December 2008

To Whom It May Concern:

The Ecological and Human Health Risk Assessments for Duck and Otter Creeks were developed through a voluntary, non-regulatory process with input from many stakeholders, including state and federal government partners, businesses, industries and citizens in the watersheds. These reports were intended specifically for use by the US EPA Great Lakes National Program Office in relation to the Great Lakes Legacy Act funding program (a voluntary program). As a result, while it follows standard guidance and protocol, these report are focused on providing information necessary to allow stakeholders, including the local community, to determine if the creeks would benefit from, or be eligible for, Great Lakes Legacy Act funding. The aim of these reports is to assist decision-makers as one part of the comprehensive assessment of the conditions and impacts to Duck and Otter Creeks. Other previous study results, data sets, and stakeholder input should also be considered in conjunction with the risk assessment reports in making decisions on any future sampling or remedial alternatives.

The comments included in the attached compendium were submitted by interested parties during a review of the draft Human Health Risk Assessment and draft Ecological Risk Assessment for Duck and Otter Creeks. The comments are only one component of an open and ongoing dialogue with stakeholders in these watersheds. All comments were considered during the development of the respective final reports. However, it was not possible or relevant to integrate all comments received into these reports. Partners for Clean Streams Inc. considered many factors when reviewing the comments for inclusion in the final report, including the specific aims of these reports, the specific audience (GLNPO), the existing scope of work and limited budget, and the need for efficient and expedient revisions. Many comments may be useful in future scopes of work and as discussion items among stakeholders and government agencies. The reports were developed through the process outlined below. The comments are provided as a compendium to give broad perspective and context to other parties interested in the Risk Assessments reports and the comments received during the preparation of these reports.

It is our hope, as a regional watershed group interested in restoring “fishable and swimmable” waters to Northwest Ohio, that these Risk Assessments will be useful tools in moving these watersheds towards cleaner and healthier conditions for both wildlife and citizens.

Partners for Clean Streams, Inc. Board of Directors

Comments on HHRA

1. Executive Summary, page ES-3. The third bullet is difficult to follow, as it attempts to provide an overview of risks and hazards from a number of different stream segments, each with differing degrees of risk and hazard. It would be better to break this into several separate bullets, based on regulatory benchmarks. For example, one bullet should clearly state that the two lower most stream segments (OC-A and DC-A) have the lowest risks and hazards. Risks in these two segments are less than OEPA's goal of 1E-05 for total additive risk, and hazards are less than one. Stream segments with risks greater than 1E-05, but less than 1E-04, should be identified/discussed in a separate bullet, and stream segments with risks greater than 1E-4 should be discussed in a third bullet.
2. The document notes that sediment risks are driven by PAHs and arsenic, however, it does not provide an interpretation of the distribution of these chemicals along the stream channels. This type of information can be very useful when trying to identify if there are any source areas within the streams, and to help explain the risk results. For example, one might conclude from the risk assessment that the reason the risks are lowest in stream segments OC-A and DC-A is strictly due to the lower exposure frequency used to evaluate exposure, however, these are also the areas with the lowest contaminant concentrations. A review of data from Otter Creek indicates that, as one progresses upstream, the concentrations of these chemicals increase. For example, the chart below compares the maximum concentrations of Benzo(a)pyrene and Arsenic in Otter Creek, progressing upstream from OC-A to OC-D.

Segment	Arsenic (mg/kg)	Benzo(a)pyrene
OC-A	38	984
OC-B	47	8300
OC-C	63	3850
OC-D	66	20000

   This type of information should, at a minimum, be discussed to help the reader understand the distribution patterns of the more toxic chemicals in the stream sediments.
3. The risks from Hecklinger Pond are very high, primarily due to the fish ingestion scenario. The risk assessment relies on modeled fish tissue concentrations, rather than measured concentrations in fish, when calculating risks to anglers eating fish. Given the inherent conservatism of the biouptake models, these predicted values are undoubtedly overestimations of fish tissue concentrations, and as such, should not be used as the basis for remedial decisions until additional empirical data have been collected to either confirm or refute the modeled results.
4. The biouptake model for fish indicates that PAHs are the primary chemical(s) contributing to risk from eating fish, due to their bioaccumulation in the fish tissue. This does not appear to be a realistic conclusion. Bioaccumulation models based on chemical partitioning can predict elevated levels of PAHs in tissue, due to the lipophilicity of these compounds. However, field data generally show that, while PAHs may accumulate in invertebrates, they do not bioaccumulate at these high predicted levels in vertebrate

tissues due to detoxification mechanisms (i.e., in fish PAHs tend to break down/get excreted rather than bioaccumulate).

5. The risks in the lower stream segments (OC-A and DC-A), while shown to be low, are still based on unrealistically conservative assumptions that recreators enter these highly secured / inaccessible areas on a regular basis. Specifically, the risk assessment assumes one half the exposure frequency as upstream segments, where there is clear evidence of regular stream use. Risks should be based on a more realistic scenario (i.e., a worker who comes into contact with the creek on a very infrequent basis, and who wears protective clothing) to provide decision-makers with defensible risk estimates.
6. Risks in the upstream segment are based on the additive assumption of 6 years exposure as a child and 30 years as an adult, for a total of 36 years exposure. The standard default assumption from USEPA for this type of scenario is 6 years exposure as a child and 24 years as an adult, for a total of 30 years. The risk assessment should be revised to reflect this standard default regulatory assumption.
7. Direct skin contact with stream sediments provided the majority of human health risk in most portions of the streams (except Hecklinger Pond). The primary reason for such high dermal risks was the assumption that, once contacted, the sediment remained on the skin. The statement is made that no sediment wash off was assumed due to contact with surface water when evaluating skin contact with stream sediment, because “washing off may be limited if exposures take place primarily adjacent to the surface water and not to sediment that is underwater. Therefore, the uncertainty introduced because of this assumption is considered minimal.” (i.e., if mud is contacted on the stream bank, it will not wash off, but if it is contacted while wading, it will wash off). Were the sediment samples collected from the stream channel, or the stream bank? If the samples came from the stream channel, then assuming no wash off introduces a very large degree of uncertainty into the risk assessment, and overestimates risks.

BP Comments on the
SCREENING AND BASELINE ECOLOGICAL RISK ASSESSMENT
DUCK AND OTTER CREEKS TOLEDO AND OREGON, OHIO

Executive Summary – see comments on Conclusions and Recommendations

2.1 Environmental Setting

A general environmental setting is provided, but the text provides little to no information on the habitats/characteristics of the creek themselves. Width, channel quality, substrate type, flow and flow patterns, pool/riffle, vegetation, riparian area, instream cover, etc., are not discussed. A habitat description should appropriately be broken down by exposure unit (i.e., stream segment). (The Ohio Qualitative Habitat Evaluation Index (QHEI) would be a good tool.) If previous biological studies were conducted, what did they find?

2.3 Identification of Chemicals of Potential Ecological Concern (COPEC)

Page 8 – notes that site-specific background values are unavailable. However, Ohio sediment reference values representing background are available, and in fact, are used later in the report (see following comments).

2.4.5 Measures of Effects

Page 12, Benthic Community – It is indicated that Ohio EPA Specific Sediment Reference Values (SRVs) for Huron/Erie Lake Plane are used as measures of effect for all metal constituents in sediment. Ohio SRVs are background values. They are not measures of effect. It is also indicated that the SRVs and sediment quality guidelines are used to evaluate potential risks. SRVs do not provide any indication as to whether a potential risk is present, only that concentrations may be elevated as compared to background. Throughout the screening evaluation, there is text discussing evaluation of risk. A screening evaluation doesn't evaluate potential risks, it only determines whether a risk *may be* present (not that a risk *is* present, or the magnitude of a potential risk) and that further evaluation may be warranted.

3.1 Methodology for Evaluating Effects on Benthic Invertebrates

This title is inappropriate for a SLERA. A SLERA does not evaluate effects. Rather this section should relate to the SLERA for (the assessment endpoint) Protection of the Benthic Invertebrate Community.

Page 13 - Text indicates SRVs for metals are based on chronic toxicity tests. This is incorrect. SRVs are background sediment concentrations.

Page 13 – End of first paragraph, text states "the concentration of the contaminant in sediment was compared to sediment criteria for the protection of aquatic life identified from these various sources". It is incorrect to refer to these criteria as being "for the protection of aquatic life". Rather, these are screening values or benchmarks by which a determination can be made as to whether further evaluation is warranted.

Page 13, second paragraph – The exposure point concentration is defined as the lesser of the 95% UCL or the maximum concentration, whichever is less. This is atypical of a Tier 1 screening evaluation, in which the maximum concentration is typically used (e.g., see OEPA guidance).

Page 13, third paragraph (and global in SLERA) – Any HQ referenced in this section should be qualified as a screening HQ.

3.4 Results for Sediment Screening

3.4.1.1 In this section, and through the corresponding sections pertaining to other creek segments, the text discusses results with respect to both probable effect criteria/severe effect levels, and lowest effect levels (chronic criteria). This is the first time that these endpoints have been discussed. They were not discussed in the measures of effect outlined earlier for the SLERA or in Section 3.1. Secondly, the lowest effect levels applied are not necessarily chronic criteria (e.g., some are background values, all are just screening values).

The presentation in this section is inconsistent with the approach outlined earlier. Comparisons against probable effect criteria/severe effect levels are not necessarily incorrect in an ecological risk evaluation. However, they don't belong in the screening section, but could be used as weight of evidence in the BERA.

Tables in general – Benthic aquatic life probable effect criteria and benthic aquatic life chronic criteria are presented for sediment screening results. Where did these endpoints come from? In some tables (e.g., Tables 13,15,17,19, etc.), the benthic aquatic life probable effect criteria header is replaced with Benthic Aquatic Life Acute Criterion. What is this? The probable effect criterion should not be portrayed as an acute criterion.

What is the screening process/outcome for birds and mammals? This does not appear to be discussed in this report.

4.2 Characterization of Ecological Effects

This section would be more effectively presented if broken down by assessment endpoint.

Page 42 Bioaccumulation Factors

How was the BSAF derived from USACE (2003)? Is the resultant BSAF based on wet weight or dry weight?

The equation for calculating the tissue concentrations for inorganics on page 43 indicates that the fraction organic carbon in sediment and the fraction lipid concentration in biota are used. This is not evident in the dose calculations presented in Appendix E. Footnotes to these tables in Appendix E indicate that the concentration was arrived at simply as the BSAF times the sediment concentration. Organic concentrations in fish or invertebrate tissue reported in Appendix E dose tables could not be reproduced.

Section 5.0 - Uncertainty Analysis

Section 5.1 - It is discussed how pore water is a better indicator of toxicity than bulk sediment analysis. This text can be expanded to discuss how the overall investigation sought to reduce uncertainty by incorporating AVS/SEM and direct toxicity tests, rather than relying solely on bulk sediment analysis.

Section 5.3 - A number of uncertainties are discussed with respect to the FCM. Many of these are also directly relevant to the other assessment endpoints, e.g., bioavailability and TRVs, and are not restricted to the FCM evaluation.

Section 5.3.3 - 100% bioavailability assumed, but it was demonstrated for metals that bioavailability is limited due to AVS. This is significant, because most of the risks to upper trophic level receptors are associated with metals. Thus, one can conclude that the projected HQs for inorganics in higher trophic level receptors may be substantially overstated. Please also incorporate a discussion of total organic carbon and its affects on biovailability. PAHs are projected to bioaccumulate into biotic tissue, but are readily metabolized in most organisms. Please discuss.

Habitat is rarely discussed in this report. How does the quality of the habitat contribute to the uncertainty and interpretation of potential risks?

Section 6.0 Conclusions

The conclusions section is very confusing, as the results of the SLERA are intertwined with results of the BERA, and SLERA results are portrayed as estimates of risk. SLERA results should not be used as risk estimates. Rather, the purpose of the SLERA is to identify which chemicals warrant further evaluation; these chemicals are then further evaluated in the BERA. It is suggested that the SLERA be discussed briefly, and that the BERA results and conclusions be broken down by assessment endpoints and discussed in the context of weight of evidence and uncertainties.

Table 36 – Benthic Aquatic Life – Probable Effect/Severe and Benthic Aquatic Life – Chronic, were presented in the SLERA and should not be presented as quantitative HQs unless they are moved to the BERA and used in the overall weight of evidence. Lesions for Bottom-Dwelling Fish should be discussed only in the context of the SLERA findings; results here represent a screening process and should not be concluded to indicate that a risk is present. In Table 36 (and other tables) a footnote should indicate that the maximum HQ among multiple chemicals is presented. Please also check numbers in the table; some do not match those presented earlier in the report.

Text following Table 36 discusses which areas had the highest risk. It is inappropriate to portray the results in Table 36 in the context of where the highest risk was located (rather the text might be revised to indicate from Table 36 which areas had the highest HQs). Interpretation of risk should be placed in the context of the uncertainty associated with the estimate and the overall weight of evidence. For that reason, "yes" should not be used as a summary statement within Table 36 (or in other tables in this section). For example, the text indicates that the highest risks in Duck Creek were in Area E. However, no toxicity was observed in Area E, so how can it be concluded that Area E had the highest risk? Similar comments for Table 37.

The text also indicates that the mink appeared to be the least sensitive receptor of those evaluated. Is this the least sensitive relative to birds and mammals, or compared to all receptors? This should probably be discussed in conjunction with Tables 38 and 39.

AVS/SEM results should be discussed with respect to interpretation of risk results.

In discussion of the FCM on page 56, it is indicated that "lead, mercury, selenium, and zinc….have the greatest impact on the belted kingfisher for Duck Creek", and "selenium is the contaminant that has the greatest impact on the mink for Duck Creek". Similar language is used in discussing Otter Creek. Although these constituents may have the highest HQs, it is inappropriate to conclude these have the greatest impacts. For example, data (AVS/SEM) suggest that bioavailability of the metals is limited. Although AVS/SEM is generally interpreted in the context of the benthic macroinvertebrate community, the data would also suggest these constituents have limited bioavailability for uptake into the food chain, thereby limiting food chain exposures. Discussion of potential risks should be couched in the context of the uncertainty and weight of evidence.

Table 38/39 –These tables are hard to follow, and provide little value for the risk manager. Remove "yes" from table. Associated text appears to quantify impacts based solely on the magnitude of the resultant HQs. Text should qualify interpretation based on associated uncertainty (e.g., bioavailability and quality of habitat), and should provide additional chemical-specific detail.

Text on page 59 briefly summarizes some previous investigations. These studies should be provided as background, and potentially expanded upon, in the introduction to the report, rather than being abruptly introduced in the conclusions section. If discussed in the conclusions section, these studies should be discussed in the context of findings from this investigation and relevance to the overall interpretation of potential risks in the creeks.

Appendices

Appendix D – A single control was used for 16 test sediments. There is no indication of how physical affects (e.g., grain size) may have differed between the test sediments and controls. Multiple controls representing similar grain size and organic carbon concentrations would be appropriate to better interpret results. This should also be discussed in the uncertainty analysis.

Appendix E – TRVs applied in Dose Calculation and Hazard Quotient Tables do not match those presented in Table E-3. For example, the fish BSAF for HMW PAHs in Table E-3 is 0.257, whereas in Table E5 a value of 1.8 is used. The invertebrate BSAF for HMW PAHs in Table E-5 is 2.4, whereas there is no invertebrate BSAF specific to HMW PAHs in Table E-3, and the highest BSAF for any individual HMW PAH in Table E-3 is roughly an order of magnitude lower than that presented in Table E-5. There is no indication that fraction lipid and fraction organic carbon were used in conjunction with the BSAFs as indicated in the text. As indicated previously, organic concentrations in fish or invertebrate tissue reported in Appendix E dose tables could not be reproduced.

Table E-14 – BSAFs are not included for PAHs. Calculated results do not match reported results in Section 4.

Recommendations

Recommendations generally appear sound. With respect to the benthic invertebrate assessment endpoint, toxicity tests (given the uncertainties noted above) suggested the potential for impacts on the benthic invertebrate community in the creek. However, no specific chemical stressor could be identified. Therefore, further evaluation may be warranted.

For the birds and mammals assessment endpoint, elevated HQs were noted; however, the actual potential for risk appears questionable, as metals bioavailability appears limited, and organic bioavailability is also questionable (e.g., due to organ carbon in sediments and limited bioaccumulation potential of PAHs). Actual bioaccumulation tests and/or field tissue collection approaches are reasonable means of reducing uncertainty in the analysis.

Lacking in both the conclusions and recommendations sections is a discussion of lesions, which was also selected as an assessment endpoint. The SLERA indicated sediment concentrations of PAHs were higher than screening values. In the BERA (Section 4.2), it is noted that SLERA results overestimated risk (note the SLERA should not be used to estimate risk). Because only a screening-level evaluation was conducted, results cannot be used to conclude that risks are present. It should be recommended, for example, that 1) there is a potential that a risk may exist, but there is insufficient information to quantify that risk and recommend no further evaluation, or 2) there is a potential that a risk may exist and recommend field studies to determine whether lesions are actually present, and their ecological relevance.

Comments on the
SCREENING AND BASELINE ECOLOGICAL RISK ASSESSMENT
DUCK AND OTTER CREEKS TOLEDO AND OREGON, OHIO

Report Structure –The report is difficult to follow and lacks an organized structure.

- A general environmental setting is provided, but the text provides little to no information on the habitats/characteristics of the creek themselves. Width, channel quality, substrate type, flow and flow patterns, pool/riffle, vegetation, riparian area, instream cover, and overall physical quality of the habitat based on stream characteristics are not discussed.
- Results of the SLERA should be distinct from the BERA. SLERA results should only identify which constituents warrant further investigation in the BERA and should not be presented/discussed as risk estimates. A screening evaluation only determines whether a risk *may be* present, not that a risk *is* present, or the magnitude of a potential risk. HQs in the SLERA should be clearly defined as screening HQs, or more preferably, only whether a screening benchmark is exceeded, thereby concluding the chemical is a COPEC. The BERA should clearly define risk analysis and characterization on the basis of the specific assessment endpoints, COPECs, and associated weight of evidence based on all measures evaluated and associated uncertainty.
- The text would be more effectively structured based on the assessment endpoints selected. For example, BERA assessment endpoints are presented in Section 4.1, but subsequent sections are structured around measures of effect, rather than clearly defined assessment endpoints.
- The conclusions section is very confusing, as the results of the SLERA are intertwined with results of the BERA, and SLERA results are incorrectly portrayed as estimates of risk. SLERA results should be distinct from BERA results.

QA Review - There are several inconsistencies/omissions/errors noted in the report. It is recommended that a detailed QA review of the report be conducted. Some issues identified are noted below:

- Ohio sediment reference values are portrayed as being effect levels based on chronic toxicity tests. This is incorrect. They are Ohio regional sediment background values (OEPA 2003).
- In the SLERA “probable effect criteria/severe effect levels” are abruptly introduced in Section 3.4.1.1. In subsequent tables, SLERA results are reported for “benthic aquatic life probable effect criteria” (sometimes also referred to as “benthic aquatic life acute criteria, e.g., Table 13, et al.) and “benthic aquatic life chronic criteria”. This is inconsistent with the SLERA methodology and terminology presented in Section 3.1.
- What is the screening process/outcome for birds and mammals? This does not appear to be discussed in this report.
- How was the BSAF derived from USACE (2003) (page 42)? Is the resultant BSAF based on wet weight or dry weight?
- The equation for calculating the tissue concentrations for organics on page 43 indicates that the fraction organic carbon in sediment and the fraction lipid

concentration in biota are used. This is not evident, and does not appear to have been applied, in the dose calculations presented in Appendix E.

- Appendix E – BSAFs applied in Dose Calculation and Hazard Quotient Tables do not match those presented in Table E-3. For example, the fish BSAF for HMW PAHs in Table E-3 is 0.257, whereas in Table E5 a value of 1.8 is used. The invertebrate BSAF for HMW PAHs in Table E-5 is 2.4, whereas there is no invertebrate BSAF specific to HMW PAHs in Table E-3.

Uncertainty Analysis

- Text can be expanded to discuss how the overall investigation sought to reduce uncertainty by incorporating AVS/SEM and direct toxicity tests, rather than relying solely on bulk sediment analysis.
- Many of the uncertainties discussed relative to the FCM are also directly relevant to the other assessment endpoints, e.g., bioavailability and TRVs, and are not restricted to the FCM evaluation.
- It is indicated in Section 5.3.3 that 100% bioavailability assumed, but it was demonstrated for metals that bioavailability is limited due to AVS. Discuss in uncertainty analysis.
- Total organic carbon and its affects on biovailability should be discussed.
- PAHs are projected to bioaccumulate into biotic tissue, but are readily metabolized in many organisms and do not biomagnify in the food chain (e.g., ASTM 1991, Eisler 1987). This should be discussed in the uncertainty analysis.
- How does the physical quality of the habitat contribute to the uncertainty and interpretation of potential risks?

Conclusions and Interpretation of Risk

- Results of the SLERA should be distinguished from the BERA results.
- SLERA results should be used to define COPECs.
    - Results related to the lesions assessment endpoint should be discussed only in the context of SLERA results. It cannot be concluded that a risk is present, but further evaluation may be warranted. What are the recommendations related to this assessment endpoint?
    - For the benthic macroinvertebrate assessment endpoint, SLERA HQs should only be used in defining COPECs.
- Only BERA results should be used for risk interpretation using a weight of evidence approach
    - For example, for the benthic macroinvertebrate assessment endpoint, risk interpretation should be based on sediment toxicity tests, AVS/SEM results, correlation analyses, and discussion of uncertainties.
- Results and conclusions should be revised after addressing inconsistencies/ omissions/errors noted previously.

Lallendorf Rd.
South of Cedar Point Rd

From: Burns, Jim (Okemos)
Sent: Friday, August 08, 2008 9:05 AM
To: executive.director@partnersforcleanstreams.org
Cc: Carlson, Matthew; Bob Wilkenfeld
Subject: RE: Duck and Otter draft reports available soon

Attachments: HERA.xls

Kris:

I have read the BERA and the HHRA for Duck and Otter Creek and I am providing comments for Chevron. Chevron may have additional comments from their internal risk assessors.

BERA

1. It would be helpful to add chemicals of concern to Tables ES-1 and ES-2. (See Tables ES-3 and ES-4 as an example). This would allow risk managers to key in on chemical constituents that drive ecological risks to benthic aquatic life.
2. The HQ for Lesions for Bottom Dwelling Fish as reported in Table 16 and Table 18 should be added to Table ES-1 and ES-2. (See Table ES-1 and ES-1 for other exposure pathways). This will show that the HQ's for Lesions for Bottom Dwelling Fish are the highest of any of the reported HQ's.
3. Tables 16 and 18 should be modified to read PAH Concentrations in Sediment. Currently it reads Sediment. The PAH's in sediment are the constituents driving risk, not the sediment.
4. The Uncertainty Analysis in Section 5 needs to include a detailed discussion on the procedures used to evaluate Lesions for Bottom Dwelling Fish. Currently, the evaluation is based upon one study conducted on a salt water species "English Sole". I do not see any mention of this right now in Section 5. As it currently standards, this single study defines that required sediment cleanup levels for Duck and Otter Creek.

HBRA

1. It would be helpful to add a summary table to the Executive Summary that reports calculated risk, constituents of concern and the receptor that drives risk. I have attached an example. This will allow risk managers to key in on constituents in Duck and Otter Creek sediment that drive risk or hazard; and
2. Section 5 describes the methods that are used to quantify risk. First the risk associated with exposure to multiple chemicals is totaled (Benzo-a-pyrene + arsenic = Total Risk). Next exposure from multiple exposure pathways is summed (ingestion + adsorbtion = Total Risk). There is no mention of adding receptors (child + adult). In Section 5.3.1 the calculated Total Risk for an adult and child is added to report a Total Risk. I have never seen this type of addition used in any risk assessment that I have reviewed. If it is an acceptable method, than it should be discussed in Section 5.

Jim R Burns, PE
Principal Engineer
Stantec
2321 Club Meridian Drive Suite E
Okemos MI 48864
Ph (517) 349-9499 Ext. 22[illegible]
Fx. (517) 349-6863
Cell (517) 202-[illegible]166
Jim.R.Burns@stantec.com
stantec.com

Example fr. Chevron

Human Health Risk Assessment
Summary of Otter Creek and Duck Creek
Calculated Risks and Hazard Index

Creek Section	Risk	Risk Drivers	Limiting Risk Receptor	HI	HI Driver	Limiting HI Receptor
OC-A	2.00E-06	b-a-p, as	a-recreationalist	0.03	NA	a-recreationalist
OC-B	8.00E-06	b-a-p, as	c-recreationalist	0.1	NA	c-recreationalist
OC-C	1.00E-05	b-a-p, 1254, as	c-recreationalist	0.6	NA	c-recreationalist
OC-D	3.00E-05	b-a-p, d-ah-a, as	c-recreationalist	0.2	NA	c-recreationalist
OC-E	3.00E-05	b-a-p, d-ah-a, as	c-recreationalist	0.2	NA	c-recreationalist
DC-A	5.00E-06	b-a-p, as	a-recreationalist	0.06	NA	a-recreationalist
DC-B	1.00E-05	b-a-p, as	c-recreationalist	0.3	NA	c-recreationalist
DC-C	8.00E-06	b-a-p, as	c-recreationalist	0.2	NA	c-recreationalist
DC-D	2.00E-05	b-a-p, as	c-recreationalist	0.4	NA	c-recreationalist
DC-E	9.00E-05	b-a-p	c-recreationalist	0.3	NA	c-recreationalist
Hecklinger Pond	3.00E-03	b-a-p, as	c-recreationalist	20	1254, as	c-recreationalist

Notes
b-a-p = benzo-a-pyrene
as = arsenic
1254 = PCB 1254
d-ah-a = dibenzo(a,h)anthracene

Example from Chevron

Sediment Toxicity	Risk Drivers HI Receptor	Piscovorous Birds (High TRV)	Risk Drivers	Piscovorous Mammals	Risk Drivers
Yes	Undetermined	Yes	zn	No	none
Yes	Undetermined	Yes	zn	No	none
Yes	Undetermined	Yes	se, PCB's	Yes	PCB's
Yes	Undetermined	Yes	se	Yes	PAH's
Yes	Undetermined	Yes	PCB's	No	none
Yes	Undetermined	Yes	se, zn	Yes	se
Yes	Undetermined	Yes	se	Yes	se
Yes	Undetermined	No	none	No	none
No	Undetermined	Yes	pb, hg, se, zn	Yes	se
No	Undetermined	Yes	se	No	none

Human Health Risk Assessment
Summary of Otter Creek and Duck Creek
Calculated Risks and Hazard Index

Creek Section	Risk	Risk Drivers	Limiting Risk Receptor	HI	HI Driver	Limiting HI Receptor
OC-A	2.00E-06	b-a-p, as	a-recreationalist	0.03	NA	a-recreationalist
OC-B	8.00E-06	b-a-p, as	c-recreationalist	0.1	NA	c-recreationalist
OC-C	1.00E-05	b-a-p, 1254, as	c-recreationalist	0.6	NA	c-recreationalist
OC-D	3.00E-05	b-a-p, d-ah-a, as	c-recreationalist	0.2	NA	c-recreationalist
OC-E	3.00E-05	b-a-p, d-ah-a, as	c-recreationalist	0.2	NA	c-recreationalist
DC-A	5.00E-06	b-a-p, as	a-recreationalist	0.06	NA	a-recreationalist
DC-B	1.00E-05	b-a-p, as	c-recreationalist	0.3	NA	c-recreationalist
DC-C	8.00E-06	b-a-p, as	c-recreationalist	0.2	NA	c-recreationalist
DC-D	2.00E-05	b-a-p, as	c-recreationalist	0.4	NA	c-recreationalist
DC-E	9.00E-05	b-a-p	c-recreationalist	0.3	NA	c-recreationalist
Hecklinger Pond	3.00E-03	b-a-p, as	c-recreationalist	20	1254, as	c-recreationalist

Notes

b-a-p = benzo-a-pyrene

as = arsenic

1254 = PCB 1254

d-ah-a = dibenzo(a,h)anthracene

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

Date: September 22, 2008

Subject: Review of *Screening and Baseline Ecological Risk Assessment, Duck and Otter Creeks, Toledo and Oregon, Ohio,* 2008

From: Brenda Jones, Environmental Scientist
Technical Assistance & Analysis Branch

To: Kristina Patterson, Executive Director
Partners For Clean Streams, Inc.

Thank you for the opportunity to review *Screening and Baseline Ecological Risk Assessment, Duck and Otter Creeks, Toledo and Oregon, Ohio, 2008.* My comments on the document are presented below.

U.S. EPA Great Lakes National Program Office (GLNPO) supports the conclusions of this document that there are impacts or potential impacts to benthic invertebrates from exposure to sediments in the Creeks and to vertebrates that consume prey from the Creeks. As noted in the document, there is a clear need for further work to define what is causing the observed toxicity and to determine the full extent of contamination.

There are specific data gaps, related to ecological receptors that should be addressed in the future. These should be added to those derived for human health concerns. The data gaps that I see, in no particular order are: (note this list is not inclusive, there may be others that GLNPO would like to address as we move forward on the project):

1. As indicated in the BLERA, a better understanding of pore water chemistry, along with additional toxicity studies might help elucidate what is causing benthic toxicity.
2. Extent of contamination both surficially and at depth is important.
3. Fish and/or benthic residue analysis would be useful to derive site-specific biota-sediment accumulation factors (BSAFs). This could be done through in-situ and/or laboratory uptake studies as well as potentially measuring residues in local infauna.
4. Benthic diversity studies might help determine if the Creeks can support benthic fauna at all, and if so, what species.

These recommendations could be supported under a Great Lakes Legacy Act project. The data that currently exists supports the need for additional work to refine the extent of contamination, determine site-specific risk drivers and develop site-specific clean up numbers (if remediation is warranted).

If you would like to more information or to talk further about my comments, please do not hesitate to contact me at 6-7188 or via email at jones.brenda@epa.gov.

Cc: David Cowgill, Chief, Technical Assistance & Analysis Branch
Marc Tuchman, Team Leader, Technical Assistance & Analysis Branch
Ajit Vaidya, Co-Project Lead

INTER-OFFICE COMMUNICATION

TO: Shannon Nabors, Chief, NWDO

FROM: Dawn Pleiman, Division of Hazardous Waste Management, NWDO

SUBJECT: **Human Health Risk Assessment, Duck and Otter Creeks dated July 21, 2008; and Screening and Baseline Ecological Risk Assessment Duck and Otter Creeks dated July 2008.**

DATE: August 18, 2008

The human health risk assessment (HHRA) and ecological risk assessment (ERA) were completed for Partners for Clean Streams, Inc. in collaboration with the Duck and Otter Creeks Partnership. The goal of these assessments was to determine whether sediment contamination in the two creeks pose "a significant risk to human health or the environment, and if so, to identify specific chemicals contributing to toxicity and define the spatial extent of risks [to human and ecological receptors]."

The following comments list items that were noticed during review of the two documents. It should be noted that the review was not exhaustive given the limited timeframe to review the documents. My review did not go into detail on topics/areas such as aquatic life assessment, ecological risk assessment calculations or biota-sediment accumulation factors (BSAFs).

HHRA

Dermal exposure

1. Table 9 of the HHRA indicates that the dermal absorption (ABS_d) value for barium, selenium, zinc and mercury is 0.1. Ohio EPA uses U.S. EPA guidance and the dermal absorption value for inorganic chemicals is 0.001.

2. The mercury gastrointestinal absorption factor (ABS_{GI}) used in the HHRA is 0.07. (Ohio EPA is assuming that the value was taken to represent mercuric chloride.) Ohio EPA uses 0.74 as the ABS_{GI} assuming insoluble or metallic mercury as a more commonly occurring chemical for this area vs. mercuric chloride. The value used by Ohio EPA was taken from *RAGS Volume I, Part E, Supplemental Guidance for Dermal Risk Assessment*.

Exposure Parameter Value

3. At the bottom of Table 8, the process used to calculate the site-specific exposure frequency is explained. It is unclear if the reason why the exposure frequency is

reduced by ½ is due to exposure only being for six months of the year. It would be helpful if the HHRA explained why the exposure frequency was reduced and the reasoning that supports the decision.

Region 9 PRG

4. Pyrene's Region 9 PRG is 2.3E+6 not 2.3E+3 as stated in Table 12 of the HHRA.

Total risk

5. According to the HHRA, when evaluating ingestion and dermal exposure to sediment at Duck and Otter Creeks the following creek segments were either at the cancer risk goal (1E-5) or exceeded the cancer risk goal: DC-B, DC-C, DC-D, DC-E, OC-B, OC-C, OC-D and OC-E. The overall hazard (non-cancer) goal of 1 was not exceeded at any stream segment when considering only ingestion and dermal exposure to sediment.

   To check the risk calculations, I used our Residential Risk Calculator found at http://www.epa.state.oh.us/dhwm/xls/DefaultResidentialRiskCalculator12_15_06.xls and adjusted several default parameters to match the HHRA's assumptions. I picked a couple creek segments and used the same exposure point concentrations as listed in the report. My results differed from the HHRA, though my conclusions are basically the same. For Duck Creek, creek segment E, my non-cancer risk results for an adult and child receptors was approximately half of the value calculated in the HHRA. The HHRA calculated 5.7E-2 and 3.9E-1 for adult and child non-cancer hazards. The hazard index was not exceeded as all results were 0.3 or less. For the cancer component of creek segment E, I calculated approximately 9E-5 compared to the HHRA's 2E-4. Looking at either evaluation, cancer risk is exceeded for this segment of Duck Creek.

   For Otter Creek, creek segment A, my non-cancer risk results matched the HHRA for an adult receptor (1.1E-2). For the cancer component of creek segment A, I calculated 5E-6 compared to the HHRA's 2E-6. Looking at either evaluation, cancer risk has not been exceeded for this segment of Otter Creek.

ERA

The ERA consisted of a variety of tests, modeling and calculations on each segment of the creeks. (ProUCL 4.0, a software program developed by U.S. EPA, was used to calculate the exposure point concentrations. This software program is also used by Ohio EPA.) Toxicity testing was performed on the sediment samples, toxicity reference values were calculated, total PAH concentrations were compared to criteria for formation of lesions in bottom-dwelling fish and food chain models (FCM) were performed. The FCMs used the belted kingfisher and mink as the possible receptors. According to the Duck Creek FCM, Exposure Area D (aka DC-D) exhibited the “greatest potential impact to these receptors – it had the highest HQs and the most constituents of concern.” According to the Otter Creek FCM, Exposure Area C (OC-C) exhibited the “greatest potential impact to these receptors.”

When evaluating all assessment methods, Duck Creek exhibited the highest potential impact to receptors at Exposure Area E and Exposure Area D had the second highest overall potential impact to receptors. At Otter Creek, Exposure Area D resulted in the highest risk potential to receptors and Exposure Area E resulted in the second highest risk to receptors when assessing all evaluation methods.

Ohio EPA conducted biological surveys over the years on these creeks and the results indicated that the creeks were “highly stressed and do not support a strong and diverse biological community” and the overall ratings for a majority of the creek segments ranged between “very poor” and “poor”. Only a few locations were rated “marginally good” to “good.” The ERA appears to be pretty thorough.

ec: Ed Lim, Manager, ERAS, DHWM, CO
Mike Allen, Supervisor, Remediation Assistance Unit, DHWM, CO
Archie Lunsey, Supervisor, DERR, NWDO
Michael Terpinski, Supervisor, DHWM, NWDO
Lynn Ackerson, DHWM, NWDO

REPORT COMMENTING ON THE DRAFT HUMAN HEALTH AND ECOLOGICAL SCREENING ASSESSMENTS

Prepared by:

William J. Walsh
Pepper Hamilton LLP
600 Fourteenth Street, N.W.
Washington, D.C. 20005

ON BEHALF OF

PILKINGTON NORTH AMERICA

Reviewed by Gradient Corporation
20 University Road
Cambridge, MA 02138

August 26, 2008

I. INTRODUCTION

This document provides Pilkington North America's (PNA) legal, policy, and technical comments on the Tetra Tech Human Health Risk Assessment, Duck And Otter Creeks, Toledo And Oregon, Ohio (July 2008) (Draft Human Health Assessment) and Screening And Baseline Ecological Risk Assessment, Duck And Otter Creeks, Toledo And Oregon, Ohio, (July 2008) (Draft Eco Assessment). This comment document was prepared by William J. Walsh of Pepper Hamilton LLP (see resume in Appendix 1) on behalf of PNA, as explained below. This comment document was also reviewed and includes input from Gradient Corporation (Gradient), an environmental and health risk assessment consulting firm (see summary of Gradient experience in Appendix 1 of this Report). Gradient has also prepared its own separate set of comments reflecting its initial review.

These two draft assessments being reviewed raise technical, legal, policy, and guidance interpretation issues. Therefore, PNA retained both legal counsel and a human health and ecological risk assessment consultant to work together.

The draft assessments have taken a significant amount of time to prepare and reflect a significant change from the 2005 draft assessment. The time allotted to provide comments is short by comparison.

Gradient has not had sufficient time to review the raw underlying data nor perform its own analysis. In some cases, Tetra Tech's methodology may not be clear and the scientific rationale may not be apparent on the face of these documents. Thus, necessity dictated obtaining Gradient's technical comments both in a separate document and through a review of these combined legal, policy, and technical comments. These comments should be considered preliminary. Other comments may be submitted or these comments may be modified as additional technical analysis is performed. PNA welcomes a continuing technical dialogue on these issues to ensure that the efforts to improve water quality in this watershed are effective and sound.

PNA appreciates the opportunity to comment on these assessments. There are a number of specific overestimations and other problems with the Draft Human Health and Ecological Screening Assessment. Each overestimation, in and of itself, causes significant biases and distorts the attempt to evaluate whether there is a significant impairment, and, if so, what is the cause of the impairment, and, most importantly, what efforts to reduce the release of chemicals from the industrial facilities in the locale are most likely to reduce this impairment. The combined impact of these problems significantly overestimates the risk from exposure to arsenic in particular --- both in assessing the absolute magnitude of the risk as well as distorting the relative risk from exposure to arsenic compared to other chemicals. Additionally, neither assessment provides sufficient emphasis on the fact that the assessment are not intended to and cannot, as written, provide a basis for triggering remedial action or setting clean up goals.

The following summarizes the major conceptual overarching problems with these two screening approaches. Section I summarizes our initial comments on the Draft Human Health Assessments. Section II provides our initial comments on the draft ecological screening assessments. Section III provides our preliminary conclusion and suggestions on the path forward.

II. COMMENTS ON THE DRAFT HUMAN HEALTH ASSESSMENT

A. Introduction

The following discusses each of the most significant issues identified in an initial review of the Duck and Otter Creek draft human health risk assessment.

B. Further Refinement Is Needed to Adequately Characterize the Human Health Risk

As will be discussed in more detail throughout these comments, the simplifying assumptions that were made regarding potential arsenic exposures mischaracterize arsenic risk. Although some site-specific exposure assumptions were used to calculate the risk, the failure to consider site-specific background (as opposed to Ohio State naturally occurring background)and the reduced oral bioavailability of arsenic in sediment, as well as use of an unvalidated model to estimate arsenic concentrations in fish, make several aspects of the risk assessment a "screening level" assessment. While as a first pass, it is common to compare environmental concentrations to accepted screening criteria, such as the U.S. EPA soil screening levels, (SSLs), for arsenic this comparison is not appropriate because background levels of arsenic in soil and sediment are well above this value (*see* below). To properly assess risks, background levels of arsenic and other contaminants on a site-specific basis must be quantified.

Additionally, while screening assessments often use an arsenic bioavailability of 100%, U.S.EPA guidance allows adjustments in the risk assessment if there is reduced bioavailability of chemicals in soil. Several studies published in the peer-reviewed literature demonstrate that the relative bioavailability of arsenic in soil is less than 50%. It is also possible to conduct site-specific tests on arsenic bioavailability and use this information to refine the risk assessment (*See* comment below for more information). Consideration of reduced bioavailability in sediment could reduce risks from incidental ingestion several fold.

Further, the risk assessment used a model to estimate arsenic concentrations in fish from exposure to sediment. This model is not used appropriately to estimate arsenic uptake into fish from sediment because it results in a gross overestimate of exposure. If there is concern about potential inorganic arsenic exposure from fish ingestion, then site specific information on the inorganic arsenic content in fish should be examined and used in the risk assessment. Presently, the ingestion of arsenic *via* the fish pathway is a major risk driver It is likely, however, that based on information in the literature concerning the relationship between arsenic in sediment and arsenic in fish, and the understanding that arsenic in fish is mostly organic, the fish in Hecklinger Pond would not pose any meaningful cancer risk above background (For more details on this point see below).

In summary, this assessment provides more information than a mere screening analysis, but, due to the lack of sufficient site-specific information, this assessment cannot be used as a reliable basis for future remedial decisions.

C. The risk assessment should state that it is intended to estimate potential risk from chemical exposures and is not recommending any specific clean-up goals.

A discussion should be added to the risk assessment that the screening criteria used to retain chemicals of concern do not reflect clean-up goals. Acceptable clean-up goals are a risk management decision and are established in a subsequent phase of the process. Clean-up goals must consider issues such as background conditions, exposure frequency, and feasibility.

For example, the Draft Human Health Assessment uses, among other things, a 0.39 mg/kg screening level for arsenic to screen sediment levels for impacts to human health.[1] The EPA national soil screening level (SSL) for arsenic based on a one-in-one million risk level

---

[1] Draft Human Health Assessment at Table 6A.

(1×10^{-6}) also is 0.39 mg/kg. As EPA noted in describing EPA's SSLs, "**SSLs are not national cleanup standards**"[2] Soil screening levels "do not trigger the need for response actions or define "unacceptable" levels of contaminants in soil."[3] In general, soil screening levels "are expected to be more conservative [i.e., lower] than site-specific levels."[4] Generally, "where contaminant concentrations equal or exceed SSLs, further study or investigation, but not necessarily cleanup, is warranted."[5] In fact, EPA and states have regularly chosen arsenic soil and sediment cleanup levels that far exceed 0.39 mg/kg (see Table 1, below).

D. A target risk range of 1×10^{-6} to 1×10^{-4} is the appropriate risk target, particularly since natural background exposures to arsenic typically exceed a 1×10^{-6} risk

Arsenic risk assessment is unique because, using current toxicity criteria, background exposure to arsenic typically results in cancer risks above 1×10^{-5}. For example, the U.S. Geological Survey study of elements in natural soil from undeveloped areas found an average of **11.7 mg/kg** of naturally occurring arsenic in **soil** in Ohio.[6] Ohio determined "Ohio-specific Sediment Reference Values (SRVs)" for naturally occurring background sediment concentrations (i.e., sediment from areas remote from any potential input to the sediment from human usage of arsenic over the centuries) for lotic (flowing) water bodies that ranged from

---

[2] EPA, Soil Screening Guidance: Users Guide at 1 (1996) (emphasis in original).

[3] Id.

[4] Id.

[5] Id.

[6] *See* Dragun, J; Chiasson, A. 1991. *Elements in North American Soils*. Hazardous Materials Control Resources, citing data from Boerngen, J. G.; Shacklette, HT. 1981. "Chemical Analysis of Soils and Other Surficial Materials of the Conterminous United States (Report and diskette data)." US Geological Survey, USGS Open-File Report 81-197. 143p (Boerngen and Shacklette 1981).

11 to 25 mg/kg, depending upon the eco-region of the State.[7] These values are not the mean concentrations, but a cutoff value, above which a concentration might be considered an outlier[8]. We have not evaluated either the validity of the data or the methodology used to calculate the SRV. These values appear to be similar to, but somewhat lower than, the USGS data for arsenic in surface soil in Ohio because the mean concentration of arsenic in soil is identical to the SRV.

The mean concentration in soil of 11.7 mg/kg and the SRV of 11 mg/kg are 30 times higher than the U.S.EPA screening level. If the arsenic cancer potency factor were correct, this would correspond to a lifetime risk level of 3×10^{-5}. In fact, little of the soil or sediment in Ohio is likely to be below 0.39 mg/kg.

Nationwide, naturally occurring arsenic in **soil** was measured in this study at concentrations up to 97 mg/kg[9] and the average background concentration of arsenic in soil has been detected at concentrations as high as 27 mg/kg at Superfund sites (*see* Table 1, below).[10]

---

[7] Ohio Environmental Protection Agency, Ecological Risk Assessment Guidance Document at 2-28 to 3-32 (2003, revised February 2008). Ohio EPA took 512 samples of sediment and analyzed the sediment for various chemicals, including arsenic. Id. at 3-29. Ohio EPA defined background "as the concentration of naturally occurring chemicals that are unaffected by any current or past activities involving the management, handling, treatment, storage, or disposal of chemicals." Id. 3-28 That is, the Ohio EPA measured naturally occurring background, not an actual site-specific background, unrelated to the specific industrial sources located near Duck and Otter Creek.

Individual constituents grouped by eco-region were evaluated in order to determine whether significant differences existed between concentrations observed in each eco-region. Id. 3-30.

[8] Id. at 3-31.

[9] Nationally, the mean natural background concentration of arsenic nationally in surface soil is 7.2 mg/kg, with a range of concentrations in individual samples of 0.1 to 97 mg/kg. See Boerngen and Shacklette 1981, *supra* note 6, at 143p. *See also* Gustavsson, N., B. Bølviken, D.B. Smith, and R.C. Severson, *Geochemical Landscapes of the Conterminous United States—New Map Presentations for 22 Elements*. U.S. Geological Survey Professional Paper 1648. Denver, Colo.: U.S. Geological Survey (2001) *available at* http://pubs.usgs.gov/pp/p1648/p1648.pdf at 15 of 44, which re-evaluates the data from Boerngen and Shacklette 1981.

[10] For example, the average background level for arsenic in Louisiana is 12 mg/kg. LDEQ, Arsenic Sampling Explained at: http://www.deq.louisiana.gov/portal/portals/0/news/pdf/arsenicexplainedjan10.pdf. Similarly, at the Heartland Superfund site in Illinois, EPA concluded that background level of arsenic in soil is between 10 to 17 mg/kg (available at: <http://www.epa.gov/region5/sites/cmcheartland/pdfs/faq-200609.pdf >). In fact, background has been found to be above 10 mg/kg at many Superfund sites. *See* Davis, A, Sherwin D, Ditmars,

(continued...)

Also, the cancer risk from background exposure to arsenic in drinking water (from groundwater) in the U.S. is 4.2 x 10^{-5} (median [1 µg/L]) and 4.3 x 10^{-4} (95th percentile [10 µg/L]).[11] Risks from inorganic arsenic in food are comparable. A study by Schoof *et al.* (1999)[12] estimated that the average daily intake of inorganic arsenic in the U.S. diet is 3.2 µg/day for adults, with a range of about 1-20 µg/day. Thus, arsenic cancer risk from typical exposure to arsenic in food is about 2.1 x 10^{-5} (median) and 4.2 x 10^{-4} (at the maximum).

Due to background exposure to inorganic arsenic, U.S. EPA has made regulatory decisions regarding arsenic based on risks above 1×10^{-5}. For example, the MCL for arsenic in drinking water. The established MCL of 10 µg/L is associated with a 90th percentile population risk ranging from 1.32 to 6.01 x 10^{-4}[13]. Similarly, EPA and States have chosen soil cleanup goals at numerous hazardous waste sites based on a life time risk as high as 10^{-4}, resulting in arsenic soil cleanup levels in some cases higher than 100 mg/kg (*see* Table 1, below).[14] At one arsenic

---

(continued...)

R., and Honeke, K. 2001. An Analysis of Soil Arsenic Records of Decision. Environmental Science and Technology 35(12): 2,401–2,406 (Davis 2001); Valberg, P., Beck, B., Bowers, T., Keating, Bergstrom, J., Boardman, P. 1997. Issues In Setting Health-Based Cleanup Levels for Arsenic in Soil. Reg. Tox. and Pharm. 219-229 (Valberg 1997).

[11] Provided by Gradient; assumes 70 kg person drinks 2L/day of water.

[12] Schoof, RA; Eickhoff, J.; Yost, LJ; Crecelius, EA; Cragin, DW; Meacher, DM; Menzel, DB. 1999. “Dietary exposure to inorganic arsenic.” In Chappell, WR; CO Abernathy and RL Calderon (Eds.) 1999. “Arsenic Exposure and Health Effects.” Elsevier Science B.V. p81-88.

[13] US EPA January 22, 2001. “National primary drinking water regulations; Arsenic and clarifications to compliance and new source contamination monitoring (Final rule.)” *Fed. Reg.* 66: 6975-7066.

[14] *See* Davis, A, Sherwin D, Ditmars, R., and Honeke, K. 2001. An Analysis of Soil Arsenic Records of Decision. Environmental Science and Technology 35(12): 2,401–2,406 (Davis 2001); Valberg, P., Beck, B., Bowers, T., Keating, Bergstrom, J., Boardman, P. 1997. Issues In Setting Health-Based Cleanup Levels for Arsenic in Soil. Reg. Tox. and Pharm. 219-229 (Valberg 1997).

sediment site, the Agency for Toxic Substances and Disease Registry (ATSDR) found that 87 mg/kg arsenic in sediments at a boat ramp was "**not an apparent health hazard**."[15]

More generally, as a matter of policy and law, EPA and federal courts have concluded that a **10^{-4} risk from a hypothetical reasonable maximum exposure of the public to a carcinogen is "safe"** at Superfund sites, for drinking water nationally, for the Clean Air Act, and in numerous other EPA and other Federal regulatory decisions.[16] Thus, it is now well established in U.S. environmental and safety regulations and court decisions that **"safe" is not necessarily the same as "risk-free," and mere exposure is not sufficient to support regulation unless there is a significant risk**.[17]

E. These screening assessments do not take into account the background levels of chemicals, as required by both EPA and Ohio guidance and good science.

EPA's hazardous waste site clean up guidance,[18] the Ohio water quality protection program,[19] EPA metals risk assessment framework,[20] and the scientific literature recommend that

---

[15] Agency for Toxic Substances and Disease Registry, Health Consultation Health risks associated with arsenic in fish from arsenic-contaminated areas of the Menominee River Near Tyco Safety Products - Ansul Marinette, Marinette County, Wisconsin, EPA Facility ID: WID006125215 at 5 (May 15, 2006) (Ansul Health Consultation).

[16] *See* 40 C.F.R. § 300.430(e)(2)(i)(A)(2); EPA, National Oil Pollution and Hazardous Substances Contingency Plan, 55 Fed Reg. 8,666, at 8,752 (1990) ("1990 NCP), upheld in *Ohio v. EPA*, 997 F.2d 9520, 1532. (D.C. Cir., 1993), 36 ERC 2,065, 20,075-76) and 40 C.F.R. § 141.32(e)(45) which states that 0.5 ppb of PCBs in drinking water (which corresponds to the 10^{-4}) is "safe" and Drinking Water; National Primary Drinking Water Regulations-Synthetic Organic Chemicals and Inorganic Chemicals; National Primary Drinking Water Regulations Implementation, 57 Fed. Reg. 31,776 (1992) (final rule)). The court in *Natural Resources Defense Council v. EPA*, 824 F.2d at 1146, 1164 (D.C.Cir. 1987) in a unanimous en banc ruling found that the Clean Air Act "requires the Administrator to make an initial determination of what is 'safe'."

[17] *Industrial Union Dep't. v. API,* 448 U.S. 607, 642 (1980) ("*Ind. Union Dep't v API*"); *Natural Resources Defense Council v. EPA*, 824 F.2d, at 1164-65 As the Supreme Court stated in 1980, zero risk is a chimera, and trying to achieve it would consume unjustifiable amounts of resources. *Industrial Union Dept., AFL-CIO v. American Petroleum Institute,* 448 U.S. 607, 664, (1980) (Burger, J., concurring).

[18] EPA, Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites at 1-1 (EPA 540-R-01-003; September 2002), available at http://www.epa.gov/oswer/riskassessment/pdf/background.pdf (EPA Background Guidance 2002).

background levels of chemicals be considered at sites. This is particularly important for arsenic which is a naturally occurring metal in soil and sediment and has been added to the environment through anthropomorphic activities. Given the importance of background, a discussion of the applicable concepts concerning background levels of arsenic in soil is relevant (albeit not controlling) in order to understand the background level of arsenic in sediment.

According to EPA, "[i]n human health risk assessments, the term "background" refers to all existing metal sources except the targeted source."[21] This is because "[a]s a result of industrialization, current environmental levels of metals can be elevated relative to naturally-occurring levels. Depending on the purpose of the risk assessment, assessors should distinguish among naturally occurring levels, existing background levels, and contributions from specific activities at the local or regional level."[22]

If a chemical of concern has a high background concentration, "it should be discussed in the risk characterization, and if data are available, the contribution of background to site concentrations should be distinguished."[23] However, "under CERCLA, cleanup levels are

---

(continued...)

[19] For example, the Ohio water quality "use attainability analysis must demonstrate that the extant fauna is substantially degraded and that the potential for recovery of the fauna to the level characteristic of any other aquatic life habitat is realistically precluded due to natural background conditions or irretrievable human-induced conditions." See Rule 3745-1-07 of the Ohio Administrative Code, Water use designations and statewide criteria, (B) (1) (g) Use designations (Aquatic life habitat), available at <http://www.epa.state.oh.us/dsw/rules/01_all.pdf >. In fact, for water bodies in the Lake Erie drainage basin, one can demonstrate the "Outside Mixing Zone Average" water quality criteria and values and chronic whole effluent toxicity levels are not necessary to protect the designated uses and aquatic life. Id.

[20] U.S. EPA, Framework for Inorganic Metals Risk Assessment 4-4 (EPA/120/R-07/001, March 2007), available at <http://epa.gov/osa/metalsframework/pdfs/metals-risk-assessment-final.pdf>.

[21] U.S. EPA, Framework for Inorganic Metals Risk Assessment 4-4 (EPA/120/R-07/001, March 2007.

[22] Id.

[23] EPA Background Guidance 2002, *supra* note 14, at B-5.

not set at concentrations below natural background levels … [or] anthropogenic background concentrations" because of "cost-effectiveness, technical practicability, and the potential for recontamination of remediated areas by surrounding areas with elevated background concentrations."[24]

In this situation, the draft assessments did not take into account that arsenic is present at background levels in soil and sediment (both naturally occurring background levels and background levels due to the ubiquitous use of arsenic by the public for centuries). This leads to the incorrect perception that unacceptable risks are the result of contamination from nearby industries. This problem is particularly of concern for chemicals (like arsenic and other metals) which are known to have significant real world background levels due to activities unrelated to industrial activities.

An average is made up of a distribution of concentrations --- some of which are greater than the average and some which are less. There must be arsenic concentrations greater than 11.7 mg/kg if the average arsenic level in Ohio is 11.7 mg/kg.

The real world background concentration of arsenic in soil is typically higher than the natural background concentration because of the large number and type of non-site specific sources of arsenic in the environment. For example, concentrations of arsenic have been detected in commercial fertilizer at levels as high as 53 mg/kg and 123 mg/kg.[25] "As a result of industrialization, current environmental levels of metals can be elevated relative to naturally

---

[24] Id. at B-6.

[25] *See* Washington State Department of Agriculture, 2001. Pesticide Management Database, http://www.app2.wa.gov/agr and (Ma et al., 2000)).

occurring levels."[26] Thus, risk assessment may "distinguish among naturally occurring levels, existing background levels, and contributions from specific activities at the local or regional level."[27]

Therefore, background concentrations of arsenic in soil (and probably sediment) consist of a distribution of naturally-occurring levels of arsenic in soil plus an occasional higher level of arsenic from use of pesticides, fertilizers, wood preservatives, or some other source. That is, there is often soil or sediment with arsenic concentrations greater than the range of naturally occurring background (e.g., greater than 50 or even 100 mg/kg of arsenic in isolated samples) due to prior human usage of products containing arsenic. This random sample containing arsenic higher than the average drives the average up from the naturally occurring arsenic background levels. Thus, the real world average background concentration of arsenic in soil for Ohio must be higher than 11.7 mg/kg and the distribution of arsenic concentrations includes concentrations significantly higher than 11.7 mg/kg. Similarly, the real world average concentration of arsenic in sediment is higher than the concentration of just naturally occurring arsenic in sediment. A Duck and Otter Creek background sediment concentration, therefore, must be determined.

Where the background level exceeds the screening risk management level (here a one-in-one million (10^{-6}) risk level), one option is to consider only arsenic concentrations that are outside the range of background concentration, not a theoretical 0.39 mg/kg arsenic concentration that is likely to be exceeded by virtually all of the soil and sediment on the planet.

---

[26] EPA, Framework for Metals Risk Assessment (March 2007) (final) (available at <**http://www.epa.gov/osa/metalsframework/pdfs/metals-risk-assessment-final-3-8-07.pdf**> at 79 of 171).

[27] Id. At 79 of 171.

The concentrations of arsenic in sediment at Otter and Duck Creeks vary from 6.9 to 140 mg/kg). However, without a determination of background, it is not possible to determine the relevance of these levels. The draft assessment should be modified to perform appropriate statistical analysis of data from the watershed to determine the background level of arsenic and other chemicals found in the sediment.

There also is a background level of arsenic in fish. Fish tissue only presents a significant incremental risk if there is a significant incremental risk from arsenic levels above background. According to the ATSDR, background levels of arsenic in fish range from 0.007 to 1.7 mg/kg. For example, "Donohue *et al*. also report that mean total arsenic in 24 freshwater fish species is 0.3 mg/kg (range 0.007-1.46 mg/kg), 17-fold lower than in marine fish."[28]

The existence of a background level of arsenic in soil, sediment and fish requires a determination of the real world background level for arsenic in sediment and fish. Otherwise, decision-makers could be misled concerning what, if any, chemicals or sources are causing any impairment. As a result, a significant amount of the limited resources devoted to attaining the common goal of reducing the impairment to the environment caused by industrial activity would be wasted or misdirected.

The practical effect of the existence of background is that arsenic is likely to be removed from one or more of the exposure units along Otter and Duck Creeks. (This and other overestimations are discussed in more detail below).

---

[28] Ansul Health Consultation, *supra* note 11, At 2.

F. **The Draft Human Health Assessment ignored a significant quantity of prior sampling, which biases the calculation of the average arsenic concentration in sediment. The risk assessment does not provide a sufficient rationale for excluding prior sampling.**

Metals (including arsenic) do not degrade. Thus, it is a serious flaw for the Draft Human Health Assessment to ignore the prior sediment data. Data collected previously contained somewhat lower arsenic results. Specifically, the 2005 human health screening assessment calculated a 95% UCL on the mean of 30.5 mg/kg (based on 48 samples) for Otter Creek and 23.2 mg/kg (34 samples) for Duck Creek, respectively. Both of these levels are lower than the 2008 95% UCL values of 45.1 mg/kg (based on 27 samples) for Otter Creek and 89.7 mg/kg (19 samples) for Duck Creek, respectively.

The prior sampling event included a larger number of samples that may more accurately characterize the mean concentration of arsenic in sediments. Since there is no obvious reason to disregard the prior samples, failing to consider all of the data may have biased the calculated mean concentrations toward higher arsenic concentrations.

One of the reasons for this discrepancy may be that, from a statistical standpoint, a smaller sample size generally translates into greater uncertainty and thus the calculated 95% UCL is a relatively higher value. Thus, some of the difference between the 2005 and 2008 calculation of 95% UCL means may be because fewer samples were used in 2008. Likewise, the 95% UCL mean for each of the Otter Creek and Duck Creek five exposure units are much higher than the mean concentration for all of the samples for each stream.

If there are sufficient samples, the revised human health screening level might use the surface area weighted sediment concentration for arsenic (as is regularly done at other sediment sites). As noted above, an appropriate method should be adopted to consider the background levels of chemicals in the sediment of Duck and Otter Creek. Clearly, if there are sufficient sediment samples in a given area and the average concentration does not exceed background levels of arsenic in sediment for this watershed, no further action is needed regarding arsenic. Historical sampling also is useful for understanding distribution patterns.

In summary, the mean concentrations in the Draft Human Health Assessment based on the 2007 data only overestimate the concentration of arsenic significantly; the risk assessment should be adjusted to include all valid and representative data.

G. Contrary to specific EPA guidance and sound science, the Draft Human Health Assessment did not consider the oral bioavailability of compounds in sediment.

Arsenic is less bioavailable in soil and sediment. Variations in biovailability can significantly lower the risk calculated from a given concentration of arsenic in sediment.

A large number of *in vitro* and animal *in vivo* studies indicate that only a fraction of arsenic in soil (and suggesting by extension sediment) is bioavailable. Using a wide range of soil types and arsenic concentrations, the *in vivo* studies collectively show that the bioavailability of arsenic in soil generally ranges between 3% and 50% (See Table 2). Additionally, there is regulatory precedent for using a bioavailability for arsenic in soil less than 100% to determine levels of concern in soils. Table 3 lists a number of examples where relative bioavailability adjustments have been used, in some cases, by *default* in regulatory settings in the U.S. For instance, the Florida Department of Environmental Protection (FDEP) recently has determined that a default bioavailability for arsenic of 33% should be used to derive the Department's Soil Cleanup Target Levels for arsenic based on the results of an *in vivo* study in which between 11% and 25% of the arsenic in soil was bioavailable to primates in five soil samples (Roberts *et al.*, 2002). There is no reason to assume that the same type of arsenic in sediment would be more bioavailable. The draft assessment must at least evaluate the bioavailability of arsenic in sediment, which it has not.

In summary, any assessment of the risk from exposure to arsenic in sediment (including those in this Draft Human Health Assessment): (1) must determine and use the actual type of arsenic present (organic or inorganic, As(III) or As(V)) and (2) must determine and use appropriate bioavailability for arsenic in sediment.

H. Arsenic risk from fish consumption must account for the fact that fish generally contain organic arsenic, which is relatively nontoxic and do not typically contain high levels of inorganic arsenic.

Generally, arsenic in fish is found in the form of organic arsenic (which is bioavailable to the humans who ingest the fish, but which has a low toxicity). As a result, little, if any, risk is presented by organic arsenic in fish. In any case, no arsenic has been reported in the fish from Hecklinger's Pond (possibly because the fish were not analyzed for total arsenic or because no arsenic was present in the fish).

EPA, other health agencies, and researchers have long recognized that "[a]rsenic's …. bioavailability varies significantly depending upon its chemical form and route of exposure."[29] EPA concluded that "[b]ecause each arsenic species (e.g., As(III) [arsenite], As(V)

---

[29] EPA, Technology Innovation Program, Contaminant Focus, Arsenic, available at < http://www.clu-in.org/contaminantfocus/default.focus/sec/arsenic/cat/Toxicology>. In analogous situations, "arsenic bioavailability has been estimated for soils from various contaminated sites (Ng et al., 1998; Freeman et al., 1995, 1993) and also through a series of solubility studies of soil from a site contaminated with mine tailings (Ng et al., 1998; Salocks et al., 1996). Additional examples are animal feeding studies with juvenile swine for lead bioavailability adjustments or in vitro tests, although the Agency currently requires additional validation of the latter approaches before they can be used as the sole basis for making bioavailability adjustments (U.S. EPA, 2006a)." (U.S. EPA, Framework for Inorganic Metals Risk Assessment 4-4 (EPA/120/R-07/001, March 2007). The Agency for Toxic Substances and Disease Registry also stated that "[u]ltimately, most arsenic [that enters surface water] ends up in the soil or sediment," not in fish tissue. Agency for Toxic Substances and Disease Registry, Public Health Statement for Arsenic, available at <http://www.atsdr.cdc.gov/toxprofiles/phs2.html>.

Dominic M. Di Toro, a prominent researcher in this field noted that "[c]urrently available methods are based on the concentration of total arsenic … that ignore bioavailability." Research Project 7: Water-sediment Model and Criteria for Arsenic and Chrome Project Leader: Dominic M. Di Toro, Ph.D., available at <http://www.med.nyu.edu/environmental/centers/superfund/project7.html>. An EPA science advisory panel concluded that: "There is general scientific consensus that a number of physical, chemical and biological factors may impact the extent of gastrointestinal absorption of a substance present in ingested soil relative to the same substance ingested in solution. For arsenic, as with several other metals, solubility of the form of arsenic present in soil is a key factor, such that increased solubility or extractability of the metal from soil to an aqueous solution is positively correlated with increased absorption." FIFRA Scientific Advisory Panel, , Preliminary Evaluation of the Non-dietary Hazard and Exposure to Children from Contact with Chromated Copper Arsenate (CCA)-treated Wood Playground Structures and CCA-contaminated Soil. at 18 (Report No. 2001-12, December 12, 2001) ("EPA SAP Review of Treated Wood Risk Assessment"). Also see M. V. Ruby, R. Schoof, W. Brattin, M. Goldade, G. Post, M. Harnois, D. E. Mosby, S. W. Casteel, W. Berti, M. Carpenter, D. Edwards, D. Cragin, and W. Chappell,

(continued...)

[arsenate], AsB [arsenobetaine], MMA_{V} [monomethylarsonic acid]), MMA_{III}) exhibits different toxicities, it may be important to take into account the fraction of total arsenic present in the inorganic and organic forms when estimating the potential risk posed to human health through the consumption of arsenic contaminated fish."[30]

Despite the high levels of arsenic in sediment at the Ansul Fire Protection site, the concentration of arsenic in fish was low.[31] Only 11 fish out of the 1,496 fish sampled (0.7%)by Wisconsin had arsenic concentrations of total arsenic that ranged from 0.4 to 0.6 mg/kg in muscle and from 1.5 to 1.7 mg/kg in whole fish.[32] In other studies, Canadian Whitefish exposed to as much as 100 mg/kg dietary arsenate (Pedlar and Klaverkamp, 2002) had total arsenic of 0.38-0.56 mg/kg in muscle (wet weight; control = 0.48 mg/kg) and 0.30-0.57 mg/kg in bone (control = 0.08 mg/kg).[33] Generally, arsenic does not present a significant risk in the real world (*see also* discussion below).

(continued...)

Advances in Evaluating the Oral Bioavailability of Inorganics in Soil for Use in Human Health Risk Assessment, Environ. Sci. Technol.,Vol . 33. No. 21, 3697 -3705. 1999 and National Environmental Policy Institute, Assessing the Bioavailability of Metals in Soil for Use in Human Health Risk Assessments (Summer 2000) ("NEPI Bioavailability Report").

[30] EPA, Technical Summary of Information Available on the Bioaccumulation of Arsenic in Aquatic Organisms (EPA-822-R-03-032, December 2003), available at <http://epa.gov/waterscience/criteria/arsenic/tech-sum-bioacc.pdf> ("EPA Tech Summary of Arsenic Bioaccumulation"). *See also* EPA, Technology Innovation Program, Contaminant Focus, Arsenic, available at < http://www.clu-in.org/contaminantfocus/default.focus/sec/arsenic/cat/Toxicology.

[31] Ansul Health Consultation, *supra* note 11, at 12. The Wisconsin Department of Natural Resources (WDNR) reported individual fish with the highest concentration in fish from Lake Michigan, the Milwaukee river, the Menominee River, the Kenwaunee River, Lake Superior, the Grand River and Muskellunge River that range from 0.4 mg/kg to 1.7 mg/kg and that 86% of the 1,496 fish samples were below the detection limit. Only 30 fish samples had reportable concentrations. Id. at 12. In the Menominee River (where Ansul Fire Protection is located), only 3 of 51 fish samples had detectable levels (6.9%). Id. By definition, if most of the samples are below the detection limit the average concentration will be much lower than the highest concentration.

[32] Ansul Health Consultation, *supra* note 11, At 4.

[33] Id. at 4..

EPA Region 6 has concluded that "most of the arsenic is in the organic form in freshwater finfish,"[34] The State of Wisconsin concluded that "80-99% of the arsenic in fish is in the form of arsenobetaine and arsenocholine, organoarsenicals that have low bioavailability, and low toxicity" (Knobeloch *et al*. 1998; Ahmed, 1991).[35] Similarly, other federal agencies also have concluded that "[a]lthough some fish and shellfish take in arsenic, which may build up in tissues, most of this arsenic is in an organic form called arsenobetaine (commonly called "fish arsenic") that **is much less harmful** (bold face added)."[36]

Similarly, EPA's guidance states that "[w]here justified by site-specific data or by changes in knowledge over time, however, non-standard methods and assumptions may be used"[37] and that "[t]o determine the need for a response action, the site investigation should include gathering site specific background data for any potential chemicals of concern and their speciation, because contaminant … bioavailability (absorption into an organism) are important considerations for the risk assessment."[38] It is widely recognized in the scientific community

---

[34] EPA Region 6 Interim Strategy: Arsenic - Freshwater Human Health Criterion for Fish Consumption, available at http://www.epa.gov/region6/water/ecopro/watershd/standard/arsenic.htm (viewed August 4, 2008, last updated August 2, 2007), citing EPA's EPA National Toxics Rule (issued December 22, 1992) (EPA Region 6 Interim Strategy).

[35] Ansul Health Consultation, *supra* note 11, at 2.

[36] Agency for Toxic Substances and Disease Registry, Public Health Statement for Arsenic, available at <http://www.atsdr.cdc.gov/toxprofiles/phs2.html>.

[37] Risk Assessment Guidance for Superfund (RAGS), Volume I -- Human Health Evaluation Manual, Part A at 3-2 (1989). Site-specific uncertainties must also be described in the risk assessment. Id. at 8-17.

[38] EPA, Soil Screening Guidance: User's Guide Second Edition at 8 (July 1996) ("SSL Guide"), available at: http://www.epa.gov/superfund/resources/soil/ssg496.pdf. Similarly, the Department of the Navy has issued a comprehensive guidance on performing bioavailability studies for metals (including arsenic). U.S. Navy, Guide for Incorporating Bioavailability Adjustments into Human Health and Ecological Risk Assessments at U.S. and Marine Corps Facilities, Part 1: Overview of Metals Bioavailability (June 2000).

that "[c]urrently available methods are based on the concentration of total arsenic … and are known not to be predictive of toxicity."[39]

Thus, there is a significant difference in the toxicity of the different types of inorganic arsenic (As(III) versus As(V)), as well as between inorganic and organic arsenic. It is widely accepted that estimating fish tissue concentration of arsenic from sediment concentration data may overestimate the concentration in fish. In the present situation, such an approach appears to be inconsistent with the concentration found in the Pond.

In fact, recently, the State of Wisconsin concluded that "[m]any studies have documented that up to 90% of arsenic in fish is in the form of organo- arsenicals that has low toxicity."[40]

As a result of these types of issues, EPA Region 6 recommends that any calculation of the risk from exposure to arsenic in fish and any comparison to arsenic criterion be "based upon the inorganic fraction that would be found in edible fish tissue."[41] Similarly, the FDA assumes that 10% of the arsenic in fish is inorganic. The FDA states that "[a]lthough the tolerable daily intake for arsenic is based on exposure to **inorganic** arsenic, most arsenic present in shellfish is in an **organic** form (which is relatively non-toxic) and most monitoring methods determine **total** arsenic. To use traditional monitoring results to evaluate acceptable levels of shellfish consumption or acceptable levels of arsenic contamination, an estimation procedure that

---

[39] Research Project 7: Water-sediment Model and Criteria for Arsenic and Chrome Project Leader: Dominic M. Di Toro, Ph.D., available at <http://www.med.nyu.edu/environmental/centers/superfund/project7.html>. Some of EPA's Science Advisory Panel members reviewing the risk assessment accepted the 25% relative bioavailability and the vast majority recommended values from 25% to 50%.EPA SAP Review of Treated Wood Risk Assessment at 20.

[40] EPA. Statement Of Basis For Ansul Fire Protection, Stanton Street Facility EPA ID No. WID 006 125 215 At 12-13 (September 12, 2007), available at <http://www.epa.gov/reg5rcra/wptdiv/permits/mr_ansul_final_SOB.pdf>.

[41] EPA Region 6 Interim Strategy, *supra* note 30..

assumes that inorganic arsenic accounts for only 10% of the arsenic in shellfish is proposed for converting measurements of total arsenic to estimates of **inorganic** arsenic.[42] Thus, either actual fish concentration data must be gathered or the total arsenic concentration estimated in the assessment should be reduced by at least a factor of 10 to reflect a low level of inorganic arsenic in fish.

In summary, any assessment of the risk from exposure to arsenic in fish (including those in this Draft Human Health Assessment): (1) must determine and use the actual type of arsenic present (organic or inorganic, As(III) or As(V)) and use information on inorganic arsenic to calculate risk and (2) must determine and appropriately model inorganic arsenic uptake from sediment into fish.

I. The Draft Human Health Assessment should not use the biota sediment accumulation factor (BSAF, i.e., the ratio used to calculate fish tissue concentrations from sediment concentrations); this model as used in the risk assessment yields results that are unrealistic and inconsistent with known information on the relationship between arsenic in sediment and uptake in fish.

The Draft Human Health Assessment uses the U.S. Army Corps of Engineers (USACE) BSAFs to derive the concentration of organic chemicals in fish allegedly attributable to sediment. The USACE guidance does not provide an arsenic BSAF because such BSAF must be site specific. That is, the USACE states that "BSAFs (Biota Sediment Accumulation Factors) are based on the relationship between lipid normalized tissue and total organic carbon normalized sediment. To date, only non-polar organic compounds have been shown to hold to this relationship and even these chemicals show a wide variation due to numerous factors."[43] In

---

[42] United States Food and Drug Administration, Guidance Document for Arsenic in Shellfish (January 1993), available at <http://www.cfsan.fda.gov/~frf/guid-as.html>.

[43] U.S. Army Corps of Engineers, BSAF Database, Frequently Asked Questions, available at <http://el.erdc.usace.army.mil/bsaf/what.html#Metals>.

this Draft Human Health Assessment, however, Tetra Tech used the BSAF value for arsenic that was derived for a different site (the Buffalo River).[44] The BSAF value derived for a site on the Buffalo River has questionable relevance to the Duck and Otter Creeks.

The surface water concentrations of arsenic are generally thought to be a better predictor of fish uptake of arsenic. In general, the relationship between arsenic in sediment and arsenic in fish is rather weak. Instead of using a BSAF from a site with different characteristics (see discussion of ecological assessment, below), the human health risk assessment should evaluate the site-specific concentrations of arsenic in surface water (which are very low) and the relative degree of contribution of arsenic from sediment and fish as this site.

Therefore, it was inappropriate to use a BSAF from another site to calculate the arsenic level in fish and laboratory tests relied upon in the Draft Human Health Assessment are of questionable site-specific applicability. As a result, the estimated risk from ingesting fish containing arsenic is erroneous. Site-specific data must be gathered to assess the risk of the bioaccumulation of inorganic arsenic in fish to understand potential risks from Hecklinger Pond.

The need for site-specific data is demonstrated by a comparison of the arsenic and fish concentrations at Duck and Otter Creek to other sites.

The arsenic concentration in the sediment at Duck and Otter Creeks is much lower than levels that have been found not to present a hazard at other arsenic sites, such as the Ansul site. At the Ansul site, notwithstanding that the sediment contained higher arsenic

---

[44] U.S. Army Corps of Engineers 2003 Volume I: Project Overview, Sediment Sampling Biological Analyses, and Chemical Analyses for Buffalo River Areas of Concern, Buffalo, New York, Engineer Research and Development Center. December. See Table 9.

concentrations than at the Duck and Otter Creeks, the fish levels did not present a hazard..[45] The average arsenic concentration in Menominee River rock bass at the Ansul site is 0.6 mg/kg (600 μg/kg) in the fish fillet (i.e., the whole fish concentration would be higher).[46] At the Ansul site, arsenic sediment levels were reported as high as 2000 mg/kg. This result clearly is inconsistent with the modeled fish data from Hecklinger Pond where mean sediment arsenic levels were only 94.5 mg/kg but estimated fish concentration (using to BSAF model) were 23.1 mg/kg.

The draft human health assessment's estimation that the risk to adults, youths, and children from ingesting fish from Hecklinger Pond is eight in one thousand (8×10^{-3}), 3 in 10^{-3} (3×10^{-3}), and 3×10^{-3}, respectively (for a total risk of one-in-one hundred (1×10^{-2}),**[47]** is an exaggeration based on unrealistic and unreliable estimations that, based on our preliminary review, seem to ignore the actual measurements of the levels of chemicals in fish taken from Hecklinger Pond and the 2005 finding of no significant risk from the ingestion of fish.

Additionally, the Draft Human Health Assessment calculated the combined lifetime risk to a child, youth, and adult who has regular contact with the sediment in Hecklinger Pond and eats the fish that may be added to the Pond in the future to be roughly 1.2 in 100 (1.2×10^{-2}), 21.7% of which is due to arsenic. This risk, however, is not based on measured levels of arsenic in fish, but on the various assumptions and calculations performed to estimate a worst-

---

[45] "Arsenic concentrations in river sediments exceeding 2000 milligrams per kilogram (mg/kg; maximum 3670 mg/kg) have been detected in the turning basin adjacent to the former stockpile (URS, 2003). Arsenic reported in sediments near the Sixth St. boat ramp (Figure 1) was 87 mg/kg." Ansul Health Consultation, *supra* note 11, at 2.

[46] Id. at 4.

[47] Draft Human Health Assessment at ES-3.

case arsenic concentration in fish tissue based on the worst-case estimations of the arsenic levels in sediment.[48] This calculation is not scientifically supportable.

More importantly, there is no current exposure to fish because Hecklinger Pond was drained and has no fish in it at this time. The only accurate description of the risk is zero present risk and at best a potential future risk.

Additionally, if the State were to restock the pond (which might not be a cost-effective approach), the frequency at which it is assumed that people will ingest fish from this Pond is unrealistically high.

The future risk from a restocked pond should not be greater than the historic risk. The draft 2008 human health screening assessment, however, ignores the actual fish data from Hecklinger Pond (which either found no arsenic in the fish or possibly did not measure arsenic) and which Tetra Tech concluded presented no significant human health risk. Instead, the draft 2008 human health screening risk assessment makes worst case assumptions that result in a calculation of a significant risk.

This assessment assumes that inorganic arsenic in sediment bioaccumulates in fish and is found in fish as inorganic arsenic. As noted above, this assumption is not adequately documented, particularly concerning whether water or sediment is the primary pathway for the accumulation of arsenic in fish and most evidence suggests that surface water, rather than sediment is the more important pathway.

---

[48] The Draft Human Health Assessment calculates a concentration of arsenic in fish tissue of 23.1 mg/kg for Hecklinger Creek allegedly based on the sediment concentration in Table 6, the biota sediment accumulation factor for arsenic, and other factors listed in Table 10 of the report, but we cannot reproduce the calculation. The 2005 draft assessment lists arsenic as a chemical of concern for sediment, but does not list arsenic as one of the chemicals found in fish during the periodic sampling of fish. As we read the 2005 assessment, it appears that arsenic was analyzed for and not found. However, given the limited time available for review, we have not reviewed the underlying data. Such review was made more difficult by the fact that the online database does not yet contain this data.

As far as we can tell, arsenic was not detected in fish from Hecklinger Pond and is typically not detected in elevated levels in fish even at sites where arsenic is present at thousands of parts per million). By ignoring the existing data on arsenic in fish, the assessment attributes approximately 21.7% of the risk from ingesting non-existent fish from Hecklinger Pond to a chemical that is either not present in the fish or is unlikely to be present at elevated levels.

Thus, real world data at other arsenic sediment sites is inconsistent with the assumptions used in the Draft Human Health Assessment.

J. The exposure assumptions in these assessments are biased toward high concentrations, high exposure frequencies, and other assumptions that take "typical" levels and make them appear excessive. PNA recognizes that environmental evaluations of this type often contain, as a practical matter, health protective assumptions. However, the purpose of the BHHRA should be to focus on and identify the COPC which present the greatest risk.

For example, these screening assessments retain chemicals of potential concern (COPC) that contribute to cumulative hazard, even when the maximum concentration or exposure point concentration does not exceed the screening value, calculate exposure point concentrations using data sets with too few sampling points, and use high, site-specific assumptions concerning the frequency of exposure that seem to be at odds with the reasonable maximum exposure assumptions used at many other cleanup sites. For example, the assumptions that a child (one year old to six years old) eats an average of 11.1 grams of fish per day (i.e., the annual ingestion of periodic meals is averaged over 365 days) from Hecklinger Pond for 365 days a year (or an average of 77.7 grams per week), and plays in Duck and Otter Creeks 2 hours a day[49]) for 60 days[50] each year for 6 years appear overly conservative and bias

---

[49] Draft Human Health Assessment at Table 8 at p. 3 footnote e, which states that child spends 2 hours out of the estimated 6 hours spend outdoors during these days. That is, 33% of the time during the day, they are playing in either Duck or Otter Creek.

the risk estimation on the high end. Ingestion of a significant amount of locally caught and prepared fish by children as young as one year old seems to be unrealistic and certainly is not supported by any site-specific data. Even for adults, there is no site-specific data supporting the existence of a population that ingests a significant amount of recreationally caught fish (25%) from this one (now drained) pond. Regulatory assumptions used to develop the standard "must bear some rational relationship" to the actual conditions.[51] The regulatory agency "may not engage in sheer guesswork"[52] and it must "justify its failure to take account of circumstances that appear to warrant different treatment for different parties."[53]

This initial, limited review did not uncover other cleanup sites or regulations that used similar assumptions. Use of unsubstantiated assumptions may create an obstacle to accomplishing the purpose of the screening assessment which is to focus on those COPCs which truly "drive" the hazard and/or risk.

As a result, these screening assessments could lead regulators toward actions that will significantly drain limited financial resources but that will not significantly reduce the level of impairment for this area of concern.

(continued...)

[50] Draft Human Health Assessment at Table 8 at p. 2 footnote b, which states that child is exposed for "4 days per week for 13 weeks (June through August) and 2 days per month for 4 months (April, May, September, and October)." Id.

[51] *Edison Electric Inst. v. EPA*, 2 F.3d 438, 446 (D.C. Cir. 1993). Also cited in *Leather Indus. of America v. EPA*, 40 F.3d 392, 402 (D.C. Cir. 1994).

[52] .*American Petroleum Institute v. Costle*, 665 F.2d 1176, 1186-87 (D.C. Cir. 1981), *cert. denied*, 455 U.S. 1034 (1982).

[53] .*Petroleum Communications v. FCC*, 22 F.3d 1164, 1172 (D.C. Cir. 1994), also cited in *Leather Indus. of America*, supra this note 50, at 403.

K. **The risks from ingestion and dermal exposure to arsenic in sediment are below a level of concern and do not warrant any action.**

Even using the exposure point concentrations for sediment provided in the draft screening human health assessment (i.e., ignoring the overestimations discussed above), the risk from ingestion and dermal exposure to arsenic in sediment for each receptor (according to the draft human health screening level) ranges from 4.7×10^{-6} to 3.2×10^{-5} , which is below the 1×10^{-4}, EPA's target level.

A **10^{-4} risk from a hypothetical reasonable maximum exposure of the public to a carcinogen is "safe"** at Superfund sites, safe for drinking water nationally, safe for the Clean Air Act, and safe in numerous other EPA and other Federal regulatory decisions, as discussed above. If background levels and the use of all of the data provide more representative concentrations, the risk levels would decrease even further. As discussed below, some of the exposure assumptions are overly conservative and not supportable. Thus, the incremental risk from arsenic in sediment due to industrial sources at these two sites is over estimated.

Even the cumulative risk from ingestion and dermal exposure to all chemicals in sediment is lower than EPA's safe level of 1×10^{-4} for all exposure units along Duck Creek and Otter Creek, except for Duck Creek exposure unit E (which presented a risk of 2×10^{-4}).[54] Six of the exposure units present a worst-case risk of 3.0×10^{-5} or less.[55] Based on EPA Superfund risk management guidance, no action is warranted for all but one of these exposure units, based on human health risk. At another arsenic sediment site, ATSDR found that 87 mg/kg arsenic in sediments at a boat ramp was "**not an apparent health hazard**."[56]

---

[54] Draft Human Health Assessment at Table 23.

[55] Draft Human Health Assessment at Table 23.

[56] Ansul Health Consultation, *supra* note 11, at 5.

III. THE FLAWS IN THE ECOLOGICAL RISK ASSESSMENT

A. Introduction

The draft ecological risk and screening assessment generally follows many aspects of regulatory guidance on assessing ecological risk, but it fails to consider historic data, ignores the presence of background levels of many chemicals found in the sediment (particularly chemicals such as arsenic (*see* above)), tends to underemphasize factors that indicate a low risk, uses problematic data, and is based on calculations that, in some circumstances, are contradicted by site-specific data and some regulatory ecological risk guidance (*see* below). In particular, it is inappropriate to use a calculation of lesion for polyaromatic hydocarbons as a screening criteria for freshwater fish because this screening method was developed for marine sediments and it may not be appropriate for liotic sediments (such as those present at this site).

Similarly, the sediment toxicity testing had significant implementation issues (see below) and, as a result, is not informative. No benthic surveys were done. Site-specific bioavailability results actually suggest high acid volatile sulfides (AVS), which is a measure of bioavailability of certain metals and concentrations and low bioavailability for metals. Although arsenic is generally not an AVS/simultaneously extractable metals (AVS/SEM) metal, some studies have shown a relationship between AVS and lower arsenic toxicity.

As such, conclusions on sediment risks were drawn on the basis of exceedances of very conservative and non site-specific screening criteria, an inappropriate PAH fish lesion screening tool, a substantially flawed sediment toxicity test, and despite evidence for low chemical bioavailability.

More generally, the risk management criteria for ecological risks are, as a practical matter, less well developed and established than for human health risk assessments. All of these factors suggest significant additional work is needed and substantial caution should be taken prior to making any decisions on how to proceed at Duck and Otter Creek.

B. The ecological risk and screening assessment relies more significantly on a screening level approach rather than a site-specific approach and fails to state clearly that such a screening level ecological risk assessment cannot be relied upon to trigger remedial action and should not be used to set clean up goals.

Federal guidance repeatedly states that screening levels cannot be used as remediation goals.[57] US EPA's basis for setting a long-term ecologically-based PRG is provided in the August 8, 2000 memorandum ("Ecorisk Memo").[58] The only ecological risk assessment guidance cited in the Ecorisk memo,clearly states that the ecorisk evaluations are "screening-level risk assessments," i.e.: the risk assessments:

> are simplified risk assessments that can be conducted with limited data by assuming values for parameters for which data are lacking. At the screening level, it is important to minimize the chances of concluding that there is no risk when in fact a risk exists. Thus, for exposure and toxicity parameters for which site-specific information is lacking, assumed values should consistently be biased in the direction of overestimating risk. This ensures that sites that might pose an ecological risk are studied further.[59]

---

[57] As stated above, US EPA guidance states that there is no "magic number" that can be set for sediment cleanups. However, if the residual SWAC concentration of the chemicals at the site exceeds a duly issued screening level additional data and information must be obtained to assess whether the conditions at the Site are protective of human health and the environment.

[58] Memorandum from J. Chapman, Ecologist, Region V, to Tom Williams, RPM, Region V, Re: Derivation of Ecologically Protective Remedial Sediment Goals, South Branch Shiawassee River, Livingston Co., MI (August 8, 2000) ("Ecorisk Memo").

[59] US EPA, Ecological Risk Assessment: For Superfund, Process for Designing and Conducting Ecological Risk Assessments at 1-2 (EPA 543-4-97-006, 1997) ("1997 Ecorisk Guidance").

This same US EPA ecological risk guidance cited in the Ecorisk Memo clearly states that: "[c]onservative assumptions have been used for each step of the screening-level ecological risk assessment. Therefore, requiring a cleanup based solely on this information would not be technically defensible."[60]

EPA's official position is that sediment screening values "are not regulatory criteria, site-specific cleanup standards, or remediation goals."[61] Rather, they are "reference values above which a sediment ecotoxicological assessment might indicate a potential threat to aquatic life."[62] The United States Army Corps of Engineers (the Federal agency which has the most experience and longest history of assessing the human health and environmental impacts from sediments contaminated with chemicals) concluded that the use of numerical sediment cleanup goals has **"no scientific basis and offered no environmental protection**."[63] (Emphasis added.)

Thus, the use of a non-site specific screening level assessment to set remediation goals at a site is arbitrary and capricious, contrary to US EPA policy, and otherwise contrary to law.

EPA guidance has long held that "where substantial ecological impacts will result from the remedy (e.g., dredging a wetland), the risk manager will need to . . . compare the

---

[60] Id. at 2-6.

[61] EPA, Incidence And Severity of Sediment Contamination in Surface Waters of The United States, Volume 1, at Appendix D p. xvii (September 1997) ("EPA Sediment Report To Congress"). *See also* EPA's Contaminated Sediment Management Strategy at Section 5, p.4 of 14 (Sept. 15, 1998) ("EPA Contaminated Sediment Strategy"), found at www.epa.gov/OST/cs/manage/strat5.html, at p. 4 of 14 .

[62] Id. at Appendix D p. xvii.

[63] Memorandum from Major General R. Fuhrman, Army Corps, to Commanders, Re: Use of Sediment Quality Guidelines in Dredged Materials Decision Making at 2 (October 28, 1998) ("Corps SQG Guidance").

mitigated impacts to the threats posed by the site contamination.[64] EPA 1996, 1997 and 1999 ecological risk assessment guidance documents stress the need to determine whether the harm caused by the remedy is worse than the ecological risk which is being remedied.[65] If the "impacts of the remedial alternative are determined to cause more environmental harm than leaving the contaminants in place, EPA may not proceed with a cleanup at that time."[66] According to EPA guidance, "[w]idespread, low levels of contamination may favor natural attenuation."[67] Similarly, if "fairly discrete areas … are removed, the rest of a site may be left alone for natural attenuation" to attain long-term cleanup.[68] As another EPA guidance states, "[u]nder any reading of the regulations [EPA] is empowered to leave the sediments in-place in a manner that will not present an unreasonable risk to human health and the environment."[69]

The triad study approach incorporates a weight-of-evidence approach that considers arsenic concentration, sediment toxicity, and benthic community characteristics. The objective of a triad evaluation is to determine the inter-dependence of these three factors, if any,

---

[64] 1997 Ecorisk Guidance, supra note 56, at 8-3.

[65] Id., at www.epa.gov/OST/cs/manage/strat8.html, at Section. 8, p. 1 of 12. *See also* Memorandum from Stephen Luftig, Director of Office of Emergency and Remedial Response to Superfund National Policy Managers Re: Issuance of Final Guidance: Ecological Risk Assessment and Risk Management Principles for Superfund Sites at 6 (OSWER Dir. No. 9285.7-28P, October 7, 1999) ("Final Ecological Risk Management Guidance"), available at www.epa.gov/superfund/programs/risk/ecolisk/final 99.pdf. It has long been EPA policy that "where substantial ecological impacts will result from the remedy (e.g., dredging a wetland), the risk manager will need to . . . compare the mitigated impacts to the threats posed by the site contamination." *See* EPA, Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments 8-3 (Interim Guidance) (EPA 540-R-97-006, June 1997).

[66] EPA Contaminated Sediment Strategy, www.epa.gov/OST/cs/manage/strat8.html, at Section 8, at p. 1 of 12, which states unequivocally that in certain circumstances "the best strategy may be … to allow natural attenuation." Id. at Chap. 8, p. 1 of 9.

[67] Id. at Chap. 8, p. 2 of 12.

[68] Id. at Chap. 8, p. 2 of 12.

[69] Memorandum form J. Carra, Office of Pollution Prevention, to Stephen Luftig, Acting Director, Office of Emergency and Remedial Response, Re: Disposal of PCBs Contaminated Sediments (April 3, 1995).

and to determine if arsenic concentrations have an actual impact on sediment toxicity or the health of the benthic community. The underlying principles are that sediment chemistry is necessary to determine contamination (i.e., the distinction between background and elevated levels), but provides no indication of biological damage. Direct toxicity testing may establish the toxicological significance of the chemistry data, but may not accurately reflect the response of the resident benthic community. The survey of the benthic community identifies possible perturbations in the resident faunal community, but may be modified based on habitat-related variations and other factors. The ultimate question is whether the contamination from a discrete source is causing a significant impact on the local ecosystem.

C. **The draft ecological risk and screening assessment places little emphasis on the Ohio water quality standard for arsenic or EPA acute or chronic national recommended water quality criteria for arsenic.**

The draft human health and ecological risk and screening assessments place little emphasis on the Ohio water quality standard for arsenic or EPA acute or chronic national recommended water quality criteria for arsenic, precisely the standard and criteria design to protect the environment.

Focusing on sediments exclusively and ignoring the impact of current surface water quality presents an impediment to rational decision making regarding how to best improve the health of both creeks.

The draft ecological risk and screening assessment compared the maximum historical concentration of chemicals measured in the surface water of Duck and Otter Creek to the Ohio water quality standard and, where there was no water quality standard, to the EPA Region 5 ecological screening level for surface water (see Tables 21 and 22 from the draft ecological risk and screening assessment, which are inserted in this letter, below).

No maximum surface water concentrations for arsenic in Duck Creek exceeded the legally binding surface water quality standard. The maximum concentration of barium and vanadium ever measured barely exceeded the nonbinding Region 5 ecological screening level (0.249 milligram per liter (mg/l) versus 0.22 mg/l and 0.019 µg/l versus 0.012 µg/l). For Otter Creek, the maximum concentration of ammonia, copper, cyanide, lead, mercury, and selenium only slightly exceed the Ohio water quality standard.

TABLE 21
COMPARISON OF MAXIMUM SURFACE WATER CONCENTRATIONS TO WATER QUALITY STANDARDS OR SCREENING LEVELS
DUCK CREEK

Chemical	Maximum Concentration	Exposure Area	Data Source	Ohio Water Quality Standard	EPA Region 5 Ecological Screening Levels (ESL)	Exceeds Standard/ ESL
Inorganics	mg/L			mg/L	mg/L	
Ammonia	0.5	Area C	a	0.6		No
Barium	0.249	Area B	b	NA	0.22	Yes
Manganese	0.153	Area B	b	NA	NA	--
Vanadium	0.019	Area B	b	NA	0.012	Yes
Zinc	0.13	Area D	a	0.3		No
Organics	µg/L			µg/L	µg/L	
Acetone	11.4	Area B	c	NA	1700	No
Trichlorofluoromethane	2	Area B, C, D, E	a	NA	NA	--

Notes:
mg/L Milligrams per liter
µg/L Micrograms per liter

Sources: Ohio Water Quality Standards – Ohio Administrative Code 3745-01,assumed a water hardness of 300 mg/L as calcium carbonate.
EPA Region 5 ESLs (EPA 2003)

a SECOR International, Inc. (SECOR). 2005. Spreadsheet Presenting Analytical Data for Surface Water and Sediment Samples for Duck Creek, Otter Creek, and the Maumee River. Samples Collected by SECOR for the Chevron USA Inc. Toledo Refinery, 2935 Front Street, Toledo, Ohio.

b Quality Specialists & Environmental Analysts, Inc. (QSEA). 1996. "Data Validation Report, Sample Delivery Groups CS001S, CS010W, 201SED, and CS310S, Maumee RAP Project, Consaul Street Location." Prepared June 1996; revised September 1996.

c BEC Laboratories. 2003. Analytical Results for Surface Water Samples Collected from Duck Creek on October 15, 2003.

TABLE 22
COMPARISON OF MAXIMUM SURFACE WATER CONCENTRATIONS TO WATER QUALITY STANDARDS OR SCREENING LEVELS
OTTER CREEK

Chemical	Maximum Concentration	Exposure Area	Data Source	Ohio Water Quality Standard	EPA Region 5 Ecological Screening Levels (ESL)	Exceeds Standard/ ESL
Inorganics	mg/L			mg/L	mg/L	
Ammonia	3.02	Area B	a	0.6		Yes
Antimony	0.012	Area D	b	NA	0.08	No
Arsenic	0.033	Area A,B	c	0.15		No
Barium	0.088	Area D	b	NA	0.22	No
Beryllium	0.0012	Area C	c	NA	0.0036	No
Cadmium	0.013	Area B	a	0.0058		Yes
Chromium	0.0805	Area B	a	0.210		No
Copper	0.055	Area B	a	0.024		Yes
Cyanide	0.018	Area C	c	0.0052		Yes
Lead	0.32	Area B	a	0.026		Yes
Mercury	0.0217	Area B	a	0.00091		Yes
Nickel	0.055	Area B	a	0.130		No
Selenium	0.07	Area D	b	0.005		Yes
Zinc	0.198	Area B	a	0.3		No
Organics	µg/L			µg/L	µg/L	
2,4-D	1.395	Area D	b	NA	220	No
Chloroform	2.9	Area A	c	NA	140	No
Ethylbenzene	1	Area C	d	NA	14	No
m&p Xylenes	6	Area C	d	NA	27	No

Notes:

mg/L	Milligrams per liter
µg/L	Micrograms per liter

Sources: Ohio Water Quality Standards – Ohio Administrative Code 3745-01 assumed a water hardness of 300 mg/L as calcium carbonate.

EPA Region 5 ESLs (EPA 2003)

a	City of Toledo (1992to 2002) Stream sampling data from 1992 to 2002.
b	ENVIRON International Corporation (ENVIRON) and The Mannik & Smith Group, Inc. (Mannik & Smith). 2003. "Resource Conservation and Recovery Act Facility Investigation (RFI) Phase I Report and Phase II Work Plan, Envirosafe Services of Ohio, Inc., Otter Creek Road Facility, Oregon, Ohio." July.
c	Ohio Environmental Protection Agency (OEPA). 1992 to 1998. Analytical Results for Phases I through III of Sediment and Surface Water Sampling in the Maumee River Area of Concern, Including Duck and Otter Creeks. Northwest District Office, Division of Surface Water.
d	SECOR International, Inc. (SECOR). 2005. Spreadsheet Presenting Analytical Data for Surface Water and Sediment Samples for Duck Creek, Otter Creek, and the Maumee River. Samples Collected by SECOR for the Chevron USA Inc. Toledo Refinery, 2935 Front Street, Toledo, Ohio.

In some cases, chemicals identified as potentially presenting a risk due to concentrations in sediment or estimated concentrations in fish have surface water concentrations that are far below water quality standards. For example, the maximum concentration of arsenic measured in Otter or Duck Creek surface water was 0.033 µg/l, well below the Ohio drinking water standard of 10 µg/l[70], and far below the EPA arsenic acute and chronic national recommended water quality criteria of 340 micrograms per liter (µg/l) to 150 µg/l, respectively.[71]

D. The laboratory test of the survival of organisms exposed to the sediment found many samples where the control sample and the sample from Duck or Otter Creek were not significantly different.

However, these laboratory tests are suspect because "[t]here are several issues with the bioassay results that should be noted. The tests were conducted with two water replacements per day, rather than aeration. This approach may cause additional agitation of the sediments and increase the physical stress levels to the organisms. It was also noted in the bioassay tests, organisms were observed floating in the test chambers, in both the test cells and the control cells. This could suggests the organisms may have had an inefficient food supply or crowding, both would cause added stress to the organisms."[72]

Additionally and more importantly, the control sediment was taken in New Jersey and is substantially different with respect to many confounding factors that are known to affect toxicity. For instance, the control sediment samples have the lowest conductivity, lowest pH, lowest

---

[70] Ohio Water Quality Standards – Ohio Administrative Code 3745-01 assumed a water hardness of 300 mg/L, as calcium carbonate, cited in the Draft Otter and Duck Creek Human Health Screening Assessment at .

Ohio Administrative Code 3745-1-33 Water quality criteria for the lake Erie drainage basin is 10 µg/l for total recovered arsenic, Table 33-2, Lake Erie drainage basin water quality criteria for the protection of human health and wildlife available at <http://codes.ohio.gov/oac/3745-1-33+> and http://www.epa.gov/waterscience/standards/wqslibrary/oh/oh_5_3745-1-33_wqs.pdf>. The statewide water quality standard for arsenic is 340 and 150 g/l of total arsenic in surface water. Ohio Administrative Code, 3745-1-07 Water use designations and statewide criteria, Table 7-1. Statewide water quality criteria for the protection of aquatic life, available at <http://codes.ohio.gov/oac/3745-1-07>.

[71] EPA, Current National Recommended Water Quality Criteria, EPA Internet Site, available at <http://www.epa.gov/waterscience/criteria/wqctable/index.html>.

[72] The Draft Ecological risk and screening assessment at 37.

alkalinity, lowest hardness, and significantly lower ammonia concentrations. The confounding factors were not taken into account when trying to link analyte concentrations to observed toxicity. The report notes that it was not possible to take into account these confounding factors, which provides the analysis with limited weight. There should be a more thorough statistical analysis to evaluate whether the above-mentioned physical-chemical parameters were more important in explaining the observed toxicity. In summary, the sediment toxicity tests hold little value in explaining the observed toxicity and linking it to contaminants in both creeks.

E. There is a high probability that the arsenic in the sediments may be bound and not significantly bioavailable to creatures in the ecosystem

The draft, on its face, acknowledges the "high probability that most of the metals in the sediments may be bound to sulfides and so are not bioavailable."[73] Yet most of the draft assessment emphasizes risks from metals. There are studies that have examined the interactions between AVS and arsenic and how it relates to toxicity. Given the limited time available for this review, we have not yet summarized that literature and applied it to this site. It is likely, however, that such a review might well have an impact the conclusions concerning the potential arsenic ecological risks at Duck and Otter Creek.

F. The ecological risk from arsenic is based substantially on the bioaccumulation of arsenic from sediment and water into fish, but the food chain model used is fundamentally flawed

Arsenic in sediment has been identified as a chemical that may present a substantial risk, almost exclusively based on bioaccumulation (as discussed above). The assumptions in the food chain model used are flawed, are not based on our current scientific understanding of arsenic bioaccumulation, and, as a result, significantly and substantially

---

[73] The Draft Ecological risk and screening assessment at 37.

overestimate the arsenic levels in fish which, in turn, result in a significant overestimate of the ecological risks to higher trophic ecological receptors (mink, kingfisher) and humans.

EPA released a technical summary of information available on bioaccumulation of arsenic in aquatic organisms (cited above). In addition, a publication by Williams *et al.* (2006)[74] reviews arsenic bioaccumulation in freshwater fish. The key findings in these reports are that bioaccumulation of arsenic is estimated from concentrations in the water, NOT the sediment. Williams *et al.*, reviewed eight field studies with arsenic water concentrations ranging from <0.5 µg/L to 56 µg/L and sediment concentrations (where reported) up to 673 mg/kg. Maximum arsenic concentrations in fish in these field studies were 2.3 mg/kg ww, but generally < 500 µg/kg. Similarly, laboratory exposures at concentrations up to 18 mg/L found total arsenic body burdens of 3.4 mg/kg ww in fish.

The levels of arsenic in Otter and Duck Creek sediment are substantially lower than those reported in this review, yet fish arsenic body burdens are modeled to be up to 26 mg/kg in Duck Creek and up to 12 mg/kg in Otter Creek. It is obvious that the BSAF value that was used to estimate fish body burdens from sediment is inappropriate.

We recommended that an appropriate BCF be selected from these studies to estimate fish body burdens in both creeks. The fact that the AWQC for arsenic, which was derived based on protection of human health (including fish ingestion), was not exceeded in both creeks underscores the flaws of the FCM that was used to estimate human health and ecological risks.

---

[74] Williams L, Schoof RA, Yager JW, Goodrich-Mahoney JW. 2006. Arsenic bioaccumulation in freshwater fishes. Human and Ecological Risk Assessment 12: 904-923.

IV. **CONCLUSION**

Both the human health and ecological risk assessments are not true, site-specific risk assessments and both require further refinement to characterize the respective risks appropriately. In general, the average arsenic concentrations in sediment overestimate the real concentrations due to a failure to consider historic data and because the averages are calculated for small creek segments which appear to result in artificially high 95% upper confidence level mean concentrations. On its face, however, the risk calculated by this assessment even using the biased high arsenic sediment concentrations result in safe levels of risk based on ingestion and dermal exposure to arsenic (i.e., a risk less than 10^{-4}). This risk is overstated because of the method used to calculate the average concentration in sediment, the failure to consider the ubiquitous background concentrations of arsenic, and the failure to determine whether the arsenic is inorganic or organic and the site-specific bioavailability of arsenic in sediment.

The model used to estimate the arsenic that theoretically might be contained in fish due to arsenic in the creeks also significantly overestimates the concentration of arsenic in fish, fails to determine whether the arsenic is organic or inorganic, and fails to determine in a scientifically sound manner the degree to which the arsenic in sediment bioaccumulates in fish. Remarkably, the assessment ignores the actual measurement of the concentration of chemicals in fish. As we read the draft report, in fact, no arsenic was detected in fish historically. Even if prior sampling did not analyze for arsenic, the assessment ignores the data from other sites indicating that the accumulation of arsenic from sediment into fish is very low.

As to the ecological risk, there are methodological flaws in the analysis. In particularly, the food chain model is seriously flawed and significantly overestimates the ecological impact of arsenic.

In summary, there are safe levels of arsenic in sediment and the hypothetical assumption that arsenic might be in fish at significant levels cannot take precedence over data demonstrating what the actual concentration of arsenic in fish would be if there were fish in Hecklinger Pond.

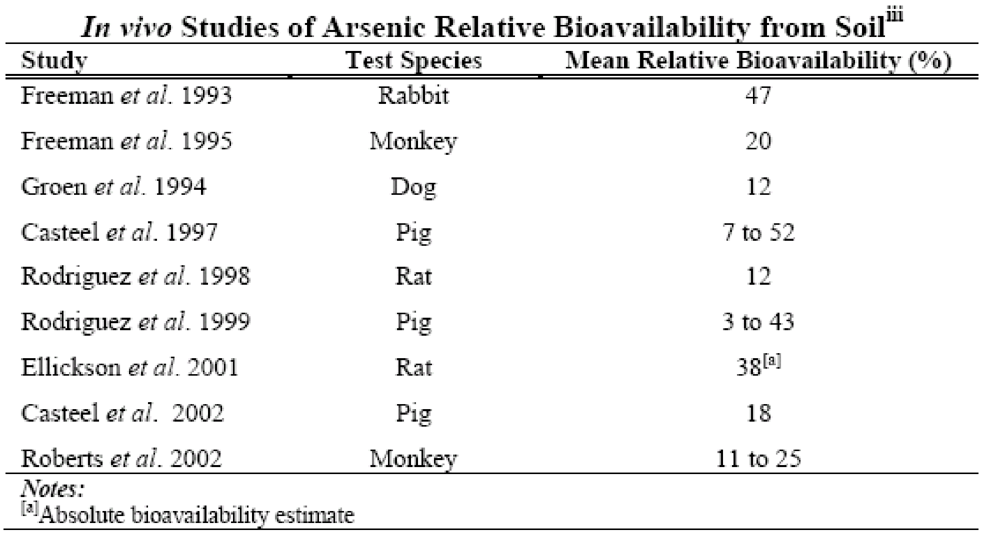
As a result, these documents must be significantly revised before they could be used to make decisions on whether any action is needed concerning the sediment in Duck and Otter Creek.

.

TABLE 1: ARSENIC SOIL CLEANUP LEVELS/BACKGROUND

Site Name and Location	Residential Soil Cleanup Level (mg/kg)	Basis of Cleanup Level	Background Concentration (mg/kg)
Arlington Blending & Packaging Co., TN (ROD, 1991)	25	Background	25
Oklahoma Refining Co., OK (ROD, 1992)	25 (surface) 305 (subsurface)	Health-based	7
Fried Industries, NJ (ROD, 1994)	27	Background	27
Crystal Chemical, TX (ROD, 1990)	30	Health-based	<1.6
Joseph Forest Products, OR (ROD, 1992)	36 (surface) 336 (subsurface)	Health-based	4 to 11
Salem Acres, MA (ROD, 1993)	40	Health-based	8.6
Shaw Avenue Dump, IA (ROD, 1991)	50	Not provided	3.4 to 7.5
National Zinc Co., OK (ROD, 1994)	60	Health-based	8
Sharon Steel, UT (ROD, 1990)	70	Health-based	<20
Vasquez Blvd & I-70 Site, CO (ROD, 2003)	70	Health-based	8
Bunker Hill Mining Complex, ID (ROD, 2002)	100	Health-based	22
Jacobs Smelter Site, UT (ROD, 1992)	100	Health-based	8
Whitewood Creek, SD (ROD, 1990)	100	Health-based	8.5
Commencement Bay, WA (ROD, 1993)	230	Health-based	20
Anaconda Co. Smelter, MT (ROD, 1996)	250	Health-based	9.3

Table 2[75]

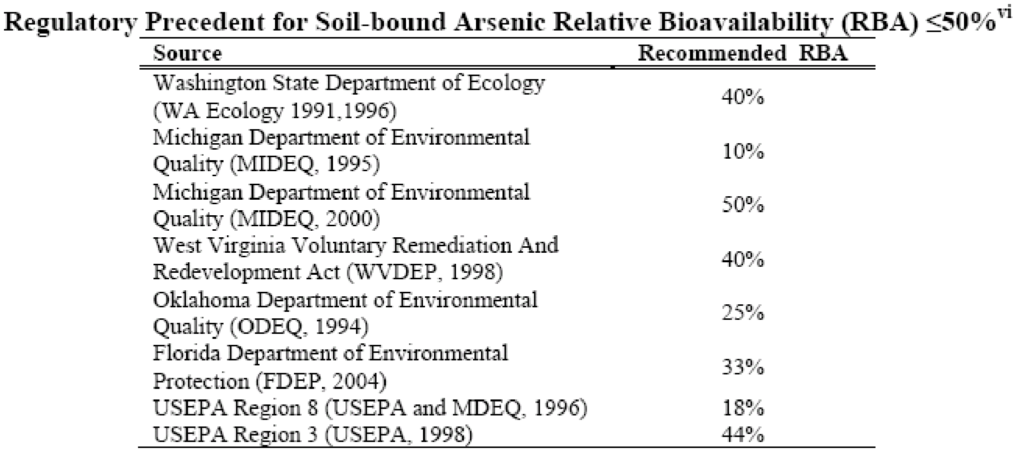


In vivo Studies of Arsenic Relative Bioavailability from Soil[iii]

Study	Test Species	Mean Relative Bioavailability (%)
Freeman *et al*. 1993	Rabbit	47
Freeman *et al*. 1995	Monkey	20
Groen *et al*. 1994	Dog	12
Casteel *et al*. 1997	Pig	7 to 52
Rodriguez *et al*. 1998	Rat	12
Rodriguez *et al*. 1999	Pig	3 to 43
Ellickson *et al*. 2001	Rat	38[a]
Casteel *et al*. 2002	Pig	18
Roberts *et al*. 2002	Monkey	11 to 25

Notes:
[a]Absolute bioavailability estimate

Table 3[76]



Regulatory Precedent for Soil-bound Arsenic Relative Bioavailability (RBA) ≤50%[vi]

Source	Recommended RBA
Washington State Department of Ecology (WA Ecology 1991,1996)	40%
Michigan Department of Environmental Quality (MIDEQ, 1995)	10%
Michigan Department of Environmental Quality (MIDEQ, 2000)	50%
West Virginia Voluntary Remediation And Redevelopment Act (WVDEP, 1998)	40%
Oklahoma Department of Environmental Quality (ODEQ, 1994)	25%
Florida Department of Environmental Protection (FDEP, 2004)	33%
USEPA Region 8 (USEPA and MDEQ, 1996)	18%
USEPA Region 3 (USEPA, 1998)	44%

---

[75] MAA Research Task Force (MAATF) March 18, 2006. "Error Comments to the Organic Arsenics: HED Combined Chapter." Submitted to US EPA, Office of Pesticide Programs. 273p. US EPA docket: EPA-HQ-OPP-2006-0201-0013.

[76] Id.

Appendix 1

WILLIAM J. WALSH
Washington, D.C., Office
Environmental

William J. Walsh heads the Washington office's environmental practice of Pepper Hamilton LLP. Bill's practice encompasses both environmental and other federal health and safety regulatory needs of corporations and industries.

He provides environmental, health, and safety counseling on compliance, permitting, transactional and litigation services. His experience includes all major federal environmental statutes (such as the Clean Air Act, the Clean Water Act, Superfund, the Resource Conservation and Recovery Act, the Toxic Substances Control Act, and many state and local environmental laws). One of Mr. Walsh's strengths lies in translating complex scientific and technical disputes into the particular environmental or health and safety statutory framework in a manner that enhances a client's defense and enables the parties to resolve the underlying regulatory issue.

Before joining Pepper in 1986, Mr. Walsh served as the chief of the U.S. Environmental Protection Agency (EPA) Drinking Water and Wetlands Enforcement branch and was lead EPA counsel on the precedent-setting hazardous waste lawsuits brought against Occidental Chemical Corporation concerning the Love Canal and related landfills.

Some of Mr. Walsh's more significant representations include:

- Negotiated more cost-effective remedies at hazardous waste sites, involving human health and ecological risk assessments

- Represents manufacturers in natural resource damages claims

- Defending a government remedial action contract in disputes with the Army Corps of Engineers over fixed price cleanup contracts.

- Prepared comments on federal and state rulemakings and proposals (e.g., the hazardous waste identification rule ("HWIR") for waste, the HWIR rule for contaminated media, the corrective action rule, the PCB disposal rules, EPA lender liability proposal, EPA's draft soil screening level guidance, Pennsylvania's Act 2 rules, and Michigan's Part 201 rules)

- Commenting on proposed American Conference of Government and Industrial Hygienists seeking modification of the ACGIH Threshold Limit Values, Consumer Product Safety Commission petitions, California Department of Health Services proposals to classify a substance as a chemical known to the State of California to be a carcinogen or reproductive toxin, and National Toxicological Program proposals to classify substances as a carcinogen in the Annual Report to Congress on Carcinogens

- Filed amicus briefs in a challenge to EPA rules

- Advised companies manufacturing and using hazardous materials concerning methods of minimizing both regulatory and litigation risks

- Developed innovative strategies addressing novel risks

- Defended manufacturers and distributors in California Safe Drinking Water and Enforcement Act (so called Proposition 65) lawsuits.

- Represented companies in personal and property damage suits:

Mr. Walsh has written and spoken on a wide range of topics, including Brownfields, the new, more stringent regulation of mercury, the feasibility of cleaning up hazardous waste sites, and the distinction between personal injury claims and regulatory limits.

Mr. Walsh served on approximately eight National Academies of Science committees providing advice on environmental issues, including a seminal report on Alternatives to Ground Water Cleanup, a report on adaptive site management, and approximately five committees addressing the destruction of nonstockpile chemical weapon materiel. In recognition of his pro bono service for the NAS, Mr. Walsh is one of the few attorneys granted the status of Associate of the National Academies of Science.

Mr. Walsh holds a B.S. in physics, *cum laude*, from Manhattan College, and a J.D. from George Washington University Law School, where he was elected to the Order of the Coif. He is admitted to practice in the District of Columbia and has passed the California bar.

Biographical Summary

David E. Merrill, M.S., Principal

Mr. Merrill has nearly 20 years of experience in negotiating cost effective solutions to environmental contamination problems. His expertise includes multi-disciplinary risk assessments, multimedia chemical fate and transport modeling, and creative data analysis. He has served as a technical expert on cases involving PRP cost allocation disputes, in toxic tort cases, including high profile PCB cases, and in cost recovery disputes. Mr. Merrill has successfully negotiated risk-based cleanup levels and remedial strategies, evaluated ecological risks and NRD claims associated with contaminated sediments, and evaluated multimedia chemical transport in water, sediments, and biological tissues. Mr. Merrill has submitted comments to the U.S. EPA relating to the multimedia modeling and risk assessment aspects of the LDR and the HWIR Rules, and has served as a scientific peer reviewer on several EPA Science Advisory Board panels.

Representative Projects

Cost Allocation Expert – PCBs at Transformer Repair Facility: Developed allocation metrics and negotiation strategy in a cost recovery dispute. Allocation factors included generator-specific and electrical industry "PCB profile" surrogates for PRPs with limited information. Case settled during mediation negotiations.

PCB Tort Cases: Evaluated historical standards of care relating to waste management, evolution of environmental regulations, evolution of awareness of PCBs as an environmental issue, and historical uses of PCBs in electrical equipment, hydraulic fluids, plasticizers/paints, among others. Evaluated Aroclor and congener fingerprints, dioxin-like PCB and dioxin-related claims. Assessed environmental distribution in sediments, soils, blood serum, tree bark and other biological matrices. Evaluated sources, background levels and correlations between environmental matrices and blood serum.

PCB Cost Allocation Expert -- Midwestern River: Expert during mediation hearings relating to PCBs in sediment associated with discharges from paper companies. Developed allocation model based on production, paper recycling/de-inking metrics, and historical waste discharges reconstructed from contemporaneous data.

Standard of Care -- Pesticide Handling/Disposal: In a tort case, evaluated issues pertaining to historical waste practices relative to Federal and State laws and regulations, and industrial norms of the time.

Generator Liability – RCRA Hazardous Waste TSD Facility: Developed risk-based analyses and provided deposition testimony addressing the need for remedial actions caused by client's wastes (DNAPL and trace metals).

Renegotiated PCB Cleanups at Natural Gas Compressor Stations: Negotiated remedial action levels for PCBs up to 500 mg/kg in soils to achieve risk-based target average of 25 mg/kg. Outcome represents EPA-approved reinterpretation of an existing Consent Order.

MGP Response Cost Recovery: Evaluated nature, extent and timing of chemical contamination at a former manufactured gas plant in New York.

Natural Resources Damage Claims: Examined sources of contamination and "NRD drivers" in negotiations involving allocation of PRP costs at a Midwestern site containing PCBs, metals, and PAHs and other constituents in sediments.

Practice Areas & Expertise

- Risk-Based Cleanup Negotiations
- Cost Allocation
- PCBs & Sediments
- Multi-Media Modeling
- Statistical & Monte Carlo Methods
- Database Design & Synthesis

Education

Ph.D., Agricultural Engineering, Cornell University (completed coursework & qualifying exams)

M.S., Agricultural Engineering, Cornell University

B.S., Soil and Water Science, University of California at Davis

EPA SAB Panels

- Multimedia, Multipathway, and Multireceptor Risk Assessment (3MRA)
- Regulatory Environmental Modeling (REM) Guidance

Selected Publications

Merrill, DE; Fendley, JE; Cohen, JT; Shifrin; NS. 1999. "Cleanup level averaging— A simple concept with huge payback for site remediation." In *Proceedings of the Environmental Solutions Exchange, The IT Group, Inc. Conference*, Orlando, FL, February 4-6.

Cohen, JT; Bowers, TS; Lampson, DW; Merrill, DE. 1997. "Quantification of exposure area cleanup thresholds when contaminant levels are uncertain." In *Proceedings of the Joint Statistical Meetings: American Statistical Association Section on Statistics and the Environment*, Anaheim, CA, August 10-14.

Li, W; Merrill, DE; Haith, DA. 1990. "Loading functions for pesticide runoff." *Research Journal Water Pollution Control Federation* 62(1):16-26.

Gradient
CORPORATION

20 University Road
Cambridge, MA 02138
Phone (617) 395-5000
Fax (617) 395-5001
Direct (617)-395-5537
dmerrill@gradientcorp.com
www.gradientcorp.com

Biographical Summary

Tim Verslycke, Ph.D., Environmental Toxicologist

Dr. Verslycke is an expert in evaluating and predicting environmental effects of endocrine disruptors, pharmaceutical, pesticides and other industrial chemicals. His primary responsibilities include the design, oversight, analysis, and interpretation of ecotoxicological studies, environmental risk assessments, chemical screening and testing procedures, and product safety studies. Before joining Gradient, Dr. Verslycke was a postdoctoral investigator at the Woods Hole Oceanographic Institution where he currently holds a position as a visiting scientist and oversees endocrine disruption studies in marine animals. Dr. Verslycke has been closely involved in research and priority setting for the regulatory screening and testing of endocrine disruptors. Dr. Verslycke completed his undergraduate and graduate studies in bio-engineering at Ghent University in Belgium and was the recipient of the Flanders Marine Institute Annual North Sea Award for his graduate thesis. Dr. Verslycke has authored over 30 peer-reviewed articles in the field of environmental toxicology and has presented his research at numerous international conferences.

Representative Studies

Site Environmental Risk Assesments:
At the request of different companies, performance of a site-specific environmental risk assessment of their manufacturing facilities, compliant with the respective state Environmental Protection Agency (EPA) requirements and US EPA requirements.

Pharmaceutical Environmental Risk Assessments:
At the request of pharmaceutical companies, evaluation of the environmental risk associated with the societal use of their products, compliant with either European or US risk assessment guidelines.

Pharmaceutical Safety Screening:
At the request of pharmaceutical companies, development of environmental risk assessment screening protocols for their active pharmaceutical ingredients (API).

Pharmaceutical Assay Development:
At the request of a pharmaceutical company, development of a targeted *in vitro* screening assay to evaluate the potential estrogenicity of their products.

Pesticide Assay Development:
At the request of the Massachussetts Institute of Technology's Sea Grant program, development of in vitro assays to evaluate the presence and potential effects of pesticides in Cape Cod coastal waters.

Endocrine Disruptor Assay Development:
Developing and validating acute and chronic assays for the screening and testing of potential endocrine disruptors, using mysid shrimp. Mysid shrimp are currently the only invertebrate model included in US EPA's Endocrine Disruptor Screening Program. This work has been funded through doctoral and postdoctoral fellowships from the Institute for the Promotion of Innovation by Science and Technology in Flanders, the Belgian American Educational Foundation, and WHOI's Ocean Life Institute.

ENDIS-RISKS:
At the request of the Belgian Federal Science Policy Office: Endis-Risks assessed the distribution and effects of endocrine-disrupting substances in the Scheldt estuary in The Netherlands (http://www.vliz.be/projects/endis/).

ED-NORTH:
At the request of the Belgian Federal Science Policy Office: Preparation of a scientific review and proposals for policy guidance which can be used for formulating governmental management decisions that will help to structure future action plans to tackle the possible impacts of endocrine disruptors on the North Sea. Funded by the Belgian Federal Science Policy Office.

Practice Areas & Expertise

- Molecular and Environmental Toxicology
- Environmental Risk Assessment
- Standard and Regulatory Chemical Screening and Testing
- Product Safety
- Endocrine Disruptors
- Pharmaceuticals in the Environment
- Personal Care Products

Education

Ph.D., Bio-Engineering/Applied Biological Sciences, Ghent University, Belgium

M.S., Bio-Engineering/Environmental Technology, Ghent University, Belgium

B.A., Bio-Engineering/Environmental Technology, Ghent University, Belgium

Selected Publications

Verslycke, T; Ghekiere, A; Raimondo, S; Janssen, CR. 2007. "Mysid crustaceans as standard models for the screening and testing of endocrine-disrupting chemicals." Ecotoxicol. 16:205-219.

Verslycke, T; Vethaak, AD; Arijs, K; Janssen, CR. 2005. "Flame retardants, surfactants and organotins in sediment and mysid shrimp of the Scheldt estuary (The Netherlands)." Environ.Pollut. 136(1):19-31.

Verslycke, T; Fockedey, N; McKenney, CL; Roast, SD; Jones, MB; Mees, J; Janssen, CR. 2004. "Mysids as potential test organisms for the evaluation of environmental endocrine disruption: a review." Environ. Toxicol. Chem. 23(5):1219-1234.

Gradient
CORPORATION

20 University Road
Cambridge, MA 02138
Phone (617) 395-5000
Fax (617) 395-5001

tverslycke@gradientcorp.com
www.gradientcorp.com

Biographical Summary

Kurt Herman, M.Eng., P.G.
Senior Project Manager

Mr. Herman specializes in the management of multidisciplinary projects which draw upon his broad expertise in contaminant fate and transport, hydrogeology, NAPLs, and historical waste practices. Over the last decade, he has designed and implemented field studies and remedies at a wide range of hazardous waste sites, and provided litigation support in the areas of insurance cost recovery, cost allocation, and toxic torts. He has researched and interpreted historical waste practices and created conceptual fate and transport models to determine contamination causation and timing at dozens of sites representing a wide range of industry sectors, including former manufactured gas plants (MGPs), glassmaking operations, brass and iron foundries and forges, flare making, dry cleaning, rail operations, and bulk petroleum storage and transfer operations.

His prior academic research at MIT and as part of the University of Arizona's Superfund Basic Research Program involved surface water contaminant transport modeling.

Representative Projects

DE (Dover) Superfund Site: Extensive multi-media (DNAPL, soil, groundwater, soil gas) investigation of chlorinated solvents released in a downtown residential/commerical area. Study findings/report accepted by agencies (U.S. EPA and DNREC) as submitted without question or comment.

MGP Historical Practices, Contamination Causation & Timing (30+ MGPs, multiple projects): Researched and evaluated historical operations (1830-1960) and NAPL fate and transport at MGPs to determine contamination causation and timing in the context of expected/intended and timing/continuity issues for insurance cost recovery litigation.

Conceptual Remedy Design: Assessed RI results and assisted in preparing a conceptual risk-based remedy (dual-phase extraction) for soil and groundwater contamination at a former pharmaceutical manufacturing facility.

Air Emissions For MGP Toxic Tort: Developed a model to quantify air emissions from a former MGP, both during and after operations (c. 1900-2005), to identify possible exposures by nearby residents.

NCP Consistency Evaluation: Evaluated the National Contingency Plan-consistency of environmental responses at 8 former MGP sites to determine the appropriateness of CERCLA cost recovery claims.

Arthur Kill Sediment Study: Planned and directed a sediment core study to assess chemical and physical feasibility of reusing dredged sediments for a stabilized soil cap at a Brownfields site.

Practice Areas & Expertise

- Contaminant Fate & Transport
- Hydrogeology
- Remedial Investigation & Conceptual Remedial Design
- MGPs
- DNAPLs
- Chlorinated Solvents
- Historical Waste Practices
- Brownfields/M&A

Education & Certifications

M.Eng., Civil and Environmental Engineering, MIT

B.A., Economics and Geology, Miami University (Ohio)

Registered Professional Geologist No. G2184, Oregon.

Selected Publications, Presentations and Awards

Herman, K. 2008. "A Standardized Method to Interpret Field Observations of MGP NAPL." Presented at 18th Annual AEHS Meeting and West Coast Conference on Soils, Sediments, and Water. March 11.

Herman, K. 2007. "Who Pays for Cleanup Costs?" Gradient Trends: Risk Science & Application. Page 1. Winter.

Langseth, DL and Herman, KD. 2006. "Liability Estimation Frameworks: Gradient Trends: Risk Science & Application. Page 3. Spring.

Sigma Xi – Scientific and Engineering Honorary, MIT Chapter (2003)

National Institute for Environmental Health Sciences (NIEHS) Superfund Colloquium (2000-2001)

December 2000 – Metal Removal in the Hyporheic Zone in a Mining Contaminated Stream in Arizona. Presentation to NIEHS Superfund Colloquium (Tucson, AZ).

Gradient
CORPORATION

20 University Road
Cambridge, MA 02138
Phone (617) 395-5000
Fax (617) 395-5001

kherman@gradientcorp.com
www.gradientcorp.com

Biographical Summary

Neil S. Shifrin, Ph.D., President and Founder

Dr. Shifrin consults on a wide range of environmental engineering topics including water quality, contaminant transport and fate, hazardous waste site cleanups and environmental response cost liability/allocation. With his broad and lengthy experience, Dr. Shifrin offers insightful interpretation of environmental conditions and big picture strategies for achieving balanced solutions. His experience extends back to the nation's first Superfund projects, such as Love Canal, and includes many complex contamination problems, such as PCBs in major receiving waters, dioxins in the Great Lakes, TCE in large aquifers beneath the major cities, and CSO pollution of Boston Harbor. Dr. Shifrin has extensive experience with DNAPL, site investigation, remedy concepts, monitoring programs, property redevelopment, historical waste practices, cost allocation, manufactured gas plants, PBT chemicals, solvents, and biological processes.

Representative Projects

VOCs in Groundwater (New Hampshire): Using groundwater modeling, developed and negotiated a groundwater remedy using pump & treat and monitored natural attenuation, including remedy effectiveness monitoring design.

Cost Allocation/NCP Consistency (New York): Between two MGP owners, proposed a cost allocation based on NCP consistency and the production relationship to contamination.

Chemical Manufacturer Cost Allocation (Michigan): Developed environmental response cost allocation at a site formerly used successively for petroleum refining, custom (Toll) chemical manufacturing, and solvent recycling.

MGP Insurance Claims (Nationwide): Waste management standards of care from 1850s - 1975 at manufactured gas plants (MGPs) for recovery of environmental response costs by numerous utilities.

M&A Due Diligence: Evaluation of data from 45 natural gas field sites to determine environmental cleanup liabilities and costs due to PCB, Hg, and Cr.

PCBs in Sediments: Renegotiated cleanup levels on the basis of exposure, risk, data statistics, and sampling at several Superfund sites.

Arsenic from Glass Manufaturer (Illinois)**:** Release mass balance and waste management standard of care.

Superfund Reform: Evaluated cost impact of using more realistic risk assessment assumptions.

Cost Allocation (NJ)**:** Developed technical factors model to allocate $18 million study costs among 158 PRPs.

Practice Areas & Expertise

- Contaminant Fate & Transport
- Remedy Negotiations
- Historical Waste Practices
- Cost Allocation
- Insurance Claims
- Environmental Measurements
- Project Strategy

Education

Ph.D., Environmental Engineering, MIT

B.S., Chemical Engineering,
University of Pennsylvania

Licensed Site Professional
in Massachusetts

Selected Publications

Shifrin, NS. 2005. "Pollution management in the twentieth century." *J. Environ. Eng.* 131:676-691.

Shifrin, NS; Toole, AP. 1998. "Historical perspective on PCBs." *Environ. Eng. Sci.* 3 :247-257.

Shifrin, NS; Beck, BD; Gauthier, TD; Chapnick, SD; Goodman, G. 1996. "Chemistry, toxicology, and human health risk of cyanide compounds in soil at former manufactured gas plant sites." *Regulatory Toxicol. Pharmacol.* 23:106-116.

Bowers, TS; Shifrin, NS; Murphy, BL. 1996. "A statistical approach to meeting soil cleanup goals." *Environ. Sci. & Technol.* 30:1437-1444.

Swallow, KC; Shifrin, NS; Doherty, P. 1988. "Hazardous organic compound analysis: lost data and misinformation for decisionmakers." *Environ. Sci. Technol.* 22(2):136-142.

Gradient
CORPORATION

20 University Road
Cambridge, MA 02138
Phone (617) 395-5000
Fax (617) 395-5001

nshifrin@gradientcorp.com
www.gradientcorp.com

Biographical Summary

Ari S. Lewis, M.S.

Ms. Lewis is an Environmental Toxicologist and the manager of the Toxicology team. Her expertise in toxicology and risk assessment allows her to manage and contribute to a variety of projects, including site-specific risk assessments, regulatory comment, product safety evaluation, and litigation support. She also has particular expertise in metal and pesticide risk assessment — specifically arsenic. In this capacity, Ari has both published and presented extensively on the carcinogenic risks of arsenic, and provided direct input to US EPA on general arsenic risk assessment issues. For litigation cases, she has performed comprehensive evaluations of toxicological and epidemiological literature to support causation analyses. Before joining Gradient, Ms. Lewis earned her M.S. at Cornell University; her thesis project investigated the molecular and cellular responses to arsenic exposure during early animal development.

Representative Projects

Arsenic Content in Dietary Supplement: Evaluated whether the amount of inorganic arsenic in a dietary supplement product line would constitute an unacceptable inorganic arsenic exposure if products were taken individually or as part of a multi-product program. Estimated exposure from supplements and compared to international guidelines for arsenic in food, typical inorganic arsenic exposure in the US diet, and levels that are known to cause adverse effects in humans.

Regulatory Comment on US EPA Risk Assessment: Led project evaluating US EPA's technical approach for assessing human health and ecological risks associated with the storage of coal combustion waste. Our evaluation was provided to US EPA during a public comment period.

Toxic Tort Involving Pesticide Exposure: In the context of litigation, analyzed whether pesticide exposure was the cause of a specific birth defect. The evaluation involved a review of toxicological and epidemiological literature, as well as a reconstruction of potential dose via complex exposure pathways.

Arsenic Bioavailability Assessment: Led project providing input on a university study to evaluate the bioavailability of arsenic in soil with and without soil amendments aimed at reducing bioavailability.

Metal Risk Assessment: Interpreted the results of a metal bioassay and potential regulatory implications. Proposed experimental approach to establish chemical mode of action and human relevance of rodent bioassay results.

Pesticide Re-registration of an Arsenic-based Pesticide: Managed a multi-faceted project in support of the re-registration of organic arsenic herbicides. This project included several presentations and technical submissions to US EPA regarding relevance of cancer data from animals to human risk, as well as directed responses to US EPA-issued risk assessments.

Product Safety: Provided an in-depth review of lead exposure and toxicology issues. Findings were presented in a report that was used by the industry group as a basis to make informed decisions about design modification and safety testing of plumbing products.

Practice Areas & Expertise

- Molecular Toxicology
- Human Health Risk Assessment
- Arsenic Toxicology

Education

M.S., Environmental Toxicology, Cornell University

B.A., Biology/Environmental Sciences, University of Pennsylvania

Selected Publications

Petito-Boyce, C; Lewis, AS; Sax, SN; Eldan, ME; Cohen, SM; Beck, BD. "Probabilistic Analysis of Human Health Risks Associated with Background Concentrations of Inorganic Arsenic: Use of a Margin of Exposure Approach." *Human and Ecol. Risk Asses.* (accepted)

Lewis, AS. 2007. Correspondence Regarding "Case Report: Potential Arsenic Toxicosis Secondary to Herbal Kelp Supplement." *Environ. Health Perspect.* 115(12):A575.

Cohen, SM; Arnold, LL; Eldan, M; Schoen, AS*; Beck, BD. 2006. "Methylated arsenicals: The implications of metabolism and carcinogenicity studies in rodents to human risk assessment." *Crit. Rev. Toxicol.* 36 :99-133.

Schoen, A; Beck, B; Sharma, R; Dubé, E. 2004. "Arsenic toxicity at low doses: Epidemiological and mode of action considerations." *Toxicol. Appl. Pharmacol.* 98 :253-267.

Awarded top 10 Best Published Paper Demonstrating Application of Risk Assessment by the Society of Toxicology Risk Assessment Specialty Section.

Gradient
CORPORATION
20 University Road
Cambridge, MA 02138
Phone (617) 395-5000
Fax (617) 395-5001
alewis@gradientcorp.com
www.gradientcorp.com

Comments on the

Draft Human Health and Screening Ecological Risk Assessments

Duck and Otter Creeks,

Toledo and Oregon, Ohio

Prepared for
Pilkington North America Inc.
811 Madison Avenue
Toledo, OH 43604-5684

Prepared by
Gradient Corporation
20 University Road
Cambridge, MA 02138

August 25, 2008

1 Introduction

On behalf of Pilkington North America (PNA), this document provides Gradient Corporation's (Gradient) initial technical comments on Tetra Tech's July 2008 Draft Human Health Risk Assessment (Draft Human Health Assessment) and Draft Screening and Baseline Ecological Risk Assessment (Draft Eco Assessment) for Duck and Otter Creeks in Toledo and Oregon, Ohio. The two draft assessments raise additional legal, policy, and guidance interpretation issues. Therefore, William J. Walsh of Pepper Hamilton LLP, on behalf of PNA, prepared a separate set of comments (see *Report Commenting on the Draft Human Health and Ecological Screening Assessments*). The separate comment document was also reviewed by Gradient and includes our input.

These comments should be considered preliminary because Gradient has not had sufficient time to review the raw underlying data nor to perform its own analysis, and a short time was allotted to provide the comments. In some cases, Tetra Tech's methodology may not be clear and the scientific rationale may not be apparent on the face of these documents. Other comments may be submitted or these comments may be modified as additional technical analysis is performed. PNA welcomes a continuing technical dialogue on these issues to ensure that the efforts to improve water quality in this watershed are effective and sound.

2 Comments

2.1 General Comments on Both Assessments

1. The draft risk assessments should clearly state that screening levels used to select contaminants of concern (COC) are not intended to be cleanup goals. Chemical-specific risk exceedances identified in the draft risk assessments do not necessarily require remediation.
2. The risk assessments do not take into account natural and anthropogenic background concentrations of chemicals, which should be considered in understanding the need for further response.
3. The risk assessments excluded data collected prior to 2007 without clear scientific rationale, and in doing so compromised the characterization of creek conditions. The number of samples, which are further separated into five locations along each creek, is insufficient to provide stable estimates of upper confidence limits on the mean, and thus, reliable exposure point concentrations.
4. The model used to estimate bioaccumulation and potential risks of arsenic to higher ecological receptors (*i.e.*, mink, belted kingfisher) and humans is flawed and overestimates risk since the model relies on inappropriate assumptions for arsenic bioaccumulation in freshwater fish.

2.2 Specific Comments on the Draft Human Health Assessment

1. Further refinement of the draft human health assessment is needed to accurately characterize potential risks from sediments in Otter and Duck Creeks. At a minimum, the reduced oral bioavailability of metals in sediments, background concentrations of arsenic in background sediments, and the relationship between sediments and uptake in fish warrant more detailed analyses. The failure to thoroughly account for these issues results in the overestimate of risk, particularly arsenic risk.
2. The assessment needs to be clear that an appropriate cancer risk target for chemicals, as established by the U.S. Environmental Protection Agency (US EPA), is 10^{-6} to 10^{-4}. Background exposures to arsenic in food, water, and soil often exceed a 1×10^{-5} cancer risk and can even exceed a 1×10^{-4} cancer risk.
3. The draft human health assessment did not consider that many compounds in sediment and soil (including arsenic) are not 100% bioavailable. With sufficient scientific support, it is appropriate to consider reduced oral bioavailability of chemicals in different media.
4. Since arsenic exposure *via* fish ingestion is the major (and possibly only) arsenic risk driver in the draft human health assessment, there should be a discussion on how the risk assessment (or the model used in the risk assessment) has accounted for the fact that fish can contain high levels of organic arsenic, which is relatively non-toxic.

5. The arsenic risk *via* fish ingestion appears to be overestimated and validation of the modeling approach should be performed.

6. The draft human health assessment should not use the biota sediment accumulation factor (BSAF, *i.e.*, the ratio used to calculate fish tissue concentrations from sediment concentrations) to assess arsenic risks. This model yields unrealistic results inconsistent with known information on the relationship between arsenic in sediment and uptake in fish.

    - As mentioned above, the model needs to account for non-toxic forms of arsenic that naturally occur in fish.
    - The relative importance of sediment *versus* surface water on arsenic uptake in fish should be addressed.
    - The resulting risk estimates based on the BSAF model appear to contradict the actual measurements of the levels of chemicals in fish taken from Hecklinger Pond and the 2005 finding of no significant risk.
    - The modeled arsenic uptake from sediment in fish yields unrealistic results which should be compared with existing data on the relationship between arsenic contamination in sediment and incremental increases in inorganic arsenic in fish (see also Comment 1 in Section 2.3, below).

7. With regard to risks from ingestion and dermal exposure to arsenic in sediment, the risk assessment should discuss that all calculated risks are within US EPA's 1×10^{-6} to 1×10^{-4} cancer risk target range, and thus below a level of concern that would warrant further environmental response.

2.3 Specific Comments on the Ecological Risk Assessment

1. The model used to estimate bioaccumulation and potential risks of arsenic to higher ecological receptors (*i.e.*, mink, belted kingfisher) and humans is flawed since it relies on inappropriate assumptions for arsenic bioaccumulation in freshwater fish.

    - The assumptions in the food chain model are not based on the current scientific understanding of arsenic bioaccumulation in freshwater fish, and consequently result in an unrealistic estimated arsenic body burden in fish (see next point). This results in unrealistic risks to higher trophic ecological receptors (*e.g.*, mink, belted kingfisher) as well as humans.
    - Previous technical documents, including a US EPA technical summary on arsenic bioaccumulation[1], have resulted in arsenic bioaccumulation factors based on concentrations in the water column, and not the sediment. A recent publication (Williams *et al.*, 2006)[2] reviewed results of eight arsenic field exposure studies. At the reviewed sites, arsenic water concentrations ranged from <0.5 µg/L to 56 µg/L and sediment concentrations (where reported) were up to 673 mg/kg. Maximum detected arsenic concentrations in fish in these field

---

[1] EPA, Technical Summary of Information Available on the Bioaccumulation of Arsenic in Aquatic Organisms (EPA-822-R-03-032, December 2003), available at <http://epa.gov/waterscience/criteria/arsenic/tech-sum-bioacc.pdf*

[2] Williams L, Schoof RA, Yager JW, Goodrich-Mahoney JW. 2006. Arsenic bioaccumulation in freshwater fishes. Human and Ecological Risk Assessment 12: 904-923.

studies were 2.3 mg/kg ww, but were generally well below 500 μg/kg. The same review document looked at fish laboratory exposures at arsenic concentrations up to 18 mg/L, and found maximum body burdens of 3.4 mg/kg ww. The levels of arsenic in Otter and Duck Creek sediment are substantially lower than those found at sites that were used in this review, yet modeled fish arsenic body burdens were higher – modeled to be up to 26 mg/kg ww in Duck Creek and up to 12 mg/kg ww in Otter Creek, based on the use of an inappropriate biota-sediment bioaccumulation factor.

2. Historical surface water, sediment, and fish data should have been considered in this assessment. In particular, historic Hecklinger Pond data should have been considered to verify the bioaccumulation factors used.

3. The draft eco assessment relies on a flawed laboratory test and calculations to estimate the potential ecological impact of arsenic on benthic organisms in the creeks. Although the laboratory test of the survival of organisms exposed to the sediment found many samples where the control sample and the sample from Duck or Otter Creek were not significantly different, the laboratory testing is suspect because "[t]here are several issues with the bioassay results that should be noted. The tests were conducted with two water replacements per day, rather than aeration. This approach may cause additional agitation of the sediments and increase the physical stress levels to the organisms. It was also noted in the bioassay tests, organisms were observed floating in the test chambers, in both the test cells and the control cells. This could suggest the organisms may have had an inefficient food supply or crowding, both would cause added stress to the organisms"

   The control sediment used in the test was from New Jersey and is substantially different with respect to many confounding factors known to affect toxicity. For instance, the control sediment samples had the lowest conductivity, pH, alkalinity, and hardness, and significantly lower ammonia concentrations. The confounding factors were not taken into account when trying to link analyte concentrations to observed toxicity (which, as TetraTech noted, was not possible). One would expect that a similar statistical analysis would have probably pointed to the above-mentioned physical/chemical parameters as being most important in explaining the observed toxicity. In other words, the sediment toxicity tests appear to hold no value in explaining the observed toxicity and linking it to contaminants in both creeks.

4. The assessment acknowledges the "high probability that most of the metals in the sediments may be bound to sulfides and so are not bioavailable" yet most of the draft assessment emphasizes risks from metals.

REVIEW AND COMMENT ON THE “DRAFT HUMAN HEALTH AND ECOLOGICAL RISK ASSESSMENTS FOR DUCK AND OTTER CREEKS”

Sunoco Inc. (Sunoco) has retained The GeoEnvironmental Consortium, Inc.® (GEC) to review and provide comments on the Tetra Tech Draft Human Health and Ecological Risk Assessments for Duck and Otter Creeks.

A review was conducted of the *Human Health & Screening and Baseline Ecological Risk Assessments, Duck and Otter Creeks, Toledo and Oregon, Ohio* reports, dated July 2008, prepared by Tetra Tech EM Inc., Chicago, Illinois. A brief summary of our comments are provided below, and specific section by section comments for each risk assessment are provided separately, as well.

In general, Sunoco believes that the HHRA and ERA Risk Assessments are overly conservative and in some cases not reasonable, based on the following:

1. The risk assumptions and data used from Hecklinger Pond are outdated and of little value, as signs are posted stating that the pond is not safe for swimming and fishing. In Sunoco’s opinion, ingestion of fish from Hecklinger pond is not a complete exposure pathway and should be eliminated from the risk assessment and/or the fraction ingested should be much less.
2. The youth and recreationalist exposure pathways around OC-A and DC-A are not complete pathways as these areas are heavily industrial with no residential setting and institutional controls are in-place that prohibit access to the creeks in these areas. Accordingly, this exposure pathway is not complete and should be eliminated.
3. PAHs are the risk driver in the HHRA. It is not appropriate to evaluate the risk of PAHs without reviewing and providing information on background PAH levels in the creeks. Based on the commercial/industrial nature of the creeks, the background PAH concentrations could account for many, if not all, of the PAH concentrations detected in the creeks.
4. The use of historical maximum surface water data in the ERA imparts a high degree of uncertainty, is not necessarily representative of current condition of the creeks, and will overestimate the potential risks to ecological receptors. Surface water samples should be collected to determine the current conditions of the creeks or this surface water evaluation should be deleted.

5. The method for evaluating PAHs in the sediments is based on liver lesions in the English sole. This fish is a bottom feeding fish with a high contact rate with sediments, and is not representative of the fishes that inhabit the creeks. The use of the English sole is not appropriate and overestimates the potential exposure to sediments. A literature review should be completed to determine common creek fishes that are more representative of the fishes in the creeks.
6. The text notes a lack of correlation between AVS/SEM results and the PAH toxicity unit results and the results of the toxicity. The toxicity tests were subject to potentially adverse test conditions, which may have resulted in the high degree of toxicity observed in the bioassay tests. Thus, the bioassay test results may be invalid and additional testing should be conducted to validate these results.

Human Health Risk Assessment Comments

Based on time constraints, this review did not include a verification of daily intake and risk calculations, information included in the database, information extracted from the database, and statistical analysis of the data (e.g., data distribution, selection of appropriate UCL, etc.). Accordingly, Sunoco reserves the right to provide additional comments on the above listed items.

General Comment:

The text makes no mention of data validation. Please indicate if the data were validated. If not, please indicate the impact on the data without the validation. The qualifiers listed with the data in Appendix B are not typical validation qualifiers. The concern is that some data that are not representative of the site may be used (e.g., R – rejected data; H – data that exceeded holding time, etc.)

Section Specific Comments:

2.2.1 Summary Statistics

- Page 5, paragraph 3: The text refers to “DL”. Is this method detection limit or a reporting limit. Also, Tables 1 through 4 – are the censored data reporting limits or method detection limits. Please clearly identify the data that are being used.

- Page 6 first line, Page 18 second paragraph: The text states that ½ the DL was substituted for censored data. Again, please identify if this is the method detection limit (instrument detection limit for inorganics) or the reporting limit. Also, please specify how elevated limits were evaluated. It is recognized that footnote b on tables 1 through 4 state that elevated limits greater than the maximum detected concentration were excluded from the statistical analysis. There are elevated limits (reporting or detection) that are less than the maximum detected concentration. The use of these will bias the results high and bias the overall risk high. Please explain how these data were addressed. Please include an explanation of this bias in the uncertainty analysis.

- Page 6, paragraph 4: Appropriate background concentrations were not identified for sediment. Please explain why background values were not determined. Based on the driving constituents in the risk, it seems reasonable to evaluate background. For example, arsenic is driving the risk in some areas. It is typical to see arsenic around golf courses because of the pesticides that are used. The PAHs are drivers in this risk assessment. Due to the industrialized area, the railroad tracks, etc. it is reasonable to assume that the PAHs would be ubiquitous in these areas. Please provide an explanation as to why something as important as background for many of these constituents is not evaluated. At a minimum, the uncertainty analysis should have text referencing the impact background values would have on the overall risk per receptor.

3.1.3 Demographics

- Page 11, paragraph 1: The text states that demographic information was obtained for a six (6) mile radius from the center of the Duck and Otter Creeks watershed. Typically, a one mile radius is used. Please explain why a six mile radius is applied due to the length of the creeks.

- Page 12, bullet items: The bullet items identify sensitive subpopulations. From an informational perspective, these data are helpful. The text should state that these data are provided only for informational purposes. It is not reasonable to assume sediment or fish ingestion exposure to any of these sensitive subpopulations.

3.2.1 Potential Receptors and Exposure Pathways and 3.2.2 Exposure Scenarios

- Page 13, Section 3.2.1, paragraphs 2 and 3 and Page 15, Section 3.2.2 paragraph 3: The text states that children are assumed to have de minimus exposure in OC-A and DC-A. Please explain why the youth and adult recreational receptors are considered to experience a reasonable exposure in these areas. Based on the figures, it is apparent that these areas are only industrial with no residential setting. It is not reasonable to assume that youth and adult recreational receptors will access the sediment in these areas, especially since there are areas located closer to their residence that they can access. Also, the heavy railway traffic will reduce the likelihood of these receptors. The text also states that in the areas of OC-A and OC-B, there are institutional controls to prohibit access to the area (e.g., fencing, security patrols, etc.). Please provide technical justification for only a reduction in the exposure of youth and adult recreational receptors in OC-A and DC-A instead of stating that exposure in these areas are incomplete.

- Page 15, Section 3.2.2 paragraph 3 and Page 17, first paragraph: The text states that Hecklinger Pond is posted with signs that state the pond is unsafe for swimming and fishing. The text also states that any fishing in the pond is assumed limited in frequency. The exposure assessment is to include reasonable exposure. Based on the posted signs and the text that states potential exposure to fish tissue from the pond is conservative, please provide technical justification for the fish ingestion exposure for all receptors. It is unclear from the information provided in the report how this is considered to be a reasonable exposure pathway.

- Page 29, paragraph 4: This text adds the carcinogenic risk among receptors for a “total risk”. This is not standard risk assessment practice. The risk among exposure pathways for a receptor are summed for a total receptor risk. Risk among receptors are not summed. Please provide technical justification for this process; otherwise please remove this text from all sections of the report and the associated tables.

- Table 6B: Please include a “Y” under the COPC column for selenium.

- Table 8: The exposure frequency values listed are high. It is unlikely that during the summer children will spend more than ½ of their week in the sediments of the creeks and those adults will spend two days per week in the sediments. It is more reasonable to assume that less than ½ of their week will be playing in the sediments. Also, it is more reasonable to assume one day for adults. Typically, adults have the weekend for outdoor activity and recreation. Therefore, one can reasonably assume that one of these days will be used for outdoor activities. With respect to exposure for OC-A and DC-A, please refer to page 12, first bullet, "Exposure Scenarios". Assumption of any exposure in these areas is not reasonable.

- Table 8: Please provide references – EPA 2000b in the "Reference "section of the report is for the Region 9 PRGs. The information associated with EPA 2000b on Table 8 was not taken from the Region 9 PRGs. Please ensure that the correct references are provided on all Tables and Figures.

- Table 8: Provide justification for the fraction ingested for aquatic life. According to the table footnote, primary fishing will occur in nearby Lake Erie and Maumee River. Please provide justification for someone fishing in a lake that is posted with a hazard warning for fishing and swimming when Lake Erie and Maumee River are nearby and one can safely fish and swim in these water bodies. The fraction of Hecklinger Pond fish ingested by a person from this area should be much less considering the information provided in this footnote.

- Table 8: The sediment adherence factor seems high. The footnote indicates that three items were reviewed to determine the adherence factor. The pipe laying worker is not appropriate for the type of exposure for the recreational users identified as receptors. This adherence factor should not be used in determining an appropriate value. An adherence factor 0.2 seems most reasonable for the setting and exposures.

Ecological Risk Assessment Comments

General Comments:

The purpose of the screening and baseline ecological risk assessment (SBERA) was to determine whether sediment contaminants pose a significant risk to the environment, and if so, to identify the specific chemicals contributing to toxicity and define the spatial extent, where risk are located, of risks to ecological receptors. The SBERA presented the results of the Tier 1 screening level ecological risk assessment (SLERA) for benthic receptors directly exposed to sediment and fish exposed to surface waters, and a Tier 2 baseline ecological risk assessment (BERA) for benthic macroinvertebrates and mammalian and avian receptors exposed indirectly to sediments in Duck and Otter Creeks. The SBERA referenced the appropriate guidance documents for conducting an ecological risk assessment from the Ohio Environmental Protection Agency (OEPA) and the U.S. Environmental Protection Agency (EPA) to support decisions to be made under the Great Lakes Legacy Act.

Overall, the SBERA is a comprehensive ecological risk assessment of the potential impacts on the ecological resources associated with Duck and Otter creeks, and utilizes the appropriate SLERA and BERA guidance in the assessment. As noted in the specific comments, there are several components of the ecological risk assessment that impart a high degree of uncertainty in the overall assessment of potential impacts to these resources including the use of the historical surface water data, the sole as the representative fish species for evaluating the exposure to PAHs in the sediments, and the confounding factors noted in the bioassay tests. However, the overall conclusion that there may be potential risks to ecological receptors coming in contact with the sediments in Duck and Otter creeks is generally supported in the ecological risk assessment.

Section Specific Comments:

2.3 Identification of Contaminant of Potential Ecological Concern (COPEC)

- Page 8: The use of background samples was not used; because site-specific background results were not available. The use of literature background values may be appropriate. It was noted that inclusion of COPECs that may be below background may contribute to overestimation of exposures and risks.

2.4.5 Measures of Effect

- Page 12: The TOC values are determined as a mean for each creek, rather than by the exposure areas. However, Appendix C lists concentrations for each exposure area within each creek. The text should clarify how the TOC values per exposure area were calculated to agree with the values presented in Appendix C.

3.2 Screening for Lesions in Bottom-Dwelling Fish

- Page 13: The method used to evaluate the PAHs in the sediment is based on incidence of liver lesions in English sole. The sole is a predominantly bottom feeding fish with a high contact rate with the sediments, and is likely not representative of the fishes inhabiting the creeks. The SBERA does not discuss what species of fish inhabit the creeks; however, a literature review of common creek fishes would provide potential fish species to use as representative of fishes in Duck and Otter creeks. The use of the sole as a representative fish species for the creeks is not appropriate and would overestimate the potential exposure to the sediments. It is recommended that the sole should not be used to evaluate the PAHs in the sediment.

3.5 Results for the Surface Water Screening

- Page 29: The use of the maximum historical surface water concentration is not representative of current conditions, and would overestimate the potential risks to ecological receptors. Based on the references cited in the tables, the historical surface water data may date back to 1992. The text should clarify the use of the historical surface water data as a conservative estimate of potential risk; and provide a summary table of the historical surface water concentrations to provide a perspective on the trend in the surface water data.

4.0 Baseline Ecological Assessment

- Page 32: The text indicates that the results of the SLERA noted potential unacceptable risks for sediments and surface water as equally unacceptable risks. However, as noted above, the assessment of the surface water was based on a maximum concentration that may have been detected over 16 years ago. The text should be clarified to state that the potential unacceptable risks for sediments and surface water were not determined using the same methodology, and the surface water potential risks have a much high degree of uncertainty. In addition, the BERA does not address surface water even though it is noted as a potential unacceptable risk. It is recommended that the evaluation of the surface water be deleted from the SBERA due to limited availability of recent surface water data for the assessment.
- Page 32: The next to last sentence in the first paragraph should be divided into two sentences, with the second sentence beginning with “However”.

4.1 Assessment Endpoints and Measures of Effects

- Page 33: It is unclear from the text if the same methodology used for the Piscivorous avian community assessment (i.e., low and high TRV, BSAF to estimate tissue concentrations) is used for the Piscivorous mammalian community in the indented paragraphs. Text should be added to the Piscivorous mammalian community paragraph noting that the same methodology is used for both assessments.

4.2 Characterization of Ecological Effects

- Page 33 & 34: The use of the sole suggests potential risk to the fish population in the creek; however, the BERA does not provide validation of this assessment. The text notes that the use of the sole probably overestimates the risks due to its extensive dermal contact with the sediments; as discussed above, the sole should note be used for evaluating the PAHs in the sediments because of the inappropriate exposure duration with the sediments as compared to the potential exposure duration with sediments for the typical fishes inhabiting the creeks.

- Page 34: The last sentence has incorrect references to the sections and should be corrected.

4.2.1 Toxicity Testing

- Page 34: The text references SulTRAC (2007) as the source of the sediment samples for the toxicity test. It is recommended that a brief discussion of the sampling method be included to clarify how the sediment samples were collected. In addition, a brief discussion of the “master stations”, and the rationale for selection of the locations of these stations, should be discussed. Sediment sampling for toxicity testing should be representative of ecologically similar areas within the study area, and should include a station that is representative of background conditions.

4.2.1.2 Toxicity Testing for Otter Creek

- Page 37: The last paragraph in this section should be included under a separate section, as it discusses limitations in toxicity testing for both creeks. In addition, the issues noted including the floating test organisms and potentially adverse test conditions are significant enough to question the validity of the bioassay tests.

4.2.2 Evaluation of Potential Stressors

- Page 37: The text notes the lack of correlation between the AVS/SEM results and the PAH toxicity unit results and the results of the toxicity tests. As indicated above, the toxicity tests were subject to potentially adverse test conditions, and the results presented in this section may indicate that the toxicity test procedures may have introduced stress to the organisms that resulted in the high degree of toxicity observed in the bioassay tests.

- Page 38: The statistical analysis of the potential stressors was inconclusive in identifying a combination of stressors that would explain the observed toxicity seen in the bioassay tests. This may substantiate the above comment that the bioassay test may be invalid due to introduced stress from the bioassay test methods used in the bioassay laboratory.

4.3.1 Quantitative Evaluation of Risk Using a Food Chain Model

- Page 39: The text notes that the exposure point concentrations for COPECs in the sediment were calculated using the 95 percent UCL about the mean. The sediment EPC concentrations used in Appendix E were obtained from the tables in Appendix A (e.g. arsenic in table A-3 for DC-A is 1.32 x 10^2 mg/kg, although the entry is cutoff potentially due to printing error) that were either selected using the 95 percent UCL or the maximum concentration if less than the 95 percent UCL. However, Table 25 states that the sediment concentration is based on the mean concentration of each COPEC in sediment collected from the site. This discrepancy should be clarified or corrected.

5.1 Analytical Data

- Page 51: This section should include a discussion on the uncertainty in the surface water historical data set, and its use in the SLERA. As noted above, the use of the maximum surface water concentration from a period spanning potentially several decades has a high degree of uncertainty in a potential risk estimate.

5.2 Use of Screening Values

- Page 52: The use of the sole for screening concentrations of PAHs in the sediments in the SLERA should be included in this section, as it likely overestimates the potential exposure to PAHs in the sediments.

6.0 Conclusions and Recommendations

- Page 55: The second and third paragraphs discuss the mink as a less sensitive receptor; however, these two paragraphs are discussing the results of aquatic receptors. The reference to the minks should be removed from these paragraphs.
- Page 59: The text references the OEPA biological surveys that were conducted for the creeks; information in these surveys should be used in the SLERA problem formulation section to identify potential ecological receptors and to evaluate the use of the sole as a representative fish species for assessment of PAHs in the sediments.

Appendix D

- The bioassay report did not observe the floating of organisms discussed in the text (page 37). The text should clarify the source of these observations, and any mitigation measures the bioassay laboratory performed to minimize the affect on the bioassay toxicity tests.

Appendix E

- Table E-3 has a wrong reference (per page 42: Bioaccumulation Factors) for total PCBs, the correct reference should be USACE 2003. Also, the text on page 42 noted the use of Wong, Capel, and Nowell 2001, which is not included as a reference in Table E-3; the use of Tracey and Hanson 1996 in Table E-3 is also not discussed on page 42.

- Several of the tables in Appendix E (e.g., E-11, E-13) had cell values indicating an error in calculation as “#value!”. These errors should be clarified or corrected in the SBERA report.

Western Lake Erie WATERKEEPER® *Association*
Western Lake Erie has the warmest, shallowest waters with the most fish in the Great Lakes
6565 Bayshore Rd. Oregon Ohio 43618
westernlakeerie.org 419-691-3788 sandy@lakeerie@aol.com

August 20, 2008

Comments on "Screening and Baseline Ecological Risk Assessment Duck and Otter Creeks Toledo and Oregon, Ohio"

Overall:
The report is highly technical and is difficult for a layman to understand. The following comments are offered:

1. Duck and Otter Creeks, particularly in the spring and when there are northern winds have water and fish coming into them from the Maumee River and Maumee Bay – also known as the seche effect. It should also be noted that the Maumee River is the most biologically productive river in the Great Lakes. The Bayshore/First Energy power plant conducted fish kill studies in 2005 and 2006 released in 2008. The studies are available at westernlakeerie.org. The studies show that the Maumee River fish numbers are in the millions and larval fish are in the billions. Some of these fish find their way in and out of Duck and Otter Creeks in the spring and when there are northern winds. The seche effect fish impacted are not mentioned or factored into the report. I believe because of the 'fishy' nature of this watershed these 'seche waters' should be factored into the Risk Assessment modeling.
2. The kingfisher is not a known fish found in the area. As can be seen in the Bayshore report – there are many fish types in these waters. I do not know if the kingfisher is representative of the types of fish in the watershed. If yellow perch, bass, and/or walleye were used instead of the kingfisher – would the results be similar?
3. Millard Ave. …Reading the report reminded me of some of the same issues for the Millard Avenue Risk Assessment. I am troubled by the fact that there are no references or discussions of the Millard Avenue information which contained sediment analysis and delineated problem areas along the creeks in the project area. In the original Millard Avenue design, Duck Creek was to be rerouted, but FHWA was worried about the contaminants and decided to put the overpass over Duck Creek(the overpass was always designed to go over Otter Creek) – at a much higher cost. I continue to believe that the information in those reports should be included in the Duck/Otter assessment.
4. In the analysis, the 'Areas' that had exceedances from the thresholds changed from step to step. Arsenic, lead, zinc, seemed to be in the sediments in all of the areas. There were other chemicals that were in some areas and not in others. How is a cleanup approached when the entire length of the creek has some chemicals that are at levels not healthy for the ecosystem?

5. Recently, it has come to some of our attention that the City of Oregon, during heavy rainfalls, at three locations along Otter Creek, pumps from the sanitary sewer into Otter Creek. This could be a contributing factor to the ammonia counts and should be looked into.
6. The recommendations include the need for additional sampling of metals, PAH's and pesticides to identify the stressor or group of stressors for better decision making. This appears to be a prudent path. Hopefully Great Lakes legacy funds can be applied for to do the additional testing.

Duck and Otter Creeks are at important junctures of the Maumee River/Bay watersheds. Improvement to sediment and water quality in these creeks can help the water quality in the creeks and help the fish that enter the creeks/and or live in the creeks.

Respectfully Submitted

Sandy Bihn
Western Lake Erie Waterkeeper

Added August 22, 2008

7. The City of Toledo cleaned a portion of Duck Creek, I believe in the 1980's That would appear to be bound by reference areas DC-D and DC-E. Was the testing data from before and after the Toledo cleanup include in the analysis of the chemicals in the creeks?