

January 17, 2006

Memo re: Response to MDEQ review of Draft Screening-Level Ecological Risk Assessment Work Plan

In this memo, we provide a disposition of comments including responses and/or clarifications regarding each of the comments that were raised by the MDEQ review of the Draft Screening-Level Ecological Risk Assessment (SLERA) Work Plan.

Responses and clarifications will be presented below in Arial font along with the original comment text as provided in the review by MDEQ (dated September 29, 2005). For clarity, the original comment text will be indented and italicized.

2.0 GENERAL ISSUES

The overall approach used by ENTRIX in the work plan is adequate and appropriate for screening-level assessments. It conforms broadly to the procedure developed by U.S. EPA (EPA, 1998) and which has become generally accepted by the risk assessment community. ENTRIX correctly recognizes the screening purposes of the approach and its limitations. Nevertheless, I identified a number of general or overarching issues that require clarification before the work plan can be considered entirely adequate

The need, or otherwise, for further risk assessment activities and the failure to recognize previous activities. *Two ecological risk assessments have already been performed for the Tittabawassee River and its floodplain. In GES (2003) risks posed by PCDDs and PCDFs in the aquatic environment and its associated food chains were evaluated. In GES (2004) the same was done for the terrestrial floodplain environment. Since it included a relatively large amount of site-specific data (sediments, fish, bird eggs), the former ecological risk assessment can be considered as being closer to the definitive end of the risk assessment scale (as distinct from the screening-level end). The terrestrial ecological risk assessment performed by MDEQ should be considered screening-level.*

While there is clearly a need for a more definitive analysis of risks on the floodplain, and there is likewise a need for the assessment of aquatic risks posed by contaminants other than PCDDs and PCDFs, the perceived need for further aquatic risk estimates for PCDDs and PCDFs in the Tittabawassee River is doubtful. Furthermore, as discussed below, sediment sampling in the Saginaw River and Saginaw Bay has clearly indicated that ecological risk may be “exported” out of the Tittabawassee River and into downriver areas. As yet, these downriver risks have not been adequately examined. I regard this as a more appropriate focus for future aquatic risk assessment activities, rather than a re-examination of the Tittabawassee River aquatic system.

The text has been updated to more clearly recognize previous ERA activities. We agree with MDEQ that there is clearly a need for a more definitive analysis of risks on the floodplain and aquatic environments for chemicals of potential ecological concern (COPECs) other than PCDDs and PCDFs. We disagree that the perceived need is “doubtful” for further aquatic risk estimates for PCDDs and PCDFs. MDEQ’s prior assessments focused only on piscivorous ecological receptors, with many simplifying assumptions and relatively great uncertainties. Further evaluations of aquatic risks of PCDDs and PCDFs are consistent with current guidance for

conducting ERAs which recommends tiered evaluations for complex sites such as the Tittabawassee River.

Geographic scope of the proposed analysis. At several places in the document (including the map in Figure 2-1, p.2-3) the geographical area of investigation is defined as the reach of the Tittabawassee River and its floodplain from Midland downriver to the confluence with the Saginaw River. Discussions with Dow and ENTRIX personnel on September 16, 2005 confirmed that no risk assessment activities are planned for downriver of the confluence. The September 16 discussions also confirmed that the reason for this geographical truncation is regulatory, rather than scientific: Dow and ENTRIX maintain that, under the terms of the permit with the State, the reaches further downriver do not need to be addressed in the current round of risk assessment activities.

Regardless of the regulatory issues, sediment sampling by the Army Corp of Engineers in 1998 and 1999 detected TCDD-EQ concentrations of up to 610 ppt (WHO avian TEFs) in the inner Saginaw Bay and exceeding 2,000 ppt in Saginaw River. More recent sampling in the Saginaw River by MDEQ and by Dow identified TCDD-EQ concentrations that were greatly elevated above background (approaching 50,000 ppt – WHO avian TEFs). The congeners that make the greatest contributions to this toxicity are the same as those in the Tittabawassee River, indicating the likelihood of a common source. Furthermore, preliminary evaluations performed by MDEQ (GES, 2003) on the Army Corp of Engineers data set indicate that the possibility that these concentrations pose unacceptable risks to ecological receptors cannot be disregarded.

Ignoring the permit and regulatory issues and concentrating solely on the implications of the risk assessment, it is obvious that the ecological risk assessment activities proposed in the ENTRIX work plan will not capture or address all of the potential watershed ecological risks due to PCDDs and PCDFs originating in Midland. Specifically, risks posed by these contaminants transported downriver of the confluence of the Tittabawassee and Saginaw Rivers will not be included.

The draft SLERA Work Plan includes the geographical scope as defined in the Operating License. The potential need for expansion of the geographic scope of the studies will be addressed in future studies as necessary to meet the requirements of the Operating License.

The omission of PCDDs and PCDFs from the screening-level assessment. ENTRIX (2005) proposes that PCDDs and PCDFs not be included in the screening-level assessment. Before discussing this issue further, I acknowledge that I agree with ENTRIX that the results of a SLERA should not be regarded as rigorously predictive of risk, and its primary purpose is to identify and eliminate from further analyses contaminants that can be safely regarded as not likely to pose unacceptable risks. Nevertheless, the relative magnitudes of SLERA hazard indices can provide at least an order of magnitude comparative assessment of the potential contributions to risk by each of the contaminants. Thus, a SLERA, in addition to eliminating contaminants from unnecessary analysis, may also provide a useful early indication of the relative importances of each of the contaminants that fail the “SLERA test”.

The ERA activities described in both the SLERA and BERA draft work plans are intended to build upon the data and results of all relevant historical activities, including those conducted previously by MDEQ. The screening results, as correctly characterized by MDEQ, “should not be regarded as rigorously predictive of risk [but rather] its primary purpose is to identify and eliminate from further analyses COPECs that can be safely regarded as not likely to pose unacceptable risks.” That is exactly the approach that is taken in the draft ERA work plans.

However, the suggestion that the relative magnitudes of SLERA hazard quotients can provide an assessment of the potential contributions to risk by each of the COPECs is not scientifically defensible as there are varying degrees of uncertainty in the hazard quotient calculation for each COPEC. These uncertainties include the use of maximal (single point) concentrations and screening benchmarks that may not be particularly relevant to the assessment endpoints of a particular site. Therefore the SLERA results should only be used to identify COPECs that will be evaluated further in the BERA.

The reasons for the omission of PCDDs/PCDFs from the proposed ENTRIX SLERA are not stated fully in the SLERA work plan, but only vaguely described as (for example) “based on historical data, it is assumed thatPCDDs and....PCDFs will continue to be COPECs” (my italics). In verbal discussions with Dow and ENTRIX personnel on September 16, they clarified their position by explaining that the reason that PCDDs and PCDFs are not to be included in the SLERA is because they accept the results of the State’s previous efforts to evaluate risks posed by these contaminants in the Tittabawassee River and its floodplain. Dow and ENTRIX apparently believe that since the State has already concluded that PCDD/PCDFs pose

unacceptable risks to biota, they need not be included in their proposed screening-level assessment. If my interpretation of what was communicated is correct, and if Dow and ENTRIX accept the State's conclusions, it should be clearly stated in the ENTRIX (2005) work plan. Otherwise, I would recommend (for the reasons given at the beginning of this paragraph) that PCDDs and PCDFs should be included in the screening-level evaluation.

The sentence quoted in this comment from MDEQ has been modified within the SLERA work plan text to read "Previously, two preliminary ERAs were performed for the Tittabawassee River and its floodplain focusing on the aquatic environment (GES 2003) and the terrestrial environment (GES 2004) and their associated food chains. Based on these analyses, it is appropriate to conclude that polychlorinated dibenzo-*p*-dioxins (PCDDs) and dibenzofurans (PCDFs) will continue to be COPECs and are currently the focus of ongoing studies that will be used in the BERA." It is our position that it is premature to draw conclusions regarding whether the current conditions within the study area present unacceptable risk to ecological receptors of concern.

***Screening-level risk assessment – worst case?** In their Introduction to the SLERA work plan (p. 1-1), ENTRIX (2005) describe the necessary degrees of protectiveness that have to be incorporated into screening level assessment to minimize the likelihood of false negative conclusions. They then go on to characterize the results of screening-level assessments as "worse case". The implication of this is that it confers a level of "over-protection" on receptors. This is not necessarily the case: just because protective parameters have been used, it does not necessarily follow that all potential ecological receptors are over-protected. While SLERA risk estimates probably define the upper end of the risk spectrum at a site, and may be adequately protective for most situations and biota, they may not be protective enough for some eventualities, for example sensitive or highly sensitive organisms with small home ranges that are superimposed on areas of maximum contamination. Also, it is a fact that we do not know how sensitive or insensitive the vast majority of species that occur in the assessment area are to PCDDs and PCDFs, and while we may hypothesize that we are being adequately protective in our selection of parameters we cannot be entirely sure.*

This statement has been edited to better represent the intent and purpose of a SLERA to identify substances that may pose a risk to the environment. As a result we have deleted the phrase "worst-case estimation" and substituted the language taken from the USEPA guidance that defines what a SLERA is and its role in ecological risk assessment.

Selection of ecological receptors and exposure pathways. It is not clear from the Entrix (2005) document how ecological receptors will be selected or which species have been selected. This should be clarified so that MDEQ can more fully evaluate the adequacy of the proposed work. Also, during verbal conversations on September 16 it was stated that hooded merganser eggs had been collected and that the results of their analyses would be included in the risk assessment. This should be made explicit in the SLERA work plan.

At this time, specific receptors have not been identified for the SLERA, because the focus of the SLERA is on using media-specific benchmarks and media-specific chemical concentrations to evaluate the need for selecting chemicals for additional study in the BERA. If a media-specific benchmark is not available for a chemical, then additional analyses will be conducted to derive a benchmark; those analyses will identify a receptor and an exposure pathway depending on the physical-chemical properties of the chemical. This approach has been clarified in the text.

Uncertainties and the uncertainty analysis. Section 4-2 (p. 4-3) of the workplan correctly points out the need for an uncertainty analysis at the conclusion of the screening evaluation. It should be acknowledged that this uncertainty analysis should include all areas of uncertainty, including those that may result in the underestimation of risk. An example of the latter would be the fact that our knowledge is very incomplete regarding how sensitive or insensitive to PCDDs and PCDFs most species that occur in the assessment area actually are.

We agree with the reviewer and have added language to the SLERA work plan that emphasizes the need to evaluate uncertainties in the analysis that can lead to an over- or underestimate of risk to receptors that inhabit the site.

3.0 SPECIFIC COMMENTS

Note that the Section and page references refer the July 1, 2005 Draft SLERA Work Plan.

Section 2.2, Figure 2-3, p.2-4. What do the error bars represent (range, standard error, standard deviation)?

The error bars represent the standard deviation of the mean. This has been clarified in the text.

Section 2.4.1, p.2-5. penultimate sentence in final para. The existing data set includes more than “a few native whole fish samples”. This creates the mistaken impression that relatively little is known about contamination in fish in the study area. In 2002 MDNR and MDEQ collected and analyzed more than 80 individual fish from 4 resident species. Also, subsequent to that in 2004, MSU collected samples from “forage fish” and two additional species (northern pike and bowfin) from the Tittabawassee River downriver of Midland. TCDD-EQ in the tissues of these samples (including the forage fish) approximated those high levels found in the MDEQ/MDNR samples. Thus, to create the impression that little is known about contaminants in fish from the study area is disingenuous. It would be more accurate to conclude that existing data confirm that elevated concentrations of TCDD-EQ are widespread throughout the fish community.

The text has been revised to read “and native whole fish”. Section 2.4.1 is simply meant to list the various sources of historical data and to provide a general description of the data available.

Section 2.4.1, p.2-6. Table 2-1. MDEQ’s 2001 sediment sampling is missing from this table. Also the bird egg data is jointly MDEQ and USFWS.

The reference for the MDEQ 2001 sampling has been added to Table 2-1. However, the bird egg data have not been included in this work plan as a report detailing these data has not been released to date. We have requested and received, under FOIA, chromatograms from the analysis of bird eggs in 2003. We will need to collate and validate this data prior to use in the ERA.

Section 2.4.2, p.2-7. What is meant by the statement that “no comprehensive ecological evaluations...study area”? Is it intended that the SLERA will be such an evaluation?

The intent of the sentence was to convey that other than PCDD/PCDF congeners, no comprehensive ecological evaluations have been conducted within the study site, to date. We have edited this statement to emphasize this point. Finally, it is not the intent of this SLERA to conduct a comprehensive ecological risk assessment, but rather to conduct a simplified, conservative assessment to identify COPECs that may need to be evaluated in the comprehensive baseline ecological risk assessment (BERA).

Section 3.1.1.1, p.3-1. The ecological receptors (“key receptors”) that are to be the focus of the SLERA are not identified in the ENTRIX work plan. They should be identified, together with the rationales for their selection.

The focus of the SLERA is to evaluate the potential risk of chemicals within the site based on a comparison of media specific concentrations to media-specific benchmarks. Risk of specific chemicals to ecological receptors would occur during a SLERA only if a screening-level benchmark were not available and needed to be developed.

Section 3.1.1.1, p.3-2 first para. The statement about the postulated “very limited assimilation and accumulation of particulate-bound of COPECs intosmall mammals” needs to be clarified. Is this a statement about conditions at the site, or is it intended to be more general? Either way it needs to be supported by references and/or data.

This statement has been clarified as requested by the reviewer. For the SLERA work plan, conservative assumption of 100% bioavailability, 100% absorption from the diet, and maximal exposure concentrations will be used to estimate potential exposure in the targeted receptors. However, in the BERA these assumptions will be tested, when possible, to better understand the abiotic and biotic factors that influence the degree of assimilation of these compounds by different receptor guilds. As part of these analyses, field data collected from the site will be used to calibrate and/or validate any models that may be used to predict the accumulation of chemical entities by receptors from specific media and the associated food chain of receptors that utilize these sites.

Section 3.1.1.2, p.3-2. 2nd sentence. Should Equation 5-1 be 3-1?

The text has been corrected.

Section 3.1.1.2, p.3-2. Are the “site use factor” and the “area use factor” synonymous?

Yes, these two parameters are synonymous. However, for the SLERA to be conservative, it will be assumed that the receptors will use the site 100% of the time. As a result, this factor will not be used in any exposure model for any potential receptors evaluated in the SLERA. This has been clarified in the text.

Section 3.1.1.2, p.3-2. How will the “fractional absorption value” be determined? Will it be site-specific or based on the literature?

While “the fractional absorption value” is used in many dietary models to estimate exposure of receptor to environmental contaminants, it will not be used in the SLERA. Rather, if it becomes necessary to develop an exposure estimate, it will be assumed that 100% of the ingested dose will be absorbed by a receptor to maintain the conservative nature of the SLERA analyses. This has been clarified in the text.

Section 3.2.2, p.3-4. Uncertainty factors. Uncertainty in important variables in risk assessment analysis can result in the underestimation of risk, as well as its overestimation. Both tendencies should be addressed and evaluated in any adequate uncertainty analysis. For example, it is not clear from the SLERA work plan how the high degree of uncertainty regarding our lack of knowledge about the sensitivity, or otherwise, of the majority of bird and mammal species at the site be addressed?

As requested, additional information has been added that addresses how uncertainty will be evaluated in the SLERA. To evaluate the sources and magnitude of uncertainty in the effects analysis phase of the SLERA, the uncertainty factor approach will be the basis for evaluating issues of interspecies extrapolation, NOAEL to LOAEL extrapolations and study duration extrapolations. The procedures to be followed relative to the selection of specific uncertainty values will be based on established guidance as outlined by the USEPA and by the US Army health and ecological assessment groups. If necessary and sufficient data are available for specific chemicals, modeling approaches could also be used to evaluate the issue of species sensitivity.

Section 2.5, p.2-7 Typo. Black-crowned night heron should be black-crowned night-heron.

The text has been corrected.

Section 4.1, p. 4-1 Typo. There are no Equations 2-1 or 2-2 in the text. Should it read 4-1 and 4-2?

The text has been corrected.

Section 1.4, p.1-2, The Section 3.0 description is incomplete.

The text has been corrected.

Section 6.0, p.6-1 Typo in Galbraith.....

The text has been corrected.

Section 6.0, p.6-2 Reference to University of California is incomplete.

This reference has been completed.