HUDSON RIVER PCBs REASSESSMENT RI/FS

# RESPONSE TO PEER REVIEW COMMENTS ON THE BASELINE ECOLOGICAL RISK ASSESSMENT

NOVEMBER 2000

For

U.S. Environmental Protection Agency
Region 2
and
U.S. Army Corps of Engineers
Kansas City District

Book 1 of 1

TAMS Consultants, Inc.
Menzie-Cura & Associates, Inc.

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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
REGION 2
290 BROADWAY
NEW YORK, NY 10007-1866

November 29, 2000

To All Interested Parties:

The U.S. Environmental Protection Agency (USEPA) is pleased to release the Response to Peer Review Comments on the Ecological Risk Assessment.

On June 1-2, 2000, USEPA, through its contractor, Eastern Research Group, convened a panel of independent scientific experts to conduct a peer review of the August 1999 Baseline Ecological Risk Assessment (ERA) and the March 2000 Responsiveness Summary for that report. The Response to Peer Review Comments describes how USEPA incorporated the peer review comments or provides the technical rationale for not incorporating a comment.

In conjunction with this Response to Peer Review Comments, USEPA is issuing a Revised ERA. The Revised ERA combines into a single report the August 1999 ERA, the March 2000 Responsiveness Summary, and the November 2000 Response to Peer Review Comments. The Revised ERA also includes revisions to the December 1999 ERA for Future Risks in the Lower Hudson River and the August 2000 Responsiveness Summary for that report. USEPA is using the results of the Revised ERA to establish acceptable PCB exposure levels for ecological receptors, which will in turn be used to develop remedial alternatives for the PCBs in the sediments of the Upper Hudson River.

If you need additional information regarding the Revised ERA or the Reassessment RI/FS, please contact Ann Rychlenski at 212-637-3672.

Sincerely yours,

William McCabe

for Richard L. Caspe, Director
Emergency and Remedial Response Division



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## NOVEMBER 2000

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## LIST OF ACRONYMS

| | |
|---|---|
| BTAG | Biological Technical Assistance Group |
| EPA | U.S. Environmental Protection Agency |
| ERA | Ecological Risk Assessment |
| ERG | Eastern Research Group, Inc. |
| GE | General Electric Company |
| LOAEL | lowest-observed-adverse-effect level |
| NOAA | National Oceanic and Atmospheric Administration |
| NOAEL | no-observed-adverse-effect level |
| NYSDEC | New York State Department of Environmental Conservation |
| PCB | polychlorinated biphenyl |
| TEF | toxic equivalency factor |
| TEQ | toxic equivalent |
| TQ | toxicity quotient |
| TRV | toxicity reference value |
| UCL | upper confidence limit |
| USFWS | U.S. Fish and Wildlife Service |

# RESPONSE TO PEER REVIEW COMMENTS ON THE ERA FOR THE HUDSON RIVER PCBs SUPERFUND SITE

## INTRODUCTION

On June 1-2, 2000, the U.S. Environmental Protection Agency (USEPA), through its contractor, Eastern Research Group (ERG), convened a panel of independent scientific experts to conduct a peer review of the baseline Ecological Risk Assessment (ERA) for the Hudson River PCBs Site, consistent with the Agency's Peer Review Handbook (USEPA, 1998a). The ERA, which was issued in August 1999 (USEPA, 1999a), was developed by the Agency for the Hudson River PCBs Reassessment Remedial Investigation and Feasibility Study (Reassessment RI/FS). The ERA evaluated the risks to ecological receptors posed by PCBs in the water, sediment, and fish of the Hudson River. In addition to the ERA, the peer reviewers were tasked to review USEPA's March 2000 Responsiveness Summary for the ERA, which provided the Agency's responses to public comment on the ERA. In addition, the reviewers were provided with other relevant documents. The peer reviewers were asked to respond to USEPA's charge questions, which covered each component of the ERA. The specific charge questions and information about the peer review are presented in the "Report on the Peer Review of the Hudson River PCBs Ecological Risk Assessment" (ERG, 2000) (the "Peer Review Report"). Excerpts from the Peer Review Report are reproduced as Part 2 of this document.

This Response describes where in the Revised ERA USEPA incorporated the peer review comments or provides the technical rationale for not incorporating a comment. This response addresses each of the peer reviewers' overall recommendations in Section 4.0 of the Peer Review Report. Those recommendations include the points summarized in the Executive Summary and Sections 2.0 and 3.0 of the Peer Review Report.

In conjunction with this Response to Peer Review Comments, USEPA is issuing a Revised ERA. The Revised ERA combines into a single report the August 1999 ERA (USEPA, 1999a), the March 2000 Responsiveness Summary (USEPA, 2000b), and the changes made as a result of the peer review comments. The Revised ERA also includes revisions to the December 1999 ERA for Future Risks in the Lower Hudson River (USEPA, 1999b) and the August 2000 Responsiveness Summary for that report (USEPA, 2000c). USEPA is using the results of the Revised ERA to establish acceptable PCB exposure levels for ecological receptors, which will in turn be used to develop remedial alternatives for the PCBs in the sediments of the Upper Hudson River.

# Response to Charge Questions

## 1. Responses to Question 1

The first charge question asked the peer reviewers to comment on the problem formulation and conceptual model of the ecological risk assessment, as follows:

> Consistent with USEPA guidance on conducting ecological risk assessments (USEPA, 1997b), the problem formulation step establishes the goals, breadth, and focus of the assessment. As part of the problem formulation step in the ERA, a site conceptual model was developed (Chapter 2.3, pp. 11–19). Please comment on whether the conceptual model adequately describes the different exposure pathways by which ecological receptors could be exposed to PCBs in the Hudson River. Was sufficient information provided on the Hudson River ecosystems so that appropriate receptor species could be selected for exposure modeling?

**Comment:** The reviewers recommended including discussions on sources of PCBs and other contaminants to the system other than the GE capacitor manufacturing plants, the extent of PCB contamination in the sediments, the chemical fate and transport of PCBs and biological uptake of PCB congeners, the ecosystems of the Hudson River, a complete description of the conceptual site model, including the ecological resources and their use by the human communities, the rationale for selection of receptor species and stakeholder input in the selection process.

**Response:** USEPA incorporated each of the above recommendations in its Revised ERA, as follows:

1) The sources of PCBs to the Hudson River are discussed the Revised ERA in Section 1.2.1: Summary of PCB Sources to the Upper and Lower Hudson River. USEPA's previous analysis of geochemical data showed that the area of the site upstream of the Thompson Island Dam represents the primary source of PCBs to the freshwater Hudson (USEPA, 1997a). This area includes GE's Hudson Falls and Fort Edward capacitor manufacturing plants and two areas that were contaminated by PCBs from the GE plants: the remnant deposits, which are sediments that were exposed when the Fort Edward Dam was removed in 1973, and the sediments in the first six miles downstream of the GE plants, known as the Thompson Island Pool.

Contaminants of concern other than PCBs that are present in the Hudson River are discussed in Section 2.2: Contaminants of Concern. Fish collected at the site have been analyzed for total DDT, total chlordane, total endrin, total endosulfan, dieldrin, aldrin, mirex, total heptachlor, total hexachlorobenzene, toxaphene, methoxychlor, individual polycyclic aromatic hydrocarbons (PAHs), cadmium, mercury, dioxins, and dibenzofurans. These analytes were found to be present at relatively low levels or below detection limits (Sloan, 1999), confirming that PCBs are the primary contaminants of concern in the Hudson River.

2) The extent of PCB contamination in the sediments is discussed in Section 1.2.3.1: PCBs in Sediment of the Revised ERA. Specifically, this section discusses the extent of PCBs in sediments as characterized by the NYSDEC 1976-1978 Sediment Survey, the NYSDEC 1984 Sediment Survey, the General Electric 1991 Sediment Composite Survey, the USEPA 1992 High Resolution Sediment Coring Program, the USEPA 1994 Low Resolution Sediment Coring Program, the General Electric 1998 Sediment Composite Survey, and the General Electric 1998-1999 Sediment Coring Program.



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3) The chemical fate and transport of PCBs is discussed in Section 2.3.1.1: Processes the Govern PCB Distribution in the Environment of the Revised ERA. Biological uptake of PCBs is covered in Section 2.3.1.2: Biological Fate and Transport Processes and a more detailed discussion of temporal changes in congener profiles across trophic levels is provided in Section 2.3.1.3: Spatial and Temporal Issues in Congener-specific Uptake. There are not sufficient data to constrain congener-specific modeling, including boundary conditions, initial conditions, and specific rate constants in the models. USEPA did, however, model the differential uptake of PCBs across trophic levels using FISHRAND. The available toxicological data also are insufficient for congener-specific analysis, and thus it is not possible to quantitatively evaluate the effects of differential uptake of specific congeners on different species, even if sufficient site data were available.

4) The ecosystems/ecological resources of the Hudson River are discussed in the Revised ERA in Section 2.1: Site Characterization, which includes descriptions of the habitats (Section 2.1.1) of the Upper Hudson River (main channel stream, riverine cultural subsystems, palustrine systems, deep emergent marsh, shallow emergent marsh, palustrine cultural subsystems, and forests) and the habitats of the Lower Hudson River (tidal river, brackish subtidal aquatic bed, freshwater subtidal aquatic bed, brackish tidal marsh, brackish intertidal mudflats, brackish intertidal short, freshwater tidal swamp, freshwater tidal marsh, freshwater intertidal mudflats, freshwater intertidal shore, and estuarine cultural subsystems). Animals living in the Hudson River area are discussed in Section 2.1.2: Hudson River Natural History, with a separate section (Section 2.1.3) on threatened and endangered species. Areas designated as significant habitats by New York State's Coastal Management Program are covered in Section 2.1.4.

5) The conceptual site model is presented in the Revised ERA in Section 2.3: Conceptual Model. Human use of the river from prehistoric times to the present is discussed in the Revised ERA in Section 2.1.5: Human Use of the River.

6) The selection of receptor species is discussed in Section 2.6: Representative Receptors, which describes the technical rationale for selecting the receptor species and the stakeholder input in the selection process. Consistent with USEPA's Ecological Risk Assessment Guidance for Superfund (USEPA, 1997b) and Guidelines for Ecological Risk Assessment (USEPA, 1998b), the receptor species were selected as models to represent a range of trophic levels and feeding preferences of animals found along the Hudson River. During the development of the ERA, USEPA invited and incorporated input from stakeholders and the general public on valued species in the Hudson River, which resulted in adding the river otter as a receptor species (see USEPA, 2000b).

**Comment:** Tributaries of the river should have been included in the ERA because receptors are not limited to the main stem of the river.

**Response:** USEPA agrees that some of the receptors may forage and spawn in tributaries of the Hudson River. However, given that the site is nearly 200 miles long, it is reasonable to assume that some receptors could spend their entire lives in the vicinity of the Hudson River. In addition, contamination in the tributaries of the Hudson River is not well-defined, but is known to exist in some of the tributaries of the tidal Lower Hudson River. Inclusion of all the tributaries would either dilute the risks posed by the Hudson (if the tributaries are uncontaminated) or confound the risks to an unknown degree (if they are contaminated). For these reasons, the Revised ERA does not include the tributaries in evaluating the risks associated with PCBs at the Hudson River PCBs site.

## 2. Responses to Question 2

The second charge question asked the peer reviewers to comment on EPA's selection of assessment endpoints, as follows:

> Assessment endpoints specify the valued ecological resources to be protected, such as local fish populations. They focus the risk assessment on particular components of the ecosystem that could be adversely affected by contaminants from the site. Please comment on whether the assessment endpoints selected (pp. 19–20) adequately protect the important ecological resources of the Hudson River. Are major feeding groups and sensitive species sufficiently covered by the selected assessment endpoints?

**Comment:** Selection of assessment endpoints should have focused on identifying species that had the highest exposures to PCBs and were most at risk for PCB-related effects.

**Response:** Focusing on species at the greatest risk would have resulted in a shorter list of receptor species. However, it would not have evaluated risks to less exposed species, such as insectivores. Consistent with USEPA's Ecological Risk Assessment Guidance for Superfund (USEPA, 1997b), USEPA selected assessment endpoints based on ecosystems, communities, and/or species potentially present at the site that represent a range of trophic levels and feeding preferences. Limiting assessment endpoints to the species with the highest exposures would not provide an overall picture of risks to various receptors along the Hudson River and would not determine which groups of receptors are likely to be exposed to PCBs. The inclusion of assessment endpoints that ultimately are concluded to not be at substantive risk is not wasted effort. These evaluations are important to the clarity of process and risk communication. USEPA preferred to do the evaluation to know that they were not at great risk rather than assume such a conclusion.

**Comment:** The panel expressed concern over whether the suite of endpoints and the major feeding groups and sensitive species addressed the important resources (*e.g.*, osprey, crayfish, blue crab, zebra mussel).

**Response:** In the Revised ERA, Section 2.6.3: Avian Receptors discusses the reasons that the bald eagle was selected as a receptor rather than the osprey. Section 2.6.1: Macroinvertebrate Communities discusses why benthic macroinvertebrate communities, which include crayfish, blue crab, and zebra mussels, was selected as an assessment endpoint. In light of the purpose of the Reassessment, which is to evaluate the need to address PCB-contaminated sediments in the Upper Hudson River, USEPA determined that the sustainability of a benthic invertebrate community, which is a food source for local fish and wildlife, was a more relevant assessment endpoint for this ecological risk assessment than the health of crayfish, blue crab and zebra mussels as individual species. Blue crabs do bioaccumulate PCBs, as shown by concentrations ranging from 0.2 ppm to 26.7 ppm in NYSDEC data from the early 1990s, and may pass them on to predators.

**Comment:** The ERA should have focused on species that are known to forage more exclusively in the Hudson River or have restricted home ranges (*e.g.*, kingfisher).

**Response:** Consistent with USEPA's Ecological Risk Assessment Guidance for Superfund (USEPA, 1997b), USEPA selected assessment endpoints based on ecosystems, communities, and/or species potentially present at the site that represent a range of trophic levels and feeding preferences. In the ERA (and Revised ERA), USEPA selected receptors that forage exclusively or predominantly in the Hudson River or have restricted home ranges. The belted kingfisher was selected as a receptor in the ERA and was retained as a receptor in the Revised ERA (<u>see</u>, Section 2.6.3 of the Revised ERA).

**Comment:** The significant habitats and threatened and endangered species assessment endpoints were difficult to assess. The ERA did not explain why certain habitats were identified as critical, and the assessment endpoint for threatened and endangered species was not supported by unique measurement endpoints.

**Response:** In response to this comment, in the Revised ERA, USEPA eliminated the assessment endpoints for significant habitats and threatened and endangered species. However, USEPA notes that the Hudson River significant habitats were defined as areas that are unique, unusual or necessary for continued propagation of key species (see, Section 2.6.6 of ERA and Section 2.1.4 of Revised ERA). Thirty-four (34) sites in the tidal portion of the Hudson River that have been designated as Significant Coastal Fish and Wildlife Habitats under the NYS Coastal Management Program (NYSDOS, 1987) and five additional sites have been identified as containing important plant and animal communities to bring the total number of sites to 39.

**Comment:** The analyses performed for the benthic community structure as a food source for local fish and wildlife seem more consistent with an assessment endpoint of protection and maintenance of local benthic and invertebrate communities.

**Response:** The analyses of benthic community structure using such parameters as abundance and biomass are consistent with an assessment endpoint of the sustainability of the benthic invertebrate community, which serves as a food source for local fish and wildlife. The overall health and structure of the benthic community can affect organisms, such as fish, that depend upon the benthic community for food. An impoverished or unhealthy benthic community can affect not only the animals feeding directly on the benthic invertebrates but also upper trophic level species.

**Comment**: Use of the term "protection" in the assessment endpoints was questioned, noting that protection is not a biological property or ecological condition that can be measured, but rather a management or regulatory activity.

**Response:** USEPA agrees that in the literal sense protection is an action, rather than an actual environmental value. In response to this comment, the assessment endpoints have been revised to read sustainability (*i.e.*, survival, growth and reproduction), rather than the protection and maintenance (*i.e.*, survival, growth and reproduction), of local populations (see, Section 2.4 of Revised ERA).

**Comment:** Some reviewers suggested that the assessment endpoints should address specific species (*e.g.*, largemouth bass), while others suggested that they address groups of species (*e.g.*, benthivorous fish, pelagic fish, insectivorous birds).

**Response:** Consistent with USEPA's Ecological Risk Assessment Guidance for Superfund (USEPA, 1997b), the Revised ERA uses receptor species as surrogate models to assess risks to groups of species, as did the ERA. Using this method, the results can be used to make inferences about the general risks to species with similar feeding behaviors.

## 3. Responses to Question 3

The third charge question addresses EPA's selection of measurement endpoints, as follows:

Measurement endpoints were used to provide the actual measurements used to estimate risk. Please comment on whether the combination of measured, modeled, guidance, and observational measurement endpoints used in the ERA (pp. 20–29) supports the weight of evidence approach used in the ERA.

**Comment:** The reviewers generally agreed that a weight of evidence analysis was not conducted in the ERA. Some reviewers thought the available data can be used to support a partial weight of evidence approach, while others thought the available data are not adequate to support a weight of evidence approach.

**Response:** USEPA agrees that the available data are not sufficient to support a full weight of evidence approach. Rather than providing a partial weight of evidence approach, in the Revised ERA, USEPA has eliminated the weight of evidence terminology.

**Comment:** Some of the measurement endpoints lack specificity. Some reviewers recommended explicit consideration of life stages when exposures to PCBs are greatest and PCB-related effects are most likely. One reviewer recommended adding spatial and temporal specificity to the measurement endpoints.

**Response:** In Section 2.5: Measurement Endpoints of the Revised ERA, USEPA considers the life stages when exposures to PCBs are the greatest and PCB-related effects are most likely by identifying measurement endpoints associated with reproduction, which are typically the most sensitive endpoints (*e.g.*, PCB concentrations in eggs of the belted kingfisher). Section 2.5: Measurement Endpoints and Section 3.0: Exposure Assessment of the Revised ERA includes the recommended specificity with respect to the measurement endpoints, such as the level of spatial and temporal averaging, whether the ambient water quality criteria are for acute or chronic exposures, and which river segments are being measured. The salinity of the river is discussed in Section 2.1: Site Characterization.

**Comment:** The reviewers disagreed about the need for site-specific toxicity studies and whether the results of toxicity studies from other sites can be applied to the Hudson River. One reviewer expressed concern that measurement endpoints involving TEQ analyses could not be calculated accurately, thus limiting the accuracy of the effects assessment using TRVs and uncertainties introduced by applying the World Health Organization's (WHO) TEFs for fish and avian species (due to the large amount of inter-species variability in the sensitivity to PCB exposure).

**Response:** USEPA has added a discussion of congener-specific uptake in Section 2.3.1.3: Spatial and Temporal Issues in Congener-specific Uptake of the Revised ERA. The USEPA Phase 2 dataset, which was provided to the reviewers on CD-ROM, contains congener-specific data. These data are one of the main prerequisites required for the TEQ analyses. USEPA's data evaluation showed the data to be usable for TEQ analyses, despite uncertainties in the quantification (see, Appendix I of ERA). These data are discussed in Section 3.1.2: Quantifying Toxic Equivalencies (TEQs) of the Revised ERA. Although there is interspecies variability in sensitivity to PCBs, the WHO TEFs represent consensus values obtained after extensive discussion, analyses, and peer reviews. Thus, USEPA considers them to be the best available TEFs.

## 4. Responses to Question 4 and 5

In their discussions, the reviewers responded to charge questions 4 and 5 at the same time. The fourth charge question addressed the exposure assessment in the ERA, as follows:

USEPA used several avian and mammalian exposure models to evaluate the potential risks due to PCBs (see ERA, pp. 37–71). Sampling data from USEPA, NOAA, NYSDEC, and USFWS collected from 1992–1996 were used to estimate current fish body burdens and dietary doses to avian and mammalian receptors. Future concentrations of PCBs were derived from USEPA's fate, transport, and bioaccumulation models, which are the subject of a separate peer review. Concentrations of PCBs in piscivorous bird eggs were estimated by applying a biomagnification factor from the literature. Please comment on the appropriateness and sufficiency of this approach to estimate ecological exposure to PCBs.

The fifth charge question also pertained to the exposure assessment documented in the ERA, as follows:

Have the exposure assumptions (ERA, pp. 46–66 and Appendices D, E, and F) for each fish and wildlife receptor been adequately described and appropriately selected? Please discuss in detail.

**Comment:** The reviewers agreed that estimates of current PCB exposures are based on a large volume of reliable site-specific environmental sampling data. The reviewers generally agreed that future exposure concentrations are difficult to evaluate without reviewing the Revised Baseline Modeling Report; however, the reviewers disagreed on the extent to which the results of the baseline modeling should be documented in the ERA. One reviewer suggested that USEPA's future modeling efforts focus on calculating relative exposure estimates for different remedial scenarios.

**Response:** USEPA acknowledges the comment regarding the extensive database that supports the current PCB exposure concentrations used in the ERA. With respect to the future exposure concentrations, the Section 3.2.1 of the Revised ERA contains a summary of the fate and transport model (HUDTOX) and the bioaccumulation model (FISHRAND) and Section 2.3.1.1 contains a discussion of the physical and chemical parameters influencing PCB fate in the environment.

USEPA notes that the Revised Baseline Modeling Report (USEPA, 2000a) was the focus of an earlier external peer review by a separate panel of independent experts, who generally found the report to be acceptable with major or minor revisions. One expert, Dr. Ross Norstrom, served on both the panel for the Revised Baseline Modeling Report and the panel for the ERA, providing some cross-over of expertise between the two panels. USEPA considered a detailed review of the Revised Baseline Modeling Report to be outside the scope of the charge to the panel reviewing the ERA. Nonetheless, to aid in responding to charge question 4, USEPA provided the peer reviewers with the Executive Summary for the Revised Baseline Modeling Report as background information. Moreover, at the March 2000 Informational Meeting, USEPA noted that other Reassessment documents, including the entire Revised Baseline Modeling Report, were available on the Agency's website, www.epa.gov/hudson, or by request (<u>see</u>, Charge for Peer Review 4). As stated in the Charge for Peer Review 4, USEPA intends to use the risk assessment methodology in the Feasibility Study to back-calculate to appropriate levels of PCBs in fish and to compare various remedial alternatives, including the No Action alternative (*i.e.*, baseline conditions), as required by Superfund law.

**Comment:** Most reviewers agreed that USEPA's selection of exposure factors was generally appropriate. One reviewer expressed concern that the ERA does not characterize the variability among TEQs that are estimated from concentrations of Tri+ PCBs, thus omitting key information on the uncertainties of calculated exposure doses. This reviewer recommended that USEPA document the range, mean, and 95% UCLs of Tri+ PCB concentrations in surface water, sediment and fish tissue for various stretches of the Hudson River. Two reviewers recommended that the ERA provide information on variability in all cases in which point estimates were used as inputs to exposure dose calculations (*e.g.*, for PCB concentrations, biomagnification factors, and relevant exposure factors). One reviewer recommended that all point estimate input parameters be replaced with distributions in cases where the variability of inputs has been characterized or can be reasonably estimated.

**Response:** In response to the peer reviewers' recommendations, Section 3.8: Uncertainty and Sensitivity in Exposure of the Revised ERA provides information on variability in exposure assumptions and their distributions. A Monte Carlo analysis was conducted for the belted kingfisher, bald eagle, mink, and river otter by specifying distributions for the input parameters, including fish and benthic invertebrate concentrations, body weight, ingestion rate, and percentage of fish in the diet. The results are presented in Section 6.5.2: Sensitivity Analysis for Risk Models of the Revised ERA.

**Comment:** One reviewer expressed concern about the assumptions made to calculate TEQs from the available sampling data and modeling results, including assumptions made to process the large number of nondetects in the fish tissue sampling data for BZ#126 and the assumption that the composition of Tri+ PCBs in Hudson River fish does not change from year to year. This reviewer recommended that USEPA calculate TEQs based on congener-specific tissue concentrations for the various species or use congener-specific biomagnification factors to estimate the profiles of PCB congeners in the species, from which TEQs can then be calculated.

**Response:** The Revised ERA includes additional information from the published scientific literature about congeners likely to be enriched (or depleted) with increasing trophic level. The literature suggests that BZ#126 is more likely to be enriched (*e.g.*, Bright *et al.*, 1995; Leonards *et al.*, 1998). Given that BZ#126 is more likely to become enriched, assuming a concentration of BZ#126 at the detection level is reasonable, although it likely overestimates the true concentration. This is a source of uncertainty, as discussed in Section 6.2.1: TEQ Quantitation of the Revised ERA.

USEPA believes that the available data are not sufficient to adequately constrain a congener-specific bioaccumulation model. As a result, FISHRAND was not designed or run to predict changes in individual congener concentrations in Hudson River fish from year to year. Although FISHRAND could be applied in that way, the uncertainty associated with the estimates would be extremely high. Therefore, USEPA assumed that the composition of Tri+ PCBs in Hudson River fish does not change from year to year. This is a source of uncertainty, as discussed in Section 6.5.3.1: Uncertainty in FISHRAND Model Predictions of the Revised ERA and in the Revised Baseline Modeling Report (USEPA, 2000a).

**Comment:** Exposure dose calculations could have incorporated finer spatial and temporal resolution, thus possibly accounting for unique feeding habits, exposures at specific life stages, and exposure histories.

**Response:** The exposure dose calculations are constrained by the spatial and temporal resolution of the HUDTOX, FISHRAND, and Farley models. The resolution of these models was determined by taking into account the needs of the ERA as well as other requirements of the decision-making process. The Hudson River is a nearly 200-mile site; finer scale spatial resolution is not appropriate given the objectives of the Reassessment.

As noted above, feeding habits were considered in the selection of the receptors. In terms of life stages, some of the TRVs that were selected focus on specific reproductive effects that occur in females of reproductive age; these reproductive effects are seen in early life stages (*e.g.*, decreased growth, reduced fry survival, reduced hatchability, reduced time to hatching, and so on), which are typically the most sensitive endpoints. The exposure parameters are based primarily on female exposures for that reason. Consistent with USEPA's Ecological Risk Assessment Guidance for Superfund (USEPA, 1997b), the Revised ERA considers current and future exposures, as did the ERA. Future conditions evaluate year-to-year exposures for 25 years, longer than the life spans of most individual receptors. However, receptors with life spans greater than 25 years may have body burdens from prior exposure when PCB concentrations in the Hudson River were higher than they are currently. The PCB body burdens could place these receptor species at greater risk than calculated in the ERA. A complex exposure history resulting in PCB body burdens is a source of uncertainty, as discussed in Section 6.5.1.1: Food Chain Exposures of the Revised ERA.

**Comment:** The reviewers asked whether the PCB concentrations predicted by the FISHRAND model are for fish sizes similar to those consumed by the various receptor species of concern.

**Response:** In short, yes. The FISHRAND model divides fish into two broad categories: forage fish (less than 10 cm) and piscivorous fish (greater than 25 cm). Representative receptor species feeding along the Hudson River will not distinguish between specific age and size classes of fish, but rather will select fish larger or smaller than some threshold size. That is, the representative receptors will consume fish from a population of fish. For example, the bald eagle typically consumes larger fish, but among the larger fish, the eagle will not preferentially consume a particular size over another. "Large fish" represent a population of available fish to this receptor. From a modeling standpoint, the way in which fish are aggregated in FISHRAND is based on feeding preferences and strategies. For example, largemouth bass above 25 cm are all primarily piscivorous, consuming predominantly forage fish.

**Comment:** Three reviewers recommended that USEPA provide better justification for the biomagnification factors for birds (28 for Tri+ PCBs and 19 for TEQs).

**Response:** Table 3-26 of the Revised ERA presents a thorough search of biomagnification factors for fish to bird egg from the scientific literature. Section 3.6.2.5: Biomagnification Factors for Predicting Egg Concentrations presents the technical justification for the biomagnification factors selected and their associated uncertainties. The original biomagnification factors did not change for most species. The biomagnification factors that were selected represent "consensus values" for much of the work done in the Great Lakes, as reported in Kubiak and Best, 1991 and Giesy *et al.*, 1995.

**Comment:** The reviewers generally commended USEPA for selecting appropriate exposure factors, and suggested consideration of other exposure factors. Two reviewers suggested USEPA consider an area use factor less than 1 and a forage effort of less than 1. One of these reviewers suggested that USEPA consider a reasonable range of values for the area use factor and forage effort; that reviewer also suggested that the total daily ingestion rate derived for mink might be less than the actual ingestion rate. Two reviewers noted that the ERA does not consider large macroinvertebrates as a food source, so receptors that eat crayfish and blue crabs may not be adequately characterized. One reviewer questioned USEPA's assumption of a bald eagle diet of 100% fish.

**Response:** USEPA acknowledges the comment regarding its selection of appropriate exposure factors. In general, the period of exposure for the representative receptor is selected to be consistent with the period of exposure in the toxicological study upon which the specific TRV is based. With respect to the area use factor and forage effort, the Revised ERA retains values of 1 for the point estimate calculations, because it is reasonable that a receptor could use and forage entirely within the large size of the site. USEPA agrees that the total daily ingestion of fish selected for mink, which is based on studies of penned mink, may underestimate the actual ingestion rate for wild mink along the Hudson and, consequently, that their risks may be underestimated. This is a source of uncertainty discussed in Section 6.5.1.1:Food Chain Exposures of the Revised ERA.

Benthic macroinvertebrate communities are evaluated because they are a food source to fish, and ultimately for the belted kingfisher, great blue heron, raccoon, and mink. Because no significant differences in PCB concentrations were detected in the various benthic macroinvertebrates (*e.g.*, isopods, oligochaetes, mollusks), the measured PCB concentrations in benthic macroinvertebrates are considered to be representative also of crayfish and blue crab levels. However, blue crabs are scavengers and may include food from higher trophic levels (*e.g.*, fish). NYSDEC has measured PCBs in blue crabs from the Hudson River at concentrations up to 26.7 ppm. Therefore, the 1:1 assumption may underestimate PCB concentrations for, and consequently risks to, predators feeding on blue crabs.

In Section 5.9: Results of the Probabilistic Dose-Response Analysis of the Revised ERA, USEPA presents the results of considering the effect of a range of exposure intakes for the belted kingfisher, bald eagle, mink, and river otter. Exposure factors for the bald eagle in the ERA were selected after discussion with Dr. Peter Nye of NYSDEC, who has been studying the bald eagle along the Hudson River for several years. These have not been modified in the Revised ERA.

**Comment:** One reviewer noted that normalized water and food ingestion data should be presented as dimensionless. Another reviewer noted that exposure doses for the mallard could have been estimated from measured concentrations of PCB in vegetation that mallards typically consume, rather than modeled concentrations.

**Response:** The equations presented in Sections 3.6: Exposure to Avian Wildlife and 3.7: Exposure to Mammalian Wildlife have been corrected to reflect the appropriate units. Mallards were considered to consume both benthic invertebrates and vegetation as the majority of their diet. There are no data available for PCB concentrations in vegetation, thus, this pathway was modeled.

**Comment:** The reviewers asked about the number of fish tissue samples used to estimate TEQs, the spatial distribution of contaminants, the sampling plans and sample sizes, the justification for use (or non-use) of certain fish tissue data, and which benthic community data were used.

**Response:** Section 1.3: Data Sources of the Revised ERA describes the data sources that were used, as did the ERA. All the available fish data were used for the TEQ analysis. The spatial distribution of PCBs (current and future) is described in the Revised Baseline Modeling Report, based on a 21-year historical data set. The data collected as part of the Phase 2 Reassessment sampling programs are summarized in Appendix B of the ERA, and the sampling plans are referenced therein. Phase 2 fish data were of limited use in development of the FISHRAND model because all the largemouth bass were too small to be piscivorous and in fact, were smaller than their presumed prey (pumpkinseed). Detailed analyses of the Phase 2 benthic community data are presented in Appendix H of the ERA.

## 5. Responses to Question 6

The sixth charge question asked the peer reviewers to evaluate how EPA assessed effects in the ecological risk assessment, as follows:

> For field-based toxicity studies, only a NOAEL toxicity reference value (TRV) was developed because other contaminants or stressors may be contributing to observed effects. Please comment on the validity of this approach. Also, please comment on whether the general approach of using uncertainty factors (interspecies, LOAEL-to-NOAEL, and subchronic-to-chronic) is appropriate in developing TRVs that are protective of Hudson River receptor species.

**Comment:** The panel was split on this issue. Three reviewers stated that field-derived LOAELs and NOAELs can be useful inputs to ecological risk assessments, while two reviewers stated that field-derived LOAELs and NOAELs were not appropriate for use in a baseline ecological risk assessment.

**Response:** Chapter 4: Effects Assessment of the Revised ERA includes both laboratory and field-based NOAELs and LOAELs. When they were considered to be the most appropriate available study, field-derived LOAELs were used to provide the best metric for assessing ecological risks. In addition, Section 6.4: Toxicological Uncertainties of the Revised ERA acknowledges the uncertainty inherent in the use of laboratory of field-based NOAEL and LOAELs.

**Comment:** The reviewers stated that data are insufficient for deriving dose-response curves for many assessment endpoints. However, one reviewer suggested using regression models to estimate effects levels, and another suggested using meta-analyses to construct defensible dose-response curves for species that have been widely researched.

**Response:** USEPA agrees that, in most cases, sufficient data are not available to develop dose-response functions. The Revised ERA includes dose-response functions for mink and pheasant, two widely studied species (Figure 4-2). The dose-response functions were obtained from the literature and are based on the same data that were used to develop the point estimate TRVs. The dose-response function for the mink was used to assess risks to the river otter and mink, and the one for the pheasant was used to assess risks to the belted kingfisher and bald eagle.

**Comment:** Laboratory-derived NOAELs for surrogate species presented in the ERA are not recommended for developing TRVs. For example, using the chicken as a representative species for wild birds is overly conservative.

**Response:** In response to this comment, USEPA reevaluated the TRVs in the revised ERA and removed sensitive domestic species, such as the chicken.

**Comment:** Three reviewers suggested that USEPA adopt approaches other than using order of magnitude factors to account for [inter-species] uncertainty. Two reviewers recommended that using empirical data sets, while one reviewer recommended bounding the TRV estimate, with the lower limit based on dividing by an uncertainty factor and the upper limit based on multiplying by an uncertainty factor.

**Response:** In the Revised ERA, interspecies uncertainty factors are not used to develop final TRVs However, alternative TRVs, developed with interspecies uncertainty factors, are presented to illustrate the potential differences in sensitivity between test species and receptors.

**Comment:** Biases in both exposure dose calculations and TRVs can lead to excessively conservative TQs. One reviewer recommended that the ERA acknowledge the limitations of the toxicity data.

**Response:** The Revised ERA acknowledges that the toxicity data are limited for certain receptors, as did the ERA. Receptors that lacked adequate toxicity data, such as amphibians and reptiles, were not evaluated in the Revised ERA or ERA.

**Comment:** One reviewer suggested that the ERA include some information on the criteria (*e.g.*, use of accepted study protocols, appropriate statistics, and relevant sampling and analytical methods) used to select certain studies for calculating TRVs and to omit others.

**Response:** Section 4.2: Selection of Measures of Effects of the Revised ERA presents information on the criteria that were used to select appropriate studies from the toxicity studies identified during the literature search.

## 6. Responses to Question 7

Charge question 7 asked the reviewers to comment on the risk characterization in the ERA, as follows:

USEPA calculated toxicity quotients (TQs) for all receptors of concern on both a total PCB and dioxin-like PCB (TEQ) basis. Please comment on whether the methodologies used in calculating these TQs are adequately protective for these receptors.

**Comment:** The ERA should characterize risks in terms of probabilities of effects, ecological consequences, or other metrics.

**Response:** Consistent with USEPA's Ecological Risk Assessment Guidance for Superfund (USEPA, 1997b), the Revised ERA uses a TQ approach (as did the ERA), which links quantitative estimates of exposure to PCBs to specific toxicological effects observed in laboratory or field studies. This approach makes it possible to calculate acceptable exposure concentrations in the Feasibility Study.

Although dose-response functions provide more specific information about the fraction of the population likely affected, these functions do not facilitate calculations of acceptable concentrations in exposure media. In addition, there are numerous uncertainties associated with combining dose-response functions with probabilistic estimates of exposure. Both the dose-response and exposure estimates rely on distributional assumptions that may or may not be applicable to the specific receptors inhabiting numerous locations along this nearly 200-mile site, and are often poorly constrained. Nonetheless, in response to this comment, the Section 5.9: Results of the Probabilistic Dose-Response Analysis of the Revised ERA incorporates dose-response functions for mink, river otter, belted kingfisher and bald eagle to estimate the probability of effects to these representative receptors.

**Comment:** One reviewer recommended that USEPA examine a wider range of published studies for derivation of the TRVs, including those specific to dioxin. Another reviewer suggested that USEPA acknowledge the uncertainties inherent in calculating and interpreting TEQs for dioxin-like PCBs.

**Response:** As noted above in response to charge question 6, USEPA reevaluated the TRVs in the Revised ERA. For the Revised ERA, hundreds of studies from the scientific literature were examined for use in deriving the TRVs, including studies specific to dioxin. Newly published and studies noted by the peer reviewers and commenters were added to Chapter 4.

## 7. Responses to Question 8

Charge question 8 also pertained to risk characterization, as follows:

The risk characterization section of the ERA (Chapter 5, pp. 117–151) summarizes current and future risks to fish and wildlife that may be exposed to PCBs in the Upper Hudson River and current risks to fish and wildlife in the Lower Hudson River. Please comment on whether the risk characterization adequately characterizes the relative risks to ecological receptors (*e.g.*, piscivores, insectivores) posed by PCBs in the Hudson River.

**Comment:** The reviewers expressed different views on how USEPA weighted multiple lines of evidence. Several reviewers recommended that USEPA examine conflicting lines of evidence more closely.

**Response:** Multiple lines of evidence including modeled toxicity quotients, measured PCB concentrations, water and sediment guidelines, and field observations were considered. However, field data are limited for many of the receptors and much of the available data has not been conducted to assess the effects of PCBs on receptors. Therefore, field data were not weighted heavily in characterizing risk to some representative receptors. The NYSDEC field observations of 3 animals per trap night caught on the river versus 26 animals per trap night caught off the river (Mayack, 2000) suggest that smaller numbers of mink and otter are present than might otherwise be expected, supporting the conclusion that exposure to PCBs is likely to impair reproduction. One of the only pieces of field data that exists, the tree swallow study, does not conflict with the results of the Revised ERA, as the predicted toxicity quotients for this receptor were below thresholds of concern.

**Comment:** Two reviewers suggested that EPA provide more specific interpretations of field studies reviewed in the ERA. One of these reviewers questioned two apparently different interpretations of the benthic community field data.

**Response:** In Chapter 5: Risk Characterization of the Revised ERA (Chapter 5), USEPA provided additional details and more specific interpretations of the field studies. The discussions in the Revised ERA have been modified to eliminate ambiguity regarding the interpretation of benthic community field data.

**Comment:** Two reviewers suggested that field studies, rather than anecdotal information, should be cited in characterizing risks.

**Response:** Where possible, field studies from the scientific literature were used to characterize risks. However, for a number of representative receptors, the unpublished field observations from anecdotal sources (*e.g.*, professional trappers) provide the only available information, especially for the birds and mammals (except for the tree swallow). However, in response to this comment, the Revised ERA has eliminated much of the anecdotal information contained in Chapter 5: Risk Characterization of the ERA.

**Comment:** One reviewer commented that statements regarding overestimation or underestimation of risks can only be made by performing a quantitative uncertainty analysis.

**Response:** The data are insufficient to perform a quantitative uncertainty analysis. However, in the Revised ERA (Section 5.9: Results of the Probabilistic Dose-Response Analysis) a probabilistic risk analysis was performed for some receptors without using uncertainty factors. Statements regarding under or overestimation of risk are based on an understanding of the underlying uncertainty and the direction of that uncertainty in the exposure and toxicity reference value estimates. For example, the FISHRAND model has been shown to predict lipid-based fish tissue concentrations to typically within a factor of two of the data. However, the model appears to consistently underestimate rather than overestimate tissue concentrations within a factor
of two. Since toxicity quotients are linear with fish concentration, if fish body burdens are underpredicted by a factor of two, then so are the toxicity quotients, leading to a statement that risks may be underestimated.

**Comment:** The risk characterization does not consider ecological effects potentially caused by stressors other than PCBs.

**Response:** Consistent with USEPA's Ecological Risk Assessment Guidance for Superfund (USEPA, 1997b), the Revised ERA focuses on evaluating risks associated exclusively with the site-specific contaminant of concern (PCBs), which are the focus of the Reassessment, as did the ERA.

**Comment:** One reviewer suggested that ecological risks might not adequately characterized if the assessment endpoints do not include receptors that are highly exposed to PCBs or highly sensitive to these exposures (*e.g.*, osprey, crayfish).

**Response:** Based on the size and complexity of the Hudson River PCBs site, it was not feasible to evaluate all potentially important ecological effects. The approach was to assess the potential for effects related to PCB exposures in representative receptor models, rather than all possible receptors. In the Revised ERA, Section 2.6.3: Avian Receptors discusses the reasons that the bald eagle was selected as a representative receptor rather than the osprey. Section 2.6.1: Macroinvertebrate Communities discusses benthic macroinvertebrate communities, which includes crayfish, as a representative receptor because they serve as a food source for local fish and wildlife. Because no significant differences in PCB concentrations were detected in the various benthic macroinvertebrates (*e.g.*, isopods, oligochaetes, mollusks), the measured PCB concentrations in benthic macroinvertebrates are considered to be representative of levels in crayfish.

**Comment:** Two reviewers found it difficult to follow the risk characterization from its presentation in the ERA to its presentation in the Responsiveness Summary.

**Response:** The Revised ERA has been modified to combine the risk characterization into one document. However, USEPA notes that the Responsiveness Summary states (p. 1) that, for complete coverage, the ERA and the Responsiveness Summary must be used together. The risk characterization in the Responsiveness Summary revised, in part, the risk characterization in the ERA, but did not supersede it.

## 8. Responses to Question 9

Charge question 9 addressed uncertainty analyses in the ERA, as follows:

The uncertainty analysis is presented in Chapter 6 of the ERA (pp. 153–165). Have the major uncertainties in the ERA been identified? Please comment on whether the uncertainties (and their effects on conclusions) in the exposure and effects characterization are adequately described.

**Comment:** The uncertainty analysis in the ERA is strictly qualitative, and does not attempt to quantify uncertainties.

**Response:** The Revised ERA contains a quantitative uncertainty analysis in Section 6.5.2: Sensitivity Analysis for Risk Models for belted kingfisher, belted kingfisher egg, bald eagle, bald eagle egg, mink, and river otter. A full uncertainty analysis covering all species, locations, and years was not possible because would result in 1,800 individual outputs (based on running full Monte Carlo models for 25 years, eight mammals/birds plus four eggs and six fish, LOAELs and NOAELs, TEQ and Tri+ PCBs). In the Revised ERA (Section 5.9: Results of the Probabilistic Dose-Response Analysis), a more quantitative uncertainty analysis is presented where the data are available to support such an analysis.

**Comment:** Different views were expressed regarding the extent to which major uncertainties were identified. One reviewer questioned the unsupported statement in the ERA that model uncertainty is probably not significant. Another reviewer thought the ERA identified most major sources of uncertainty, but suggested that USEPA consider uncertainties associated with the assumed dietary composition of various species, particularly mink, and the assumed foraging behavior for species with large home ranges.

**Response:** As described in Section 6.5.3: Model Error of the Revised ERA, USEPA believes the model uncertainty is probably a relatively insignificant source of uncertainty, given the ability of the model to predict lipid-based PCB concentrations in fish within a factor of two of the monitoring data (USEPA, 2000a). The foraging behavior of mink is based on studies on mink in New York State (Hamilton, 1936, 1940, and 1959) and only 50.5% of its diet is assumed to come from the river (34% fish and 16.5% invertebrates). Therefore, the mink diet is considered reasonable. However, in response to this comment, a distributional analysis of mink exposure was added in Section 5.9 of the Revised ERA, which also contains information on the distributions developed for the uncertainty analysis. Exposure distributions are described in Chapter 3.

**Comment:** Two reviewers described why they thought the uncertainty analysis was confusing. One reviewer offered specific recommendations for the sensitivity analysis.

**Response:** In response to this comment, the text in Chapter 6: Uncertainty Analysis has been modified in the Revised ERA.

**Comment:** One reviewer suggested that USEPA better characterize the uncertainty associated with the assumption that BZ#126 concentrations in fish are equal to the detection limit and the uncertainty associated with inter-species toxicity extrapolations used to derive TRVs.

**Response:** These sources of uncertainty are very difficult to quantify. As documented in the Revised ERA and noted in response to charge question 4 above, the scientific literature suggests that BZ#126 is a congener more likely to be enriched than not (as compared to BZ#77, which mammalian and avian receptors are able to metabolize). Given that BZ#126 is likely to become enriched, and the assumption of BZ#126 at the detection level is clearly an overestimate of the true BZ#126 concentration, it would seem this is not an inappropriate assumption to make. If anything, BZ#126 could be present at higher concentrations in future (but BZ#77, accordingly, would be more likely to show decreased levels). Thus, the uncertainty in the assumption is likely one-sided, that is, the proportion of BZ#126 may be overestimated under current conditions but it is unknown what may happen in future.

In terms of the uncertainty associated with interspecies toxicity extrapolations to derive TRVs, some information is available. For example, studies on mammals have shown that the ratio of sensitivity of the least to the most sensitive species, on the basis of dietary dose of toxicant, ranges from 1.9 to 100 (Hayes, 1967). An interspecies uncertainty factor of ten has been proposed to account for this interspecies variability in toxicity (Dourson and Stara, 1983). A similar study on interspecies variability in birds found that the most sensitive individuals are within a factor of four of the median sensitivity for 75% of the chemicals tested, and 95% are within a factor of 10 (Hill *et al.*, 1975; USEPA 1995). A similar comparative study is not available for fish, however the range of lowest to highest LOAELs for effects of total PCBs and Aroclors on fry mortality is about 100 (Table 4-5), and the range of lowest to highest LOAELs for effects of dioxin-like compounds on early life stage mortality is 125 (Table 4-7). Uncertainty associated with the development of the TRV for the effect of total PCBs on fish may be greater than for other taxonomic groups since fewer studies are available for fish (Tables 4-5 through 4-8) than for birds (Tables 4-9 through 4-16) and mammals (Tables 4-17 through 4-22).

**Comment:** One reviewer stated that the ERA should characterize the uncertainty associated with the 19 locations of co-located sediment and benthic infauna samples, perhaps by assessing how representative these data are of conditions throughout the 200 miles of the Hudson River PCBs site.

**Response:** Section 1.2.3.1: PCBs in Sediment of the Revised ERA discusses the distribution of PCBs in the Upper Hudson River, where the highest concentrations are found. The co-located sediment data are representative of conditions, in that they show variability within an overall trend of decreasing concentrations moving downriver, which is also shown by the hundreds of other sediment samples in the Hudson River Database (USEPA, 2000d; Release 5.0). The benthic data are diverse and are believed to represent the diversity of benthic communities within the river, based on the different communities observed at various locations along the river.

**Comment:** The reviewers recommended adding discussion on the relative uncertainty in ecological data versus ecotoxicological data.

**Response:** In Section 4.2: Selection of Measures of Effects, TRVs have been revised to remove much of the uncertainty associated with them. A discussion of the relative toxicological uncertainties has been added to Section 6.4: Toxicological Uncertainties and Section 6.5: Exposure and Modeling Uncertainties has been expanded.

**Comment:** One reviewer suggested that USEPA conduct basic bounding arguments and sensitivity analyses to identify key uncertainties, particularly those that can be reduced, and then design studies to reduce major sources of uncertainty.

**Response:** No further data collection or studies have been planned for the Hudson River, thus, designing additional studies was not an option. The uncertainty in the exposure parameters was evaluated in Chapters 3 and 6. Sensitivity was evaluated through the use of a Monte Carlo model. Through this model, rank correlation as well as the contribution to variance were calculated.

## 9. Responses to General Question 1

General charge question 1 asked as follows:

> A goal for Superfund risk assessments is that they be clear, consistent, reasonable and transparent and adequately characterize risks to sensitive populations (*e.g.*, threatened and endangered species). Based on your review, how adequate are the ERA and the Responsiveness Summary when measured against these criteria?

**Comment:** The reviewers offered a number of suggestions to improve the clarity, including presentation of the ERA and the ERA Responsiveness Summary into a single report.

**Response:** The Revised ERA has been reorganized, incorporating into a single report the ERA, ERA Addendum, their associated Responsiveness Summaries, and the changes made to address peer review comments. The Revised ERA follows the standard USEPA format used for all Hudson River PCBs Reassessment reports, with tables and figures separate from the text, due to the large amount of information contained in the reports.

**Comment:** Two reviewers offered suggestions to improve the transparency of the ERA.

**Response:** The Revised EPA reflects editing to improve transparency of the report. USEPA has added background information on how USEPA selected assessment endpoints (Section 2.4), an overview of the fate, transport, and bioaccumulation modeling (Section 3.2), and the criteria used to selected studies for deriving TRVs (Section 4.2). In addition, some text has been eliminated to streamline the document. For example, only the mean exposure estimates for future exposure (1993-2018), rather than mean and 95% UCL (on the mean) estimates are presented, because they are not significantly different.

**Comment:** Three reviewers offered comments on the reasonableness of the ERA. Two reviewers stated that USEPA should not base remedial decisions on the current version of the document.

**Response:** USEPA is issuing a Revised ERA that has been rewritten, reorganized, and expanded in response to reviewers' comments on this and the other charge questions. The Revised ERA provides an appropriate framework for calculating target levels in exposure media that are protective of the environment, based on ecological receptor exposures.

**Comment:** The reviewers commented on whether the ERA is consistent with USEPA policy on ecological risk assessments. Two reviewers thought it was inconsistent with Agency policies, while another noted that it was consistent with other USEPA ecological risk assessments.

**Response:** The Revised ERA focuses on population-level risks and is consistent with USEPA policy. The sensitivity analysis has been revised and is consistent with USEPA guidance for Monte Carlo analysis.

## 10. Responses to General Question 2

General charge question 2 asked as follows:

Please provide any other comments or concerns, both strengths and weaknesses, with the ERA not covered by the charge questions, above.

**Comment:** One reviewer stated that the ERA does not account for factors that could dramatically alter the Hudson River ecosystem, such as introduction of zebra mussels. Another reviewer stated that the Responsiveness Summary occasionally provides incomplete responses by citing policy rather than technical arguments.

**Response:** As described above, Section 5.1.1.2 of the Revised ERA contains a discussion of the zebra mussel, as did the ERA. The zebra mussel is found only in the Lower Hudson River, due to the absence of suitable substrata in the Upper Hudson River. In contrast, the highest concentrations of PCBs are found in the Upper Hudson River. While the effect of the zebra mussel on PCB concentrations is unknown, it is not considered to be one of the main factors influencing PCB availability based on where it is found.

USEPA's goal of the Responsiveness Summary is to respond fully to each public comment. For convenience, a few responses may have cited Agency policy that supports the basis for a technical decision, rather than restating the technical rationale itself. However, as the risk assessment is intended to follow Agency policy to the extent practicable, citing consistency with Agency policy as a basis for a technical decision is reasonable.

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## EXECUTIVE SUMMARY

Seven independent peer reviewers critiqued the "Baseline Ecological Risk Assessment" (ERA) for the Hudson River PCBs Superfund site and the ERA's Responsiveness Summary, which were prepared as part of the U.S. Environmental Protection Agency's (EPA's) site reassessment. Of the six reviewers who attended the June 2000 peer review meeting, four found the ERA and its Responsiveness Summary to be "acceptable with major revisions," and two found the documents to be "unacceptable." During their closing statements, the reviewers unanimously agreed that EPA should not base remedial decisions on the current version of the ecological risk assessment.

During the 2-day meeting, the peer reviewers answered 11 charge questions that addressed various aspects of the ecological risk assessment. When answering these questions, the reviewers agreed on many topics (e.g., a detailed ecological context for the Hudson River is missing from the problem formulation) but had various opinions on others (e.g., the utility of toxicity quotients in a baseline ecological risk assessment). A common theme expressed throughout the peer review, however, was that the ERA provides a very conservative account of ecological risks, which the reviewers felt was appropriate for a screening-level risk assessment, but not for this baseline ecological risk assessment. Section 2.1 of this report summarizes the reviewers' responses to the charge questions and lists several recommendations for improving the ERA.

At the close of the peer review meeting, the reviewers compiled the following list of their main findings and recommendations to EPA. This list, plus additional major findings and recommendations gleaned from the reviewers' discussions follows. Specific examples of the reviewers' many other suggested revisions and recommendations can be found throughout this report.

- **Some reviewers considered the ERA to be a screening-level effort; others thought that the information currently available is sufficient for EPA to conduct an adequate baseline risk** assessment. All of the reviewers agreed, however, that the current assessment needs to be reworked.

- All reviewers commented that EPA should have included more field data—either ecological surveys of river and terrestrial biota or *in situ* toxicity data—in the ecological risk assessment. Where such field data existed, the reviewers noted that EPA did not weigh the implications of the data against the results of the TQ approach.

- All reviewers thought the assessment should have begun with an ecological survey, or at least included more direct ecological information in the conceptual model.

- The reviewers generally found the dose estimates for current exposures to be adequate, but they found it difficult to evaluate dose estimates for future exposures without having reviewed EPA's fate and transport and bioaccumulation models. The reviewers offered several suggestions for improving the exposure assessment.

- The reviewers expressed a wide range of opinions on how ecotoxicological data should be evaluated in a risk assessment. Some thought LOAELs and NOAELs derived from field studies can be useful inputs to ecological risk assessment, but others saw little utility in these thresholds. None of the reviewers thought the laboratory-derived NOAELs for surrogate species presented in the ERA were appropriate for developing toxicity reference values.

- All reviewers thought the lack of a quantitative uncertainty analysis was a deficiency in the ecological risk assessment.

- All reviewers found the organization of the reports an impediment to efficient review of the ecological risk assessment.

- Some reviewers thought more data could have been obtained with the time and resources available for this project. They thought the ERA would have been improved had it included various additional types of information, such as population data, site-specific bioaccumulation studies, *in situ* toxicity data, and ecological survey data on bivalves, decapods, fish, birds, and mammals.

## 2.0 RESPONSES TO SPECIFIC CHARGE QUESTIONS

The peer reviewers opened their discussions by addressing the nine specific charge questions pertaining to the ERA. When answering these, the reviewers engaged in free-flowing discussions, after which the technical chair summarized where the reviewers agreed and how their opinions differed. A general record of the peer reviewers' discussions on each charge question follows, and additional comments on the ERA can be found in the reviewers' responses to the two general charge questions (see Section 3). Finally, following the discussions of both the specific and general charge questions, the reviewers offered several recommendations to EPA; these are documented in Section 4.

Readers interested in only a brief overview of the reviewers' responses to the charge questions should refer to the summary presented below in Section 2.1; a more detailed account of the responses to specific charge questions can be found in Sections 2.2 through 2.9.

Note: The reviewers' initials used to attribute comments are as follows: PdF (Dr. Peter deFur), LK (Dr. Lawrence Kapustka), DM (Dr. Dwayne Moore), RN (Dr. Ross Norstrom), TT (Mr. Tim Thompson), and JT (Dr. John Toll).

### 2.1 Overview of Responses

After answering the charge questions, the reviewers prepared a brief written summary highlighting their key findings. The summary the reviewers presented at the peer review meeting, with editorial and other revisions, is presented below. An account of the discussions that led to these summary statements is provided in Sections 2.2 through 2.9.

- *Responses to Charge Question 1: Problem Formulation (see Section 2.2 for further details).* The reviewers emphasized the importance of presenting the reader a clear basis for understanding the physical, chemical, and biological processes that govern PCB uptake and ultimately risk within the receptor species selected. The problem formulation, therefore, should provide a solid foundation for the conceptual site model—upon which all other endpoints, decisions, and characterization of risk is based. The reviewers recommended that EPA address the following key issues in the final ERA:

- *Ecosystems of the Hudson River*. The reviewers unanimously agreed that perhaps the most important element lacking from the ERA is a description of the Hudson River ecosystem, including the ecological resources and their use by the human communities. Without a description of the habitats, the species occupying the Hudson River, and the spatial and temporal use of habitats by species considered in the conceptual site model, the reviewers did not think it was possible to defend the risk characterization or the selection of assessment endpoints, measurement endpoints, and modeling assumptions.

- *Conceptual site model*. There was uncertainty among the reviewers whether the species currently in the conceptual site model are representative of the Hudson River. The reviewers thought EPA might have omitted some important species, and suggested that these be considered. The reviewers agreed that the ERA does not clearly defend the reasons for selecting species of concern, and they noted that justification for the conceptual site model requires a careful description of the ecosystems, as described above, and documentation of decisions that were made for including species based upon values assigned through the Biological Technical Assistance Group (BTAG) process. The reviewers recommended that EPA better describe how it developed the conceptual site model.

- *Contaminants of concern*. The risk assessment documents how PCBs from the GE facilities have contaminated the Upper Hudson River, but the reviewers recommended that EPA discuss the impacts of other PCB sources on the system. In addition, though they recognized the specific scope of the reassessment, the reviewers thought information on other contaminants of concern in the Hudson River is needed in the ERA for perspective.

- *Nature and extent of PCBs*. Currently, the ERA draws from relatively few sediment samples over the 200-mile Superfund site, even though hundreds of additional sediment samples have been collected. The reviewers wondered if the 17 sediment samples can provide a representative account of spatial distributions of PCBs. Noting that EPA has included chemical isopleths in other Reassessment reports, the reviewers thought the ERA should present these isopleths and more thoroughly discuss the nature and extent of PCB contamination.

- *Fate and transport*. The reviewers thought the ERA describes biological fate and transport mechanisms adequately, but should have described chemical fate and transport of PCBs more thoroughly. The reviewers suggested that the ERA include a summary of key findings from the baseline modeling efforts, such as information on water and sediment transport and the physical and chemical properties that govern PCB fate. Several reviewers emphasized the importance of discussing differential uptake, biomagnification, depuration, and metabolism of the PCB congeners by the species of concern.

- *Responses to Charge Question 2: Assessment Endpoints (see Section 2.3 for further details).* The reviewers expressed different views on the appropriateness of the stated assessment endpoints. Concerns included whether the suite of endpoints and the major feeding groups and sensitive species addressed the important resources (e.g., osprey, crayfish, blue crab, zebra mussels) and the fact that several endpoints were included that are ambiguous or impossible to assess (e.g., significant habitats). The reviewers agreed that EPA used no unique measurement endpoints or species-specific analyses to evaluate the assessment endpoints that focused on endangered species.

  The reviewers generally agreed that EPA could have focused its efforts on those endpoints known to be most sensitive to PCBs and suspected of having greatest exposures had the Agency refined the conceptual site model and assessment endpoints in multiple iterations. Ultimately, the reviewers attributed the deficiencies in the assessment endpoints, in part, to limitations in the conceptual site model, which they thought narrowed the choices of measurement endpoints, constrained options for analyzing effects, and ultimately compromised the quality of the risk assessment.

  The reviewers also raised questions of process, noting that the ERA did not describe (1) how the agency solicited stakeholder input on valued resources, (2) EPA's rationale for grouping, segregating, eliminating, or "parking" potential endpoints, and (3) other critical considerations they viewed as essential to the problem formulation phase of an ecological risk assessment.

- *Responses to Charge Question 3: Measurement Endpoints (see Section 2.4 for further details).* The reviewers found that many measurement endpoints were ambiguously stated, making it difficult to evaluate assessment endpoints and impossible to conduct an appropriate uncertainty analysis. The reviewers noted that comparing sediment, water, and tissue residue values to toxicity reference values (TRVs), while an important part of the ERA, is only one independent line of evidence in a weight of evidence approach. The reviewers felt that other independent lines of evidence, such as *in situ* and ambient tests and field studies, are desirable for a weight of evidence risk assessment. The reviewers recommended that EPA discuss the intended use and weight of each of the measurement endpoints, including the population endpoints, at the beginning of the ERA. They also recommended that EPA include in the ERA all available population data for the selected receptor species on the Hudson River.

- *Responses to Charge Questions 4 and 5: Exposure Assessment (see Section 2.5 for further details).* The reviewers agreed that the exposure assessment for current conditions was generally adequate but that evaluating exposures for future conditions was difficult because of the limited information provided in the ERA. The reviewers thought, for example, that the ERA should have thoroughly summarized EPA's fate and transport and bioaccumulation modeling effort as well as the findings of the independent peer review of this modeling.

The reviewers listed numerous specific comments on the exposure assessment. For instance, some questioned EPA's use of point estimates (without presenting detailed information on variability) instead of a distributional analysis throughout the exposure assessment. The reviewers noted that several exposure assumptions are conservative, such as the assumption that the bald eagle's diet consists of only Hudson River fish and that raccoon and mink feed exclusively along the Hudson River. They added that some potentially critical elements in the aquatic food chain (e.g., crayfish in the Upper Hudson River and blue crabs in the Lower Hudson River) were ignored, which might have biased exposure calculations for species that consume these overlooked items. Finally, they questioned the use of 95% upper confidence limits (UCLs) for cases in which true statistical normality of the data was not adequately demonstrated.

The reviewers also questioned assumptions EPA made to process congener-specific data for calculating toxic equivalents (TEQs). They noted that assigning BZ#126 concentrations equal to the detection limit is conservative, given that this congener was not detected in roughly half the samples collected. The reviewers added that this assumption might lead to considerably higher exposure estimates, because BZ#126 accounts for a large fraction of TEQs in several species. The assumption that TEQs bioaccumulate was also criticized, since PCB congener patterns are known to alter as they bioaccumulate, especially at higher trophic levels. The reviewers suggested that EPA reevaluate several other assumptions: use of invariant TEQ to Tri+ PCB[3] ratios at all trophic levels; assigning a fixed congener profile to Tri+ PCBs over the modeling forecast period; and reliance on biomagnification factors for birds (i.e., 28 for Tri+ PCBs and 19 for TEQs) that have not been defended in the open literature. The reviewers thought the ERA could have drawn from additional congener-specific bioaccumulation data for PCBs documented in the scientific literature.

- *Responses to Charge Questions 6: Effects Assessment (see Section 2.6 for further details).* Some reviewers felt that using TRVs derived from lowest-observed-adverse-effect levels (LOAELs) and no-observed-adverse-effect levels (NOAELs) was inappropriate for this assessment, while others felt that appropriate receptor-specific field-based NOAELs have the advantage of not relying on a lab-to-field extrapolation. The reviewers agreed, however, that EPA should have used dose-response curves, where possible, instead of NOAELs and LOAELs. The reviewers also felt that avian TRVs based on chicken studies were inappropriate and too low, primarily because chickens are at least an order of magnitude more sensitive to PCBs than other bird species. Most panel members believed that uncertainty factors should not be applied in deriving TRVs in this assessment.

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[3] "Tri+ PCBs" is a term used throughout this report. It refers to the subset of PCB congeners having three or more chlorine atoms attached. This subset of congeners was the focus of much of EPA's baseline modeling efforts and of the ecological risk assessment.

- *Responses to Charge Question 7: Risk characterization (see Section 2.7 for further details).* The peer reviewers agreed that the toxicity quotient (TQ) calculation methodologies in the ERA—though commonly used in risk assessment—are, by their conservative design, protective of the ecological risk receptors. They added that the TQs calculated in the ERA probably are overprotective, in the sense that the probability of a false negative conclusion (i.e., little likelihood of underpredicting risks) is very low, and the probability of a false positive conclusion (i.e., likelihood of overpredicting risks) is high. The reviewers felt that the exposure dose calculations and TRVs used in the TQ calculations both may have been very conservative.

  The reviewers felt that risk assessments should generally strive to portray and describe risks accurately and that striving to be protective is a risk management function. They thus found that use of conservative dose and toxicity estimates that likely overstate risks is best for preliminary risk screening but not appropriate for a detailed study that EPA will use to support remedial decisions. Some reviewers believed that use of conservative risk estimates will create a misconception if a detailed risk assessment later concludes that risks are lower, even if such a risk assessment is more defensible. Noting that the TQ approach does not provide information about how risks would change if exposures were reduced, the reviewers advocated the use of dose-response curves and population response models, where available, to support remedial decisions.

  Two specific recommendations that came out of the panel's discussion on this question were that EPA should use Peterson's pheasant data to derive more realistic TRVs. Some reviewers felt that EPA should calculate TEQs for exposures to dioxins and furans. Additionally, one reviewer made the point that the TEQ methodology used in the ERA is incomplete, overly conservative, and not scientifically defensible; another reviewer, however, defended the use of this methodology.

- *Responses to Charge Question 8: Risk Characterization (see Section 2.8 for further details).* The reviewers did not think the ERA adequately characterizes the magnitude and nature of PCB risks to ecological receptors in the Hudson River, and raised a variety of concerns on this issue. The reviewers generally agreed that field observational data were inappropriately discounted, and could be used better to characterize relative risks to ecological receptors. One reviewer stated that EPA had adequate information available to characterize relative risks, but that TQs are insufficient for the task because they do not provide information about how changing exposure levels would change risks. Using dose-response and population response models would provide a much better basis for estimating relative risks. Other concerns included: failure to account for effects due to multiple stressors (an issue of particular concern for interpreting the benthic community data), the need for a more in-depth review of the literature on PCB toxicity, consideration of literature on *in vitro* and *in vivo* inter-species sensitivity to derive more realistic effects estimates, and internally inconsistent interpretations of the field data on benthic community structure.

- *Responses to Charge Question 9: Uncertainty Analyses (see Section 2.9 for further details).* The reviewers thought the qualitative discussion of sources of uncertainty in the ERA was useful, but they noted that some sources of uncertainty were not adequately discussed or were understated (e.g., errors and uncertainties in the fate and transport and bioaccumulation models and in the TEQ approach). As an example of their concern, the reviewers thought the ERA overstates the uncertainty associated with field-based studies, while understating the uncertainties associated with the TRV-based line of evidence. Additionally, several reviewers found statements in chapter 6 indicating low uncertainty for hazard quotients for various assessment endpoints misleading; they noted that use of different, reasonable assumptions could have produced considerably lower quotients.

  Many reviewers agreed that EPA should have performed a quantitative sensitivity and uncertainty analysis in this assessment. They recommended that such analyses follow the guidance and reporting practices outlined by EPA in "Guiding Principles for Monte Carlo Analysis."

- *Responses to General Question 1: Clarity, Consistency, Reasonableness, and Transparency (see Section 3.1 for further details).* The reviewers did not think the ERA and its Responsiveness Summary achieved the goals of clear, consistent, transparent and reasonable to the extent they thought possible. They thought the large amount of information presented in multiple sources, particularly information split between the ERA and Responsiveness Summary, was an impediment to comprehension. Given the organization and limited content of the documents, the reviewers had difficulties following certain lines of evidence, reasoning, and assumptions in the ERA because specific information (equations, modeling inputs, selection criteria, and so on) was either not included or was contained in background documents that were not available. To improve the presentation, the reviewers suggested that EPA reorganize the information in such a way that makes the whole assessment clearer and more transparent and that EPA delete repetitive explanatory material, achieving some shortening. The reviewers found the conclusions of the ERA were not adequately supported by the evidence presented; thus, some reviewers did not find key findings in the report reasonable.

## 2.2 Responses to Question 1

The first charge question asked the peer reviewers to comment on the problem formulation and conceptual model of the ecological risk assessment:

> Consistent with USEPA guidance on conducting ecological risk assessments (USEPA, 1997), the problem formulation step establishes the goals, breadth, and focus of the assessment. As part of the problem formulation step in the ERA, a site conceptual model

**was developed (Chapter 2.3, pp. 11–19). Please comment on whether the conceptual model adequately describes the different exposure pathways by which ecological receptors could be exposed to PCBs in the Hudson River. Was sufficient information provided on the Hudson River ecosystems so that appropriate receptor species could be selected for exposure modeling?**

The reviewers agreed that the conceptual model used in EPA's ecological risk assessment lacked focus on the Hudson River's ecological resources, but they had differing opinions on how the construct of the conceptual model affects the quality of the risk assessment. One reviewer commented that the conceptual model, though generic, is probably adequate for the risk assessment (TT); another reviewer agreed that the conceptual model might be adequate, but only as a generic conceptual model that appropriately identifies food web transfer as an important exposure pathway for PCBs (PdF); similarly, other reviewers thought the conceptual model seemed appropriate for a screening-level assessment (LK,DM,JT); and others added that the ERA does not provide enough information to determine if the conceptual model is adequate (LK,RN). A detailed account of the reviewers' specific comments follows:

- *Lack of information on site-specific ecological resources.* One reviewer indicated that the risk assessment's problem formulation lacks a clear description of ecological resources along the Hudson River—an omission he considered a serious shortcoming of the ecological risk assessment (LK). This reviewer explained that the problem formulation step of an ecological risk assessment needs to include spatial and temporal characterization of habitats, ecological resources, and environmental contamination, such that these factors can be appropriately integrated into a meaningful conceptual model. Noting that the problem formulation presented in the ERA does not fully consider these factors, this reviewer was concerned that EPA's ecological risk assessment relies on a generic conceptual model with little focus on conditions that may be unique to the Hudson River ecosystem.

  At some point in the discussion, every other peer reviewer agreed that the ERA does not thoroughly describe ecological resources along the Hudson River. They offered various insights on this issue. One reviewer, wondering if the ERA's lack of ecological context merely resulted from the fact that EPA organizes information into multiple reports, suggested that EPA compile all information relevant to the ecological risk assessment into one document (TT). Further, several reviewers were concerned that the selection of receptor species might not have been adequate, given the lack of ecological context in the ERA (PdF,LK,DM)—an issue discussed in greater detail below.

- *Use of a more focused approach to selecting receptor species.* The reviewers offered several different comments on the approach EPA took to selecting receptor species, but most reviewers agreed that the approach, as documented in the ERA, lacked focus. For example, one reviewer thought EPA should not have simply selected representative species from different trophic levels; rather, he thought, EPA should have selected receptor species by reviewing and weighing the factors most relevant to ecological risk, such as trends in PCB contamination, ecological resources in the Hudson River, and studies on how PCBs biomagnify in the food chain (DM). This reviewer noted that such an approach could have led to a much shorter list of species to evaluate, thus allowing EPA to assess ecological risks to each species more thoroughly, and with a true weight of evidence approach.

  Other reviewers agreed that a more thorough consideration of the ecological context was needed to select appropriate receptor species (PdF,LK,JT). One reviewer explained that, if EPA had a well-defined ecological context, the agency could have stepped through the entire range of species and documented briefly why each species was or was not selected (LK). Using such an approach, this reviewer argued, EPA could have focused its assessment on the species that are most exposed to PCBs and most sensitive to this exposure. Agreeing with this sentiment, another reviewer stressed that a more thorough problem formulation would have resulted in a more focused list of receptor species, not necessarily a longer one (JT). Summarizing these comments, a reviewer indicated that it was unclear from the ERA whether EPA considered sufficient information (i.e., a complete ecological context) to select appropriate receptor species for the risk assessment (PdF).

  As a specific example of potential flaws in EPA's selection of receptor species, several reviewers discussed whether the risk assessment should have explicitly considered the osprey (PdF,DM,RN). One reviewer noted that an appendix to the ERA indicates that the osprey was not evaluated because anecdotal information suggests that they are rarely seen in the Upper Hudson River (RN). Another reviewer argued, however, that the apparent presence or absence of a species should not weigh too heavily in the selection of assessment endpoints; he explained that the Upper Hudson River might actually be a suitable habitat for ospreys but some other factor might prevent them from nesting there (DM). Other reviewers agreed, again indicating that a more detailed ecological description (e.g., a habitat evaluation or an assessment of historical osprey population trends) is needed in the ERA problem formulation to select receptor species (PdF).

  (When responding to charge question 2, the reviewers provided additional specific comments on the species that EPA selected for the risk assessment. These comments are summarized in Section 2.3.)

- *Consideration of "valued species" in the conceptual model.* The reviewers had differing opinions on the extent to which the ecological risk assessment addresses valued species. For instance, one reviewer indicated (LK), and another agreed (PdF), that the problem formulation does not appear to capture the communities' and stakeholders' interests. This reviewer acknowledged that risk assessments need not have lengthy accounts of community values, but he suggested that the ERA should at least document the process by which EPA weighed the values expressed by the BTAGs, other stakeholders, and the community.

  On the other hand, another reviewer commended EPA for identifying in the ERA stakeholders and other interested parties and the process by which their opinions were solicited and incorporated into the problem formulation (JT). Specifically, this reviewer noted that EPA held technical and public meetings to discuss the risk assessment problem formulation with various stakeholders, though he added that the ERA did not clearly indicate how the content of problem formulation discussions varied between the technical and public meetings. This reviewer thought the ERA likely accounts for valued species, given the fact that public comments on the ecological risk assessment did not recommend that EPA evaluate additional species.

- *Incorporating PCB chemical, physical, and biological properties into problem formulation.* Three reviewers indicated that the problem formulation should have included more information on how PCBs—and PCB congeners—behave physically, chemically, and biologically (LK,RN,JT). For instance, one reviewer indicated that the problem formulation does not provide extensive information on differential uptake and depuration of PCBs by the various receptor species in the Hudson River (JT). Another reviewer agreed, and added that the ecological risk assessment makes many assumptions that are inconsistent with what is known about environmental and biological fate and transport of PCBs (RN). Specifically, this reviewer questioned the assumptions that the composition of "Tri+ PCBs" does not change with time or across different trophic levels and that PCB exposures and bioaccumulation can be assessed as Aroclor 1254, though the original source was primarily Aroclor 1242. Though these reviewers agreed that the problem formulation step for an ecological risk assessment need not analyze fundamental chemical, physical, and biological properties, they did indicate that the problem formulation must at least reflect a basic understanding of PCB environmental and biological fate and transport processes (LK,RN).

- *Other issues pertaining to the conceptual model.* The reviewers identified several other issues they thought should have been considered in the problem formulation step of the ecological risk assessment. For instance, two reviewers thought potential exposures to contaminated floodplain soils should have been considered in the conceptual model (DM,JT). (Later in this discussion, EPA clarified that their conceptual model acknowledges that exposures to PCBs in floodplain soils might occur. EPA stated that this issue was not explicitly evaluated in the risk assessment, because the site reassessment focuses explicitly on evaluating how the PCB-contaminated sediments affect human health and the environment. One of the reviewers [JT] clarified that he believed the floodplain soils should have been considered in the conceptual model as a source contributing to sediment PCBs.)

On another issue, two reviewers questioned why EPA's conceptual site model artificially constrains the risk assessment to the main channel of the Hudson River, given the fact that many receptors (e.g., birds, mammals, and fish) may use a far broader range of habitat (LK,RN). These reviewers were concerned that the risk assessment, with its current spatial construct, becomes too narrow in scope. As examples of this concern, one reviewer noted that the risk assessment does not consider the fact that many fish species may forage and spawn in tributaries to the Hudson River, which should be factored into the exposure calculations (LK); another reviewer noted that bald eagles, though found to nest in the Hudson River valley, might forage only to a limited extent in the main channel of the Hudson River—an issue he too thought should be considered when evaluating exposures (RN).

Other issues that reviewers thought EPA should have addressed in greater detail in the problem formulation and conceptual model include the following: one reviewer thought the risk assessment should consider PCBs from all sources, not just from the GE facilities (JT); the same reviewer suggested that the problem formulation acknowledge the influences that other chemical and physical stressors might have on ecological risk and note the fact that risks will change with location along the Hudson River as the PCB congener mix changes; another reviewer suggested that the problem formulation include more information on environmental fate and transport in order to provide the reader with greater understanding of the physical distribution and physical fate and transport of contaminated sediments (TT).

## 2.3 Responses to Question 2

The second charge question asked the peer reviewers to comment on EPA's selection of assessment endpoints:

> Assessment endpoints specify the valued ecological resources to be protected, such as local fish populations. They focus the risk assessment on particular components of the ecosystem that could be adversely affected by contaminants from the site. Please comment on whether the assessment endpoints selected (pp. 19–20) adequately protect the important ecological resources of the Hudson River. Are major feeding groups and sensitive species sufficiently covered by the selected assessment endpoints?

The peer reviewers gave various responses to this question. Generally, their responses addressed how some of them would have selected assessment endpoints differently, what they thought about specific assessment endpoints, and what consideration should be given to ecological resources that might not be adequately protected by EPA's risk assessment. Specific examples of these comments, organized by topic, follow:

- *General comments on EPA's selection of assessment endpoints.* The reviewers expressed a wide range of general opinions on the assessment endpoints documented in the ERA. For instance, referring to his comments on charge question 1 (see Section 2.2), one reviewer reiterated that selection of assessment endpoints would have been more effective had EPA focused its efforts on identifying species that had the highest exposures to PCBs and were most at risk for PCB-related effects (DM). He added that the analyses in the ERA are quite repetitive and could have been more focused with a shorter list of assessment endpoints, such as "protection and maintenance of benthic, fish, avian, and mammalian populations." Another reviewer agreed, noting that many assessment endpoints are either inadequate or not supported by appropriate measurement endpoints (as described in detail in the following bulleted items); he referred to his premeeting comments for an example of selecting appropriate assessment endpoints that are supported by meaningful measurement endpoints (LK). This reviewer stressed that clearly articulated assessment endpoints are critical to establishing appropriate measurement endpoints and characterizing ecological effects.

- *Adequate selection of receptor species and ecological resources.* The reviewers provided various comments on the species that were and were not specifically addressed in the assessment endpoints. A common theme among these comments was that the ERA did not provide enough information for the reviewers to comment thoroughly on how EPA selected receptor species. Of particular concern was that EPA failed to document the species that were *not* selected and explain the rationale for not selecting them (RN). Regarding the species evaluated in the ERA, one reviewer thought EPA appropriately selected several species (e.g., bald eagle, mink, river otter, tree swallow, heron), but he wondered why EPA did not select other species (e.g., snapping turtle and osprey) for which studies have documented PCB-related effects in other ecosystems (RN). Similarly, other reviewers wondered why EPA did not select crayfish (PdF) and smallmouth bass (LK) for the assessment. One reviewer noted that crayfish seemed to be an appropriate species to select, given their presence in the Hudson River and the fact that their eggs, which might lie in PCB-contaminated sediments, might be sensitive to developmental and reproductive toxins (PdF). Because of the omission of crayfish and any other macroinvertebrate from the ERA, this reviewer wondered if the conceptual model overlooked a whole guild that represents a unique type of trophic transfers.

Another reviewer thought foraging behavior should have weighed more heavily in EPA's selection of receptor species (DM). Specifically, he questioned EPA's selection of receptor species that likely do not spend a lot of time foraging in the main channel of the Hudson River (e.g., bald eagle), and suggested that the agency should have instead focused on species that are known to forage more exclusively in the Hudson River or have restricted home ranges (e.g., kingfishers). (Note, EPA clarified that it did consider the belted kingfisher in the ERA.) He added that considering those species that forage primarily in the Hudson River would eliminate the need to introduce uncertain assumptions in the exposure assessment.

One reviewer provided different insights on this issue. Based on his review of the public's comments on the ERA, as documented in the Responsiveness Summary, he noted that the public and stakeholders apparently did not suggest that EPA add more assessment endpoints to the risk assessment, which gave him confidence that the assessment endpoints protect valued resources (JT). This reviewer added, however, that commenting more specifically on the stakeholders' interests was difficult because the risk assessment does not document the outcomes of Biological Technical Assistance Group (BTAG) and public meetings.

- *Protection of critical habitats as an assessment endpoint.* One reviewer questioned whether EPA truly assessed "protection of significant habitats" in the ERA (DM). He explained that the ERA addressed this endpoint solely by evaluating risks to biota within selected habitats using toxicity reference values (TRVs), but not by evaluating how PCBs could cause increased habitat fragmentation, alteration of physical characteristics of habitats, or any other outcome more representative of the entire habitat. He noted that merely assessing risks to species of concern does not adequately characterize risks to habitats.

  Other reviewers also questioned the utility of this assessment endpoint, noting that the ERA fails to explain why the "critical habitats" are truly valued (PdF,LK,TT). One reviewer then listed several reasons why habitats may be considered "critical": certain valued species may occupy the selected habitat, trustees may be concerned about fragmentation, or potential remediation decisions might lead to physical disruption of the habitat (LK). This reviewer indicated that the risk assessment's conceptual model needs to explain clearly why the selected habitats are valued as critical, so that this assessment endpoint can then be supported by meaningful measurement endpoints. Another reviewer concluded that "protection of critical habitats" is not sufficiently specific to be an assessment endpoint (PdF).

- *Protection of threatened and endangered species as an assessment endpoint.* Though peer reviewers acknowledged the cultural and societal value placed on protecting threatened and endangered species (PdF,JT), three reviewers thought EPA did not evaluate this assessment endpoint in any important or meaningful way (LK,DM,JT). For instance, one reviewer explained, the analyses of risks to shortnose sturgeon (a threatened species) were essentially identical to those for other species (DM); he added that EPA could have conducted more detailed analyses of shortnose sturgeon using data sets identified by Larry Barnthouse during the observer comment period (see Appendix F). In short, this reviewer argued that the assessment endpoint of protecting threatened and endangered species was not supported by appropriate measurement endpoints. Another reviewer agreed that the ERA lacked unique analyses of risks to threatened and endangered species, particularly for the shortnose sturgeon, though he acknowledged that EPA included some specific analyses for the bald eagle (PdF).

- "*Benthic community structure as a food source for local fish and wildlife*" *as an assessment endpoint.* Three reviewers provided different opinions on EPA's selection, as an assessment endpoint, of benthic communities as a food source. One reviewer thought this assessment endpoint was not clearly stated, given that the measurement endpoints and risk characterization do not, in turn, address the extent to which the benthic community serves as a food source to higher trophic levels (DM). He said, and another reviewer agreed (PdF), that the analyses performed seemed more consistent with an assessment endpoint of protection and maintenance of local benthic and invertebrate communities.

Another reviewer agreed with these comments, and added others (LK). His comments centered, however, on the fact that this assessment endpoint is not clearly coupled with the valued ecological resource (which he suspected was fish populations). Specifically, this reviewer noted that the ERA does not specify whether EPA places value on the benthic communities or on fish populations. If value is placed on fish populations, this reviewer argued, the risk assessment should characterize whether PCB contamination causes changes in the benthic communities (e.g., population estimates, levels of PCB contamination) that, in turn, affect the fish population. If benthic communities themselves are valued, however, he wondered if EPA would base a remedial decision solely on perceived risks to the benthic population. This reviewer stressed that assessment endpoints ultimately need to be selected to support public policy decision making, and he was not certain whether this assessment endpoint meets that criterion.

Indicating that he believes a thriving benthic community has intrinsic value, another reviewer commented that the assessment endpoint addressing benthic communities is appropriate (TT). To support his comment, this reviewer argued that the various species in the Hudson River, from benthic invertebrates to fish, should all be protected. He added that this particular assessment endpoint emerged from the BTAG process and thus likely represents some societal value. Another reviewer agreed that including benthic communities in the assessment endpoints is appropriate, noting that there is "nothing intrinsically invaluable" about maintaining benthic communities, though he acknowledged that society tends to place greater value on species in higher trophic levels (PdF).

- *Use of the term "protection" in assessment endpoints.* One reviewer questioned using the term "protection" in the assessment endpoints, noting that protection is not a biological property or ecological condition that can be measured, but rather a management or regulatory activity (LK). He, and another reviewer (DM), noted that the main goal of an ecological risk assessment is to understand risks and determine whether problems exist, after which stakeholders and risk managers decide whether protection or some other action is necessary. As a result, one reviewer wondered why charge questions 2 and 7 address protection—he thought a risk assessment should instead focus on characterizing risk. Another reviewer added that the concept of protection applies to screening level risk assessments, but not to analyses that attempt to characterize actual risks for remedial decision-makers, because of the potential costs and ecological impacts of excessive remediation (JT).

- *Additional comments.* The reviewers raised several additional comments when responding to charge question 2. For instance, referring to an example of assessment endpoints presented in one reviewer's premeeting comments (LK), the reviewers debated whether assessment endpoints should address specific species (e.g., largemouth bass) or groups of species (e.g., benthivorous fish, pelagic fish, insectivorous birds) (LK,TT). One reviewer suggested that an assessment endpoint should be broad, possibly addressing groups of species with similar feeding behaviors (TT). The other reviewer agreed, but noted that assessing risks to an entire guild or trophic group demands a much more comprehensive list of measurement endpoints and presents particular challenges for conducting toxicity assessments (LK).

  Finally, one reviewer made a correction to an issue raised in Table 1 of his premeeting comments (see Appendix C) (JT). Based on an article recently published in *Environmental Toxicology and Chemistry*, which presents a meta-analysis of sediment quality thresholds, this reviewer now believes that the statement, "Washington State sediment management standards are for Puget Sound sediments and wouldn't be applicable to the Hudson River," might be incorrect. He said the Washington standards are probably applicable to the Hudson River.

## 2.4 Responses to Question 3

The reviewers then answered the third charge question, which addressed EPA's selection of measurement endpoints:

> Measurement endpoints were used to provide the actual measurements used to estimate risk. Please comment on whether the combination of measured, modeled, guidance, and

observational measurement endpoints used in the ERA (pp. 20–29) supports the weight of evidence approach used in the ERA.

The following bulleted items summarize the reviewers' responses to this question, which focused primarily on whether the available data can support a weight of evidence approach to assessing ecological risk, whether EPA used such an approach, and what ambiguities exist in the measurement endpoints:

- *Whether the available data can support a weight of evidence approach.* The reviewers had different opinions on this issue: one reviewer argued that the available environmental and ecological data for the Hudson River are not adequate to support a weight of evidence approach (DM), and other reviewers indicated that the available data can support a "partial" (JT,TT) or "weak" (LK) weight of evidence approach. Detailed examples of the different viewpoints follow. (Note, the reviewers' comments on whether EPA truly conducted a weight of evidence analysis from the available data are presented in the next bulleted item.)

  The reviewer who did not think the available data support a weight of evidence approach explained that weight of evidence analyses typically draw from three independent lines of evidence: *in situ* toxicity tests, comparison of chemical measurements to toxicologic data, and evaluation of field biological surveys (DM). In this case, said the reviewer, biological surveys are available for only a few assessment endpoints and no *in situ* toxicity tests have been performed. He acknowledged that sufficient data are available for conducting toxicologic evaluations, but he argued that the evaluations presented in the ERA comparing estimated exposure doses to TRVs were suitable only for a screening-level ecological risk assessment. This reviewer indicated that more refined toxicologic evaluations would have considered, for example, comparing distributions of exposure doses to an entire corresponding dose-response curves. Based on these arguments, this reviewer thought the measurement endpoints are not sufficient to support a weight of evidence approach.

  The reviewers who thought the available data are sufficient to support a "partial" or "weak" weight of evidence approach had slightly different opinions on the topic. For instance, one reviewer argued that the available sediment sampling data, fish tissue sampling data, tree swallow data, fish population data, and data from other studies are sufficient for conducting an adequate baseline ecological risk assessment using a weight of evidence approach (TT), though he acknowledged that all sources of data were not thoroughly evaluated in the ERA (see the next bulleted item) and that other studies should have been conducted to provide a more complete account of ecological risks. This reviewer stressed that comparing measured surface water, sediment, and fish tissue sampling data to appropriately selected TRVs is a valid component in a weight of evidence approach.

Another reviewer agreed that the available data support a "partial" or "weak" weight of evidence approach: the measurement endpoints clearly address two independent lines of evidence for some assessment endpoints and therefore provide the basis for conducting a limited weight of evidence analysis (JT). This reviewer questioned, however, whether EPA truly weighed the different lines of evidence in the few cases where they were available (see the next bulleted item). Similarly, another reviewer questioned EPA's approach to weighing multiple and inconsistent lines of evidence, as described below (LK). This reviewer identified significant data gaps, such as population dynamics or other independent ecological metrics, that should have been filled to determine whether risks estimated from the theoretical toxicologic evaluations are meaningful. Without these supportive or confirmatory independent lines of evidence, this reviewer thought, the ERA is not based on a complete weight of evidence approach.

During this discussion, another reviewer suggested that EPA's analysis might have benefitted from a comparison of the abundance, diversity, and reproductive success of Hudson River species to the same characteristics for organisms in a river without extensive PCB contamination (RN).

- *Whether EPA conducted a weight of evidence analysis from the available data.* Citing various reasons, the reviewers generally agreed that the ERA does not present a weight of evidence approach. First, one reviewer indicated that the ERA fails to mention some sources of data, particularly fish population data for the Lower Hudson River, that appear to be relevant to a weight of evidence approach (TT). This reviewer suggested that EPA either include such data in the risk assessment or justify why they are being excluded. Another reviewer agreed that EPA should incorporate all existing data into the ecological risk assessment, but he maintained that the available data do not include extensive field biological surveys or any *in situ* toxicity tests, and are therefore not sufficient for conducting a thorough weight of evidence analysis (DM).

  Several reviewers commented that EPA did not weigh the multiple lines of evidence, in the few cases in which they were available (PdF,LK,DM,JT,TT). For example, one reviewer indicated that the ERA apparently dismisses certain field data, such as data collected on the benthic communities and fish populations, from the conclusions (LK). This, said the reviewer, results in a risk assessment that essentially relies on a single line of evidence (i.e., toxicologic evaluations) that was applied multiple times. Noting that the toxicologic evaluations in the ERA are based on a number of assumptions and uncertainties, this reviewer suggested that conclusions drawn from TQs need to be supported by a more robust characterization of ecological risks, drawing from independent lines of evidence. Another reviewer referred to EPA's conclusions on risks to tree swallows (see ERA, page 175) as a specific example of how the risk assessment relied on a single line of evidence even when multiple lines of evidence were available (JT). This reviewer argued further, and another reviewer agreed (DM), that in cases where multiple lines of evidence were available, EPA tended to base its conclusions on the lines of evidence indicating the greatest potential of effects occurring, rather than weighing the sometimes contradictory outcomes of multiple lines of evidence. Agreeing with these comments, another reviewer indicated that the ERA does not adequately justify why certain lines of evidence are dismissed (PdF). This reviewer thought EPA should have provided more sophisticated analyses to examine inconsistent findings between multiple lines of evidence, rather than dismissing information.

The reviewers offered several suggestions for how EPA can use a weight of evidence approach in the ERA. First, several reviewers indicated that methodologies for evaluating measurement endpoints from multiple lines of evidence have been published both in reports prepared by environmental agencies (e.g., Environment Canada, 1999) and in the scientific literature (e.g., Hill, 1965; Menzie et al., 1996) (PdF,LK,DM). Second, a reviewer noted that weight of evidence approaches specifically for evaluating contaminated sediments have been formalized in a series of publications (Chapman, 1986; 1990; 1996) (DM). Third, this same reviewer indicated that weight of evidence approaches have been successfully applied to ecological risk assessments of other rivers with contaminated sediments (e.g., the Clark Fork River, Clinch River, and East Fork Poplar Creek), as documented in his premeeting comments (see Appendix C).

- *Ambiguity of measurement endpoints.* Several reviewers commented that some of the measurement endpoints in the ERA lacked specificity, and they offered different opinions on how this might have affected the quality of the risk assessment (PdF,LK,JT). For instance, one reviewer noted that many of the measurement endpoints in the ERA simply restate their corresponding assessment endpoints, without clearly stating what was to be measured (LK). He suspected this ambiguity in the measurement endpoints was likely an outcome of a poorly crafted conceptual model.

Commenting more specifically, one reviewer questioned whether the measurement endpoints were sufficient for identifying PCB-related effects that occur at the most sensitive life stages, particularly early life stages (PdF). This reviewer explained that recent studies have documented PCB-related developmental effects in various species, including a study that found PCB-related mortality effects at very early life stages (e.g., at the egg stage) in both fish and birds in the Great Lakes. Further, he indicated that his own research has not only found that different species exhibit a wide range of exposures to environmental contaminants, but also that individuals within a given species have exposures that vary with season and life stage. Given these findings, this reviewer indicated, and another agreed (LK), that measurement endpoints in the ERA should have been more focused on the PCB-related effects and exposure trends of greatest significance, as documented in the literature. Summarizing this comment, another reviewer explained that measurement endpoints need to consider the life stages when exposures to PCBs are greatest and PCB-related effects are most likely (LK).

Agreeing that many measurement endpoints are ambiguous, both spatially and temporally, another reviewer commented on how the ambiguity relates to conducting uncertainty analyses (JT). He gave a specific example: a measurement endpoint for protecting and maintaining local fish populations reads "measured and modeled TEQ-based median and $95^{th}$ percentile PCB concentrations in water compared to NYSAWQC [New York State Ambient Water Quality Criteria] for the protection of benthic aquatic life." This measurement endpoint does not specify the level of spatial and temporal averaging, whether the ambient water quality criteria are for acute or chronic exposures, which river segments are considered saline, and so on. This reviewer referred to a table in his premeeting comments (see Appendix C) for additional examples of his concern regarding the ambiguity in the measurement endpoints (JT).

- *Additional comments on measurement endpoints.* Several reviewers provided additional comments on EPA's selection of measurement endpoints. First, noting that EPA's fate and transport models estimated future concentrations of only Tri+ PCBs and not for a large number of representative congeners, one reviewer was concerned that measurement endpoints involving TEQ analyses could not be calculated accurately, thus limiting the accuracy of the effects assessment using TRVs (RN). This reviewer was also concerned about the uncertainties introduced by applying the World Health Organization's TEFs for fish and avian species, given the large amount of inter-species variability in the sensitivity to PCB exposure. Finally, this reviewer thought EPA should have considered impacts of other chemical stressors (e.g., dioxins and furans) in the measurement endpoints. Note, additional comments on the TEQ analyses are documented in the responses to charge question 7 (see Section 2.7).

During this discussion, other reviewers debated the utility of toxicity studies conducted in other river systems for assessing risks to species in the Hudson River. Specifically, one reviewer commented that the lack of site-specific toxicity assessments are a significant data gap in the ecological risk assessment (DM). Another reviewer questioned whether such toxicity assessments need be conducted on every site and whether, as an example, findings from a study in which fish from the Saginaw River were fed to minks can be applied to the Hudson River (TT). In response, the other reviewer indicated that site-specific data are always preferable, since the mixture of environmental contaminants and the presence of other stressors vary from one ecosystem to the next (DM). Other reviewers did not comment on this specific issue, but the reviewers, when answering charge questions 6 and 7 (see Sections 2.6 and 2.7) debated the pros and cons of using various types of studies to derive TRVs.

## 2.5 Responses to Question 4 and 5

In their discussions, the reviewers responded to charge questions 4 and 5 at the same time. The fourth charge question addressed the exposure assessment in the ERA:

> USEPA used several avian and mammalian exposure models to evaluate the potential risks due to PCBs (see, ERA, pp. 37–71). Sampling data from USEPA, NOAA, NYSDEC, and USFWS collected from 1992–1996 were used to estimate current fish body burdens and dietary doses to avian and mammalian receptors. Future concentrations of PCBs were derived from USEPA's fate, transport, and bioaccumulation models, which are the subject of a separate peer review. Concentrations of PCBs in piscivorous bird eggs were estimated by applying a biomagnification factor from the literature. Please comment on the appropriateness and sufficiency of this approach to estimate ecological exposure to PCBs.

The fifth charge question also pertained to the exposure assessment documented in the ERA, and asked the reviewers:

> Have the exposure assumptions (ERA, pp. 46–66 and Appendices D, E, and F) for each fish and wildlife receptor been adequately described and appropriately selected? Please discuss in detail.

In general, the reviewers agreed that estimates of current PCB exposures are based on a large volume of reliable site-specific environmental sampling data, but they also generally agreed that estimates of future exposure concentrations are difficult to evaluate without having reviewed EPA's baseline modeling efforts. Most reviewers indicated that EPA's selection of exposure factors was generally appropriate, but some reviewers listed cases in which more appropriate (and less conservative) exposure factors should have been used. A detailed account of these and other comments follows:

- *Accounting for variability in the exposure dose calculations.* Several reviewers' comments addressed the variability in key parameters of the exposure dose calculations (DM,JT,TT). For instance, one reviewer was concerned that the ERA does not characterize the variability among TEQs that are estimated from concentrations of Tri+ PCBs, thus omitting key information on the uncertainties of calculated exposure doses—an



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issue the reviewers discussed in greater detail when responding to charge question 9 (see Section 2.9) (TT). This reviewer thought the ERA should have documented the range, mean, and 95% UCLs of Tri+ PCB concentrations in surface water, sediment, and fish tissue for various stretches in the Hudson River to give the reader a clear account of the distributions of exposures to PCBs. Additionally, this reviewer questioned how EPA evaluated data sets in which 95% UCL concentrations exceeded the corresponding maximum concentrations. Echoing some of these concerns, two other reviewers suggested that the ERA provide information on variability in all cases in which EPA used point estimates for inputs to exposure dose calculations (e.g., for PCB concentrations, biomagnification factors, and relevant exposure factors) (DM,JT).

A specific example of the reviewers' concerns about variability in the exposure dose calculations was one reviewer questioning whether what the ERA reports as a 95% UCL daily dose actually represents the 95% UCL value (DM). This reviewer explained that doses are calculated from several inputs, many of which (primarily the exposure factors) are characterized by point estimates. As a result, he argued, the 95% UCL doses presented in the ERA only account for the variability of a subset of inputs to the dose calculations and the true variability in the estimated daily dose is not known. This reviewer suggested that EPA replace all point estimate input parameters with distributions in all cases in which the variability of inputs has been characterized or can be reasonably estimated.

- *Concerns about assumptions made to calculate exposures to PCBs and TEQs.* Though he supported a limited use of TEQs in ecological risk assessments, one reviewer listed several concerns about specific assumptions EPA made to calculate TEQs from the available sampling data and modeling results (RN). First, this reviewer questioned assumptions made to process the large number of nondetects in the fish tissue sampling data for BZ#126. He noted that replacing nondetects with a concentration equal to the detection limit is clearly a conservative approach to processing these data, and other approaches (e.g., using one-half the detection limit as a surrogate concentration or a randomly selected concentration between zero and the detection limit) would have been more reasonable. Given that BZ#126 accounts for a large fraction of fish-based TEQs, this reviewer noted that the approach to processing nondetects for this congener introduces considerable uncertainty to the TEQ calculations.

  Second, this reviewer questioned an inherent assumption in EPA's baseline modeling efforts, and thus in the ecological risk assessment, that the composition of Tri+ PCBs in Hudson River fish does not change from year to year (RN). Referring to comments he made during the peer review of the agency's Baseline Modeling Report, he suggested that EPA calibrate and run its fate and transport and bioaccumulation models for a small set of representative congeners to test the validity of this assumption. This reviewer stressed that computing TEQs directly from Tri+ PCB concentrations will not be accurate if the congener composition of Tri+ PCBs changes from year to year, as he suspected would happen.

Third, this reviewer thought EPA should remove the assumption that TEQs biomagnify in the food chain from the risk assessment (RN). This reviewer explained that receptors are ultimately exposed to PCB congeners, not to TEQs, and the relative quantities of these congeners in organisms vary across trophic levels. Giving an example of how some species can metabolize certain PCB congeners more readily than others, this reviewer noted that BZ#77 is not a particularly persistent congener in birds, though it is in fish. (Note, during their later discussions, two reviewers provided examples of other species, snapping turtles and eels, that clearly have unique congener metabolization and depuration behaviors.) As a result, he thought, assessing exposures to TEQs was inappropriate, primarily because PCB congener profiles differ considerably in organisms at different trophic levels. He suggested that EPA should either calculate TEQs based on congener-specific tissue concentrations for the various species of concern or use congener-specific biomagnification factors to estimate the profiles of PCB congeners in the species of concern, from which TEQs can then be calculated.

- *Comments on EPA's baseline modeling efforts.* Several reviewers noted that the ERA does not provide enough information on EPA's fate and transport and bioaccumulation models to allow readers to evaluate whether model predictions provide a reasonable account of future exposures (DM,JT,TT). These reviewers had different opinions, however, on the extent to which EPA should have documented the models in the ERA. One reviewer acknowledged that accurate fate and transport and bioaccumulation modeling is a critical input to the ecological risk assessment, but thought that checking the validity and calibration of these models was beyond the scope of this peer review, especially considering that an earlier peer review panel critiqued the models (TT).

Two reviewers, on the other hand, thought documentation of EPA's models was necessary because estimates of future exposure clearly depend on the modeling results (DM,JT). These two thought EPA should have given the panel more information on the modeling equations, input parameters, assumptions, and limitations; this would have made it possible for the reviewers to comment on the estimates of future PCB concentrations. One of these reviewers (DM) was particularly interested in evaluating the inputs and assumptions in FISHRAND, the probabilistic bioaccumulation model used in the baseline modeling effort. Given the links between the modeling and the exposure assessment, he thought the ERA should have included a brief summary of the fate and transport and bioaccumulation models. Agreeing that additional information should have been provided, another reviewer indicated that he needed to review the model calibration and validation to assess the quality of the predicted PCB concentrations (JT). This reviewer suggested that EPA's future modeling efforts focus on calculating relative exposure estimates for different remedial scenarios.

Other issues raised about EPA's fate and transport and bioaccumulation models include whether they explicitly account for bioturbation (PdF), whether they can account for effects caused by changes in the biological composition of the ecosystem (e.g., introduction of zebra mussels) (PdF), and whether the outputs of FISHRAND characterize how PCB tissue concentrations vary with different age classes of fish (RN). In response, one reviewer noted that the models do not include a mechanistic account of bioturbation but rather account for bioturbation effects indirectly, through model calibration parameters (LK). No reviewers commented on the other two issues raised.

- *Comments on inherent assumptions in the dose calculations.* The reviewers listed several cases in which the exposure dose calculations could have incorporated finer spatial and temporal resolution, thus possibly accounting for unique feeding habits, exposures at specific life stages, and exposure histories. The various comments are summarized below, classified by topic.

First, two reviewers commented on the spatial resolution of the exposure dose calculations (LK,DM). One reviewer was concerned that the limited spatial extent of sampling could have biased the exposure dose calculations (LK). This reviewer explained that risk assessments based on such limited data often must assume that the measured levels of contamination apply over broad regions. He was concerned that the dose calculations might rest on such assumptions, but he added that the ERA does not provide enough information on the sampling efforts to make it clear if this is the case. Another reviewer added that the spatial variations in PCB contamination should be linked to the home ranges of receptor species of concern (DM). As an example of this concern, he noted that 95% UCL sediment PCB concentrations might be an appropriate input for fish species that forage over a large area, but would be inappropriate for less-motile species, like crayfish and mussels. This reviewer suggested that the ERA explain how the spatial extent of PCB contamination is calculated for the various measurement endpoints and subsequently linked to the corresponding assessment endpoints.

Second, one reviewer stressed the importance of evaluating exposures in the context of critical life stages (RN). This reviewer noted, as an example, that the timing and duration of exposures to metabolizable PCB congeners is important to consider when assessing exposure concentrations in early life stages. For instance, eggs from birds exposed to low levels of PCBs throughout a year will likely have relatively low levels of metabolizable congeners (e.g., BZ#77), but eggs from birds with high PCB exposures during the time when yolks are formed will likely have relatively high levels of metabolizable congeners. Another example of the reviewer's concern is that piscivorous birds consume fish of various sizes, with feeding size preference varying among species and within species, among age classes. This reviewer questioned whether the PCB concentrations predicted by the FISHRAND model were for fish sizes similar to those consumed by the various receptor species of concern.

Third, several reviewers indicated that a receptor's exposure history can be an important factor affecting PCB body burdens (PdF,RN,JT). For instance, one reviewer noted that some long-lived receptors might have a complex exposure history, possibly dating back to years when PCB exposure concentrations in the Hudson River were considerably higher than they are today (RN). He suspected that body burdens for these receptors would reflect their history of exposure more than their current exposures to PCBs. Two other reviewers agreed, citing data on bioaccumulation in catfish (Garman and Hale, 1998) (PdF) and a study of largemouth bass in the Lower Hudson River published in a recent issue of *Environmental Science & Technology* (JT). These reviewers did not suggest that EPA's exposure calculations for current daily doses are incorrect, but rather that assessing exposure histories might be necessary to estimate PCB body burdens for long-lived species.

Finally, three reviewers offered specific comments on EPA's use of biomagnification factors to assess exposures to birds (DM,RN,JT). Noting that the ERA's biomagnification factors for birds (28 for Tri+ PCBs and 19 for TEQs) are not adequately defended in the scientific literature, two reviewers questioned whether these factors truly represent biomagnification among avian receptors and recommended that EPA justify their validity (DM,JT). Another reviewer agreed, and suggested that congener-specific PCB biomagnification factors documented in the scientific literature should have been used in the ERA (RN).

- *Comments on specific exposure factors used in the dose calculations.* Though the reviewers generally commended EPA for selecting appropriate exposure factors in the risk assessment, they provided several specific examples of cases in which different exposure factors should be considered. For instance, two reviewers questioned the rationale for setting all modifying factors (e.g., "area use factor" and "forage effort") to 1 (LK,DM). Both reviewers cited bald eagles, which likely forage to a large extent in areas other than the main channel of the Hudson River, as an example of how the selection of modifying factors can be overly conservative. They both agreed that setting all modifying factors to 1 is acceptable for a screening-level ecological risk assessment, but not for a more refined analysis of ecological risks. One of these reviewers suggested that EPA could have investigated risks for a reasonable range of modifying factors, rather than assuming that the maximum possible exposures occur (DM).

Further, one reviewer suggested that the total daily ingestion rate for mink might understate actual ingestion rates (DM). Noting that the ingestion rate presented in the ERA is based on a study of penned mink, this reviewer suspected that the data might not represent ingestion rates for wild mink, which typically expend more energy foraging for food and defending territories. Additionally, this reviewer indicated that the dietary composition for mink can be very broad, ranging from between 0 and 75% fish, depending on the food sources available. Thus, he thought a case could be made for estimating exposures to mink under various dietary compositions, rather than considering only a point estimate (i.e., 34% fish in the diet).

Other reviewers provided additional comments on the dietary compositions incorporated in the ERA (PdF,LK,DM). Specifically, two reviewers indicated that the exposure dose calculations in the risk assessment do not consider macroinvertebrates as a food source, so exposure doses to species that consume crayfish and blue crabs may not be adequately characterized (PdF,LK). One of these reviewers added that studies have reported a broad range of dietary compositions for individual bald eagles (i.e., between less than 10% and nearly 100% fish), thus raising questions about the ERA assuming bald eagle's diets might consist entirely of fish (LK).

Some reviewers offered other miscellaneous comments on the exposure calculations, such as pointing out that normalized water and food ingestion data presented in the ERA should be dimensionless (DM) and suggesting that exposure doses for mallards could have been estimated more reliably from measured levels of PCB contamination in the vegetation that mallards typically consume, rather than modeled estimates of these levels (JT).

- *Questions about the data used to assess exposures.* The reviewers had several questions about how environmental data from various sources were collected and incorporated into the exposure assessment. For instance, one reviewer could not determine from the ERA the number of fish tissue samples used to estimate TEQs—an issue he viewed as important for evaluating the variability in the TEQ estimates (TT). Two reviewers noted that the ERA does not provide a detailed account of the spatial distribution of contaminants, as determined by field sampling and modeling (PdF,LK). Another reviewer indicated that the available sampling data are difficult to assess without detailed information on the sampling plans, sample sizes, and so on (DM). Citing a public comment submitted by GE, one reviewer noted that the analyses in the ERA might not include all available fish tissue sampling data; he suggested that the ERA either include the data of concern or justify why they are omitted (TT). He and another reviewer (LK) indicated that EPA should clearly specify which benthic community data are used in the risk assessment, whether the results varied with samples collected at different sediment depths, and how these variable results might relate to exposures among benthivorous species.

## 2.6 Responses to Question 6

The sixth charge question asked the peer reviewers to evaluate how EPA assessed effects in the ecological risk assessment:

> For field-based toxicity studies, only a NOAEL toxicity reference value (TRV) was developed because other contaminants or stressors may be contributing to observed effects. Please comment on the validity of this approach. Also, please comment on whether the general approach of using uncertainty factors (interspecies, LOAEL-to-NOAEL, and subchronic-to-chronic) is appropriate in developing TRVs that are protective of Hudson River receptor species.

This and the following charge question generated lengthy debates among the reviewers on the utility of the TQ approach in ecological risk assessment, and opinions on this issue clearly varied from reviewer to reviewer. When responding to this questions, the reviewers provided general comments on the advantages and disadvantages of using field-derived TRVs, laboratory-derived TRVs, and uncertainty factors in ecological risk assessment. Though they had differing opinions on the utility of TRVs, the reviewers agreed that use of a single threshold toxicity value provides less information on ecological risks than does information on a range of dose-response data. (Note, the reviewers debated the use of TRVs further when responding to charge question 7.) The reviewers' comments fell into the following general categories:

- *Comments supporting the use of field-derived LOAELs and NOAELs.* Three reviewers thought LOAELs and NOAELs derived from field studies can be useful inputs to ecological risk assessments (RN,JT,TT). For instance, one reviewer argued that LOAELs and NOAELs published in field studies, if interpreted in proper context, are useful metrics for assessing ecological risks, because these studies characterize actual effects that occur in "real world" exposure scenarios (TT). More specifically, this reviewer noted that field studies on species of concern are certainly preferable to laboratory studies on surrogate species (more details follow on the reviewers' concerns about use of toxicity thresholds derived from such laboratory studies). Finally, he noted that research recently conducted on PCB-related ecological risks among various avian species in the Great Lakes provide an adequate basis for using TRVs to characterize ecological risks. Voicing a slightly different viewpoint, one reviewer thought EPA should have used field-derived LOAELs in the ecological risk assessment (JT), while noting that observed effects might be attributed to stressors other than PCBs. Finally, a third reviewer cited Sean Kennedy's premeeting comments, which indicated a preference for using field-based NOAELs to derive TRVs, rather than relying on laboratory studies of surrogate species (RN).

- *Arguments against the use of field-derived LOAELs and NOAELs.* Two reviewers listed several reasons why they thought use of field-derived LOAELs and NOAELs was not appropriate for a baseline ecological risk assessment, but they generally noted that the TRV approach used in the ERA was excessively conservative and best suited for a screening-level risk assessment (LK,DM). One reviewer acknowledged that using field-derived NOAELs is preferable to extrapolating laboratory studies to field conditions, but he presented three reasons why he thought using field-derived NOAELs was not acceptable for the ERA (DM). First, he noted that NOAELs derived from field studies are essentially unbounded and may be considerably lower than their corresponding LOAELs, thus causing toxicity assessments based on field-derived NOAELs to rely on very conservative toxicity thresholds. (Note, another reviewer argued that NOAELs derived from some field studies might, in fact, not be conservative at all, due to poor statistical power or other limitations in the study of concern; such NOAELs would be higher than exposure levels at which effects actually occur [JT]). Second, this reviewer said that the methodology for deriving field-based NOAELs has not been sufficiently formalized and validated, as methodologies for estimating sediment effects concentrations have (DM). Finally, he added that the scientific literature provides "overwhelming support" for why field-derived NOAELs and LOAELs are not appropriate metrics for evaluating ecological risks from low levels of environmental contamination; he referred to several citations in his premeeting comments he believes support this assertion (see Appendix C).

Another reviewer offered similar and additional arguments against the use of field-derived LOAELs and NOAELs in ecological risk assessments that go beyond the screening level (LK). Supporting a comment made by another reviewer (DM), this reviewer indicated that several articles in the scientific literature conclude that the analysis of variance approach to deriving TRVs is not scientifically defensible in ecological risk assessments. This reviewer explained that the design of field studies can bias the resulting threshold values to levels that do not correlate with the actual biological responses. He added that toxicity thresholds, in general, do not provide information on the shape of the dose-response curve and instead provide a binary account of risk: doses are either above or below the threshold value. This reviewer suggested, and another agreed (DM), that more sophisticated toxicologic evaluations should have been included in an ecological risk assessment of this nature. Examples of more detailed approaches include using regression models to estimate effects levels (LK) and using meta-analyses to construct defensible dose-response curves for species that have been widely researched using studies with similar protocols (e.g., mink) (DM). The reviewers noted, however, that insufficient data are available for deriving dose-response curves for many assessment endpoints; one reviewer felt strongly about this point (TT).

- *Comments on the use of laboratory-derived NOAELs.* Citing various concerns, none of the reviewers thought the laboratory-derived NOAELs for surrogate species presented in the ERA were reliable bases for developing TRVs. As an example of these concerns, one reviewer indicated that the TRVs for birds (i.e., 0.33 mg PCBs/kg egg and 0.01 µg TEQ/kg egg) derived from laboratory studies on chickens were unrealistically low and excessively conservative (RN). Elaborating on this issue, this reviewer did not believe that reproductive or developmental effects were likely at the threshold doses, and he added that the TRVs were lower than avian exposures to PCBs in many uncontaminated areas in North America. Other reviewers agreed that the TRVs derived from laboratory studies on surrogate species were overly conservative (DM,TT), and added that using the chicken as a representative species for wild birds was not defensible (as described in greater detail in the next bulleted item).

  It should be noted that the reviewers' criticisms of laboratory studies focused primarily on those that examine surrogate species. One reviewer indicated that laboratory toxicity studies on species selected in assessment endpoints are appropriate to consider in ecological risk assessments, though he acknowledged that such studies may be difficult to conduct (TT).

- *Comments on the use of uncertainty factors.* The reviewers who commented on uncertainty factors (LK,DM,RN) thought EPA should have adopted approaches other than using order of magnitude factors to account for uncertainties. For instance, citing a paper authored by Peter Chapman, one reviewer argued against the use of arbitrary uncertainty factors in the risk assessment altogether (LK). He explained that risk assessments ultimately should characterize risks and their inherent uncertainties, such that risk managers can then make informed decisions, invoking uncertainty or safety factors if they so choose. He added that most of the order of magnitude uncertainty factors applied in the ERA have no technical basis. Another reviewer agreed, to a certain extent, with these comments, noting that risk assessors typically apply uncertainty factors either for technical reasons (i.e., to account for variability in data) or for policy reasons (i.e., as required by risk assessment guidance) (PdF). Another reason cited for not using order of magnitude uncertainty factors to derive TRVs was one reviewer's impression that such an approach is suitable for only a screening-level ecological risk assessment (DM).

  Two reviewers suggested approaches for characterizing uncertainty, other than relying on default order of magnitude assumptions (DM,RN). One reviewer recommended using empirical data sets to derive more realistic uncertainty factors, following approaches published by Peter Chapman and Ed Calabrese (DM). Another reviewer agreed, noting that EPA could have used information from *in vitro* and *in vivo* inter-species sensitivity studies to derive TRVs from laboratory studies, rather than relying on the simplistic factors of 10 (RN). Finally, echoing a comment raised earlier, one reviewer suggested an alternative approach for deriving TRVs from laboratory studies on surrogate species: for cases in which the surrogate species is believed to be more sensitive to PCB-related effects than are the assessment endpoints (as might be the case for the chicken and avian receptors), EPA should have considered bounding the TRV estimate with the lower limit based on dividing by an uncertainty factor and the upper limit based on multiplying by an uncertainty factor (DM).

- *Comments on how TRVs were applied in the ERA.* Three reviewers commented specifically on the approaches EPA used to apply TRVs in the ERA. First, one reviewer indicated that biases in both exposure dose calculations and TRVs can lead to excessively conservative TQs: by invoking many conservative assumptions that led to both overstated exposure doses and unrealistically low TRVs, EPA calculated extremely conservative TQs (LK). This reviewer found such an approach appropriate for only a screening-level risk assessment. Though he did not disagree with these comments, another reviewer noted that EPA did not always select the most conservative threshold values (JT), as other reviewers had implied. Referring to Table 4-26 in the ERA, this reviewer indicated that the more conservative laboratory-derived TRVs were not selected in cases in which relevant field-derived TRVs were available.

On a different issue, one reviewer stressed that the TRVs for many assessment endpoints are actually based on a very limited number of toxicity studies (DM). He thought the reliance on a small number of studies to characterize a large number of assessment endpoints indicated that not enough information was available to allow EPA to assess risks to most fish, bird, and mammalian species separately. He suggested that the ERA prominently acknowledge the limitations of the toxicity data, and he indicated that the risk assessment would have been more defensible had EPA evaluated assessment endpoints using species-specific bioassays to derive TRVs.

- *Documentation of criteria used to select field studies for deriving TRVs.* Noting that some sediment toxicity studies (e.g., those published by Long and MacDonald) have been extensively scrutinized before having their TRVs widely accepted, one reviewer suggested that the toxicity studies EPA used to derive TRVs should have been subject to an equally rigorous level of scrutiny (DM). At the very least, he recommended that the ERA include some information on the criteria (e.g., use of accepted study protocols, appropriate statistics, and relevant sampling and analytical methods) that EPA used to select certain studies for calculating TRVs and to omit others. This reviewer specifically questioned whether the laboratory study of chickens was an acceptable basis for deriving TRVs for such a wide range of avian species.

## 2.7 Responses to Question 7

Charge question 7 asked the reviewers to comment on the risk characterization in the ERA. Specifically, the question asked: "USEPA calculated toxicity quotients (TQs) for all receptors of concern on both a total PCB and dioxin-like PCB (TEQ) basis. Please comment on whether the methodologies used in calculating these TQs are adequately protective for these receptors." The reviewers presented several insights on this issue, and revisited their discussion on the utility of TRVs in ecological risk assessment, as described below:

- *The "protective" nature of the methodologies used to calculate TQs.* Referring to earlier discussions and to the peer reviewers' premeeting comments, one reviewer indicated that the reviewers seemed to agree that EPA's methodologies for calculating toxicity quotients are very conservative, and therefore protective (PdF). Other reviewers agreed, explaining that the use of multiple uncertainty factors to derive TRVs and conservative assumptions to estimate exposure doses essentially ensured that the calculated TQs would be protective

(LK,DM,RN). None of the reviewers thought EPA's methodology was under-protective for any receptor of concern.

- *Comments on the need for ecological risk assessments to be protective.* Revisiting an issue discussed in response to charge question 2 (see Section 2.3), one reviewer again questioned whether EPA's risk assessments should be "protective" (DM). He indicated, rather, that the main goal of conducting risk assessments is to characterize risks in as much detail as possible, leaving the decision of how protective remedial actions should be to risk managers, regulators, and stakeholders. He suggested that a risk assessment designed to be overly conservative, and thus "protective," is entirely appropriate for a screening-level risk assessment, but not for a more refined ecological risk assessment. As a result, this reviewer thought EPA should not have used excessively conservative TQs in the interest of being protective, but should have rather used a more sophisticated methodology that characterizes risks in terms of probabilities of effects, ecological consequences, or other more meaningful metrics.

  Two reviewers gave specific examples of their concerns about publishing protective risk assessments. First, one reviewer thought the ERA could present risk communication challenges, because the report concludes that most receptors are at risk but does not prominently acknowledge the many conservative assumptions made in reaching this conclusion (LK). He was therefore concerned that the public might view any future release of less conservative TQs with great suspicion, even if such revised risk estimates might be more realistic. Another reviewer agreed, and added that the conservative risk estimates also present risk management challenges (DM). Specifically, he used an analogy of "conservative" weather forecasting to illustrate how overly protective predictions do not particularly help people make informed decisions.

- *Continued debate on the utility of TRVs for ecological risk assessment.* When answering this question, four reviewers revisited their earlier discussions (see responses to charge question 6 in Section 2.6) on the utility of TRVs in ecological risk assessment. One reviewer felt strongly that a TRV analysis, without consideration of other independent lines of evidence (i.e., *in situ* toxicity tests or biological surveys) of ecological effects, is not a particularly insightful methodology for assessing risks (DM). As an example of his concern, this reviewer noted that a single TQ is far less insightful than a more detailed and ecologically relevant risk characterization, such as "a 20% probability of a 30% reduction in fecundity" will result from site-specific exposures. He reiterated that the TQ approach is appropriate for a screening-level assessment, but needs to be supported with independent lines of evidence for assurance that the TQ results are realistic. This reviewer acknowledged, however, that it may be idealistic to demand incorporation of three independent lines of evidence for every assessment endpoint.

  Another reviewer also questioned the utility of conservative TQ analyses in refined ecological risk assessments (LK). This reviewer viewed TQs as being useful primarily for understanding the factors that contribute to observed population-level effects, rather than being used to predict whether such population-level effects occur. He added that risk managers might have difficulty interpreting the TQ analyses in the ERA. As an example, he indicated that remedial options that focus on reducing TQs to less than 1, in this case, would likely involve removing PCB contamination to levels below background.

In contrast to the comments described above, two reviewers provided arguments supporting the risk characterization methodology EPA used in the ERA (PdF,TT). First, one reviewer noted that the approach EPA used to calculate TEQs and TQs is clearly consistent with current ecological risk assessment practice, provided the assumptions used to calculate exposure doses and TRVs are defensible (see responses to charge questions 4 and 5, in Section 2.5, for the reviewers' comments on these assumptions) (TT). Further, he added that the TQ approach is generally appropriate for assessing risk, particularly in cases where rigorous field studies have established a link between exposures to PCBs and ecological effects in a receptor of concern. Though he acknowledged the utility of using *in situ* toxicity tests and biological surveys in conjunction with a TQ analysis, this reviewer noted that all three types of data often are not available to risk assessors, that collecting these types of data is sometimes infeasible, and that *in situ* toxicity tests and biological surveys also have limitations.

Expanding on this final comment, another reviewer noted that TQ analyses have utility because biological surveys are sometimes insufficient for characterizing certain types of effects (PdF). More specifically, this reviewer explained that population surveys, though useful for characterizing mortality and other effects, might not reveal insights on toxicity that is not overtly manifested at the population level. As a result, he saw benefits in using TEQs and TQs to assess sub-lethal effects that might be notable, yet difficult or impossible to observe at the population level.

- *Additional comments on the methodologies for calculating TQs and TEQs.* Two reviewers provided additional comments on charge question 7. First, one reviewer indicated that EPA could have improved its derivation of TRVs by considering a wider range of published toxicity studies, including those specific to dioxins (RN). For instance, this reviewer suggested that EPA consider basing its TRV for avian receptors on data published in a study of dioxin toxicity to pheasants and bluebirds (Peterson et al., 1993). Noting that these species appear to be quite insensitive to dioxin-related effects, especially in comparison to the chicken, he suspected that EPA might find considerably lower risk estimates if it derives TRVs for avian receptors using this study. Similarly, this reviewer indicated that a paper recently published on aquatic mammalian toxicology could be used to derive TRVs for certain receptors, though he acknowledged that this study was published after the ERA was released. Second, noting that the TEQ approach is based on considerable uncertainty, one reviewer argued that this approach is useful only for a screening-level risk assessment and suggested that the ERA acknowledge the uncertainties inherent in calculating and interpreting TEQs (LK).

## 2.8 Responses to Question 8

Charge question 8 also pertained to risk characterization, and asked the peer reviewers:

> The risk characterization section of the ERA (Chapter 5, pp. 117–151) summarizes current and future risks to fish and wildlife that may be exposed to PCBs in the Upper Hudson River and current risks to fish and wildlife in the Lower Hudson River. Please comment on whether the risk characterization adequately characterizes the relative risks to ecological receptors (e.g., piscivores, insectivores) posed by PCBs in the Hudson River.

The reviewers provided many comments on the risk characterization in the ERA. As a general comment, one reviewer thought EPA should have used a more detailed, quantitative risk characterization—possibly one that comments on probability of effects and ecological consequences—rather than using a more qualitative characterization (DM). The reviewers discussed many other specific aspects of the risk characterization, as described below:

- *Comments on how EPA weighed multiple lines of evidence.* The reviewers had lengthy discussions on the extent to which EPA weighed multiple lines of evidence in the risk characterization. This discussion focused first on whether EPA discarded useful lines of evidence and next on whether EPA truly weighed disparate findings from multiple lines of evidence. A review of this discussion follows:

  Based on the writing style presented in the risk characterization, one reviewer thought EPA essentially dismissed relevant biological findings and instead relied entirely on the TQ calculations to characterize risks (LK). He noted several paragraphs where the risk characterization opens by citing findings from biological studies but closes by concluding that receptor species are at risk because of the elevated TQs. Other reviewers disagreed, explaining that they viewed the risk characterization paragraphs as first presenting the findings of the biological studies, then presenting contradictory findings from the TQ analyses, but never implying that populations are in danger (JT,TT). One reviewer then cited several passages where EPA acknowledges that species of concern are reproducing, which he thought was consistent with the limited biological data available for the Hudson River (TT). The reviewer who originally indicated that EPA dismissed biological data eventually retracted his comment, but noted that the wording in the risk characterization is vague and open to various interpretations (LK).

  Several reviewers then commented that the risk characterization presents findings from multiple lines of evidence, but does not interpret the conflicting findings from different lines of evidence (PdF,LK,DM,JT). As a result, these reviewers were troubled by paragraphs in the risk characterization that present biological data and TQ analyses with conflicting findings and suggested that EPA should have examined these contradictory findings more closely. For instance, one reviewer thought EPA could have discussed the uncertainties in the dose calculations and TRVs to put the TQ estimates into perspective (JT); another reviewer thought EPA should have evaluated the representativeness of the biological data, possibly by commenting on sampling locations, confounding factors, and accuracy (LK). Other reviewers agreed, noting that EPA generally did not attempt to explain the significance of elevated TQs when biological studies confirm that populations are reproducing (PdF,LK,DM).

The reviewers had different opinions on the perception that the risk characterization does not adequately integrate the biological data and TQ analyses. For instance, one reviewer thought identifying the most sensitive indicator of ecological risk is an appropriate approach for a screening-level risk assessment, but he thought the ERA should have thoroughly examined and interpreted disparate findings from independent lines of evidence (JT). Another reviewer stressed that risk assessors typically present an integrated summary of all relevant lines of evidence in the risk characterization, rather than listing a series of conflicting lines of evidence (LK). A different reviewer agreed, adding that he was not sure if the ERA, by relying so heavily on the TQ approach, forms an adequate basis for making remedial decisions (DM).

- *Consideration of multiple lines of evidence in the risk characterization.* A reviewer had concern as to whether multiple lines of evidence were actually considered in the risk characterization. For instance, he stressed that the "multiple lines of evidence" EPA considered were primarily various comparisons to TRVs, and therefore not independent lines of evidence (DM). He added that EPA used certain lines of evidence, such as comparing levels of contamination to sediment and water quality criteria, to address almost every assessment endpoint. Moreover, many of the lines of evidence, he argued, had questionable relevance to the receptor of concern. For instance, this reviewer did not think comparing PCB sediment concentrations to corresponding sediment quality criteria was an adequate metric for characterizing risks to racoons.

- *Comments on specific interpretations of the available field studies.* Two reviewers recommended that EPA provide more specific interpretations of field studies reviewed in the ERA (DM,JT). As one example, one reviewer thought EPA should discuss the ecological significance of anomalous nesting behavior in tree swallows, when reproductive fecundity is apparently not affected (JT). Another reviewer agreed, noting that the risk characterization should describe why this behavior is of concern, when no other PCB-related effects have been observed (DM).

  This reviewer also questioned EPA's interpretation of the field studies on benthic community structure (DM). He explained that the ERA suggests a weak relationship between levels of PCB contamination and benthic community metrics. He questioned the importance of this relationship, however, given that the ERA acknowledges that "when PCB concentrations were normalized to TOC [a more accurate indication of bioavailable PCBs], there were no significant differences between stations" (page 120). This reviewer was concerned that the risk characterization then finds that "the analysis shows a reduced macroinvertebrate community . . . [and] all three lines of evidence [of which the field study is one] suggest an adverse effect of PCBs on benthic invertebrate populations." Noting the two different interpretations of the same study, this reviewer suspected that EPA might have had a bias toward finding risk, regardless of whether the data support such conclusions.

- *Use of anecdotal information to characterize risks.* Two reviewers questioned whether the ERA should cite anecdotal information, rather than biological data, to characterize ecological risks (LK,RN). For instance, one reviewer found it curious that the ERA notes sightings of osprey and mink in the risk characterization (LK). Not only did this reviewer question the utility of anecdotal information when more rigorous biological data could have been collected, but he also questioned the validity of the data, given that a trapper reported the osprey sightings and a fisher the mink sightings. Another reviewer agreed, and found quotes such as "mink numbers are large and increasing and there are quite a few otters" to be too vague to allow meaningful interpretation (RN). As one example of his concern, this reviewer indicated that sightings of mink and otter in or near tributaries to the Hudson River might have little bearing on site-related ecological risks. He suggested that EPA should cite field studies in the ERA, rather than rely on anecdotal information.

- *Comments on the possibility that the ERA understates risks.* One reviewer took exception with several quotes in the risk characterization that suggest "true risks are likely underestimated" (DM). Given that EPA based its risk characterization largely on the TQ approach and that the calculated TQs are based on many conservative exposure and toxicity assumptions, this reviewer thought such statements are inappropriate. He added that EPA could only comment on whether risks are understated or overstated by performing a quantitative uncertainty analysis on the TQ calculations, without using any uncertainty factors.

- *Lack of consideration of multiple stressors.* Three reviewers commented on the fact that the risk characterization does not consider ecological effects potentially caused by stressors other than PCBs (PdF,LK,TT). Opening this discussion, one reviewer wondered if the risk characterization in the ERA is complete if certain effects might be caused by PCBs acting in combination with other stressors (e.g., chemical stressors, water quality parameters, human activity) (PdF). Another reviewer agreed, noting that using a conceptual model that does not account for other stressors prevents EPA from putting risks into a "real world" context (LK). This reviewer suspected, however, that Superfund guidance and regulations might mandate this risk assessment's focus on evaluating risks associated exclusively with the site-specific contaminants of concern, despite the reviewers' concerns about how the interplay of multiple stressors affect ecological risks. To highlight the concern about multiple stressors, another reviewer presented an example where chemical stressors other than PCBs might confound results of certain studies (TT). Specifically, he noted that the benthic infauna study reported observing reduced populations in PCB-contaminated sediments; however, the sediments were also found to have several metals at levels that exceed various sediment quality thresholds, thus confounding interpretation of these data.

- *Selection of appropriate assessment and measurement endpoints to characterize risk.* When discussing the adequacy of the risk characterization, two reviewers referred to their previous comments on selection of appropriate assessment and measurement endpoints (PdF,TT). First, one reviewer noted that the ERA might not adequately characterize ecological risks if the assessment endpoints do not include receptors that are highly exposed to PCBs or highly sensitive to these exposures (PdF). As an example of this concern, noting that EPA did not select osprey or crayfish for the assessment endpoints, he wondered if the risk characterization might overlook some important ecological effects. Second, another reviewer added that EPA might have been able to characterize risks more thoroughly had the agency used more specific wording when developing the assessment endpoints (TT). As examples, he suggested that assessment endpoints of "reproducing populations" or "populations free from sub-lethal effects" are more specific than "protection and maintenance" of populations.

- *Consistency of risk characterization in the ERA and Responsiveness Summary.* Two reviewers found it difficult to follow the risk characterization from its original presentation in the ERA to its revised presentation in the Responsiveness Summary (LK,TT). For instance, one reviewer followed the risk characterization for various fish species through the two documents, and he was concerned that the Responsiveness Summary, which he viewed as the "final" document, reports that "fish populations are at risk" without acknowledging the findings of the fish population studies (LK). He and another reviewer (TT) were concerned about this and other risk characterization statements in the Responsiveness Summary, primarily because they thought the wording in this volume replaces the findings in the ERA. These reviewers agreed that this presentation was confusing—an issue they revisited when responding to general question 1 (see Section 3.1).

## 2.9 Responses to Question 9

Addressing uncertainty analyses in the ERA, charge question 9 asked the peer reviewers:

The uncertainty analysis is presented in Chapter 6 of the ERA (pp. 153–165). Have the major uncertainties in the ERA been identified? Please comment on whether the uncertainties (and their effects on conclusions) in the exposure and effects characterization are adequately described.

During the discussions, several reviewers noted that the uncertainty analysis in the ERA is strictly qualitative, and lacks a focused attempt to quantify uncertainties (DM,JT,TT). One reviewer was particularly surprised that EPA did not conduct a quantitative uncertainty analysis, considering the large volume of environmental and ecological data available for the Hudson River (DM). The reviewers then made several comments and suggestions about conducting uncertainty analyses and discussed several other topics related to this issue, as described below:

- *Major uncertainties not identified in the ERA.* The reviewers commented briefly on the extent to which the ERA identifies major sources of uncertainty. One reviewer thought modeled PCB concentrations in surface water, sediment, and fish are a major source of uncertainty, and he questioned EPA's claim that ". . . model error is probably not a significant source of uncertainty" (page 165) (JT). This reviewer thought this statement, without any supporting data or interpretations, is a weak argument for not evaluating the uncertainty in model predictions. Another reviewer thought the ERA identifies most major source of uncertainty, but he suggested that EPA consider uncertainties associated with the assumed dietary composition of various species, particularly mink, and the assumed foraging behavior for species with large home ranges (DM).

- *Comments on how uncertainty is presented in the risk characterization.* One reviewer was concerned that the Executive Summary in the ERA indicates, for many assessment endpoints, that ". . . uncertainty in this analysis is considered low" (DM). Noting the disconnect between the TQs and the biological data, this reviewer suspected that uncertainties were actually rather high, but he added that EPA presented little evidence to support the characterization of uncertainties being low. Another reviewer questioned what EPA truly meant by "low" uncertainties (JT). He suspected that "low uncertainty," in this case, means that there is low probability of a "false negative" (i.e., that ecological risks are present, even though they are not predicted). Both reviewers agreed, and added that one should not conclude that there is high probability that risks are occurring based solely on the TQ analyses.

- *Specific comments on the uncertainty analysis.* Several reviewers offered specific comments on the uncertainty analysis presented in the ERA. One reviewer, for example, criticized the sensitivity analysis (page 164), noting that it provided little information on the rationale for selecting various input distributions (DM). He thought the reviewers could have commented on the sensitivity analysis more thoroughly, had the ERA authors thoroughly described the inputs and results, as recommended by EPA guidance on documenting Monte Carlo and sensitivity analyses.

Another reviewer had two specific comments on the uncertainty analysis (RN). First, this reviewer thought EPA could have easily quantified the uncertainty associated with assuming BZ#126 concentrations in fish are equal to the detection limit; he suspected this assumption was a large source of uncertainty, as described in greater detail in the reviewer's responses to charge question 4 (see Section 2.5). Second, this reviewer thought EPA could have characterized the uncertainty associated with inter-species toxicity extrapolations used to derive TRVs by evaluating *in vitro* and *in vivo* studies of PCB and dioxin toxicity. Noting that inter-species sensitivity to PCB-related effects can be extremely variable, he thought evaluating this source of uncertainty was particularly important.

Finally, one reviewer thought EPA should have characterized the uncertainty associated with the sediment and benthic infaunal data, perhaps by assessing how representative these data, which were collected at 19 locations, are of conditions throughout the 200 miles of the Hudson River PCBs site (TT). Another reviewer voiced concern about the uncertainty in the FISHRAND model predictions, noting that some model calibration parameters were uncertain but not variable (JT). He noted that allowing fixed parameters to vary raises questions about model calibration, and therefore the reliability of model predictions.

- *Discussion on the relative uncertainty in ecological versus ecotoxicological data.* Two reviewers thought the ERA generally understates the uncertainty associated with calculating TQs while overstating the uncertainty in ecological studies, and both reviewers took exception to this apparent bias (LK,JT). For instance, noting that the ERA implies that the data from selected ecological studies on the Hudson River were too erratic to consider in the risk assessment, one reviewer thought EPA unfairly criticized the studies without providing more specific arguments for dismissing them (LK). He added that uncertainties in ecological studies can be characterized, though he could not tell if EPA made any attempt to do so. Another reviewer was concerned about this apparent bias in characterizing uncertainty, primarily because he suspected EPA might now select remedial options based on the TQ approach, even though he was not convinced that this was the least uncertain tool for characterizing risk (JT).

  When discussing the relative uncertainties in ecological and ecotoxicological data, the reviewers listed several advantages and disadvantages of incorporating ecological data into risk assessments. One reviewer, for example, indicated that researchers can now develop a definitive understanding of ecological risks to fish populations through various methods of monitoring, though he acknowledged that ecological studies often cannot provide statistically meaningful findings for species with limited numbers (e.g., bald eagle in the Hudson River) (LK). Another reviewer agreed, and added that ecological studies often cannot characterize subtle, sub-lethal effects (JT). Noting strengths and weaknesses with ecological studies and ecotoxicological evaluations, another reviewer stressed the importance of integrating both approaches into a risk assessment (PdF).

- *Suggested approaches for addressing and reducing uncertainty in risk assessment.* After indicating his preference for conducting quantitative uncertainty analyses rather than providing a qualitative description of uncertainty, one reviewer suggested how EPA could have better identified and reduced the uncertainties inherent in the risk assessment (DM). As an alternative approach, he noted that EPA could have conducted basic bounding arguments and sensitivity analyses at the start of the risk assessment process to identify key uncertainties, particularly those that could be reduced. Having conducted this initial evaluation, this reviewer suggested, EPA could have then designed studies to reduce major sources of uncertainty and therefore better characterized uncertainties in the final risk assessment.

## 3.0 RESPONSES TO GENERAL CHARGE QUESTIONS

After answering the nine specific charge questions, the reviewers then discussed two general questions that addressed issues of clarity, consistency, and transparency, and strengths and weaknesses in the ERA that might not have been covered by the specific questions. When answering the general questions, the reviewers reiterated many of the findings they had presented earlier in the meeting and offered additional comments for discussion. A general record of the peer reviewers' discussions on the two general questions follows. The reviewers' final conclusions and recommendations for the meeting are listed in Section 4.0.

Note: The reviewers' initials used to attribute comments are as follows: PdF (Dr. Peter deFur), LK (Dr. Lawrence Kapustka), DM (Dr. Dwayne Moore), RN (Dr. Ross Norstrom), TT (Mr. Tim Thompson), and JT (Dr. John Toll).

### 3.1 Responses to Question 1

The first general charge question asked the peer reviewers:

A goal for Superfund risk assessments is that they be clear, consistent, reasonable and transparent and adequately characterize risks to sensitive populations (e.g., threatened and endangered species). Based on your review, how adequate are the ERA and the Responsiveness Summary when measured against these criteria?

Following are the reviewers' impressions on the clarity, transparency, reasonableness, and consistency of the ERA:

- *Comments on clarity.* The reviewers' main comment on the clarity of the ecological risk assessment addressed the presentation of information in the multiple volumes of the ERA and in the Responsiveness Summary. Some reviewers found this presentation difficult to follow and suggested that EPA should have instead placed all relevant information into a single report (LK,RN,TT). For instance, one reviewer thought EPA should have produced a draft and final ERA, rather than documenting the findings of the risk assessment in both the ERA and the Responsiveness Summary (TT). Another reviewer agreed, and suggested that a risk assessment should serve as a stand alone document and not rely on other documents to provide the reader a complete understanding of how and why important decisions were made (LK). Though not disagreeing with these comments, another reviewer questioned whether EPA could compile the large volume of information collected and decisions made into a single volume report (JT). Other suggestions for improving clarity in the documents were that EPA incorporate key figures and tables directly into the text of the ERA and that EPA present its responses to public comments immediately after the comments appear in the Responsiveness Summary, rather than presenting all the comments first, and all the responses later (RN).

- *Comments on transparency.* One reviewer did not think the ERA was sufficiently transparent to allow a reader to understand important inputs to the risk assessment (LK). He listed several examples of information he thought the ERA should include to be more transparent, such as information on the ecological resources of the Hudson River, background on how EPA selected assessment endpoints, an overview of the fate and transport and bioaccumulation modeling effort, and the criteria used to select studies for deriving TRVs. Another reviewer agreed, and added that EPA could include these types of information in the ERA without having an excessively long report (DM). To achieve this, he suggested that EPA delete repetitive analyses (e.g., presenting the same lines of evidence for multiple assessment endpoints) from the ERA, and insert discussions on the topics listed above.

- *Comments on reasonableness.* Three reviewers commented on whether the analyses in the ERA and the Responsiveness Summary are reasonable. First, noting the reviewers' extensive comments raised in response to charge questions 1–9, one reviewer thought the ERA was reasonable only as a screening-level risk assessment (DM). To be considered a higher tiered risk assessment, he suggested the ERA should document the probability of effects occurring, the ecological consequences of these effects, and the impact of remedial actions on risk. This reviewer and another (JT) found it unreasonable that EPA might make a remedial decision based on what he considered to be a screening-level risk assessment. Second, another reviewer did not think it was reasonable for EPA to present conflicting findings from multiple lines of evidence, without attempting to explain or interpret the disparate findings (PdF).

- *Comments on consistency.* The reviewers' comments on consistency primarily addressed the extent to which the ERA is consistent with various EPA policies on ecological risk assessment. One reviewer noted the ERA focuses on toxicity assessments and therefore evaluates risks to individuals rather than examining risks to populations—a focus he found inconsistent with EPA policy on ecological risk assessment (LK). Another reviewer agreed that the ERA focuses on an ecotoxicological approach, but he noted that many EPA risk assessments rely heavily on this approach, regardless of what policies suggest (PdF). On another issue, yet another reviewer did not think the description of the sensitivity analysis in the ERA was consistent with EPA's "Guiding Principles for Monte Carlo Analysis" (DM).

### 3.2 Responses to Question 2

The second general charge question asked the reviewers to: "Please provide any other comments or concerns, both strengths and weaknesses, with the ERA not covered by the charge questions, above." The reviewers did not answer this question during the scheduled time on the agenda, but rather referred to their premeeting comments for other issues not addressed in charge questions 1–9. At the end of the meeting, however, the reviewers identified two general issues of concern that were not captured by their conclusions (Section 2.1) and recommendations (Section 4.1). First, several reviewers noted that the ERA does not account for factors that could dramatically alter the Hudson River ecosystem, such as introduction of zebra mussels (PdF,LK,RN). One reviewer added that the Responsiveness Summary occasionally does not completely address some public comments, and sometimes cites policies, rather than technical arguments, in responses (RN).

## 4.0 REVIEWERS' OVERALL RECOMMENDATIONS

After answering the specific and general questions in the charge, and after listening to the second set of observer comments, the reviewers reconvened to present their final findings on the ERA and its Responsiveness Summary. The reviewers, as a group, developed several conclusions and recommendations; after which the reviewers offered their individual perspectives on EPA's reports, during which other reviewers did not discuss or debate each reviewer's final statements. Section 4.1 summarizes the reviewers' key findings; Section 4.2 presents their individual recommendations.

### 4.1 Key Findings

Based on their responses to the charge questions, as documented in Section 2 and 3, the reviewers prepared a short list of conclusions and recommendations for EPA. This list, along with other common themes among the reviewers' discussions, is presented in the Executive Summary of this report. The reviewers' specific key findings follow:

- Some reviewers considered the ERA to be a screening-level effort. Others expressed that information was available for EPA to conduct an adequate baseline risk assessment, but the current assessment needs to be reworked.
- All reviewers commented that EPA should have included more field data—either ecological surveys of river and terrestrial biota or *in situ* toxicity data—in the ecological risk assessment.
- All reviewers found the organization of the reports an impediment to efficient review of the ecological risk assessment.
- All reviewers thought the assessment should have begun with an ecological survey, or at least included more direct ecological information in the conceptual model.
- Many reviewers thought more data could have been obtained with the time and resources available for this project. They thought the ERA would have been improved had it included various additional types of information, such as population data, site-specific bioaccumulation studies, *in situ* toxicity data, and ecological survey data on bivalves, decapods, fish, birds, and mammals.



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- All reviewers thought omitting a quantitative uncertainty analysis was a deficiency in the ecological risk assessment.

After presenting these findings, the reviewers discussed two additional topics at the request of EPA: (1) whether the reviewers think ecological risks are occurring in the Hudson River, regardless of the conclusions of the ERA, and (2) whether the ecological risks are sufficient to warrant remedial actions. The reviewers briefly discussed the first topic, but most said they were uncomfortable applying their professional judgment from other sites to comment on ecological risks at the Hudson River without having conducted their own assessment (DM,JT,TT). When discussing the second topic, the reviewers decided to answer the question, "Can the ERA be used as a basis for a remedial action decision?" The unanimous response to this question was no. Expanding on this response, one reviewer noted that unacceptable risks might exist, but he stressed that the ERA does not provide enough information to determine if this is the case (LK).

## 4.2 Peer Reviewers' Final Statements

The peer review meeting concluded with each reviewer providing closing statements on the ERA and its Responsiveness Summary, including an overall recommendation in response to the final question in the charge: "Based on your review of the information provided, please select your overall recommendation for the ERA and explain why.

1. Acceptable as is
2. Acceptable with minor revision (as indicated)
3. Acceptable with major revision (as outlined)
4. Not acceptable (under any circumstance)"

Before providing their final statement the reviewers established criteria for classifying their recommendations into the four categories. These criteria follows: "acceptable with minor revisions" meant the reports can be improved with a simple rewrite and limited additional analyses of data; "acceptable with major revisions" meant that the available data can be used to form the basis of a remedial decision, but that EPA would need to conduct additional analyses on the data, review relevant literature, and rewrite the report before basing a decision on ecological risks; and "unacceptable" meant that remedial decisions should not be made with the current document and that the ERA will not be acceptable unless additional studies are performed or other data sources considered.

In summary, four of the reviewers found the ERA and its Responsiveness Summary to be "acceptable with major revisions," and two reviewers found the documents "unacceptable." A brief summary of the reviewer's individual final statements follows:

- Dr. Peter deFur found the reports to be "acceptable with major revisions." He believed that EPA can revise the existing reports into an acceptable risk assessment, without preparing an entirely new assessment.

- Dr. Larry Kapustka concluded EPA's ecological risk assessment is "unacceptable" and thought the documents require major changes—from the conceptual model through the risk characterization—to become acceptable.

- Dr. Dwayne Moore also concluded that the reports are "unacceptable," noting that the ERA does not characterize the probabilities of risk or ecological consequences of these risks. He did not think the ecological risk assessment, as written, should be used to make remedial decisions.

- Dr. Ross Norstrom found EPA's ecological risk assessment to be "acceptable with major revisions." Suggested revisions included conducting congener-specific analyses, reviewing the scientific literature on PCB biomagnification and toxicity to better characterize inputs to the TQ analyses, and integrating the available ecological data into the assessment.

- Mr. Tim Thompson concluded that the ERA is "acceptable with major revisions." He noted that the available ecological and environmental data for the Hudson River are sufficient for conducting an adequate baseline ecological risk assessment and forming the basis of a remedial decision.

- Dr. John Toll also concluded that EPA's ecological risk assessment is "acceptable with major revisions." He thought only minor revisions were necessary to make the ERA an acceptable screening-level risk assessment, but major revisions are needed to make the

ERA into an acceptable baseline ecological risk assessment.

## APPENDIX A

## LIST OF EXPERT PEER REVIEWERS

United States
Environmental Protection Agency
Region 2

# Peer Review of Hudson River PCBs Reassessment RI/FS Phase 2 Reports
## Ecological Risk Assessment

Holiday Inn
Saratoga Springs, New York
June 1 - 2, 2000

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# APPENDIX B

# CHARGE TO EXPERT PEER REVIEWERS

**Hudson River PCBs Site Reassessment RI/FS**
**Risk Assessments**
**Peer Review 4**

## Charge for Peer Review 4

The peer review for the Human Health Risk Assessment and the Ecological Risk Assessment is the fourth and final peer review that the U.S. Environmental Protection Agency (USEPA) is convening for the major scientific and technical work products prepared for the Hudson River PCBs site Reassessment Remedial Investigation and Feasibility Study (RI/FS). USEPA previously has peer reviewed the modeling approach (Peer Review 1) and the geochemistry studies (Peer Review 2). The peer review for the computer models of fate, transport, and bioaccumulation of PCBs (Peer Review 3) will conclude on March 28, 2000.

This peer review is comprised of two panels of independent experts: one for the Human Health Risk Assessment and one for the Ecological Risk Assessment. The reviewers are asked to determine whether the risk assessment they review is technically adequate, competently performed, properly documented, satisfies established quality requirements, and yields scientifically valid and credible conclusions. The reviewers are not being asked to determine whether they would have conducted the work in a similar manner.

In making its remedial decision for the PCB-contaminated sediments in the Upper Hudson River, USEPA will answer the three principal study questions that are a focus of the Reassessment RI/FS:

1. When will PCB levels in fish meet human health and ecological risk criteria under continued No Action?

2. Can remedies other than No Action significantly shorten the time required to achieve acceptable risk levels?

3. Could a flood scour sediment, exposing and redistributing buried contamination?

The risk assessments will be used to help address the first two questions. Specifically, the risk assessments will be used in the Feasibility Study to back-calculate to appropriate levels of PCBs in fish to compare various remedial alternatives, including the No Action alternative (i.e., baseline conditions) required by federal Superfund law.

## Human Health Risk Assessment

The goal of the Human Health Risk Assessment (HHRA) is to evaluate the cancer risks and non-cancer hazards associated with human exposure to PCBs in the Upper Hudson River in the absence of remediation of the PCB-contaminated sediments and any institutional controls, such as the fish consumption advisories that are currently in place (i.e., under baseline conditions). The following documents will be provided to the peer reviewers:

Primary

- Human Health Risk Assessment, Upper Hudson River, August 1999
- Responsiveness Summary for Human Health Risk Assessment, Upper Hudson River, March 2000

References

- Human Health Risk Assessment Scope of Work, July 1998
- Responsiveness Summary for Human Health Risk Assessment Scope of Work, April 1999
- Executive Summary for the Human Health Risk Assessment, Mid-Hudson River, December 1999
- Executive Summary for the Baseline Ecological Risk Assessment, August 1999
- Executive Summary for the Baseline Ecological Risk Assessment for Future Risks in the Lower Hudson River, December 1999
- Executive Summary for the Revised Baseline Modeling Report, January 2000
- Suggested charge questions from the public for the HHRA, February & March 2000

The reference documents listed above are being provided to the reviewers as background information, and may be read at the discretion of the reviewers as time allows. The reviewers are not being asked to conduct a review of any of the background information.

Additional Reassessment RI/FS documents are available on USEPA's website (www.epa.gov/hudson) and/or by request. Additional documents include the following:

- Hudson River Reassessment RI/FS Database, August 1998
- Executive Summaries for other USEPA Reassessment RI/FS Reports
- Peer Review Reports from first two peer reviews
- Responsiveness Summary for first peer review
- New York State Department of Health advisories for chemicals in game and sportfish (www.health.state.ny.us/nysdoh/environ/fish.htm)

**Specific Questions**

Hazard Identification/Dose Response

1) Consistent with its risk assessment guidance (USEPA, 1993), USEPA considered scientific literature on PCB toxicity, both as to cancer and non-cancer health effects, published since the 1993 and 1994 development of the non-cancer reference doses (RfDs) for Aroclor 1016 and Aroclor 1254, respectively, and since the 1996 reassessment of the cancer slope factors (CSFs). Based on the weight of evidence of PCB toxicity and due to the Agency's ongoing reassessment of the RfDs, USEPA used the most current RfDs and CSFs provided in the Integrated Risk Information System (IRIS), which is the Agency's database of consensus toxicity values. The new toxicity studies published since the development of the RfDs and CSFs in IRIS were addressed in the context of uncertainty associated with the use of the IRIS values (see, HHRA, pp. 76-77 and Appendix C). Please comment on the reasonableness of this approach for the Upper Hudson River.

Exposure Assessment

2) Since 1976, the New York State Department of Health has issued fish consumption advisories that recommend "eat none" for fish caught in the Upper Hudson River. To generate a fish ingestion rate for anglers consuming fish from the Upper Hudson River under baseline conditions (i.e., in the absence of the fish consumption advisories), USEPA used data on flowing water bodies in New York State (1991 New York Angler survey, Connelly et al., 1992) to derive a fish ingestion rate distribution. The $50^{th}$ and $90^{th}$ percentiles were used for the fish ingestion rates for the central tendency (average) and reasonably maximally exposed (RME) individuals (i.e., 4.0 and 31.9 grams per day, equivalent to approximately 6 and 51 half-pound meals per year, respectively) (see, HHRA, pp. 24 and 37). Please comment on whether this approach provides reasonable estimates of fish consumption for the central tendency and RME individuals for use in the point estimate calculations.

3) Superfund risk assessments often assume a 30-year exposure duration, based on national data for residence duration. However, because an angler could move from one residence to another and still continue to fish the 40 mile-long Upper Hudson River, USEPA developed a site-specific exposure duration distribution based on the minimum of residence duration and fishing duration. The residence duration was based on population mobility data from the U.S. Bureau of Census (1990) for the five counties that border the Upper Hudson. The fishing duration was developed from the 1991 New York Angler survey (Connelly et al., 1992). The $50^{th}$ and $95^{th}$ percentiles of the distribution were used for the central tendency (average) and RME exposure durations (i.e., 12 and 40 years, respectively). Please comment on the adequacy of this approach in deriving site-specific exposure durations for the fish ingestion pathway (see, HHRA, pp. 23 and 49-57).

4) PCB concentrations in Upper Hudson River fish generally have declined in past decades and the decline is expected to continue into the future. Therefore, to evaluate non-cancer effects for the RME individual, USEPA used exposure point concentration in each medium (water, sediment, and fish) based on the average of the concentrations forecast over the next 7 years (1999 to 2006), which gives the highest chronic dose considered in the HHRA. For the central tendency exposure point concentrations, USEPA used the average of the concentrations forecast over 12 years (1999 to 2011), which is the $50^{th}$ percentile of the residence duration developed from the population mobility data (U.S. Bureau of Census, 1990). In addition, for completeness, USEPA averaged the exposure concentration over 40 years (1999 to 2039) to evaluate non-cancer hazards for the same time period over which cancer risk was calculated. Please comment on whether this approach adequately addresses non-cancer health hazards to the central tendency and RME individuals (see, HHRA, pp. 67-68).

Monte Carlo Analysis/Uncertainty Analysis

5) USEPA policy states that probabilistic analysis techniques such as Monte Carlo analysis, given adequate supporting data and credible assumptions, can be viable statistical tools for analyzing variability and uncertainty in risk assessments (USEPA, 1997a). Consistent with this policy, USEPA used a tiered approach to progress from a deterministic (i.e., point estimate) analysis to an enhanced one-dimensional Monte Carlo analysis of the fish ingestion

pathway (see, HHRA, Chapter 3, pp. 33-59). Please discuss whether this Monte Carlo analysis makes appropriate use of the available data, uses credible assumptions, and adequately addresses variability and uncertainty associated with the fish ingestion pathway (e.g., defining the angler population, PCB exposure concentrations, ingestion rates, exposure durations, cooking losses) qualitatively or quantitatively, as appropriate, in the analysis (see, HHRA, pp. 72-74).

6) For the Monte Carlo analysis, USEPA evaluated a number of angler surveys, but excluded local angler surveys, such as the 1996 and 1991-1992 Hudson Angler surveys (NYSDOH, 1999; Barclay, 1993), due to the fish consumption advisories. The 1991 New York Angler survey (Connelly et al., 1992) was used as the base case and other surveys were used to address sensitivity/uncertainty in fish ingestion rates (see, HHRA, pp. 37-46). Please comment on the adequacy of USEPA's evaluation and use of existing angler surveys in the Monte Carlo analysis of the fish ingestion pathway.

Risk Characterization

7) The risk characterization section of the HHRA (Chapter 5, pp. 67-80) summarizes cancer risks and non-cancer hazards to individuals who may be exposed to PCBs in the Upper Hudson River. Please comment on whether the risk characterization adequately estimates the relative cancer risks and non-cancer hazards for each pathway and exposed population. Have major uncertainties been identified and adequately considered? Have the exposure assumptions been described sufficiently?

General Questions

1) A goal for risk assessments is that they be clear, consistent, reasonable and transparent and adequately characterize cancer risks and non-cancer hazards to the exposed population, including children (USEPA, 1995b, 1995d). Based on your review, how adequate are the HHRA and Responsiveness Summary when measured against these criteria?

2) Please provide any other comments or concerns, both strengths and weaknesses, with the HHRA not covered by the charge questions, above.

Recommendations

Based on your review of the information provided, please select your overall recommendation for the HHRA and explain why.

1. Acceptable as is
2. Acceptable with minor revision (as indicated)
3. Acceptable with major revision (as outlined)
4. Not acceptable (under any circumstance).

## Ecological Risk Assessment

The goal of the Ecological Risk Assessment is to evaluate the risks to ecological receptors associated with exposure to PCBs in the Hudson River in the absence of remedial action of the PCB-contaminated sediments (i.e., under baseline conditions). The following documents will be provided to the peer reviewers:

Primary

- Baseline Ecological Risk Assessment, August 1999
- Responsiveness Summary for the Baseline Ecological Risk Assessment, March 2000

References

- Ecological Risk Assessment Scope of Work, September 1998
- Responsiveness Summary for Ecological Risk Assessment Scope of Work, April 1999
- Executive Summary for the Baseline Ecological Risk Assessment for Future Risks in the Lower Hudson River, December 1999
- Executive Summary for the Human Health Risk Assessment, Upper Hudson River, August 1999
- Executive Summary for the Human Health Risk Assessment, Mid-Hudson River, December 1999
- Executive Summary for the Revised Baseline Modeling Report, January 2000
- Suggested charge questions from the public for the ERA, February 2000

The reference documents listed above are being provided to the reviewers as background information, and may be read at the discretion of the reviewers as time allows. The reviewers are not being asked to conduct a review of any of the background information.

Additional Reassessment RI/FS documents are available on USEPA's website (www.epa.gov/hudson) and/or by request. Additional documents include the following:

- Hudson River Reassessment RI/FS Database, August 1998
- Executive Summaries for other USEPA Reassessment RI/FS Reports
- Peer Review Reports from first two peer reviews
- Responsiveness Summary for first peer review

## Specific Questions

Problem Formulation/Conceptual Model

1) Consistent with USEPA guidance on conducting ecological risk assessments (USEPA, 1997), the problem formulation step establishes the goals, breadth, and focus of the assessment. As part of the problem formulation step in the ERA, a site conceptual model was developed (Chapter 2.3, pp. 11-19). Please comment on whether the conceptual model adequately describes the different exposure pathways by which ecological receptors could be exposed to PCBs in the Hudson River. Was sufficient information provided on the Hudson River ecosystems so that appropriate receptor species could be selected for exposure modeling?

Assessment and Measurement Endpoints

2) Assessment endpoints specify the valued ecological resources to be protected, such as local fish populations. They focus the risk assessment on particular components of the ecosystem that could be adversely affected by contaminants from the site. Please comment on whether the assessment endpoints selected (pp. 19-20) adequately protect the important ecological resources of the Hudson River. Are major feeding groups and sensitive species sufficiently covered by the selected assessment endpoints?

3) Measurement endpoints were used to provide the actual measurements used to estimate risk. Please comment on whether the combination of measured, modeled, guideline, and observational measurement endpoints used in the ERA (pp. 20-29) supports the weight of evidence approach used in the ERA.

Exposure Assessment

4) USEPA used several exposure models to evaluate the potential risks due to PCBs (see, ERA, pp. 37-71). Sampling data from USEPA, NOAA, NYSDEC, and USFWS collected from 1992-1996 were used to estimate current fish body burdens and dietary doses to avian and mammalian receptors. Future concentrations of PCBs were derived from USEPA's fate, transport, and bioaccumulation models, which are the subject of a separate peer review. Concentrations of PCBs in bird eggs were estimated by applying a biomagnification factor from the literature. Please comment on the appropriateness and sufficiency of this approach to estimate ecological exposure to PCBs.

5) Have the exposure assumptions (ERA, pp. 46-66 and Appendices D, E, and F) for each fish and wildlife receptor been adequately described and appropriately selected? Please discuss in detail.

Effects Assessment

6) For field-based toxicity studies, only a NOAEL toxicity reference value (TRV) was developed because other contaminants or stressors may be contributing to observed effects. Please comment on the validity of this approach. Also, please comment on whether the general approach of using uncertainty factors (interspecies, LOAEL-to-NOAEL, and subchronic-to-chronic) is appropriate in developing TRVs that are protective of Hudson River receptor species.

Risk Characterization/Uncertainty Analysis

7) USEPA calculated toxicity quotients (TQs) for all receptors of concern on both a total PCB and dioxin-like PCB (TEQ) basis. Please comment on whether the methodologies used in calculating these TQs are adequately protective of these receptors.

8) The risk characterization section of the ERA (Chapter 5, pp. 117-151) summarizes current and future risks to fish and wildlife that may be exposed to PCBs in the Upper Hudson River and current risks to fish and wildlife in the Lower Hudson River. Please comment on

whether the risk characterization adequately characterizes the relative risks to ecological receptors (e.g., piscivores, insectivores) posed by PCBs in the Hudson River.

9) The uncertainty analysis is presented in Chapter 6 of the ERA (pp. 153-165). Have the major uncertainties in the ERA been identified? Please comment on whether the uncertainties (and their effects on conclusions) in the exposure and effects characterization are adequately described.

General Questions

1) A goal for Superfund risk assessments is that they be clear, consistent, reasonable and transparent and adequately characterize risks to sensitive populations (e.g., threatened and endangered species). Based on your review, how adequate are the ERA and the Responsiveness Summary when measured against these criteria?

2) Please provide any other comments or concerns, both strengths and weaknesses, with the ERA not covered by the charge questions, above.

Recommendations

Based on your review of the information provided, please select your overall recommendation for the ERA and explain why.

1. Acceptable as is
2. Acceptable with minor revision (as indicated)
3. Acceptable with major revision (as outlined)
4. Not acceptable (under any circumstance).

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