

# USEPA Review of the University of Michigan Dioxin Exposure Study (UMDES)

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# EPA's Dioxin Science Plan

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- The U.S. Environmental Protection Agency is currently addressing several issues related to dioxins and dioxin-like chemicals in the environment.
- To move forward with these efforts, EPA Administrator Lisa P. Jackson requested that a clear plan, with definite timelines, be developed.
- On May 26, 2009, Administrator Jackson announced EPA's science plan for dioxin activities in the agency.

# “Dioxin Reassessment”

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EPA will release a draft report that responds to the recommendations and comments included in the National Academy of Sciences’ (NAS) 2006 review of EPA’s 2003 draft dioxin reassessment by December 31, 2009.

- *EPA will prepare a limited response to key comments and recommendations in the NAS report*
- *The draft response will be provided for public review and comment and independent external peer review.*
- *The peer review will be conducted by the EPA Science Advisory Board*

# Dioxin Reassessment

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EPA will release the final response to comments report and focus on completion of the dioxin reassessment.

- *By the end of 2010, EPA will release the final response to comments report.*
- *By the end of 2010, EPA will complete the final dioxin human health and exposure assessment and release it to the public, subject to further consideration of the science.*

# Other Dioxin Related Activities

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EPA will review currently available information from a dioxin exposure study by the University of Michigan (UMDES).

- *EPA's Office of Research and Development (ORD), Region 5, and the Office of Solid Waste and Emergency Response (OSWER) are working together to review a new study of dioxin exposures in the Midland, Michigan area*
- *EPA will determine the relationship of this work to addressing potential risks from dioxin exposure*
- *The review of the study will be completed by September 30, 2009.*

# Dioxin Soil Clean-Up Levels

EPA will evaluate information about the basis for dioxin soil clean-up levels.

- *ORD is reviewing information about the basis for state dioxin soil clean-up levels.*
- *ORD will prepare a report for OSWER that includes a survey and evaluation of the clean-up levels in the states*
- *The report will characterize the science that these values are based on, as well as the degree of peer review, if any that was done.*
- *OSWER will announce an updated interim dioxin soil clean-up level to the public by December 31, 2009.*

## EPA will release the final report on Dioxin Toxicity Equivalency Factors (TEF).

- *EPA will complete its report entitled, “Recommended Toxicity Equivalency Factors (TEFs) for Human Health Risk Assessments of Dioxin and Dioxin-Like Compounds.”*
- *This document will describe EPA’s updated approach for evaluating the human health risks from exposures to environmental media containing dioxin-like compounds.*
- *This report will be completed and released to the public by December 31, 2009.*

# EPA's Objectives for the UMDES Review

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- Evaluate study design, methodologies, implementation and results
- Evaluate usefulness of study results to EPA's mission to protect human health and the environment

# EPA's Approach – What we Did

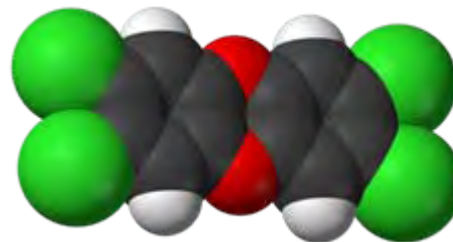
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- Reviewed material on the UMDES web site:
  - Study protocol
  - August 2006 Report
- Reviewed peer reviewed publications, published and in press
- Conducted Interviews
  - UMDES investigators: David Garrabrant, Alfred Franzblau
  - UMDES Advisory Board Members: Linda Birnbaum, David Kleinbaum
  - Michigan Government staff: Linda Dykema, Deborah MacKenzie-Taylor
  - Michigan consultants: John Kern
  - NGO contacts: Tracey Easthope, Ted Schettler
- EPA did not obtain or reanalyze raw data collected as part of study

# UMDES Objectives

- To describe the pattern of blood dioxin levels among adults living in the Midland area
- To understand the factors that explain variation in these levels

*(from UMDES Study Protocol, January 2005, revised)*



*Graphic of 2,3,7,8 TCDD: Ben Mills,  
provided through about.com*

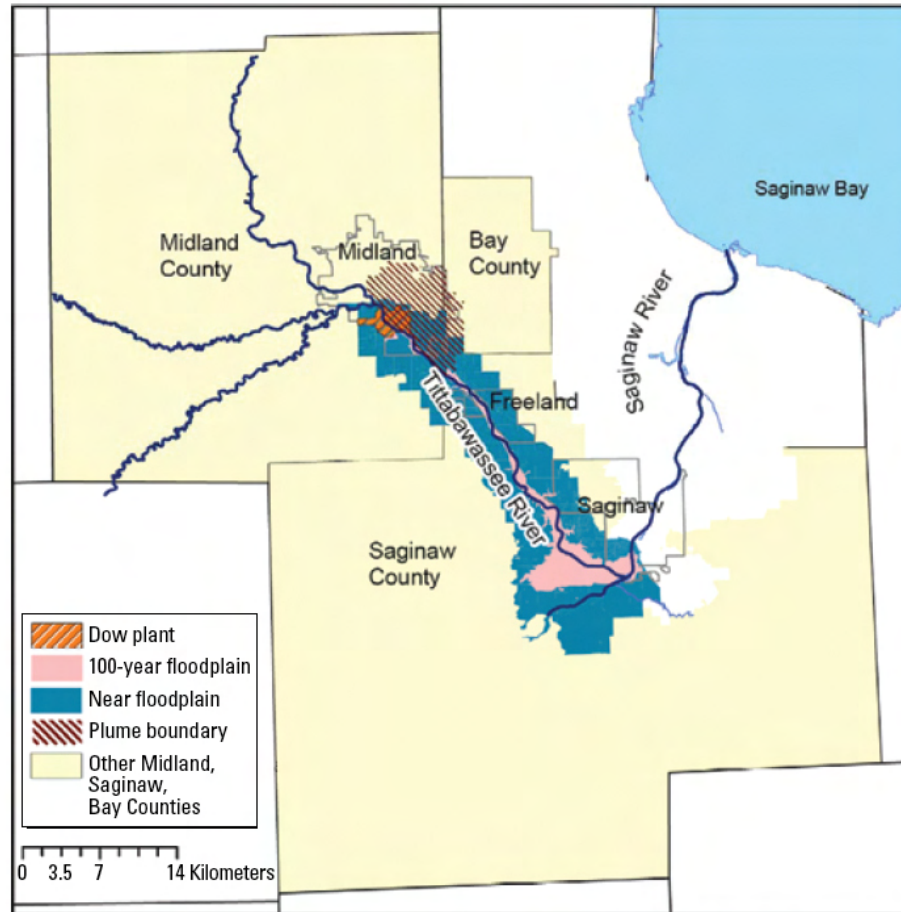
# UMDES Description

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- Extensive sample survey, the largest of its kind
- Included about 900 adult participants: 700 from Midland/Saginaw areas and 200 from a reference area in Jackson/Calhoun counties all selected using a probability sampling design
- Sampling included blood from adult individuals, soils and dust from household properties
- Extensive questionnaire used to collect information about household demographics, lifestyle and diet
- Sample collection, handling, and analytical methods were appropriate to study objectives (although full quality assurance information was not available)

# UMDES Description

- Four study locations in Midland/Saginaw area
- One reference population in Jackson/Calhoun counties



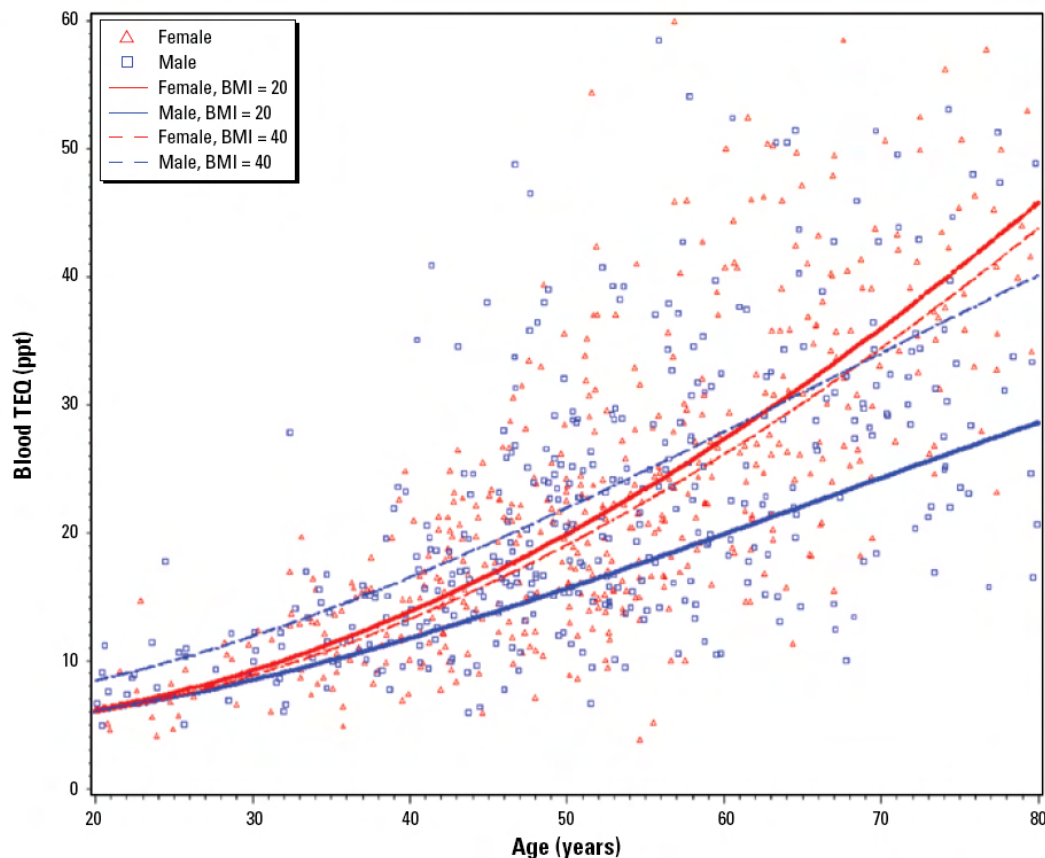
**Figure 1.** Map of Midland, Saginaw, and Bay counties, Michigan, showing the Dow Plant and the 100-year floodplain of the Tittabawassee River.

***The study provides substantial information on patterns of dioxin in blood, dust, and soil:***

- Properties in the Midland area have higher soil dioxin concentrations than properties in the reference area
- People living in the Midland area have higher blood dioxin levels than people living in the reference area
- People who worked at Dow from 1940-1959 tend to have higher blood dioxin levels
- Household dust from the Midland Plume area contain higher dioxin levels than household dust from other study areas

- ***The study identified associations between blood dioxin levels and several demographic factors:***

- Of the factors considered, the largest part of the variation in blood levels were associated with a combination of 9 demographic factors including age, gender, and body mass index (BMI)
- Combined, these 9 factors were associated with about 40% of the variation in blood levels
- Age alone not a good predictor of blood levels
- Note: association does not demonstrate causation



**Figure 1.** Serum TEQ by age among 946 UMDES participants, with predicted values by age, sex, and BMI. Blood TEQ values are shown only up to the 95th percentile to prevent compression of the scale by outliers.

***The study provides limited data regarding some important potential sources of dioxin exposures:***

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- Representation of properties having soils with high concentrations of dioxin is limited
- Representation of people engaging in specific activities that would be reasonably expected to increase exposure to dioxin is limited

# Representation of Soils Having High Concentrations of Dioxin

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- The UMDES did not report a strong statistical relationship between soil/dust and blood dioxin levels, however....
- The study may not have included enough soils with high concentrations of dioxin to enable full evaluation of the relationship between soil/dust and blood dioxin levels
- Typically, dietary exposure is responsible for most dioxin exposure and exposure due to soils is small; therefore, not surprising that statistical relationship between soil and blood dioxin is hard to detect
- Therefore, an adequate number of samples that represent exposure to high soil concentrations are needed to estimate an overall relationship between blood levels and soil concentrations

# Representation of Soils Having High Concentrations of Dioxin

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- UMDES did target geographic areas anticipated to contain elevated levels of dioxin
  - Area of the Dow incinerator plume to the northeast of Midlands
  - The 100 year floodplain downstream of the Dow plant
- UMDES ultimately included 23 properties with dioxin levels exceeding 1000 ppt (current EPA soil cleanup level)
- Review suggests that UMDES is unlikely to fully characterize the relationship between soil and blood serum dioxin levels
- Other studies suggest soils having significantly higher concentrations of dioxin are present in the floodplain adjacent to the river

# Representation of People Engaged with Certain Activities

- The study may not have included enough people engaging in specific activities on contaminated soils to evaluate dioxin exposures from these pathways (gardening, consuming local fish/game, or raising animals for local consumption).
- The study design did not ensure these activities were represented
- A different study design might have been more effective in identifying the impact of specific activities on dioxin exposure



# Representation of People Engaged with Certain Activities

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- UMDES identified two specific situations that were associated with elevated blood dioxin levels (one gardener and one farmer)
- UMDES showed that people who consume fish tend to have higher blood dioxin levels; however, conclusions about consuming fish from contaminated areas are somewhat inconsistent
- UMDES showed that people engaging in outdoor recreational activities in the contaminated areas had higher blood dioxin levels; however, the strength of these associations appeared to vary among reports

# Implications of the Study for EPA

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- Scope limited to exposure only; no health status information collected.
- The study results have limited use in risk assessment to support management decisions where the focus is typically on both the general population and highly exposed and/or sensitive subpopulations; the latter not targeted by UMDES
  - Children were not sampled
  - People engaged in activities that could tend to increase exposure
- Background exposure to dioxin via the normal diet is already at a level of concern, so exposures above background merit consideration.

# Conclusions

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- UMDES has produced a credible data set and has contributed to our understanding of dioxin exposure
- This is a work still in progress; additional data analysis may provide some clarity about the relationship between dioxin levels in blood and factors like soil concentrations.
- Further study of specific subpopulations in the UMDES sample (like those exposed to high soil concentrations or those consuming large amounts of fish and game) may provide the basis for additional insights.
- Study results have limited application for risk-based decision-making. Highly exposed and/or sensitive subpopulations not specifically targeted in the UMDES sample

**Thank You!**

**Questions and  
Comments?**