

From: Jim Sygo (Vickie Plummer)
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Date: 4/1/2009 4:57:37 PM
Subject: March 30, 2009, Meeting

Dr. Garabrant:

We would like to thank the University of Michigan Dioxin Exposure Study team for meeting with the Michigan Department of Environmental Quality (MDEQ), the Michigan Department of Community Health (MDCH), the U.S. Environmental Protection Agency (U.S. EPA), the Agency for Toxic Substances and Disease Registry (ATSDR), The Dow Chemical Company (Dow), and Kern Statistical Services, Inc. (KERN), a contractor to the MDEQ, on March 30, 2009, to discuss KERN's review of the University of Michigan's Dioxin Exposure Study (UMDES). We appreciate the opportunity to share and discuss the MDEQ's concerns regarding the UMDES statistical evaluation and analysis. These concerns were communicated to you via the March 5, 2009, "Review of UMDES Statistical Modeling Methods, Analysis, and Interpretation" by John Kern, Ph.D.

While issues remain unresolved, we believe that a mechanism has been established to use our combined expertise to further evaluate and, hopefully, resolve those issues. It is anticipated that the agencies, Dow, and the UMDES team will work collaboratively to develop hypotheses and supporting statistical and graphical analyses that can be investigated through analysis of UMDES data.

The primary objective of this collaborative effort is to develop analyses necessary to improve understanding of the strengths and limitations of results that may be derived from the UMDES studies and for the agencies and the UMDES team to jointly develop a set of study conclusions that are well-supported by the data. As discussed during the meeting, we expect that these conclusions will be developed and communicated to the public in one or more collaboratively authored, publication-quality documents.

This effort will focus on effects of critical variables such as soil and dust, hunting and game consumption, fishing and fish consumption, and floodplain recreational activities. The need for these analyses was identified in your 2006 findings document, due to associations between predictors. The MDEQ agrees further analyses are necessary to fully support and understand these relationships and their implications to interpretation and application of results.

As discussed during the meeting, the collaborative team will proceed to develop a suite of specific combinations of variables and factors that can be incorporated into statistical models in efforts to reduce uncertainty about the effects of key risk management variables on dioxin levels in blood serum. Attached are the draft notes from the "white board" discussion where meeting participants identified the topics that would serve as a framework for that effort. Please note that while some specific draft questions and issues are described in the attachment, it is anticipated that these efforts will be interactive and the need for new or different analyses will develop.

It was agreed that the collaborative team will meet on April 28 and 29, 2009, at the University of Michigan. The MDEQ, MDCH, ATSDR, and KERN will participate in the meeting. The EPA will determine whether EPA staff will participate. Although not discussed on March 30, 2009, we would recommend that you also extend an invitation to the Natural Resource Trustees through Dr. Lisa Williams at the U.S. Fish and Wildlife Service to participate in this effort. In the interest of efficiency, the agencies have designated Dr. Kern to interact directly with the UMDES statistical team. Dow also indicated they would have representatives participate in this meeting and that they would identify a representative to coordinate Dow's comments and questions.

Participants in the March 30, 2009, meeting agreed to start working on further evaluation of the soil and dust relationship to blood prior to the meeting. Dr. Kern will provide models to start on this by April 17, 2009. Please provide the code book described by your team for identification of questionnaire variables to use for these models as soon as possible to Dr Kern.

We look forward to working with you and your team on this collaborative effort. If you have any questions, please contact Dr. Deb MacKenzie-Taylor at 517-335-4715 or mackenzie-taylord@michigan.gov.

Sincerely,

Jim Sygo
Deputy Director

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DRAFT "White Board" Notes from 3/30/09 UMDES Meeting

1. General Statistical Topics:
 - a. Conduct a detailed analysis of critical variables: Soil, dust, hunting and game consumption, fishing and fish consumption, and floodplain recreational activities
 - b. The effects of confounding factors will be investigated in detail to help the agencies and Dow to understand the strengths and limitations of primary findings
 - c. Effects of the finite population correction for variance estimates may be investigated to determine if precision of estimation can be improved
 - d. Particular statistical models will be specified by participants
2. Integrate ATS data for properties in the floodplain
 - a. Create new variables for these properties
 - b. Incorporate SWACs after Dow finishes (Dow GeoMorph report with SWACs due 6/1/09)
 - c. Integrate U.S. EPA data from "exposure unit" sampling events
3. Explore dust and soil models: HP1, HP2, SC, FP1, FP2, SoilMax (Run all)
 - a. Base + 1: M/S only; J/C only; or add interaction term between location and soil concentration.
 - b. Estimate B, C1. If not significant and wide, C1 is done.
 - c. Not done until item 1 is incorporated
4. Fish and game: statistical modeling
 - a. Base + 1
 - b. Evaluate confounders:
 - i. F4 (how many yrs have you eaten fish from any source?)
 - c. Need to include plots to illustrate duration, frequency-number of meals (indicators of exposure)
 - d. Henry Anderson (WI) studies (Linda Dykema)
 - e. Concerns about under-represented populations (e.g., African American)
 - i. Separation of Tittabawassee River fish from Saginaw River and Bay appropriate?
 - ii. Collect more data? No, not in the current path forward
 - iii. Run small, specific statistical analysis
 - iv. Another type of outlier study (identify high fish consumers)
 - v. Oliviet Joliet – highest observed blood level and compare to predicted value from base model ($\bar{\delta}x$)
5. High fish consumers: mechanistic modeling
 - a. Run in parallel with statistical modeling – model increase in blood concentration based on fish consumption patterns using Entrix data ($\bar{\delta}y$) and MDCH survey data.
 - b. Compare $\bar{\delta}x$ to $\bar{\delta}y$
 - c. If equal, we conclude that fish contribute to serum DLC
 - d. If not equal, to be determined...