Health Consultation

Exposure Investigation Report

A PILOT EXPOSURE INVESTIGATION:
DIOXIN EXPOSURE IN ADULTS LIVING IN THE
TITTABAWASSEE RIVER FLOOD PLAIN

SAGINAW COUNTY, MICHIGAN

EPA FACILITY ID: MID980994354

NOVEMBER 1, 2007

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Agency for Toxic Substances and Disease Registry
Division of Health Assessment and Consultation
Atlanta, Georgia 30333

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Prepared by:

Michigan Department of Community Health
Under a Cooperative Agreement with the
Agency for Toxic Substances and Disease Registry

Foreword

On July 8, 2005, the Michigan Department of Community Health (MDCH) released the Public Comment Draft of the Public Health Consultation "A Pilot Exposure Investigation: Dioxin Exposure in Adults Living in the Tittabawassee River Flood Plain Saginaw County, Michigan EPA ID# MID980994354." MDCH received comments from the public until September 11, 2005.

MDCH in cooperation with the Agency for Toxic Substances and Disease Registry (ATSDR) is releasing this Final Public Health Consultation (PHC) to provide responses to comments received on the public comment draft. This Final PHC does not address new environmental or biological data that have become available since the draft PHC was released. Any future PHCs that address the Tittabawassee River flood plain will incorporate these data as appropriate.

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Acronyms and Abbreviations

ATSDR	Agency for Toxic Substances and Disease Registry
CI	confidence interval
CDC	Centers for Disease Control and Prevention
CDD	chlorodibenzo-*p*-dioxin
CDF	chlorodibenzo-*p*-furan
DLC	dioxin-like compound
EMEG	environmental media evaluation guide
MDCH	Michigan Department of Community Health
MDEQ	Michigan Department of Environmental Quality
PCB	polychlorinated biphenyl
PEI	Pilot Exposure Investigation
pg/g	picograms per gram
ng/m^2	nanogram per square meter
ppt	parts per trillion
TCDD	tetrachlorodibenzo-*p*-dioxin
TEF	toxic equivalency factor
TEQ	toxic equivalent
EPA	U.S. Environmental Protection Agency

Summary

The Michigan Department of Community Health (MDCH), in cooperation with the Michigan Department of Environmental Quality (MDEQ) and the Agency for Toxic Substances and Disease Registry (ATSDR), conducted a Pilot Exposure Investigation (PEI) in the flood plain of the Tittabawassee River. The purpose of the PEI was to test exposure investigation methods and to provide information about the levels of dioxin-like compounds (DLCs) in soil, indoor dust, and human blood samples. Properties that were frequently flooded were identified and, with the consent of the property owners, soil was tested to verify DLC soil contamination. Residents on properties where the DLC level in surficial soils was elevated above the MDEQ residential soil criterion of 90 parts per trillion (ppt) were asked to allow MDCH to take dust samples in their homes, to provide a blood sample, and to respond to a questionnaire designed to identify occupational and dietary exposure to DLCs.

The interview questionnaire and the soil, dust, and blood sampling methods were adequate to meet the purpose of the PEI. However, the occupational history section of the interview questionnaire was confusing to participants and should be revised before the questionnaire is used again.

Indoor dust samples collected from homes confirmed the presence of DLCs in the indoor environment. Results obtained from the questionnaire indicated that participants had not been exposed to DLCs at their jobs. Some participants indicated they had eaten fish or wild game from the Tittabawassee River or flood plain, but not recently or in great quantity.

The level of DLCs measured in participants' blood serum samples fell within the range of preliminary estimated background levels for people with no known exposure to dioxins and furans beyond background. However the mean (average) blood levels for the participants were higher than the mean background estimates for people of the same age. In addition, total dioxin toxic equivalent (TEQ) concentrations in five PEI participants were elevated above the 90^{th} percentile of the age-specific estimated background levels. TEQ concentrations in the blood of two of these five were also elevated above the 95^{th} percentile of the estimated background levels.

The participants were selected for the PEI because the soil on their property was known to be impacted by the dioxin contamination. Because the selection process was biased and because of the small number of people participating in this investigation, generalizing from these limited results to the larger population of people living in or near the flood plain it is not possible.

Purpose

In March 2002, the Michigan Department of Community Health (MDCH), in cooperation with the Agency for Toxic Substances and Disease Registry (ATSDR), released a "Petitioned Health Consultation: Tittabawassee River Floodplain Dioxin Contamination South of Midland, Midland and Saginaw Counties, Michigan" for public comment. The final version of the Public Health Consultation was released in August 2004, including the comments received during the comment period and the agencies' responses. The Public Health Consultation addressed concerns related to dioxin contamination in soil samples taken from the floodplain of the Tittabawassee River downstream of Midland (MDCH 2004b).

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 (PCBs), is often referred to collectively as "dioxins" or "dioxin-like compounds" (DLCs). Because the data to determine if people living in the flood plain are being exposed to DLCs in the soil were not available, the Public Health Consultation recommended that ATSDR and MDCH design an evaluation of site-specific exposure factors for residents of the properties in the flood plain, including biota sample analysis if feasible (MDCH 2004b).

On December 1, 2003, MDCH released for public comment a draft protocol for a Pilot Exposure Investigation (PEI) of dioxin exposure in adults living in the Tittabawassee River flood plain. The MDCH released a final PEI protocol on May 25, 2004 that included responses to comments received during the comment period. The full PEI protocol is available at http://www.michigan.gov/mdch-toxics. The purposes of the PEI were:

- To provide information on the levels of dioxins in soil, indoor dust, and blood samples for a limited number of residents of the flood plain.
- To test sampling criteria, questionnaire, and blood and indoor dust sampling methods prior to the implementation of a larger investigation.

The current report provides the results of soil, indoor dust, and human blood serum analyses for 20 residents living on frequently flooded property within the Tittabawassee River flood plain.

Background

The Dow Chemical Company (Dow), founded in 1897, operates a chemical manufacturing plant in the city of Midland, Michigan. The Dow plant encompasses approximately 1,900 acres on the southern perimeter of the city. The Tittabawassee River flows through the plant site and then southeast to the confluence with the Cass and Shiawassee rivers to form the Saginaw River, which continues northeast to the Saginaw Bay of Lake Huron (Figure 1).

Chlorophenol production began at the Dow Midland site in about 1915. 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 (Brandt 1997). Dow currently operates its own on-site wastewater treatment plant. However, historical releases of DLCs have resulted in contamination of Tittabawassee River sediments and biota. The Tittabawassee River often overflows its banks as a result of heavy rains in the spring and the fall, and melting snow in the spring. The floodwaters have deposited DLC contaminated sediments onto upland areas resulting in soil contamination extending in some locations to several feet below the ground surface. The depth of the contamination indicates that DLCs have been accumulating in the Tittabawassee River flood plain over an extended period of time (MDEQ 2003).

The Michigan Department of Environmental Quality (MDEQ) sampled soil and sediment in the Tittabawassee River and flood plain. In its Phase II final report released in June of 2003, the MDEQ concluded that DLC contamination is extensive in soils and sediments throughout the 100-year flood plain downstream of Midland. The degree of contamination on a property appears to be dependent upon depositional characteristics of the river and how frequently a property is flooded (MDEQ 2003).

Methods

DLCs are most often found as a group in environmental samples and in biota, including human blood serum and other tissues. Each chemical member of the group is called a congener. The most toxic congener in the group of DLCs is 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (2,3,7,8-TCDD). Toxic equivalency factors (TEFs) have been developed to compare the relative toxicity of other DLCs to that of 2,3,7,8-TCDD. The levels of DLCs measured in a sample are multiplied by a TEF to produce a 2,3,7,8-TCDD toxic equivalent or TEQ concentration. The resulting TEQs for all DLCs measured in a sample are then added together to determine the total dioxin TEQ concentration for that sample (De Rosa 1997a,b). Total dioxin TEQs in all media sampled in this investigation were calculated using the 1998 World Health Organization TEFs (Van den Berg et al. 1998).

Target Population

In the summer and fall of 2003, the MDEQ sampled soil on 22 properties believed to be frequently flooded by the Tittabawassee River. Analysis of surficial soils for chlorinated dioxins and furans indicated DLC contamination above the MDEQ criterion of 90 parts per trillion (ppt or ng/kg) on 15 properties (MDEQ 2004).

The residents of these 15 properties were contacted to determine their willingness and ability to participate in the blood and dust collection activities of the PEI. Participation was limited to adults aged 18 years or older who had lived at their current residence in the flood plain for at least 5 years. Participation was limited to adults because of the need to collect a relatively large volume of blood for serum dioxin analysis. Participation was also limited to those who had lived in the flood plain for at least 5 years to ensure adequate exposure duration to dioxin in flood plain media (soil, dust, etc.).

Individuals were excluded if they were pregnant, had breastfed a child in the last 6 months, weighed less than 95 pounds, had lost more than 15 pounds in the last year, or if they had a blood clotting disorder or other medical condition that precluded them from donating an 80 milliliter (ml) blood sample. The residents of four properties were excluded either because of recent weight loss or because they declined continued participation in the PEI, leaving 11 eligible properties.

The PEI protocol detailed a participant scoring system in the event that MDCH identified more than 25 potential participants. This system proved to be unnecessary because only 21 potential participants were identified.

Soil Sampling and Analysis

Residents were asked to identify which entrance to the home was most frequently used and other areas of frequent use on their properties. The MDEQ collected surface soil samples near the house entrance used most often and another sample was collected in a high-use area (e.g., play area where adults may congregate with children, garden area). Additional soil samples were taken as necessary to characterize exposures and contamination, including the frequently flooded area(s) of the property.

Samples were manually collected using hand augers. Two to five surficial soil samples were taken on each participant's property. The depth of the samples ranged from one to three inches below the ground surface. Decisions regarding the exact location of a sample were made on the

basis of the physical characteristics of the sample site. Vegetative cover was removed before sample collection. The hand auger was decontaminated before sampling the next location, and used sample pans, spoons, and gloves were discarded.

Samples were handled, stored, and shipped in accordance with applicable U.S. Environmental Protection Agency (EPA) and Department of Transportation guidelines. Discrete soil samples were analyzed at Triangle Laboratory, Durham, North Carolina for DLCs using EPA Method 1613.

Indoor Dust Sampling and Analysis

Two indoor floor dust samples were collected inside of each home following the EPA Standard Operating Procedure detailed in the PEI protocol. One sample was taken inside the most frequently used door to the home and another was taken from an area of frequent use (e.g., the family room or living room).

A Nilfisk® vacuum equipped with a HEPA filter was used to vacuum an area sufficient to yield a minimum of 10 grams of dust. A square-meter was measured and marked using masking tape and additional area was added as necessary. Surfaces vacuumed included wood, tile, and carpet or rugs. Surface type and the total area of sample collection were recorded. Dust samples were analyzed for DLCs at Eno River Labs (formerly Triangle Laboratory), Durham, North Carolina using EPA Method 1613. The weight of dust samples were reported and were used to calculate dust loadings in nanograms per square meter.

Blood Sampling and Analyses

Participants were given an appointment to come to the Greenpoint Nature Center in Saginaw, Michigan where the blood samples were collected by a licensed MDCH phlebotomist. One participant did not arrive for the scheduled appointment and was dropped from the PEI. Thus, 20 blood samples were collected.

Blood samples were collected in eight 10-ml glass Vacutainer® tubes. After collection, blood samples were held at room temperature for 1-2 hours and allowed to clot. The samples were stored on ice and delivered to the Centers for Disease Control and Prevention (CDC), National Center for Environmental Health (NCEH) Laboratory in Atlanta, Georgia, for analyses.

The serum samples were analyzed for chlorinated dioxins and furans and coplanar PCBs by the NCEH laboratory using gas chromatography/isotope dilution-high resolution mass spectroscopy. These measurements were not analyzed for the level of mono-ortho-substituted PCBs, which may add substantially to the sum TEQ. The blood serum samples were also analyzed for total lipid content, so the results could be expressed as a blood lipid concentration. All DLC serum levels described in this report are given in picograms per gram of blood lipid (pg/g or ppt).

PEI blood serum results were compared to preliminary background estimates for age-group specific dioxin TEQ levels developed by CDC and ATSDR scientists. The background estimates shown in Table 1 were drawn between 1996 to 2001 from 588 participants with no known exposure to dioxin-like compounds other than background. Known exposure is defined as documented epidemiological evidence of previous occupational, diet, or residential proximity to potential industrial exposure sources (Patterson et al., 2004). Where congener-specific analytical results were below the level of detection (i.e., non-detect) one-half (1/2) the detection level was used to quantify total dioxin TEQ results.

Table 1 provides the estimated average or "mean" TEQ background level by age group. The background data are grouped by age because TEQ levels increase with age. Table 1 also presents the lowest (minimum) and highest (maximum) TEQ level as well as the 75th, 90th, and 95th percentile TEQ level for each age group. A percentile is a value on a scale of 1 to 100 that indicates the percent of the data that are equal to or below that value. For example, in the table below, the mean dioxin TEQ for the 90th percentile is 29.5 for people 45 to 59 years old. This means that 90 of 100 people will likely have a dioxin TEQ of 29.5 or less.

Table 1. Preliminary Estimates for Background Total Dioxin TEQ Levels (pg/g of lipid), by Age Group.

Age Group In years	Mean	75th Percentile	90th Percentile	95th Percentile	Minimum TEQ Observed	Maximum TEQ Observed
15-29	6.4	7.8	11.7	14.0	0.0	53.9
30-44	11.8	16.6	21.1	23.2	0.2	50.4
45-59	16.9	22.3	29.5	32.8	0.8	55.4
60+	36.1	45.6	69.2	85.4	3.4	146.4

(Patterson et al 2004)

Interviews

An interview questionnaire was administered to each study participant at the same time blood was collected. The questionnaire was designed 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.

Consent Form

Prior to administration of the PEI questionnaire or biological and environmental testing, each participant in the PEI signed an informed consent form.

Results

Soil Results

Table 2 presents total dioxin TEQ concentrations (ppt) in surficial soils on the 15 properties chosen for the PEI. The number of samples taken on each property ranged from two to five. Sample results ranged from <5 ppt to 2,530 ppt.

Table 2 presents the sampling results progressing from left to right from the house on the property toward the Tittabawassee River. In general, DLC concentrations tended to be higher in soil samples taken nearest the Tittabawassee River compared to those taken nearest the most frequently used entrance to the home. However, this trend was not apparent at all properties.

One possible explanation is that flood plain soil had been moved and used as fill material when these homes were built.

Table 2. Total Dioxin TEQ Levels (ppt) in Soil Samples from the Pilot Exposure Investigation

House Entryway ⟶		Tittabawassee River
50	270	410
240	50, 30	810
80	No intermediate samples.	240
<5	80, 150	400
30	<5, 370, 280	920
1110	<5	400
80	180	550
70	20, 50	260
50	90, 850	1100
50	50, 60	250
10	90, 230	230
260	310	270
30	410, 2530	1130
770	45, 81, 240	450
990	300	580

(MDEQ, unpublished data, 2004)

Indoor Dust Results

Two indoor dust samples were taken from each of the 20 participant's homes for a total of 11 residences sampled. An adequate quantity of dust was obtained for all samples. Indoor dust sample results are provided in Table 3 as both bulk sample results in picograms per gram of total dust (ppt) and as surface loading in nanograms per square meter of surface. The order in which properties are presented does not correspond to that shown in Table 2 to prevent matching of indoor dust results to previously presented soil data.

Table 3. Total Dioxin TEQ Levels in Indoor Dust Samples from the Pilot Exposure Investigation[1]

Frequently Used Entrance		Living Area	
TEQ in ppt	TEQ in ng/m^2	TEQ in ppt	TEQ ng/m^2
10.2	0.00051	11	0.0012
85	0.00047	37	0.0012
61	0.055	71	0.037
59	0.054	267	0.19
27	0.00027	31	0.015
7.5	0.054	23	0.12
22	0.014	60	0.0412
34	0.0039	54	0.102
120	0.051	114	0.0702
110	0.058	67	0.0034
51	0.00016	44	0.0022

(TriMatix 2004)

[1] Indoor dust sample results differ slightly from those presented in the Public Comment Draft.

Blood Results

Blood serum samples from 20 adults were analyzed for DLCs. Nineteen of the samples are described in this report. One sample is not included in the report to protect the identity of the participant. Table 4 compares the PEI blood total dioxin TEQ results to the CDC/ATSDR background estimates. Data are provided only for the two age groups with enough participants to protect the identity of the individuals.

Table 4: Comparison of DCL levels (pg/g of lipid) from the Pilot Exposure Investigation to Preliminary Background Estimates by Age Group.

Study	Age Group	Number of People	Mean	Standard Deviation	95% confidence interval	Range
PEI	45 – 59	10	26.8	6.6	22.7, 30.9	16.7 – 37.4
Background	45 – 59	160	16.9	9.6	15.4, 18.4	0.8 – 55.4
PEI	60 +	9	40.2	19.0	27.8, 52.7	17.7 – 74.7
Background	60 +	113	36.1	24.9	31.5, 40.7	3.4 – 146.4

Patterson et al 2004

Detection levels for chlorodibenzo-*p*-dioxin (CDD) in blood serum varied slightly between samples. On a lipid-adjusted basis in pg/g (ppt), detection levels were 0.5 to 1.4 for 2,3,7,8-TCDD, 0.5 to 2.3 for penta, hexa, and hepta-CDD congeners, and 49.0 to 93.5 for octa-TCDD. Detection levels for chlorodibenzo-*p*-furan (CDF) on a lipid adjusted basis in ppt were 0.4 to 1.3 for tetra- and penta-CDFs, 0.4 to 1.5 for penta, hexa, and hepta-CDF congeners, and 1.4 to 3.3 for octa-CDFs. Detection levels for coplanar polychlorinated biphenyls (PCBs) ranged from 1.4 to 3.3 ppt. As for the Patterson 2004 data, congener-specific PEI results below the level of detection (i.e., non-detect) were set at one-half (1/2) the detection level to quantify total dioxin TEQ results.

Table 4 provides the mean (average) level calculated for each age group in both the PEI and in the background data. Because these mean levels are only estimates, 95 percent (95%) confidence intervals are also provided. Confidence intervals account for the variability in the data used to calculate the mean. The true sample mean is expected to fall between the lower and upper limits of the confidence interval 95% of the time.

Ten PEI participants were between 45 and 59 years old. The mean total dioxin TEQ for this age group is 26.8 ppt. This level is higher than the mean total dioxin TEQ of 16.9 for comparison TEQs for this age group. In addition, the 95% confidence interval of 22.0 to 30.9 ppt for the PEI mean does not overlap the confidence interval of 15.4 to 18.4 ppt for the background mean. On the average, dioxin TEQ levels found in the PEI participants ages 45 to 59 years are higher than TEQ levels included in the background estimates for this age group.

As indicated in the final PEI protocol (MDCH 2004a), blood serum dioxin results greater than the 90^{th} percentile of the preliminary age-adjusted estimate background data are considered to be elevated. The 90^{th} percentile estimated background total dioxin TEQ is 29.5 ppt for people ages

45 to 59 years (Table 1). Four of the total dioxin TEQ levels for participants in this age group were greater than the 90th percentile. In addition, two of these four participants had total dioxin TEQ serum levels greater than the 95th percentile of 32.8 ppt.

Figure 2 presents a comparison of the estimated background total dioxin TEQ levels and the PEI results for people aged 45-59 years. The total dioxin TEQ levels are broken down into 5 ppt ranges and are shown on the horizontal axis. The vertical axis presents the percentage of blood samples in the PEI (darker bars) compared to the background estimates (lighter bars) for each range of total dioxin TEQ levels.

Nine PEI participants were 60 years of age or older. The mean total dioxin TEQ for this age group is 40.2 ppt. This level is higher than the mean of 36.1 for the estimated background TEQs for this age group. However, the 95% confidence interval of 27.8 to 52.7 ppt for the PEI mean overlaps the confidence interval of 31.5 to 40.7 ppt for the background mean. Therefore, it is not certain if this difference in average TEQ levels reflects a real difference between the PEI participants and the background estimates for this age group. Figure 3 presents the total dioxin TEQ results for people aged 60 years for the PEI and the estimated background data.

The 90th percentile estimated background total dioxin TEQ is 69.2 ppt (Table 1). Only one of the total dioxin TEQ levels for participants in this age group were greater than the 90th percentile. None of the participants in this age group had total dioxin TEQ serum levels greater than the 95th percentile of 85.4 ppt.

Table 5 presents a comparison of the PEI and estimated background data for 2,3,7,8-TCDD TEQ only. The mean for each of the PEI age groups is higher than the mean of the estimated background TEQ levels.

Table 5: Comparison of 2,3,7,8-TCDD Levels (pg/g of lipid) from the Pilot Exposure Investigation to Preliminary Background Estimates by Age Group.

Study	Age Group	N	Mean	Standard Deviation	95% confidence interval	Range
PEI	45 – 59	10	3.5	1.5	2.6, 4.5	1.7 – 6.3
Background	45 – 59	160	1.9	1.6	1.7, 2.1	0.3 – 9.3
PEI	60 +	9	5.9	5.0	2.6, 9.2	0.7 – 15.5
Background	60 +	113	3.9	3.7	3.2, 4.6	0.3 – 22.6

Patterson et al 2004

The mean of 3.5 ppt for 2,3,7,8-TCDD TEQ levels in the PEI participants ages 45 to 59 years is higher than the mean of 1.9 ppt for the estimated background 2,3,7,8-TCDD TEQ levels for this age group. In addition, the 95% confidence intervals for the means do not overlap. On the average, 2,3,7,8-TCDD levels found in the PEI participants ages 45 to 59 years are higher than levels included in the background estimates for this age group.

The mean of 5.9 ppt for 2,3,7,8-TCDD TEQ levels in the PEI participants ages 60 years and older is higher than the mean of 3.9 ppt for the estimated background 2,3,7,8-TCDD TEQ levels

for this age group. In this age group the 95% confidence intervals for the means overlap. Therefore, whether the difference in average levels reflects a real difference between the PEI participants and the background estimates is not certain .

Background data for other dioxin and furan congeners are not currently available but may be addressed in future documents related to the Tittabawassee River.

Interview Results

Adequacy of Design

Overall, the interview questionnaire was of adequate design to elicit information about personal characteristics or behaviors that could affect exposure to DLCs. However, redundancy in the "Occupational History" series of questions (29 to 42) resulted in some confusion on the part of both the interviewers and the participants.

Participant Characteristics

Participants ranged in age from 18 to 79 years. Residence time at their property within the Tittabawassee River flood plain ranged from 11 to 39 years. About half of the participants were male (n=11) and half were female (n=9).

Seven of the nine female participants had given birth to one to four children, and four of these women had breastfed their children. The most recent birth occurred in 1986.

Eleven participants reported having ever smoked cigarettes; two of these reported currently smoking. Thirteen reported using pesticides around their home, primarily for insect control. Four participants reported getting their drinking water from a private well, but none of the wellheads had ever been submerged during flooding of the Tittabawassee River.

Occupational History

One participant reported work experience with hazardous waste. However, further inquiry indicated this person had used organic solvents rather than materials that might be expected to contain DLCs. No participant indicated that they had ever been employed in jobs where they manufactured or used 2,4-D, 2,4,5-T, hexachlorophene, or pentachlorophenol. None of the participants indicated they had worked in brush or hardwood control, railroad right-of-way clearance, chemical warehouses, paper mill pond management, waste incineration, or had handled phenolic wastes. Participants reported a variety of previous work experience that included sales, general office work, homemaker, electrician, machine operator, and the practice of medicine.

Sport-Caught Fish Consumption

Sixteen participants indicated they had ever eaten sport-caught fish from Michigan lakes and streams, and 10 of these indicated they had done so in the last five years. Eight participants indicated they had eaten fish from the Saginaw River or Saginaw Bay in the last 5 years. Six participants indicated they had ever eaten fish from the Tittabawassee River, however only two had eaten these fish in the last 5 years. Only walleye were reportedly eaten in the year before the investigation. Walleye and bass were most often eaten in prior years; however, one participant reported having at one time eaten all species of sport fish from the Tittabawassee River including carp and catfish.

Wild Game Consumption

Nine participants reported having ever eaten locally harvested wild game and five of these had eaten game harvested from the Tittabawassee River flood plain. The most frequently eaten species were squirrel, rabbit, and deer. The reported number of meals per year of these game species was no more than four to six.

Home-Raised Meat and Produce

Six participants reported having ever eaten home-raised meat and two of these reported having eaten meat raised in the flood plain of the Tittabawassee River. Within the year before the PEI, one person had eaten home-raised lamb from the flood plain. Another participant reported having eaten home-raised beef in prior years.

Sixteen participants reported having eaten produce grown in the flood plain of the Tittabawassee River. Two participants reported having eaten eggs from chickens that were kept on property in the flood plain and two others reported not knowing whether they had eaten eggs that were produced in the flood plain.

Discussion

Soil

DLC concentrations in one or more surficial soil samples at all properties included in the PEI exceeded the MDEQ residential clean up criterion of 90 ppt and the ATSDR screening level of 50 ppt.

The MDEQ clean up criterion for DLCs is protective of dermal contact with and incidental ingestion of soil under a residential exposure scenario. MDEQ uses an age adjusted formula that assumes exposure both as a child and as an adult, and a mix of average and upper bound exposure assumptions to calculate a soil DLC concentration that is protective of a reasonable maximum exposure. The current MDEQ criterion for DLCs is calculated from a cancer potency value based on liver cancer incidence in rats. The MDEQ assumes that 3 percent of DLCs in soil will be absorbed through the skin and 50 percent will be absorbed through the gastrointestinal tract if soil is ingested.

The ATSDR screening level of 50 ppt for DLCs is the chronic environmental media evaluation guide (EMEG) for 2,3,7,8-TCDD in soil. The EMEG was developed from the ATSDR minimal risk level (MRL) on the basis of neurodevelopmental effects observed in offspring of female rhesus monkeys exposed during pregnancy and after birth through nursing (ATSDR 1998). EMEGs are very conservative and protective values. Generally, if soil concentrations do not exceed the EMEG, ATSDR assumes that exposure is not likely to result in adverse health effects. However, if soil concentrations exceed the EMEG, this does not mean that adverse human health effects will always occur. Instead, soil concentrations greater than 50 ppt total dioxin TEQ indicate further site-specific evaluation is necessary (De Rosa et al. 1997a).

In 1997 and 1998, the MDEQ collected soil samples from 68 urban and rural locations in Michigan (MDEQ, Waste Management Division. 1999. Michigan Soil Background Dioxin Data). These samples were taken to gain an understanding of statewide DLC concentrations that have resulted from industrial activities, waste incineration, and chemical use. Analysis of these samples indicates that DLC soil background concentrations vary from less than 1.0 ppt

TEQ to 35 ppt TEQ with an average of 6.0 ppt TEQ. Similar nationwide efforts by the U.S. EPA found an average DLC soil concentration of 10 ppt TEQ (MDEQ 1999).

Twenty-two properties were originally sampled for the PEI. Soil analytical results for only 15 properties showed levels of DLCs greater than the MDEQ residential cleanup criterion of 90 ppt. This suggests that predicting whether an individual property is impacted is not as simple as just determining whether the property lies within the 100-year flood plain or if the Tittabawassee River has flooded it. On impacted properties, levels of DLCs tended to be higher nearest the river but this pattern was not apparent for all properties indicating that human movement of soil is a significant way soil could become contaminated with DLCs.

Because the numbers of PEI participants and properties are small, determining whether DLC levels in soil correlate with levels found in participant's blood is not possible.

Indoor Dust

Detectable DLCs were found in all dust samples collected from the homes of PEI participants. These samples were analyzed to qualitatively determine whether DLCs were present in homes located on properties where soil had been impacted by DLCs. No state or federal criteria or guidelines exist for the acceptable level of DLCs in indoor dust. The human health effects of exposure to DLCs in indoor dust are not known.

Blood

All people in the United States are believed to have some level of DLCs in their body fat and blood (ATSDR 1998). DLCs are found throughout the environment and most people are exposed to low levels in air, soil, or food. In areas that have not been impacted by an accident or other release, background DLC levels in soil are around 6 to 10 ppt (MDEQ 1999). For people living in these areas, most of their intake of DLCs comes from eating foods of animal origin, such as meat, poultry, fish, or dairy products (ATSDR 1998). DLCs are in these foods because they are in the animals' environment and because DLCs tend to accumulate in the fatty tissues of animals and fish.

People who live in or near areas such as the Tittabawassee River flood plain, where the level of DLCs in environmental media (e.g., air, soil or sediment) and biota (e.g., animals and fish) are higher than background, may be exposed to above-background levels of DLCs (ATSDR 1998). DLCs have been detected in the flood plain at concentrations up to 7,300 ppt in soil and 2,100 ppt in river sediments (MDEQ 2003). The contribution of DLC intake from exposure to soil and sediment in the flood plain to a person's total intake of these chemicals will likely be higher than background.

The Michigan Fish Advisory cautions against eating carp, catfish, and white bass taken from the Tittabawassee River because these fish have been found to contain unacceptable levels of DLCs. Women of childbearing age and children also are cautioned not to eat smallmouth bass. Limited consumption is recommended for all other fish species such as walleye (MDCH 2003). On September 14, 2004, the MDCH issued a Wild Game Advisory for the flood plain, recommending that people not eat the liver of white-tailed deer or turkey meat and skin, and limit their consumption of deer and squirrel muscle meat (MDCH 2004c). This advisory was based on elevated levels of DLCs that had been found in the edible tissues of these wild game species. People who eat fish or wild game taken from this area may be exposed to higher than background levels of DLCs.

When people eat foods or are exposed to air, soil or sediment that contain DLCs, these chemicals can accumulate in their bodies. People who are exposed to higher levels in the environment and in food will tend to accumulate more DLCs in their bodies. Most of the DLCs are stored in adipose tissue (fat), blood serum, and the liver, and can remain in the human body for many years. The time it takes to remove one-half the amount of 2,3,7,8-TCDD in a person's body is 7 to 12 years (ATSDR 1998). Other congeners may take more or less time to be eliminated from the human body. The amount of DLCs in a person's body is often referred to as the "body burden" and will be different for each person depending on how much they are exposed to, how much they absorb into their body, and how fast they eliminate these compounds. Age, gender, and health status can all affect how fast DLCs will accumulate and be eliminated from a person's body (ATSDR 1998).

Blood serum samples generally are used to measure a person's body burden of DLCs, although these compounds have been found in all tissues and in breast milk. These tests are not routinely available to the public.

All serum TEQ levels measured in blood samples provided by the PEI participants fell within the range of preliminary estimated background TEQ levels shown in Table 1. However, the mean TEQ levels for age groups 45-59 years and 60 years and older were higher than the mean background estimates for people the same age. Because of the small number of people participating in the PEI, generalizing from these limited results to the larger population living in or near the flood plain is not possible.

Conclusions

The interview questionnaire and the soil, dust, and blood sampling methods were adequate to meet the purpose of the PEI. Redundancy in questions concerning occupational history on the interview questionnaire should be eliminated.

Soil samples collected from 15 properties located at least partially within the flood plain of the Tittabawassee River showed total dioxin TEQ levels greater than the MDEQ residential criterion of 90 ppt for DLCs. These findings further confirm earlier results indicating that elevated DLC levels within the 100-year flood plain downstream of Midland are widespread.

Indoor dust samples collected from homes located on properties where outdoor soil contains levels of DLCs greater than 90 ppt confirm the presence of DLCs in the indoor environment of these homes.

The mean total dioxin TEQ level in 10 adult PEI participants aged 45 to 59 years was higher than the mean estimated background level for this age group. The mean 2,3,7,8-TCDD level in this PEI group was also higher than the estimated mean value in the background data.

Total dioxin TEQ blood levels in four participants aged 45 to 59 years were greater than the 90^{th} percentile of the estimated background levels for this age group. Two of these were also greater than the 95^{th} percentile. Total dioxin TEQ blood levels in these four participants are elevated.

The mean total dioxin TEQ level in nine adult PEI participants 60 years of age and older was slightly higher than the mean estimated background level for this age group, but fell within the 95% confidence intervals for the estimated background mean. The mean 2,3,7,8-TCDD TEQ in this PEI group was also higher than the estimated mean value in the background data, but again fell within the 95% confidence intervals for the estimated background mean. Therefore, whether

these data reflect a real difference between the PEI participants and the estimated background levels cannot be known for certain.

The total dioxin TEQ blood level in one participant in the 60 plus age group was greater than the 90^{th} percentile of the estimated background comparison level and is elevated.

Although, mean serum TEQ and 2,3,7,8-TCDD levels in the PEI groups were higher than the estimated background levels, all TEQ and 2,3,7,8-TCDD levels observed in the PEI participants fell between the lowest and highest values observed in the estimated background data.

Recommendations

- The PEI interview questionnaire should be revised to eliminate redundancy in the occupational history questions before the questionnaire is widely used.
- A comprehensive exposure investigation should be conducted to evaluate the potential for unacceptable human exposures to DLC contamination in flood plain environmental media and biota including:
    - Identification of properties where DLC concentrations exceed applicable State of Michigan clean up criteria and/or the ATSDR screening level.
    - Evaluation of the bioavailability of DLCs in flood plain soils and sediments.
    - Identification of DLC levels in fish, wild game, and domestic animals or animal products in the flood plain and eaten by people.
    - Identification of people who may be more highly exposed to flood plain DLCs such as fishers, hunters, or people who are highly exposed to soil contamination.
- Actions should be taken to limit exposures to elevated DLC levels in environmental media and biota.

Public Health Action Plan

- MDCH and ATSDR will revise the interview questionnaire before it is used again.
- MDCH and ATSDR will remain available to participate in the development or review of work plans to conduct a comprehensive exposure investigation for the Tittabawassee River and flood plain.
- MDCH and ATSDR will consider the feasibility in conducting health outcome studies to determine if rates of disease for people living in or near the flood plain differ from persons who live in a comparison location, if a comprehensive exposure investigation identifies environmental dioxin exposure in or near the floodplain is above background levels.
- MDCH and ATSDR will continue to provide health education to residents and health care professionals so that they can make informed decisions to limit their exposure to DLCs.
- MDCH will maintain and update fish and wild game advisory information for the Tittabawassee River and flood plain.

Contact Information

If any citizen has additional information or health concerns regarding this Tittabawassee River flood plain Pilot Exposure Investigation consultation, please contact the Michigan Department of Community Health, Division of Environmental and Occupational Epidemiology at 1-800-648-6942.

References

ATSDR (Agency for Toxic Substances and Disease Registry). 1998. Toxicological Profile for Chlorinated Dibenzo-*p*-Dioxins. US Department of Health and Human Services, ATSDR, Atlanta. Available at http://www.atsdr.cdc.gov/toxprofiles/tp104.html.

Brandt, E. N., 1997. Growth Company: Dow Chemical's First Century, Michigan State University Press, East Lansing, MI.

De Rosa, Christopher T. et al. 1997a. Dioxin and Dioxin-Like Compounds in Soil, Part 1: ATSDR Interim Policy Guideline. Toxicology and Industrial Health, 13(6), pages 759-768.

De Rosa, Christopher T. et al. 1997b. Dioxin and Dioxin-Like Compounds in Soil, Part 2: Technical Support Document for ATSDR Interim Policy Guideline. Toxicology and Industrial Health, 13(6), pages 769-804.

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

MDCH (Michigan Department of Community Health). 2004a. Pilot Exposure Investigation: Dioxin Exposure in Adults Living in the Tittabawassee River Flood Plain, Saginaw County, Michigan. May 5, 2004.

MDCH (Michigan Department of Community Health). 2004b. Health Consultation: Tittabawassee River Floodplain Dioxin Contamination. Tittabawassee River, Midland and Saginaw County, Michigan. EPA Facility ID: MID980994354. August 12, 2004.

MDCH (Michigan Department of Community Health). 2004c. State of Michigan Issues Health Advisories For Consuming Wild Game From Tittabawassee River Flood Plain. http://www.michigan.gov/mdch. September 14, 2004.

MDEQ (Michigan Department of Environmental Quality), Remediation and Redevelopment Division. 2003. Final Report: Phase II Tittabawassee/Saginaw River Dioxin Flood Plain Sampling Study. June 2003.

MDEQ (Michigan Department of Environmental Quality), Remediation and Redevelopment Division. 2004. RRD Operational Memorandum #1: Part 201 Generic Cleanup Criteria/Part 213 Risk-based Screening Levels, Attachment 1.

MDEQ (Michigan Department of Environmental Quality), Remediation and Redevelopment Division. 2004. Preliminary Analytical Results for Soil Samples Taken at Residential Properties in the Tittabawassee River Floodplain by the DEQ in June through December 2003." Available at http://www.deq.state.mi.us/documents/deq-rrd-TR-PreliminaryResultsFeb2004.pdf.

Patterson D.G., et al. 2004. Age Specific Dioxin TEQ Reference Range. Organohalogen Compounds 66:2878-2885 (2004).

TriMatrix Laboratories. 2004. Report and Data Package from Eno River Labs. September 24, 2004.

Van den Berg, et al. 1998. Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, PCDFs for Humans and Wildlife. Environmental Health Perspectives, 106(12), pages 775-792.

Appendix A - Responsiveness Summary

MDCH provided a 60-day comment period that closed on September 11, 2005. Comments were received from:

- The Midland County Health Department
- The Saginaw County Department of Public Health
- The Dow Chemical Company
- ChemRisk, Inc.
- Two private citizens

Comments that impugn the personal integrity of the researchers, the ATSDR, and the MDCH are not germane to the public health consultation process and will not be addressed further here.

Where appropriate, MDCH has combined similar comments from two or more sources to limit redundancy. In the interest of maintaining the focus on substantive comments, grammatical comments or suggestions are not provided here. However, as appropriate these comments have been addressed in the revised PEI report and MDCH is grateful for these comments.

Some commenters requested that technical information be included in the PEI report. In general, public health consultations are intended for the average reader who does not have any specific training or expertise in the sciences. Highly technical information that would be reported in a professional journal publication is not included in the typical consultation. However, in response to commenters' requests, some technical information has been added to the PEI.

1. Comment: Notwithstanding the need to preserve confidentiality, there is no legal, ethical or scientific reason why the congener data cannot and should not be presented in the final report or otherwise be made available as soon as possible to the residents of the tri-county community, the public at large and the scientific community. Identifying information could be removed before releasing the congener profile data to protect the confidentiality of the results yet allow scientists to review the data.

> **Response:** MDCH received several requests for the PEI data, including requests for the congener profiles for the serum blood test results. Before responding to these requests, MDCH consulted with the office of the Michigan Attorney General as to the legal status of the data and our responsibility to comply with Michigan law concerning confidentiality of data.
>
> In January of 2004, the PEI was designated as a "Medical Research Project" under the Michigan Public Health Code, Act No. 368 of the Public Acts of 1978, MCL 333.2631. The designation is signed by Dr. Matthew L. Boulton, then Chief Medical Executive and State Epidemiologist. Section 333.2631 of Act 368 makes confidential all "information, records of interviews, written reports, statements, notes, memoranda, or other data" collected by the MDCH in relation to the PEI.
>
> The next section, MCL 333.2632, specifies that "The information, records, reports, notes, memoranda, or other data shall not be exhibited nor their contents disclosed in any way, in whole or in part, by the department or its representative, or by any other person, agency or organization, except as is necessary for the purpose of furthering the medical research project to which they relate."

Section 333.2638 specifies that a person who discloses data related to a Medical Research Project "is guilty of a misdemeanor, punishable by imprisonment for not more than 1 year, or a fine of not more than $1,000.00 or both, and if the person is an employee of the department shall be subject to immediate dismissal." This section illustrates the serious intent of the Michigan Legislature on these issues. These provisions do not apply, of course, to individual participants who may do as they please with their own test results.

Beyond the legal impediments to releasing the data, there is an ethical need to maintain confidentiality. MDCH made a commitment to the PEI participants that their test results and the answers they gave to the questionnaire would be kept confidential. Participants were asked to sign an informed consent stating that:

"Your name and test results will be kept private to the extent allowed by the law. Your name will not be used in any reports written about this investigation. Any reports that are written about the investigation will only use dioxin levels. All names and test results will be kept in a locked file. Only the contact person shown below will have access to these files."

MDCH chose to publish aggregate data only for two age groups that included nine or ten participants each. The results from a third age group were not published because of the small number of participants in that age group would have made it very difficult to maintain confidentiality. The soil data for each of the properties sampled as part of the PEI were previously made public by the MDEQ, as required by law. It would therefore be very easy to identify the 11 properties included in the PEI and match the PEI participants to their addresses, particularly since many participants have chosen to speak publicly about their DLC blood levels.

2. Comment: It is inappropriate for the MDCH and ATSDR to enter into confidentiality agreements that preclude release of the congener data to the public. Such agreements effectively provide a shield for MDCH and ATSDR scientists allowing them to say anything they please without the benefit of scientific peer review.

Response: Confidentiality agreements are not only appropriate, they are required by the State of Michigan Public Health Code, by the MDCH Institutional Review Board for the conduct of research with human subjects, and by the U.S. Department of Health and Human Services. Confidentiality agreements provide privacy of medical information for participants. Such agreements are standard practice for reputable researchers including those conducting the University of Michigan Dioxin Exposure Study.

3. Comment: "It would be quite easy to suggest that MDCH representatives involved in this project have a bias on the dioxin issue and are not capable of objective, scientifically based, development of reports. I hope this is NOT the case, but the targeted findings in this Report and especially the press release are troubling. It is imperative that our local community is able to develop trust with the MDCH representatives so that we may effectively deal with this issue."

Response: The scientific results of the PEI soil, dust and blood testing stand by themselves and are objectively presented in the consultation without undue interpretation. It would be inappropriate for MDCH to characterize the results as either "good news" or "bad news". The reader is left to make that subjective determination.

All stakeholders involved in this issue enter the discussion with personal bias. Members of the regulated community and other community members also have the potential for personal gain or loss that colors their interpretation of results. Thus each person who reads the PEI report does so from the perspective of his or her bias. State health officials do not stand to profit personally from positive or negative findings and are without a vested personal interest in the outcome of these issues. Their professional interest is the uncompromised objective of protecting the health and safety of all of the citizens that they serve.

4. Comment: "With only 21 participants, we can't base many conclusions on such a limited sample size. However, all participants were within the background range for dioxin exposure as compared to the work done by Don Patterson in 2004."

Response: These conclusions are stated in the Summary and Conclusions section of the PEI report.

5. Comment: "Quote Page #1 paragraph #4 – 'The level of DLCs measured in participant's blood serum samples fell with range of preliminary estimated background levels for people with no known exposure to dioxins and furans beyond background' Why isn't normal - normal?"

Response: Dioxins and furans are not "normal" constituents in human blood. While most people living in developed countries will have some level of these chemicals in their bodies, this is so because these chemicals have been released into the environment and have entered the human food supply. It is not known at this time what health effects may result from exposures within the background range, however some scientists think that subtle health effects are occurring at these levels in the general population.

6. Comment: "The PEI candidates were specifically selected by MDCH because they felt that those individuals were exposed to dioxins and furans beyond background. This was discussed in paragraph #5 in the first sentence. The second sentence is well stated in that generalizing from these limited results to the larger population is not possible. That is why we will learn much more from the University of Michigan Dioxin Exposure Study and be able to draw some conclusions about the Tittabawassee River Flood Plain residents."

Response: Comment noted.

7. Comment: "Some confusion exists within the document regarding: how many participants, how many homes, how many dust samples and how many soil samples at each location. I'm somewhat confused with the various statements: 15 of 22 properties, 21 participants, 20 blood samples collected, 19 blood sample results with one not included, and 11 residences sampled for dust. While these are minor in relation to the overall study, it adds to the confusion of the overall study results."

Response: MDCH apologizes for any confusion, however the number of properties and participants in the PEI changed as data became available. Initially soil sampling was conducted on 22 properties. Soil dioxin levels exceeded 90 ppt on 15 of these. Four of these 15 were excluded from the PEI because the people who lived there either declined further participation in the PEI or were excluded because of recent weight loss. Thus 11 properties remained in the PEI and dust sampling was conducted in each of these homes. MDCH identified 21 eligible participants living on these 11 remaining properties. All 21 were scheduled to have blood drawn, but one person did not show up for the

appointment, leaving 20 participants. MDCH did not report blood results for one of these 20 because that person was the only PEI participant in an age group.

8. Comment: "The first paragraph within the Target Population would appear to provide ammunition for HB 4617 and SB 0390 regarding testing for properties before they can be designated facilities by MDEQ. MDEQ sampled soils on properties believed to be frequently flooded and suggested those properties as candidates for the PEI study. The soil results of the PEI still only found 15/22 properties to be above 90 ppt. DEQ is currently making assumptions that properties in the Flood Plain and in Midland are above 1000 ppt. Based on this information MDEQ was wrong 32% of the time in speculating for 90 ppt. The error rate will likely be much higher when speculating for 1000 ppt. Should properties be declared facilities based solely on the current available information? More testing may be warranted."

Response: The comment is noted; however it refers to a program not within the MDCH jurisdiction or the scope of the PEI.

9. Comment: "The most obvious conclusion isn't mentioned. All participants fell within the normal background range, even though they were hand picked in anticipation of having high levels of dioxin in their blood. The study compares a hand picked population to a random population from the US, and the hand picked group STILL was within the normal range. Our communities should take comfort from these results, even though it was a small sample size."

Response: Participants were selected for the PEI because the soil on their property was known to be impacted by dioxin contamination at concentrations greater than 90 ppt. The purpose of the PEI was to determine the level of dioxins in the indoor dust on these properties and in the blood of people living on these properties.

10. Comment: "MDCH obviously knew about the NHANES results prior to release of this report but made no mention of it." The 2001-2002 NHANES data were available from CDC as of May 2005. This dataset provides background information on all 17 2,3,7,8-substituted congeners.

Response: The Centers for Disease Control and Prevention (CDC) announced the availability of the *Third National Report on Human Exposure to Environmental Chemicals,* referred to as the NHANES report, on July 21st, 2005 **after** the PEI report was printed on July 8th and released on July 13th. This report was released by the CDC's National Center for Environmental Health (NCEH). Neither NCEH/ATSDR nor MDCH were aware that the CDC's National Center for Health Statistics (NCHS) had publicly posted the raw data on the agency's website in May 2005.

Prior to the July 2005 release of the NHANES report, NCEH scientists assured MDCH that the data presented in the report would not be usable as a comparison for the PEI data. NCEH has strongly cautioned MDCH against statistical analysis of the data available on the NCHS web site without a thorough understanding of how these data were gathered. NCEH scientists who reviewed the suggested analysis provided by the commenter have indicated to MDCH that the analysis is an inappropriate analysis of the NHANES data.

11. Comment: "Recent NHANES results indicate that nationwide background dioxin blood levels are somewhat higher for most age groups than the Patterson data suggests. When the PEI results are compared to NHANES, the PEI participants are even more within the normal ranges."

Response: The NHANES report, released on July 21, 2005, does not break the data down into age groups. Data are aggregated for all participants age 20 years and older. Patterson et al. (2004) data suggest that combining across all age groups may underestimate background dioxin levels for older age groups and overestimate background dioxin levels for younger age groups.

The NHANES report does not provide estimated total dioxin TEQ values because "the proportion of results below the level of detection was too high to provide a valid result." A comparison to the Patterson data or the PEI data is therefore not possible.

The NHANES report does provide results for each individual dioxin/furan congener. Table 93 presents the results for 2,3,7,8-TCDD (lipid adjusted). For most of the samples, the data show that 2,3,7,8-TCDD was not detected above the level of detection (LOD) of 5.8 pg/gram of blood lipid. Because the data are so limited, CDC again does not present a mean value because "the proportion of results below the LOD was too high to provide a valid result." The NHANES report does provide 95th percentiles for 2,3,7,8-TCDD for females (6.4 pg/g) and non-hispanic blacks (7.4 pg/g) but not for the general population. By comparison, Patterson presents 95th percentiles of 5.0 pg/g for people ages 45-59, 10.9 pg/g for people 60 years and older, and 6.0 for people of all ages. Differences in how the data are aggregated prevent a direct comparison; however these values are very similar.

NCEH scientists have strongly cautioned MDCH against any further statistical analysis of the data presented in the 2005 NHANES report. Additional data may be forthcoming and will be incorporated into a revised PEI report when available.

12. Comment: "There is discussion of a comprehensive exposure investigation in bullet point #2. The UMDES is that study yet you make no mention of it. The UMDES has been designed as a quality study with significant input from the best scientists from ATSDR, EPA, and others. MDCH has also offered input into the UMDES and is a regular participant on the conference calls. Yet, there seems to be almost a denial of the existence and importance of this study. MDCH needs to publicly explain their position on the UMDES."

Response: MDCH agrees that the dioxin study conducted by the University of Michigan and other studies funded by the Dow Chemical Company (e.g., bioavailability studies) will likely fulfill the list in bullet #2 of the Recommendations section. However, it is the practice of MDCH and ATSDR to make general recommendations rather than endorsing specific actions by either a responsible party or a state or federal clean up program. For example, MDCH may recommend that a plume of contaminated groundwater be remedied, but will not specify who should conduct the remedy or what technology should be used to do so.

13. Comment: "Community should take some comfort from the results. It's encouraging that we don't have high levels in these 21 people."

Response: MDCH concurs with the comment.

14. Comment: It is important for reviewers of the PEI report to understand how the individuals that actually participated in the PEI were selected and the degree to which this selection technique deviated from the protocol. It is unclear whether there was an effort to adhere to the selection protocol or whether the protocol was dismissed entirely.

Response: The participant selection process shown schematically in Figure 2 on page 8 of the PEI protocol was closely followed for selection of the PEI participants. MDCH had approval from the ATSDR to analyze up to 25 blood samples at the CDC laboratory. The ***Target Population*** section of the PEI report (page 3) details the steps followed to identify the final participants. Soil sampling conducted by the MDEQ identified 15 properties on which total dioxin levels in soil exceeded 90 ppt. Properties on which total dioxin levels in soil did not exceed 90 ppt were excluded from the PEI. The Eligibility Questionnaire (Attachment A of the PEI protocol) was administered by phone to the people living on these properties. Four properties were eliminated because the residents had recently lost weight or declined further participation. The selection process thus identified 21 eligible and willing participants. One person did not keep the appointment for a blood draw and was eliminated from the PEI. Since MDCH had not identified more than the 25 participants, it was not necessary to score and rank the participants for the purposes of limiting the number of blood analyses authorized by ATSDR.

15. Comment: The commenter asks for information pertaining to the fraction of the floodplain population represented by the PEI participants, was the selection technique random or biased or on a volunteer basis, what statistical methods were used to select the number of 25, does use of only 21 impact the validity of the PEI?

Response: The PEI protocol (May 25, 2004) states on page 14 "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." No statistically-based sampling strategy was used to enroll participants; therefore the number of final participants does not affect the validity of the PEI.

16. Comment: Were only certain geographic regions of the floodplain between Saginaw and Midland evaluated and, if so, why?

Response: Properties included in the PEI were believed to be frequently flooded by the Tittabawassee River. No effort was made to target specific areas of the floodplain.

17. Comment: How many residents were asked but refused to participate. Did any residents agree to participate but then drop out.

Response: The commenter is referred to the Target Population section on page 3 of the PEI report.

18. Comment: Were participants made aware of the nature of the study?

Response: The commenter is referred to Attachment A of the PEI protocol, which provides the information provided to participants as part of the Informed Consent. In addition, MDCH remained available to participants throughout the conduct of the PEI.

19. Comment: Are the dietary habits of the participants understood? Was there any attempt to keep a dietary diary?

Response: The commenter is referred to the PEI protocol. No dietary diary was included in the protocol. The Questionnaire is provided in Attachment D and includes questions about consumption of fish, wild game and home-grown vegetables and animal products.

20. Comment: Why was soil sampling conducted on only 22 of the 25 properties of interest identified by the MDCH?

Response: Three of the 25 property owners declined participation in the PEI.

21. Comment: A review of the soil sampling results in the PEI report indicates that the study protocol was not followed as there is no information reported regarding high use areas.

Response: The PEI protocol does not specify that soil sampling results for high use areas will be presented separately from the remainder of the soil data. Soil sampling was conducted as specified in the PEI protocol.

22. Comment: The PEI report should report data in a format that utilizes [soil sample] categories defined in the approved study protocol.

Response: The PEI protocol does not define categories for soil samples. However, MDCH will clarify that samples indicated as near the House in Table 2 are the samples taken near the most often used entryway identified by the home owner.

23. Comment: MDCH failed to conduct comparisons of congener profiles to the normative data. The researchers should discuss the noncompliance issues and provide explanation regarding why there was noncompliance with the approved study protocol.

Response: The last paragraph on page 8 or the PEI report indicates that background data for dioxin and furan congeners other than 2,3,7,8-TCDD were not available from the CDC in July of 2005. Congener specific comparisons will be presented in an amended PEI report as they become available.

24. Comment: The PEI report should provide the detection limit achieved for the individual congeners in blood serum.

Response: Detection limits for chlorinated dibenzo-dioxin in blood serum on a lipid adjusted basis in pg/g (ppt) were 0.5 to 1.4 for 2,3,7,8-TCDD, 0.5 to 2.3 for penta, hexa, and hepta-CDD congeners, and 49.0 to 93.5 for octa-TCDD. Detection limits for chlorinated dibenzo-furan (CDF) on a lipid adjusted basis in ppt were 0.4 to 1.3 for tetra- and penta-CDFs, 0.4 to 1.5 for penta, hexa, and hepta-CDF congeners, and 1.4 to 3.3 for octa-CDFs. Detection limits for coplanar polychlorinated biphenyls (PCBs) ranged from 1.4 to 3.3 ppt. This information has been added to the Blood Results section in the PEI report,

25. Comment: The PEI report describes only bulk dust concentrations. There does not seem to be any information provided regarding dust loading. This information can be useful when conducting human health risk assessment.

Response: This discussion has been added to the PEI report in the Indoor Dust Results section.

26. Comment The PEI report should attempt to match dust total dioxin TEQ concentrations with soil total dioxin TEQ concentrations. This should be done on a concentration basis and congener profile basis. Congener-specific data was not provided or analyzed as indicated in the PEI protocol. It is impossible to determine if the dust TEQ resembles the soil TEQ.

Response: ATSDR and MDCH have concluded that the number of soil and dust samples collected for the PEI is not sufficient to support the statistical analysis suggested by the commenter.

27. Comment: It is interesting that the PEI report provides 95% confidence intervals for the Patterson et al. (2004) dataset. Confidence intervals were not provided in the publication itself so

they must have obtained from Patterson et al. or calculated by MDCH/ATSDR. The MDCH and ATSDR should make these [this] data available to the general public so that interested individuals can verify these calculations.

Response: 95% confidence intervals for the means provided in the Patterson et al. (2004) dataset were calculated using the standard deviation provided in the published data. The standard Excel spreadsheet formula of $\bar{x} \pm 1.96\left(\sigma/\sqrt{n}\right)$ (i.e., the CONFIDENCE worksheet function) was used to perform the calculations.

28. Comment: There appear to be errors in Tables 4 and 5.

Response: MDCH apologizes for these errors. The following corrections have been made:

- Table 4: the lower 95% confidence interval for the PEI age group 45-59 has been corrected from 22.0 to 22.7 ppt.
- Table 4: the minimum value for the 60+ age group in the background estimates has been corrected to 3.4 ppt.
- Table 5: the confidence intervals for the background estimates for the age group 45-59 have been changed to 1.7 and 2.1 ppt.

MDCH has also added standard deviation values to these tables.

29. Comment: The PEI report indicates that participation was limited to adults aged 18 years or older and who had lived at their current residence in the flood plain for at least five years. The authors should explain the significance of the 5 year time limit.

Response: An explanation has been added to the "Target Population" section.

30. Comment: Were the PEI analytical results validated and if so, what was the conclusion of the validation effort?

Response: The analytical results for the PEI were validated by the laboratory performing the analysis. All data reported in the PEI met the data quality requirements specified in the applicable analytical methods. The blood serum samples were reviewed by a quality assurance officer at the CDC laboratory to assure that they conformed to acceptable quality standards. All dust and soil samples were analyzed at Eno River Labs, LCC according to procedures described in EPA Method 1613B (September 1997).

31. Comment: What method was used for the determination of lipid content of the blood?

Response: Serum total lipids are calculated using an enzymatic 'summation' method as described in Akins J.R., Waldrep K., and Bernert J.T. Jr. "The Estimation of Total Serum Lipids by a Completely Enzymatic 'Summation' Method. Clin Chim. Acta. 184: 219-226 (1989).

32. Comment: The MDCH and ATSDR should describe how non-detects are handled in Patterson et al. (2004) and then indicate if they were handled in a similar manner for the PEI.

Response: In both Patterson et al. (2004) and the PEI, congener-specific analytical results that were below the limit of detection (i.e., non-detect) were set at one-half (1/2) the detection limit to quantify total dioxin TEQ results. A discussion has been added to the PEI report.

33. Comment: Coplanar PCBs were measured in blood to facilitate comparison with the results of Patterson et al. (2004). Where coplanar PCBs not measured in soils and dusts? There are other DLCs in the environment such as polybrominated biphenyls, polychlorinated naphthalenes, polybrominated dipehyl ethers etc. Why were these DLCs not evaluated in the PEI?

Response: The DEQ had analyzed many soil samples for co-planar PCBs and other DLCs as part of previous studies of the Tittabawassee River floodplain. In every instance, PCBs were found to be a very minor component (1% or less) of the total TEQ in soil samples from the Tittabawassee River floodplain. Based on the previous analysis, the DEQ decided to not expend limited state funds for this purpose.

34. Comment: A possible explanation for the lack of a trend in soil concentrations moving from the river towards the homes is that there is no relationship between dioxin levels near the homes and those near the river.

Response: While that is certainly a possible explanation, extensive soil and sediment sampling in the Tittabawassee River and the flood plain indicate that the river and the flood plain are contaminated with dioxins and furans. Further, that concentrations tend to be higher near the river and generally decrease with decreasing distance from the river except where human activities have relocated flood plain soils.

35. Comment: MDCH and ATSDR should provide information about the non-detects associated with TCDD. What percentage of PEI samples was ND for TCDD?

Response: 2,3,7,8-TCDD was reported to be below the laboratory's level of detection in two of 20 PEI (10 percent) blood specimens. Information of limits of detection have been added to the Blood Results section.

36. Comment: It is recommended that the interview results be summarized in a table in a quantitative fusion.

Response: The intended purpose of the PEI was to test sampling criteria, questionnaire and sampling methods prior to implementation of a larger investigation, and to provide dioxin levels in soil, indoor dust and blood samples for a limited number of people. The protocol does not indicate that MDCH will provide any rigorous interpretation of the results of the questionnaire or the relationship of the results with that of dioxin blood results. A quantitative summary of the questionnaire results will not add to the general public's understanding of the results.

37. Comment: Why do the MDCH and ATSDR not mention the USEPA policy of 1 ppb TCDD TEQ for cleanup at Superfund sites?

Response: The flood plain of the Tittabawassee is not a federal Superfund site nor is EPA the lead regulatory agency for this site. The flood plain is being addressed under the Corrective Action program administered by the Michigan Department of Environmental Quality under authority of the Resource Conservation and Recovery Act (RCRA) delegated to the State of Michigan. As such, any action taken in the flood plain is subject to State of Michigan law. The 90 ppt standard is a promulgated rule under the Michigan Natural Resources and Environmental Protection Act, 1994, PA 451, as amended. Further, the ATSDR dioxin policy indicates that soil total dioxin TEQ levels greater than 50 ppt warrant further study.

38. Comment: The MDCH and ATSDR present a discussion of the basis of the 90 ppt criterion. It is unclear how this value is calculated. Details about the formula and how this value was generated should be provided.

> **Response:** Derivation of the MDEQ cleanup criterion is outside the PEI. The commenter is referred to the MDEQ for this information.

39. Comment: To be sure it [the PEI] was NOT a study.

> **Response:** The PEI is an *Exposure Investigation*. It was not and was never intended to be a "study".

40. Comment: It is only a presumption on the part of the MDCH that human health may be affected by the levels of dioxin in our area.

> **Response:** Whether or not dioxin contamination in the city of Midland and along the Tittabawassee River has affected human health cannot be known until appropriate studies are conducted. However, the presumption that dioxin exposure ***can*** affect human health is based on sound scientific research that is endorsed by the World Health Organization, the U.S. Department of Health and Human Services, the Centers for Disease Control and Prevention, and the U.S. Environmental Protection Agency.

41. Comment: Designating blood levels that are above the 90^{th} or 95^{th} percentile of the average background levels as "elevated" in the draft report is incorrect and may lead laypeople to believe that there is a health risk in this population.

> **Response:** The PEI protocol indicated that MDCH would consider individual blood serum dioxin results greater than the 90^{th} percentile of the normative data to be elevated. The PEI was an exposure investigation and does not address potential health risks that may occur at these blood levels.

42. Comment: The final report should take full advantage of the available information and demonstrate correlations, or their lack, between soil and house dust DLC levels, between soil and blood DLC levels, and between house dust and blood DLC levels.

> **Response:** This commenter provided the following comment on the PEI protocol, "Conclusions regarding the source of an elevated blood level can only be determined after careful analysis of a number of factors; e.g. age, body weight, recent weight loss, occupation, lifestyle, lipid levels, smoking and diet, particularly consumption of local fish. Only after these considerations along with a careful analysis of possible exposure pathways can conclusions regarding possible exposure sources be reliably made. This level of evaluation is beyond the scope of this study from both a design and statistical analysis perspective."
>
> MDCH concurs with the commenter's original thoughts on this issue. The PEI report states on page 11, "Because the numbers of PEI participants and properties are small, determining whether DLC levels in soil correlate with levels found in participant's blood is not possible."

43. Comment: The lack of discussion as to the statistical analysis performed makes it unclear what was done and whether what was done was performed correctly.

Response: Simple descriptive statistics - range, mean and 95% upper confidence interval on the mean – were calculated for dioxin blood serum levels using standard statistical formulas. Actual values were presented for soil and house dust DLC levels and no statistics were performed on these values, therefore no discussion of statistical analysis is presented.

44. The final EPI report must avoid stating implicitly or explicitly that the PEI results are anything more than background DLC levels, or imply that they have some health significance.

Response: The PEI reports repeatedly states that "the level of DLCs measured in participants blood serum samples fell within the range of preliminary estimated background levels." The PEI report does not address the likelihood of health effects as a result of dioxin blood levels.

45. Comment: MDCH and ATSDR should refrain from making indeterminate or general recommendations about reducing some unidentified exposure to DLCs that is not supported by the data.

Response: The application of objective sound science indicates that exposure to DLCs at some level will cause adverse health effects in human populations. It is prudent public health policy, therefore, to caution people to reduce their exposure to DLCs whenever possible. MDCH and ATSDR will continue to provide health education to residents and health care professionals so that they can make informed decisions to limit their exposure to DLCs. In addition, the MDCH will continue to maintain and update fish and wild game advisories for the Tittabawassee River and flood plain as we deem necessary.

46. Comment: Since the MDCH and the MDEQ consider this population to be among the most highly exposed persons in the area, these findings should provide reassurance to the regulatory authorities as well as the larger flood plain community.

Response: MDCH and MDEQ do not consider people who live on contaminated soil to be the most highly exposed persons in the area. As indicated in the report, very few of the participants regularly ate fish, wild game, or other animal products produced in the floodplain. It is likely that those people who regularly consume these foods are more exposed than people who simply live on contaminated soil.

The PEI report repeatedly states that the results of the PEI cannot be generalized to the larger floodplain community.

47. Comment: The sampling protocols and interview instrument should be attached to the final reports as appendices.

Response: These are contained in the PEI Protocol (May 25, 2004). Because of the length of these documents, MDCH and ATSDR decided not to attach them to the PEI report but instead provided information on how to obtain copies from the MDCH web site.

48. Comment: What determined the number of soil samples taken on a property?

Response: At least two samples were obtained from each property, one from the area that would frequently flood near the river, another outside the frequently flooded area, and one near the most often used entrance to the home. In several instances, samples were taken in a transect from the area near the river towards the property boundary at the

road. The samples were biased with prior knowledge of flooding and residential use of the property.

49. Comment: It is not clear if individual soil samples were analyzed or if the individual samples were homogenized into a combined soil sample.

Response: Soil samples were not combined. Each individual sample was analyzed separately.

50. Comment: A single sample for the house entrance areas is insufficient and arbitrary.

Response: The intent of this sample set was to obtain evidence of contamination. The sample plan was not designed to adequately characterize the property for contamination or to determine the extent of the contamination.

51. Comment: It is not clear why some soil samples were taken at one inch and some were taken at three inches below the ground surface. Samples taken from the top 2 centimeters are preferred to assess direct contact exposures.

Response: The samples reported as obtained from 0-3" below the ground level were from a prior sample set. The samples obtained as part of the Phase 3 Residential Sampling were taken from 0-1" below ground level. All of the surficial samples were obtained from soils just below the vegetation.

52. Comment: Physical characteristics of a property that were used to determine the location of soil samples should be clearly defined.

Response: The intent of this sample set was to obtain evidence of contamination. The sample plan was not designed to adequately characterize the property for contamination or to determine the extent of the contamination.

53. Comment: Combined dust samples from different houses are not comparable. The important information on the relative percentages of wood surfaces, carpet, and so forth vacuumed for the indoor dust sample in each house is missing and needs to be included. It was not documented how often the sample areas were cleaned in the past and when the last cleaning occurred.

Response: If dust sampling results were being used to quantify exposure, MDCH agrees this would be important information. However, at the request of this commenter, the PEI protocol was altered to indicate that dust samples would be used only to "indicate the potential for exposure" therefore the information now requested is not necessary to meet the requirement of the protocol.

54. Comment: What are the "unpublished MDEQ –data from 2004 in tables 2 and 3 (page 6)?

Response: The soil data shown in Table 2 are taken from an MDEQ web site report entitled "Preliminary Analytical Results for Soil Samples Taken at Residential Properties in the Tittabawassee River Floodplain by the DEQ in June through December 2003." These data are available at http://www.deq.state.mi.us/documents/deq-rrd-TR-PreliminaryResultsFeb2004.pdf. The citation in the PEI report has been revised appropriately.

The indoor dust sample data shown in Table 3 are taken directly from analytical reports provided by TriMatrix Laboratories, Inc. The citation in the PEI report has been revised appropriately.

55. Comment: It is unclear if all samples have been analyzed for the homologue sums as indicated in EPA Method 1613.

Response: Page 4 of the PEI report states that "Samples were handled, stored, and shipped in accordance with applicable U.S. Environmental Protection Agency (EPA) and Department of Transportation guidelines. Discrete soil samples were analyzed at Triangle Laboratory, Durham, North Carolina for DLCs using EPA Method 1613." Soil sample analysis was performed as required in EPA Method 1613.

56. Comment: Table 2 demonstrates considerable variability in soil TEQ per residence suggesting that any exposure through soil is likewise highly variable and many potential soil exposures are currently to TEQ concentrations below the 90 ppt residential value established by MDEQ.

Response: As expected, soil concentrations varied as a function of proximity to the Tittabawassee River. However, the soil sampling conducted by the MDEQ in support of the PEI was not intended to fully characterize potential residential exposures and therefore do not support the conclusions suggested by the commenter.

57. Comment: Several suggestions were made for additions or improvements for the interview questionnaire.

Response: MDCH will take these suggestions under consideration if the questionnaire is used again in the future. However, these changes cannot be made now as the PEI is completed.

Tittabawassee River Floodplain

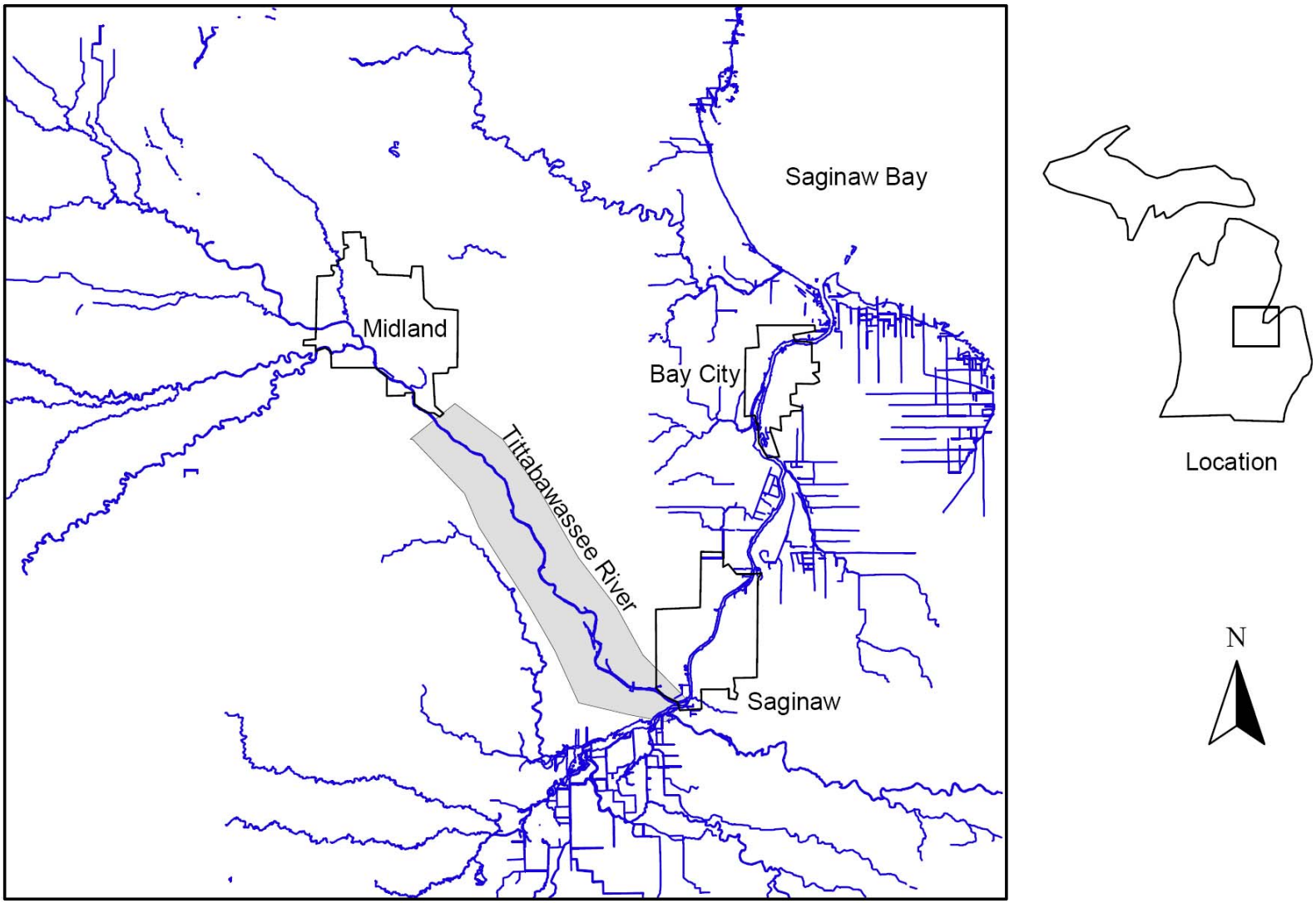


Figure 1.

Figure 2.
Comparison of Estimated Background and PEI dioxin TEQ (ages 45-59)

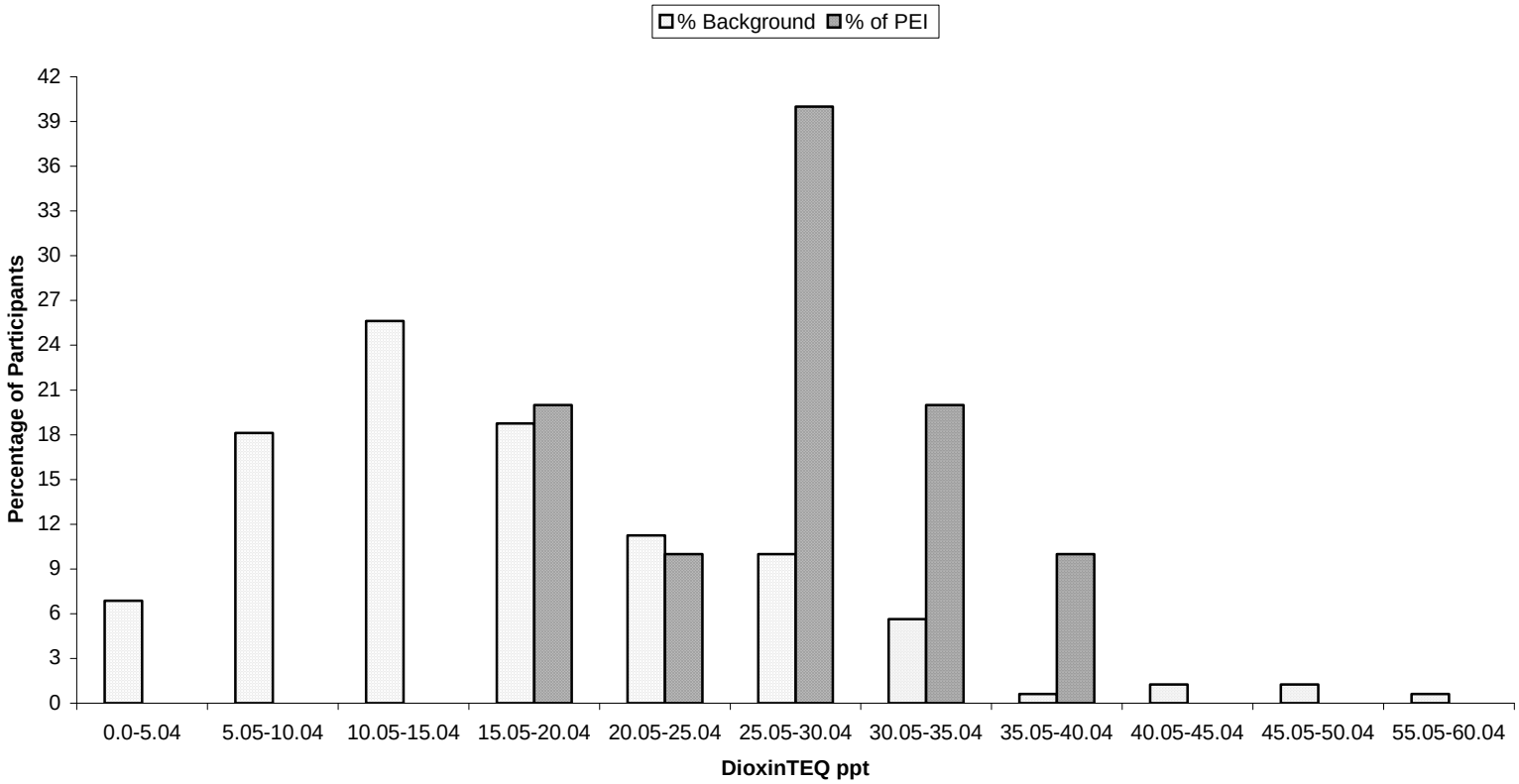
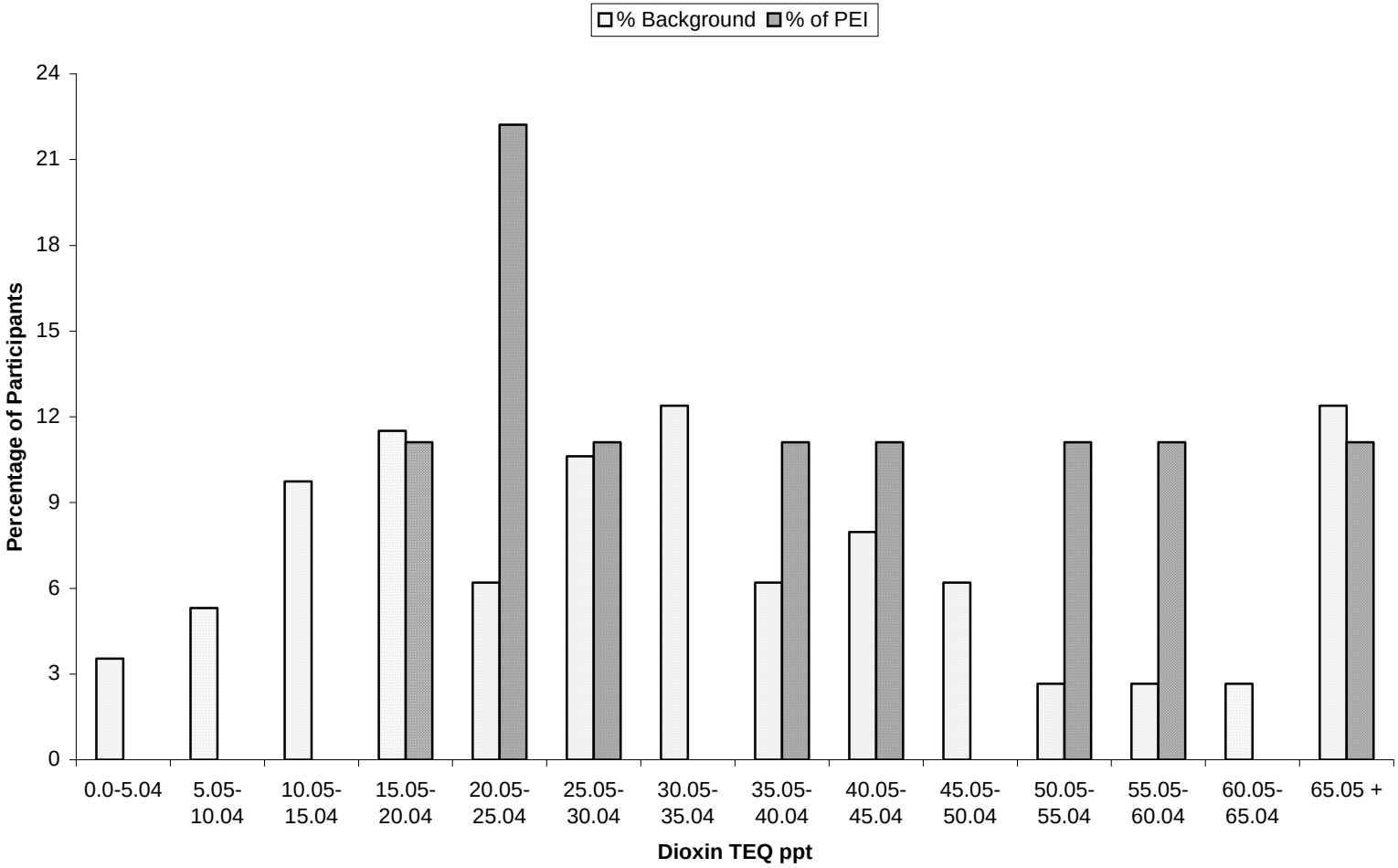


Figure 3
Comparison of Estimated Background and PEI dioxin TEQ (ages 60 years and older)



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Certification

This Tittabawassee River Floodplain Health Consultation was prepared by the Michigan Department of Community Health under a cooperative agreement with the Agency for Toxic Substances and Disease Registry (ATSDR). It is in accordance with approved methodology and procedures existing at the time the health consultation was begun. Editorial review was completed by the Cooperative Agreement Partner.

Technical Project Officer, CAT, CAPEB, DHAC, ATSDR

The Division of Health Assessment and Consultation, ATSDR, has reviewed this public health consultation and concurs with the findings.

Team Leader, Cooperative Agreement Team, CAPEB, DHAC, ATSDR