ECOLOGICAL RISK ASSESSMENT for the
REST OF THE HOUSATONIC RIVER
By the EPA

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February 16, 2004

I. INTRODUCTORY REMARKS:

I appreciate the opportunity to participate in the peer review of the Ecological Risk Assessment (ERA) for the Rest of the Housatonic River conducted by the Environmental Protection Agency (EPA). The experience has been challenging, interesting, and instructive. As a behavioral endocrinologist and an avian biologist, I have learned a tremendous amount about field evaluation of risk from PCBs. Much of my work has been devoted to avian species, and in assessing the consequences of embryonic and life time exposure to endocrine disrupting chemicals (EDCs). These studies have focused on establishing reliable indices of EDC exposure and have addressed questions of species and age-related sensitivity to the chemicals. In addition, the research by colleagues at Patuxent Wildlife Research Center and many other laboratories have provided a growing body of research on the consequences of EDC exposure in birds and on the basic biology of birds. We now understand many of the mechanisms that regulate reproductive endocrine and behavioral responses in both laboratory models and in wild birds, specifically those that are likely to be impacted by EDCs. It is from these vantage points that I have read the information provided and formulated responses to the charge questions, with a focus on the relevance of measurements for assessment of long-term consequences for field populations.

Our charge was to review the EPA's ERA in terms of EPA policy and guidance; protocols used in the risk assessment, interpretation of findings from the studies, and the ERA conclusions. The ERA ocuses on the portion of the river from the confluence of the river, 2 miles below the GE facility to Woods Pond dam and associated floodplain, and is termed the Primary Study Area (PSA). A great deal of information was provided to the Panel, which reflects a considerable body of work and a great deal of effort by many professionals over a number of years. My responses are based on these written documents and on the information that was provided to us at the two meetings and tour of the site at Pittsfield, Massachusetts in October and December 2003. Those meetings were extremely helpful in providing information about the site from a chronological aspect as well as to see how the site appears today, including areas undergoing active remediation. I found the second meeting helpful in that the scope of numerous studies were placed in context for the panel. Both the EPA and GE teams are to be complemented for their extensive work on this project and the EPA team in collaboration with the GE team did an excellent job of ordering the material for us in a logical manner.

Several points deserve further attention. This is clearly an extremely complex site, with relevance for the ecosystem including the human impact. As such, the ERA includes multifaceted assessment endpoints and summarizes the risks based on the "weight of evidence". This approach, while appropriate, tends to oversimplify the consequences of the long-term PCB exposure by virtue of repeated data reduction, even though the models take into account the probabilities and uncertainties. Some of my comments are directed at potential error in conclusions due to the need to summarize the findings to the point that salient data become overwhelmed. Although appropriate in the "weight of evidence" approach, my concern is that the risk to selected groups of wildlife is underestimated or minimized. Detailed comments are provided below in response to the questions provided in the Charge to the Panel.

II. RESPONSES TO THE QUESTIONS IN THE PANEL'S CHARGE

1) **Question 1. Was the ecosystem of the Housatonic River watershed properly characterized, and was this information appropriately applied in the Problem Formulation and subsequently in the ERA?**

***General Comments*:**

The Pre-ERA provided an appropriate characterization of the ecosystem of the Housatonic River watershed. The surveys of wildlife, benthic and aquatic communities, and overview of the habitats provided a thorough review of the constituents of the ecosystem and the elements of the ecosystem that warranted further assessment. The characterization included data collected most intensively over the last 10 years, with some information available from earlier studies. Unfortunately, there appear to be few historical data available on species richness in the region at the time of early stages of contamination by chemicals of concern (COCs). Therefore the pre-ERA assessment and species surveys represent populations that potentially have already been impacted by the COCs. This is relevant when considering reference areas, especially in the case of wildlife that may move within the region over successive generations from an area relatively unaffected by the COCs to the primary study area (PSA) or vice versa. In light of the available surveys and information, the problem formulation was logically constructed and focused on the relevant classes of organisms. In the case of avian species, several have been considered as representative species in the categories of insectivorous birds, piscivorous birds, and threatened and endangered species. However, the choice of the representative avian species did not include ground dwelling species, such as turkeys, quail, or pheasants, which would receive exposure through seeds and sediment. Moreover, turkey eggs and mallard ducks, which were collected opportunistically, had measurable tPCBs, indicating exposure of these species. Similarly, the woodcock takes in approximately 10% (dry weight of intake) sediment in its diet (Rattner et al., Handbook of Ecotoxicology, p. 157; 2003). Although known to occur in the PSA, the woodcock was not selected as a representative species because it is too secretive and therefore difficult to study. This is reasonable, but the choice of the kingfisher as a representative species and the continuation of the study when difficulties arose becomes questionable. Therefore, it is not clear that the choice of representative wildlife species was appropriate in all cases.

Specific Comments (references to the ERA documents are included in some sections):

[1.ES-4] The ERA focus is on "the river from the confluence, 2 miles below the GE facility to Woods Pond Dam; the pond is the first impoundment downstream, with a depositional environment". Ecological characterization was conducted in detail and some of the GE studies are incorporated. It is not clear if these earlier characterizations were thorough. The inventory conducted as part of the ecological characterization included reference areas. A mention was made of relatively high calcium levels in the Housatonic River, which was not the case in many of the reference areas. Therefore, reference areas have additional variables that would potentially confound comparisons.

[1.ES-12] Risk characterization includes site-specific studies, result analysis, conclusions, and Weight of Evidence (WOE), with consideration of uncertainties for the endpoint and risk to receptors (outside representative species) and risk to downstream receptors. This is an appropriate and logical sequence. Playback data yielded assurance that the species were present, but these were not necessarily the species that were examined as part of the ERA. Further, there was little opportunity for following up on the surveys to ascertain the species diversity over several years and the historical data are not complete relative to species surveys. Therefore, the characterization included a record of species observed and their habitat, but were insufficient for assessing populations and consequently for assessing impact to populations.

[I. B6] Clarify the description of soil background levels ("not detected at a sample quantitation limit of less than 0.5mg/kg or detected at a concentration of less than 0.3 mg/kg). As stated in later in the document, it appears that measurements below assay sensitivity are assigned ½ the level between zero and the sensitivity limit. If this is correct, then please clarify in this section.

[B16-Soil Preliminary Remediation Goals (PRG)] Lowest observed adverse effect level (LOAEL) from Sample et al., 1996 for soil was based on the woodcock and the shrew; however the woodcock was not evaluated in the ERA. The rationale given was that the woodcock is secretive and not easy to find. Conversely, several avian species that were used for modeling also were not found in the PSA and the kingfisher that was studied occurred in such low numbers that there was low confidence in the results of the study.

[B18] No observed adverse effect level (NOAEL) was determined from "effects of potential "ecological significance" evaluated (e.g., lethality and reproductive effects)". As will be discussed below, these endpoints are not necessarily sensitive to the COCs in some of the representative species. In addition, aside from embryos and prepubescent animals, there was little consideration of age-related or seasonal effects in the ERA as they impact some species.

[B25] Tier III elimination of PAHs and pesticides was based on the presence of these compounds in fish tissue or on likelihood of metabolism in fish. This eliminates consideration of these compounds for other species and may be a confounding factor due to mixture effects.

[Attachment B.2] Reanalysis of pesticides in fish tissue (only) resulted in lowered baseline risk assessment. How does this impact wildlife and what are the implications for the validity of the measurements?

2) **Question 2. Was the screening of contaminants of potential concern (COPCs), selection of assessment and measurement endpoints, and the study designs for these endpoints appropriate under the evaluation criteria?**

General Comments:

The screening and identification of COPCs and subsequent contaminants of concern (COCs) was thorough and considered a range of possible contaminants. The elimination of some COPCs is rationalized, although not completely convincing in the case of some pesticides, which may occur in a patchy distribution, especially along areas of the river in proximity of agricultural activities. Moreover, relatively small concentrations of some pesticides are known to interact with PCBs and/or with other contaminants, thereby confounding the biological responses observed and potentially obscuring some of the interpretations. For example, lack of consideration of these COPCS at some regions downstream or even in the reference sites (which had low level total PCBs (tPCBs) may result in a masking of the responses, ultimately diminishing the magnitude of difference in a measurement endpoint for the animals in the PSA.

The selection of assessment and measurement endpoints are of concern because most measures are relatively insensitive. Detection of significant differences in these endpoints, primarily mortality and reduced reproduction, with monitoring of survival of young in selected species, will be significant when the indigenous population may be in jeopardy in that region. Biologically relevant measurement endpoints that are responsive to established actions of the constituent PCBs, such as thyroid hormone in some cases, neurochemicals, or behavior would have provided sensitive and reliable indices of exposure and impact that would precede catastrophic impact to a population. The study designs appeared to be limited by the realities of fieldwork. For example, there were only 9 kingfisher nests identified and 3 of these nests were depredated, leaving a very low sample size and questionable reference data. Similarly, the osprey was known to inhabit the PSA, but no field studies were conducted; the ERA rests on models built from information in the literature. This is a reasonable approach, given the lack of field data in the ospreys on the primary study site (PSA), and the models for risk assessment did consider considers data on measured levels of tPCBs in prey species found in the PSA. However, data collected in some additional avian species would have provided a more complete assessment with less uncertainty. Moreover, the field studies in birds would be much stronger if there had been some simply designed laboratory studies to test the impact of the tPCBs known to occur in the PSA. These studies could have been one-generation reproduction tests (refer to OECD avian toxicity test) or egg injection studies in representative species, such as quail or mallard eggs (not chicken as this species is known to be highly sensitive to PCBs) in which known concentrations of tPCBs are administered and then teratological consequences or other selected end points are monitored (see papers by Dave Hoffman for further detail). These types of studies would have clarified the extent of potential consequences due to COCs exposure at selected stages of development and would have verified the conclusions of the field work in the tree swallows within the context of potential sensitivities of ground dwelling birds or other passerines.

Specific Comments [C 6.7-C8.3.25]:

There appear to be some qualitative difficulties with meeting the criteria for the wildlife selected for study possibly due to the availability of representative species. Does this mean that there are insufficient data to meet the requirements of the weight of evidence (WOE) approach? Please rationalize the selection of each wildlife species and ascertain which of the criteria for the ERA have been met to satisfy the WOE approach (see additional specific comments below). Further, the PSA and the downstream regions appear to be regarded very separately due to the decreasing levels of COCs. This is appropriate because the risk of exposure decreases, but it does not completely eliminate risk, which seems to be the general attitude, especially when considering the issues within the ERA. Therefore, it would be appropriate to have more detailed discussion about appropriate actions, if needed for selected areas downriver (below the ERA) in order to balance potential risk (with runoff or unusual rain events that cause dam opening or other such responses) with the generally low probability of contact with COCs.

Presumably the attribute-scaling factor would be low if the data were collected during one season only (and not during breeding season). Specifically, small mammals were collected in Aug-Sept 1999, mallard and wood duck samples were collected in Aug-Sept 1998, tree swallows were the exception in that they were collected in May-June 1998, 1999, 2000; others including 5 house wrens and 3 chickadees were opportunistically collected in May -June 1999. As a consequence, how was the specific wildlife data scaled and did the lack of multiple years of data for a species result in an underestimation of the attribute scaling? How were the data from the wood ducks used in the assessment?

C7.8, line 24-25 what was different about the bird samples?
C.8.3.20 Do any of these sites represent reference sites used in the subsequent studies? How many nest boxes were installed at each site? What happened to the 1998 samples?

A comprehensive pre-ERA characterization was conducted including an overview of the habitat and species within these habitats. However, in the body of the ERA, little mention is made to this information relative to the selection of representative species for the ERA, except at the end of the report in which there is a general listing of potential effects to other species. The ERA would be strengthened with a discussion of a listing of the species observed in the survey, including estimated population numbers. In the case of field data collected as part of the ERA, information about the sex ratio of the small mammals collected in the traps in both years, with the species density and distribution would also be helpful. These additional considerations will strengthen the logic and support the process used to ultimately identify the representative species and corroborate the conclusions of the ERA. Finally, figures that integrate sediment concentrations, sites of exposure, and species observed at those sites would clearly show the potential relationships of these elements of the ERA.

3) Charge Question 3. For each of the 8 assessment endpoints evaluated in the ERA, address the following questions: (discuss and label responses as 3. (assessment endpoint number).(question letter) for consistency).

General Comments:

The process for the ERA included identification of representative species, conduct of exposure assessments, effects assessments, and risk characterization. This sequence is clearly

laid out in the Executive Summary; however, it is sometimes difficult to follow the flow in the body of the ERA. For example, the field surveys are intermixed with the laboratory studies in the amphibian or benthic invertebrate community sections. As such, it becomes difficult to follow the logical sequence, through to the WOE. The presentation made by the EPA, including the GE data, served to integrate the flow of these field and lab studies much more logically and was more convincing in reaching a reasonable WOE conclusion. The flow charts used are excellent and clarify the approach (ex. I.5-7; Figure 5.1-4). As discussed below, the survey demonstrate that amphibians provide an excellent potential index of exposure by considering species density and populations; unfortunately there is a lack of detailed data from more than one species of frog.

The studies on fish are the most complete and include both field and laboratory studies. In addition, the sentinel species are representative of bottom feeders, and water column dwellers, selected to include varied habitats within the ecosystem. This is appropriate due to the primary contamination of the aquatic environment; thereby making aquatic species potentially subjected to higher and more sustained exposure, especially the benthic bottom feeders. Predatory species also would be expected to receive higher exposure due to biomagnification and bioaccumulation.

Studies in insectivorous birds should have included other representative species. For example, samples, such as turkey or duck eggs were opportunistically collected, but the results were not utilized in the ERA, even from the standpoint of some additional information. In wildlife, as in other categories, assessment endpoints are limited by field constraints. Consideration of impact on wildlife is primarily determined in field studies (with the exception of the mink study), or construction of models based on available literature. It would have been valuable to have additional studies on captive wild species taken from the PSA or a mallard duck study conducted using materials from the PSA, similar to the mink study. In the case of the osprey, the model is entirely based on the literature.

3.1 Survival, growth, reproduction, and structure of the benthic invertebrate community.
(3.1.a) *Were the EPA studies and analyses performed (e.g., field studies, site-specific toxicity studies, comparison of exposure and effects) appropriate under the evaluation criteria, and based on accepted scientific practices?*

Overall, the EPA studies were appropriate, with the following comments. Sediment grain size and habitat sediment characteristics contain inherent bias, which may affect conclusions. WOE concluded intermediate to high risk, which decreases with distance from source; this conclusion depends on no further movement of sediment into the flow of the river with exposure of downstream populations. The variables in the system, including sediment grain size and resultant variation in the distribution of contaminants of concern (COCs) increase the uncertainties in the interpretation of the data and make assessments less reliable.

(3.1.b) *Were the GE studies and analyses performed outside of the framework of the ERA and EPA review (e.g., field studies) appropriate under the evaluation criteria, based on accepted scientific practices, and incorporated appropriately in the ERA?*

There were a number of studies conducted by GE over the course of the pre-ERA and ERA. These studies have been included in the ERA, along with discussion of analyses and

uncertainties, reanalyses in some cases, and inclusion of the data when appropriate. However, there were no GE studies conducted for this receptor.

(3.1.c) *Were the estimates of exposure appropriate under the evaluation criteria, and was the refinement of analyses for the contaminants of concern (COCs) for each assessment appropriate?*

The assessments appear to be appropriate. However, organochlorine pesticides were eliminated from the ERA due to apparent contradictions in the laboratory analyses leading to reducing the estimates (reference to laboratory interference may be found in Volume 2. 6.2). This means that impacts due to effects of mixtures were not considered, even with potential spotty exposure as discussed below.

The estimates of exposure were based on a measurements of samples collected in surveys of aquatic, sediment, and soil samples, assessing the results of these analyses, and then refining the longer list to COCs based on levels and persistence of chemicals (i.e., likely to result in impact to indigenous organisms). This is a reasonable approach that meets EPA criteria. The only uncertainty remaining is that in most cases, pesticides and other contaminants are generally not considered. Therefore, areas of the PSA that include or border agricultural fields or golf course are likely to contribute pesticide load to the aquatic environment; especially during runoff events, which were not considered in the models. The patchy nature of this type of exposure also leads to uncertainty and is in the realm of factors that are present, but hopefully do not result in substantial impact upon the wildlife in the ecosystem.

In the case of many of the models, the relationship between TEF, TEQ, and LD50 data from the literature are not implicitly obvious. This is due, in part to the complexity of the data and consequently the necessary sophistication of the models used to estimate risk. However, as pointed out above, there needs to be a clear summary linking the chemicals to the species, their sensitivity, and the resulting potential risk in areas of the PSA and downstream. This would facilitate decision-making regarding future action. For example, understanding the association of data shown in Figures 7.4-1, 7.4-2 and linking these data to interpretations from the field studies are somewhat difficult and confusing.

(3.1.d) *Were the effects metrics that were identified and used appropriate under the evaluation criteria?*

The effects metrics were a compilation based on the surveys and data collected as part of the pre-ERA and ERA. Relatively traditional wildlife assessment endpoints were used, including survival and reproductive measures. These data are valuable, but not always sensitive indices of exposure. In the case of measures of the benthic invertebrate community, the metrics appeared appropriate, overall. One study observed that survival was impaired in one species (*Chironomus*) tested in 4 locations. Due to the varied conditions, sediment composition, and changing aquatic conditions, effects metrics for the benthic invertebrate community are complex. Given the complexity of this class of receptor, more conservative MATCs are appropriate.

(3.1.e) *Were the statistical techniques used clearly described, appropriate, and properly applied for the objectives of the analysis?*

The statistical techniques appear adequate, however there are a multitude of questions regarding the appropriate statistics, given the data collection methods and the necessity to integrate in the grain size and other variables that are inherent in the river system. As such, the statistical analyses should consider spatial and species characteristics in a multivariate approach. The resulting models should be discussed relative to these variables, both in the PSA and downstream.

(3.1.f) *Was the characterization of risk supported by the available information, and was the characterization appropriate under the evaluation criteria?*

The information from the models was used in a WOE approach to estimate and characterize risk. This approach was reasonable, especially considering the complexity of the ERA. There are numerous uncertainties, which have been discussed above. The approach of using the threshold for COCs derived from available literature using most sensitive and most tolerant species to develop a threshold range [see 2.6-25] should yield a conservative estimate of risk. The conclusion of high impact to populations and declining risk with distance from PSA appears appropriate. The inherent uncertainties must be considered for future decision making relative to remediation activities.

(3.1.g) Were the significant uncertainties in the analysis of the assessment endpoints identified and adequately addressed? If not, summarize what improvements could be made.

Yes, there were significant uncertainties based on sediment differences and consequential species variation. With reanalysis of the data as discussed above, this will remove some of the uncertainties and allow more straight forward interpretations.

There was a detailed discussion of uncertainties with each category within the ERA. These discussions were well done and thorough. As such, they emphasize many of the same issues that have been highlighted in my comments to this point.

(3.1.h) *Was the weight of evidence analysis appropriate under the evaluation criteria? If not, how could it be improved?*

General Comments: The WOE is an excellent approach and very necessary in a large, complex study such as the Housatonic Rest of River ERA in which a final overall assessment must be achieved. However, in the process of arriving at the final ERA, some pertinent information is overlooked in the rush to find a single answer. This process oversimplifies a complex and dynamic situation.

This WOE is reasonable based on the data, but limited by items discussed above. Reanalysis may alter the WOE somewhat. In any event the process used to reach the WOE must be made more transparent, including more subjective professional judgments in the process.

(3.1.i) *Were the risk estimates objectively and appropriately derived for reaches of the river where site-specific studies were not conducted?*

General Comments: Studies were conducted to estimate the impact of tPCBs below PSA to 128 miles downstream (using specific endpoints and measures) [Section I.2-5]. Surveys of tPCBs indicate that there is potential for exposure risk downstream, which diminishes outside

the limits of the PSA. This suggests that the potential for exposure is relatively low. As discussed below, it may be important to consider effects from mixtures of compounds and their interactions with the low level tPCBs in these regions of the river. The distribution of low levels of tPCBs is likely to be patchy, as the contaminants may be trapped in contaminated sediment.

These risk estimates are in line with the selected measurements of sediment and based on the samples collected considering the distance from the PSA. Conversely, if there is more agricultural activity in these areas, mixed exposure to PCBs and to pesticides may complicate the level of risk to the benthic invertebrate community. There is also uncertainty due to the variation in sediment across the habitats, with movement downstream.

(3.1.j) *In the Panel members' opinion, based upon the information provided in the ERA, does the evaluation support the conclusions regarding risk to local populations of ecological receptors?*

General Comments: Based on the information provided in the ERA, the conclusions about risk for representative species are premature and require some additional information. This is due to the potential underestimated risk associated with the local sediment environments and particle size of the sediment that would result in varying concentrations of tPCBs.

3.2 Reproductive success, development, maturation, and condition of the amphibian community.

(3.2.a) *Were the EPA studies and analyses performed (e.g., field studies, site-specific toxicity studies, comparison of exposure and effects) appropriate under the evaluation criteria, and based on accepted scientific practices?*

There were several studies, both in the field and in the lab. In total, these studies provide useful information for the ERA and lead to reasonable risk assessments for these populations. However, there are flaws and limitations in many of the studies, which make them difficult to interpret and somewhat confusing. The leopard frog study is limited by small sample size and by lack of reference site animals. This results in heavier reliance on evidence from the wood frog. The wood frog appears to be an appropriate species because of its use of vernal pools containing sediment; however the time of PCB exposure is limited to larval stages; therefore the studies were conducted [I.4-15 (Figure 4.2-3] to assess the COC impact on eggs in the vernal pools. The amphibian community study supports the impact of tPCBs on species richness, with wood frog larval stages most impacted. Finally, if there was a high rate of deformities in the tadpoles, these individuals would not be likely to show up in the adult population, thereby underestimating the rate of deformities (DELTs). In line with this comment, there were no observations on failed metamorphosis, which would indicate thyroid system abnormalities, potentially due to the PCBs.

(3.2.b) *Were the GE studies and analyses performed outside of the framework of the ERA and EPA review (e.g., field studies) appropriate under the evaluation criteria, based on accepted scientific practices, and incorporated appropriately in the ERA?*

The survey of leopard frog eggs was limited by selection of appropriate sites and lack of reference sites. The number of sites associated with the 4 ranges of tPCBs was small and led to

conclusions of no differences associated with level of contamination. More study would be needed in order to definitively make this conclusion based on the other data collected in amphibians in the PSA. The wood frog field study Resetarits (2002) was well designed, but had an additional variable of density, which was exacerbated by predation in all the sites. Differential density pressures among replicates add to the variability and make the data more difficult to interpret. In addition, this study was not included in the assessment because exposure did not occur during the late larval stage (most sensitive stage); moreover, little effect was attributed to maternal transfer. The study is difficult to interpret or even analyze due to the lack of reference sites.

(3.2.c) *Were the estimates of exposure appropriate under the evaluation criteria, and was the refinement of analyses for the contaminants of concern (COCs) for each assessment appropriate?*

The amphibian community assessment endpoint relies primarily on field data from the wood frog and leopard frog with additional studies. Accordingly, it would have been valuable to have data on species richness in various portion of the PSA beyond the initial survey to relate to the findings from these studies. The leopard frog is a good model in terms of more potential contact with the COCs. However, several questions/issues should be addressed to minimize uncertainties in these data. 1) Were the number or species surveyed at various sites sufficient to assess differences at the PSC? 2) Were there appropriate reference sites in the field surveys and for field samples? The laboratory tests used appropriate measurement endpoints for ascertaining PCB impact in the wood frog. However, the sperm abnormalities data were not statistically analyzed due to a small n. 3) There is an assumption that the histological evidence indicates that the adults would be sterile; however there was no attempt to assess these animals as adults and no endocrine parameters were measured to determine if these animals were affected. Therefore, this is not a legitimate assumption even if it appears to be correct direction! In total, the risk characterization not obvious based on the data. 4) If salamanders may be at greater risk, why were they not studied, even in a laboratory study? 6) Lack of a reference area control presents some uncertainty, but is the best option in the situation that occurred. 7) As in the birds, the identification of the PCB congeners should point to some specific endpoints that may be more sensitive measures of exposure and would complement other data collected in the reproductive laboratory study. 8) Finally, mixtures of chemicals are of concern for the amphibians, especially those whose habitat is in the proximity of agricultural activity.

(3.2.d) *Were the effects metrics that were identified and used appropriate under the evaluation criteria?*

The wood frog studies would have been more complete if thyroid hormones had been analyzed as a specific responsive hormone to PCBs. Also, the number of tadpoles that did not metamorphose properly or were abnormally metamorphosed would have provided additional information. If possible, the laboratory studies would have been stronger if a dose-response relationship had been examined, especially relative to selected measurement end points that are reliable indices of PCB exposure in amphibians.

(3.1.e) *Were the statistical techniques used clearly described, appropriate, and properly applied for the objectives of the analysis?*

The information from the analytical techniques should be considered in the overall analyses in that there would be implications in potential underestimation of the MATCs. Further, the life history of each species examined needs to be integrated into the models developed. For example, the wood frog has a relatively short time of potential exposure in the vernal pools; therefore, using data from this species in the field may result in a model that underestimates the risk to other amphibian species. Finally, the specific analysis used in each study requires clarification, especially as the results are then integrated into the WOE.

(3.2.f) *Was the characterization of risk supported by the available information, and was the characterization appropriate under the evaluation criteria?*

The risk characterization is supported by wood frog data and by data from the surveys, but action to address the experimental flaws and subsequent reanalyses are needed.

(3.2.g) *Were the significant uncertainties in the analysis of the assessment endpoints identified and adequately addressed? If not, summarize what improvements could be made.*

Yes, there were significant uncertainties in some additional targeted endpoints, such as thyroid hormones in the Northern Leopard Frog study might correlate with the observed delay in larval development as well as low incidence of metamorphosis. Measurement of thyroid hormones would be an important measure as well as histological analysis of the delayed individuals to determine if the thyroid was abnormal.

(3.2.h) *Was the weight of evidence analysis appropriate under the evaluation criteria? If not, how could it be improved?*

The WOE appears to be appropriate and studies were thorough. Some difficulties arose from the following: there were relatively few animals found in the initial survey [I. 4-21], whereas in the EPA survey, there were differences in species richness in number of wood frogs and in species of salamanders (I.4-64; Figure E.2-1). Reference site and purchased controls (none available from the reference sites) potentially confound the interpretation. Leopard frog data were difficult to interpret because of low fertilization success in the field collected females. Elevated sperm abnormalities in males [I. 4-36] may be an important COC indicator for these species.

(3.2.i) *Were the risk estimates objectively and appropriately derived for reaches of the river where site-specific studies were not conducted?*

The risk estimates are based on the GE survey in 2003 and on the Leopard frog egg mass numbers in the PSA, which did not relate to tPCBs. Based on the EPA species richness data and on the effects data, the impact of PCBs decreases at lower soil concentrations and are of concern in areas retaining high soil PCB levels.

(3.2.j) *In the Panel members' opinion, based upon the information provided in the ERA, does the evaluation support the conclusions regarding risk to local populations of ecological receptors?*

The data support the conclusions in spite of some shortcomings in the data set.

3.3 Survival, growth and reproduction of fish.

(3.3.a) *Were the EPA studies and analyses performed (e.g., field studies, site-specific toxicity studies, comparison of exposure and effects) appropriate under the evaluation criteria, and based on accepted scientific practices?*

As with other wildlife species, some species of fish move within the PSA and may receive varying exposure to contaminants. Therefore, the identification of classes of fish and the selection of representative species within each is an excellent approach. The Phase I Largemouth bass study showed a number of endocrine and histological end points relevant for reproductive impact, including reduced steroid hormones and gonadal abnormalities. These are reliable and appropriate measurement endpoints for reproduction; however these data are not provided in the tables or figures. The field studies (EPA and GE) assessed species abundance, density, and largemouth bass reproduction and population, respectively.

(3.3.b) *Were the GE studies and analyses performed outside of the framework of the ERA and EPA review (e.g., field studies) appropriate under the evaluation criteria, based on accepted scientific practices, and incorporated appropriately in the ERA?*

The GE study in bass did not relate contaminant concentration to response. It is interesting that the adults were generally older. This may only be a sign of year to year differences in the hatching and survival of young of the year (YOY) or it may reflect survivorship of a subpopulation that are more resistant to the COCs. Because PCBs have been in the environment for a long time and bass are long-lived fish, it is likely that the older adults are survivors of the environmental challenge.

(3.3.c) *Were the estimates of exposure appropriate under the evaluation criteria, and was the refinement of analyses for the contaminants of concern (COCs) for each assessment appropriate?*

The field survey includes a number of species and residue analysis of appropriate n of animals. Gut contents were not analyzed, so the foraging area is assumed according to the species. There appears to be sufficient data to estimate the COCs in the fish. As mentioned above, the bass in the population were older individuals, suggesting lower sensitivity of these individuals and potentially different metabolic characteristics associated with the liver enzymes and oxidative metabolic processes.

(3.3.d) *Were the effects metrics that were identified and used appropriate under the evaluation criteria?*

Basic reproductive end points were measured, including eggs and nests. These are not necessarily the most reliable or sensitive measures. In addition, measures of health, including morphological abnormalities should be incorporated into the assessment even though individuals survive with these deformities.

(3.3.e) *Were the statistical techniques used clearly described, appropriate, and properly applied for the objectives of the analysis?*

Representative models, including the range of species and habitats should bracket the sensitivities and exposure scenarios. As such, the models reflect the variety of species and range of habitats. The models should also consider differences in body lipid, which will influence the

PCB body burden. More detail is needed to clearly explain the analyses in relation to the range of species and environments that they prefer.

(3.3.f) *Was the characterization of risk supported by the available information, and was the characterization appropriate under the evaluation criteria?*

The risk conclusions are supported by data collected and models generated. Reanalysis of the data may result in some increase in risk.

(3.3.g) *Were the significant uncertainties in the analysis of the assessment endpoints identified and adequately addressed? If not, summarize what improvements could be made.*

There were a number of uncertainties, especially associated with the habitat variation. The assumptions appear justified. Additional sampling and data collection may be warranted to address some of these uncertainties and to link data in the lab to observations in the field.

(3.3.h) *Was the weight of evidence analysis appropriate under the evaluation criteria? If not, how could it be improved?*

The WOE is appropriate given the data, interpretations, and models. Reanalysis may change the conclusions, especially for warm water species.

(3.3.i) *Were the risk estimates objectively and appropriately derived for reaches of the river where site-specific studies were not conducted?*

The risk estimates are based on sediment content and on some samples taken from selected sites. As with the benthic invertebrates and the amphibians, there are going to be areas of potential higher exposure, which are not an issue unless the individual encounters those areas. Therefore, the risk decreases downstream, but there remain areas of concern for exposure.

(3.3.j) *In the Panel members' opinion, based upon the information provided in the ERA, does the evaluation support the conclusions regarding risk to local populations of ecological receptors?*

Yes, with consideration of some of the points made in the earlier discussion.

3.4 Survival, growth, and reproduction of insectivorous birds.

(3.4.a) *Were the EPA studies and analyses performed (e.g., field studies, site-specific toxicity studies, comparison of exposure and effects) appropriate under the evaluation criteria, and based on accepted scientific practices?*

The tree swallow study was done carefully and well designed. Sites of nest boxes and reference sites appear reasonable; however the mean accumulation of tPCBs in tissue residues at the Taconic Valley site was 137 mg/kg [ref G-23], which suggests that these birds may have been affected and not true reference animals. Birds from other reference sites had 8.44mg/kg and 11.7mg/kg, respectively. The study contained basic measures of residues and reproduction. More sensitive end points may have provided some indication of biological response to the COCs that do not approach levels that would impair reproduction. No laboratory studies were conducted on representative species (example: bobwhite quail or mallard ducks) to complement field observations and to confirm risk to ground dwelling birds that have the potential for contact with the sediment. Finally, there were some inconsistencies in the models, which in part

originate from the use of measured tissue concentrations in pippers and nestlings as an estimate of maternal deposition. This should have been predictive of impact and suggests the possibility that the highly contaminated individuals may not be the ones to inhabit and nest in that area the next year. Were there any banding, recapture studies done on the tree swallows?

(3.4.b) *Were the GE studies and analyses performed outside of the framework of the ERA and EPA review (e.g., field studies) appropriate under the evaluation criteria, based on accepted scientific practices, and incorporated appropriately in the ERA?*

The representative species for insectivorous field birds were tree swallows (EPA study) and robins. In the field study in robins, higher egg tPCB was found in the PSA compared to reference sites; however, no differences detected in clutch size with tPCB concentrations. EPA reanalyzed this study, and there were concerns about a small n and inclusion of only active nests in the analysis. It would have been valuable to have historical data and to have some of the individuals banded for recapture studies over several years to determine survivorship of the young fledged in the PSA. Moreover, it would be important to ascertain which individuals are nesting in the PSA, i.e., the same individuals and pairs over successive seasons or an influx of new animals each year. If the latter is the case, then the individuals will not have the same body burden of tPCBs as would animals that repeatedly nest in the PSA.

(3.4.c) *Were the estimates of exposure appropriate under the evaluation criteria, and was the refinement of analyses for the contaminants of concern (COCs) for each assessment appropriate?*

Estimates of tPCBs rely on the survey information. Tree swallows are known to be relatively insensitive to PCBs; many of the measurement endpoints were also relatively insensitive [see Table 2.6-1 (I.2-47] for listing of endpoints identified as responsive to PCBs. In spite of this, there was significantly reduced hatching success in 1999 and a negative correlation of dead embryos and higher tPCBs (some of the highest ever recorded; 2.7-88) in 1998 and 1999. In the context of refinement of the COCs, the issue of pesticides remains because some of the insects are likely to come from fields in which agricultural pesticides are in use. This is also true for the study on robins, which provided some additional exposure information. An additional issue is that of the relative diversity of species found in the areas of continued contamination. More information on ducks would have been helpful, especially in the context of providing a broader view on the chemicals that bioaccumulate in avian species that are constantly in contact with the aquatic environment.

(3.4.d) *Were the effects metrics that were identified and used appropriate under the evaluation criteria?*

Some more targeted endpoints should have been measured to detect effects associated with moderate stress or even a hormesis response. This would have provided a more complete overview of the organisms' responses and level of stress in the environment. Furthermore, as the area has been contaminated for a number of generations, it is possible that the population now resident in the PSA is a selected subpopulation that has higher resistance to the COCs.

The reproductive axis often continues to function despite environmental challenges up to some point, at which time the system is likely to collapse. This collapse, often associated with

heightened adrenal system activity then results in the cessation of egg production and testicular regression. Tree swallows appear to be very hardy and are able to persist in reproduction in spite of environmental challenges. They may however, have altered physiological responses (ex. EROD 2.7-71) and associated alteration in biochemical measures from the PCB exposure that would provide a reliable index of exposure, be indicative of lower level exposures, and be predictive of some level of adverse impact. These endpoints could include steroid hormones and hypothalamic neurotransmitters, which would provide potentially more sensitive endpoints.

(3.4.e) *Were the statistical techniques used clearly described, appropriate, and properly applied for the objectives of the analysis? Survival, growth, and reproduction of insectivorous birds.*

The models generated were complex due to the complexity of the ERA [see 2.6-26 for risk curves relative to low, intermediate, and high risk categories]. This approach is sound and has been conducted in a most thorough manner. The criteria for estimating risk are as follows: representative species criteria for risk=20% probability for exceeding threshold for most sensitive species=low risk; greater than 20% probability for exceeding the threshold for the most tolerant species=high risk. In some cases, this yields a large intermediate range and especially in the case of the tree swallow may artificially inflate the intermediate range and ultimately underestimate risk to other passerines. The integration of the two models (TEQ and microexposure) is not transparent and it is not clear which (or if both) model has been used for the summarized ERA. A more detailed and clearer explanation should be included.

The TDI exposure models for tree swallows are reasonable and reflect the higher residues found at the Taconic Valley site. The TDI exposure model for TEQ consequently shows a very wide intermediate range with a relatively high dose to achieve the intermediate-high criterion. This reflects the relatively insensitivity of the tree swallow to PCBs and is likely to underestimate risk to other insectivorous species. Other species, including the ground dwelling galliformes, pheasants, ducks, and geese are likely to be more sensitive to PCB impact. Data from these species would have provided a more inclusive and representative data set and a more accurate Monte Carlo analysis. In spite of this shortcoming, the models consistently predicted a higher risk than was found in the field studies, suggesting that there are uncertainties in the data set (in part due to the choice of representative species among other factors). Finally, a broader range of insectivorous birds should have been sampled and field studies should have included a subset of these species

(3.4.f) *Was the characterization of risk supported by the available information, and was the characterization appropriate under the evaluation criteria?*

The risk characterization was supported by the data; however, as discussed above, there were some issues associated with the selection of species and in the outcomes. Moreover, the models resulted in varying predictions due to some of the data used to generate the models, with the microexposure models appearing to be more predictive of a range of species. Clarification and possible reanalysis is recommended, with consideration of aligning observed effects with the models generated.

(3.4.g) *Were the significant uncertainties in the analysis of the assessment endpoints*

identified and adequately addressed? If not, summarize what improvements could be made.

There were a number of uncertainties, already discussed above. As such, there are issues that must be addressed in order to draw realistic conclusions regarding the impact to insectivorous birds. This may require additional field surveys, including egg collections and analyses for PCBs and for other environmental chemicals. As in the frogs, analysis of thyroid hormone is an important endpoint that was ignored in all these studies, yet the relationship to PCB exposure has been established. Alterations in the thyroid hormone axis would be predicted to influence timing of nesting, as well as viability and hatching of offspring.
Further, in the robin study, growth rate was slightly reduced (G59), similar to findings in chickens. In the study in chickens, longer exposure also resulted in reduced fertility and productivity. This suggests that the study should have been carried out longer and with more birds. Also, the number of nests should be increased and better documentation of abandoned nests should be conducted. There should be bird survey information available over several years in order to discern possible differences in species richness and nesting densities in the PSA and reference areas.

(3.4.h) *Was the weight of evidence analysis appropriate under the evaluation criteria? If not, how could it be improved?*

The WOE is appropriate under the findings from the representative species. As pointed out above, there are difficulties with the representative species chosen and with some of the endpoints that were not included in the assessments. Similarly, the study with robins had experimental flaws due to difficulties in the field study. Consequently, the conclusions drawn using a WOE approach are not compelling in this receptor.

(3.4.i) *Were the risk estimates objectively and appropriately derived for reaches of the river where site-specific studies were not conducted?*

Birds were not considered at risk, based on tree swallow data. This conclusion follows the data collected, but may be an underestimate based on the choice of representative species and also does not consider pesticides or compounds that may be associated with industries, such as the paper mill. The survey of species in the downstream region should be revisited to verify this conclusion.

(3.4.j) *In the Panel members' opinion, based upon the information provided in the ERA, does the evaluation support the conclusions regarding risk to local populations of ecological receptors?* No. Data from other species would be required to make a valid conclusion of low risk to passerines and ground dwelling insectivorous species. In addition, there were data from wood ducks and mallard ducks collected from Reaches 5 and 6 that had moderate tPCBs (7.7-6.1ppm and 4.99-15.3ppm in the breast tissue, respectively; section 6.4.7) and low levels of pesticides. Opportunistic collection of house wren eggs (n=5; Reach 5) contained significant tPCBs levels and pesticide residues. Similarly, chickadee eggs (n=3) had tPCBs at moderate levels and pesticides.

3.5 Survival, growth, and reproduction of piscivorous/carnivorous birds.

(3.5.a) *Were the EPA studies and analyses performed (e.g., field studies, site-specific toxicity studies, comparison of exposure and effects) appropriate under the evaluation criteria, and based on accepted scientific practices?*

Studies on piscivorous/carnivorous birds included a belted kingfisher study, which is a productivity study with visual monitoring of the nests. There was a limited n (n=9; 3 nests depredated) and the study was conducted in one breeding season. There was no assessment of growth; reproduction did not differ with tPCBs content. The rationale for the osprey study was that "belted kingfisher and osprey are the only piscivorous birds common to the area". However, the osprey study is a model, based on the foraging area being the entire PSA. As such, the number of birds actually impacted is not clear. There may be other avian species appropriate for the ERA, which inhabit the PSA in larger numbers. Candidate species might include owls, hawks, gulls, herons, or perhaps a species of egret.

(3.5.b) *Were the GE studies and analyses performed outside of the framework of the ERA and EPA review (e.g., field studies) appropriate under the evaluation criteria, based on accepted scientific practices, and incorporated appropriately in the ERA?*

Although the Belted Kingfisher study was well conceived, with excellent observation techniques, there were a very small number of nests and no reference nests. Exposure was estimated by analysis of fish from the areas of the nest, which is an indicator of fish fed to the young. This results in making some aspects of the kingfisher study difficult to interpret. Steps to take include: clarify the number of nests in each area and relate to tPCBs of fish in the area of fishing by the parents, determine if there are any exposures that could qualify as reference area nests, and possibly include the additional nest observed by EPA contract staff (if data have been collected in a similar manner). Alternatively, a study with another avian species would address these issues.

(3.5.c) *Were the estimates of exposure appropriate under the evaluation criteria, and was the refinement of analyses for the contaminants of concern (COCs) for each assessment appropriate?*

Belted Kingfishers were studied to determine productivity, nest density; COCs were determined from the fish in the nest and estimates from samples collected in the area of the nest. The osprey model was generated from estimates of fish in the PSA and therefore may not be verified by data collected within the ERA. Because these species are more wide ranging in their foraging, it is possible that they routinely encounter the COCs in a patchy manner. Likewise, these birds are also likely to contact other contaminants, including pesticides applied to the agricultural fields, weed killers, and other environmental chemicals. Therefore, it is appropriate to consider other COCs for these species.

(3.5.d) *Were the effects metrics that were identified and used appropriate under the evaluation criteria?*

The metrics were appropriate, but limited as discussed above.

(3.5.e) *Were the statistical techniques used clearly described, appropriate, and properly applied for the objectives of the analysis?*

The models were based on appropriate literature and as such should be reasonable. They should also consider the distribution of size of the fish that they consume and potential tPCB contents. There are some issues as discussed above in the conclusions presented in the two types of models that should be addressed.

(3.5.f) *Was the characterization of risk supported by the available information, and was the characterization appropriate under the evaluation criteria?*

The risk characterization is in line with the models, except that the osprey models are based on the literature and on the measured tPCBs in the fish that constitute their prey.

(3.5.g) *Were the significant uncertainties in the analysis of the assessment endpoints identified and adequately addressed? If not, summarize what improvements could be made.* There were uncertainties in the data for the belted kingfisher due to small n of nests and there were no data collected in the PSA for osprey, resulting in a model-based approach for the ospreys. The inclusion of dose response data from laboratory studies is valuable and there is no reason to disregard data from any species, including the domestic chicken unless the sensitivity estimate is available for the species under study. Furthermore, exclusion of data, such as those from domestic poultry will potentially underestimate the risk for other species.

(3.5.h) *Was the weight of evidence analysis appropriate under the evaluation criteria? If not, how could it be improved?*

The WOE shows potential risk, but the interpretation is somewhat inconclusive due to the limited measures conducted on the animals collected. It would have been valuable to have both historic data on the species in the PSA as well as studies that were conducted over several years.

(3.5.i) *Were the risk estimates objectively and appropriately derived for reaches of the river where site-specific studies were not conducted?*

Eagles identified as potentially at risk, based on the information on sediment tPCBs and on the potential sensitivity of these species to contaminants.

(3.5.j) *In the Panel members' opinion, based upon the information provided in the ERA, does the evaluation support the conclusions regarding risk to local populations of ecological receptors?*

There is a great deal of uncertainty due to the field study and to the limited information used to model the risk. The assessment remains somewhat inconclusive although it is reasonable based on the tPCBs in the prey. Ultimately, the real extent and potential for long-term impact is not clear for these species.

3.6 Survival, growth, and reproduction of omnivorous/carnivorous mammals.

(3.61.a) *Were the EPA studies and analyses performed (e.g., field studies, site-specific toxicity studies, comparison of exposure and effects) appropriate under the evaluation criteria, and based on accepted scientific practices?*

Four years of field surveys showed species diversity in the PSA, with some indication of differential distribution of the species. Representative species chosen were red fox and northern short-tailed shrew. Foxes were observed throughout the PSA; however the models relied on data

from the literature. Female mammals (primarily white-footed mice) were trapped; counting placental scars assessed fecundity. This is a good measure, but placenta scars in adult females should be considered in combination with estimates of survival of the young of that year, total number of animals trapped, sex ratio, and percentage of females that were immature or infertile.

(3.6.b) *Were the GE studies and analyses performed outside of the framework of the ERA and EPA review (e.g., field studies) appropriate under the evaluation criteria, based on accepted scientific practices, and incorporated appropriately in the ERA?*

The Boonstra study (2002) showed no negative effects of tPCBs on short-tailed shrews. There are some difficulties in interpretation of these data without a population assessment; stability in population may be due to immigration.

(3.6.c) *Were the estimates of exposure appropriate under the evaluation criteria, and was the refinement of analyses for the contaminants of concern (COCs) for each assessment appropriate?*

Field studies attempted to assess population and fecundity and relate these data to tissue residues from trapped animals. Both types of data are important. Additional data from a lab study with mice exposed to contaminated soil would have been valuable. This type of a study would have provided more direct information about the response of the species and the viability of offspring. It is possible that there has been some selection of a subset of the population that could survive and reproduce in the PSA environment with the COCs.

(3.6.d) *Were the effects metrics that were identified and used appropriate under the evaluation criteria?*

The effects metrics were appropriate with some difficulties in interpretation.

(3.1.e) *Were the statistical techniques used clearly described, appropriate, and properly applied for the objectives of the analysis?*

These models are also primarily based on the literature. The results for the EPA and GE data sets should be compared and aligned. If the difference is due to omission of data, then the rationale for leaving some of the data out of the analysis must be considered.

(3.6.f) *Was the characterization of risk supported by the available information, and was the characterization appropriate under the evaluation criteria?*

The overall risk characterization is supported by the information, but there is uncertainty due to the lack of effects found in the field study in shrews. Potentially, there should be separate risk assessments for some of the species considered, especially those with greatly differing life histories.

(3.61.g) *Were the significant uncertainties in the analysis of the assessment endpoints identified and adequately addressed? If not, summarize what improvements could be made..*

There were some inconsistencies in GE field study, leading to a reanalysis of the data by EPA.

(3.6.h) *Was the weight of evidence analysis appropriate under the evaluation criteria? If not, how could it be improved?*

There are inconsistencies in the field assessments and in the WOE, which need clarification.

(3.6.i) *Were the risk estimates objectively and appropriately derived for reaches of the river where site-specific studies were not conducted?*

The lower reaches should pose reduced threat due to diminishing contamination.

(3.6.j) *In the Panel members' opinion, based upon the information provided in the ERA, does the evaluation support the conclusions regarding risk to local populations of* ecological receptors?

The endpoints measured and some flaws in the design of the field studies limit data interpretation. Risk assessment follows from the available information.

3.7 *Survival, growth, and reproduction of piscivorous mammals*.

(3.7.a) *Were the EPA studies and analyses performed (e.g., field studies, site-specific toxicity studies, comparison of exposure and effects) appropriate under the evaluation criteria, and based on accepted scientific practices?*

The representative species chosen were mink and otter. The MSU feeding study with mink fed fish from the PSA showed effects on the survival of kits in the 3.7mg/kg tPCB group at 6 weeks of age; jaw lesions were observed in kits in a dose-dependent manner. These additional measures are important for the ERA; specifically as there was a dose-dependent relationship observed in EROD and in jaw lesions in the kits. The significance of the lesions should be considered, i.e., are lesions associated with impaired immune response or localized tumorgenesis. The survey provided valuable information about the presence of mink and otter; scat samples gave information about prey.

(3.7.b) *Were the GE studies and analyses performed outside of the framework of the ERA and EPA review (e.g., field studies) appropriate under the evaluation criteria, based on accepted scientific practices, and incorporated appropriately in the ERA?*

Field survey (2001-03) showed evidence of mink and otter in winter, but in low numbers at other seasons compared to informal data from sightings in the previous years. There is an uncertainty due to the sampling and observations.

(3.7.c) *Were the estimates of exposure appropriate under the evaluation criteria, and was the refinement of analyses for the contaminants of concern (COCs) for each assessment appropriate?*

The mink study was conducted in both the field and lab. Laboratory studies confirmed the impact of fish from the PSA on kits produced by exposed females. Field studies were less conclusive. Field data on otters (sightings) provided information on the presence of this species and likely prey in the areas of observation. Models developed should be reasonably accurate because the COCs would have been present in the laboratory study.

(3.7.d) *Were the effects metrics that were identified and used appropriate under the*

evaluation criteria?

The laboratory studies with the mink included endpoints that were informative and were included as part of the assessment. Field studies appeared to be well conceived, but yielded somewhat confusing results due to apparent seasonal differences in the presence/distribution of individuals.

(3.1.e) *Were the statistical techniques used clearly described, appropriate, and properly applied for the objectives of the analysis?*

The models for the mink and otter populations are reasonable, given the laboratory data and information from the literature. However, there may be an underestimate of the long-term impact to mink, based on the data collected. Although this was in addition to the some of the stated objectives, these data should be considered as relevant for long-term impact and potential population level impacts.

(3.7.f) *Was the characterization of risk supported by the available information, and was the characterization appropriate under the evaluation criteria?*

The risk characterization was supported by the literature and by the laboratory data. There were few field data to rely upon for the models.

(3.7.g*) Were the significant uncertainties in the analysis of the assessment endpoints identified and adequately addressed? If not, summarize what improvements could be made.*

The uncertainties resent in the field studies were discussed. As discussed for other receptors, the traditional measurement end points are likely to be inadequate to detect more subtle sub lethal effects of some toxins, such as endocrine disrupting chemicals. The lesions observed in the mink may be a symptom of immune system impact. Although not used in these studies as a measurement end point, future assessments may be more comprehensive if some more subtle measurement end points are included.

(3.7.h) *Was the weight of evidence analysis appropriate under the evaluation criteria? If not, how could it be improved?*

The WOE was appropriate given the data from lab, literature, and to a lesser extent, field data. The same comment as in 3.7g is pertinent.

(3.7.i) *Were the risk estimates objectively and appropriately derived for reaches of the river where site-specific studies were not conducted?*

Yes, based on the measured tPCBs downstream.

(3.7.j) *In the Panel members' opinion, based upon the information provided in the ERA, does the evaluation support the conclusions regarding risk to local populations of ecological receptors?*

Yes, based on the models and information presented.

3.8 Survival, growth, and reproduction of threatened and endangered species.

(3.8.a) *Were the EPA studies and analyses performed (e.g., field studies, site-specific toxicity studies, comparison of exposure and effects) appropriate under the evaluation criteria, and based on accepted scientific practices?*

Representative species were the bald eagle, American bittern, and small-footed myotis; eagles and bitterns have been observed in the PSA. Models were based on prey item tPCBs and estimated sensitivities, based on the literature from related species.

(3.8.b) *Were the GE studies and analyses performed outside of the framework of the ERA and EPA review (e.g., field studies) appropriate under the evaluation criteria, based on accepted scientific practices, and incorporated appropriately in the ERA?*

Surveys would consider these species, but data were not available.

(3.8.c) *Were the estimates of exposure appropriate under the evaluation criteria, and was the refinement of analyses for the contaminants of concern (COCs) for each assessment appropriate?*

COCs were estimates based on prey tPCBs and species sensitivity estimates. This was appropriate given the limitation of access to these animals.

(3.8.d) *Were the effects metrics that were identified and used appropriate under the evaluation criteria?*

There were few data collected at the PSA. Maternal deposition of tPCBs into the egg was used as an estimate of embryonic exposure. This is appropriate due to known sensitivity of raptors to PCBs.

(3.1.e) *Were the statistical techniques used clearly described, appropriate, and properly applied for the objectives of the analysis?*

The models are based on available information and similar species, where possible. It is appropriate to use the range of sensitivities to tPCBs determined in lab and field studies for the models. This increases the likelihood that the true sensitivity of an organism is within the range of sensitivities and is warranted because the loss of even one individual of an endangered species is critical to the population.

(3.8.f) *Was the characterization of risk supported by the available information, and was the characterization appropriate under the evaluation criteria?*

The risk characterization is supported by the literature to the extent possible.

(3.8.g) *Were the significant uncertainties in the analysis of the assessment endpoints identified and adequately addressed? If not, summarize what improvements could be made.*

Uncertainties are associated with the model development due to the use of information developed from other species. As most of this information is from peer reviewed journal papers, there is some level of confidence in the rigor of those data.

(3.8.h) *Was the weight of evidence analysis appropriate under the evaluation criteria? If not, how could it be improved?*

The WOE depends on models generated from the literature and are predictive given the data from the content of tPCBs in their diet.

(3.8.i) *Were the risk estimates objectively and appropriately derived for reaches of the river where site-specific studies were not conducted?*

Yes, based on the data available.

(3.8.j) *In the Panel members' opinion, based upon the information provided in the ERA, does the evaluation support the conclusions regarding risk to local populations of ecological receptors?*

Risk assessment appears to be reasonable given available information

4. **Are the summary discussions and conclusions in the ERA supported by the information provided in the report, and did the conclusions describe the risks in an objective, reasonable, and appropriate manner?**

The summary discussions and conclusions in the ERA are supported by the information presented in the report. These conclusions do describe the risks in an objective, reasonable, and appropriate manner and include consideration of uncertainties in the data. As mentioned in the Introduction, there is a tremendous amount of data that have been collected as part of the ERA by both the EPA and GE teams. The shortcomings pointed out relative to data collected in wildlife do not detract from the wealth of information that is in the ERA and in fact provide the opportunity to address some items to further verify the conclusions of the ERA. In this way, we can be increase the certainty of the conclusions in the ERA and increase the confidence of future actions in the Rest of the River ecosystem.

5. **To the best of the Panel's knowledge, is there other pertinent information available that was not considered in the ERA? If so, identify the studies or data that could have been considered, the relevance of such studies or data, and how they could have been used in the ERA.**

Yes, there is pertinent information that should have been collected, considered, and discussed within the ERA. Although the tree swallow is a commonly studied field species, this species may be a poor choice as a representative species for passerines, despite its presence in the PSA due to the relative insensitivity of this species to PCBs. As discussed above, many of the end points chosen for study in wildlife were not particularly sensitive and would reveal impact at a point that the population might be in jeopardy. The statistical models serve to fill in these gaps in that they do provide a conceptual framework in which to make objective determinations. Although these models vary with the underlying assumptions, collapsing the conclusions from the available data and statistical models, using the WOE does provide an overall thoughtful and logical summarization of the risk to the various populations. The ultimate use of these models and the resultant conclusions, using the WOE approach will provide the final demonstration of the degree of responsibility in our stewardship of environmental resources, including the wildlife present within this ecosystem.