial Health Effects from Fish."

Based on our review, we have very serious concerns about this document, which is scientifically flawed and inadequate in several aspects. As it exists in its current state, it is not a product that NCEA will endorse or approve as it does not reach the level of scientific rigor routinely demonstrated by EPA. This is an extremely important public health issue, and until the scientific concerns raised by EPA have been fully addressed, NCEA cannot provide support for the document and cautions against releasing it.

This FDA report bases its conclusions on models that use very limited inputs from studies that have significant problems for risk analysis. It also uses inputs from relatively gross apical measures for risk and benefits analysis. The result is an oversimplification of the relationship

between the risk of eating fish contaminated with methyl mercury and the benefits of eating fish. The report's departure from clearly outlining risk and benefit considerations of eating fish low in methyl mercury gets lost in the oversimplified conclusions. The FDA analysis uses gross measures of age of walking and talking and global IQ measures from limited studies (Iraqi poisoning epidemic and the Seychelles study). Additionally, it fails to consider outcomes most sensitive to developmental effects from methylmercury (e.g., Boston naming test, California Verbal Learning Test, etc.). Importantly, the report fails to consider outcomes from other critical studies identified by the National Academy of Sciences in their 2000 review.

Further, there are several scientific issues with the cardiovascular analysis portion of the report. Choices made regarding the modeling are not clearly explained, the authors incompletely and inaccurately describe the literature, and nonfatal coronary heart disease events are not considered.

Overall, we have very serious concerns about the report. There are serious scientific flaws, and this is not a product that EPA should endorse as it does not reach the level of scientific rigor routinely demonstrated by the Agency. The scientific, statistical and methodological limitations of this work are too great for it to serve as a tool for governmental decision making regarding risks from methylmercury in seafood – or for characterizing and communicating these risks to the public. This is an extremely important public health issue, and until the concerns raised by EPA have been fully addressed, NCEA cannot provide support for the document and cautions against releasing it. Our full comments are attached.

CC: Rita Schoeny, Office of Water
Denise Keehner, Office of Water
Kevin Teichman, Office of Research and Development
George Gray, Office of Research and Development
Stan Barone, Office of Research and Development
Kacee Deener, Office of Research and Development
Glenn Rice, Office of Research and Development
Kathleen Raffaele, Office of Research and Development