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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

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SUBJECT: U.S. EPA Questions/Clarifications on Draft V5 Executive Summary, undated, Peer Review Panel, Allied Paper/Portage Creek/Kalamazoo River Superfund Site, Michigan

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Line 216 "...a comprehensive conceptual model might include mink as one of the terrestrial receptors of concern. ...[Mink] in the winter may rely primarily on terrestrial animals. ...MSU studies have developed data on levels of PCBs in mink livers as an indication of exposure."

The Panel recommendation to utilize MSU mink exposure data (Millsap, et al. 2004) does not address the strengths, limitations or uncertainties of the study for providing inferences on mink exposure as a terrestrial receptor. A thorough peer review of the MSU mink studies is necessary for regulators to consider using the mink data.

For example, the highly skewed sex ratio, 9 KRAOC males with only 1 (Millsap, et al. 2004 text) or no (Millsap, et al. 2004 Table 2; and Beckett, et al. 2005 text) KRAOC females, is consistent with trapping of transient mink in KRAOC (males are known to range more widely than females). A higher proportion of females would be expected in a resident population. Is the skewed sex ratio a valid concern regarding the site-relatedness of the mink exposure data? Is this a constraint on using the data for drawing inferences on mink terrestrial exposures from the KRAOC?

The Millsap, et al. (2004) site-specific mink dietary composition is based on 7 mink, each of which had only one identifiable prey category in their gastrointestinal tract. The remaining 5 mink had no identifiable prey remains. The reported dietary composition of 72 % mammals, 14 % fish, and 14 % crayfish is therefore based on 5 mink with only fur remains, 1 mink with only scales, and 1 with only crayfish exoskeleton. Would the Panel comment on the appropriateness of combining the individual mink single-category prey remains together into an

overall prey composition, and the strengths, limitations, and uncertainties associated with the dietary data?

Millsap, et al. (2004) apparently did not identify prey fur remains to species or genus. Kay, et al. (2005) treat the mink mammalian prey remains as muskrat (see their Figure 3). What are the procedures recommended by the Panel and the uncertainties for allocating mink mammalian prey among aquatic and terrestrial mammals?

Mink were only trapped in the winter, so seasonal data on prey selection are unavailable. Contrary to the Panel's assertion that mink rely primarily on terrestrial animals in winter, some studies show increased utilization of fish in winter when fish may "become more available due to being less active in the lower water temperature" (cited studies in Halliwell and MacDonald 1996). Linscombe, et al. (1982) wrote "The responsiveness of mink to available prey results in a diet that is extremely variable by season and location." What are the implications of uncertainty over seasonal variations in mink dietary composition for evaluating mink risk to terrestrial prey?

If the Panel recommends including mink as one of the terrestrial receptors of concern, please review the strengths, limitations and uncertainties of the various effects measures reported by MSU (Millsap, et al. 2004; Beckett, et al. 2005). Note that the SOP included evaluation of mink sex ratio, but this measure was excluded from Millsap, et al. (2004) reportedly because of insufficient sample size (J. Giesy, pers. comm.).

The Beckett, et al. (2005) study was cited as indicating a lack of "any negative population level effects in mink" (Blankenship, et al. 2008). Please comment on the strengths, limitations, and uncertainties of the MSU mink studies for making population-level inferences.

Literature Cited

Beckett, K., S. Millsap, A. Blankenship, M. Zwiernik, J. Giesy, and S. Bursian. 2005. Squamous epithelial lesion of the mandibles and maxillae of wild mink (*Mustela vison*) naturally exposed to polychlorinated biphenyls. Environ Toxicol Chem 24: 674-677.

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Kay, D., A. Blankenship, K. Coady, A. Neigh, M. Zwiernik, S. Millsap, K. Strause, C. Park, P. Bradley, J. Newsted, P. Jones, and J. Giesy. 2005. Differential accumulation of polychlorinated biphenyl congeners in the aquatic food web at the Kalamazoo River Superfund Site, Michigan. Environ Sci Technol 39: 5964-5974.

Linscombe, G., N. Kinler, and R. Aulerich. 1982. Mink. *In*: Wild Mammals of North America: Biology, Management, and Economics. (Eds.: J. Chapman and G. Feldhamer). John Hopkins Univ. Press, Baltimore. pp. 629-643.

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Draft V5 Executive Summary

The Panel recognizes the considerable level of effort committed by the MSU team to gather site-specific information in support of assessing risks to terrestrial wildlife in the KRSS. The Panel concludes that most of these data do meet the scientific standards appropriate for incorporating into a weight-of-evidence approach to risk management, including the important addition of an area-specific risk assessment at Trowbridge.

The work by the MSU team provides useful data both for quantitative exposure estimates and for a qualitative, weight-of-evidence approach to estimating effects. The published papers provided to the Panel each contribute some data and information that could be used in a weight-of-evidence assessment of risks along with other data and approaches used in the BERA. However, there remain large uncertainties in the MSU data, issues with the MSU study design, and insufficient documentation (and lack of agreement) among TRV derivations. Consequently, the MSU studies are not adequate for use as stand-alone documentation for a quantitative risk analysis, as discussed further below. On the other hand, MSU has not yet taken full advantage of the data that they have developed, and there is the potential for additional analyses using these data that would enhance their contribution in a weight-of-evidence risk assessment.

The Panel identified the following as the primary strengths of the MSU field studies:

1. An important strength of the MSU studies is that they focused on directly measuring aspects of several endpoints of concern in the real-world environment, rather than primarily being based on literature-derived data. The field studies provide site-specific direct measurements of PCB concentrations in eggs and body burden concentrations of PCBs, thereby reducing some uncertainties inherent in the BERA approach of using primarily literature-based values. Also, measurements on the endpoints of concern provide investigators with the ability to extend the statistical and modeling analyses beyond those used by USEPA. In addition, the MSU data provide direct measurement of PCB concentrations in prey items and soil, plus the analysis of actual diets of receptors of choice from the field studies. The field-collected information incorporates soil-specific effects (e.g., soil carbon), congener-specific differences in accumulation rates, and species-specific information on diets related to the Trowbridge site. Each of these facets of the MSU studies can provide valuable input into the weight-of-evidence risk assessment and decision-making process.

2. MSU's congener-specific data are a major strength that allows the examination of congener patterns, total TEQs, and the contribution of individual congeners to total TEQs. This congener-specific approach reflects the current state-of-the-

science in this field and provides an important supplementary line of evidence for evaluating exposure even if Michigan regulations focus on total PCBs.

3. Studies of productivity of the bluebirds, wrens, and great horned owls potentially provide useful, qualitative evidence of reproductive performance of on-site species. The strength of these studies is that they are directly measuring one of the assessment endpoints ("do PCBs affect reproduction of birds?").

4. Data on concentrations of PCBs in shrews and soils provide the opportunity to develop spatially explicit shrew:soil bioaccumulation functions that can be applied to other former impoundments. This may further reduce the uncertainty associated with bioavailability of PCB congeners in soils.

The following items summarize the primary limitations of the MSU studies:

1. There is an absence of a comprehensive conceptual model identifying pathways of exposures and relating effects to endpoints of concern. The data analysis and risk assessment methods employed by MSU should be consistent with the underlying conceptual model. Unfortunately, without an explicit conceptual model, interpretation of the analytical results found in the MSU papers is difficult, if not compromised.

2. The nest productivity studies are limited by small samples sizes (which in some cases are insufficient to draw defensible conclusions), and there are issues with pseudo replication and other aspects of study design as well as the calculation and analysis of reproductive parameters.

3. Reliance on species for which aquatic organisms are a significant portion of the diet (specifically bluebirds, swallows, and owls) and lack of direct measurements of PCB concentrations in diets of robins (the most highly exposed avian species addressed in the BERA) limit the utility of these studies in assessing risks associated with terrestrial exposure pathways.

4. If the former impoundments will change to a more terrestrial environment over time, as anticipated, it will be important to consider the potential for changes from the current species assemblage. Therefore, while the species utilized in MSU give a picture of current selected receptors and exposures, these may be different from those that may be present in a few decades.

5. There is a failure to account for observational artifacts (such as time of nest initiation or failure) in the great horned owl study.

6. The MSU studies include confounding effects of habitat differences between the KRSS sites and the reference site (Fort Custer) and the situation in which the bluebird boxes have been on-site for years at Fort Custer but were newly erected at Trowbridge (box use is known to be significantly affected by familiarity of the birds with the placement of the boxes).

7. The MSU studies included averaging exposures over an entire impoundment area, rather than developing spatially explicit models of uptake and exposure. This is especially important for species whose foraging ranges are small relative to the scale of the impoundments. MSU did not develop probabilistic exposure distributions representing the relative variability in exposure over space. However, the Panel believes that such analyses may be possible with the MSU data.

8. The Panel believes that selection of the TRVs following a statistical approach that incorporates all available relevant toxicity data is a preferred approach, in part because that approach addresses issues of cross-species extrapolations. This is important both because the species of concern may be more sensitive than some tested species, and because the trophic structure of the ecosystems may change over time, resulting is different species of concern.

9. There are inadequate documentation and justification of the selected TRVs. The Panel strongly feels that because the selection of the TRV values is critical to determining the results of HQ-based risk assessments, there must be adequate documentation and justification of the data and the process used to derive the TRVs. If MSU is to base a TRV on a selected individual toxicity study instead of a statistical approach, then the rationale for selecting the particular study as the basis for the TRV and for rejecting other studies needs to be provided. This will avoid any *perception* that the assignment of the TRV used in Hazard Quotient calculations involved selective cherry-picking from available datasets. However, the particular TRV selected for shrews seems appropriate and representative of the available data. Thus, the point here is not that the TRV values used by MSU are necessarily incorrect, but, rather, that their derivations need further justification, and, since the selection of a TRV directly affects the results of the risk assessment, extra care needs to be placed on both the reality and the perception of an unbiased process.

10. The Panel noted several inconsistencies and incomplete explanations of methods in some of MSU's papers and Standard Operating Procedures.

11. There are conflicts between the statistical methods used by MSU and the methods prescribed in the Sampling and Analysis Plan and the Standard Operating Procedures provided to the Panel. For example, the SOPs outlined stratified random sampling. However, subjective selection of sampling sites was used in the field studies.

12. The MSU studies overuse or inappropriately use results of tests of null hypotheses to pool data sets and reach conclusions. There is a general lack of quantification of sources of uncertainty in exposure and effects metrics. This is essential information for a decision-maker to use in a weight-of-evidence-based approach.

13. The MSU studies failed to address plausible future scenarios of the environmental conditions at the former impoundment sites; examples include removal of the remnant dam structures, as planned by the State, the potential effects of climate change, and an understanding of habitat succession at the sites of concern. Such

changes could directly alter the trophic structure that determines exposure pathways and therefore risks.

14. The species studied (bluebirds, wrens, and owls) do not necessarily represent the most highly exposed or the most sensitive species present in the riparian corridor. Therefore, they are not adequate surrogates for addressing the question of risk to all avian species that may potentially use the site.

The following items summarize remaining uncertainties that should be resolved as the risk-management process on the KRSS moves forward. The data collected by MSU may help to reduce many of these uncertainties; however, none has been directly addressed in the published papers.

1. Uncertainty concerning the importance of the earthworm pathway — No worms were found in the diets of bluebirds and house wrens, and only a small number of earthworms were collected and analyzed by MSU. Some data were presented from shrew studies, but these have not been fully examined in the context of a comprehensive conceptual model of risk pathways. Hence, in spite of the critical importance of the earthworm-to-robin pathway shown in the BERA, understanding the risks associated with the earthworm pathway is still unresolved. Information is also needed on the locations of the earthworm samples relative to the soil samples used to derive BSAF values. These locations should also be compared to the range of soil values in the Trowbridge Impoundment.

2. Uncertainty concerning population-level effects — The nest productivity studies conducted by MSU address organism-level effects but do not support inferences concerning population-level effects of PCB exposures.

3. Uncertainty concerning assessment of passerine reproductive productivity — MSU's analysis of reproductive success would have been enhanced significantly by the use of standard methods (e.g., the Mayfield method) and an integrated measure of fledging rate based on the number of all nests initiated. MSU's analysis parsed reproductive success into various subcomponents and used only subsets of nests for some measures (e.g., the "predicted number of fledglings" used the smallest subset of nests, and "fledging success" ignored nests in which no eggs hatched). This approach potentially underestimated the cumulative effects of nest failure, embryonic mortality, and pre-fledgling mortality. For example, the Panel recalculated an overall measure of reproductive success by multiplying clutch sizes (# of eggs laid/initiated nest) by productivity (number of fledglings/egg laid), resulting in a 47% lower estimate of fledglings per nest initiated for bluebirds and 18% lower for house wrens at Trowbridge compared to the reference area. The full value of MSU's reproductive data is uncertain until a more thorough reanalysis is conducted along the lines noted above.

4. Uncertainty concerning extrapolation to other species — The species chosen for study by MSU were selected based on amenability to study and are not necessarily representative of typical species utilizing the site or of the most highly exposed or the most sensitive species. In particular, there is still substantial uncertainty concerning risks to ground-feeding birds such as robins and woodcocks.

5. Uncertainty concerning extrapolation to other sites — Types of habitats and plant communities found in the former impoundments appear similar, but the impoundments differ with respect to the relative size and spatial distribution of habitat types. Detailed comparisons of within-species differences in diets of bluebirds and house wrens foraging in Trowbridge vs. Fort Custer could be used to bound the possible range of diet variation among the other impoundments. The habitat characteristics of the Fort Custer site differs so much from the former impoundment sites that its utility as a reference site is quite limited.

6. Uncertainty concerning extrapolation to future conditions — Key habitat characteristics in all of the former impoundments can be expected to change over time from several plausible causes, including normal ecological succession, climate change, and a State-planned removal of remnant dam structures at Trowbridge, which will likely change the hydrological regime of the site and result in a significantly altered set of exposure pathways. It may be possible to use the data from the MSU diet studies, together with predictions of future habitat conditions, to predict future diets and exposure levels.

The following items summarize the Panel's recommendations for using the results of the MSU studies in future risk assessment and risk management activities on the KRSS.

1. As an initial point-of-departure, it would be informative to perform a cross-comparison between MSU and BERA studies, by using the MSU data and assumptions as inputs to the BERA models and the BERA data and assumptions as inputs to the MSU models; an example of this is included in the Panel's report, in which BERA and MSU exposures and TRV values are interchanged. Such comparisons may illustrate the magnitude of differences resulting from the two approaches and provide insights into the causes of the differences. Such a comparison would inform risk managers concerning validity and defensibility of each set of analyses.

2. A more systematic approach to using the available data from both MSU and BERA is recommended. Suggested activities include the following: (1) evaluation of the ability to pool the MSU and BERA data into a unified data set; (2)

evaluation of the methods used to quantify the magnitude of PCB concentrations generated by each study (e.g., are the analytical chemistry results consistent among studies?); (3) calculation of uncertainty in the BERA results based on the extended data generated by MSU; (4) re-evaluation of the statistical results using alternative statistical estimates of the "most likely" value; (5) comparison of BERA and MSU results using formal uncertainty analysis methods; (6) evaluation of the effect of temporal variability on the MSU and BERA findings; (7) comparison of the BERA findings to model-based findings that could be generated using the MSU data (see Appendix A); (8) evaluation of the findings in light of the conceptual model employed by each study; and (9) evaluation of the BERA findings in light of the quantifiable relationships between PCB source concentrations and PCB egg and body burden concentrations that may be obtainable with the MSU data (note: these analyses were not implemented by MSU, but the MSU data set suggests that such analyses may be possible).

3. Use the MSU data in area-specific risk assessments — Given knowledge of differences in habitat characteristics among impoundments, the MSU studies could provide data that could be used to develop area-specific conceptual models and exposure assessments.

4. Recognize the reality of floodplain dynamics and lack of independence of aquatic and terrestrial exposure routes — By demonstrating the significant linkages between aquatic and terrestrial food chains, the MSU studies may show that remedial actions to reduce exposures to aquatic biota would also reduce exposures to "terrestrial" avian species that feed at least in part on emergent aquatic insects.

5. Develop a more comprehensive conceptual model of the pathways of exposures to the various endpoints of concern. For instance, a comprehensive conceptual model might include the mink as one of the terrestrial receptors of concern. This species feeds on both aquatic and terrestrial animals and in the winter may rely primarily on terrestrial animals. It is known to be sensitive to the effects of PCBs and MSU studies have developed data on levels of PCBs in mink livers as an indication of exposure. Other opportunities presented by a comprehensive conceptual model include more clearly addressing the critical risk pathway identified by the BERA (via earthworms) and more clearly addressing the ecological risks in an altered future environment.

6. Perform quantitative uncertainty and sensitivity analyses on all models that utilize the MSU data, so that decision-makers are more fully informed about uncertainties inherent in these models and their parameterizations.