



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

APR 25 2008

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Chairman Dingell:

Thank you for your letters dated February 28, 2008, and March 27, 2008, in which you raise concerns regarding the Agency for Toxic Substances and Disease Registry's (ATSDR) draft report titled, "*Public Health Implications of Hazardous Substances in the Twenty-Six U.S. Great Lakes Areas of Concern*," and an ATSDR employee. Please excuse the delay of this response.

Your letters also make a number of specific requests, including production of documents; an explanation of the decision to postpone release of the report and who made that decision; notification to employees of certain rights; and suspension of any adverse personnel actions related to employees involved in the Great Lakes Report.

As noted in your March letter, ATSDR staff has responded to these requests by providing a number of documents and by sending a notice to employees regarding preservation of documents. We have also posted several drafts of the Great Lakes Report on the Web, in addition to peer-review comments and other information related to the concerns that necessitated further work on the report before its release.

We discussed the draft Great Lakes Report, the decision to postpone its release, and related issues, at a meeting on March 28, 2008, between John Arlington of your committee staff and Dr. Henry Falk, Director of the Coordinating Center for Environmental Health and Injury Prevention, which oversees the National Center for Environmental Health (NCEH)/ATSDR. Below is further information in response to your letters.

Decision to postpone release of the draft Great Lakes Report:

ATSDR is committed to providing people of the Great Lakes Region with accurate scientific information about environmental conditions and protecting residents from possible health effects. This is evidenced by ATSDR's longstanding involvement in a range of activities in the Region, including assessing potential health effects related to exposure to hazardous substances at hundreds of hazardous waste sites in the eight Great Lakes states, providing technical and financial support to states to conduct these assessments at sites, and funding universities and state health departments to conduct research under the Great Lakes Human Health Effects Research Program.

The decision to postpone release of the report was made by Dr. Howard Frumkin, Director of ATSDR and of NCEH at the Centers for Disease Control and Prevention (CDC). The decision was based on concerns about serious scientific deficiencies in the environmental and health data, exposure information, and analysis. Many of these concerns had been raised by reviewers but not addressed. More detailed information on the basis for that decision is in numerous documents that have been provided to your staff, including various peer review comments and other documents posted on the website, and a Statement of Concerns (enclosed). ATSDR has revised the draft report and will release a draft for public comment in the near future.

IOM Review of Draft AOC Report and of ATSDR Decision to Postpone Release

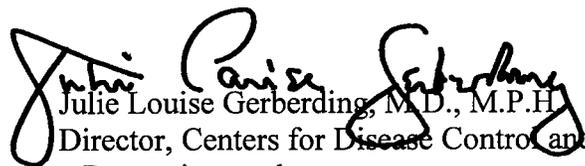
The Institute of Medicine (IOM), an independent, unbiased, authoritative source of science-based health information, has agreed to review the science in the July 2007 draft report and the decision to take additional time to improve its content prior to publication. The first meeting of the IOM panel is scheduled for May 1, 2008. ATSDR staff has provided your staff with information on the members of the IOM panel, and will continue to keep your staff informed of meetings and other information available concerning the IOM review.

Protection of Employee Rights

As requested in your letter, and in accordance with the Notification and Federal Employee Antidiscrimination and Retaliation (NOFEAR) Act, we have advised employees of their rights under the whistleblower protection laws. I assure you that we respect employee rights and are committed to complying with the range of laws designed to protect those rights. As discussed in more detail in documents that have been provided to your staff, decisions regarding Dr. Christopher DeRosa's responsibilities have been based solely on his performance.

We are committed to continuing to work diligently with you and your staff, and will provide additional documents in response to your requests as they become available. I also will provide this response to Mr. Bart Stupak who cosigned your letter.

Sincerely,


Julie Louise Gerberding, M.D., M.P.H.
Director, Centers for Disease Control and
Prevention, and
Administrator, Agency for Toxic Substances
and Disease Registry

Enclosure

**Scientific Concerns About the Draft Report,
*Public Health Implications of Hazardous Substances
in the Twenty-Six U.S. Great Lakes Areas of Concern***

Understanding environmental conditions in the Great Lakes region and protecting residents from possible health effects is a priority for the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR). Community members in the Great Lakes region deserve accurate information provided in a timely manner. In July 2007, ATSDR's Office of the Director determined that the draft report *Public Health Implications of Hazardous Substances in the Twenty-Six U.S. Great Lakes Areas of Concern*, was not ready for public release. CDC and ATSDR reports undergo extensive review before they are released to the public. These reviews ensure that when information is released, it is scientifically reliable and can be used with confidence by those making decisions to protect public health and the environment. The decision to take additional time to improve the draft report in order to ensure its scientific quality was difficult, but it was necessary. CDC is currently taking actions to remedy several important scientific deficiencies in the draft document.

This document summarizes some of ATSDR's scientific concerns that guided its decision to delay release of the draft report until those scientific concerns could be addressed.

Background

The International Joint Commission (IJC) was created in 1909 to prevent and resolve disputes along the U.S.–Canada boundary. Under the Great Lakes Water Quality Agreement of 1972, the IJC reviews and evaluates binational efforts to protect the Great Lakes ecosystem. The IJC has identified environmentally degraded “Areas of Concern” (AOCs) within the Great Lakes Basin. For example, an AOC may be a polluted stretch of river, a hazardous waste site, or an abandoned factory. There are 43 AOCs: 26 located entirely within the United States, 12 located wholly within Canada, and 5 shared by both countries.

In 2001, the IJC requested ATSDR's “assistance in evaluating the public health implications of environmental contamination in Great Lakes AOCs by providing information on ATSDR's public health assessments of hazardous waste sites within these AOCs.” This request resulted in preparation of the draft report *Public Health Implications of Hazardous Substances in the Twenty-Six U.S. Great Lakes Areas of Concern*. The intent of the draft report was to help decision-makers set future priorities for research and public health action.

ATSDR staff identified and assembled certain existing data related to both environmental pollutants and health, and they distributed a draft report for peer review in 2004. Between April 2004 and July 2007 the draft report was under revision. When the draft report was reviewed by ATSDR leadership in June 2007, significant scientific shortcomings were identified. Similar concerns have also been expressed by multiple levels of scientific leadership within CDC, ATSDR, and among various partners and stakeholders. (see also “scientific review” below).

CDC/ATSDR Scientific Concerns About the Great Lakes Draft Report

A high standard of science guides CDC/ATSDR internal review and clearance processes. CDC and ATSDR believe the Great Lakes report should contain high-quality science and information that can guide future research, policy-making, and personal health decisions.

Hazardous substances exist in the Great Lakes region; therefore, it is important to know whether people in this region are being exposed to environmental contaminants in ways that could affect their health. A solid science base requires accurate environmental data, knowledge of whether and how people are being exposed to environmental toxins, accurate health outcome data, correct data analysis, and conclusions that are supported by the data. The exposure data and the health data need to correspond in geographic location and in time. The process of collecting, analyzing, and interpreting information should be presented clearly and transparently so readers can assess the science. ATSDR is taking steps to improve the quality and communication of the draft report in all of these areas.

From the perspective of ATSDR senior scientists, the July 2007 draft report suffered from several serious deficiencies. Below are short summaries of some of the major concerns:

Scientific methods: The methodology for this draft report was unclear; readers of the draft report could not identify key processes the authors used to analyze the data and draw conclusions, particularly relating to using county health data.

- For example, the statistical methods used to identify how counties compared to other counties were inadequately described. Some of these instances were:
 - There was no discussion of how “peer counties” were selected.
 - The reported Web reference on the health outcome data did not exist.
 - Methods of analysis were incorrectly described. The draft report stated that health status indicators that exceed the upper 90th percent confidence limit of the median for the peer county range and those that exceed the median of the U.S. rates are reported. However, 90% confidence limits were not calculated. Any health indicator was considered elevated if it was above the median value (a type of average) among peer counties and all U.S. counties.

Environmental data: Environmental data that identifies releases and conditions at various times and locations across the counties might not accurately reflect current conditions in specific AOCs. The draft report, however, does not adequately acknowledge these gaps when juxtaposing health and environmental data.

Exposure information: The information summarized in the draft report generally does not indicate whether, when, and how people might have been exposed to environmental contaminants. The draft report does not adequately acknowledge these gaps when juxtaposing health and environmental data.

Health data: Health and environmental data were presented in ways likely to be misinterpreted. For many reasons, the inappropriate juxtaposition of certain health and environmental data was the draft report's most challenging shortcoming. Some of those reasons were:

- The health data originally were collected for purposes other than assessing health effects of environmental exposures. The data as presented in the draft report, therefore, included indicators of health status, such as lack of prenatal care, that are not related to environmental exposures.
- The health data were collected before the environmental release data were collected. It is therefore difficult to determine whether the exposures happened before the measured health outcomes. An exposure to an environmental hazard cannot cause a health effect that existed before the exposure occurred.
- If there is not a large enough group of exposed individuals to affect county health data, then county rates will be unrelated to the AOC regardless of whether they are above or below the median.
- Finally, the draft report did not account for confounding factors (i.e., other factors that might explain apparent associations between environmental measures and health outcomes).

Although the draft report discussed some of these, the data are still presented in ways that are likely to be misinterpreted.

Statistical analysis: The statistical methods used in the draft report were unconventional and cause readers to overestimate linkages between environmental data and health problems. Specifically, health measures for a county were classified as "elevated" if they were greater than the median nationally and for its peer group. Using these methods it would be expected that approximately half of all health indicators for any county in the nation would have been classified as elevated, whether or not any environmental exposure occurred. This problem was compounded when the boundaries of a single AOC extended into multiple counties. This meant that more counties were included and more health outcomes measured. Thus, it was more likely that some of the measures were elevated by chance alone.

Scientific review: Several rounds of peer and expert review of the draft report were conducted; however, many important reviewer comments were not adequately addressed. For example, as shown in Table 1, many comments relating to juxtaposition of these health outcome data with the available environmental data mirror the concerns of CDC/ATSDR leadership. These comments still had not been adequately addressed in the 2007 draft report.

2004	"We recommend adding a more detailed explanation of how human health outcomes were generated and evaluated for this [draft] report...."
2005	"County wide health outcomes may not be indicative of the potential impacts of sub-county sized AOCs. There is not one to one correspondence."
2005	"While the [draft] report clearly prefaces that health outcome data (e.g., birth defects) examined in counties in the Areas of Concern were not used to make causal inferences between exposure and health effects, additional consideration needs to be

	given to potential misunderstanding or misuse of the [draft] report. Some people still may draw an inappropriate connection between AOC proximity and negative health effects.”
2007	“US EPA strongly recommends that these [expert] comments be carefully considered and fully utilized prior to ATSDR's releasing the [draft] report for public comment. US EPA is concerned that the document, if released in its current form, could impact the credibility of the ATSDR's effort (some of EPA's comments are matters of fact), and US EPA would like to continue to work closely with ATSDR to assure the [draft] report provides the most value to ATSDR and the public”
2007	“It is particularly problematic the way the [draft] report presents and discusses health data. While comparisons are made between a targeted site and peer counties, the basis for conclusions about increased incidence of health outcomes is unclear.”

While many comments were not sufficiently addressed, other revisions were made that would tend to amplify challenges after the bulk of peer review was seemingly complete.

- After the peer review of the 2004 draft report was completed, a new table was inserted, Table 7.2. This table presented “elevated” rates of morbidity and mortality for the 26 U.S. Great Lakes AOCs, and suffered from the same statistical deficiencies outlined above. Moreover, including this table appeared contrary to the advice from peer reviewers who raised concerns about making the very types of associations presented in the table. The table also appeared to contradict conclusions of the 2004 draft report that stated, “No particular patterns among the TRI release data, waste site contaminant data, and county-wide health outcome data were observed in terms of possible associations for follow up.”

Draft Report Conclusions: The draft report states that its information cannot be used to link health effects to environmental data because it is not an epidemiologic study, but it contradicts this statement in many places. One of these instances is:

- On page 8, the draft report states, “Since the report is not an epidemiologic study, no causal inferences are drawn regarding an observed health effect and the presence of a contaminant known to be associated with that health effect.”
- However, on page 390, the draft report states it “... would tend to underestimate patterns of contamination as well as potential health effects to vulnerable populations.” The draft report cannot underestimate a health effect that it hasn’t estimated.

Lack of public health recommendations: Recommendations in the draft report for additional public health action or further research were very limited or missing.

Next Steps

ATSDR is revising the draft report to advance it to an acceptable scientific standard. In addition, CDC and ATSDR have requested an independent review of the science presented in the draft report and the decision to delay its release. This review will be conducted by the Institute of Medicine (IOM), an independent, unbiased, authoritative source of science-based health

information. In addition, the entire set of materials being reviewed by the IOM will also be publicly available on the ATSDR website.

Summary

Understanding environmental conditions in the Great Lakes region and protecting residents from possible health effects is a priority for CDC and ATSDR. Community members in the Great Lakes region deserve accurate information provided in a timely manner. The decision to take additional time to improve the draft report in order to ensure its scientific quality was difficult, but it was necessary. The delay in issuing the draft report has not deprived the public of critical environmental health information because the health assessments and other environmental data on which the draft report was based already are publicly available elsewhere.

CDC and ATSDR consistently have provided the people living in the Great Lakes states with up-to-date information to help protect them from exposures to toxic chemicals. Between January 2001 and February 2008 in the 8 Great Lakes states, ATSDR has developed and supported 756 documents pertaining to 528 sites and both ATSDR and CDC's National Center for Environmental Health have many ongoing scientific and programmatic activities in those states. CDC and ATSDR are committed to providing useful, scientifically sound information that will help decision-makers protect public health and the environment.