

## Comments on the draft Public Health Implications of Hazardous Substances in the 26 U.S. Great Lakes Areas of Concern

Frank Bove, DHS, March 23, 2006

### I. General Comments

It is important to mention the limitations of TRI. The “Scorecard” lists these limitations:

“While TRI is the most comprehensive national source of information about toxic chemical releases, it has critical limitations:

- 1) TRI **may significantly underreport releases**, because companies use unreliable emissions factors to estimate their releases, rather than monitor their actual emissions. Issues impacting the quality of TRI data are explained in How Reliable Are TRI Data?
- 2) TRI does not cover all toxic chemicals that have the potential to adversely affect human health or the environment.
- 3) TRI does not require reporting from many major sources of pollution releases.
- 4) TRI does not require companies to report the quantities of toxic chemicals used or the amounts that remain in products.
- 5) TRI does not provide information about the exposures people may experience as a consequence of chemical use.”

EPA lists these limitations in its brochure on TRI:

#### Limitations of TRI Data

“TRI data reflect releases and other waste management of chemicals, not exposures of the public to those chemicals. Although the Agency has expanded the TRI program, it does not cover all sources of releases and other waste management activities such as car emissions, nor does it cover all toxic chemicals or industry sectors. Beyond reporting release and waste management activities, only limited and very general information on chemical storage is provided. In addition, while many facilities base their TRI data on monitoring data, others report estimated data to TRI as the program does not mandate release monitoring.”

To supplement TRI, you may want to consider EPA’s National Air Toxics Assessment (NATA) data which covers all the HAPs including some of the IJC criteria pollutants and EPA’s National Emissions Inventory.

The Community Health Status Reports utilize indicators that can provide a community health profile for prioritization of health needs and targeting resources. These indicators

are definitely NOT sensitive indicators for environmental exposures. Indicators sensitive to environmental exposures would be: specific cancer incidence data (not mortality data which is significantly affected by access to care issues), in particular cancers that have been linked to (or at least suspected to have links to) the IJC criteria pollutants, small for gestational age or term low birth weight, specific birth defects (e.g., neural tube defects, oral clefts, heart defects, and urogenital defects), and possibly developmental disorders (e.g., autism, ADHD, or possibly an indicator of IQ deficit). Some of the CHSI indicators are not relevant to environmental exposure, (e.g., homicide), or are not health indicators at all but are indicators of SES or access to care (e.g., no first trimester care, unmarried mothers). If the interest is in characterizing the county by SES, there are better indicators available from census data or other sources, e.g., percent below poverty level, median income, unemployment rate, and percent high school graduate. Finally, the CHSI provides information on a county, but it is rare that environmental exposures affect such a large area. Most of the time, small areas (e.g., neighborhoods, census blocks) are affected. So, these limitations of the CHSI should be stated in the text. In particular, the CHSI definitely cannot be used effectively “to screen for possible associations between pollutant release and adverse health outcomes.” (chapter 7, Conclusions, page 1) The CHSI were simply not designed to accomplish this. The project was designed to assist in prioritizing health needs and allocating resources to meet these needs. Even the health outcome data (HOD) assessments (conducted at specific sites as part of the PHA; for these sites) are often conducted at a geographical unit (e.g., county, city, zipcode even census tract) that is too large to evaluate the effects of exposures from these sites or even to “screen for possible associations”. Moreover the HOD assessments often are limited by small sample sizes, too few years of data, and inaccuracies and biases that make it difficult to detect an effect of exposure when one truly exists.

There are some sites for which more recent information is necessary to determine whether complete exposure pathways exist (or have existed in the past). These documents need to be obtained so that the document is up to date.

Although so far I have been critical of the document, I want to acknowledge that the report summarizes a huge amount of material, and does a good job of doing so. This will be an important document, and I appreciate all the hard work that went into doing this. I want to congratulate you on a job well done!

## II. Specific Comments

Chapter 1, page 8, last paragraph of section 1.4 : “If PCBs have been detected at sites with health outcomes of LBW, the association between the potential exposure to PCBs and LBW at a site would be confounded by the simultaneous presence of lack of medical care during the first trimester of pregnancy (or unmarried mother status).” Change “would be confounded” to “could be confounded” since there is no guarantee that these two risk factors would be confounders. To be confounders, they would have to be associated with exposure status. In addition, there are other important risk factors that could be potential confounders such as smoking, occupational exposures, and other

measures of SES such as education and race/ethnicity of the mother. I think it is also important to state the limitations of the CHSI in this section.

Chapter 1, page 8, section 1.5, first sentence: I would describe this report as descriptive rather than “investigational” and not a “study”.

Chapter 1, Section 1.10 Limitations of the report: There are a number of risk factors besides “lifestyle factors” that are potential confounders of health outcomes such as low birth weight including SES factors, occupational exposures, maternal illnesses and medications, etc. Use of the CHSI and HOD may not only miss “subtle health outcomes” such as IQ deficits, but also not-so-subtle outcomes such as the incidence of specific childhood and adult cancers, small for gestational age, and specific birth defects.

Chapter 2, section 2.2.4.1 Hazardous Waste Sites, page 17: the City of Rochester – APCO site was a potential source of IJC pollutants but the site is now remediated.

### Specific Comments for Chapter 3, Lake Erie

page 30, Abby Street site: the thyroid conditions identified in the survey were ~~se-~~ reported. The NYSDOH investigated further (Health Consultation, April 2004) and obtained medical record confirmation for half of those reporting a thyroid condition. The NYSDOH concluded that: “This follow-up showed a variety of predisposing conditions for almost all of the participants in the follow-up with thyroid conditions, and therefore suggests that further investigation, seeking alternative explanations for these diagnoses, is not warranted.” Also make changes in the summary on page 36 (Issues for Follow-up).

page 34, Pfohl Brothers LF: In the conclusion, I would replace the words “probably contributed to human...” with “possibly contributed...”, at least for human exposure burden, since no complete exposure pathway was evident. (You could say “possibly but not likely” contributed to human exposure). The health outcome data did indicate unusual patterns of breast cancer and prostate cancer incidences but it was concluded that these excesses were not site related.

page 35, section 3.1.4.1 Hazardous Waste Sites: Can you get more recent info on Ernst Steel (e.g., whether site is fenced or remediated)?

Page 57, Fields Brook site: “. Potential exposure pathways included absorption through skin or through ingestion.” You should mention that this is an onsite exposure pathway.

Page 58, Laskin Site: again, the complete exposure pathway is onsite.

Page 59, New Lyme LF: the complete exposure pathways are all onsite.

Page 60, 3.3.4.1 Hazardous Waste Sites: You should say that the Fields Brook Site is remediated (not “under remediation”).

Page 100, Contaminants of Concern for Carter Industrials: “Inhalation of PCB-contaminated fugitive dusts was considered a principal route of exposure because PCBs were found in particulates in rain gutters of nearby homes.” Change “nearby homes” to nearby homes.

Page 101, Ford Motor Co. Allen Park Clay Mine: Smoking, at best, is a very minor risk factor for brain cancer. Alcohol use is not a risk factor for brain cancer. Some occupational exposures appear to be risk factors, in particular exposures involving PAHs, such as occupational exposures to asphalt. But for the most part, there is little known about risk factors for brain cancer. So I would change the summary here to state that some occupational exposures might be related to brain cancer including those involving PAHs and benzene exposure, but that little is known about the causes of brain cancer.

Page 104, Master Metals: the 2005 health consult stated that there is no public health hazard. Also, make change on page 114, Issues for Follow-up, since the site has been remediated.

Pages 108-9: Hi-Mill: It should be mentioned in the conclusion that workers were likely exposed to TCE contaminated drinking water and that exposures were through ingestion (before the contamination was known) and, after bottled water was distributed, through inhalation/dermal if they took showers or washed their hands with the water.

Page 110, Rose Twp Dump: “**Category of Public Health Hazard:** This site was categorized in 1888 by ATSDR...” I think you mean 1988, but is there new information on this site? In particular, is there new information on private well contamination?

Page 126, G & H LF: “**Public Health Outcome Data:** A 1982 health outcome study...” Change the word “study” to assessment. This is not a study!

Page 128, S. Macomb Disposal: The section describing the public health outcome data is not accurate. A “death survey” was conducted by 2 individuals but the data were deemed insufficient due to lack of information on the geographic boundaries of the survey (and I suspect the time period boundaries were also not clear!), the types of cancers and important risk factors. There was a physical examination report on one resident that indicated the person had a persistent rash and hepatitis but it was not clear this had anything to do with the site. Finally there was an autopsy finding for one individual who died of cirrhosis, but the medical record was not available.

#### Specific Comments for Chapter 4, Lake Huron

Page 138, Bay City Middlegrounds: “Cancer incidence for the zip code area including the site and Bay City west of the Saginaw River (48706) and for the zip code area including Bay City east of the Saginaw River (48708) for 1990 through 1993 indicate a slight, statistically significant elevation in incidence and rate for the entire period 1990-1993 (but not for any single year) in 48706, as compared with age- and sex-specific incidence rates for Michigan. None of the incidences or rates for 48708 were statistically

significantly increased.” The standardized morbidity rate (SMR) for all cancers for zipcode 48706 was 1.07 for the combined period 1990-1992. For the individual years, the SMR was also around 1.07, so there is no difference in the SMRs among these years; it is essentially 1.07. The only reason the 3-year combined SMR is statistically significant (and the single year SMRs are not) is due to larger numbers of cancer cases when you aggregate over 3 years. So I would delete the phrase “(but not for any single year)”. It is also not relevant to evaluate each year separately unless there is a reason for this based on the exposure situation.

Page 143, Velsicol site: The MI Dept of Health has published a PBB fact sheet which summarizes what has been found for this cohort (the PBB registry), and this should be used to summarize the public health data.

Page 145, Spiegelberg dump: “...the sites were categorized as *Public Health Hazards* (category 4)...” I think you mean category 2.

Page 148, Dow: “An analysis of cancer incidence data for zip codes 48640 (south west area of Midland including the Dow plant site) and 48642 (area northeast of the Dow plant) as compared with Midland County, Bay County, and the state of Michigan showed no elevated incidences of specific cancer types in these two zip code areas.” Since no tables were provided in the health assessment, I cannot tell whether “no elevated incidences” means that the incidences (SMRs) were close to 1.0 or whether what is meant is simply that the SMRs were not statistically significant. Given the likely low statistical power at the zipcode level for specific cancers, it is important to know whether the SMRs were close to 1.0 (i.e. not elevated) or whether they were not close to 1.0 but were simply not statistically significant. It is also not clear why the data were difficult to interpret. Later on page 152, it is mentioned that the excess in all cancer incidence was in the zipcode that was upwind from the site. That should be mentioned here as well.

The Dow worker study is very likely affected by healthy worker effect biases. That is the reason why deaths were lower than expected. These biases might have also led to underestimates of the excesses found for specific cancers. I do agree that this study is probably not relevant to residential exposures, but it should be stated why this is so, i.e., that the exposure situation is probably very different for workers.

Page 149, Tittabawassee River site: The conclusion section should mention the lack of data on possible exposures.

Page 152: The county CHSI data should be summarized in the text.

#### Specific Comments for Chapter 5, Lake Michigan

Page 165, Dupont site: I disagree that there is no completed exposure pathway. Private wells were contaminated. This should be mentioned in the conclusion as well.

Page 173, Section 5.1.4.1, Hazardous Waste Sites: for the Ruddiman Creek site, children are *possibly* exposed to *sediments in the creek*.

Page 183, Rockwell site: In the conclusion, it is stated that the site "...probably contributed to human exposure...", but no evidence is provided for this statement. What is the completed exposure pathway?

Page 184, Allied Paper: the Public Health Hazard category is 2, not 3. Is there more recent information on the proposed fish consumption study?

Page 185, Auto Ion site: The conclusion states that the site contributed to human exposure, but no completed exposure pathway was mentioned.

Page 197, American Chemical Services: the cancer incidence health outcome data was for the entire town, and therefore not very useful for determining any problems in the 8 block area. Moreover, the population of the city (around 17,000) and the amount of incidence data, 3 years, makes it likely that even at the level of city, there is little statistical power. The county mortality data is much less useful as you point out.

Page 198, Midco I: It is not clear to me why this is a category 2 when there is no completed exposure pathway.

Page 200, 9<sup>th</sup> Ave Dump: The conclusion states that the site may have contributed to human exposure but no completed exposure pathway is mentioned.

Page 205, West Pullman Iron & Metal: "In 1985, some people were diagnosed with lead poisoning." The "some people" were workers involved in demolition and salvage work, and this should be mentioned in this sentence instead of "some people".

Page 223, Outboard Marine: In the summary of public health outcome data, a study of Lake Michigan fish eaters is mentioned but no results are given. There was a study published in Environmental Health Perspectives in June 2001 (Vol 109, #6) on "Memory and learning in older adults exposed to PCBs via consumption of Great Lakes fish" that seems to be part of this research program and these results should be mentioned here. I am not sure if other studies have been published on Lake Michigan fish eaters as part of this research program.

Page 224, Precision Chromium: Are there any recent data on the public water system?

Page 226, section 5.4.4.1 Hazardous Waste Sites: the last paragraph mentions vinyl chloride in groundwater migrating to a municipal well. Has it reached the well yet?

Page 236, Fadrowski Drum: The conclusion states that the site has not been associated with a completed exposure pathway, but the section on exposure pathways mentions a soil pathway that is completed. In the public health outcome data summary, the effort

was definitely not a “disease cluster investigation” but rather a health outcome data assessment.

Page 237, Former Tannery: In the conclusion, emphasize that asbestos is an onsite threat.

Page 239, NW Barrel: The conclusion should mention that during remediation work, VOCs were released into the air causing symptoms to occur among local residents.

Page 239, P & G Bus Service: The conclusion should emphasize that onsite soils had HCB levels of concern.

Page 241, St. Francis Auto: You could mention in the conclusion that children playing in the vacant lot could be potentially exposed.

Page 243, section 5.5.4.1 Hazardous Waste Sites: the last sentence mentions that the Boerke Property may pose a health threat to “on-site recreational visitors”. I think you should instead label them trespassers.

Page 254, Sheboygan Harbor: You might also mention that the small numbers of people studied was also a limitation.

Page 261, Better Brite Plating: this should be updated with the 1998 PHA and 2002 Health Consult which are both online.

#### Specific Comments for Chapter 6, Lake Superior

Page 290-1, St. Louis River: The new Consult is available, and based on what I read, there are probably not any completed exposure pathways.

## Ashizawa, Annette (ATSDR/DTEM/ATB)

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**From:** Williamson, G. David (ATSDR/DHS/OD)  
**Sent:** Wednesday, July 25, 2007 9:42 AM  
**To:** Ashizawa, Annette (ATSDR/DTEM/ATB)  
**Cc:** De Rosa, Christopher (Chris) (ATSDR/DTEM/OD); Sowell, Anne (ATSDR/DHS/OD); Bove, Frank J. (ATSDR/DHS/SRB)  
**Subject:** FW: comments to DTEM's great lakes report

**Attachments:** Comments on the draft Public Health Implications of Hazardous Substances in the 26 U.doc

Annette:

Have attached Frank's most recent comments below - My comments were duplicative, but we'll be happy to discuss if you'd like.

David

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**From:** Bove, Frank J. (ATSDR/DHS/SRB)  
**Sent:** Thursday, June 28, 2007 11:50 AM  
**To:** Kapil, Vikas (ATSDR/DHS/OD); Sowell, Anne (ATSDR/DHS/OD); Williamson, G. David (ATSDR/DHS/OD)  
**Subject:** comments to DTEM's great lakes report



Comments on the  
draft Public H...

On 10/31/2006, I was asked again to review a revised version. I had little time to do so because of Lejeune and other commitments. I made the following additional comments (I was trying to be nice!):

The report looks fine. I have two comments.

One comment is that on page 383 the text states that "unmarried mother" and "no first trimester care" are "health outcomes". They are not health outcomes but socioeconomic factors that are risk factors for low birth weight and preterm birth. I would not call them "surrogates for SES status" but instead, indicators of SES status.

On page 384, last paragraph before section 7.5, second sentence: I would add the words "might be real or" after the words "...the association between the potential exposure to PCBs and LBW at a site..." Confounding is not the only issue when evaluating health outcomes and exposures at the ecologic level. Ecological biases are also possible. But the association can also be real, especially given the epidemiological research at the individual level that suggests a link between PCB exposure and LBW. So, if a county has both elevated LBW and PCB contamination, then the "association" can be real, or biased by confounders and/or biased by ecological bias.

Note: "LBW" = low birth weight

"SES" = socio-economic status (also involves "cultural factors" that impact social/economic/class status)

"PCBs" = polychlorinated biphenyls

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## Ashizawa, Annette (ATSDR/DTEM/ATB)

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**From:** Orloff, Kenneth G. (ATSDR/DHAC/OD)  
**Sent:** Monday, November 06, 2006 3:27 PM  
**To:** Ashizawa, Annette (ATSDR/DTEM/ATB)  
**Subject:** Great Lakes comments

### **Public Health Implications of Hazardous Waste Sites in the Twenty-Six Great Lakes Areas of Concern (AOC)**

Introduction - Page 4: *"Health-based guidance values are used by ATSDR assessors to determine if the levels of toxic substances at a site exceed guidance values for health."*

This statement is not quite accurate, since exceeding a comparison value (such as an EMEG) will not necessarily result in an adverse health effect. Comparison values are not thresholds of toxicity. A more accurate statement is,

"ATSDR health assessors use comparison values to identify chemicals that need to be further evaluated for their impact on human health under site-specific conditions."

Chapter 7 - Page 9: *"Health status indicators that exceed the upper 90% confidence limit of the peer county range and also exceed U.S. rates are highlighted in this document."*

It is not clear if the comparison is to the 90% UCL of the mean, median, or range (?) of the county rates. If the comparison is to some measure of central tendency, this seems to be a rather low standard to identify something as being elevated. By definition, about half of any population will exceed the mean or median. (I have no sense of how wide the 90% UCL is.) In our Exposure Investigations, we typically define elevated as being above the 95<sup>th</sup> percentile of a comparison population or about 2 standard deviations above the mean.

Chapter 7 - Page 10: Limitations of the report

Another limitation that might be mentioned is that when you search for multiple adverse health outcomes in a community, you would expect some outcomes to be elevated by pure statistical chance; the more outcomes you look for, the higher the probability of a "false positive."

*Executive summary:* A recommendation is made to conduct other health studies which examine sensitive health outcomes such as cognition, immune function, and fertility.

Most environmental epidemiological studies suffer from poor characterization of exposure. Living in an area with environmental contamination is a very poor surrogate for exposure. In order to increase the value of such studies in assessing the health impact of environmental contamination, they should incorporate a measure of an individual's exposure to the contaminant of concern (i.e., biomonitoring).

DHAC concurs with this document and offers the above comments for consideration.

Ken Orloff, ADS

**Ashizawa, Annette (ATSDR/DTEM/ATB)**

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**From:** Welsh, Clement (ATSDR/DRO)  
**Sent:** Tuesday, November 07, 2006 8:23 AM  
**To:** Ashizawa, Annette (ATSDR/DTEM/ATB)  
**Subject:** FW:

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**From:** Welsh, Clement (ATSDR/DRO)  
**Sent:** Monday, November 06, 2006 2:09 PM  
**To:** Ashizawa, Annette (ATSDR/DTEM/ATB)  
**Subject:** RE:

Annette,

It appears that there are about 20 references in the current document. (There are obviously many more studies that have described issues in the Great Lakes Area -- but not cited here). However one of the initial portions mentions that over 100 ATSDR documents were used to compile the material summarized in the report. It would be helpful to reference those ATSDR documents somewhere.

Clem

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**From:** Ashizawa, Annette (ATSDR/DTEM/ATB)  
**Sent:** Monday, November 06, 2006 2:02 PM  
**To:** Welsh, Clement (ATSDR/DRO)  
**Subject:** RE:

Clem,  
There is a reference list at the end of chapter 7. Is the sufficient or were you thinking of something else?  
Thanks.  
Annette

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**From:** Welsh, Clement (ATSDR/DRO)  
**Sent:** Monday, November 06, 2006 1:19 PM  
**To:** Ashizawa, Annette (ATSDR/DTEM/ATB)  
**Subject:**

Annette,

Comments on the Great Lake Report.

It would be helpful to add a bibliography of the ATSDR documents. These are "relied-on" for the assessments in the document, and would help future investigators following the release of the report.

I would like to see what might be called an "executive summary map". This would be a map of the entire region that would show the sites (for all lakes) where the primary contaminants are still a concern (i.e., not remediated or controlled). This would give readers a regional view of the problem vs. a site by site view.

One of the referenced in the reference list is incomplete (see Schantz).

Hope these are helpful,

Clem

1/15/2008

**COMMENTS FROM ATSDR DIVISIONS  
REGARDING THE AOC REPORT  
AND DTEM'S RESPONSE**

**I. DTEM Responses to Comments from Mark Jackson, Ph.D., DRO, regarding the DTEM Report "Public Health Implications of Hazardous Substances in the Twenty-Six U.S. Great Lakes Areas of Concern".**

**DRO:** 1a) It may be described in another section of the document, but the criteria for selecting which ATSDR sites have relevance to the U.S. AOCs is not clear. It appears that the geographical location of the waste site in the same county as the AOC was the basis for inclusion.

**DTEM Response:** The criterion for inclusion of sites evaluated by ATSDR is presented in Chapter 1, Section 1.1. The presence of the sites within the AOC boundaries was the key determinant for the selection of the sites included in this report.

**1b) However, there may be no relationship between those sites and the contamination in the Areas of Concern in the Great Lakes. Therefore, remediation or lack of remediation of those ATSDR-investigated waste sites may have no impact of the status of the AOCs.**

**DTEM Response:** No statements regarding the contribution to contamination of sites is made in this report. However, the inclusion of the sites is critical to provide the fullest possible characterization of contaminants located within the AOCs.

**DRO:** The summary of the ATSDR-evaluated sites would be more useful if it was in a table format where information such as date of evaluation, exposure pathway(s) evaluated, hazard category, status of remediation, exposed population, document citation, etc. could be included in a more standardized way.

**DTEM Response:** A table of the ATSDR-evaluated sites is being prepared for chapter 7.

**DRO:** The statements in the site summaries are more informative about the limitations of data reported in HazDat and the status of implementation of recommendations made in the ATSDR documents, rather than informative about the status of the AOCs.

**DTEM Response:** The statements in the site summaries are based on recommendations in the ATSDR health assessments and consultations used in this report and relate to measures intended to avert potential threats to human health. The

site summaries document the status of these recommendations and the work that still needs to be done to protect human health. As such, they provide insights regarding the potential contributions of these sites to contamination within the AOCs.

**DRO: In Table 7-1, the zero values should be changed to "not reported", since there is no verification that there are zero releases.**

**DTEM Response:**

- 'Not reported' has been added to the table.

**DRO: The references for Table 7.2 "Elevated Rates of Morbidity and Mortality within 26 U.S. Great Lakes AOCs" are not included. Are these reported in ATSDR documents?**

**DTEM Response:**

Health outcome data for the counties that immediately encompass and surround the 26 U.S. AOCs were obtained from *Community Health Status Reports* (<http://www.phf.org/data-infra.html>), Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (DHHS) and is cited in Chapter 1, Section 1.4. This information has also been added to the footnotes at the bottom of Table 7.2.

**DRO: Does a blank field mean that there is not an elevation or that it was not evaluated?**

**DTEM Response:** 'Not reported' has been added to this table to clarify this point.

**DRO: Is it based on county-wide data or specific to the site under investigation [Table 7-2]?**

**DTEM Response:** As stated in Chapter 1, Section 1.4 and in the footnote for Table 7.2 (Chapter 7), this was based on county-wide data.

**DRO: Under the Saginaw River and Saginaw Bay AOC description in Chapter 7, the list of sites is incorrect. The last 2 should be:**

**Shiawassee River**

**Tittabawasee River- Dow Chemical, Midland location**

**DTEM Response:** This point has been verified and these sites have been added to the list in chapter 7.

## **II. DTEM Responses to Comments from Clem Welsh, DRO, regarding the DTEM Report "Public Health Implications of Hazardous Substances in the Twenty-Six U.S. Great Lakes Areas of Concern".**

**DRO:** It would be helpful to add a bibliography of the ATSDR documents. These are "relied-on" for the assessments in the document, and would help future investigators following the release of the report.

**DTEM Response:**

A complete bibliography is being compiled for inclusion in the report as requested.

**DRO:** I would like to see what might be called an "executive summary map". This would be a map of the entire region that would show the sites (for all lakes) where the primary contaminants are still a concern (i.e., not remediated or controlled). This would give readers a regional view of the problem vs. a site by site view.

**DTEM Response:**

A map of the Great Lakes with the AOCs identified is now presently in chapter 1. This can now be cross referenced with the contaminant data for specific sites within the AOCs.

**DRO:** One of the references in the reference list is incomplete (see Schantz).

**DTEM Response:**

This has been corrected.

**DRO:** It appears that there are about 20 references in the current document. (There are obviously many more studies that have described issues in the Great Lakes Area -- but not cited here). However one of the initial portions mentions that over 100 ATSDR documents were used to compile the material summarized in the report. It would be helpful to reference those ATSDR documents somewhere.

**DTEM Response:**

A complete list of ATSDR references has been compiled and will appear in the revised reference section.

## **III. DTEM Responses to Comments from Ken Orloff, Ph.D., DHAC regarding the Public Health Implications of Hazardous Waste Sites in the Twenty-Six Great Lakes Areas of Concern (AOC)**

**DHAC: Introduction - Page 4:** *“Health-based guidance values are used by ATSDR assessors to determine if the levels of toxic substances at a site exceed guidance values for health.”*

This statement is not quite accurate, since exceeding a comparison value (such as an EMEG) will not necessarily result in an adverse health effect. Comparison values are not thresholds of toxicity. A more accurate statement is,

**“ATSDR health assessors use comparison values to identify chemicals that need to be further evaluated for their impact on human health under site-specific conditions.”**

**DTEM Response:**

Thank you. This statement has been added to the report in place of the original language on page 4.

**DHAC: Chapter 7 - Page 9:** *“Heath status indictors that exceed the upper 90% confidence limit of the peer county range and also exceed U.S. rates are highlighted in this document.”*

It is not clear if the comparison is to the 90% UCL of the mean, median, or range (?) of the county rates. If the comparison is to some measure of central tendency, this seems to be a rather low standard to identify something as being elevated. By definition, about half of any population will exceed the mean or median. (I have no sense of how wide the 90% UCL is.) In our Exposure Investigations, we typically define elevated as being above the 95<sup>th</sup> percentile of a comparison population or about 2 standard deviations above the mean.

**DTEM Response:**

Heath status indictors that exceed the upper 90% confidence limit of the median for the peer county range and the median of the U.S. rates are reported. This is now clarified in the report.

**DHAC: Chapter 7 - Page 10: Limitations of the report**

**Another limitation that might be mentioned is that when you search for multiple adverse health outcomes in a community, you would expect some outcomes to be elevated by pure statistical chance; the more outcomes you look for, the higher the probability of a “false positive.”**

**DTEM Response:**

The following change will be made:

Elevated rates of certain health outcomes may be due statistically to chance alone. Chance alone may not be responsible in instances such as the association between

potential exposure to PCBs at an AOC site and the simultaneous elevated occurrence of low birth weight. The association may be real, given the epidemiologic research that suggests this linkage.

**DHAC: *Executive summary:*** A recommendation is made to conduct other health studies which examine sensitive health outcomes such as cognition, immune function, and fertility.

Most environmental epidemiological studies suffer from poor characterization of exposure. Living in an area with environmental contamination is a very poor surrogate for exposure. In order to increase the value of such studies in assessing the health impact of environmental contamination, they should incorporate a measure of an individual's exposure to the contaminant of concern (i.e., biomonitoring).

**DTEM Response:**

These prospective analytic epidemiologic studies should address sensitive health outcomes (e.g., functional deficits in cognition, immune function, and fertility); confounding factors; critical exposure periods and disease latency; and the effect of mixtures of chemicals. Ecological studies are not being proposed. The proposed studies would use actual exposure data.

**IV. DTEM Responses to Comments from Frank Bove, Ph.D., DHS regarding the Public Health Implications of Hazardous Waste Sites in the Twenty-Six Great Lakes Areas of Concern (AOC)**

**DHS:** One comment is that on page 383 the text states that "unmarried mother" and "no first trimester care" are "health outcomes". They are not health outcomes but socioeconomic factors that are risk factors for low birth weight and preterm birth. I would not call them "surrogates for SES status" but instead, indicators of SES status.

**DTEM Response:**

This change has been made.

**DHS:** On page 384, last paragraph before section 7.5, second sentence: I would add the words "might be real or" after the words "...the association between the potential exposure to PCBs and LBW at a site..." Confounding is not the only issue when evaluating health outcomes and exposures at the ecologic level. Ecological biases are also possible. But the association can also be real, especially given the epidemiological research at the individual level that suggests a link between PCB exposure and LBW. So, if a county has both elevated LBW and PCB contamination, then the "association" can be real, or biased by confounders and/or biased by ecological bias.



**DTEM Response:**

This change has been made.

Submitted by: Annette Ashizawa, 11/7/06

Reviewed, revised, approved by: Dr. De Rosa, 11/17/06