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STATE OF MICHIGAN  
DEPARTMENT OF ENVIRONMENTAL QUALITY  
LANSING

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September 28, 2004

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Professor of Occupational Medicine and Epidemiology  
School of Public Health  
University of Michigan  
1420 Washington Heights, Room 6529  
Ann Arbor, MI 48109-2029

Dear Dr. Garabrant:

**SUBJECT:** Meeting on the Study Protocol for the University of Michigan Dioxin Exposure Study (UM DES)

The Michigan Department of Environmental Quality (MDEQ) appreciated the opportunity to meet with the UM DES team on September 15, 2004, to discuss the UM DES study design. We learned a great deal from these interactions; in particular, the limitations that the confidentiality agreements between the UM and study participants place on the study design and the reporting of the results.

The following is a summary of topics discussed at the meeting, including items we believe were points of agreement between the UM and the MDEQ, points that the MDEQ would like to see the UM consider further, and points that require further clarification.

**Points of Agreement:**

- (1) Additional characterization of dioxin and dioxin-like compounds (DLCs) in soils within the city of Midland would improve the study design by better defining the boundaries of this subpopulation that is likely to be exposed to elevated soil concentrations. The UM indicated they would discuss the possibility of conducting additional soil characterization in the Midland area with local officials to allow this study to potentially include evaluation of soil exposures in Midland. The UM also will consider sampling more intensely (i.e., oversampling) in this area.
- (2) It was agreed that food chain exposures, based on current scientific understanding, are likely to be the greatest contributor to DLC serum concentrations from local DLC contamination. The UM agreed to demonstrate in the revised protocol that the proposed design will adequately represent food chain exposures from local DLC contamination including consumption of sport fish, agricultural crops and livestock by farmers and their families, and wild game impacted by the contamination.

- (3) The UM DES team agreed to consider additional information provided by the MDEQ during a conference call held on September 23, 2004, in determining the extent of the floodplain study group.
- (4) For all study properties with a soil contact zone, the UM DES will determine the soil concentrations of DLCs in the soil contact zone(s) to better evaluate the relationship between exposure to contaminated soils and blood serum concentrations. It was agreed that the multiple factor models may be appropriate based on Ah-receptor soil concentrations and/or high-resolution gas chromatography (HRGC) and high-resolution mass spectrometry (HRMS) soil concentrations for testing selected hypotheses. However, these analyses must be accompanied by a rigorous demonstration of the equivalence of Ah-receptor bioassay soil concentrations and HRGC/HRMS soil concentrations with data sets from this study. The MDEQ recommends that multiple-factor modeling results based on HRGC/HRMS and Ah-receptor bioassay soil concentrations be compared. (The MDEQ would welcome the opportunity to discuss particular statistical models incorporating these data.)
- (5) The UM DES team will consider alternatives that will provide adequate sample sizes within study groups to differentiate between effects of soil direct contact and dietary exposures to DLC from The Dow Chemical Company (Dow). The MDEQ is willing to assist in obtaining information from the Michigan Department of Natural Resources and Michigan Department of Agriculture to help select individuals likely to have elevated dietary exposure (e.g., local sport fish consumption and wild game consumption - fishing and hunting license and permit holders; livestock consumption - agricultural use information).
- (6) It is agreed that because of limitations due to the confidentiality agreements between the UM and study participants, data from the UM DES will not provide specific information regarding serum or soil DLC concentrations at individual properties or smaller groups of properties within the frequently flooded areas.
- (7) The UM DES protocol will be revised by early October 2004 and submitted to the MDEQ for review and comment.

**Points for Consideration:**

- (1) In addition to the point of agreement in (1), above, the MDEQ considers the exposures related to contaminated soils in Midland to be sufficiently different in geographical distribution, exposure patterns, soil characteristics, and congener distribution to require representation of Midland exposures in a study group that is independent of study groups intended to represent Tittabawassee River floodplain contamination and regional nonsoil exposures.

- (2) In addition to the point of agreement in (2), above, the MDEQ would like to see the UM stratify the target population based on local sport fish, local agricultural crops and livestock, and local wild game consumption behaviors. As the design currently stands, there may be a likelihood that these target subpopulations may be inadequately represented and that effects of these factors may be confounded with soil contact or other related factors.
- (3) The United States Environmental Protection Agency's Superfund Innovative Technology Evaluation Study may provide useful information that should be considered in the selection of the most appropriate soil screening technique (e.g., Ah-receptor bioassay) for this study.
- (4) A map that clearly shows the census blocks in Midland County and Saginaw County superimposed over the delineations of the study groups would be useful for the MDEQ to understand the relationship between the UM DES census blocks for sampling and the target populations of interest to the MDEQ. If whole census blocks are randomly sampled and include areas within and outside the Tittabawassee River floodplain, this would further increase the MDEQ's concern that there will not be sufficient participants with exposures to elevated soil concentrations within the UM DES sample populations to determine the relationship between concentrations of DLCs in soils and blood serum in the population(s) exposed to contaminated soils.

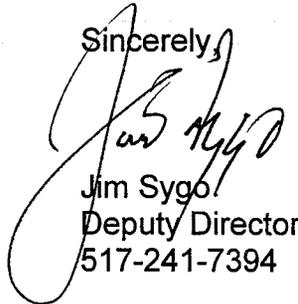
**Points for Clarification:**

- (1) To date, the required comprehensive Remedial Investigation has not been completed to determine the full nature (composition and concentration) and extent of contamination of Dow's off-site releases in the proposed UM DES study areas. The Remedial Investigation is essential for determining if there are additional contaminants of concern other than the DLCs. Other contaminants, contaminated areas, exposure pathways, etc., may be identified during the Remedial Investigation that may also be appropriate for this type of exposure study/investigation. Since these types of exposure studies have substantial confidentiality requirements and are intrusive to the participants, further participation may be difficult to recruit if additional studies are warranted. Therefore, the MDEQ cautions that this exposure study may be premature to conduct based on the limited contamination characterization that has been performed so far.
- (2) The MDEQ would like to clarify that the UM DES will not replace the procedures for human health risk assessment for determining site-specific cleanup criteria. Although the UM DES may provide some information on regional food consumption patterns, length of residence, and soil contact frequencies, this is not likely to represent target (exposed) population(s) independent of other populations. In addition, the UM DES will not:

- a. Provide information on:
    - i. Incidental soil ingestion rates
    - ii. Dermal soil adherence or surface area
    - iii. Children's exposure factors
  - b. Determine absorption efficiencies (oral or dermal bioavailability)
  - c. Replace assumptions related to toxicity assessment:
    - i. Extrapolation across species
    - ii. Uncertainty factors
  - d. Provide any information related to ecological exposures or risks
- (3) The objectives of the pilot study should be clarified in the UM DES study protocol. The MDEQ would appreciate a statement that clarifies that this pilot study will not determine or evaluate whether contaminated soils have been relocated to uncontaminated areas.
- (4) What is the rationale behind not testing nonproperty owners? Is this precluded in all cases? How will this affect the results of the study?

Thank you for your consideration of these comments. Although the goals of the UM DES will not satisfy Dow's regulatory requirements for corrective action, the MDEQ believes that further communication and interaction with the UM DES team will be mutually beneficial. If you have any questions, please contact Dr. Deborah MacKenzie-Taylor, Hazardous Waste Section, Waste and Hazardous Materials Division, at 517-335-4715, or you may contact me.

Sincerely,



Jim Sygo  
Deputy Director  
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