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Memo re: Response to MDEQ review of Draft Baseline Ecological Risk Assessment Work Plan

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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 Baseline Ecological Risk Assessment (BERA) Work Plan.

Responses and clarifications will be presented 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

I have identified seven overarching issues that should be recognized by MDEQ in their consideration of the ENTRIX BERA work plan:

1. The relationship of the BERA to previous studies and data collection and analyses, and the need for further ecological risk assessment. *Since about 1980, a large quantity of data has been gathered characterizing the degree and extent of environmental contamination in the Tittabawassee River watershed. These data sets describe contaminant concentrations in sediments, surface water, soils, and biota. Based on these data, two ecological risk assessments have already been performed for the Tittabawassee River watershed (GES, 2003; GES 2004). The former focused on the aquatic environment, while the latter addressed risks to biota on the floodplain of the Tittabawassee River. 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 floodplain (terrestrial) ecological risk assessment performed by MDEQ should be considered screening-level.*

Reading the ENTRIX (2005a) work plan, one could be forgiven for concluding that comparatively little information was available regarding contamination of the study area by organochlorines, bioaccumulation in food chains, or exposure and risks to predatory wildlife. This is because the ENTRIX work plan fails to acknowledge, to an adequate extent, the fact that a large amount of data has already been gathered and analyzed. In fact, the Tittabawassee Watershed is a comparatively well-characterized system. It is also the case that contaminant concentrations in many of the components of the aquatic and terrestrial ecosystems have been assessed and in each the result is the same – high levels of contamination that greatly exceed baseline. During the September 16 discussions, ENTRIX personnel stated that their proposed work should be regarded as "building on" or "extending" previous studies (including MDEQ studies). If this is the case, a more comprehensive acknowledgement of previous studies and their contributions to our understanding of environmental risks should form part of the BERA work plan.

The previous studies notwithstanding, there are three outstanding risk assessment "data needs" for the Tittabawassee River watershed:

1. *There is a need for a more definitive analysis of risks on the floodplain (where the MDEQ assessment is at the screening level).*

2. *There is a need for the assessment of aquatic risks posed by contaminants other than PCDDs and PCDFs in the aquatic environment.*

3. *Sediment sampling in the Saginaw River and Saginaw Bay (discussed below) has clearly indicated that ecological risk may be "exported" out of the Tittabawassee River and into downriver areas. As yet, however, these downriver risks have not been adequately examined. They could be a much-needed focus of future risk assessment.*

   The studies described in the ENTRIX BERA clearly focus on data need numbers 1 and 2. They do not, however, address data need number 3 (see below). Moreover, a large component of the BERA work plan describes studies that revisit an issue that the State has already completed much work on: the risks to ecological receptors in aquatic food chains in the Tittabawassee River from PCDD/PCDFs. Future time and resources would be better spent if the BERA focused mainly on the three data needs identified above.

The text has been revised to provide more details on previous studies, including the limitations of previous studies and data gaps. The aquatic study by GES (2003) made substantial contributions to the body of fish residue data available for the Tittabawassee River. However, the limitations of this study are that it focused exclusively on PCDDs and PCDFs, piscivorous exposure pathways were the only pathways directly assessed, the specimens of fish were generally large, and dietary risks were calculated from an overly simplified diet that does not account for species-specific and site-specific dietary exposures. The draft BERA Work Plan will address risks from PCDDs and PCDFs *and* other COPECs that are retained after the SLERA is completed. This will allow a direct comparison of relative risks for each COPEC and receptor of concern. In addition, aquatic-based receptors, both piscivorous and non-piscivorous, will be evaluated using site-specific dietary information from field studies, and residue concentrations in receptor tissues. The terrestrial study by GES (2004) is acknowledged to be at a screening-level, clearly providing a basis for a more definitive analysis of risks on the floodplain. (See also the response to Comment #2 regarding geographic scope.)

2. Geographic scope of the proposed analyses. *At several places in the document (e.g., p. 1-1 first para., p. 1-4 first para., Appendix C, Figure C-1) the main geographical area of investigation ("the Site") is defined as the reach of the Tittabawassee River and its floodplain from Midland downriver*

to the confluence with the Saginaw River. A work plan for a screening-level risk analysis that I previously reviewed (ENTRIX 2005b) also restricted the study area to the Tittabawassee River and its floodplains. This definition of the area of investigation is, however, not entirely consistent: in the package of BERA materials that I received from MDEQ there were three alternative versions of Appendix C, one of which includes plans for sampling on the Saginaw River close to Saginaw Bay. During discussions with ENTRIX personnel on September 16, it was made clear that the BERA will only cover the Tittabawassee River as far downriver as its confluence with the Saginaw River and that Saginaw River and Bay would not be included. During the September 16 discussions ENTRIX and Dow stated that under the terms of the permit with the State the reaches further downriver need not be addressed.

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. This last maximum concentration is almost an order of magnitude greater than the sediment samples gathered in the Tittabawassee River. 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 in Midland. Furthermore, preliminary evaluations performed by MDEQ (2003) on the Army Corp of Engineers data 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 clear that the ecological risk assessment activities proposed in the ENTRIX BERA 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 BERA 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.

3. Multiple lines-of-evidence approach. *Throughout the BERA work plan (ENTRIX, 2005a) it is repeatedly stated that the intended approach to*

assessing risks to wildlife will be via multiple lines-of-evidence. In effect, this will mean that estimated and measured exposures, and the resulting calculated risks, to wildlife species will not be the only factors used in assessing risk to biota. Using data that is expected to be provided by the Dow-funded Michigan State University Studies, ENTRIX will also incorporate (for example) population abundance, reproductive success, and individual health data into its overall evaluation of risk.

The intent in using a lines-of-evidence approach, particularly one involving measures of population "health", in risk assessment, is typically to address the question "are impacts really occurring among receptors for which risk may or may not be predicted"? Thus, the BERA, as proposed, combines two separate concepts – risk and impact. The reason for utilizing such an approach in risk assessment is often given as being intended to reduce the uncertainty inherent in risk modeling. While uncertainty does exist in the estimation of risk from exposures (modeled or measured), the important question is: to what extent are the results of field studies free from uncertainty? In a multiple lines-of-evidence approach to risk assessment there is often a temptation to regard the results of field studies as free from uncertainty and, therefore, the ultimate arbiters of whether or not risk actually exists. This may not be appropriate since it fails to recognize that the results of field studies may be as fraught with uncertainty as risk assessment modeling and, by disregarding the results of the latter in favor of the former, we may only be replacing one set of uncertainties with another. In effect: field studies may not be "silver bullets" that pierce through uncertainty to provide unambiguous or clear results.

The uncertainties inherent in the interpretation of the results of field studies largely grow out of the uncontrolled or only partially controlled nature of such studies. For example, spatial or temporal differences in the breeding productivity of a wildlife species may arise from factors not controlled for (and potentially uncontrollable) in the study design. Such factors may include: the intermittent presence of a predator in the study area, local weather variability, localized disturbance by humans, or local short-term disruption in the food supply. All of these factors may be likely to go unrecognized by researchers. Nevertheless, it is typical that such factors result in a considerable amount of "noise" in field study results. Against this background of noise, it can be very difficult to unambiguously distinguish the "signal" being sought after. Thus the interpretation of productivity data from the field may be as fraught with as much uncertainty as that of model results.

If the variable being measured in the field is density or abundance a whole new set of uncertainties is introduced. It is well known among population biologists that the densities of organisms measured at specific sites in the field may have little or no relationship to the local presence or lack of stressors. So called "sink populations" of organisms may exist in an area where their population "health" and productivity is low, but they are supported and maintained by immigration from "source" areas where productivity is high.

The concerns that I have outlined above are not intended to imply that field studies do not have a role in ecological risk assessment. They do. However, the results of field studies should not be viewed as unambiguous data that "trump" the predictions of ecological risk prediction. I maintain that, while they may provide useful supporting information, they should be treated as circumspectly as the modeled predictions. If a situation arises where risk modeling predicts unacceptable risk, but field studies fail to show an impact, it should not be regarded as axiomatic that there is no risk, only that the field impacts may not have been detected. This is especially the case with PCDDs and PCDFs which do not usually result in "kills" in wildlife species, but are expressed in much more subtle and difficult to detect effects, including reductions in fecundity, and morphological and behavioral abnormalities.

In the September 16 discussion, ENTRIX personnel agreed that the field study results would not be used to trump risk assessment predictions but that each line of evidence would be weighted and a final evaluation derived from the integration of these weighted results. This raises the question: how will the various elements be weighted? This should be addressed in the BERA.

Utilization of all available lines of evidence is important in understanding the complex interactions that may occur when assessing exposures and potential effects. The text has been modified to clarify how this information will be utilized. It is not a question of whether the field study results may or may not "trump" the risk assessment predictions. Among other types of information the field studies will obtain concentrations of tissue residues in receptors of concern, which integrate their exposures spatially and temporally. These concentrations can be compared to what is predicted from modeled exposure estimates, but more importantly, can be compared to tissue residue-based effect levels available from the scientific literature. The alternative is to rely almost exclusively on a single line of evidence, estimates of dietary exposures, for which risk assessors must make significant assumptions regarding bioavailability, temporal and spatial utilization of the site, and dietary composition. Note that this approach is not a direct assessment of effect, but is a direct measure of exposure. Uncertainties of this approach will be presented in the BERA. Comparison of both approaches may reveal site-specific deviations from

generic dietary models. Thus, these field studies are critical to "ground truth" model estimates. An additional aspect of the field studies includes an assessment of potential "impact". While such assessments have uncertainties as suggested by GES, these uncertainties will be discussed in the BERA. Furthermore, the field studies were designed in such a way as to minimize these uncertainties. For example, while weather events might influence productivity measurements in birds, the use of multiple years of data and multiple locations may allow an evaluation of the impact of such events on the results.

> ***4. Protection of all receptors.*** *Presumably, the intent of the BERA is to provide results that will be protective of all, or at least the great majority, of receptors at the site. However, the BERA focuses on only a small subset of receptors. How will the risk assessors ensure adequate levels of protection for all exposed species? For the great majority of birds and mammals that inhabit the assessment area we have little or no information regarding their potential sensitivity or insensitivity to PCDDs or PCDFs. There is no* a priori *reason to assume that some of these species could not be as, or more, sensitive than the most sensitive species that have thus far been tested. It is not clear how the ENTRIX study will extrapolate from the selected receptor species to the ecological community as a whole.*

The draft BERA Work Plan incorporates an uncertainty approach regarding development of toxicity reference values (TRVs) that is consistent with applicable guidance. Uncertainty concerning interpretation of the toxicity test information among different species, different laboratory endpoints, and differences in experimental design, age of test animals, duration of test, etc., are addressed by applying uncertainty factors (UFs) to toxicological data in order to derive the final TRV.

> ***5. Receptor species.*** *The ENTRIX BERA identifies 7 bird species (house wren, tree swallow, great horned owl, belted kingfisher, American robin, bald eagle, and great blue heron) and 3 mammals (mink, meadow vole, and short-tailed shrew) as receptors for the proposed ERA. Several questions are prompted by this list:*
>
> - *Why are two species of insectivorous passerine birds being studied? It would seem that one should be sufficient.*

Each insectivorous passerine species occupies a different niche and represents a different feeding guild. With the house wren consuming a predominantly terrestrial-based diet and the tree swallow consuming a predominantly aquatic-based diet.

- *Why are some highly exposed organisms that MSU is already collecting data for (hooded merganser and wood duck) not included in this list?*

Data have been collected for the hooded merganser and wood duck, however they are not currently receptors of concern because other birds that have been identified at the site as receptors are more representative of site-specific conditions and have more potential for exposure. The existing data for merganser and wood duck can be incorporated into the BERA and the toxicological significance of any chemicals measured in these samples will be evaluated using the multiple lines of evidence approach that has been outlined in the BERA workplan. Furthermore, data on concentrations of PCDD/DF in eggs of these birds suggests that they are not present at concentrations that would be expected to exceed the most conservative estimation of hazard (Augspurger, T.P. *et. al*. 2005 poster # RP092, SETAC North America 26th Annual meeting).

- *Why are mammalian top predators on the floodplain absent from the list? Assuming that mink is at least partly aquatic in its diet, there should be animals such as red fox included?*

A mammalian top predator has not been included in the list of receptors of concern because the likely candidates, red fox, long-tailed weasel, and coyotes, have mitigating factors that reduce the potential for exposure. For example, red fox diet can include up to approximately 31% herbaceous material (USEPA, 1993). In addition, field observations from the MSU research team and local trappers suggest that the floodplain does not offer significant areas of suitable habitat for the red fox or long-tailed weasel and thus these species are rarely seen on site. The coyote represents an alternative terrestrial carnivore since they are abundant on the floodplain and are frequently trapped along the river. However, the coyote has a larger foraging range than the red fox. This expanded foraging range likely extends outside of the area of concern.

- *Why are no vermivorous animals (e.g., American woodcock) included in the list of receptors?*

American robins have been documented to consume up to 15% earthworms in their diets with a greater proportion of worms being consumed during the sensitive life stages in the spring when eggs are developed and nestlings are fed (USEPA, 1993; MSU field team observations). Site specific data will be available for American robin dietary exposure and tissue residues in the Tittabawassee River floodplain. The short-tailed shrew is also included as a receptor of concern and consumes soil dwelling insects and worms. In addition, while it would be possible to include the

woodcock in a theoretical exposure evaluation, ongoing field studies indicate that woodcock is not a resident species on the site. Therefore consideration would have to be given to the transient nature of this migratory species that spends minimal time on the site, a few days per year, based on field observations.

> *The impression is conveyed by the BERA list that the only organisms chosen are ones that are already being studied as part of the MSU research. While these animals are, for the most part, suitable candidates, appropriateness, rather than overlap with MSU target organisms, should be the major criterion.*

Receptors that have been listed in the BERA work plan were chosen based on several criteria that included their presence within the site and reference locations, the inclusion within a feeding guild that has relevance in terms of their potential exposure to COPECs via exposure pathways, and sensitivity to specific COPECs (e.g. PCDDs, PCDFs) that have been measured at the sites. In addition, species were selected in part due to the fact that they have been extensively investigated and are widely accepted by regulatory agencies such as EPA and Fish and Wildlife Service (FWS) as indicator species for contaminant availability and effects. As such, they have been included in the BERA work plan as potential receptors of concern. If credible scientific evidence is found that indicates that a feeding guild not currently listed in the BERA is at risk, a representative species from that feeding guild will be included in the BERA and, if possible, additional data will be collected to ascertain its status within the site.

> ***6. Assessment and measurement endpoints.*** *In Section 3.4 of the BERA work plan "Reproductive Success and Population Sustainability" is identified as the overall assessment endpoint. To actually put this into use, quantifiable measurement endpoints (e.g., Toxicity Reference Values) must be developed. In Section 5.2 of the BERA work plan there is some discussion about how measurement endpoints may be developed. However, it is still unclear how these will relate back to the assessment endpoints. Can it be assumed that if (for example) the endpoint is avian reproductive success and population sustainability, and that the egg tissue residue threshold (the TRV) is exceeded, resulting in a hazard index of greater than unity, that the standard of the assessment endpoint has not been met?*

To evaluate whether the reproductive success and population sustainability assessment endpoint has been met, multiple lines of evidence will be evaluated as suggested in the USEPA 1997 guidance for ecological risk assessment. Table 3-5 has been added to the BERA work plan to better demonstrate the relationship

between the measurement endpoints and the assessment endpoints. Exceedance of a criterion for a single measurement endpoint may not ultimately lead to the conclusion that an assessment endpoint has not been met.

> *Also, PCDD/PCDF toxicosis may result in a suite of effects that are not immediately translatable into population effects. For example, edema in embryos, limb malformations. Will these be looked for and will it be assumed that if they are found in study animals they will automatically result in embryo mortality?*

As part of the field studies with certain avian species, embryos will be evaluated for a number of endpoints including abnormalities and deformities as well as growth rates. For specific endpoint measures, please refer to the appropriate study plans. Observations of abnormalities, deformities, or inhibited growth in embryos will not automatically be inferred to result in embryo death. Rather, the severity and occurrence of such observations will be evaluated in terms of incidence in natural populations as documented in the scientific literature or by observations in reference areas; and the potential for embryo death or reduced long-term survival will be discussed in the risk characterization section of the BERA.

> ***7. Use of existing data sets.*** *Several important data sets already are available to describe contamination at the site. These include data sets for sediments, soils, water, and biota. It is not clear from the BERA work plan, however, which, if any, of these data sets will be incorporated into the proposed analyses. The work plan needs a clear statement about which of these data sets are* likely *to be used.*

The text has been revised to more clearly describe which data sets will be utilized.

3.0 SPECIFIC COMMENTS

> ***p. 1-1, 2nd para.*** *The statement that there is currently minimal information on PCDD and PCDF levels in the tissues or diets of wildlife is not correct (see general comment 1 above).*

The text has been edited to better reflect the data that are currently available in regards to PCDD and PCDF concentrations in tissues and dietary items of wildlife that inhabit the Tittabawassee River and it's floodplain. However, these data are not sufficient to accurately ascertain the risk these chemicals may pose to receptors

inhabiting the site. As a result, additional field studies are being conducted to address many of the uncertainties in the original risk evaluations.

> ***p. 1-1.*** *In the Purposes and Scope Section there are 8 bullets describing the purposes of the proposed analyses. Nowhere in these bullets does it explicitly state that the one of these purposes is to identify and quantify risk.*

The fourth bullet has been edited to explicitly state that one of the objectives of the BERA is to identify and quantify risk.

> ***p. 1-2, second bullet.*** *What is meant be pathway analysis and how is it intended to be used to mitigate exposure?*

This statement has been clarified and now states that the pathway analysis is to examine the exposure pathways of the receptors of concern identified in the BERA.

> ***p. 3-1, third para.*** *Use of the term "potential risk". Since some level of risk is always present, potential risk is a misleading term. The real question is whether the risk is acceptable or unacceptable.*

This statement has been edited to state that the potential for unacceptable risks will be evaluated.

> ***p. 3-1, third para.*** *"Galbraith, 2003" should be GES, 2003.*

The citation has been corrected.

> ***p. 3-4, Table 3-3.*** *Why are wood duck and hooded merganser not included in this list or receptors? We already have data that characterizes their exposure and MSU has already gathered eggs of both species.*

Data have been collected for the hooded merganser and wood duck, however they are not currently receptors of concern because other birds that have been identified at the site as receptors are more representative of site-specific conditions and have more potential for exposure. The existing data for merganser and wood duck can be incorporated into the BERA and the toxicological significance of any chemicals measured in these samples will be evaluated using the multiple lines of evidence approach that has been outlined in the BERA workplan. Furthermore, data on concentrations of PCDD/DF in eggs of these birds suggests that they are not

present at concentrations that would be expected to exceed the most conservative estimation of hazard (Augspurger, T.P. *et. al*. 2005 poster # RP092, SETAC North America 26th Annual meeting).

> ***p. 3-5, Section 3-4.*** *Can we infer from this section that if unacceptable risks are shown to apply to reproductive endpoints that this axiomatically implies risk to population sustainability (see general issue 5 above)?*

While measures of reproductive success are sensitive indicators of contaminant toxicity and are indicators of population sustainability, they are not direct measures of how populations behave in ecological systems. Evaluation of population sustainability includes consideration of multiple factors including reproduction, growth, and survival. Density-dependent and density-independent factors all have a role in determining whether a population is sustainable at any given location and must be taken into account when assessing the potential impact of COPECs on a particular receptor. For this reason, a multiple line of evidence approach will be used to assess the impact of COPECs in which toxicological and ecological data will be used to assess the health and sustainability of receptor populations and to apportion the potential causes for any alterations in populations characteristics found at different locations within the reference and down river sites. (Note: this issue is related to general issue 6 and not 5.)

> ***Figure 3-1.*** *This conceptual model diagram of the terrestrial exposure pathways needs clarification: how are insectivorous mammals exposed via small mammals? Which of the species robin, house wren, and tree swallow is a carnivorous bird – should the box be labeled Omnivorous/Insectivorous? How would piscivorous birds be exposed via a terrestrial food chain? Wouldn't birds such as robins or house wrens be depredated by carnivorous mammals?*

Both the terrestrial and aquatic conceptual site model diagrams have been revised.

> ***p. 3-6, Section 3-6*** *identifies the "risk question" that should be the central issue of the proposed studies. However, as framed, this is not a question about risk at all, it is about impacts. The question should be: Does exposure to site-related COPECs result in unacceptable risks to ecological receptors?*

The risk question has been rephrased to address the potential of unacceptable risks at the site as requested.

> ***p. 3-6, Section 3-6****. The Massachusetts Weight of Evidence Workgroup is referred to. If this reference is to be used a justification for the lines of evidence approach much more detail has to be given about the composition of this group, their regulatory status, the agencies involved, etc.*

The reference to the Massachusetts Weight of Evidence Workshop was given as an example of a multiple lines of evidence approach that has been used at other contaminated sites, specifically in the state of Massachusetts, and that have been published in peer-reviewed literature. We have included additional references pertaining to multiple lines of evidence approaches that include ones that have been proposed by various authors that are part of USEPA ecological risk assessment guidance document (USEPA 1997).

> ***p. 3-6, Section 3-6.*** *How, exactly, will measurement endpoints be "evaluated" for the three listed attributes, particularly the second and third?*

Additional information related to how measurement endpoints will be evaluated has been included in the revised BERA.

> ***p. 3-6, last para.*** *The intent of this paragraph is not clear. What is measurement endpoint "outcome"; "indication of risk of harm"; measurement endpoint "weight"; "magnitude of response"? This seems to be an important statement of intent, but it suffers greatly from lack of transparency.*

Section 3.6 "Risk Questions" has been significantly revised to address the reviewers concerns and more clearly define the overall approach.

> ***p. 3-7, first para.*** *What will happen in situations where multiple lines of evidence are not available? For example, if the only data for a particular bird species is egg residues (which may or may not exceed TRVs). Would the species be eliminated from further analyses or would risk decisions be made on the basis of the one line of evidence available?*

The use of a single line of evidence in evaluating the potential for unacceptable risk has been incorporated into the revised BERA work plan. In these situations, the first step of the multiple lines of evidence approach will be followed and any estimate of risk will be accompanied with an evaluation of uncertainties involved in the risk calculation as well as a determination of how these uncertainties affect the interpretation of the risk calculation.

> ***p. 5-2.*** *If FAVs are to be applied to soils, sediments, diet, etc., they may also have to be used to calibrate the results of TRV data. If this is not done, the comparison of dose with TRV may be inappropriate.*

The use of FAVs relative to the exposure model has been modified. The exposure model that will be used in modeling exposure of wildlife receptors is based on the generalized exposure model given in the Eco-SSL guidance. The model presented in the BERA work plan has been modified to reflect potential differences in bioavailability of chemicals associated with soils but not for dietary items. For dietary items, it will be assumed the absorbed fraction of a chemical in a dietary item in the field is similar to that observed in laboratory studies.

> ***p. 5-3, final para.*** *It is stated that the results obtained from the MSU sampling grids will be extrapolated to the wider environment of the site. However, since the sample sites that were chosen for the grids were subjectively selected (i.e. they were not, apparently, based on a random model or a systematic grid with randomized start point) any statistical inferences from a grid should be confined to that grid, or perhaps, to comparisons between grids. How will the risk assessors address this limitation?*

The use of data collected from the grids will not be extrapolated to the wider site, rather the data collected from these grids will be used to derive parameters that can be used in models to assess the potential exposure of receptors found at other locations within site and reference locations. The exposure model, using site-specific parameters along with chemical data from soils collected a part of the nature and extent studies will be used to estimate exposures for targeted receptors throughout the site. This approach is commonly used along with GIS methodologies to “map” areas of potential risk based on soil chemical concentrations.

> ***Table 5-1.*** *The sample size for many matrices is given as 14. How is this arrived at given that there are only 6 grids and two sampling events per grid?*

The target sample size for all matrices has been corrected.

> ***p. 5-5. Section 5.2.1.*** *Why explicitly is doubt being cast on the Saginaw Bay carp mink feeding study in a work plan? Is it being contended that the study has no predictive value elsewhere? Or is that the TCDD-EQ approach to evaluating risk is being questioned?*

The Saginaw Bay mink study is not flawed when interpreted relative to the risk question that was being asked at the time of the study. That is, what are the risks posed to mink populations that consume fish from the Saginaw Bay? However, this study is not appropriate for use in the current assessment due to the presence of co-contaminants in the feeding study. For example, when total TEQs derived from a biological assay (H4IIE) were compared to those derived from chemical analyses, the chemically derived TEQ values only accounted for approximately 40 to 50% of the total TEQ quantified by the biological assay. The remaining TEQs were never identified chemically. Finally, since the carp used in the feeding study were collected in the 1980's from Saginaw Bay, an area with numerous industrial inputs, it is likely that other non-AhR contaminants were present. Taken together, the use of data from these studies tends to overestimate potential risks.

The Saginaw Bay mink feeding study has been used in many ERAs because it was one of the only studies that was available at the time of those assessments. Currently, however, there are other studies that have fewer co-contaminant issues.

> ***p. 6-1, Section 6.1.1.*** *There is an inconsistency in the logic and terminology in the 2nd complete paragraph. If it is to be assumed that HQ values less than unity indicate that* unacceptable risks *are unlikely, then it should be assumed if the HQ values are greater than unity that* unacceptable risks *are likely. Also, what can be deduced if the HQ value is exactly one?*

The logic used in the BERA work plan relative to the interpretation of HQ values is not inconsistent in that HQ values less than 1 indicate that the potential for unacceptable risk is not likely to occur. However, for HQ values greater than or equal to 1, the potential for unacceptable risk cannot be ruled out, and the magnitude of the effect on a particular receptor cannot be inferred based on the magnitude of the HQ. This is due to the fact that HQ values are not statistical probabilities of adverse effects but rather an indicator of the level of concern regarding the potential of unacceptable risks. EPA has clearly described some of the limitations of assessing HQ values (USEPA, 1998, p. 96): "*A number of limitations restrict application of the quotient method. While a quotient can be useful in answering whether risks are high or low, it may not be helpful to a risk manager who needs to make a decision requiring an incremental quantification of risks. For example, it is seldom useful to say that a risk mitigation approach will reduce a quotient value from 25 to 12, since this reduction cannot by itself be clearly interpreted in terms of effects on an assessment endpoint*." Additional information and discussion of the HQ concept has been added to the revised BERA work plan.

> ***p. 6-1, first bullet****. See my previous comment on "potential risk". If the dose exceeds the LOAEL and the LOAEL-based HQ is >1.0 it provides evidence of risk not "potential" risk.*

Have added the word "unacceptable" to the bullet.

> ***p. 6-2, bullet.*** *This is not completely correct. If the dose exceeds the NOAEL, but is less than the LOAEL, the risk manager must be included in the assessment of whether or not that level of risk is acceptable.*

We have edited the bullet as requested by the reviewer.

> ***p. 6-2, Uncertainty approaches****. Will the uncertainty evaluation include those uncertainties that could shift the risk estimates upward, or will it be confined to those that might reduce risk estimates?*

Additional information has been added to the uncertainty section that indicates the factors related to over- and underestimating risk will be examined and discussed in the BERA.

> ***QUAPP, p. 2-5****. Is the identification of clean-up criteria a goal of the BERA?*

No, the derivation of clean-up criteria is not a goal of the BERA. This has been corrected in the text.

> ***QUAPP, p. 3-9****. Typo in Table #.*

Typo has been corrected as requested.

> ***Study Plans. Exposure Pathway Analysis (p. C-4)****. The stated rationale for this study largely ignores the results of previous studies. We know that various species of predatory and forage fish have bioaccumulated PCDD/PCDFs. We know what their tissue residues are. We know that at least two species of duck have bioaccumulated PCDD/PCDFs, and that their eggs have high levels of contamination. Every ecosystem component that has been thus far investigated has proven to be contaminated to relatively high levels. It is disingenuous to describe the information that has been collected thus far as "limited".*

The study plans from MSU were included with the BERA work plan as supporting evidence for the type of data that will be collected for inclusion in the BERA. These are not ENTRIX work plans and as a result changes have not been made to these documents.

> ***p. D-13. Use of HSI models****. HSI models can provide useful approximate measures of habitat quality. However, their results can be over-interpreted: comparisons of two scores of (e.g.,) 0.8 and 0.4 may be legitimate, but a comparison of 0.8 and 0.6 may not be. Also, the main problem with most existing HSI models is that they have not been tested or calibrated in the field. Without this they are highly conjectural and probably not suitable for use in ERA. How will the HSI models to be used in this BERA be field-validated?*

The MSU study plans discuss the evaluation of habitat for the receptors of concern using standard habitat suitability index (HSI) models used by the USFWS. The mink HSI, in particular, has been field validated for the Midwest. The validity of the model and quality of the data will be evaluated for use in the BERA when the data become available from the field studies.