

From: Tracey Easthope [tracey@ecocenter.org]
Sent: Wednesday, March 17, 2004 2:54 PM
To: David Garabrant
Subject: Resend: Comments on proposed dioxin exposure investigation

March 11, 2004

Dr. David Garabrant
and Dioxin Exposure Investigation Research Team
School of Public Health
University of Michigan

Thank you for the opportunity to comment on the proposed exposure investigation. These comments are preliminary and do not represent an exhaustive list of our questions and concerns. In addition, we expect more questions when the UM develops a study protocol.

We would appreciate acknowledgement of receipt of this letter, and look forward to your response.

Regards,

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The following are concerns we have about both the process and the content of the proposed study:

CONCERNS ABOUT THE GENESIS OF THIS STUDY

* We are concerned that this study is funded by Dow, and that Dow has had an influence on the study questions and design thus far. Obviously, the company approached the University of Michigan, and has broadly defined the parameters for the study. The company is proposing to spend a significant amount of money on the study. Dow has a very substantial monetary interest in the outcome of this study. Therefore, we believe the University of Michigan must be diligent both in appearance, and in fact, in providing the independence that Dow suggests the institution has.

* The public outreach thus far appears to have been designed by Dow, based on the best information we have. The meetings in the floodplain to discuss the study excluded plaintiffs in the class action lawsuit now in the courts. We understand the rationale given was that Dow is not allowed to have contact with the plaintiffs. However, there are regular community advisory panel meetings in the state attended by both Dow and plaintiffs. Further, the invitation list did not extend to the entire population to be studied (Saginaw and Midland county residents, or Michigan residents) but only to a selected subset of those living in the most contaminated area. One hand-picked reporter was allowed to attend. No taping or photos were permitted. When asked, the UM suggested that the directors of county Health Departments would serve to represent the public. Further, petitioners responsible for the ATSDR Health Consultation were not invited to these meetings.

* The first public announcement of the study came from a Dow press release. The press release clearly stated that the purpose of the study was to compare the dioxin blood levels of residents in the most contaminated areas with a comparison population - those living in the region but outside of the worst contamination. We obviously objected to the characterization of that population as an appropriate control population, given the likelihood of dioxin exposures for this group.

* This sequence of events must be viewed in the broader context of Dow's continued efforts to:

- * Misinform the public about the extent and nature of dioxin's hazards, and the body of evidence available about the compound

- * Deny responsibility for the contamination

- * Fund endless consultants to challenge state cleanup law at every possible juncture including seeking to challenge the state's dioxin cleanup standard
- * Seek to stall national efforts to finalize the national dioxin reassessment
- * Conduct parallel studies to already ongoing state studies

ADVISORY PANELS

* We are concerned about the independence of the Scientific Advisory Board. UM should not choose the committee that will then review their work. The committee should be chosen by qualified people external to the UM process. In addition, we object to the committee reporting only to Dow. That committee should report to other stakeholders as well. Further, we would like clarification on the 'independence' of Board members. Is that narrowly defined as conflict of interest, or is it more broadly defined? What is the UM's definition? What set of circumstances would disqualify someone?

* According to the UM Feb. 19 presentation, qualifications for the Community Advisory Panel include those who 'don't have a stake in the issue.' How is that defined? Doesn't anyone living in a contaminated area or working on the issue have a stake in the issue? Will that exclude the informed and active public?

* We strongly believe that the community should have access to an expert with training in relevant fields funded with study money to provide input into study design on behalf of community/environmental interests.

* We strongly believe that ATSDR and MDCH should have early and regular opportunities for input into study design and implementation plans.

* We object to the narrow definition of the community employed by the University thus far. The community, as defined by UM, doesn't include environmental organizations who have worked on the issue for decades, the original petitioners to the ATSDR on this site, citizens outside the immediate floodplain, nor does it include members of the class action lawsuit. This eliminates many active, informed and involved citizens. Surrogates of the community, like the directors of community health departments, are not adequate.

* We are not clear about the role of the community advisory panel. We do not think it is appropriate for this committee to serve as ambassadors for the study, which appears to be the role assigned to them. Will the citizen advisory panel be invited to comment on study design? Again, will they be given the resources to hire technical expertise in order to provide that advice?

* We are interested in the detailed roles and responsibilities of the advisory panels. Study design seems to be well on its way, while the advisory panels aren't yet even formed.

* What is the public health mission of the University's School of Public Health in relation to sites of environmental contamination?

CONTROL OF SAMPLES AND DATA

* Who has control over the data and samples? Where will the samples be stored? Under what conditions? Will Dow have control of the blood, dust and soil samples, or will those be the property of the University? Who will have access to the raw data? Who is the ultimate owner? Will the ownership of the data be clearly communicated to study participants?

PUBLIC COMMUNICATION

* Will Dow or the University of Michigan be responsible for communication to the public about the study? Will Dow continue to issue press releases as the study continues?

PURPOSE OF THE STUDY

* The purpose of the study is the most fundamental concern we have about the

proposed exposure investigation. The specific research questions or null hypotheses you will forward are unclear. The presentation and discussion offered some clues, but the study design does not seem to match the stated purpose.

* Is the null hypothesis that there is no difference between the blood levels of dioxin of those on the floodplain when compared with those that live in the region? Elsewhere in the State?

* There appears to be another null hypothesis: Dioxin levels in the soil and dust and consumption of local wildlife are not good predictors of elevated serum levels of dioxin? Is that correct? If not, what is the null hypothesis?

* The statistical analysis proposes to "characterize the distribution of dioxin blood levels in the region of the Tittabawassee River outside of the flood plain." What is the purpose of this investigation? How will it serve the public health? Do median blood levels of dioxin tell you what you need to know if you were interested in designing interventions to protect the public health? Shouldn't the study be oversampling for those most likely to be the most exposed? If oversampling for those most likely to be most exposed is not conducted, the study may not answer some of the most important public health questions-- including - are there people in the floodplain who are excessively exposed to dioxin.

* What is the purpose of comparing the "distributions of dioxin blood levels in the populations of Saginaw and Midland counties who live within and outside of the Tittabawassee River flood plain." How will it serve the public health? What conclusions can be drawn from that comparison by people who live there? Will the group of people who are more highly exposed (if they exist) be served by this analysis? Why does the study propose to compare medians only? How will the actual distribution of dioxin levels be addressed to acknowledge who may be excessively exposed?

* The statistical goals for the study also include "test for potential effects of variables such as age and other exposures on blood dioxin levels." If this is the case, why are the soil and dust samples being archived for one year? Also, why doesn't the study propose to oversample those most likely to be excessively exposed, who may provide far more information on this question?

* How will this study advance the public health for the residents that live on the floodplain or in the contaminated area? If the study finds it is difficult to correlate soil levels of dioxin with blood levels, does this mean dioxin contamination of a region is not a problem? Does it even mean that there isn't a correlation, particularly

given the random sample design? Does it mean that the dioxin contamination does not pose a health risk? How do you take into account the overall loading of dioxin into the environment (a serious public health problem) and thus its ubiquity in our bodies and food chain, and the consequent increased risk to all people?

* What is the rationale for the phasing of the study and the populations proposed for each phase of the study? Why study Midland and Saginaw county residents outside of the floodplain first?

TECHNICAL ISSUES

STUDY POPULATION

* Why does the sampling of residents living in the contaminated floodplain end at the Center Street Bridge? What is the rationale for this?

* Will the sample of people living within the contaminated floodplain include plaintiffs in the lawsuit? If so, why weren't they invited to community information meetings? If they are excluded, what is the rationale?

* If plaintiffs are excluded, and the judge certifies the class action lawsuit, there will be virtually no residents along the contaminated floodplain to sample. The judge's decision is due in April (unless there are further delays). How will the study handle this contingency?

* What is the rationale for including people who have resided in the area for five years or longer. Why five years? Why not seven, or ten?

* How will a representative sample of Michigan residents be chosen? What variables will be considered when selecting this sample? Is this meant to provide a "background" level of dioxin contamination in the State, or in urban areas in the State? Do you intend this data to be considered as part of the data available on national background levels of dioxin?

* It appears the study anticipates comparing the MDCH pilot exposure investigation results to the Phase I results of the UM study, although at other points the study suggests the comparison will be between the UM phase I and II study populations. Will both occur? Please explain.

* The overheads refer to a "referent" group compared with an exposed group. What is your definition of 'referent' group? What is the definition of a "control" group in this study?

* Dioxin levels are generally higher in older populations, increasing approximately 1 ppt per decade of life. Does the study design take this into consideration?

FISH CONSUMPTION

* There are dioxin advisories on some Lake Huron fish. Will this be included in the fish questions as well?

* A dichotomous variable for fish consumption in the statistical analysis is a very gross measure of this important exposure. How will this be handled?

LABS AND SAMPLING PROTOCOLS

* What labs will be used and what are the analytical capabilities of the labs? What are the detection limits for the various media sampled?

* Will PCB's be analyzed in all samples? Will all potential dioxin-like compounds be considered?

* Will the study consider other relevant factors when considering serum levels of dioxin: serum lipid levels, weight change history, breast feeding and parity, etc?

RISK COMMUNICATION

* Sampling the bodily fluids of residents requires some risk communication. How will levels of dioxin in the blood be interpreted? On what basis will those interpretations be made? What advice will you give the most heavily exposed? Have you consulted experts in the field on this issue? What interventions will be proposed? In particular, what interventions would be proposed for women of childbearing years who might be particularly highly exposed?

INDOOR DUST SAMPLING

* Does dust sampling in highly trafficked areas exclude areas where dust may settle undisturbed yet in high use areas (vents, above refrigerators, etc). If so, what is the rationale? This seems like a more accurate view of exposures, and is less likely to be regularly vacuumed, swept etc. What dust sampling studies (besides carpet) will be used as models? Will the age of the carpet, housecleaning practices, etc, be assessed?

* Why are the soil and dust samples being archived for a year?

MISCELLANEOUS

* What are the implications of this study for the class action lawsuit?

* How might this study be used in setting cleanup standards?

* What is the relationship between this study and the ongoing characterization and cleanup efforts? Will this study delay those efforts? Will the results of this study be used in probabilistic risk assessments meant to develop a site specific cleanup standard for this site?

* During the presentation, there was a discussion of modeling the plume from Dow's operations. How will that be done? Who will do it, using what models? There are numerous other reasons that those living in proximity to Dow may be more exposed than the general population, for instance, contaminated fill used throughout the region, dust from contaminated areas, etc. Will this be considered?

CC: MDCH
ATSDR
MDEQ