

Pilot Exposure Investigation:

Dioxin Exposure in Adults Living in the Tittabawassee River Flood Plain, Saginaw County, Michigan

May 25, 2004

Michigan Department of Community Health
Division of Environmental and Occupational Epidemiology

TABLE OF CONTENTS

Project Overview 1

Protocol Summary 1

Stakeholder Review 1

Needs Assessment 2

Scientific Advisory Group 2

Investigators & roles / Collaborators & roles 2

Technical Assistance 2

Funding and Budget 2

Introduction 4

Background Summary 4

Site Description 5

Target Population 6

Procedures/Methods 7

Phase I Timeline 7

Participant Selection Process 8

Participant Selection Process 9

Soil Sampling 10

Indoor Dust Sampling 11

Biologic Sampling 12

Interviews 13

Reporting Phase I Results 14

Limitations Of The Phase I Pilot Exposure Investigation 14

Follow-Up Activities 15

References 16

TABLE OF FIGURES

Figure 1. The Tittabawassee River Flood Plain Investigation Area 4

Figure 2. Participant Selection 8

TABLE OF ATTACHMENTS

Attachment A. Informed Consent

Attachment B. Whole Blood Collection and Processing for Serum Dioxin

Attachment C. Collection of Indoor Dust Samples from Carpeted Surfaces for Chemical Analysis Using a Nilfisk GS-80 Vacuum Cleaner

Attachment D. MDEQ Draft Soil Sampling Protocol and Consent to Enter Private Property

Attachment E. Dioxin Exposure Investigation Questionnaire

Attachment F. Responsiveness Summary

Attachment G. MDCH Internal Review Board Determination

PROJECT OVERVIEW

A Pilot Exposure Investigation:
Dioxin Exposure in Adults Living in the
Tittabawassee River Flood Plain,
Saginaw County, Michigan

Protocol Summary

The Michigan Department of Community Health (MDCH) and the Michigan Department of Environmental Quality (MDEQ) will conduct soil, indoor dust, and blood sampling for polychlorinated dioxins, furans, and coplanar PCBs. Based on the results of preliminary soil sampling in residential yards, 25 adults will be asked to participate in the Pilot Exposure Investigation. Participants will be asked to complete a questionnaire about their occupations and about behaviors such as consumption of sport-caught fish that could contribute to dioxin body burdens. Blood samples will be drawn from participants and indoor dust samples will be taken from participants' homes.

One purpose of the Pilot Exposure Investigation is to provide information on the levels of dioxins in soil, indoor dust, and blood samples for 25 residents of the flood plain. If the investigation results suggest the need, residents can use this information to modify their behavior to limit exposure to impacted media.

Another purpose of this Pilot Exposure Investigation is to test the sampling criteria, questionnaire, and blood and indoor dust sampling methods prior to the implementation of a larger investigation that will include residents from the city of Midland, the flood plain of the Tittabawassee River, Saginaw County, Michigan and a control community with no known exposure to polychlorinated dioxins, furans, and coplanar PCBs beyond background. The Pilot Exposure Investigation may provide preliminary information about the relationship, if any, between dioxin blood levels and dioxin TEQ levels in soil, and indoor dust. This information will be used to refine the design of the larger investigation to be conducted in the future.

Stakeholder Review

The MDEQ has created a Community Advisory Panel (CAP) to provide stakeholder input on off-site corrective action activities conducted under the hazardous waste facility operating license issued to the Dow Chemical Company on June 12, 2003. The CAP acts in an advisory capacity, not as a decision-making body. The role of the CAP is to provide focused input to the MDEQ on issues related to corrective action activities for Midland area soil contamination and Tittabawassee/Saginaw River sediment and flood plain soil contamination. The CAP will recommend actions necessary for minimizing exposure and preventing exacerbation of contamination, and to determine whether there any other currently unmet needs (e.g., advisories, public communication/education) to be addressed. Meetings are held approximately monthly in the Midland/Tittabawassee River/Saginaw area.

CAP members include representatives of local governments, the local health departments for Midland and Saginaw counties, the Dow Chemical Company, the Michigan Department of

Agriculture, statewide environmental organizations, and local citizens. MDCH staff plays an important role in the CAP and attend all meetings.

The MDCH presented the Pilot Investigation Protocol to the CAP on December 3, 2003. Public comments were accepted through February 6, 2004. Comments and MDCH responses are provided in Attachment F.

Needs Assessment

The MDCH conducted a needs assessment in the city of Midland and in the flood plain of the Tittabawassee River in preparation for the future larger exposure Investigation. The Needs Assessment elicited public opinion about the conduct of the larger investigation of dioxin levels in people living in the flood plain and the city of Midland, whether they would be willing to participate in such an investigation, and whom they think should pay for and conduct the investigation. The MDCH had committed to the Needs Assessment with the city government in Midland, to the Midland and Saginaw health departments, and to the Dow Chemical Company. The Needs Assessment was implemented in January 2004. Separate reports of the findings for the city of Midland and the flood plain of the Tittabawassee River were released by the MDCH on May 24, 2004. Copies of the reports may be obtained from the MDCH web site at www.michigan.gov/mdch.

Scientific Advisory Group

The MDCH will form a panel of scientific experts to provide advice on the conduct of the larger, future Exposure Investigation in the city of Midland and the Tittabawassee River flood plain if such a study is implemented. The Dow Chemical Company and the Petitioners will be asked to nominate scientists for this group. Preference will be given to nominees with no real or perceived conflicts of interest. Recognized experts in the fields of dioxin toxicology, epidemiology, and laboratory analysis will be included in the group. If feasible, this group will begin meeting concurrent with the conduct of the pilot investigation.

Investigators & roles / Collaborators & roles

- MDCH – Linda Dykema, Principal Investigator
- MDCH – Brendan Boyle, Community Involvement/Department Specialist
- MDEQ – Tittabawassee Workgroup, Soil and Indoor Dust Sampling

Technical Assistance

- ATSDR – Mark Johnson, Region 5
- ATSDR – Division of Health Assessment and Consultation, Atlanta,
- ATSDR – Exposure Investigation and Consultations Branch, Atlanta,
- ATSDR – Division of Health Studies, Atlanta, GA

Funding and Budget

Soil and indoor dust analysis for dioxins will be funded by the MDEQ. All activities performed by MDCH staff will be funded under the Program No. 01043 “Program to Conduct and Coordinate Site-Specific Activities” Cooperative Agreement grant. The MDCH requests that

ATSDR provide the following funding for analysis of blood samples and for the necessary equipment to collect indoor dust samples.

Blood analysis (25 samples at \$1500/sample)	37,500.00
Nilfisk model GS-80 vacuum cleaner (one)	820.00
Vacuum cleaner bags (50 bags at 13.05/5 bags)	131.00
Vacuum cleaner filter (one)	147.00
Miscellaneous equipment/supplies	500.00
Total	<u>\$39,098.00</u>

INTRODUCTION

Background Summary

On May 1, 2001, a resident of Midland, Michigan and two Michigan-based environmental organizations petitioned the Agency for Toxic Substances and Disease Registry (ATSDR) to conduct a public health assessment of dioxin contamination in communities adjacent to Midland, where contamination originating from the Midland area has been "transported...via air and water" (MDCH 2002).

The Dow Chemical Company (Dow) operates a chemical manufacturing plant in the city of Midland, Michigan. The Tittabawassee River forms the southern boundary of the plant site and flows southeast from Midland through Saginaw County to the confluence with the Shiawassee and Cass Rivers to form the Saginaw River. The Saginaw River then flows northeast to Bay City where it empties into the Saginaw Bay of Lake Huron (Figure 1).

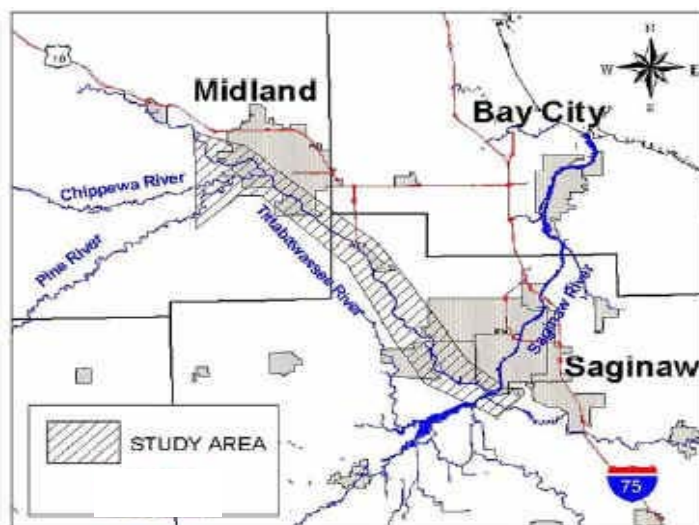


Figure 1. The Tittabawassee River Flood Plain Investigation Area

Chemicals that have been produced at the Dow plant include, but are not limited to: styrene, butadiene, picric acid, mustard gas, Saran Wrap, Styrofoam, Agent Orange, and various pesticides including Chlorpyrifos, Dursban and 2,4,5-trichlorophenol (2,4,5-T). Chlorophenol production began in 1915 and wastes generated from this process were initially disposed of in 600 acres of on-site waste ponds. During high flow periods in the early 1900s, wastes from these ponds would be intentionally released to the Tittabawassee River. Dow currently operates its own on-site wastewater treatment plant. However, repeated annual flooding within the 100-year flood plain has carried dioxin-laden wastes down the Tittabawassee River and has resulted in the deposition of contaminated soil and sediment onto upland property.

Environmental sampling conducted by the MDEQ from April 2000 through December 2002 indicates that concentrations of total dioxin toxic equivalents (TEQ) are elevated throughout the flood plain in both soil and sediment. Dioxins are a group of chlorinated chemicals with similar structures and chemical properties. This group of chemicals, which includes chlorinated dioxins,

furans, and some coplanar polychlorinated biphenyls, is often referred to collectively as "dioxins" or "dioxin-like compounds." The most toxic chemical in the group is 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (2,3,7,8-TCDD). Toxic equivalency factors (TEF) have been developed to compare the relative toxicity of other dioxins and dioxin-like compounds to that of 2,3,7,8-TCDD. The levels of other dioxin-like compounds measured in the environment are multiplied by a TEF to produce a 2,3,7,8-TCDD toxic equivalent or TEQ concentration. The resulting TEQs for all dioxin-like compounds measured in a sample are then added together to determine the total dioxin TEQ concentration for that sample (De Rosa 1997). Total dioxin TEQ concentrations have been detected up to 7,261 parts per trillion (ppt) in soil and up to 2,000 ppt in sediment in the Tittabawassee River (MDEQ 2002)

The MDCH completed a "Petition Scoping Report" and provided the information obtained from these activities to the ATSDR on August 31, 2001. The ATSDR responded in writing to the petitioners on November 2, 2001, stating that, "After reviewing the public health issues and community concerns about potential dioxin contamination and the Dow Midland facility, ATSDR has found a reasonable basis to prepare public health consultations to address the concerns associated with the Dow facility." The MDCH agreed to conduct the petitioned health assessment and released a draft public health consultation addressing flood plain soil contamination in March 2002. The consultation recommended "a comprehensive evaluation of site-specific exposure factors...including biological sample analysis if feasible" (MDCH 2002).

Site Description

The Pine, Chippewa, and Tittabawassee Rivers join above Midland. The Tittabawassee River flows through Midland, then south and east to the confluence with the Shiawassee and Cass Rivers to form the Saginaw River. The stretch of the river from the city of Midland to the confluence covers approximately 22 miles. Several communities including Freeland (population 5,147), Shields (population 6,590), and Saginaw Township (population 38,795) are located at least partly in the 100-year flood plain of the Tittabawassee River. Outside of these communities, land use is primarily rural-residential with some small-scale agricultural production.

Sampling conducted by the MDEQ from April 2000 through December 2002, indicates that it is likely that the entire 100-year flood plain of the Tittabawassee River is contaminated with polychlorinated dioxins and furans. Initial sampling efforts in 2000 found TEQ concentrations up to 7,261 ppt near the confluence with the Saginaw River (MDEQ 2001). MDEQ conducted two phases of additional sampling, gradually stepping up the Tittabawassee towards and above the city of Midland. Most of the upland soil samples were taken from public parks or from properties already under investigation for other contamination (MDEQ 2002).

In Phase II, MDEQ sampled upstream of Midland and confirmed that the contamination originates in Midland and that the likely source is the Dow plant site. Soil samples from above Midland or outside the 100-year flood plain showed TEQ concentrations similar to anthropogenic background in Michigan (1-10 ppt TEQ). MDEQ conducted an assessment of the relative contribution of each dioxin or furan congener to the total TEQ concentration detected at each sampling location and produced illustrative color bar charts or congener profiles. The

congener profiles for sampling locations above Midland and outside the 100-year flood plain are consistent with the Michigan background distribution of dioxin congeners (MDEQ 2002).

At most Phase II locations within the flood plain, soil samples were taken at three depths; 1-3 inches, 3-6 inches, and 12-15 inches. TEQ concentrations ranged up to 3,400 ppt. The highest concentrations were found in the 3-6 and 12-15 inch samples, however TEQ concentrations above both the ATSDR screening level of 50 ppt and the action level of 1,000 ppt were found consistently in the 1-3 inch samples. Deep soil borings taken at one location indicate that TEQ concentrations are elevated from the surface to four feet below ground surface. Congener profile analysis of soil samples with elevated TEQ concentrations shows a consistent pattern of congener distribution that differs significantly from Michigan background (MDEQ 2002).

One residential property was sampled in a particularly at-risk location. Dioxin TEQs were detected up to 780 ppt in the 1-3 inch samples and up to 1,400 ppt in the 3-6 inch samples. The family living at this residence were raising free-range chickens and eating the eggs. Four eggs were analyzed for dioxins and showed 16-48 ppt total TEQ. In 1997, the United States Food and Drug Administration (FDA) developed a level of concern of 1 ppt for dioxins in egg, meat and poultry products. This level of concern was used by the United States Department of Agriculture in guidance issued to producers of poultry, livestock and eggs (USDA 1997). While this level of concern was developed in response to a specific incidence where animal feed was contaminated, it provides a reasonable basis of concern for consumption of eggs containing dioxin in excess of this level. Therefore, the family has been advised by MDCH to discontinue egg production and consumption on their property. Congener profile analysis of soil and egg samples from this property are nearly identical to one another and to that of all other flood plain samples showing elevated TEQ concentrations (MDEQ 2002)

Groundwater sampling conducted as part of Phase II did not detect TEC concentrations above the U.S. EPA maximum contaminant level (MDEQ 2002).

The MDCH has issued advisories for several years for the Tittabawassee and Saginaw Rivers as well as the Saginaw Bay based on the concentrations of PCBs and dioxins in fish. Women of childbearing age and children are advised not to eat carp, catfish, or smallmouth bass from the Tittabawassee River. The advisory suggests that these groups limit their consumption of all other species to one meal per month. The general population is advised not to eat carp, catfish, or white bass from the Tittabawassee River and to limit their consumption of all other species to one meal per week (MDCH 2003).

Target Population

MDCH is proposing a phased exposure investigation (EI) approach. This pilot investigation will constitute Phase I of the EI. In Phase I, MDCH will identify 25 adults currently living in the Tittabawassee River flood plain with potentially high exposure to the contamination based on dioxin levels in the soil at their homes. MDCH will administer an interview instrument, and conduct biomedical and indoor dust sampling to quantify exposure.

PROCEDURES/METHODS

Phase I Timeline

June 2003

MDEQ, with MDCH assistance, reviewed the soil and sediment data currently available for the Tittabawassee River flood plain to identify a data set of at-risk residential property. Property where sampling has indicated elevated levels of dioxins and furans, as well as properties where the depositional characteristics of the river or historical reports suggest repeated flooding has occurred, were included in the data set.

July-December 2003

MDEQ, with MDCH assistance, will conduct focused soil sampling on residential properties identified using the screening process described above (See Attachment D). MDCH will participate in planning activities and will review the data as it becomes available. Landowners will be informed of the sampling results in writing by the MDEQ.

May-August 2004

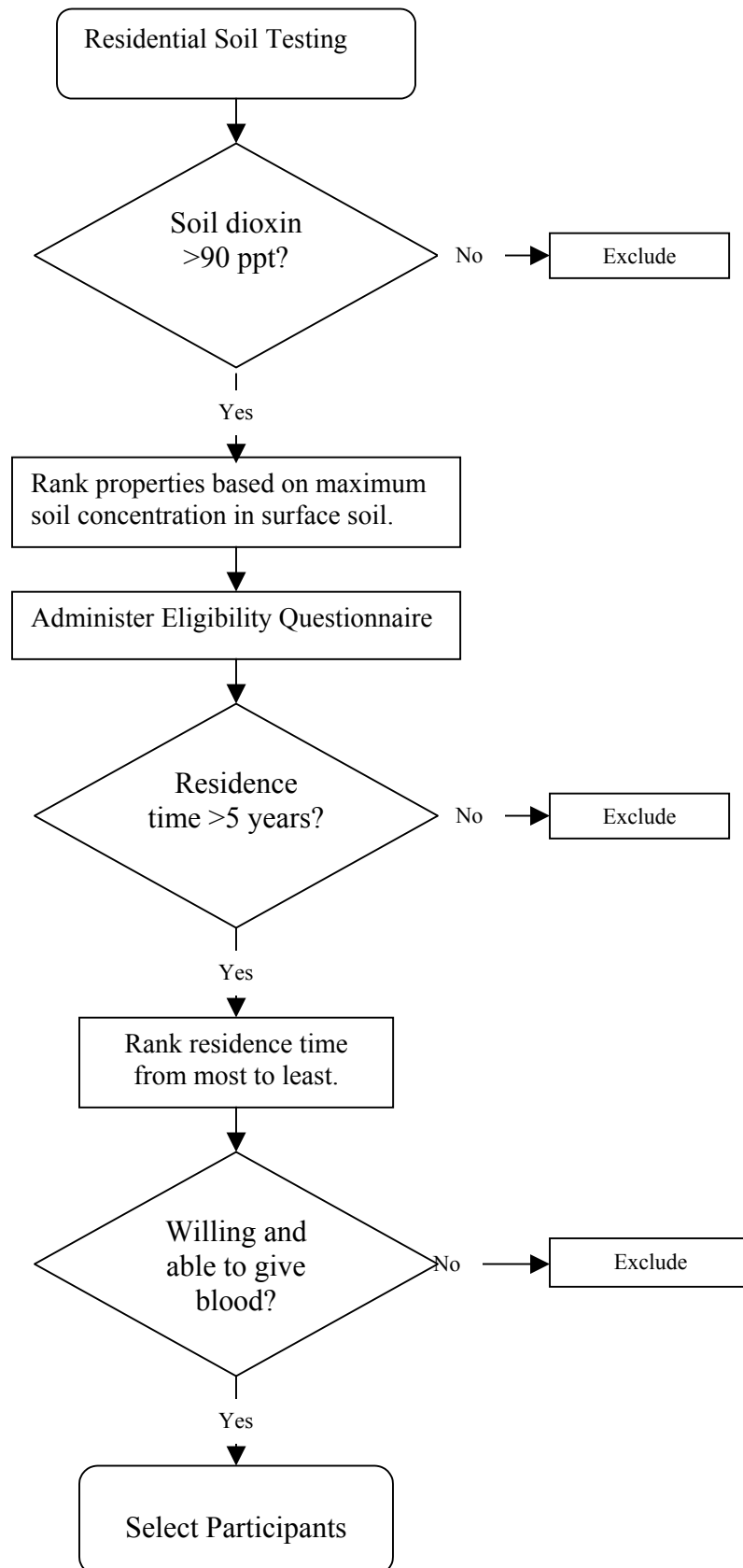
MDCH will identify a subset of 25 flood plain resident adults to participate in blood and indoor dust sampling (see Figure 2). Participants will be contacted by phone to 1) determine their fitness to give blood samples, and 2) to schedule a time to administer the interview questionnaire and take indoor dust and blood samples.

- MDCH will administer an interview questionnaire to identify exposure pathways and personal behaviors (e.g., consumption of sport-caught fish) that could affect exposure and, therefore, body burden.
- MDCH will collect blood samples from these same individuals. Blood will be analyzed by the Centers for Disease Control (CDC) for polychlorinated dioxins and furans, and coplanar polychlorinated biphenyls.
- MDCH and MDEQ will conduct indoor dust sampling in homes.

September-December 2004

The participants will be informed of their blood and dust sample results in writing by the MDCH. MDCH, with the assistance of MDEQ and ATSDR, will produce a report of the investigation findings.

Figure 2. Participant Selection



Participant Selection Process

The following discussion provides the details for the participant selection process depicted in Figure 2. The intent of this process is to give preference in selection to those people with the highest potential for exposure to dioxin in the flood plain of the Tittabawassee River. The process considers the level and extent of contamination in participants' residential yards, as well as the length of time they have lived at their current residence.

Property Selection and Scoring - In June of 2003, the MDCH and the MDEQ compiled a list of 25 residential properties in the flood plain of interest for soil sampling. Properties were included on the list if the owner indicated willingness for the property to be sampled, and if the agencies identified the location as likely to have been subject to repeated flooding based on property characteristics (e.g., proximity to and elevation above the river). The MDEQ will conduct soil sampling on these properties to identify the presence and level of dioxin contamination. The MDCH will consider for inclusion all properties where total dioxin TEQs in at least one surficial soil sample is greater than the MDEQ residential soil direct contact criterion of 90 ppt TEQ. The MDCH will exclude any property where total dioxin TEQ concentrations in all surficial soil samples are less than 90 ppt.

The MDCH will rank properties from highest to lowest, based on the maximum total dioxin TEQ detected in surficial soil. The ranked list will be divided into quartiles and assigned a score of 1 to 4, where a score of 4 represents the quartile of properties with the highest maximum TEQs.

The MDCH will also consider whether detected total dioxin TEQs are greater than 90 ppt at all sampling locations on the property or are isolated in one portion of the property (e.g., near the river). Many of the homes in the flood plain are constructed on fill material built up above the elevation of the flood plain. Therefore, soil near the home may not have been subject to the repeated flooding that has occurred closer to the river. A score of 3 will be assigned to those properties where surficial dioxin TEQs greater than 90 ppt are found at all sampled locations. A score of 2 will be assigned to those properties where dioxin TEQs greater than 90 ppt are found in the sample taken nearest the home, but not at all sampled locations. A score of 1 will be assigned to all other properties where dioxin TEQs greater than 90 ppt were found, but not in the sample location nearest the home.

The score of 1 to 4 assigned for the maximum total dioxin TEQ concentration will be added to the score of 1 to 3 assigned for the location of the dioxin contamination for a total *property score* of from 2 to 7.

Resident Selection and Scoring – MDCH will telephone the residents who live on eligible properties and obtain the names of all household members over the age of 17. Only adults over the age of 17 will be considered for inclusion in the investigation. The “Pilot Exposure Investigation Eligibility Questionnaire” provided in Attachment A will be administered to each eligible adult.

Residents will be asked a series of questions about their ability to give an 80 ml sample of blood and about how long they have lived at their current residence. Residents will be excluded from the investigation if they indicate that:

- they have lived at their residence for less than 5 years,
- they have a bleeding disorder,
- have received chemotherapy in the last 6 weeks,
- weigh less than 95 pounds,
- have lost more than 15 pounds in the last year,
- or are pregnant or breastfeeding.

Responses to the questionnaire will be used to create a list of eligible participants.

Residents will be ranked based on residence time at their current residence from highest to least. The list will be divided into quartiles and assigned a *resident score* of 1 to 4, where a score of 4 represents the quartile of highest residence time.

Participant Selection – For all potential participants, the MDCH will add the property score and the resident score described above to derive a *participant score* of from 3 to 11. MDCH will develop a list of potential participants and their associated scores ranked from 11 down to 3. Participants with a score of 11 will be selected first, then those with a score of 10, and so forth. This process will continue until 25 participants are selected.

If more than one potential participant lives at the same address, the person with the highest residence score (i.e., who has lived at the property the longest) will be selected. If all residents at a property have identical residence scores, one person will be randomly chosen and placed on the list. Eligible household members will be asked to draw a card from a deck of standard playing cards. The household member who chooses the highest card will be selected first. An ace will be considered the highest card.

If it is not possible to include all those within a score level, the needed number of participants will be selected based on residence time to meet the total number of 25. For example, 20 participants are selected with scores of 9 through 11, but there are more than 5 people with a participant score of 8. People with a participant score of 8 will be ranked based on actual residence time and those with the 5 highest residence times will be selected.

If 25 participants are not identified through this process, eligible people living at the same address as a selected participant will be reconsidered with preference given to those with the highest participant score.

Soil Sampling

Justification - Exposure to contaminants in soil can occur through skin contact and incidental ingestion (e.g., swallowing of inhaled soil particles, hand-to-mouth activities) (ATSDR 1998). Soil particles can also be inhaled and then absorbed from the lungs into the blood (ATSDR 1998). Concentrations of total dioxin TEQs in soil will be used to indicate the potential for exposure. It is important to emphasize that the amount of dioxin detected in soil is not necessarily equivalent to the amount that is bioavailable.

Participants - Soil sampling will be conducted on properties within the flood plain where depositional characteristics of the river suggest a high potential for contamination. Soil sampling will be conducted prior to biomedical sampling to identify those properties where the potential for exposure to dioxins in soil are the greatest.

Consent Forms – Prior to collecting soil samples, the MDEQ will ask the resident/property owner to sign a consent form. A copy of the MDEQ consent form is provided in Attachment D.

Protocol for Soil Sample Collection – Surface soil samples will be collected from each individual's yard: at least one sample will be collected near the entryway used most; another sample will be of surface soil in a high-use area (e.g., play area where adults may congregate with children, garden area). Residents will be asked to identify those areas of high use. Additional soil samples will be taken as necessary to characterize exposures and contamination on the property. Samples will be handled, stored, and shipped in accordance with applicable EPA and DOT guidelines. Soil sampled will be analyzed for dioxins using USEPA Method 1613 and for coplanar PCBs using EPA Method 1668. Please see Attachment D for a detailed description of the soil sampling protocol.

Interpretation – Total dioxin TEQs in soil will be calculated using the 1998 World Health Organization TEFs. Congener profile analysis of dioxin TEQs in soil will be conducted to determine the relative contribution of each dioxin-like congener to the total TEQ.

Soil sampling results will be compared to the MDEQ statewide residential cleanup criterion of 90 ppt for total dioxin TEQ in soil, the ATSDR 50 ppt screening level and 1,000 ppt ATSDR action level for dioxins in soil. Detected levels above 50 ppt indicate the need for further investigation and levels above 1,000 ppt indicate the need for public health actions to interdict exposure (De Rosa 1997).

Indoor Dust Sampling

Justification – The lack of indoor samples represents a significant data gap because residents report that river water and sediments have repeatedly entered their home during flood events. Exposure to contaminants in indoor dust can occur through skin contact and incidental ingestion (e.g., through hand-to-mouth activities). Dust particles can also be inhaled and then absorbed from the lungs into the blood. Concentrations of total dioxin TEQs in indoor dust will be used to indicate the potential for exposure. It is important to emphasize that the amount of dioxin detected in dust is not necessarily equivalent to the amount that is bioavailable.

Participants – Indoor dust samples will be collected from the homes of selected participants (see Figure 2).

Consent Forms - Prior to collecting indoor dust samples, the resident/property owner will be asked to sign a consent form. Consent for indoor dust sampling is included in the Consent form provided in Attachment A.

Protocol for Dust Sample Collection – Two indoor floor dust samples will be collected inside of each home following EPA Standard Operating Procedure (EPA 2000). A Nilfisk® vacuum equipped with a HEPA filter will be used to vacuum the marked area. A minimum of 10 grams of dust is needed to yield an analytical detection limit of 1 part per trillion (ppt or ng/kg). If the sample bag does not appear to have collected enough dust from the square-meter area, then another adjacent square-meter area will be vacuumed. The surface vacuumed can include wood, tile, carpet, etc. Both the surface type and the total area of sample collection will be recorded. One sample will be collected from the entryway used most often. The other sample will be collected from an area where the resident(s) spends the bulk of their time. A square-meter will be measured and marked using masking tape. The protocol for indoor dust sampling is provided in Attachment C. Dust samples will be analyzed at Triangle Laboratory, Durham, North Carolina using USEPA method 1613 for dioxins and furans.

Interpretation - Total dioxin TEQs in indoor dust will be calculated using the 1998 World Health Organization TEFs. Congener profile analysis of dioxin TEQs in indoor dust will be conducted to determine the relative contribution of each dioxin-like congener to the total TEQ.

There are no specific action levels or criteria for dioxins in indoor dust. However, the results of the dust sampling will be used to determine if dioxin levels in indoor living spaces have been affected by outdoor soil contamination.

Biologic Sampling

Justification - When absorbed into the body, dioxin is stored in fatty tissues including blood serum. The half-life for elimination of dioxin is estimated to range from 7-14 years. Therefore, levels of dioxins in blood serum are a good indication of past and on-going exposure and can be used to estimate total body burden of dioxins. *In vivo* tests in animals can be used to estimate bioavailability of dioxin in soil and dust, and may be useful later in analyzing the relative contributions of various exposure pathways to the body burdens shown by these human measurements. Human biological sampling is preferred and will provide a direct measure of dioxin body burdens in the affected population.

Participants - Biological sampling will be restricted to adults over the age of 17 currently living in the flood plain on property where soil sampling indicates elevated levels of dioxins. No children will be sampled. Potential participants will be excluded if they are pregnant or if they have a medical condition such as anemia that precludes them from being able to safely donate an 80 ml blood sample.

Consent Forms - Prior to collecting any biologic samples, the participants will be asked to provide consent for this testing. Each participant must sign the informed consent form provided in Attachment A.

Protocol - A certified phlebotomist will collect 80-ml of blood (about 5.5 tablespoons) by venipuncture from all consenting participants. Blood samples will be collected in eight 10-ml glass Vacutainer® tubes. After collection, blood samples will be held at room temperature for 1-2 hours and allowed to clot. The samples will then be stored on ice and delivered to the Centers

for Disease Control and Prevention, National Center for Environmental Health (NCEH) Laboratory in Atlanta, Georgia, for analyses. The protocol is provided in more detail in Attachment B.

Serum samples will be analyzed for dioxins, furans, and coplanar PCBs at the CDC NCEH lab using gas chromatography/isotope dilution-high resolution mass spectroscopy. The blood serum samples will also be analyzed for total lipid content so the results can be expressed in blood lipid concentration.

Interpretation - Total TEQs in blood serum samples will be calculated using the 1998 World Health Organization TEFs.

To determine if blood dioxin TEQ levels in investigation participants are different than normative background levels, the results will be compared to dioxin TEQ levels in the upcoming National Health and Nutrition Examination Survey (NHANES) report. If the NHANES data are unusable or are not available in a timely manner, dioxin TEQ levels calculated from dioxin studies conducted in the mid to late 90s will be used as a comparison data set. These data comprise a nonrepresentative sample of approximately 350 people who live in Arkansas, Missouri, New York, North Carolina, and Wisconsin who have no known exposure to dioxin beyond background. Age-specific comparisons between investigation results and the normative data will be made if the data to do so are available.

MDCH will compare individual blood dioxin results to the distribution of normative data and will identify the percentile in the normative data associated with the detected level of blood serum dioxin. MDCH will consider blood serum dioxin results greater than the 90th percentile of the normative data to be elevated.

Congener profile analysis of dioxin TEQs in blood will be conducted to determine the relative contribution of each dioxin-like congener to the total TEQ. To identify similarities and/or differences, the MDCH will compare the congener profile analysis for serum blood samples to 1) the congener profiles for soil and indoor dust samples at the participant's property and in the flood plain soil samples, and 2) the congener profiles for the normative data.

Interviews

Justification - The interview questionnaire will be used to identify personal behaviors (e.g., consumption of sport caught fish, occupation) or characteristics (e.g., gender, age, diet, weight) that could affect exposure and dioxin body burdens. The Interview Questionnaire is provided in Attachment E.

Participants – MDCH will administer the interview questionnaire to all individuals who consent to soil, dust, and blood samples.

Consent Forms – Prior to administration of the interview questionnaire, the participants will be asked to provide consent. Each participant must sign the informed consent form provided in Attachment A.

Protocol – An MDCH staff member will administer the interview questionnaire. The interviewer will ask the participant each question and will record responses in a prescribed format for data entry.

Interpretation – For each individual participant, MDCH will consider whether personal behaviors or characteristics may have had an effect on their dioxin blood test results.

REPORTING PHASE I RESULTS

Individual test results and an explanation of their significance will be provided to the participants in writing within 30 days of MDCH's receipt of the results. An MDCH or ATSDR toxicologist will be available to discuss the findings with the participants.

Individual test results will not be available to the public, and confidentiality will be protected according to Federal and State laws. At the conclusion of the investigation, MDCH will prepare a report that will summarize the findings of the investigation, but will not reveal personal identifiers.

LIMITATIONS OF THE PHASE I PILOT EXPOSURE INVESTIGATION

The participant selection process is intentionally biased and the results of the Phase I Exposure Investigation will not be generalized to the larger population of people who are or have lived in the flood plain.

While the results of the Pilot Investigation cannot be generalized to all people living in the flood plain, it will provide the opportunity to test the survey questionnaire and blood and indoor dust sampling methods prior to the implementation of a larger investigation that may include residents from the city of Midland, the flood plain of the Tittabawassee River, and a control community with no known exposure to dioxins beyond background. The Pilot Exposure Investigation may provide information about the relationship, if any, between dioxin blood levels and exposure to dioxins in soil, indoor dust, and locally caught or grown foods for these 25 people. This information could provide information to refine the design of the larger investigation. Lastly but perhaps most importantly, the Pilot Investigation will provide information on the levels of dioxins in soil, indoor dust, and blood samples for 25 residents of the flood plain. If the investigation results suggest the need, the residents that participated in the Pilot investigation can use this information to modify their behavior to limit exposure to impacted media.”

If dioxins are found in soil and dust samples, it will not be possible to definitively identify the origin of the contamination or if the contaminants are bioavailable to people. However, congener profiles analysis will be conducted and compared to existing data for flood plain soil. If the congener profiles are consistent with current data, it will be assumed that there is a

common origin for these contaminants. The bioavailability of dioxins in dust and soil samples will not be determined in this investigation. However, if congener profiles for blood samples are consistent with those for soil and dust, this may be an indication of local exposures.

If dioxins are found in blood samples, it will not be possible to quantify the relative contribution of plausible exposures pathways to levels of dioxin in blood. It will not be possible to determine how exposure to soil on people's properties or dust in their homes has affected their blood levels of dioxin. The interview questionnaire will provide only qualitative information about exposures that may have influenced levels of dioxins found in blood. This investigation will provide information that can be used to design future studies to elucidate exposure pathways.

The Phase I investigation will not provide any information on chemicals other than dioxin and other dioxin-like chemicals to which people in the flood plain may be exposed. People may be exposed to other contaminants in the environment, in their workplace, or through recreational activities such as hobbies that require chemical use. Exposure to multiple chemicals may lead to additive or synergistic interactions that could increase or decrease the expected adverse health impact.

The Phase I Investigation will not provide any information about whether participants could experience adverse health effects as a result of the level of dioxins found in blood. It is important to first determine if people have been exposed to dioxins in the flood plain and whether they have taken these contaminants into their bodies.

FOLLOW-UP ACTIVITIES

The Phase I Pilot Investigation will serve as an initial test of the Exposure Investigation protocol. Follow-up health activities may include health education for residents and their health care providers

The results of this investigation may be used to determine the need to provide interim exposure controls on contaminated property within the flood plain of the Tittabawassee River. If elevated levels of dioxins are detected in environmental media, recommended follow-up may also include additional sampling and analysis.

In addition, this investigation could provide information to refine the design of other studies that address the extent of dioxin contamination and possible dioxin exposure pathways in the Tittabawassee River floodplain area and City of Midland.

REFERENCES

ATSDR (Agency for Toxic Substances and Disease Registry). 1998. Toxicological Profile for Chlorinated Dibenzo-*p*-Dioxins. December 1998.

De Rosa, Christopher T. et al. 1997. Dioxin and Dioxin-Like Compounds in Soil, Part 1: ATSDR Interim Policy Guideline. Toxicology and Industrial Health, Vol. 13, No. 6, 1997. pages 759-768.

EPA (United States Environmental Protection Agency). 2000. Environmental Response Team (ERT); Collection of indoor dust samples from carpeted surfaces for chemical analysis using a Nilfisk GS-80 vacuum cleaner; 2000.

MDCH (Michigan Department of Community Health). 2002. Dioxin Contamination in the Tittabawassee River Floodplain South of Midland, Michigan, March 4, 2002.

MDCH (Michigan Department of Community Health). 2003. Michigan Family Fish Consumption Guide.

MDEQ (Michigan Department of Environmental Quality). 2000. Part 201 Generic Cleanup Criteria Tables. June 7, 2000.

MDEQ (Michigan Department of Environmental Quality). 2001. Environmental Response Division. 2001b. Unpublished: Greenpoint – Tittabawassee River Dioxin Study Area Phase II Sampling Program. October 2001.

USDA (United States Department of Agriculture). 1997. Letter to “Owners and Custodians of Poultry, Livestock and Eggs.” Mark Mina, DVM, Deputy Administrator, Field Operations, Food Safety and Inspection Service. July 8, 1997.