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 50th and 90th 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 50th and 95th 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 50th 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).

APPENDIX C

PREMEETING COMMENTS, ALPHABETIZED BY AUTHOR

Note: With one exception, this appendix includes a copy of the premeeting comments that were distributed in a bound volume at the peer review meeting, without revision. Dr. Larry Kapustka submitted a revised set of comments to include in this report. The nature of his revisions were strictly editorial.

Peer Review of the Hudson River PCBs Human Health & Ecological Risk Assessments

Premeeting Comments

Saratoga Springs, New York
May 30–June 2, 2000

Ecological Risk Assessment Review

Ecological Risk Assessment Charge

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

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- Executive Summary for the Revised Baseline Modeling Report, January 2000
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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).

Peter deFur

May 7, 2000

EPA posed three principle study questions in this phase of the 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?

General comments:

The Ecological Risk Assessment (EcoRA) was then designed and performed to provide information relevant to these three study questions. Most of the EcoRA addresses questions 1 and 2 in that the EcoRA predicts harm from present and future PCB exposures, including predictions of PCB levels now and into the future.

Generally, the EcoRA is designed and conducted in accordance with accepted practice. The assessment does seek to draw on several types and sources of data such as direct measurements, modeled PCB levels and comparisons with data from other investigations. The assessment also uses field observations in this analysis, not relying solely on lab or computer estimates. In this regard, the EcoRA is commendable.

The EcoRA could be improved by determining the presence (and abundance) or absence of large macroinvertebrates in the Upper Hudson River and tidal freshwater Lower Hudson River. This point is made in detail below and is not elaborated here. If present, the EcoRA has omitted an important component of the system. If absent, then the EcoRA should address why certain species or groups expected to be present, or historically present, are no longer found in their anticipated habitat.

<u>Problem Formulation/Conceptual Model</u>

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).
4. 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.

The conceptual model does rely on measured and modeled values here and in other systems with PCB contamination to characterize the exposure pathways for ecological components. The Ecological Risk Assessment (EcoRA) indicates multiple exposure pathways (not sources), as food, water and direct (incidental) consumption of contaminated sediments. These three pathways are the known and measured pathways for PCB's from contaminated sediments into living ecosystem components based on other field, lab and computer modeling work. In this regard, the EcoRA is quite complete.

5. Was sufficient information provided on the Hudson River ecosystems so that appropriate receptor species could be selected for exposure modeling?

The EcoRA provided a great deal of information on which to base the selection of receptor species. But the approach used, as recommended by EPA at the regional and national level, is not complete in how this question is approached. The present EcoRA identified the sources of PCB's from local sources, sediments, etc., and quite effectively examined species that are or are likely impacted by the toxic effects of PCB exposures. The EcoRA, however, did not, however, begin with a complete (or nearly so) characterization of the ecosystem(s). The difference is whether the risk assessment effort is started with an assessment of ecosystem status, or with a source characterization. Because the sources have been known for decades, the EcoRA began with the present PCB contamination, and followed the PCB's through the known ecosystem components. Any elements of the ecosystem not known and already under consideration would be omitted, and I fear were not considered.

If major or important species or groups are present and not included in the EcoRA, then the ecosystems are not sufficiently well characterized to be sure that the receptor selection is appropriate.

Assessment and Measurement 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.

6. Please comment on whether the assessment endpoints selected (pp. 19-20) adequately protect the important ecological resources of the Hudson River.

Ecosystem components that have changed since the earlier assessments may well have been overlooked. Even major ecosystem elements that were not already known or anticipated could well have been overlooked. Several groups or species fall into this category. The following would be expected in the Hudson River system, yet were given little or no treatment in the Eco RA:

- Crayfish in the upper reaches of the study area
- Zebra mussels in the entire study system
- Freshwater mussels in the upper reaches of the study area
- Blue crabs in the lower portions of the system, but especially in the tidal reaches of the freshwater Hudson River

The two decapod crustaceans are mobile, large, predatory and move substantial distances. Preliminary investigations on the part of this reviewer (Pers. Comm. with Bob Daniels of NY State Museum and Dave Strayer of Inst. For Ecosystem Studies), revealed the likely or know presence of all the above species or groups of species.

7. Are major feeding groups and sensitive species sufficiently covered by the selected assessment endpoints?

As raised in the answer to charge question number 6, if the large bivalve or decapods crustaceans are present in the Hudson River ecosystems, then the endpoint selection may not be adequate, depending entirely on the abundance and distribution of such species.

Of the above mentioned groups, both crayfish and blue crabs are omnivorous/carnivorous, highly mobile (blue crabs are migratory) and among the largest members of the benthic/epibenthic invertebrate community. Both crayfish and blue crabs disturb the sediments and feed on infaunal invertebrates and/or dead animals. These two features offer enhanced pathways for movement of sediment borne contaminants to move into the water column or the food web.

The endpoint of "habitats" was selected, and the lower river includes the tidal freshwater portion of the river. According to this reviewer's initial research, this portion of the river is used by blue crabs, especially small male crabs that will molt in these habitats, as in other tidal freshwater rivers of the east coast (see research by deFur in 1990, by A.S. Hines and by T. Wolcott and colleagues). As such, the crabs utilizing this habitat are more sensitive than usual to the effects of chemicals that alter hormone-driven systems, as molting is controlled by a steroid hormone (ecdysone).

Measurement endpoints were used to provide the actual measurements used to estimate risk.

8. 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.

The combination of several types of measurement endpoints is a strength of the EcoRA. The use of these types of endpoints that use information from quite different sources means that the weight of evidence can include consistency of data in the assessment.

Exposure Assessment

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 US EPA'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.
9. Please comment on the appropriateness and sufficiency of this approach to estimate ecological exposure to PCBs.

This approach of using multiple exposure "models" in the exposure assessment is appropriate and provides a richer result than if all the exposures were assessed from one type of information. While direct measurements from actual field data are often harder to explain, owing tot he larger number of variables and the inability to identify and control variable sin field work, their use makes the outcome more reliable and credible. Using modeled, measured and estimated exposures provides the opportunity to examine consistency and to make a more complete and accurate assessment. Without using multiple exposure "models", the exposure assessment would be limited. The values obtained from the literature have been peer-reviewed and evaluated in several different contexts, lending strength to their use here. These values are scientifically defensible for use on the same or similar species here in the Hudson River system.

10. 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.

3.4.1 Benthic invertebrates. This exposure pathway does not include carnivorous invertebrates such as crabs and crayfish. In the lower river,

estuarine snails and polychaetes (e.g. *Nereis*) may also be carnivorous and thus will also be exposed via diet from consuming contaminated invertebrates. At present, the model treats all benthic invertebrates as the same trophic level, when, in fact, they are first level carnivores if the decapods are present. Blue crabs are reported in the lower Hudson, and may be present in large numbers in the tidal freshwater reaches.

3.4.2 Fish. It is not clear from this explanation if the exposure analysis includes direct exposure to the eggs and fingerling fish; presumably it does, based on EPA's experience with fish egg susceptibility to PCB's and dioxins in the great Lakes system (EPA 1993. Interim Report on Data and Methods for Assessment of ,3,7,8 Tetrachlorodibenzo-p- dioxin Risks to Aquatic Life and Associated Wildlife", EPA /600/R-93/055. US EPA ORD Washington DC 20460), and the abundant literature on the topic (see Rolland, Gilbertson and Peterson, 1997 for review). The exposure of the egg to PCB's through the yolk also has to be addressed. Again, it is not clear if this exposure is adequately considered in the present model effort.

The comment that direct uptake of PCB's by invertebrates could not be assessed due to data and model incompleteness does not seem adequate to this reviewer.

3.4.3 The Avian exposure pathways seem complete, given that the uptake and distribution also addresses the deposition into the yolk and subsequent exposure of the developing embryo. Presumably, the reproductive and developmental endpoints rely on this exposure pathway. Section 3.4.3.3 refers to invertebrates as a single dietary source – this is correct so long as all occupy the same trophic level. If, however, significant dietary consumption of carnivorous or omnivorous or scavenger invertebrates occurs (crabs, crayfish), then this assumption is not valid and a second category of diet items must be added.

3.4.4 Mammalian exposure pathways and factors are standard as used in other assessments for similar situations. The use of data for mink make the data and results less uncertain. As with the avian exposures, this mammalian exposure through food will have to be adjusted if it turns out that the wildlife

species are consuming crabs, crayfish, zebra mussels or freshwater mussels, as would be expected if these groups and species are present.
The statement of the first paragraph page 63 regarding the sources of information on diets for the mammals is not fully satisfactory; compiling the information into a table would be a great help for ease. Are there any species or major food groups that occur (or not) in the areas studied in the literature cited, and not directly applicable to the Hudson River system?

Effects 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.

11. Please comment on the validity of this approach.
The use of only NOAEL toxicity values would seem to be an appropriately protective method for using data from field-derived data. That is, when data on toxicity were obtained from actual field experiments, only NOAELs were used. This approach is valid if toxicity to the endpoint in question is principally determined by PCB's, AND if the interaction between PCB's and any other stressors is neither synergistic nor resulting in novel outcomes. Another way to consider this point, is if there is reason to believe that removing the stressor of the PCBs will likely diminish the harmful effect to the ecosystem endpoint.

On the other hand, if other chemicals have highly synergistic interactions with PCB's, then the use of NOAELs will not provide sufficient protection. In the present case, data from Cook (see chapter in Rolland, R., M. Gilbert and R. Peterson, eds. 1997. Chemically Induced Alterations in Functional Development & Reproduction of Fishes. 220 pp. SETAC Press, Pensacola, FL) and from Bemis and Seegal (Bemis, J.C. and Seegal, R.F. 1999. Polychlorinated biphenyls and methylmercury act synergistically to reduce rat rain dopamine content *in vitro*. Environ. Health Perspect. 107: 879-885), indicate that PCB's can act synergistically with other contaminants that are common in many areas, including the Hudson River. These contaminants include dioxin and methyl

mercury, both of which are found throughout waters of the US. If these compounds act synergistically in the Hudson River system, then the actual effects could be many times greater than anticipated by the EcoRA.

12. 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.

The general approach of using uncertainty factors has proven to be protective, notwithstanding criticisms in the literature. Uncertainty factors are not appropriate if there is reason to believe that the factor of safety is either much greater or less than the actual difference between real and expected values. EPA's data used in other applications (such as the Great Lakes and national guidance on water quality criteria and standards) suggests that ten fold safety factors are appropriate for interspecies, NOAEL to LOAEL and subchronic – chronic extrapolations. Considering that the present applications use only a single safety factor, and thus never extrapolate more than an order of magnitude, there is less chance that the results dramatically over estimate the risks to aquatic life and wildlife.

The greater concern is whether there are enough data and experience with PCB's and related compounds for the receptors in this case to be confident that the results are not dramatically under estimating the risks.

Risk Characterization/Uncertainty Analysis

USEPA calculated toxicity quotients (TQs) for all receptors of concern on both a total PCB and dioxin-like PCB (TEQ) basis.

13. Please comment on whether the methodologies used in calculating these TQs are adequately protective of these receptors.

Based on the concept of using TEQ based evaluations that are accepted internationally, this EcoRA is wise to use both forms of toxicity quotient

analysis. The strength of this approach is that it has been worked out for problem

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.

14. 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 risk characterization does a good job of characterizing the risks as described it the body of the EcoRA. If the EcoRA has failed to identify a significant food item or trophic component (e.g. crayfish, crabs), then the risks may be much greater than characterized here. The greatest source of error is likely to be the presence of crayfish in the upper Hudson in sufficient numbers that they are a major food source for such animals as mink, raccoon, some birds, etc. If crayfish make up a significant part of the diet, and the crayfish are not contaminated, then the actual dietary uptake of PCB's is less than predicted in the EcoRA. If crayfish are in the diet and contaminated, then the actual PCB uptake will be greater than predicted at present.

A related issue is the role of zebra mussels in the trophic system of the Hudson River. The EcoRA gives some consideration to zebra mussels, but does not adequately evaluate the consequences to the trophic system and transfer of PCB's through the food web. Such a large biomass and of filter feeders is known to alter the trophic system of a system. Two recent evaluations have demonstrated this point – the loss of oysters from the Chesapeake Bay, and the population explosion of zebra mussels in certain Great Lakes systems. This point needs for analysis in the present EcoRA.

The uncertainty analysis is presented in Chapter 6 of the ERA (pp. 153-165).

15. Have the major uncertainties in the ERA been identified?

Yes, with the exception of the elements of the ecosystem – does the system

contain the species or groups identified in the earlier section? The uncertainty analysis is almost exclusively qualitative. Not being a quantitative uncertainty analysis expert, it is not clear that more quantitative analysis could be or should be conducted. But I look forward to reading the comments of the other reviewers, some of whom have expertise in quantitative uncertainty analysis.

16. Please comment on whether the uncertainties (and their effects on conclusions) in the exposure and effects characterization are adequately described.
The results are adequate, but could be presented and likely conducted more quantitatively. It is not clear how the results are influenced by the use of tri+ PCB's in the model estimates as used here. Did EPA attempt any alternative approaches and obtain results that could be compared and presented? Such comparisons would be more than helpful in satisfying concerns that the tri+ PCB assessment introduces an error that could be corrected AND that alters the outcome of the assessment.

General Questions

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).
17. Based on your review, how adequate are the ERA and the Responsiveness Summary when measured against these criteria?
The EcoRA is more than adequate in conforming to the EPA criteria. Improvements could be made in avoiding jargon and in stating conclusions in a more direct and obvious fashion. When several lines of evidence converge in a clear and obvious pattern, some with an obvious outcome (e.g. the consistent and large TQ's), the EcoRA does make a clear conclusion. Other areas are not so clear and the conclusions or outcome statements in most of these cases are less definitive.

I do not recommend writing an additional characterization, or dramatically altering the present one. The present EcoRA can and should be improved as indicated in the peer review.

One of the areas not discussed was the return of species that are now excluded form the area because of the PCB contamination. Some consideration is given to this issue with regard to individual species – bald eagles. But the EcoRA should address whether other species may increase dramatically or return if the PCB levels fall below some point, or by 90%.

18. Please provide any other comments or concerns, both strengths and weaknesses, with the ERA not covered by the charge questions, above.
The major comment is included in general comments above – an assessment of the status of the ecosystem should have revealed the expected presence of zebra mussels, freshwater mussels, crayfish, and blue crabs in the tidal freshwater Hudson River.

One strength of the EcoRA is the structure and consistency from section to section. Some of the repetition of structure and following the form of the EcoRA as set out results in a larger document that repeats material. That result is an unavoidable consequence of needing to follow a strict form.

The EcoRA needs to conduct more analysis of the presence or growth of the populations of zebra mussels, especially in the upper reaches of the river. The brief discussion does indicate that this species may represent a massive flux of PCB's out of sediments (or the water column) and into the food web. If this is the case, as may be happening in the Great Lakes, then the entire model for PCB changes in the future may be in error, although the magnitude of this error is not clear. The most likely outcome is an extension of the time for PCB levels to fall, given the extensive and massive loading of PCB's in this river system.

<u>Recommendations</u>

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). The recommendation is for a major element to be added to the EcoRA. This element is determining the distribution and abundance of crayfish, blue crabs, zebra mussels and freshwater clams in the study area. This work may be simple and straightforward and not require extensive modification, but these are important elements of the system that *may* have been omitted. This reviewer's initial research indicates that blue crabs are abundant in the tidal freshwater portions of the river, that crayfish do occur in the upper portion of the river and that zebra mussels and freshwater mussels have historically occurred in the upper regions.
4. Not acceptable (under any circumstance).

Lawrence Kapustka

Lawrence A. Kapustka is President and Senior Ecotoxicologist with ecological planning and toxicology, inc., a firm he founded in Corvallis, Oregon in 1990. In addition to managing the business, Larry provides technical leadership in the areas of ecological risk assessments, plant ecotoxicology, and other aspects of ecological applications. He is Certified as a Senior Ecologist (#89, 1982; re-certified in 1987, 1992, and 1997) by the Ecological Society of America. He is a member of the Society of Environmental Toxicology and Chemistry (SETAC) Ecological Risk Assessment Advisory Group (ERAAG) and an active member of the American Society for Testing and Materials (ASTM) Biological Effects and Environmental Fate Committee (E47). After receiving a Ph.D. from the University of Oklahoma, Norman in 1975, he was on the faculty at the University of Wisconsin-Superior and Miami University, Oxford, Ohio for 13 years where he developed a research program on dinitrogen fixation and plant-microbial interactions in grasslands. From 1988-1990 he was with the US EPA Environmental Research Laboratory-Corvallis as Research Ecologist and Team Leader of the Plant Toxicology and Hazardous Waste groups. As Team Leader of Plant Toxicology and Hazardous Waste Teams he was responsible for planning, budgeting, and managing the research focused on characterization of plant physiological and ecological responses to xenobiotic chemicals, development of ecological risk assessment methods, development of ecological/toxicological assessment approaches, and methods for hazardous waste sites. Currently, in addition to providing a range of consulting services in the areas of toxicology, natural resource injury, and ecological risk assessment, Dr. Kapustka is engaged in research on plant uptake models, terrestrial food web analysis, and wildlife habitat suitability models. He has published more than 125 professional articles and technical reports, and delivered scientific seminars and technical papers throughout the United States as well as Canada, Chile, China, England, Hungary, Poland, Spain, Sweden, and Yugoslavia.

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?*

The Conceptual Model developed for the Hudson River Ecological Risk Assessment (EcoRA) was adequate for a preliminary examination of broad categories of potential exposures to ecological resources in the Main Channel of the Hudson River. Construction of a Conceptual Model requires multiple iterations among stakeholders, risk managers, and risk assessors. To facilitate this process, the USEPA instituted Biological Technical Advisory Groups (BTAGs)[1] in the early 1990s. BTAGs were intended to provide a forum to engage critical discussions on major issues related to any particular site. It is remarkable, that with the opportunity to air views on a major resource such as the Hudson River, that this reassessment effort was constrained by such an elementary-level Conceptual Model.

[1] In some Regions called Ecological Technical Advisory Groups (ETAGs).

One would hope that the administrative record, which should have included minutes of BTAG meetings, would have documented decisions made with respect to finalizing the Conceptual Model for the EcoRA. No such materials were provided for this review. Moreover, in response to a direct question I posed during the briefing meetings in March 2000, we were informed that no published materials characterizing the biological communities were available from this project. Ultimately, the Conceptual Model should be simplified to focus discussions on selection of assessment endpoints, guide the selection of surrogate species used as assessment species, and to evaluate potential measurements endpoints that would address the assessment endpoints. If such dialogue occurred, it was not captured in any of the documents available for review. The detail provided regarding the Conceptual Model fails to meet minimum standards of completeness, openness, and clarity of the process.

At a minimum, the Conceptual Model for an EcoRA of the scale of this project required a succinct description of the major ecological resources of the system. To do this, one requires a description of the major physical/biological units that ecologists would routinely use to describe the resources. For different recognized resources, this means descriptions of habitat. From an ecological view, this requires consideration of connections among critical habitats for the dominant species and for those of greatest interest to the public. To be of value for ecological analyses, this requires more than a generic list of the species that inhabit the river. Clearly, much more is known about the Hudson River system. Only after this ecological system overlay is added to a conceptual model of contaminant fate and transport (potential exposure) can meaningful discussion of assessment endpoints occur. Most of the populations of species of interest identified in the EcoRA (particularly the fish, birds, and mammals) are not confined to the channel of the River. The influence of tributaries, wetlands, and other features of the flood plain on these populations is not considered in this EcoRA. By these omissions, one has little context to understand mitigating factors that relate to exposure or population-level effects. The superficial nature of the Conceptual Model foreshadow many of the subsequent deficiencies that define the character of this EcoRA.

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?*

Articulating Assessment Endpoints is both the most difficult and the most important feature of an EcoRA. Considerable dialogue is needed among stakeholders and risk assessors to ensure (1) the ecological resources of interest to stakeholders are identified; and (2) that the expressions of these values are articulated in terms that can be assessed through scientific processes. If the values to be protected (assessment endpoints) are not assessable through hypotheses testing or weight-of-evidence approaches, then they cannot be addressed properly in the EcoRA. Poorly stated assessment endpoints

are ambiguous and do not suggest reasonable measurement endpoints that allow meaningful determination of risk.

The Assessment Endpoints stated for this EcoRA were defined poorly. Of the five bulleted "assessment endpoints" (middle of page 20, August 1999 Vol. 1 of 3), the lead action is "Protection." Protection is a regulatory or management activity, not an ecological condition.

The first assessment endpoint (first bullet) could have been improved if it were phrased in terms of viable populations of fish and wildlife. Subsequent, component (or subsidiary assessment endpoints) could then have specified which fish populations and which wildlife species were selected as surrogates for guilds, trophic groups, or other groupings. Typically, the maintenance of viable benthic communities would be defined as a subordinate assessment endpoint to fish populations instead of being granted equal standing with the fish or wildlife populations. In other words, this first assessment endpoint should have been subsumed into portions of the second and third bulleted items.

Apart from the problem with "protection" being included in bullets two and three, these statements of assessment endpoints were reasonable starting points. Unfortunately, the path forward from these broad statements was not described sufficiently, nor was it apparent that much thought went into placing these broad statements into project specific context. It was at this point in the process, that the BTAG should have engaged in an iterative process to refine the Conceptual Model and to refine the Assessment Endpoints. Explicit descriptions of the interface of critical ecological relationships among key valued fish and wildlife species and potential PCB exposure routes should have occurred. If such discussions occurred, they were not captured in the reports and background information provided for this review.

The third and fourth bullets (Protection of Wildlife and Protection of Significant habitats fail the formal tests of assessment endpoint[2]. These may well have been expressions of valued resources forwarded by various stakeholders. However, the obligation of the risk assessment team was to have become sufficiently engaged in the dialogue so that these expressions could be translated into endpoints that could be assessed. Instead the assessment states vaguely that there were "discussions with agency representatives." There was an obligation to articulate the critical factors for the eight designated areas in terms that could be assessed formally.

No description or explanation was provided regarding the selection of species in the macroinvertebrate, fish, avian, or mammalian that are to be assessed or that served as surrogates for species to be assessed. This section begs for a coherent description of the biological communities (composition and

[2] Assessment Endpoint-Formal expression of the actual environmental value to be protected; Measurement Endpoint-The physical, chemical, biological, or ecological condition that is quantified; ideally, this yields information on the effect of a hazard; to be useful in site assessment, the measurement endpoint must correspond to or be predictive of an assessment endpoint.

abundance of species) which include the assessment species. This section should also have included explicit criteria which were used to select the species of interest, so that a reader might know which other species were considered, which species represent collections of other species, reasons why other species were not selected, etc. Instead, there was a rather authoritative presentation without any supporting documentation. What was the rationale for choosing largemouth bass over small mouth bass? Were crayfish considered? What assumptions were imposed on the selection process?

The criticisms presented are not raised from mere academic perspective, but rather as cornerstones for conducting quality EcoRAs. Each assessment species has different requirements or habitat preferences. Each also has different behavioral features which influence habitat use (i.e., where they feed, when they feed, where they loaf, where they breed, and others). Without such information, it is impossible to determine whether the procedures used to estimate exposures were reasonable or whether they were wildly biased in one direction or another.

The report submits that the assessment endpoints were phrased as assessment questions and paired with measurement endpoints. That was not done effectively. Most of the "measurement endpoints" simply restate the "assessment question" without providing meaningful information. An example of the construction that would have been appropriate is:

Assessment Endpoint:..... sustainable populations of largemouth bass

Assessment Endpoint Question:... Are PCB concentrations in the Hudson River sufficiently high to adversely affect reproduction of largemouth bass?

Measurement Endpoint$_1$:..... concentration of PCBs in largemouth bass tissues (whole body, eggs) to be compared against toxicity response relationships.

Measurement Endpoint$_2$:..... size (age)-class distribution of largemouth bass at (appropriate number) sites in the Hudson River system.

Methodology for ME$_1$..... obtain fresh tissue samples from selected locations; process and analyze the tissues [state analytical chemistry procedure and detection limits]

Methodology for ME$_2$..... [choose among several seining, electroshocking, trapping methods] to enumerate populations of

different size/age classes at representative locations in the River; [state DQOs].

The first measurement endpoint would permit direct measurement and modeling efforts to extend or interpolate sampling data to other portions of the river. It would permit comparisons to threshold values and re-calculation of data into TEQ values. But it would also strive to use more than a mere threshold concentration (and thus be limited to a quotient); it would provide a basis for expressing a probability of a 10%, 20%, or 50% impairment in reproduction.

The second measurement endpoint would ask the central question of whether the exposures are translated into ecological effects. If the size (age)-class distribution shows an abnormal profile, then one has evidence to corroborate predicted effects. Alternatively, if the data indicate a normal profile, then it suggests that either recruitment from other areas is occurring or the predicted effects are being mitigated by factors that lower exposure levels or other important biological processes.

As they were stated in the report, the assessment questions and measurement endpoints restrict opportunities for developing a robust EcoRA. They forecast that the EcoRA would be an exercise in Quotients and that ecological data would have very little importance. For example, for fish, the first four measurement endpoints were structured to look solely at measured or modeled PCB concentrations in relationship to point estimates (TRV, AWQC, or sediment benchmark). The fifth endpoint ("available field observations on presence or relative abundance...") provided little basis for setting meaningful data quality objectives to be used to make this assessment.

The specific directive and question we were presented for this review [*Please comment on whether the assessment endpoints selected (pp. 19-20) adequately protect the important ecological resources of the Hudson River.]*; and *[Are major feeding groups and sensitive species sufficiently covered by the selected assessment endpoints?*]can be answered yes. But a more important question, "Were the assessment endpoints articulated properly?" the answer is clearly no.

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.*

As described under Charge 2 above, the assessment endpoints were not properly articulated and the measurement endpoints were inappropriately restrictive. In effect, the focus of the EcoRA was on PCB concentrations in various media (water, sediment, and selected tissues). These data were analyzed in different ways to generate total PCBs and TEQ values, which were then compared to TRVs. Not discounting the tremendous effort this involves to qualify all the analytical data, in the end this distills down to different ways to calculate ratios. In order to have a solid weight-of-evidence approach, much

greater credence to ecological data was required. EPA made no effort to characterize any of the populations of fish, birds, or mammals of interest in the project area. Their field work was limited to a small benthic community survey, and in the end the results of the survey were largely discounted.

If one applies Hill's (1965)[3] logic tests to the suite of measurement endpoints, it becomes obvious that field data are needed to establish a weight of evidence argument (partial list of Hill's criteria):

- *strength* – [Is the magnitude of effect associated with exposure to the stressor high?],
- *gradient* – [Does a positive correlation between stressor and effect exist, (i.e., is there a "dose"-response relationship)?],
- *experimental evidence* – [Did the data analysis confirm or reject the null hypotheses?], and
- *coherency* – [Are the hypotheses tested relative to the stressor effects consistent with ecological and toxicological knowledge?].

Absent collection of ecological data specifically for the project, it was possible to rely on data collected for other purposes. Most of the ecological data from other sources that were cited in the EcoRA are counter to the predicted adverse effects generated by the modeling approach. If one wishes to claim reliance on a weight-of-evidence approach, then such data cannot be dismissed. So to respond to the charge of the reviewers, the simple answer is yes a weight-of-evidence approach could be developed from "the combination of measured, modeled, guideline, and observational measurement endpoints used in the ERA," but in the end, that was not done.

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.*

Characterization of PCB concentrations in selected sampling stations in the Upper and Lower Hudson River in water and sediments were quite extensive. There were also a number of measures of PCB congener concentrations in benthic invertebrates and in fish tissues. These measured values were used to describe changes in congener pattern downstream and were compared among media for co-located samples. An analysis of congener data was undertaken to bridge different analytical techniques reported from various studies. This analysis was quite elegant and provided reasonable descriptions of down-stream and temporal changes in patterns among congeners. For the most part, the "fate and transport"

[3] Hill, A. B. 1965. The environment and disease: Association or causation? Proc. Royal Soc. Med. 58: 295-300.

components of exposure assessment within the physical compartments was done well. The two most problematic features of this fate and transport effort were the change in sediment sampling cores and the failure to consider that bio-perturbation could account for seasonal or episodic bursts of suspended materials in the water column. Spawning activities, particularly by common carp; burrowing by various benthic organisms; as well as wake and prop motion from boats, disturb sediments. Although the cause for the episodic events was not attributed correctly, the description of patterns of suspension was probably still reasonable.

The modeling effort to project the various concentrations into biological tissues cannot be dissected adequately here, because the documentation of exposure models was not provided and review comments from a separate panel are not yet available. There was some indication that the predicted values were tested against measured tissue concentrations from fish sampled between 1992 and 1996. Typically, there are many assumptions in exposure models. It is not clear which were calibrated to fit the measured data, (i.e., which parameters were adjusted in the benthic or fish bioaccumulation models to bring the predicted values in line with the measured values). The accuracy of the long-term predictions depends on what was done in these calibration steps. Presumably, these features will be addressed thoroughly by the other peer review panel.

The use of measured concentrations in food items to estimate "current" dietary exposure was appropriate. However, there are many other critical assumptions in exposure models. One needs to revert to the Conceptual Model to address whether the underlying assumptions were reasonable or not. There were several starting assumptions that should have been evaluated more thoroughly in this section (albeit that would have required a more sophisticated conceptual model than the one reported). The assumption that piscivorous birds received 100% of their diet from main channel fish was appropriate for a first-cut screening level risk assessment. However, for a project at the stage of this re-assessment, much more was warranted.

Bald eagles for example are quite opportunistic in their feeding preferences. Individuals (more accurately nesting pairs of) bald eagle diets in other portions of the country range from <10% to nearly 100% fish. Foraging, though it may focus on the main channel, would also extend a few kilometers overland and into other water bodies. Eagles will also take ducks, rabbits, and other similar sized animals when an opportunity presents itself. Tests of different scenarios are important to explore the likelihood of different levels of exposure. Similarly, the exposure assumptions for raccoon, otter, and mink should have considered different scenarios that could be refined with site specific information. Too little effort went into these critical steps.

The importance of getting exposure right, is made more important by the overall approach used by EPA in this EcoRA. In particular, the sole reliance on Hazard Quotients, and underscoring the different magnitudes of exceedence, elevates the importance of exposure assumptions. The practice of selecting

the lowest threshold values (No Effect Levels discussed in the effects charges) and often dividing these concentrations by 10, provides a very small TRV. When one has a very small TRV, a very small change in exposure produces a very large quotient. If indeed the dietary exposure is overestimated, as it might be, these assumptions alone can result in 50-fold changes in the hazard quotients. Clearly, more importance and more effort should have been placed of refining the exposure assumptions for current conditions. If this were done, then the forecasts for exposures over the long-term would be more accurate.

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.*

One of the most critical assumptions in the exposure estimates for fish and wildlife was setting the "Area Use Factor" or "Forage Effort" equal to one. Though the total area covered by the channel of the Hudson is large, it is relatively narrow with respect to landscape use patterns of wildlife. Even for fish, consideration of connections to tributaries, or connections between deep-water areas and shallows have great influence on exposure.

In general, the equations used to estimate exposure project a sense of detailed knowledge that far exceeds reality. Each of the input parameters to the equations in itself is an estimate with many underlying assumptions. When used as algebraic expressions, one simply calculates a value. The choice of input parameters appears to have been skewed to provide "protective" levels. The problem this introduces is that each "protective" value gets applied on top of other "protective" values. After two such protective values are pieced together, the result is that predictions cannot be verified because the calculated value is outside the range of experience (measured values). Two steps that may have been performed, but are not prominent in the report, that could illuminate problems with assumptions, are sensitivity analysis and probabilistic risk assessment.

A detailed sensitivity analysis should have been performed to identify the level of precision required for different input parameters (and assumptions). Such an effort would rather quickly focus on a select few parameters that could then have been given special consideration. Critical parameters such as K_{ow} have different reported values. How sensitive are the exposure models to variations in the K_{ow}? How critical is the lipid fraction of the receptor? ... metabolic rate? assimilation efficiency? rate of depuration? and many others.

A probabilistic approach would have permitted additional sensitivity analysis as well as place the estimates in closer agreement with field data. For example, the actual concentrations of PCBs in benthic invertebrates could have been "sampled" through thousands of runs to produce percentiles of different exposure concentrations. Each of the major assumptions could have been described as a function about the mean to eliminate the compounding of error that occurred from using multiple "protective" values.

It is important to note, that the basic structure of the exposure estimating procedures, outlined in this section, follows normal practice for EcoRAs. However, the level of detail achieved in this EcoRA was appropriate for a preliminary study, or a screening-level EcoRA. The use of *protective* assumptions is fully warranted for screening level efforts – if despite the assumptions, there is no indication of a problem, then the work is done; however, if there is an indication of a problem, it is a signal that more effort is needed. In this project, it was quite surprising to find that the follow-up definitive work was not done. The effort describe here was fine for studies at the start of the reassessment. It was quite inadequate for the current stage of the project.

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.*

For most of the last decade EPA and others have known of the significant technical limitations pertaining to the use of NOAELs and LOAELs. The arguments were presented by Chapman *et al.* (1996)[4] and are the basis of a growing consensus that the ANOVA designs used to estimate threshold values are inappropriate for ecotoxicology or for risk assessment. Briefly, they have shown that the concentration interval, the number of replicates, and variance, (both in responses and in measurement of concentrations), have more bearing on the value obtained than the *true* toxic response. Moreover, the point estimates do not provide any information related to the shape of the concentration-response relationship. There is no distinction between steep-sloped responses or shallow-sloped responses. A much more useful construct is one that uses a regression model to describe and effect-level (e.g., EC_{20}). The regression approach provides confidence intervals as well as a ready means of translating the information into a risk characterization. Also, all the data from a regression model study are used to arrive at the point estimate, providing a more robust analysis of the data (i.e., less subject to nuances of study design. In using NOAEL and LOAEL values from individual studies to calculate TRVs, there is no opportunity to know how much experimental error is imbedded in the number. It would be better (if one felt compelled to use NOAEL-LOAEL data) to use data from more than one study. The NOAELs and LOAELs of different studies could be arrayed ala Long and Morgan (1991)[5]. Alternatively, the MATCs (Maximum Acceptable Toxicant Concentration determine as the median or the geometric mean of NOAEL and LOAEL), of individual studies could be calculated and a grand mean of all studies used as the TRV.

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[4] Chapman, P. M., R. S. Caldwell, and P. F. Chapman. 1996. A warning: NOECs are inappropriate for regulatory use. *Environ. Toxicol. Chem.* 15: 77-79.

[5] Long, E. R. and L. G. Morgan. 1991. The potential for biological effects of sediment-sorbed contaminants tested in the National Status and Trends Program. NOAA Technical Memorandum NOS OMA 52, National Oceanic and Atmospheric Administration. 175 pp.

There is no technical foundation for a decade safety factor being applied for any extrapolation (i.e., either interspecies or sub-chronic to chronic). The arguments against using assessment factors were presented by Chapman *et al.*, (1998)[6]. The use of an assessment or safety factor is entirely a policy decision, notwithstanding that some scientists might wish to hedge their answers and favor assessment factors.

Even more troubling than the use of NOAELs and LOAELs, is the extensive reliance on the TRV construct. The purpose for developing Threshold Toxicity Response Values is to provide a rapid means of screening chemicals into or out of a more detailed risk analysis. The comparison of the TRV and the Environmental Concentration provides the simplest means for identifying situations of "little or no concern" versus situations with "possible concern." Because the Hazard Quotient that emerges from this comparison is a unitless value, and because there is no scalar to equate the severity of an increasing quotient to a toxicological response, the approach has no further utility than to classify situations into the two categories. A quotient of 100 should not be characterized as being 10-fold worse than a quotient of 10. A quotient of 100, based on a *protective* TRV and a high-end concentration range (e.g., 95% UCL) may still be below the toxicity threshold response level. Due to the several policy decisions that force the risk assessor to pick the lowest threshold levels and the highest possible environmental concentrations, many (maybe even most) exceedences are in the toxicity *di minimus* range.

The use of Hazard Quotients has great value in streamlining EcoRAs. The role for the Quotients, as stated above, is in the screening phase of a risk assessment, to focus on key receptor groups, on selected portions of the site, and to suggest topics for more detailed investigation. When used properly, one can justify the high bias toward protectiveness. The consequence of not being screened out is that the costs of investigation increase. As one proceeds through the more detailed EcoRA, the *protective* default assumptions are replaced by empirical site data. Moreover, as one reaches the later stages of the EcoRA, the shift of emphasis should proceed from "what is possible toxicologically" to "what is probable ecologically." In other words, one begins to place the toxicological data in context. Whereas the toxicological data (especially laboratory studies) were developed for individual level effects, the ecological data incorporates population- or community-level dynamics. This is not how EPA conducted this EcoRA. Rather, EPA used a screening-level tool for what should have been a definitive-level EcoRA. Consequently, EPA has greatly overstated the level of risk to receptors.

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.*

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[6] Chapman, P. M., A. Fairbrother, and D. Brown. 1998. A critical evaluation of safety (uncertainty) factors for ecological risk assessment. *Environ. Toxicol. Chem.* 17:99-108.

As with the TRV approach, the TEQ is a simplified tool to handle a lot of complicated information quickly and easily to arrive at a screening-level determination of risk. There has been much written to justify the TEQ, mostly for human health applications. But one should not lose sight of the large number of assumptions imbedded in the summaries. A frank analysis of the process highlights that the underlying data set used to establish relative risk among compounds is far from robust. There are multiple assumptions, all biased to be protective, that contribute to the relative values. The physical chemical properties of dioxins, makes them extremely difficult to work with. Large measurement errors are the norm. Add to this the reality that quantifying concentrations of PCB congeners can be as much art as science, one has a large uncertainty. Again, the nature of the process is to err on the side of protection.

Whereas this may be appropriate for most human health concerns, and it may be fine as a forecasting effort for siting a new facility, there is little reason to rely so extensively on the TEQ approach for a definitive EcoRA. EcoRAs of existing sites have the luxury of relying on analyzing populations and communities of receptors directly. A TEQ approach might have merit in assigning causality to a documented adverse population or community condition. However, as a stand-alone forecaster, the TEQ approach is designed to be biased and as such will predict harm when none may exist.

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 and insectivores) posed by PCBs in the Hudson River.*

Virtually all of the Effects Characterization (Chapter 4) dealt with evaluation of exposure concentrations and toxicity tests reported in the literature. No effort was made to relate the exposure levels to effects – and certainly there was no effort to relate toxicity measurements to population-level effects. Experience in ecotoxicology is that concentrations shown to have effects on individuals, typically requires similar or higher concentrations to be manifest in the field. Here, however, toxicity data were routinely divided by ten as an *uncertainty* factor. This policy issue belongs with risk managers and should not be imbedded in the technical portion of the EcoRA. The "Effects" chapter set a target concentration well below all known no-effect levels. Subsequently, exceedence of these target concentrations, biased toward protection, were used as confirmatory *evidence* to claim adverse effects were occurring, that unacceptable risks were prevalent, and for the future unacceptable risks were projected.

The risk characterization chapter also relied on national water quality or sediment quality criteria that were established to regulate discharges. Even for discharges, site specific characteristics are used to adjust the values. It is inappropriate to merely compare concentrations to these values without more in-depth analyses. As with the HQ, exceedence does not mean harm will occur. It is merely indicating that under some circumstances harm may occur. The approach used here would have been appropriate for a screening-level EcoRA, but is inadequate for an 11-year reanalysis of a site.

Exceedence of a toxicity NOAEL adjusted by a 10-fold safety factor should not be construed as an indicator of adverse population effects. Even exceedence of a toxicity-based LOAEL requires evaluation of all circumstances affecting bioavailability and compensatory mechanisms that govern populations before a conclusion of unacceptable risk is warranted.

Fish Populations (p. 128-)

Point 1: ... bass, bullhead, spottail shiner, yellow perch, pumpkinseed ... The information of survey data was described as qualitative. Because some would interpret this to mean *presence* versus *absence* comparison, instead of quantifiable population data, this characterization is misleading. For the EcoRA, had legitimate assessment endpoints been articulated in terms of sustainable populations, the clear conclusion would have been that PCB concentrations were not adversely affecting the populations. As is, the EcoRA rejected critical information that would have dismissed PCBs as harming fish populations. This apparently was done in favor of elevating an untested speculation that problems are occurring, even though population data indicates no such harm.

Point 2: This characterization even more boldly rejected relevant data so as to accept untested speculation in a most unscientific manner. It was quite disingenuous to dismiss sustained monitoring information over the entire period of peak contamination (a couple of decades) in order to hold out that with a little more time, with substantially lower levels of contamination, effects will manifest into dire consequences.

Point 3: In the face of a longer period of monitoring showing that an endangered species has continued to increase in population, in spite of the major insult from PCB contamination, the EcoRA again reached for extraneous dismissals such as "decades are too short to evaluate populations of sturgeon" (that require seven to ten years to mature).

Point 4: This further exposes an apparent pre-disposition to find that PCBs were harming populations. Coupled with the first three points, there is evidence that *r*-selection and *K*-selection species have increased their populations during the period of highest PCB exposures. Those data refute any speculative assignment of adverse effects of PCBs to these receptors. The data demonstrate the extensively protective nature of the TRV-HQ process, appropriate for screening-level work, where exceedingly little opportunity exists for gathering field data, but inappropriate for the level of EcoRA needed for this project.

Bird Populations (p. 129-)

As above, exceedences of safety-factor adjusted NOAELs should not be used as proof of adverse effects.

Overall, the focus on the Hazard Quotient approach based on NOAECs or LOAECs fails to consider the slope of the response curves for PCBs. Experimental designs for PCB studies should be more robust than they have been. However, even with the limitations of the predominantly ANOVA based studies, the NOAEC-LOAEC ranges are an order of magnitude. So a quotient of ≅10 for a NOAEC may still be below a LOAEC. In that assessment factors of 10 were applied routinely, a quotient of ≅100 is still likely to be below the LOAEC. And, if a true LOAEC were determined, this still would not translate automatically to a population-level effect.

Through p.137, modeled values from HUDTOX were used to predict exposure levels. No documentation of HUDTOX was available for this review. However, if it also incorporates protective assumptions, then the quotient would be biased further so that exceedences of the quotient of ≅1,000 still might have no population-level effects. Indeed, this is precisely what the various population monitoring data indicate.

EPA chose to downplay the value of field observations. The survey (pp. 137-138 and 146), which was conducted, was described as "not formally structured." The social sciences have well-established procedures to structure formal surveys. Why was the opportunity lost? The rationale offered, that the "diversity of experiences of interviewees" diminishes the value of the information should not be accepted as a legitimate excuse for dismissing critical information. Indeed, conflicting views among interviewees on some topics were selectively presented when they favored EPA's conclusions. It was not clear what was intended (page 139) by writing paragraphs attributing observations to certain individuals. Is something implied because it was Mike Brown, or Jim Brushek? What is the relevance of a professional tracker to observations, or more correctly non-observations, of birds?

What is even more interesting was the presentation on page 148. This paragraph began by praising the knowledge of professional fishers in terms of their observational skills (having previously remarked that field observations had limited value). The report then named one fisherman, provided no context for the statement made, but used the statement to refute a statement of Mr. Brushek regarding mink. So, EPA managed to use Mr. Brushek (a tracker, trapper) to refute bird experts on issues of osprey and a fisherman to refute Mr. Brushek on matters central to his expertise, mink.

Throughout this section, there were unexplained conflicting statements. For example (p.138 second full paragraph) the statement "... however studies in this area are limited" was followed (next paragraph) by "Avian wildlife are well studied along the Upper Hudson River." The statement, "The king rail was reported to be nesting, but nests haven't been confirmed" required better description of the nature of the initial report and the criteria needed for confirmation. In a subsequent paragraph, EPA used an authoritarian argument to cover apparent absence of definitive information. If additional insights were needed to understand the claims made, then those insights should have been described in sufficient detail.

The observations, reported in the first paragraph on page 139, should have been presented prominently with detailed tabulation of observations in earlier chapters. Putting these data at this point in the document as an aside, signaled that the data were not particularly important – when in fact they were the most germane data for the EcoRA. Throughout the section, it was clear that EPA took a stance that modeled data would take precedent over real observations.

On page 142, the discussion of mink tissue concentrations from the mid-1980s was legitimate. What was needed for this reassessment was a re-survey of mink now. EPA chose to report observations from a Mike Brown (page 147). If his observations are reasonable, the information in that one paragraph should carry more weight than all of the modeled exposure estimates, TRV derivation, and Hazard Quotient work undertaken in this project. Those observations would establish the important population consequences that had proper assessment endpoints been articulated would have concluded:

a) past conditions adversely lowered populations;

b) populations have improved with source control; and

c) in the future, there will likely be continued improvement of populations.

On page 148, the discussion regarding modeling largemouth bass to represent sturgeon was superfluous. Solid data showing an improving sturgeon population already addressed this issue.

Collectively, this section was unnecessarily constrained to reliance on screening-level tools, which by design were biased significantly toward protection. This EcoRA deserved a much more credible treatment. The methods for sound characterization of effects at population and community levels exist. They are not prohibitively expensive when applied correctly. Nor are they fraught with large uncertainty, certainly not nearly as ambiguous as all of the uncertainties imbedded in the modeled exposures, TRVs, and Hazard Quotients. The clear answer to the formal review question is that absolutely the conclusions reached here are protective of all ecological receptors. A more appropriate review question would address whether the conclusions are reasonable and useful. In light of monitoring data presented or alluded to in the report, the clear answer is that the conclusions grossly overstate the severity of the contamination. The conclusions were reached only by dismissing credible data in a most unscientific manner. And finally, if one hopes to inform decision-makers, there is nothing particularly useful to evaluate any management options. One could only define attainment criteria in terms of water or sediment chemistry, and this is without regard to any ecological considerations. Ultimately, someone will have to evaluate certain remediation options in terms of benefits (reduction of risk) realized against cost. In that no adverse population risks were demonstrated, any active removal of sediments would almost certainly have greater consequences than the contaminants. Sadly, a well-focused EcoRA would have provided the basis for such evaluations. This one falls far short.

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.*

Beginning with page 156 (Conceptual Model), the discussion was unnecessarily vague. A conceptual model should represent what occurs at the site. To say it is generalized and "not intended to mimic actual individuals or species" may be fine for a classroom activity pursuing a theoretical case, but it shows deficiency in the application of the process intended to address a significant site. It lacks the necessary rigor and renders the results merely hypothetical instead of contributing directly to management decisions.

A statement on page 158 "Typically no more than 10" was used as a safety factor – were larger factors applied? I interpreted the materials to be: no safety factor greater than 10 was used.

The uncertainty chapter was cast in very generalized terms. Nothing in the chapter leads to the several statements that claim uncertainty in this analysis is low. What the EPA appears to have meant is that it is highly unlikely that any problems greater than projected could occur. To this extent, the statement is correct. However, the uncertainty as to whether any of the projected problems would develop is very large – indeed refuted by the various monitoring reports. In that regard, the uncertainty of the process employed for this EcoRA is very large; it just happens to be biased in a ways consistent with screening-level efforts.

The uncertainty analysis provided little documentation to support its statements. No effort was made to quantify uncertainty in the individual components of the assessment. There were no analyses of the uncertainty in the individual toxicity studies relied upon to set TRVs. There were no sensitivity analyses reported to show how the Hazard Quotients would respond to the choice of the TRV or the modeled exposure concentrations. There were no efforts to display probabilistic data to show how the assumptions in selecting a 95% UCL, would change predicted quotients. As many of the assumptions used were screening-level assumptions intended to be overly protective, there was inadequate description of how those policy-driven decisions impacted the results. But more importantly, EPA's dismissal of field data as being too erratic to rely on, presented a false description of the science of ecology. The uncertainties in monitoring data can be described fairly. Ironically, many seem to have lost sight of the connection that it was field data on the condition of ecological resources that led us to understand the effects of toxic substances. It is disingenuous to discard current ecological information that can provide demonstrative evidence of improving conditions. In this regard, one must conclude that EPA underplayed the protectiveness bias inherent in the HQ approach and overplayed the uncertainty in monitoring data and other ecological observations.

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?*

If the goal was to be clear, then the decision to issue a response summary to a draft, but not re-write the risk documents was incongruous. As it is, one must migrate back and forth between a review draft document and a "responsiveness" report to piece together the final position EPA is making. This is inexcusable for such a high-profile project. The cost of reprinting a complete document is trivial compared to the costs already incurred in assembling the report.

The traits of clarity and consistency are challenged in the Executive Summary. I began my review by reading the executive summary to understand where the body of information in the various reports was headed. This was one of the most confusing executive summaries I recall reading. For each receptor group, there was a leading statement that suggested that overall there were no adverse effects from PCBs for that receptor group. The subsequent sentences contradicted that umbrella position by claiming that the receptor group in each of the sections for the Upper Hudson exceeded the TRV; and for the Lower Hudson the effects may be less. These statements are internally inconsistent and irreconcilable. Ultimately, what became clear is that the first statement was supported by the data, but that the modeled screening-level analysis suggested there should have been grave problems.

In response to EG8 (page 24 Responsiveness document on the SOW), EPA exposed a significant inconsistency in its policies while commenting on the rebound of fish populations following fish advisories. The argument forwarded by EPA that fish advisories may have had a greater overall effect on abundance of various species is accurate. However, the gist of the comment ignores the most important issues posed. The comment underscores that purported effects of the contaminants are overestimated and exaggerated. The fact that fish advisories led to a rebound in populations, even with the contaminants, provides sound technical evidence that the contaminants have a minor impact on the fish population-level endpoints. The oft-stated policy of EPA is that it focuses on populations. The decisions made in this EcoRA were clearly inconsistent with EPA policy.

In terms of transparency, I would think this EcoRA would be extremely difficult to follow for most stakeholders. The data presented in companion volumes is not particularly illuminating. In a number of situations, I went to the supplemental volumes to find data referred to in the main volume, only to find that no substantive information was there. A very large quantity of trivial information was packaged into the supplemental volumes. For example, instead of a description of the communities of interest within the site, one finds a table of species that might inhabit the site. All of the information on modeling was the

purview of a different review team. Because the models were so prominent in terms of the conclusions, it would seem that much more detail was appropriate to meet a standard of transparency.

The conclusion section is not balanced. For example, the presentation of benthic community data showed differences in five sites, but the TOC normalization erased the differences. It is now interesting that in the conclusion, this very tenuous connection with PCBs was attributed as a solid line of evidence. The pattern of selectivity exercised by EPA was evident with each conclusion. Fundamentally, the analyses presented in the body of the EcoRA do not support the categorical conclusions stated in this chapter.

Failure to assess populations makes it impossible to characterize risk at the site with any sense of realism. Moreover, there is no foundation to judge any aspects of risk reduction, to select among remediation options, or to convey sound information to the public. This was described as a way to do the risk assessment without unacceptable delays and to control costs. In reality, each of the major groups of interest could have been evaluated directly in much less time and at no greater cost than this lesser effort apparently required. This is especially true, as those studies will be required if one is to use scientifically valid information to evaluate remediation options. Indeed, the total cost to correct the problems introduced by this limited effort will be much greater than had they been incorporated into the original scope of work.

In its assessment (p29) the statement was made, "The major strength of observational studies is that the receptor is examined directly and the results have a 'real world' feel. People often have greater confidence ..." It is not just 'people' in general; it is the core of science. If it is not observable (testable), it fails. Despite this statement, the assessment was designed to avert direct observations as a matter of policy. In the next paragraph, there were inaccuracies that compromised the assessment by taking it out of the realm of science. It was wrong if not disingenuous to avert field observations as having lesser importance than other approaches due to variability in natural systems. Virtually all we know about ecology is grounded in field observations. The assertion that modeled estimates have higher precision is not and cannot be supported. The concern that a receptor may be harmed by other factors is a one-sided concern and this is one that the regulator would not have to contend with if the population is doing fine. If the population of interest is doing poorly, then it is true that more proof is required. But in the case at hand, if the population parameters were nominal, then one should conclude that the claims of adverse effects predicted by models would be refuted.

The Addendum (Dec. 1999) was less of an addendum than a selective repeat of major segments of the August 1999 report. The key differences are that the modeling data was incorporated and ecological descriptions or observations were not reported. The effect was to move further from reality and made it more difficult to challenge conclusions. The extremely tenuous conclusions made in the earlier report at least had to sidestep or otherwise ignore contrary data. Here, these conclusions were posited with much

greater authority and as being factual. The fundamental reality remains – each of the target populations are reportedly doing well since source controls were implemented. The conclusions of risk can be achieved only through discounting several independent lines of data from trustees. This required discounting all direct observations that were contrary to the hypothetical adverse conditions. Thus the refinement of the risk estimates appear to be attempts to demonstrate adverse conditions into the future (when exposure levels should be declining) despite several independent observations that demonstrate that extant conditions are already better than the risk assessment predicts should be happening now.

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

There are several troubling aspects of this situation that beg for candid disclosure. Having been at the forefront of development of procedures used in EcoRA for more than a dozen years, and having performed large-scale EcoRAs, I cannot reconcile what happened here. The Hudson River PCB problem has been one of the most prominent high-profile sites in the Nation. EPA guidance going back to 1989[7] promoted use of ecological data to characterize conditions at sites. EPA's *Framework*[8] documents advanced many of the critical aspects of setting assessment endpoints introduced in the 1989 guide. Judged against those documents, which were highly visible and widely used across the Agency when the Hudson River reassessment began, there is no convincing explanation for the major deficiencies of this EcoRA. The several reports here emphasized compliance with the newest EPA guidance with the eight-step process. This is despite the reality that most of the work had been completed prior to issuance of this 1998 document. Moreover, the 1998 Guidance emphasizes use of field observations. Clearly, the practices followed here never got beyond a preliminary assessment typical of a screening-level effort. In that the site had already been examined in some detail, one could easily have skipped the screening-level exercises and moved toward definitive analyses.

Relying on policy, EPA decided to rely solely on toxicity endpoints and "individual risk" in lieu of population-level metrics. This was consistent with the bottom-up policy. However, the position as described suffers from being technically false. The consequence is that the EcoRA is based on untested concatenated hypothetical situations. This is despite the technical feasibility to test many of the assumptions directly. Failing to test what is testable should not be hidden behind policy. Proposing things that are not testable is counter to the foundations of science. The response is technically weak. Indeed the acknowledged limitations of the TRV process in this response would seem to have laid the foundation for greater reliance on field measurements of populations.

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[7] W. Warren-Hicks, B. Parkhurst, & S. Baker, Jr. (eds.). *Ecological assessment of hazardous waste sites.* EPA/600/3-89/013. U.S. Environmental Protection Agency, Environmental Research Laboratory, Corvallis, OR.

[8] US EPA. 1992. *Framework* for Ecological Risk Assessment. Risk Assessment Forum. EPA/630/R-92/001.

Perhaps the most troubling of all the concerns about this EcoRA has been the attitude portrayed in the responsiveness documents. Collectively, the responses to legitimate technical issues were dismissed by citing policies. Each of the legitimate questions posed during the comment periods that asked for clarification of assumptions of models or to rectify predictions of risk with contrary observations on the conditions of the resource were rejected. The consequence is the stance taken by EPA was to diminish the quality of the EcoRA. Had the legitimacy of the technical questions been acknowledged, there would have been ample time to address them properly. If this current review process is a serious one, EPA must revisit its position to preempt scientifically sound data by imposing policy.

Detailed Comments:

The following statements contain additional observations and questions raised in reviewing the various reports that were not covered in my responses to the nine specific charge questions and the two general charge questions. These appear in sequence of appearance and are attributed to the specific reports.

Responsiveness to Scope of Work – Sep. 98

p. 13. The response to EP-3. Not making comparisons to other sites may have legal justifications, but it is nonsensical from a scientific or technical perspective.

p. 13. The response to EG-1. The response is policy driven and is unsupported by science. By ignoring field information at the start of the assessment, there is no context for basing the substantial effort of the study. Indeed early field observations provide the most focused work and substantial lower costs. The same goes for the response to EG-5 on page 15. The policy is without foundation if one is conducting a technical assessment. It may well be a choice of managers to then move in these directions, but it is inappropriate to respond to technical questions by invoking policy. The questions remain unanswered.

The third part (bottom of p. 15) averts direct analysis of populations or communities, relying instead on key biological receptors. However, the "key" receptors were not selected through a rigorous process. Justification for the selection in documented poorly.

p. 17. Here and in several places the odd redundant combination "potential risk" is used. Risk implies a potential expressed in qualitative or quantitative terms for some adverse consequence to occur in the future.

p. 18. Response to EG-7. The policy line is repeated.

p.20. Response to EG-12. The declaration of the choice of largemouth bass over smallmouth bass begs for justification of this selection.

p.25. The assertion that assimilation rate, metabolic efficiency, and the structure of PCB congeners ingested *"is beyond the scope of the EPA SOW"* underscores the reason field data on tissue residues and populations would be more important in process than modeling alone.

p.26. The assumption of using "location" data instead of looking at average areas fails to account for the long time for equilibrium to establish in tissues (body burden) and the magnitude of movement of fish diurnally and seasonally within the River system.

p.31. Response to EN13 cites policy that is ignored in the reply to EG-8 on page 24.

The response to EG-19 again relies on policy to trump the legitimate technical concern. The policy fails to in that it is counter to science. The list of rationalization points provided in response to Eg-2 and EC-3 on p. 32 underscores the weakness of the policy. EPA appears to have consistently hidden behind a policy to cover serious deficiencies of the modeling approaches and assumptions it used. Moreover, it used these policies to side-step direct field data that would answer the question posed.

Phase 2E – Aug. 99

p.17. It is interesting that aquatic plant uptake of PCBs was considered in as much as uptake through roots of terrestrial plants is virtually non-existent and in general relative to terrestrial plants, aquatic plants are less dependent on root uptake.

p.18. It is not clear why terrestrial exposure was discussed at all as it was not part of the SOW,

p. 76. The statement "The TEQ/TF provides a toxicity measurement for all AhR-binders" is not accurate. The method is not a measurement, it is merely an estimator.

p.78. The explanation about differences between terrestrial and aquatic animals pertaining to dose and concentration is not accurate. Fish eating fish eat the entire animal. What is different is that some portion of exposure comes directly from adsorption/absorption across gill tissue.

p. 78-79. To do the TRVs, all of the data (from the initial toxicity study plus the environmental sample analysis must report concentrations for each congener. In that these conditions are seldom met, there is great uncertainty introduced in these derivations. This uncertainty was largely ignored in the EcoRA.

p.80. The first bullet regarding toxicity tests of other species assumes that the target species is more sensitive than the test species. There is no basis presented for this policy decision for an assessment factor. It automatically creates an impression of adverse conditions and is a major reason for the use of field observations to document population-level effects.

Also, there is no basis for relying on the human health default policies regarding RfDs. The processes are fundamentally different in part because HHRA focuses on the health of individuals whereas an EcoRA is purported to focus on sustainable populations.

p.94. It seems strange to adjust an eight-week study by a factor of ten when the endpoints measured were reproductive endpoints.

p.96. McCarty and Secord (1999) reported field data from three locations along the Upper Hudson River during 1994 and 1995 field seasons evaluating various reproductive endpoints. They compared results to reference areas (Ithaca and Lake Champlain) as well as other published results on tree swallow reproduction. Several important reproductive endpoints did not differ significantly among sites or between the reference areas and the assessment sites. The authors suggested that nest abandonment was a strong indicator of an adverse effect from PCBs. Though there was an apparent increase in abandonment and eggs failing to hatch between references and assessment areas, there was an unexplained relationships that the relationship among assessment sites was inverse; that is as PCB concentration rose there was less hatching failure and fewer eggs abandoned. Other critical reproductive endpoints such as growth of nestlings, return of adults in the second year, and such were not significantly different. Variance between years was much greater than the differences attributed to PCB concentration. On the whole, it appears that some interesting observations were made. There is a clear indication that exposure to PCBs is occurring, but there is not strong evidence that populations-level effects are being manifest at the site. EPA repeatedly holds out this study as an indication that population-level effects were demonstrated, but a fair reading of the data indicates that the claims should be tempered considerably.

p. 98. It is wrong to conclude that interperitoneal injections simulate oral exposure because the material is absorbed by the liver. What is missed in this oversimplification is the portion of contaminant taken orally that passes through the feces unabsorbed.

p. 118. It is not clear why there were five sampling stations. Also there were no selection criteria provided. It may have been a compromise imposed by cost, access, safety, or some other factors; but no explanation was provided.

p. 119. In reality, each of the diversity indices is highly correlated with the others. Any will provide some comparative base to look at community composition, although there is limited useful information regarding stressor effects that can be deduced from diversity indices.

p. 121-122. It seems as if the NOAA SEC should have been introduced in Chapter 3 not here.

Responsiveness Report – Mar. 00

p.16. Response to Eg.1.1. The policy on "bottom-up" approaches should not be cited as justification for technical limitations. It should remain as part of the risk management package. By asserting policy, EPA effective dismisses legitimate challenges in interpretation. It is particularly disturbing, because this is not an either or situations – both approaches could be handled nicely in the EcoRA (without incurring delays or adding costs in the long run). In this case, field data would likely demonstrate minimal population impacts from the contaminants, would show the large uncertainty (or highly protective assumptions used) in the TRV, HQ approach, and require re-evaluation of conclusions of risk. Though a diminished population would not necessarily equate to causality being assigned to the contaminant, a nominal population would demonstrate that adverse effects were not occurring. Adhering to the policy ignores the very important conclusions that might have been reached.

p. 24-25. EF-1.4 and EP-2.1. The argument that habitat mapping was not feasible given the large size of the site fails a test of reasonableness. A key feature of an EcoRA is Ecology! To organisms, habitat is everything. The largest factor in calculating risk to fish or wildlife is exposure; exposure is determined by habitat first and bioavailability second. Ultimately, the results of the EcoRA are to be considered in light of remediation options. By failing to consider habitat, the EcoRA becomes largely irrelevant.

p.27. Response to EG-1.14. (repeated in response to EL-1.8 and EL-1.10) EPA justified its estimates of TEQ on the basis of not being over-estimated by more than a factor of 2. However, the projected decline of PCB levels by a factor of 2 drops some HQs to 1 or below. The concluding sentence further *justifies* the approach by claiming that "calculated risk levels exceed acceptable levels by orders of magnitude." It is fundamentally incorrect to argue that an HQ of <1 is "the acceptable level of risk at a site." The HQ of a toxicity endpoint says nothing about the population-level effect, especially when the quotient was based on a NOAEC. Moreover, what is "acceptable" is defined by stakeholders in the broad sense and may have little relationship to a toxicity quotient.

p.31. Response to EF-1.17. Again EPA incorrectly equates HQ with risk. This is not valid, the HQ ≠risk; rather it is a signal that effects may be occurring. The procedure requires evaluation of exposure in terms of habitat use, bioavailability, and relationships among toxicity endpoints and ecological effects (at the population-level).

p.35. Response to EL-1.17. EPA's response fails to take into account the numerous tributaries flowing into the Hudson as well as nearby wetlands and lakes that would be used by birds. Though the site is large, bird use does not conform to the site boundaries. Accordingly the estimated risks to birds overestimate the conditions.

p.36 and 37. Same as above.

p. 62. Response to EP-2.4. The assertion that there was insufficient toxicological data to conduct a probabilistic effects assessment is curious. Ranges of values were discussed in the reviews discussed in the TRV sections. Such data could have been used to describe the response relationships instead of electing to use only NOAEC or LOAEC values. A probabilistic approach also could have incorporated variability in measured exposure parameters. EPA elected not to do a probabilistic study; the decision had little to do with how robust the data set was.

p. 62. Response to EG-1.27 By acknowledging that an order of magnitude error was acceptable, it would have been more truthful to acknowledge in the uncertainty sections that a HQ of 10 or more would suffice as the warning flag for a screening level assessment which would trigger a more detailed risk characterization.

p.75. Response to EL-1.41. The argument that ecological samples were biased toward samples containing invertebrates is not a credible explanation for differences in the modeled output. That explanation would work partially if PCB levels were so high as to kill all invertebrates. As a basic premise of science, measured observations always take precedent over hypothetical expectations. Models cannot be validated; they can be calibrated – but ultimately, they still generate hypothetical expectations. Whenever real data exists, it should displace all modeled projections. The implication of modeled values being superior to measured data further indicates that the predicted exposures in the food chain models magnified these errors. Therefore, real world conditions are less adverse than estimated in this risk characterization.

p.84. EG-1.9. Again EPA posits that important endpoints such as "reduced fecundity, decreased hatching success, and similar kinds of reproductive impairment" are "difficult to observe in the field" is not supported scientifically. These endpoints were identified historically as being important because they explained observed changes in populations in the field. EPA in effect elected to ignore relevant ecological data when the data did not conform to the hypothesized situations. Science practice requires the reverse action – that is, reject the modeled or hypothesized conditions in favor of observations.

p.89. E.G. 1.36. EPA argues that one eagle plasma sample and one eagle fat sample "are high enough for concern" but dismisses bald eagle breeding data from 1992 to 1999 that illustrates a trend toward successful reproduction with fledglings of 1, 4, and 5 from 1997, 1998, and 1999. EPA's stance is consistent in that ecologically relevant data was again given less credence than direct measures.

p. 96. Response to E.P-2.9. Acknowledging that salmonids are the most sensitive species to dioxin-like compounds, EPA nevertheless uses this value as the TRV to apply to non-salmonid species. If it is appropriate to use an assessment factor to account for unknown interspecies sensitivity, then by the same logic, one should use a fractional assessment factor to adjust for species known to be less

sensitive. The use of the salmonid value virtually assures that the resulting H.Q. would be overly protective of non-salmonids (as reflected by the population data for fish in the system).

p. 101. Response to EL-1.46. This response by EPA asserts its policy over relevant ecological data. This signals that principles of science are not to be considered if they are inconvenient.

p. 101-102. Response to EF-1.64. "Although all the Thompson Island pools had viable benthic macro-invertebrate communities that could support local fish populations, the PCB concentrations ... indicate that some benthic species may be adversely affected." This statement clearly ignores the thrust of EPA guidance that focuses on population level effects to the assessment endpoint species. It signals further a disregard for the process, after repeatedly citing policy, and process to justify other actions.

p.102. Response to EG-1.34. EPA argues that "The gradient of PCB concentration along the 200 mile river ... increases the difficulty of ascribing particular effects to PCBs" is patently contrary to principles of ecology. Indeed, gradients provide the most powerful tool for assigning causality. Gradient analysis is at the heart of ecology. That PCB concentrations do not correlate with population responses; that other factors (e.g., fishing ban or improved water quality) are reflected in the improving conditions, underscores the limited adverse effects of PCBs on the populations.

p. 103. Response to E.G. 1.37. Whether or not duck meat is considered safe for human consumption is not a concern for the EcoRA. That is solely a concern for HHRA.

Section III. Revisions.

p.1. "...Revisions do not change the conclusions of the August 1993 (presumably 1999) EcoRA for any receptors of concern" appears to have been an *a priori* decision rather than a serious consideration of the comments. Proper attention to several of the concerns raised should have resulted in substantial modification of the presentation and the conclusions of risk.

p. 3. "...considered to be a field study ..." If a study is done in the lab (even with field collected samples), then it is a lab study. This explanation is a poor example of communication.

p.4. The discussion of the Hazelton and Prouty (1980) study points to the problems that occur from relying on a single study, which was conducted using a woefully inadequate study design. There is no basis for accepting an unbounded LOAEL or an unbounded NOAEL (except in limit studies). Even more troubling is the application of "extrapolation factors to such toxicity parameters.

p.4. The extensive discussion on bald eagle data seems to be reaching. It is doubtful that truly significant differences in reproductive endpoints existed between mean concentrations of 5.5 and 8.7 mg/kg given all the uncertainties associated with analytical detection. This seems like a lot of effort to

change a value from 3.0 to 5.5, especially knowing that the assumptions imbedded in the exposure estimates overwhelm these minor changes.

p.5. The uncertainties of EPA's approach to setting TRVs is illustrated in the laboratory based NOAEL and LOAEL (0.02 and 0.01; presumably reversed) and the new field NOAEL of 0.214. This indicates that for these studies the lab values substantially overestimated the hazard (by more than an order of magnitude). If one were to apply the 10x assessment factor to the NOAEL to get at the earliest threshold response of ecological relevance, then the lab value would be 200x lower than appropriate.

There is no scientifically accepted practice for using NOAELs or LOAELs. This is solely a policy-driven precedent.

The entire revision undertaken seems to have hinged on adjusting models to make minor changes in predicted exposure concentrations (on the whole, the adjustments provided higher "exposure" estimates) and to tinker with TRVs to produce relatively insignificant changes. The overall effect was to predict slightly longer periods of "unacceptable risks."

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

5. *Acceptable as is*
6. *Acceptable with minor revision (as indicated)*
7. *Acceptable with major revision (as outlined)*
8. *Not acceptable (under any circumstance).*

For the purposes of this reassessment effort, I must conclude that this EcoRA is Not Acceptable. The effort was unnecessarily constrained to a screening-level assessment. Elegant chemical analyses were performed to characterize sediments and water (and to a lesser extent biota) along the River. However, the decision to ignore ecological data, to forego opportunities for analyses of populations of interest, and to reject population trend data are fatal errors of omission which require this recommendation.

Sean Kennedy

Problem Formulation/Conceptual Model

1) As a general description of exposure pathways, and as a description of which ecological receptors are potentially exposed to PCBs, pages 11-19 appear adequate. However (as indicated with examples in my answers to question 2), this section does not provide sufficient rationale to indicate why certain fish and bird species were *not* selected as receptors for this Risk Assessment.

Assessment and Measurement Endpoints

2) This section, along with Table 2-7 indicates the selected assessment endpoints. It was certainly appropriate to select a broad range of taxa and species with different exposure pathways. However, it is not explained why certain species were *not* selected. For example, Tables 2-4 indicates that snapping turtles are "potentially" found along the Hudson River. They would have been a useful additional receptor because the work by Bishop *et al.* in the Great Lakes (1991, 1998) could probably have been used to develop a field-relevant NOAEL. Similarly, Table 2-5 indicates that the Double-crested Cormorant and Osprey are "breeding birds of the Hudson River". If Cormorants and Osprey had been selected as receptors, then data from several studies in the Great Lakes and other locations could have been used to establish field-relevant NOAELs (p. 138 of the Risk Assessment indicates that Everett Nack has observed, "... small numbers of osprey following the herring runs"). Common mergansers are also indicated as "breeding birds of the Hudson River" (Table 2-5), and Mark Brown of the New York State Department of Environmental Conservation has reported seeing this species of diving duck along the Hudson River (p. 139). Why were they not included? I am also curious to know why none of the species of fish that have been studied for their relative sensitivity to PCBs and dioxins (e.g., Elonen *et al.*, 1988) were included. I would not expect a complete listing of why *all* species were not included, but it seems to me that the Risk Assessment should include statements on why certain obvious (at least to me) 'candidate' receptors were not selected.

3) The combination of measured, modeled, guideline and observational measurement endpoints is supportive of the "weight of evidence" approach used for US EPA ERAs, but I do not know how the phrase "weight of evidence" is used officially. In my experience at other locations of concern in the United States, I have not seen the phrase particularly well defined. Perhaps there should be discussion of its meaning of at the Peer Review meeting.

Exposure Assessment

4) My expertise is not in the area of model development and validation, but in the area of toxicological and biochemical effects of PCBs and dioxins on birds and fish. However, I reviewed chapter 3 carefully, and I have the following comments:

- The Risk Assessment recognizes that there are changes in PCB patterns as they

move up the food chain. However, it is not clear to me if this fact is taken into account when estimating TEQ concentrations in birds from PCB concentrations in their diets. Would one expect bioconcentration of the dioxin-like PCBs, and if so, what effect would this have on TEQ estimates?

- BZ#126 was below the detection limit in many of the samples, and its detection limit was used for TEQ calculations for these samples. It is stated in the Risk Assessment (p. 40) that, "The exact magnitude of the error introduced by the omission of BZ#81 and setting BZ#126 equal to the detection level is not known, but is likely within an order of magnitude at most". As far as I can see, no justification for this conclusion is made. The Risk Assessment should show the rationale to this conclusion. I view this as an important point because if BZ#126 were indeed 10-fold lower in some samples (e.g.,dietary dose for mallards in Thompson Island Pool; fish in several locations), then the TEQ-based hazard quotients would become 10-fold lower, thus affecting final conclusions regarding likely risk. This problem, if taken into consideration with possibly unreasonable over-estimates of NOAELs from laboratory-based bird studies (see below), needs to be considered for establishment of appropriate and un-biased final conclusions. Because BZ#81 has a low TEF in fish, and because it is usually present in the environment at very low concentrations, I would imagine that it would have little influence on the TEQ concentrations in fish.

- It is assumed that the diet of bald eagles is 100% fish from the Hudson River. I would be surprised if the year-round diet is 100% fish. In other locations, bald eagle diet is not 100% fish; small mammals and birds are included.

- Were there no other data on PCB concentrations in avian eggs from the Hudson River (other than tree swallows and one mallard egg) that could have been used for the Risk Assessment? Such data would not, in themselves, allow for definitive conclusions, but they would have strengthened the quality of the assessment. Why were other eagle blood/egg data from eagles that spend only part of each year feeding on fish in the Hudson River not included (p. 33 implies that there are data in a 1999 paper by Nye) ?

- Comments by General Electric suggest that there are considerable residue data in fish in the Hudson River that were not used for the Risk Assessment. Is this true? I have no idea how such data would affect conclusions of the Risk Assessment, but I wonder why they were not included if they indeed exist. Regardless of whether the models for predicting fish concentrations are adequate or not, an explanation for not including all available residue data in the receptors chosen should be made clear in the Risk Assessment.

5) I made a few comments regarding my concerns with how exposure was estimated under question 4, above. As indicated in my opening sentence that question, I am not an expert in model development and application. However, it is certainly obvious that many

assumptions are made, and it might be better to express exposure in terms of likely ranges of exposure rather than absolute amounts. If done in this manner, one would be able to use exposure estimates along with estimated ranges of hazard quotients to help provide a better assessment of impacts of PCBs to biota in and along the Hudson River

Effects Assessment

6) The first part of this question asks for comments on the validity of using *only* NOAEL TRVs from field-based toxicity studies. In my opinion, this approach is appropriate because, as the authors correctly state, there is the potential of exposure to contaminants other than PCBs which makes it difficult (and often impossible) to establish reliable LOAEL-based TRVs. However, I do not know if the use of NOAELs and LOAELs is the *only* requirement for assessing risk in EPA risk assessments. Can/should EPA Risk Assessments also include studies to look for site-specific evidence of demonstrable effects in fish and wildlife?

Unfortunately, there are practical limitations associated with using field-based studies for establishing NOAEL TRVs for PCBs and TEQs because there are usually very few, or no, data for the species selected for a particular risk assessment. This is certainly a problem for the Hudson River Risk Assessment. The authors located only one study (Weimeyer *et al.*, 1993) for the bald eagle, and the studies by Secord and McCarty (1997; paper by McCarty and Secord, *in press*) were the only papers used for the tree swallow. There were no field PCB NOAEL TRVs for other species of birds. Laboratory-based PCB NOAEL TRVs were derived for only one-half of the species of fish selected for the risk assessment, and there were no field TEQ NOAELs for fish. Because there are so few data, one must be cautious when interpreting hazard quotients.

It should be noted that at least two field studies on bald eagles were not used for the Risk Assessment. A paper by Donaldson *et al.* (1999) suggests that the PCB NOAEL TRV for bald eagles might be closer to 20-30 mg/kg egg rather than 3 mg/kg egg (revised to 5.5 mg/kg egg in the Responsiveness Summary, March, 2000). A paper by Elliott *et al.* (1996) on bald eagles in British Columbia suggests that a mean TEQ concentration of 0.3 ug/kg egg (using hatching success as the endpoint) was the NOAEL for embryotoxicity of the mixture of PCDDs, PCDFs and PCBs found in these bald eagles. This is 30-fold higher than the NOAEL used in the Hudson River Risk Assessment. I am not familiar enough with the literature on fish field-based studies to know which studies might not have been included.

The second part of this question asks for comments on whether the general approach of using uncertainty factors (interpecies, LOAEL-to-NOAEL, and subchonic-to-chronic) is protective of Hudson River receptor species. The approach is certainly protective in most cases; in fact, there are situations where the TRVs are likely to be unrealistically low. For example, with the exception of the Great Blue Heron, all laboratory-based TRVs for PCB NOAELs and LOAELs were derived from a study with chickens (Scott, 1977). The authors of the Risk Assessment recognize that the chicken is the most sensitive species to

PCBs and dioxin-like PCB congeners, yet they simply use the chicken study to calculate hazard quotients. Although perhaps unconventional, would it not make some sense to **multiply** chicken TRVs by 10 (or more) to get more reasonable TRVs based, in part, on the findings of Brunstrom *et al.*, Sanderson *et al.*, Hoffman *et al.*, Powell *et al.*, Peterson *et al.*, Kennedy *et al.* and other investigators that show that **all** species are less sensitive to PCBs than chickens. This alternative approach could certainly be done with some confidence with the mallard in my opinion, because Brunstrom's egg injection studies showed that the mallard is approximately 10-50 times less sensitive to the lethal effect of PCB 77 than the chicken.

The Risk Assessment indicates that the NOAEL for all species of birds is 0.33 mg/kg egg. This conclusion is based upon the paper by Scott (1977). In my opinion, it is obvious that a PCB concentration of 0.33 mg/kg egg is unlikely to cause problems with growth, development and reproduction in wild birds. Otherwise, all birds in North America would still be at risk from PCBs. This concentration is approximately the background level in many un-contaminated areas of North America (e.g., the Bay of Fundy, which has been used as a reference site for herring gulls for many studies carried out by the Canadian Wildlife Service). Similarly, a TEQ concentration of 0.01 ug/kg egg (derived from the paper by Powell *et al.*, 1996a) is unlikely to be toxic in wild birds. This is approximately the background TEQ concentration in bird eggs in many areas of North America and elsewhere.

In summary, my opinion is that the laboratory-derived PCB- and TEQ-NOAEL TRVs for wild birds (with the exception of the ring-necked pheasant, which was not a receptor for this Risk Assessment) are unrealistically low, thus making the hazard quotients unrealistically low. Similarly if the LOAELs were truly applicable to wild birds, then one would come to the conclusion that ALL birds in most areas of North America are being affected. This conclusion is simply not supported by evidence of sustainable (and often growing) populations of many species exposed to PCB concentrations of 2.2 mg/kg egg and/or 0.02 ug/kg egg TEQ. There are similar problems with several of the fish TRVs. Because the authors found no laboratory data on several species, results from lake trout were used. Lake trout are well known to be one of the most sensitive species; thus the TRVs for some of the species of fish selected for the Hudson River might be too low. Alternatively, some of the receptor species of fish might have similar sensitivities, but we simply do not know the answer to this question due to the paucity of laboratory studies and site-specific studies to determine population changes.

7) As indicated in my response to question number 6, it is my opinion that the toxicity quotients calculated using both total PCBs and TEQs are likely to be protective of the receptors. However, my concern is that there the toxicity quotients derived from laboratory studies for birds and fish may be unrealistically high because chicken and lake trout data were used in several cases.

8) This section appears to adequately characterize the relative risks to the receptors selected, if one accepts the exposure estimates and NOEALs presented earlier in the report.

However, I think that the meaning of some of the wording (e.g., "suggest the potential for population-level adverse reproductive effects") is difficult to interpret, in part due to my concerns outlined above regarding exposure estimates and highly conservative application of chicken and lake trout based NOAELs. What are the criteria for making this statement?

As I write, I do not know if the evidence from bird "Observational Studies" (pp. 137-139) is, indeed, comprehensive. Note that Everett Nack (p. 138) has seen osprey, but Jim Brushek has not (p. 139). Were more systematic studies not conducted by the US Fish and Wildlife Service and/or other agencies?

9) The uncertainty analysis is written in terms that are too general, in my opinion. This section would be substantially improved if the uncertainties were clearly identified, and applied to the actual and modeled data to show the range of uncertainty for the hazard quotients.

General Questions

1) Overall, it appears to me that the authors of the Risk Assessment have attempted to write a clear, consistent, reasonable and transparent report. However, I think that the conclusions and Executive Summary need to be modified such that the uncertainties inherent to the TRVs and hazard quotients are presented in a manner that is much easier to interpret. Could this be done by showing ranges of hazard quotients for the different receptors (or, perhaps by more sophisticated manners that I presume have been developed and used at other sites)?

2) The major weaknesses of the Risk Assessment include (*i.*) the limited amount of site-specific data on exposure of potentially vulnerable organisms to PCBs, (*ii.*) limited, to apparently non-existent, documentation of changes to fish and wildlife populations that might have occurred due to PCB exposure, (*iii*) limited attempts to document pathological and physiological effects of chosen receptors, and (*iv.*) explanations why certain receptors were not studied at all.

Recommendations

I do not view the Risk Assessment as "unacceptable". It appears to be "acceptable", but I do not know the criteria for deciding between "acceptable with *minor* revisions" and "acceptable with *major* revisions. Certainly, I think changes are required to address the points I address above. I will wait until the Peer Review meeting before I provide my final recommendation.

General Comment: I do not understand why there were so few field studies to assess the effects of PCBs on fish and wildlife during the past nine years. The Hudson River is one of the most PCB-contaminated rivers in North America. Data from field studies would have been extremely useful for the Hudson River, and other risk assessments in PCB-contaminated sites in the United States, and globally.

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Dwayne Moore

Biography - Dwayne Moore

Dr. Dwayne Moore has a B.Sc. in Biology from the University of Western Ontario, and a M.Sc. and Ph.D. in wetland community ecology from the University of Ottawa. After graduating, he worked for six years at Environment Canada, the first two years developing environmental quality guidelines for industrial chemicals, and the last four years conducting ecological risk assessments for priority substances. He has been a Senior Associate with the Cadmus Group for the last four years.

Dr. Moore has considerable expertise in ecological risk assessment, the development of environmental quality guidelines and criteria, community ecology, multivariate statistics, uncertainty analysis, and analysis of toxicity data. Since joining the Cadmus Group in May, 1996, Dr. Moore has managed over 40 projects for Canadian, U.S. and international clients in government and industry and participated in many others. Dr. Moore has led projects to assess the ecological risks of a variety of chemicals including hexachlorobenzene, chloroform, chlorinated wastewater effluents, waste crankcase oils, phenol, mercury, PCBs, and hexachlorobutadiene. Dr. Moore has also been involved in the Environment Canada probabilistic risk assessments of ammonia and chloramines. He led the effort to update and considerably expand Environment Canada's guidelines for the conduct of ecological risk assessments of priority substances under the *Canadian Environmental Protection Act*. Recently, Dr. Moore authored the chapter on probabilistic risk assessment in *Ecological Risk Assessment and Prioritization Process* for the Department of Energy (DOE). The chapter includes state-of-the-art statistical and modeling techniques for use in higher tier assessments including: first and second order Monte Carlo analysis, variance propagation, probability bounds analysis, fuzzy arithmetic, interval analysis and cost-benefits analysis. To illustrate these and other techniques, Dr. Moore prepared a case study that estimated the effects of methylmercury and PCBs to mink and kingfishers at a CERCLA/RCRA site near Oak Ridge, Tennessee and compared these effects to the costs and benefits of several remediation alternatives. Dr. Moore is currently involved in projects to prepare guidance, training, and case studies for probabilistic risk assessments for several agencies including the CMA, CEFIC, and the U.S. EPA Office of Pesticide Products. He also is conducting a detailed evaluation of a large spatially-explicit population model (PATCH) for the U.S. EPA Office of Research and Development, and is leading the development of ambient water quality criteria for mercury for the Water Environment Research Foundation. Dr. Moore recently co-chaired the Society of Environmental Toxicology and Chemistry (SETAC) Pellston conference on the use of uncertainty analysis in ecological risk assessment and co-edited the book that followed from the conference. He is currently serving on the SETAC Pellston steering committee for Probabilistic Risk Assessments of Pesticides, and has served on a past steering committee to develop an ecological risk assessment decision support system. Dr. Moore has participated in several other Pellston workshops (e.g., assessing multiple stressors, re-evaluation of environmental quality criteria), and has participated in numerous EPA Science Advisory Panels and other EPA peer review workshops. He is a charter member of the SETAC Ecological Risk Assessment Advisory Group. Dr. Moore has been a member of the editorial board for *Human and Ecological Risk Assessment* journal since its inception and is a member of the editorial board for *Environmental Toxicology and Chemistry*.

Hudson River PCBs Baseline Ecological Risk Assessment

- Peer Review Comments From Dwayne Moore -

In the charge to peer reviewers, reviewers are asked to determine whether the baseline ecological risk assessment (ERA) "is technically adequate, competently performed, properly documented, satisfies established quality requirements, and yields scientifically valid and credible conclusions." If the Phase 2 Hudson River ERA had been intended as a screening level assessment, I would answer yes to the question, although I have concerns about the lack of documentation on the modeling exercises and the uncertainty analysis briefly referred to in section 6.5 of the baseline ERA. My understanding, however, is that the baseline ERA was intended to be a higher tier ERA that could be used "to back-calculate to appropriate levels of PCBs in fish and to compare various remedial alternatives, including the No Action alternative ... required by federal Superfund law." As a higher tier ERA, the Hudson River PCBs baseline ERA is lacking, primarily because it relied on highly conservative and deterministic quotients as quantitative indicators of risk. In addition, no information was provided on what remedial alternatives were being considered, what risk reductions they would provide, and what countervailing risks they would introduce. As outlined in a recent publication (Moore et al. 1999a), I believe that risk management decisions should not rely on toxicity quotients because:

> "(1) quotients do not quantify, or even acknowledge, the uncertainties inherent in ecological risk assessment, (2) the degree of conservatism of quotient-based risk estimates are unknown, (3) the appropriate place for applying conservatism is during the risk management stage (i.e., the stage at which societal interests are normally considered), and (4) quotients do not provide the basis for estimating the likelihood that a desired level of risk reduction will be achieved for any given remedial action alternative ... At best, conservative quotients can be used to screen out negligible risk scenarios, but otherwise provide little useful information to the risk manager or public. At worst, the use of conservative quotients results in situations where low level risks are subjected to costly mitigation measures."

In my opinion, a higher tier ERA should answer the following questions (see Kaplan and Garrick 1981):

- What can happen (i.e., what can go wrong)?
- How likely is it that it will happen?
- If it does happen, what are the consequences?

The toxicity quotients relied on in the Hudson River PCBs assessment were useful in answering the first question, but provided next to no information on the probabilities of effects of differing magnitudes, and the consequences of those effects to Hudson River populations and communities, if they were to occur. The tools exist to conduct probabilistic risk assessments (Landis et al. 1998; Warren-Hicks and Moore 1999), case studies have been published (e.g., Dakins et al. 1994; Moore et al. 1999a,b; Sample and Suter 1999) and guidance is available on how to use these tools in Superfund ERAs and other EPA programs (U.S. EPA 1997, 1999). Similarly, sophisticated ecological modeling tools are available for prospective risk assessments of effects to populations and communities (e.g., Caswell 1989; Bartell et al. 1992; Jorgensen et al. 1996; RAMAS software tools) and have been used in the past to support environmental decision making with, for example, striped bass populations (e.g., Barnthouse et al. 1990). Given the uncertainties and complexity of the Hudson River assessment and the economic costs that could arise as a result of this assessment, I am disappointed that readily available higher tier tools which would substantially improve our understanding of risks were not employed in the baseline Hudson River ERA.

Problem Formulation

(1) For the most part, the conceptual model adequately describes the different exposure pathways by which ecological receptors could be exposed to PCBs in the Hudson River. I would have used the problem formulation and the results of the Phase I risk assessment to have reduced the scope of the baseline ERA to consider only the most important exposure pathways for the species and communities at highest risk. Because PCBs are persistent and bioaccumulative, it seems likely that piscivorous fish, birds and mammals are receiving the highest exposures, particularly long-lived species with small home ranges that forage exclusively in or near the Hudson River. For these species, food web exposure is really the only important exposure pathway. Thus, I would have used the problem formulation exercise to eliminate the need to consider dermal, air and water pathways of exposure. Had

this been done early on, a greater proportion of the monitoring effort could have been targeted to prey species that are important components of piscivore diets.

Although floodplain soils are not likely a major exposure pathway for piscivores, I do not understand why they are "beyond the scope of the assessment." It would seem that some of the assessment endpoints chosen for the Hudson River PCBs ERA (e.g., raccoons, brown bats, tree swallows) receive a significant proportion of their exposure via terrestrial sources that are in contact with floodplain soils. Perhaps more importantly, floodplain soils may act as a long-term, continuous source of PCBs to the Hudson River through leaching, erosion, resuspension during flooding, etc. If true, remedial decision making ought to account for this source. No information was provided to determine whether floodplain soils are a major source of PCBs to the river or to terrestrial biota.

(2) I believe the list of assessment endpoints could have been shorter by focussing only on high risk, piscivorous species. This would have eliminated the need to consider benthic invertebrates, forage fish and insectivorous birds and mammals. I also would not have chosen species that spend a significant portion of their time foraging outside the Hudson River area (e.g., bald eagles), because this behaviour will likely reduce their overall exposure. With a reduced set of assessment endpoints, it would have been possible to consider use of population models, uncertainty propagation techniques, etc to better understand risks and consequences of possible remedial actions for the high risk species.

The assessment endpoint entitled "Benthic community structure as a food source for local fish and wildlife" strikes me as a curious choice. The approach for this endpoint was to examine benthic community structure and to compare water and sediment levels to generic water and sediment quality criteria. None of these approaches makes any attempt to assess how risks to benthic species could be transmitted to "local fish and wildlife." Based on the analyses that actually took place, this assessment endpoint should be re-labelled to "protection and maintenance of local benthic invertebrate communities" to reflect the analyses done and to be consistent with other endpoint descriptions (e.g., local fish populations, local insectivorous birds, etc).

Although I understand their importance, a separate assessment endpoint for protection of threatened and endangered species is not required. Previously stated assessment endpoints for maintenance and protection of fish, birds and mammals overlap this endpoint. Further, the approaches taken to assess effects to fish, birds and mammals are aimed at estimating risks to individuals, the level of organization which is usually the focus for threatened and endangered species. Finally, the measures of effects and exposure for threatened and endangered species are not specific to these species (e.g., shortnose sturgeon, bald eagle), and completely overlap approaches for previously selected species. No new studies or analyses were conducted aimed specifically at improving our understanding of risks to threatened and endangered species. Thus, the ERA appears to be doing the "right thing" by focussing on threatened and endangered species, but the reality is that we have gained no further understanding of risks to these species by including this assessment endpoint in the ERA.

The assessment endpoint for protection of significant habitats is meaningless. The concern for PCBs is with maintenance and protection of biota, which was adequately addressed with the other stated assessment endpoints. It is difficult to imagine how PCBs could affect habitat in any other way (e.g., increased habitat fragmentation, alteration of physical characteristics of habitat, etc). My point is reinforced by the fact that the assessors (again) chose some of the same measures of exposure and effect as were used for the assessment endpoints aimed at maintaining and protecting biota. Thus, no new understanding of risks is gained by including this assessment endpoint in the ERA.

(3) The combination of measured, modelled, guideline and observational measurement endpoints used in the baseline ERA are inadequate and do not support the weight of evidence approach that the authors claim to be using. Nearly all of the "weight" for the assessment amounts to nothing more than comparing conservative and deterministic measures of exposure in tissues or the surrounding media to hyperconservative and deterministic effects thresholds. For most of the assessment endpoints (e.g., piscivorous birds, waterfowl, local wildlife, threatened and endangered species), the "observational studies" were limited to anecdotal evidence or studies designed for purposes other than

assessing the risks of PCBs. Perhaps most surprisingly, no ambient or *in situ* toxicity tests were conducted (e.g., caged fish studies, sediment and water bioassays, fish feeding studies to mink, etc). This is an important line of evidence in a site-specific ERA, and has been a major component of assessments conducted for other contaminated riverine systems (e.g., Clinch River, Clark Fork River, East Fork Poplar Creek)(Kemble et al. 1994; Jones et al. 1999; Halbrook et al. 1999). Such studies are currently being conducted as part of the Housatonic River PCBs ERA (personal communication with Roy Weston staff and subcontractors). The weight-of-evidence approach simply means use of information from all sources, but particularly from three techniques, a "triad" of (a) toxicity tests, (b) chemical measurements, and (c) biological surveys in the field (Environment Canada 1999). For sediment, the approach has been formalized (Chapman 1986, 1990, 1996). The weight of evidence approach should not necessarily attribute equal strength to each line of evidence – Menzie et al. (1996) have proposed a formal and quantitative means to combine lines of evidence when estimating risks. Thus, in addition to the shortcomings in the ERA with respect to not obtaining the data required to build a weight-of-evidence assessment, none of the available methods for formally combining lines of evidence were used in the assessment. At best, the measures of effect and exposure specified in the problem formulation could be used in a screening level assessment. For a Phase II baseline assessment, the measures of effect and exposure and their use in a weight-of-evidence assessment fall far short of what is required. The argument in the responsiveness document that there were was insufficient time for additional toxicity tests and field studies is unacceptable given the 10 year timeframe since this assessment began.

Exposure Assessment

(4) The general approach of using the HUDTOX and FISHRAND models to estimate concentrations of PCBs in water, sediment and fish tissues is a reasonable one and likely the only feasible approach for estimating concentrations well into the future. It also appears that the models have been calibrated to existing data and their performance shown to be generally acceptable. I had two major frustrations in evaluating the appropriateness and sufficiency of the modeling approach. First, the equations underlying the HUDTOX and

FISHRAND models were not presented, nor were the modeling inputs, concepts, assumptions and rationales adequately described. I understand that other reports and peer review panels have or will deal with this issue, but more could have been presented so that the ERA peer reviewers could be in a position to properly evaluate the models. As an example, we are told that the FISHRAND model is a probabilistic model (e.g., pages 44 and 46) that predicts 25th, 50th and 95th percentiles. Yet, no equations or input distributions are described. How can we evaluate this probabilistic model without this information. The authors should consult the *Guiding Principles for Monte Carlo Analysis* (U.S. EPA 1997) which describes reporting requirements for probabilistic analyses. My second frustration with this chapter is that little or no information was provided on sample designs and sample sizes for the chemical monitoring studies that were undertaken. How are we to judge the credibility of the various measures of centrality and variance without this information?

Egg concentrations in piscivorous receptors were estimated by applying a biomagnification factor from the literature (28 for total PCBs, 19 for TEQ-based concentrations). I would guess that this number would vary depending on species and species condition, congener composition (for total PCBs), and environmental conditions. It would be useful to provide information on the expected variability (e.g., standard deviation, range) of parameters that are crucial to the exposure calculations. Better still, would be to conduct probabilistic analyses so that the impacts of variability and incertitude in the input parameters on predicted exposures can be determined.

On page 40, the report states that the TEQ congener distribution was assumed to be constant from year to year in the FISHRAND bioaccumulation model. Based on statements elsewhere in the report that lower chlorinated PCBs with chlorines in the ortho position degrade faster than higher chlorinated PCBs with chlorines in the meta and para positions, constant congener composition over time seems unlikely.

Total PCBs concentrations in water, sediments, benthic invertebrates and fish are described as "averages" (arithmetic mean or geometric mean???) and 95% upper confidence limits (UCL) on the mean. The rationale for using 95% UCL on the mean in exposure

calculations is not clear. It was argued in the report that predators tend to "average" their exposures over time and space (e.g., sometimes eating more contaminated fish, other times less contaminated fish). For predators, the issue is to determine what the "average" is and its associated uncertainty. Confidence intervals about the mean are the appropriate measure of this uncertainty (although lower confidence limits should also be calculated and used to bracket the quotient calculations). This rationale does not apply for all assessment endpoints. For example, non-motile invertebrates (e.g., clams) and plants cannot spatially average their exposures over the river segments that were the basis for estimating exposures. For these assessment endpoints, a better representation of exposure variability would be to estimate the 5th and 95th percentiles of the lognormal distribution, which will be much wider than the 5th and 95th confidence limits on the mean. Gilbert (1987) provides the formula for calculating 5th and 95th percentiles (and confidence limits about these percentiles) for parameters that are lognormally distributed.

For those fish species in which a fillet to whole fish conversion factor for lipid content was unavailable, fillet concentrations were used instead of whole body concentrations. The net result of this decision is that fish concentrations for white and yellow perch were underestimated by roughly a factor of two. A more defensible decision would have been to use a range of conversion factors based on factors observed in other fish species (weighted towards more similar species).

Although not my area of expertise, it is my understanding that toxicity equivalency factors are only roughly known for particular fish, bird and mammal species (e.g., within an order of magnitude of reported values). Treating TEFs as point estimates ignores this uncertainty. Further, assuming that BZ #126 was at the reported detection limit when it occurred at levels below this value seems to have little scientific justification. A better approach would have been to use distributional techniques to extrapolate to levels below the reported detection limit. If this technique is infeasible (because of few positive detections), then a range of approaches should be used and the results compared (e.g., assume detection limit, half detection limit, zero).

(5) The exposure equations for the wildlife receptors are well described and, for the most part, the inputs have been adequately specified and justified. Most of the issues described below are fairly minor in nature. The only major problem I have with the exposure approach for wildlife was the continued reliance on conservative point estimates, rather than use of distributions. In my introductory comments, I pointed out that there are published case studies and Superfund guidance available that describe how to conduct probabilistic exposure modelling for wildlife.

In several places in the exposure chapter, water or food ingestion rates are labelled as "normalized". The units provided (e.g., L/day), however, indicate that the rates are not normalized to body weight (i.e., L/kg body weight/day). The exposure equations also show body weight in the denominator, which negates the need to normalize the ingestion rates in the numerator. I believe the ingestion rates therefore are not normalized rates. If they are, then a major error has occurred because the units would not cancel out to mg/kg/day for average daily dosage.

The wildlife exposure equations are used to estimate both mean average daily dose and 95% UCL average daily dose. Only the input variables for concentration (e.g., water, sediment, diet), however, are treated as having variability. Unless other important input variables (e.g., ingestion rates, foraging effort, dietary composition, etc) are treated as distributions, the 95th UCL average daily dose has little meaning because major sources of variability are being ignored. Note that 95th UCL outputs cannot be calculated by combining 95th UCL inputs according to the exposure equation (when a series of 95th percentiles are multiplied together the result will be a percentile >>> 95th percentile in the output distribution). Uncertainty propagation techniques such as first order error propagation or Monte Carlo analysis are required for this computation.

The exposure analyses all assumed that the wildlife assessment endpoints forage exclusively in the Hudson River year round (i.e., all modifying factors = 1). This may be a reasonable assumption for non-migratory species with small home ranges (e.g., kingfishers), but seems grossly conservative for species that migrate, have large home ranges, or forage in upland

areas less affected by PCB contamination (e.g., bald eagles, raccoons).

The total daily ingestion rate for mink was based on a study by Bleavins and Aulerich (1981). This study was a pen study and it seems likely that total daily ingestion rate would be much higher for wild mink because they must expend more energy foraging for food, defending territories, etc. Food ingestion rate also varies with food quality (ingestion rate increases as gross energy of diet items decreases). An alternate approach that takes account of these and other factors is described in Moore et al. (1997, 1999a).

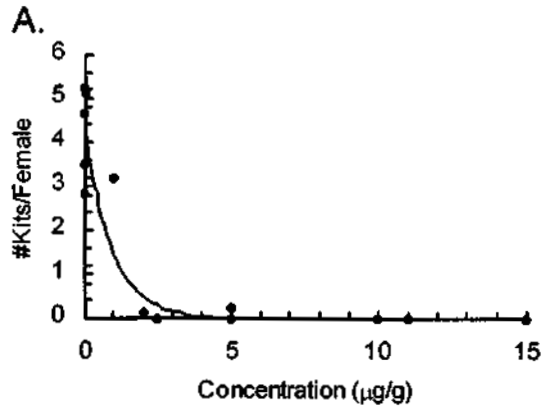
The mink diet for the Hudson River was assumed to consist of 34% fish and 16.5% invertebrates (the remainder was not specified). Mink are, however, opportunistic carnivores with highly variable diets. Studies cited in the Wildlife Exposure Factors Handbook (U.S. EPA 1993) indicate that fish composition in the diet may vary from 0 to 75%, while muskrats and other small mammals may be insignificant or major components of the mink diet. For the exposure analyses for mink, a range of different possible diets should have been explored to determine the consequences on estimated average daily dose.

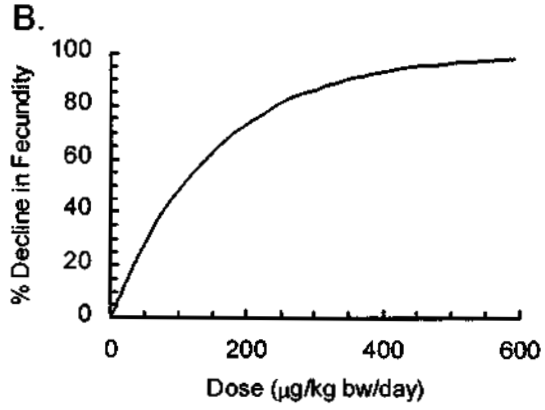
Effects Assessment

(6) While there are some advantages to deriving field-based NOAELs (e.g., avoiding lab-to-field and interspecies extrapolations), I do not support their use in this assessment for three reasons: (1) the field-based NOAEL is unbounded because no corresponding LOAEL was derived, (2) the methodology for deriving the field-based NOAEL has not been sufficiently developed and validated (see, for example, the extensive database, methods development and validation efforts that have taken place for developing sediment effects concentrations – MacDonald et al. 2000), and (3) there is general accord that NOAELs (and LOAELs) are poor choices for estimating low toxic effects in ecological risk assessment (Stephan and Rogers 1985; Suter 1996; Moore and Caux 1997; OECD 1998; Environment Canada 1999; many others). Using generic order-of-magnitude uncertainty factors to derive TRVs from laboratory- or field-derived NOAELs or LOAELs is perhaps an acceptable approach in a screening level ERA (i.e., to identify risk scenarios in need of further analysis). The TRVs

approach, however, should not be the basis of an effects assessment in a higher tier ERA such as the baseline Hudson River PCBs ERA. The TRV approach is deficient in many ways including: (1) multiplying ten-fold safety factors for each of several extrapolations (e.g., LOAEL to NOAEL, interspecies, etc) results in hyperconservative threshold estimates of toxicity, (2) use of one NOAEL (or LOAEL) result ignores much of the available information from other studies (laboratory and field) or from other treatments within the same study, (3) the ten-fold safety factors ignore much of the available information that could be used to develop empirical safety factors (Chapman et al. 1998), and (4) TRVs provide little information to risk managers about the potential magnitude of effects that may be occurring if they are exceeded. A far superior approach would be to develop concentration- or dose-response relationships (based on one or multiple studies) for each assessment endpoint. Moore et al. (1999a) used this approach to develop dose-response curves for mink exposed to mercury and to PCBs (see text box 1 for an example). Additional comments on the effects assessment follow.

Text Box 1. (A) Log Poisson regression model for combined results from 3 long-term PCBs feeding studies to mink. (B) Estimated dose-response curve.





The wide range of NOAELs and LOAELs for body burdens is used as a rationale for not developing

body burden TRVs for benthic invertebrates. This is an unfair summary of the data because toxicity results from a wide range of congeners and Aroclors are being lumped together. The ranges would narrow considerably if only appropriate Aroclor mixtures (e.g., 1242 or 1248) were considered, although the available data are somewhat limited.

There appears to have been no attempt to evaluate the quality of the toxicity studies before selecting the key studies used to derive the TRVs. I would have expected acceptability criteria to have been developed (e.g., for control responses, use of appropriate protocols and statistics, etc) against which each toxicity study would be judged. TRVs should not be based on studies that are not of acceptable quality. If studies were evaluated prior to deriving TRVs, this should be indicated in the ERA along with the acceptability criteria used to evaluate the studies.

The same toxicity studies tended to be used over and over again to derive TRVs for the various fish, bird and mammal assessment endpoints. This indicates to me, that the ERA lacks the capability to separately assess risks to different fish species, different bird species or different mammal species. Had specific bioassays been performed for each of the assessment endpoints (or closely related surrogates), there would be justification for developing separate TRVs for each endpoint. This was not the case. Instead of pretending to have the capability to assess effects and risks to each of a large number of fish, bird and mammal species, the authors should be more forthright and admit that, at most, this assessment can only assess risks to fish, bird and mammal species for which toxicity data are available or are available for close surrogates (e.g., spottail shiners, mallards, mink). Alternatively, TRVs could be developed from species sensitivity distributions that would be protective of, for example, 95% of fish, birds and mammals. In the latter case, the list of assessment endpoints would be reduced to three generic ones – protection and maintenance of fish, bird and mammals. This approach would also make for a far less repetitious ERA.

The implicit assumption in using an interspecies extrapolation uncertainty factor to derive a TRV is that the assessment endpoint is always more sensitive then the test species (by 10-

fold!). There is equal probability, however, that the assessment endpoint is less sensitive than the test species. Had NOAELs and LOAELs been multiplied by a factor of ten, instead of divided by ten, most of the toxicity quotients would go below one. That is, uncertainty cuts both ways. It would be a far more intellectually honest exercise to develop bounds or, better still, a distribution for TRVs. This would facilitate development of bounded or probabilistic quotients (see Bartell 1996). Then risk managers would have a proper perspective on which to judge the credibility of the risk estimates.

The LOAEL for pheasants on page 95 appears to be off by two orders of magnitude.

Risk Characterization/Uncertainty Analysis

(7) The question posed here on "whether the methodologies used in calculating ... TQs are adequately protective of ... receptors" is a misleading one. The objective of an ecological risk assessment is not to be "protective" but to estimate and characterize risks to biota. It is then up to risk managers, with input from stakeholders and the public, to decide what remedial actions are required to ensure protection for receptors of concern. It is an easy exercise to design toxicity quotients that are "protective". Simply pile on the safety factors and conservative assumptions and you have "protective" quotients. The approach, however, lacks credibility. To take a well worn analogy – if weather forecasters predict rain every day (to be protective), then eventually people will start ignoring the forecasts because they have no credibility. Thus, a forecast of "it will very likely rain" when rain is highly unlikely is not helpful; rather we would like to know the true odds, and act according to our attitude toward risk.

(8) The risk characterization does not adequately characterize risks posed by PCBs in the Hudson River to receptors of concern. Risk describes the relationship between probability and magnitude of effect (Warren-Hicks and Moore 1998). The TQs that were by far the dominant line of evidence in the risk characterization chapter do not address probability or magnitude of effect. Further, the consequences of any effects that could occur to populations or communities were not explored with ecological models or other techniques.

Specific comments on the risk characterization chapter follow.

The field evidence for effects of PCBs to benthic organisms is very weak. Although there may be a relationship between PCBs concentrations and some of the benthic community metrics, thes relationship is confounded by differences in the sediments between sampling locations. In fact, "when PCBs concentrations were normalized to TOC [a more accurate indication of bioavailable PCBs], there were no significant differences between stations" [page 120]. Perhaps a more sophisticated multivariate technique would have provided stronger evidence of a relationship between PCBs concentrations and benthic community structure. Non-metric clustering and association analysis, for example, can identify clusters based on community composition and ranks variables (e.g., TOC, sediment grain size, metals concentrations, PCBs concentrations, etc) in order of importance for distinguishing the observed clusters (see Landis et al. 1996 for an example). This technique is more sophisticated than the crude and insensitive approach described in chapter 5 of using ANOVAs to tests for differences in community indices between locations. Nevertheless, the evidence as presented in chapter 5 gives little indication that PCBs have caused effects to benthic community structure in the Hudson River. By the conclusions chapter (chapter 7), however, the field evidence is seen in a somewhat different light – "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 ...". Uncertainty in the analysis is further stated as being low. In my opinion, this conclusion is not supported and further suggests that the assessment is biased towards finding risks even when this is not warranted on appeal to the available evidence. Similar biases are evident elsewhere in chapter 5 and the conclusions chapter (e.g., interpretation of the tree swallows field study, discounting of evidence of healthy fish, kingfisher and waterfowl populations).

Often the same line of evidence was used repeatedly as an indicator of risk to assessment endpoints. For example, concentrations of PCBs in water were compared to ambient water quality criteria for the assessment endpoints involving benthic community structure, fish, bird and mammal populations. The connection between this line of evidence and, for example, risks to tree swallows seems very tenuous indeed. Similarly, many of the TRVs derived for different fish, bird and mammal species are based on the same toxicity studies.

In the end, I do not believe that the ERA has taken a weight-of-evidence approach, primarily because most of the so-called lines of evidence are slight variations on the same theme – comparing observed or predicted concentrations to generic TRVs. With the exception of the field studies for benthic community structure and tree swallows, little field evidence is available to support the risk characterization (anecdotal evidence from a few individuals is of little use). No ambient or *in situ* toxicity tests were conducted to support the ERA.

In several places in chapters 5 and 7, statements that "true risks are likely underestimated" appear. Ignoring for the moment the difficulties with the notion of "true risks", the statements ignore the obvious conservatism that was built into the TQ calculations. For example, the comparison of Tri+ PCB concentrations in water to water quality criteria is stated as underestimating risk to fish because the criteria are based on the sum of all congeners (page 127). The PCBs criterion, however, is a conservative threshold based on concern for protection of wildlife. Because the same concentration of PCBs in water leads to higher exposures in top food chain species than in fish species, it seems likely that a PCBs criterion for wildlife will be highly conservative when applied to fish. Thus, I doubt very much that "true risks" are being underestimated in this or any other risk scenario.

(9) Many of the important sources of uncertainty in this ERA were identified and discussed in chapter 6. Obviously, I would have preferred that quantitative uncertainty analyses be conducted. Nevertheless, a qualitative discussion of uncertainties is an important exercise in ecological risk assessment, and the discussion in chapter 6 is reasonably comprehensive. Perhaps more discussion of the uncertainties about TRVs for individual assessment endpoints should be added (because assessment endpoints may also be less sensitive than test species). Also, the influence of assumptions about diet for mink, and foraging behaviour of species with large home ranges should have been explored.

The sensitivity analysis described in section 6.5.2 is of no use. No information is provided on input parameters, nor were rationales provided. Exposure parameters were all apparently assigned triangular distributions, yet this distribution has no theoretical plausibility for any stochastic environmental variable I can think of (see Seiler and Alvarez 1996). TRVs were

assigned uniform distributions that spanned an order of magnitude. However, since assessment endpoints have an equal probability of being more or less sensitive than the chosen test species, the appropriate range should have been two orders of magnitude (more if additional safety factors were used). A uniform distribution also assumes that all possible values for sensitivity are equiprobable. This will not be the case – very few species are highly sensitive or highly tolerant. The appropriate distribution would likely be the log-logistic or lognormal distributions for TRVs. As a result of these shortcomings, I have no faith in the results of the sensitivity analyses, nor do I believe "the output distributions of toxicity quotients generated by this Monte Carlo analysis represent population heterogeneity". Again, the authors should refer to Agency guidance (U.S. EPA 1997, 1999) for reporting the results of a Monte Carlo analysis.

General Questions

(1) For many of the reasons stated in the preceding responses, I do not believe that the Hudson River PCBs ERA adequately characterizes risks to sensitive populations. Although the assessment is reasonably clear (except for the missing information describing the equations, inputs and their rationales for the HUDTOX and FISHRAND models), consistent and transparent, it fails the criterion on being "reasonable". In my opinion, the assessment is excessively conservative and superficial. In the end, I have no idea of the seriousness of the risks posed by PCBs to Hudson River biota. What are the probabilities of effects of differing magnitudes? What are the ecological consequences of any effects that do occur? How will proposed remedial actions reduce risks? What are the countervailing risks introduced by the remedial actions? The ERA provides little information to help answer these and other important questions. Without this information, I do not see how effective environmental decision making can take place.

(2) I think I have said enough (too much, more likely).

Conclusion

In its current form, I do not believe this ERA is acceptable. To make it acceptable, ambient and in situ tests and field studies are required, new analyses (e.g., probabilistic risk analyses, ecological modeling), and a major re-write are required. Whether this will occur, I cannot say. Thus, I am unsure whether to choose the "acceptable with major revisions" option, or the "not acceptable" option.

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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.

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?*

As a general comment, I confess to an intense dislike for the jargon that frequently accompanies these exercises. Perhaps the legal wording behind the process requires that terms like 'receptors' be used instead of potential species at risk, or some other descriptive term. Receptor used in this way is very non-standard terminology, and would never be used in the wildlife toxicology scientific literature. A receptor, biochemically, is a specific protein that has a site with an affinity for binding a particular chemical or group of chemicals. The Oxford Standard dictionary refers to an organ or cell that responds to an external stimulus and transmits a signal to a sensory organ, or a region of a tissue or molecule in a cell membrane, etc. which responds specifically to a substance. None of these definitions even remotely encompass a species, population or community. That does not mean the new meanings should not be assigned when they helps to clarify, but these terms only obfuscate, in my opinion. Another grand word for which confuse could be substituted!

As pointed out in the life history and ecology of the various species in the appendices, very few of the chosen terrestrial organisms can be classified as exclusively piscivorous without supporting field evidence, and the one species for which this could safely have been assumed, the osprey, was not included for some inexplicable reason. It may be that bald eagles *are* primarily piscivorous on the upper Hudson, but they are certainly known to eat birds and scavenge carcasses of dead animals in other areas, and there was no particular attempt to verify the feeding habits of Hudson River bald eagles as part of this ERA, as far I could figure out. Therefore, it may be that mink, bald eagles, and kingfishers should be classified in the far right box – as consuming a variety of prey although primarily piscivorous. The other main criticism I have with the conceptual model is that the exposure of amphibians and reptiles is only via flood plain soils. What about amphibians that are almost exclusively aquatic throughout their life phases, and furthermore may form an important food source for reptiles, providing a direct aquatic link? Herptiles are ultimately eliminated from the ERA process because of a paucity of information, but honestly, the quality of information on a lot of the other species is not much better, and the very large worldwide concern for decline in amphibian populations would seem to me to be enough reason to have attempted to include them. They are likely to be more endangered than the great blue herons that eat some of them, in any case.

I am fully in support of the criticisms that the conceptual model should have been constructed on the basis of field surveys. For example, what is the status of the mink population in the Hudson river ecosystem (as opposed to tributaries) at this time? Are there any at all? The only reference that is provided in this regard is Foley et al. (1988) which is hardly up-to-date nor comprehensive in the first place. In this survey, insufficient detail is given to be sure that any mink were taken on the Hudson River proper. The data were grouped by large areas including several counties on either side of the Hudson River. My suspicion is that most animals were not from near the river, since PCB concentrations in the Upper and Lower Hudson River area mink were a factor of two or less higher than most other areas of the state, which makes no sense if they were eating Hudson River fish. A statement is made that, "Collection of animals near bodies of water known to be contaminated with PCBs, including the Hudson River and Lake Ontario, required more intensive efforts than in other areas of the state." Absence of mink along the shores of the Great Lakes is widely considered to be indicative of the effects of PCBs on reproduction. Although this is difficult to prove, the very extensive literature on the sensitivity of the species, plus assessment of available habitat, makes a cause-effect relationship, in this case absence of the species, much easier to establish than is the case for many of your other chosen species.

The evidence is stronger from the Foley et al. (1988) study that river otter were taken from the Hudson River proper, which is now further defined as 'valley'. Concentrations in Hudson River valley Otter were much higher than in other areas of the state. Assuming that river otters still do occupy the river, consideration should be given to assessing their reproductive status, and if trapping is done, comparing data on baculum length in males with the studies carried out by Henny on the Columbia River. Incidentally, none of Henny's work, which is the most extensive available on river otter, was used in this assessment. The work of Harding et al. (Environ. Health Persp. **107**:141-147, 1999) on correlation of reproductive and morphological condition in mink and river otter in relation to organochlorine contamination has also been ignored.

Pg. 12, 2nd para. The description of the SARs that determine which PCBs are more readily metabolized and excreted is far too simplistic. First of all, the comments should be placed into taxonomic context. Fish and invertebrates are poor metabolizers of PCBs, although lower chlorinated congeners may be excreted back to water unchanged as was pointed out. However, birds, mammals and at least some reptiles, metabolize PCBs according to quite well-defined rules in which substitution pattern of the chlorines, degree of induction of enzymes, etc. is more important than degree of chlorination, although the latter also has some influence. Thus, PCBs with no chlorine at a *m-p* position on at least one ring are much more readily metabolized than those that are substituted at both *p,p'* positions. Birds and mammals that are exposed to dioxin-like (Ah receptor active) compounds may have sufficiently induced enzymes to metabolize them. This is especially the case for BZ#77, but has also been shown to occur for BZ#118 and possibly BZ#105 in man, seals and polar bears. In fact, polar bears are efficient metabolizers of even BZ#126. Thus, generalizations such as are made in para. 2, page 13 about hexachlorobiphenyls taking a long time to reach equilibrium cannot be made. Some of them are metabolized quite quickly by birds and mammals, although most are not. It is even more unconscionable to generalize to Aroclor 1254, which contains several congeners which are easily metabolized by birds and mammals. Aroclor 1242, the major Aroclor of concern in the Hudson river, has an even higher percentage of metabolizable congeners.

<u>Assessment and Measurement Endpoints</u>

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?*

The aquatic endpoints appear to have been adequately chosen, but after reading through the life histories of the various species in the appendices, I began to wonder why so many terrestrial species need to be included. Not only is there a fair degree of uncertainty in feeding ecology in many cases, there is little (no?) comparable information on PCB levels from other areas (e.g., raccoons and bats), and therefore no field studies that might give a hint as to possible toxic effects. This, combined with TRVs derived from rats, makes the risk assessment process more like guess work than science. This is especially true for TEQs (see below for comment on TEFs and TEQs).

The WHO TEFs are an improvement over the largely rodent-based values which were in

common use until recently. However, it must be understood that there is still a large variability in species sensitivity within each group. This has been adequately demonstrated for fish and birds, but there is still very little information on mammals. *In vitro* studies with bird hepatocytes, which has also been ignored in this assessment, indicate that there is likely to be considerable variability in sensitivity to specific congeners as well (i.e., variable TEFs among species within a group). I therefore believe the study should have been restricted to terrestrial species for which we have site-specific information, extensive data from other areas, or assessments (laboratory or field) indicating that the species is sensitive: mink, otter, bald eagle, tree swallow and great blue heron. Given what we know about the sensitivity of mink, if action or no-action is protective of this species, it will be for the others as well. We do not even need to do a formal risk assessment to reach this conclusion.

I initially believed osprey might have been a better choice than bald eagles because of their exclusive piscivory, although when I reached chapter 5 I discovered that anecdotal information indicates osprey they are rare in the upper Hudson River, and probably breeding on nearby lakes when present. However, bald eagles seem to be similarly scarce, so it is moot which species would have been the better choice.

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.*

In all of the Assessment Endpoints, I consider gathering actual field data, and making comparisons of species abundance, diversity and reproductive endpoints in a similar, uncontaminated riverine ecosystem, to be the most important and accurate approach as to assessing whether there is current harm. Because concentrations of PCBs are not predicted to increase, evidence (or lack thereof) of effects under current conditions is by far the best predictor of potential future risk. This was quite eloquently defended on page 29, but then criticized as not being sensitive, confounded by other stressors, etc. I find most of these arguments untenable. Can observational data be any less useful in assigning cause-effect relationships than not knowing if there are even any effects present (even if the species is present) and then using a water-quality guideline to estimate probable risk? I think not. While it is true that observational data may require time to gather, and is best done over a period of time to look at trends, it is also true that EPA has had ample time to have been gathering data over past years, and chose not to take that approach. Having not done so is no excuse for not doing it in the future before decisions are made on action/no-action.

Various water and sediment water quality guidelines, while useful in the absence of other methods, may seriously over- or underestimate risk, given the lack of adequate experimental data to support relative sensitivity of many of the species under consideration, and other large uncertainties involved in their derivation. I found the repetition of these guidelines (and other endpoints) under virtually every heading unnecessary. Why could they not have been discussed once, if they have such general applicability? I do not think TRVs derived this way add much to weight of evidence.

The wording of the benthic community endpoint strikes me as odd. Was the purpose solely to preserve structure as a food source for fish? What about the importance of maintaining the

benthic community for its own sake? Note the transposition of the Endpoints 2 and 3.

I question how accurately TEQ values can be calculated for protection and maintenance of fish, given the quality of the data base that is available. In fact, I am not so sure about total PCBs either. I assume Endpoint 3 for fish refers to sufficient loss of benthic species that it would affect the food supply of fish dependent on this community? This appears to overlap somewhat the statement above.

In general, the multiplicity of endpoints, provided the data to support them have a scientifically sound basis, which is well beyond the purview of this process, and therefore cannot be assessed, will tend to support the weight of evidence, but this will undoubtedly vary considerably in quality and certainty among the various groups of animals. TRVs based on estimated exposure rates are the most problematical to deal with, especially for mammals (and especially for TEQs – see later). Body burdens/concentrations will be very difficult to estimate from exposure alone, especially for a mammal like a raccoon, for which there is no experimental data, including its capability to metabolize PCBs, and for which the diet is uncertain. BMFs in bird eggs are fairly well established, and there is a considerable body of information on embryotoxicity related egg to concentrations, so this likely to be one of the stronger endpoints. However, uncertainty in diet composition (and substitution of a few representative species, as surrogates for those actually eaten), is a problem even here.

Furthermore the available data in the literature has not been fully explored as to its applicability to the Hudson River exposure situation (or toxicity for that matter). Having references spread through several different volumes and places made it difficult to assess what may or may not have been taken into consideration. However, it appears that one reference with which I am very familiar, Braune and Norstrom (1989), which provides forage fish/herring gull whole body, liver and egg biomagnification factors for a range of PCB congeners, as well as PCDDs, PCDFs, and other OCs has not been used. It would have been a much better reference for estimating body burdens and egg residues for species like great blue heron, bald eagle and kingfisher which are also primarily piscivorous and probably accumulating residues over a much longer period of time, than a passerine insectivore like the tree swallow or a generic BMFs for PCBs in birds of 28. The assumption that patterns of exposure in prey species are going to be highly conserved is probably not true for any bird or mammal other than tree swallows (see discussion below). The relatively large amount of data for tree swallows and the reliance on it has therefore hindered, rather than enhanced the ERA, in my opinion.

Characterization of risk for sensitive species can only be poorly understood because of lack of detailed information on food web structure, and inherent patchiness of feeding ecology of upper trophic level species. The conclusions that can be reached are only as strong as the data base available for the assessment. This is not intended to be a criticism. Riverine ecosystems are actually much more complicated than large lake ecosystems, such as Lake Ontario, which we are only beginning to understand after many years of study and a much bigger investment in time and resources. The list of species in the Hudson River in the Appendices is adequate demonstration that this is not a simple system.

I believe that the authors of the conceptual model and providers of background ecological information have done an admirable job of attempting to distill the complexity of the Hudson River

ecosystem and how it relates to the PCB contamination into something manageable, although I think too many terrestrial species were included, as indicated above. A more open-minded and pragmatic approach, e.g. use of *in vitro* studies, more extrapolation from field BMFs in other species, etc. may not have yielded answers which are much more concrete than the ones which were reached. That is difficult to prejudge, but my opinion is that a better feeling for the probability of impact on various species would have been achieved if the process had been more transparent and clear. On this point, I am in agreement with GE that there is a unnecessary degree of complexity and opacity in the process which is not fully penetrable with the resources (information and time) allotted to this peer review. There were many times when I found myself wondering where I had seen this table or that, and in which volume it resided. Sometimes I just gave up trying to figure it out.

I disagree completely with the philosophy stated in the middle of page 29 that, "because the receptor my be affected by a variety of other factors unrelated to the stress of interest," observational studies are not sensitive. If a species is already under stress from another source, for example, a poor food supply (mentioned as cause of mortality in juvenile raccoons), mercury, habitat destruction, etc., then protection of the species from effects of PCBs may be either moot, or it may be the deciding factor in survival. For example, resident adult bald eagles in coastal areas of British Columbia appear to resort to eating seabirds outside of the breeding season, and consequently some individuals have very high levels of PCBs, even though their chicks, which are being fed local fish, may have quite low concentrations. I simply do not accept the single chemical approach to risk assessment. Identical exposures, body burdens, whatever approach is taken, may have different outcomes in different areas if the health of the whole ecosystem, including exposure to other chemicals, is not taken into account.

I found Appendix J to be almost unfathomable.

Exposure Assessment

4) *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.*

I found the methodology for determining the non-ortho PCBs, especially BZ#126, suspect and inadequate, and consequently the calculation of TEQs unacceptable. The only data indicating what the actual relative concentrations of toxic minor components, such as BZ#126, were to total PCBs are in the largely unreadable Figure K-43. Using a ruler and a magnifying glass, I estimated the mass fraction of BZ3126 to be ca. 10^{-4}, which is approximately what I would have expected. However, there are no data given for its mass fraction in Aroclors for comparison, even though this information was published several years ago by at least two groups I am aware of. It is standard practice in all of the laboratories I know of to do a prior separation of non-ortho PCBs on a carbon column, usually along with PCDDs and PCDFs, add ^{13}C-labelled internal standards for the target analytes and use mass spectrometry detection. There are three very good reasons for this. Sensitivity

is improved because the sample can be taken to much lower volume if the mega PCBs are first removed (purely a chromatographic reason), accuracy and precision are significantly enhanced by isotope dilution calculations, and the chances of false positives are virtually eliminated. Apparently the BZ#126 data passed the qualification test, but it is not at all clear what level was spiked to reach this conclusion. If the spike was at a substantially higher concentration than the native concentrations in the samples, then the precision and accuracy of the BZ#126 data may be much poorer than assumed.

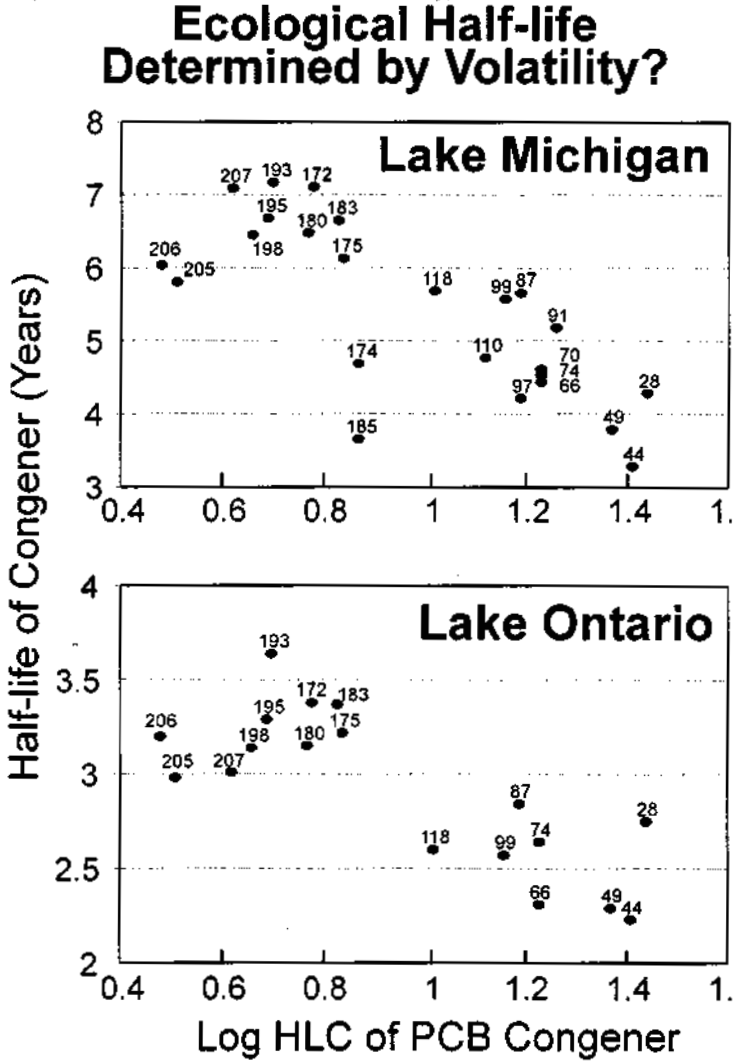
Because an insensitive method was used, a high proportion of the samples had undetectable BZ#126. Given my concerns about how well the qualification was carried out for this congener, there may also be concerns about the accuracy of the data that were above detection. The decision to use the detection limit as a surrogate for the real concentration is completely unacceptable in a risk analysis. For purposes of statistics, sometimes a half-detection limit is used, and sometimes it is desirable to assign random numbers from zero to the detection limit for multivariate analysis. But when BZ#126 is estimated to represent 33-85% of the fish-based TEQs (Table 3-1), then real numbers are required. Incidentally, the heading and overall description of what is actually being presented in Table 3-1 leave a lot to be desired. Upper River mean in what? Egg and Chick of what species? There is no question that the TEQs will be overestimated by this procedure, but by how much is impossible to say. As far as I am concerned, calculation of TEQs should not even have been attempted for those samples with non-detect BZ#126. On page 40, Book 1 of 3, it is stated that the error is "likely within an order of magnitude at most". Is this degree of uncertainty acceptable? It is quite unnecessary to have lived-with if up-to-date analytical procedures had been followed. This inadequacy compromises the TEQ-based assessment.

While I agree in general with procedure used to develop TEFs for Tri+ PCB concentrations, subject to concerns about BZ#126 above, I think it is a very large assumption that congener distribution will remain relatively consistent from year to year. It was one of my major recommendations in the BMR review that HUDTOX and FISHRAND be calibrated for a small number of specific congeners, then run into to the future to validate whether the assumption of unchanging congener composition is valid.

In figure 1, the half life of various congeners in Lake Michigan and Lake Ontario over a 10 year period is shown to be dependent on air/water partitioning (HLC). Some of the changes in Lake Ontario may be due to differences in Aroclor loading patterns from the Niagara River in the early time period, but the changes in the Lake Michigan data (which is influenced by Aroclor 1242 from the Fox River, and therefore similar in some respect to the Hudson River) are thought to be largely due to evaporative losses. Although the half lives are different in the two lakes, the change in rate of decrease with HLC (slope) is similar in the two lakes: a two-fold difference between tricholoro and octa-/nonachloro congeners. These data illustrate that considerable alteration in congener composition *may* occur over the time frame that HUDTOX and FISHRAND are intended to operate, and such a possibility should be included in the HUDTOX model.

I also objected in my review of BMR to the approach of estimating distributions of concentrations in fish based on Bayesian optimization of distributions of parameters with already known distributions, such as log K_{ow} and lipid percentages fish. It was my opinion that modeling specific congeners as suggested above would provide a more rigorous calibration of the model because these parameters would no longer be available for adjustment. It was also my feeling that

the model should predict distribution of concentrations according to size of fish, especially for large species like large-mouth bass, not just an overall population distribution. That way, size preferences of the various species could be factored into the analysis. Given the other imponderables, such as actual composition of the diet of piscivorous species, this may not be as important as I thought at the time, but it is still by far the most scientifically valid approach. FISHRAND, despite its purported mechanistic approach (and that is somewhat debatable), becomes a statistical empirical model the



way it is applied. Although it appears quite successful at predicting Tri+ PCB concentrations this is accomplished to a degree by artificially altering the distribution of log K_{ow} values. Is this an indication that congener distributions were changing over time the model was calibrated?

Figure 1. Ecological half life of PCB congeners in herring gull eggs from Northern Lake Michigan (mouth of Green Bay) and Scotch Bonnett Island Lake Ontario, 1971-1981 vs. Henry's Law Constant

One of the biggest problems that I have with the Exposure assessment relates in various ways to what I have already alluded to above – unrealistic extrapolation and assumptions. The data base is so limited and incomplete that this has to be done, unfortunately, but it could be done with a lot

more circumspection and awareness of how biological differences affect bioaccumulation.

For example, what is the point of calculating avian and mammalian TEQs in water, sediment, invertebrates and forage fish (Tables 3-3 to 3-6 - note that the heading should say TEQs based on TEFs)? This might be useful for piscivorous fish, which do not metabolize PCBs to any extent. But since a large proportion of TEQs is contained in BZ#77, which is quite rapidly metabolized by both birds and mammals, and an indeterminate amount of the BZ#126 values are not real numbers to start with, an exposure assessment based on these values in the absence of some biological and kinetic considerations is quite meaningless.

TEQs should not ever be used for exposure assessment. They are only useful in the context of converting measured concentrations in the species being studied into a better measure of possible effects due to Ah-receptor mediated toxicity. TEQs are not bioaccumulated!

I am assuming from Tables J-2 and J-3 that BZ#77 was an important contributor (concentrations as well as TEQs) in tree swallows. That is probably because the females are deriving a large proportion of egg lipid from their diet of highly contaminated emergent insects, as opposed to lipid reserves. This is frequently the case for passerine birds, which lay a high proportion of their body weight in eggs. If the diet during rapid yolk deposition happens to be highly contaminated with PCBs, as is the case here, then there is little opportunity for metabolism to occur. In migratory species that probably are much less exposed most of the rest of the year, but use exogenous sources for egg production, local diet has a bigger influence on residue levels. However, this will probably not be the case at all for any of the mammals, and probably not also for species like the bald eagle, which lay a smaller percentage of their body weight as eggs, are not so dependent on lipid from endogenous resources, and may be resident and therefore exposed over a longer period of time. Another case in point are mallards. I do not know off-hand what strategies mallards have for obtaining lipid sources deposited in eggs, but geese and ducks lay a high proportion of their body weight in eggs, and some species (e.g., the snow goose) rely entirely on endogenous resources for lipids. In this case, the concentrations in eggs reflect what is retained by the female from exposure over the previous year (more or less, depending on metabolism of the congener). Therefore, amount

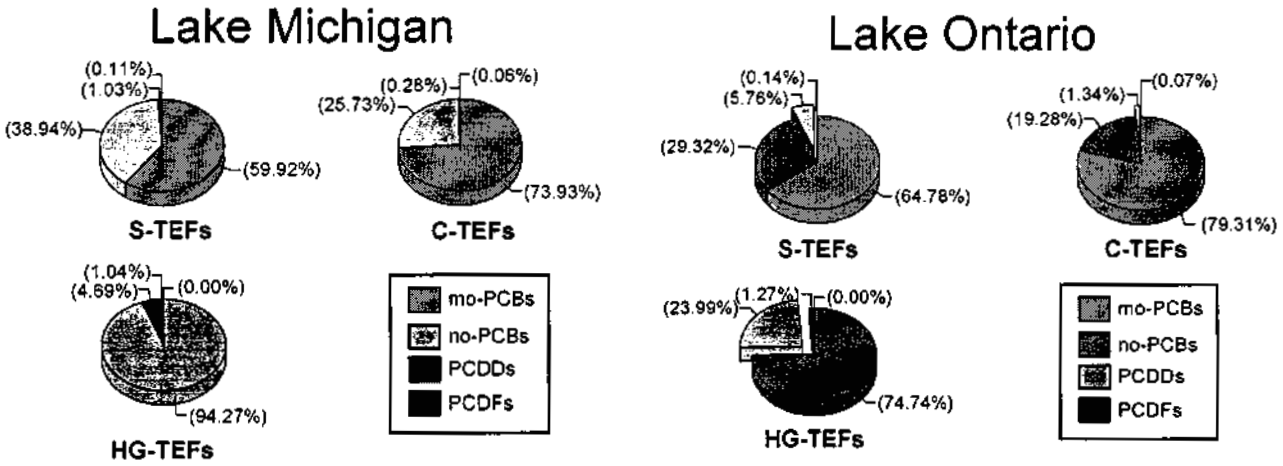


Figure 2. Calculated proportion of contribution to TEQs from mono-ortho and non-ortho PCBs (all of the congeners listed in Table 4-2, Book 2 of 3 in the ERA) in herring gull eggs

from northern Lake Michigan (mouth of Green Bay) and Scotch Bonnett Island Lake Ontario, 1971-1981. S-TEFs are based on those derived by Safe et al. C-TEFs and HG-TEFs are chicken and herring gull based values taken from studies on EROD induction in cultures of primary hepatocytes of embryos of these species by Kennedy and coworkers.

of PCB deposited to eggs may have little to do with local conditions, unless the individual is resident.

To state it simply, the relative contribution of BZ#77 (and probably also BZ#81), cannot be assumed to remain the same in birds and mammals as it does in water, sediments, invertebrates or fish. This another case where only real measurements will tell the story. From my experience, there is ample evidence that BZ#77 accumulation is much lower in the majority of birds (and their eggs) than BZ#126 if exposure to PCBs occurs over a relatively long period of time. Incidentally, this applies to an even greater extent to 2,3,7,8-TCDF. If there is high exposure during yolk formation in some species, TCDF is found in bird eggs, but if exposure is spread out over a long period of time, it is metabolized so rapidly it seldom shows up at all.

It is not exactly pertinent to this charge question, but the contribution of PCDFs to any assessment of exceedance of TEQ-based TRVs is something that cannot be ignored. Although not listed in Table 4-2, it is very clear from the complete table in van den Berg et al. (1998) that TCDF is very toxic to birds (although not readily bioaccumulated), for example. PCDD/Fs are much more important in fish than PCBs as well. Since 2,3,7,8-TCDF and 2,3,4,7-PnCDF are important contaminants in Aroclors, and are closely associated with them, it is unconscionable that they were completely ignored just because they happen to have a structure that is a little different from PCBs. PCDF data should have been obtained.

To illustrate the difficulties in use of TEQs, Figure 2 shows application of three different TEF indices to the same data set from two colonies of herring gulls in the Great Lakes. At the time of this analysis, avian WHO values were not generated, but if they were applied, the proportion of TEQs would appear similar to those based on HG-TEFs. The important thing to note is that the contribution of mono-ortho PCBs is close to 80% of the total if chickens are used as the reference species. They are still a significant proportion if rats are the reference species, but their importance disappears completely if the herring gull-specific values are applied. Herring gulls simply do not respond to BZ#118 or BZ#105, and that is likely true for most wild birds. Wild gallinaceous species have shown greater sensitivity than others in both *in vivo* (pheasants) and *in vitro* (turkey) tests, but in no case does the absolute or relative sensitivity approach that of the chicken. It is one of those amazing things that happens every now and then in science. The sky appears to be falling, when it isn't (reference to the story of Chicken-Little for those of you with a children's literature bent). While there is always the possibility that EROD-based TEFs derived in this manner are not reflective of embryotoxicity, the evidence accumulated from studies by Brunström's research on the effect of injection of PCBs (primarily BZ#77) into eggs of various species of birds strongly suggests that there is a rank-order correlation of embryo LD_{50}s and EROD induction.

The take-home message is that BZ#126 is very important to Ah-receptor mediated toxicity in birds, and failure to come up with an adequate assessment of exposure/bioaccumulation of this congener negates the TEQ approach to TRVs, in my opinion. Another take-home message from

Figure 2 may be that PCDFs are not all that important. That is probably true for most species which are continuously exposed, but it would also be a mistake for some species. TCDF has a very high TEF in avians. For tree swallows (*vide infra*), which may deposit TCDF into eggs before they have a chance to metabolize it because of utilization of exogenous resources for lipids, it could be a more significant compound than the PCBs themselves.

Because birds do not metabolize BZ#118 or BZ#105, but do metabolize BZ#77 (Norstrom, R.J. 1988. Patterns and trends of PCB contamination in Canadian wildlife. In: Hazards, Decontamination and Replacement of PCB, J.-P. Crine, ed., Plenum Publ. Corp., New York, pp. 85-100.), it is also important to understand the kinetic implications of the bioaccumulation of the BZ#77 in eggs, as indicated earlier.

Note the publication by Froese et al. (ET&C, 17:484-492, 1998), another one of the many relevant references that are not were not used in this assessment (it was published 2 years ago). They state in the abstract that, "Our results indicate that patterns of relative concentrations of PCB congeners change with trophic level, specifically from sediment to invertebrates and from tree swallow eggs to nestlings." This is very true, and the substance of my criticism of the use of TEQs as an exposure TRV. They recommend a TRV of 0.015 TEQ/g total organic carbon in sediment as protective of sensitive avian species. While I do not agree with this conclusion, why was this reference was ignored as part of this assessment.

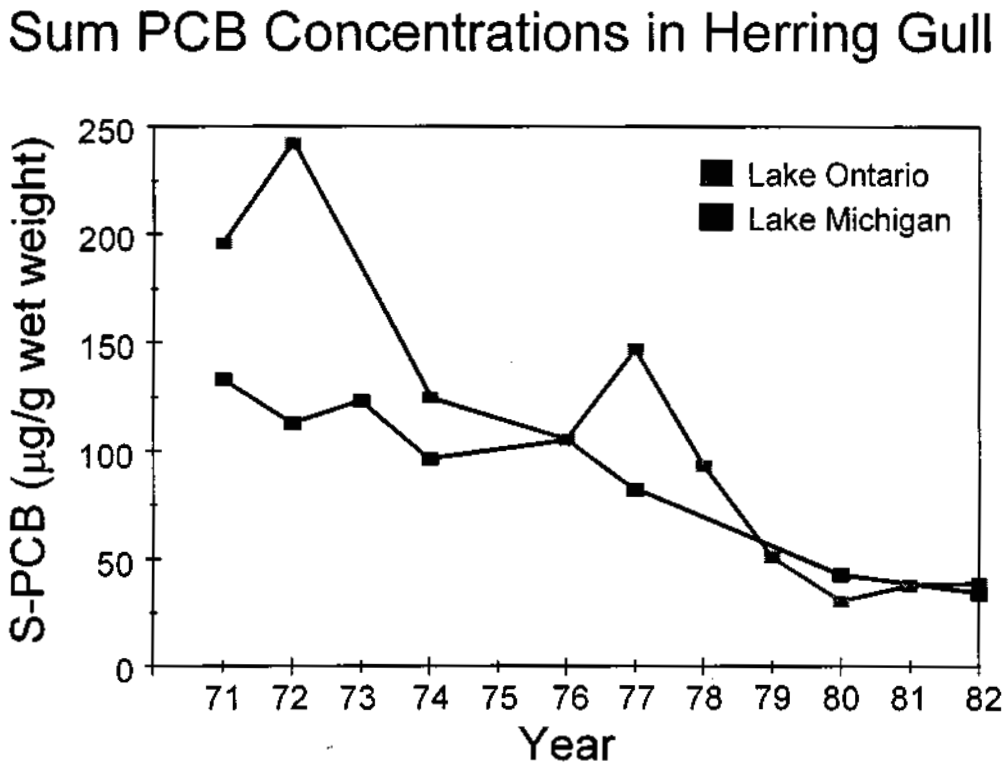
5) *Have the exposure-assumptions (ERA, pp. 46-66 and Appendices D, E, and F) for each fish and wildlife receptor been adequately described and appropriately selected? Please discuss in detail.*

The feeding rates and diet composition assumptions have been addressed as well as possible under the circumstances. However there need not have been so many assumptions if more field data had been obtained. I have only one major difficulty, which is the treatment of biomagnification factors in eggs (3.4.3.5). Egg BMFs of 28-30 for total PCBs is a reasonable value based on a continuous exposure scenario. However, as pointed out below, I do not think it is feasible to discuss BMFs of TEQs. The composition of congeners contributing to TEQs is expected to vary between fish and birds/mammals due to metabolism, especially of BZ#77. TEQs should only be used for tissue concentration-based TRVs. The very low BMFs of 2 for tree swallows and 3 from one mallard and two wood duck samples are undoubtedly a reflection of the fact that the diet being used for this calculation is an overestimate of the true exposure (much lower) of the species to PCBs prior to egg formation. Although this is probably a fair representation of reality, it must be remembered that the actual source of PCBs in eggs of these species may not be the Hudson River, or if it is, a considerable proportion may have been retention from previous years' exposure, allowing time for metabolism of congeners such as BZ#77 to occur. Under these circumstances, calculation of BMFs is not valid – - comparison of apples and oranges.

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.



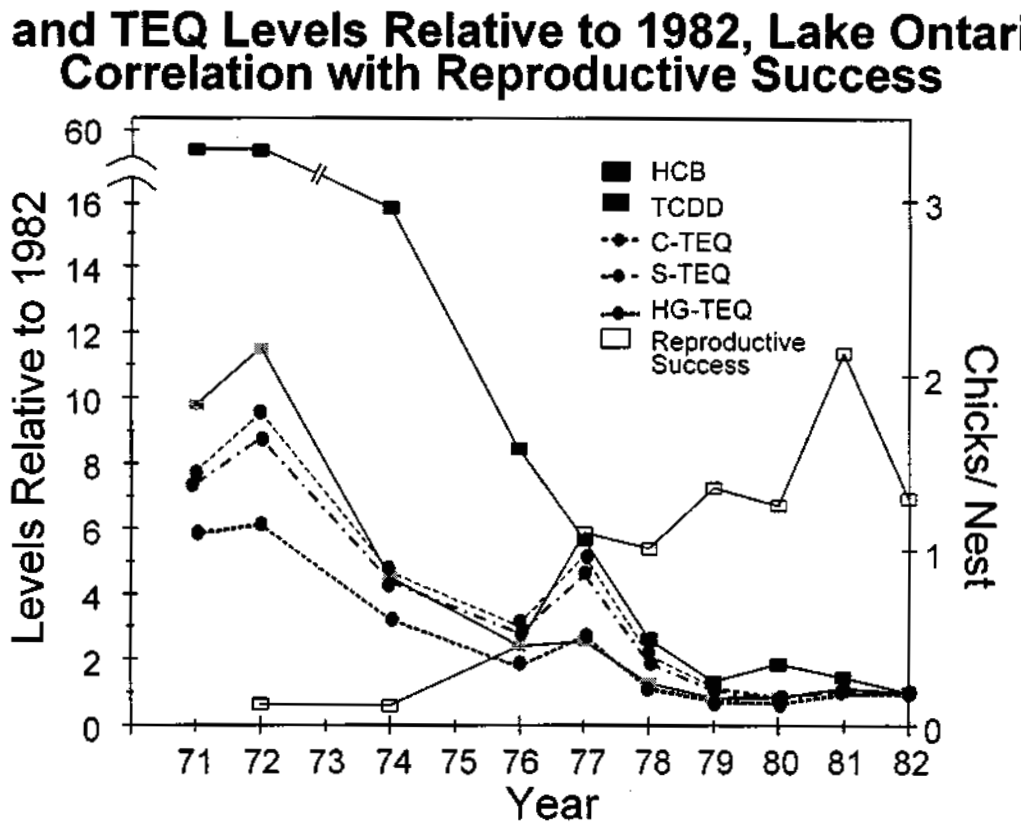


Figure 3: Sum of PCB concentrations and TEQs ion eggs, and reproductive success of herring gulls from northern Lake Michigan (mouth of Green Bay) and Scotch Bonnett Island Lake Ontario, 1971-1981

The whole idea of doing a risk assessment is to protect an ecosystem/species. How is this possible if multiple stressors are not figured-in? I grant you that using most-sensitive-species like chickens or mink birds will be protective. But is it real? It will probably be overprotecive for most species. On the other hand, the lack of an ERA which integrates exposure to all of the potential stressors (esp. PCDFs), may miss real effects that are there.

I have little doubt that mink, and possibly river otter, will be affected by the present and near-future levels of PCBs in the Hudson River. All the other assessments pale by comparison.

As shown in Figure 3, concentrations of PCBs in herring gull eggs were similar in Lake Ontario and northern Lake Michigan in the early 1970s and declined steadily to the early 1980s. Although herring gulls were experiencing reproductive failure in the late 1960s in Lake Michigan, this may have been due to DDE-induced eggshell thinning rather than embryotoxicity of PCBs. During the period represented in Figure 3, reproductive success was (anecdotally) normal in Lake Michigan, despite similar concentrations of PCBs as in colonies in Lake Ontario that were experiencing essentially zero reproductive success (note that adults of both populations are resident, so there is no confusion introduced by migration). Note also that during the fairly rapid increase in reproductive success of herring gulls in Lake Ontario between 1974-77, there was no significant change in TEQs, TCDD (a significant contributor to TEQs in Lake Ontario – see Fig. 2), or total

PCBs (not shown). HCB concentrations were in excess of the LD_{50} in the early 1970s, and its decline correlates much more strongly with improvement in reproductive success than other OCs. Spearman Rank Order Correlation tests of reproductive success vs. chemical concentrations is given below. HCB wins, but TCDD and HG-TEQs are also in the race. Chorostyrenes are functionally correlated to HCB because the source of both was carbon electrodes used in chlorine production. S-PCBs do not seem to be much more important than many other OCs, despite concentrations over 200 ppm in the early 1970s.

Chemical/ Class	p-level
HCB	0.0009
TCDD	0.0072
HG-TEQ	0.0072
S-PCDD	0.0072
S-CStyr	0.0125
S-PCB	0.0199
S-DDT	0.0298
C-TEQ	0.0298
S-TEQ	0.0358
S-Mirex	0.0424
Dieldrin	0.0610
S-PCDF	0.1544
b-HCH	0.2351

I do not wish this analysis to be perceived as underestimating the significance of PCB contamination. There is no question that reproduction of mustelids is sensitive to PCBs, and that alone is sufficient to be concerned about PCBs in the Hudson River. Within the avian world, there is some indication that terns are more sensitive than gulls, but they are not part of the assessment. And, we have no information at all for many species, especially mammals. Nevertheless, it is important to use the best scientific information available and realize when we are barking up the wrong tree. Herring gulls can quite clearly sustain normal reproduction with PCB concentrations exceeding 200 mg/kg in their eggs. That does not mean that their immune systems were not compromised, or that behavioral problems did not exist. But if these effects were present, they did not affect recolonization of Lake Ontario by herring gulls in the late 1970s. If anything, forage fish community structure changes were more important. In Lake Erie, the invasion of zebra mussels has been the single most important factor in exposure of piscivorous avians to contaminants.

Kannan et al. (Hum. Ecol. Risk Assess. 6:181-201, 2000) point out that NOAELs and LOAELs may be artifacts of the study design, and may not reflect the specific point of the dose-response relationship. Because they felt NOAELs were overprotective, and LOAELs were underprotective, they chose a mean of the two as the likely threshold at which effects would occur. Although this approach is a debatable one, it certainly is worth having the debate, and seeing if a

consensus could be reached on its utility.

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.

They are probably over-protective for birds in many cases, see the example of the herring gull above. Peterson et al. (1993, Critical Reviews in Toxicology **23**:283-335) provides LOAELs, NOAELs and LD_{50}s for embryotoxicity of TCDD in birds. The LOAEL and the LD_{50} for pheasant was in the 1-2 mg/kg range, and the LOAEL for the eastern bluebird was 10 mg/kg. Given the lower sensitivity of birds to PCB-based TEQs than mammals, and the apparently overall low sensitivity to Ah-receptor based toxic effects, I believe the TQs to be considerably overprotective for birds. Note that Elliott et al. (1996) proposed a LOAEL of 210 ng/kg TEQs for CYP1A induction in bald eagle eggs, whereas this ERA came up with a TRV of between 10-20 ng/kg (pg. 106). The Elliott et al. estimate is arguably not a toxic effect, rather an indication of biochemical sensitivity to exposure. Concentrations of total PCBs in yolk sacs were in the order of 200-400 ng/kg lipid, and there was no indication of concentration-related effects for morphological, physiological or histological parameters. The true LOAEL for significant toxic effects may therefore be much higher than 210 ng/kg. However, since TQs using average and upper confidence limits were frequently in the 100 range for bald eagles using the low TRV values, they would likely be greater than 1 even if the higher values were used.

Kannan et al. recently published a thorough analysis of the derivation of TRVs for aquatic mammals (Kannan et al. 2000. Toxicity reference values for the toxic effects of polychlorinated biphenyls to aquatic mammals. Human and Ecol. Risk Assessment **6**:181-201.) This paper was published subsequently to the preparation of this report, but must be considered in the final analysis. I am not in any way endorsing the conclusions of the publication, since there was insufficient time to assess it. However, it must be taken into account in the final revision of the ERA, and appears to have a been a very reasoned analysis of aquatic mammalian TRVs. Most of the conclusions are based on studies of mink and European otter. Note that they are in agreement with my assessment that dietary BMFs of TEQs are precluded as an approach to developing TRVs, "due to site-specific differences in congener composition and species-specific differences in toxicokinetic and toxicodynamics,"

The conclusion was that threshold concentrations for effects were preferable to NOAELs or LOAELs. Maximum allowable toxicant concentrations (MATCs) were defined as the toxicant concentration in mammalian 'receptor' species that is likely to be without appreciable risk of deleterious effects, calculated as the geometric mean of NOAEL and LOAEL. The values were 9 mg/kg total PCBs and 520 pg/g TEQs in lipid in liver. Dietary exposure TRVs were expressed as a range of values: 0.01-0.15 mg/kg of total PCBs and 1.4 to 1.9 pg/g TEQs, wet weight. The method of derivation of TEQs was not assessed, so these values would be subject to re-analysis before being accepted.

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.

As discussed earlier, the risk to piscivorous birds is probably overestimated, but by how much can only be estimated with any degree of certainty for bald eagle. In this case, I believe the TRV to be at least an order of magnitude too low, and perhaps two orders of magnitude. If this is the case, the risks are likely to be borderline to this species. However, the risk to mink and otter is high as determined. There is no real basis to determine the validity of the risk assessment for raccoons and bats, because of the paucity of information on these species.

Note that the reference to Table 5-84 on page 146 should read Table 5-85.

The anecdotal information in Table 5-85 that mink numbers are large and increasing and there are 'quite a few otters' needs to be verified, especially as to the exact location of these populations. Are the mink on the main stem, or on tributaries and other areas nearby, and therefore not necessarily exposed to PCBs. If, indeed, there are successfully breeding mink populations on the mainstem, this would suggest that the risks are being overestimated.

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.*

See discussion above about the problems of calculating TEQs when there are so many non-detects for BZ#126, and the lack of consideration of metabolism of BZ#77. These are major sources of uncertainty which are glossed over in the analysis.

Toxicological uncertainties are discussed adequately. However, I feel that better use could have been made of *in vitro* comparative toxicology studies in birds to reduce the level of uncertainty.

Uncertainty in long-range extrapolation of exposure due to congener composition changes over time is not dealt with.

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?*

The fragmented way in which the whole process is being conducted, with baseline modeling,

ecological and human health assessments essentially divorced from each other, makes it very difficult for peer reviewers to obtain a 'big picture'. I was fortunate to have participated in both the BMR and ERA, so I had some continuity of perspective in how concentrations were derived. In fact, I requested to be involved in both for that reason. Perhaps it will not turn out to have been as important as I imagined, but my opinions of BMR certainly influenced how I viewed how I approached this review of the ERA.

I found the volume of material, and the requirement to jump around between three volumes of material in order to make sense of statements was very time consuming, and probably contributed to me missing several points that I should have addressed. I therefore have to give the risk assessment a low grade on clarity and transparency.

I did not have adequate time to cover the responsiveness Summary at this writing, however, I will have done so prior to the peer review meeting and provide comments at that time.

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 with major revision (as outlined)

I would like to see the results of individual congener modeling from HUDTOX and FISHRAND before making final conclusions as to the acceptability of using the long-term predictions of Tri+ PCB concentrations in the risk analysis, especially the stability of the ratio of TEQs/Tri+ PCBs.

If possible, the approach to calculating TEQs based on non-detectable BZ#126 numbers should be re-visited.

The use of TEQ BMFs should be reassessed, and probably eliminated.

Much better use needs to made of the available literature. I did not have time to assemble a list, but there are many relevant studies that were not considered at all, and may have considerable influence on the TRV values that were used.

The literature on bald eagles suggests that the TRVs used for this species are too high. Note that early attempts to ascribe bald eagle reproductive failure in the Great Lakes to PCBs was confounded by high levels of DDE, and it was probably the latter compound which was responsible (egg shell thinning). Another source of information which is highly relevant, but not readily accessible, are studies on white-tailed sea eagle reproductive success in the Baltic Sea (Helander et al., 1999, White-tailed sea eagles *Haliaeetus albicilla* in Sweden: reproduction in relation to DDE, PCB, coplanar PCB and eggshell parameters; manuscript in thesis of Anders Olsson, University of Stockholm). I will bring a copy of the thesis with me to the meeting.

Although some attempts were made to obtain anecdotal information on presence of species, this effort was wholly inadequate to provide appropriate observational-based assessments. This should be addressed in any follow-up studies, especially the status of mink and otter populations.

See other comments above.

Timothy Thompson

ThermoRetec
Smart Solutions. Positive Outcomes.

May 11, 2000

John Wilhelmi
Eastern Research Group
110 Hartwell Avenue
Lexington, MA 02421

Re: Hudson River Ecological Risk Assessment Review

Dear Mr. Wilhemi

Thank you for this opportunity to review the report entitled *Baseline Ecological Risk Assessment; Hudson River PCBs Reassessment RI/FS.* As will be reflected in my comments below, I believe that the document authors did a good job following the EPA guidance on risk assessment for Superfund, and that the document is generally well-written. I believe that there conclusions concerning overall baseline environmental risk within at least the upper Hudson are probably correct, but it is my recommendation for the ERA that EPA consider some major revisions before it should be released as final. The basis for my concern fall into three major categories as follow:

- ***Transparency.*** I am concerned that the ERA does not meet the basic requirement for clarity and transparency defined in the *Ecological Risk Assessment Guidance for Superfund, Process for Designing and Conducting Ecological Risk Assessments* (USEPA 1997). Clear documentation and communication is paramount to evaluating the need for risk reduction through remediation. I found that document(s) difficult to follow and logic paths not always laid out in a way that myself as an experienced environmental scientist could understand the decisions made.

  There is a great deal of background information on that is simply referenced in other documents, that are not clear to the reader unless he/she consults and reads the entire document. For example, what was the determination about existing data that lead to sampling additional stations in 1993, and what was the logic that supported using only eight samples to characterize risk for the Thompson Island Pool, two for Stillwater and one for the Federal Dam reaches of the River. In addition, decisions are made on data inclusion/exclusion without presenting to the reader a satisfactory explanation as to why they were included/excluded (e.g., previous sediment sampling done by NYSDEC, or the NYSDOH 1976 - 1985 benthic macroinvertebrate study). Another example is the apparent dropping

of the 95% UCL calculation from FISHRAND projections in the *Responsiveness Summary* (see Tables 3-10 and 5-9 in that document), without any discussion. There are very likely good reasons for all of the above, but they are not readily reflected in the *Scope of Work*, *ERA*, or the *Responsiveness Summary*.

- ***Technical Deficiencies.*** There is a tremendous amount of good data that has been compiled into the Hudson River Database (HRDB), that was never used in the ERA. My own opinion is that an ERA should be conducted in a way that allows for the evaluation of remedial alternatives. This apparently is also what the authors of EPA's *Ecological Risk Assessment Guidance for Superfund* intended as well, since they site OSWER Directive 9285.7-17 in noting that the objective of the ecological risk assessment process is "(1) to identify and characterize the current and potential threats to the environment from a hazardous substance release; and (2) to identify cleanup levels that would protect those natural resources from risk".

  Much of the sediment data in the available in the HRDB could be utilized to strengthen the risk characterization, and produce a document upon which a feasibility study could be constructed. For example, the NYSDEC sediment data could be incorporated with EPA's 1993 data to produce PCB-contaminant isopleths for the River. Such maps would help communicate that there are PCB exposure levels over an entire reach (e.g., Thompson Island Pool), and avoid the criticism that reach wide risks in the ERA have been characterized using too few stations that do not reflect all conditions within a reach. I also offer the recommendation that the more recent datasets for sediments or benthic infauna be incorporated into the ERA (e.g., the 1998 Exponent benthic infaunal analyses, the 1998 surface sediment data collected by GE — incorporated into the model calibration, but apparently not into the baseline ERA). If there are very good technical or data quality assurance reasons why those should not be, then that needs to be better communicated in the ERA.

- ***Organization.*** While the writing is good in this document, it is difficult to track information over multiple documents to evaluate statements or decisions made in the ERA. There are four separate documents comprising the ERA, and an additional five to seven additional documents one must access in order to have a complete picture of all the elements that comprise this ERA. Perhaps this reflects a personal preference, but I believe that an ERA should be a stand-alone document that would include the following elements:

  Section 1: Introduction. Fairly similar to the introduction section provided in the ERA now, including purpose and organization

  Section 2: Background. A more complete background section that could be something as simple as the executive summary and relative figures from a remedial

investigation. This section should lay out the description of the entire Hudson River as relevant to the ERA. This should include not only a description of the PCBs in the system, but also other sources of potential chemicals of potential concern. It would include a better description of the PCB distribution in the depositional zones (currently only identified as "hot spots" in the ERA figures. Finally, a complete description of the fate and transport processes from a hydrodynamics perspective (e.g., depositional vs. scour zones) is a precursor to understanding the model dynamics, as well as understanding important fish habitats within the River.

Section 3: Data. Inclusion of a summary of the three reports that comprise the data used in the ERA; the 1995 *Database Report*; the 1997 *Data Evaluation and Interpretation Report*, and the *Low Resolution Sediment Coring Report.* In addition, the fish and bird data collected by NYSDEC, NOAA, US Fish and Wildlife, and General Electric. A description of the data sets, and especially the relevant quality assurance determination (e.g., are the data compliant with National Contingency Program standards, or are they supportive data from the standpoint of a defensible ERA) is important for the reader to understand as we evaluate the findings. While this was done for the congener data used in this ERA, as a reader I need to understand the data useability for all facets of the ERA.

In addition, this section should cover the statistical treatment of any data. For example, the current ERA does discuss calculation of a 95% upper confidence limit on the mean (95% UCL), but omits a discussion of what happens when the 95% UCL exceeds the maximum concentration (see for example Table 3-7 where 95% UCLs for Brown Bullhead and Largemouth Bass exceed the maximum measured concentration). This section should also include rules for determining percentiles (which the current ERA omits). For example, what is the minimum number of samples needed to determine a percentile ($n > 10$), and what value is used when "n" data are not available.

Section 4: HUDTOX/FISHRAND. A more complete description of the HUDTOX and FISHRAND models. This is instrumental in understanding the prediction of future risks, and deserves a more complete description within the ERA. The presentation material given by Ed Garvey at our meeting in March would make an excellent chapter. While the reviewers have the benefit of his presentation by slide and video, an external reader will not. This relates back to the issue of transparency — the tools and decisions used in the ERA must be clear to the reader. I note that limitations and uncertainties to the predicted model results are not discussed in Section 6 of the ERA — something that clearly needs to be included. This proposed Section 4 should discuss the strengths, and limitations of the models; which should then be reflected in the Uncertainty Section of the ERA.

ThermoRetec

The subsequent chapters would then focus on the problem formulation, exposure characterization, assessment, risk characterization and uncertainty, as previously discussed.

The attachment that follows focuses on the specific questions given to the reviewers to answer. I trust that my responses will be helpful in assisting EPA in crafting a document that assists in developing risk management decisions. Should you have any questions, please feel free to contact me at 206 624 9349.

Sincerely,

Timothy A. Thompson

Tim Thompson
Senior Environmental Scientist
ThermoRetec Corporation

ThermoRetec

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?*

In the narrow sense of the question posed, the conceptual model for biological fate and transport within the Hudson River is adequate for the purposes stated. However, from a risk communication, standpoint, I recommend that EPA consider adding or supplementing the existing ERA in order to help the reader understand the overall environmental system and the compilation of data used in the ERA. Specific examples are provided below.

P. 3. Sect. 1.3. Site Investigation and Hudson River Data Sources

This is very high of level overview of the data collected and used in the ERA. Without accessing and reading the data management reports, there is no ability to assess whether information collected met the requirements for useability under the National Contingency Program; i.e., whether the data from each of the data sets listed could be fully validated, or whether it could be listed only as supporting information for the purposes of a Superfund assessment.

Much of the sediment and water information is available through the TAMS *Database Report*, in the *Low Sediment Coring Report* (December 1988), and the February 1999 *Addendum*. However, there does not appear to be a single source of information that describes the validation for each of the data sets, unless that would be the *Data Evaluation and Interpretation Report*, which is was not available to me, nor is a copy at EPA's Hudson website.

Again for transparency purposes, it would be useful to summarize that within a separate section of the RA.

P. 10. Sect. 2.2 Contaminants of Concern

While it is acknowledged that PCBs are the focus of the re-assessment for the Hudson River, it would be very useful to include a discussion of other chemicals of potential concern (COPC) known to exist in the River is necessary in order to put into perspective potential risks from PCBs. For example, metals as COPCs and their potential effect on benthic populations appear in Appendix H.

In Table H-10, the levels of lead, chromium, and mercury are at levels that exceed several different sediment benchmarks, including both the threshold effects, and the probable effects concentrations, of the consensus-based sediment quality guidelines for freshwater ecosystems (MacDonald et al, *in press*). While the ERA needn't assess risk for these other COPC, at least their effects on the eco-receptors (especially the benthic infauna) needs to be accounted for in the uncertainty section.

P. 11. Sect. 2.3.1, Exposure Pathways in the Hudson River Ecosystem

A fundamental question not defined in this ERA is the nature and extent of PCB contamination throughout the Hudson River. The ERA cited three documents that discussed in detail the magnitude and extent of contamination *(Baseline Modeling Report, Data Evaluation and Interpretation Report, Low Resolution Coring Report)*. However, I did not find that those documents (I did not have the *Data Evaluation and Interpretation Report*) laid out the data in a way that at least the spatial distributions could be understood. . The type of PCB-distribution maps put together apparently with the 1984 NYSDEC data (as cited in the Executive Summary for the *Data Evaluation and Interpretation Report*) would be very useful. It is this reviewers opinion that a knowledge of the contaminant distribution is necessary in order to evaluate whether the 10 sampling locations used in 1993 are representative of the entire PCB distribution in the upper Hudson River.

The remainder of section 2.3 is well-written and adequately covers the conceptual site model, as shown in Figure 2-4.

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?*

With the following two suggestions, the assessment endpoints listed in the ERA appear to follow guidance and are adequate to assess risk to the important receptors of the Hudson River.

P. 20. Sect. 2.4, Assessment Endpoints

Phytoplankton are an important primary producer, particularly in ponded (i.e.,with dams or wiers) sections of many riverine systems. Phytoplankton are identified as an important component of the FISHRAND food web -- as a principle food source for Spottail Shiner -- but are not identified as an important assessment endpoint in the ERA. If phytoplankton communities are not an important endpoint, then why they are excluded should be carefully defined.

Protection of significant habitats as an assessment (and measurement) endpoint is poorly defined. There is never a definition given on what constitutes a "significant" habitat, and how PCBs might affect those. This is a common critic in the comments to the ERA, and it could use some reconsideration. For example, in the *Responsiveness Summary*, Page 25 in response to EF 1.4 and EP 2.1, the comment is made that the significant habitats were not mapped due to the length of the Hudson (200 miles). The *Remedial Investigation for the Lower Fox River and Green Bay* has prepared habitat maps for all of the River and both shores of Green Bay using information compiled from federal (e.g., USFWS, NOAA), state (Wisconsin and Michigan Departments of Natural Resources), consultant reports (Exponent on behalf of the Fox River Group), and several commercial sources that sell maps for Geographic Information Systems. I believe the relationships between exposure to PCBs and species/habitats would be strengthened by this type of presentation.

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.*

The measurement endpoints, as defined, are generally adequate to support the ERA. The exception may be the measurement endpoints selected to judge effects on significant habitats. The connection between "significant habitats" and surface water or sediment PCB concentration is ambiguous and tenuous at best. I would also note that in the ERA, body burdens relative to TRVs are discussed in Section 5.8 (Evaluation of Assessment Endpoint" Protection of Significant Habitats) as being indicative of risks to significant habitats, but that these are not listed as measurement endpoints. This is reiterated by EPA on page 21 of the *Responsiveness Summary* (Response to EL-1.2, EL-1.6, EL-1.7, and EG 1.3, third paragraph) where the exposure of fish, avian, and mammalian receptors is held up as a potential threat to significant habitats. If that case is to be made, then those should be listed as measurement endpoints earlier in the document.

As I recommended above, mapping of the significant habitats along the Hudson River would be an excellent way to communicate where those habitats exist, and how they are important to the overall assessment of risk.

I would recommend that the revised ERA include a better definition of when percentiles are employed, versus the use of the upper confidence limit on the mean. This is to some degree clarified in the *Responsiveness Summary* (see Page 21, Response to EF-1.9), but it again reflects the burden placed on the reader to read all of the associated documents in order to understand the analysis of ecological risks.

Available field observations of the presence and abundance of specific receptors is an important consideration for an ERA. The measurement endpoints used in the Hudson River ERA rightly acknowledge that fact. As I will discuss further below, I believe this ERA needs to include what data

are available on receptor populations in the Hudson River Valley in a weight-of-evidence approach. The discussion on Page 29 of the ERA argues that the major weakness of observational studies is that the a variable, and may not account for larger differences over time. Cause and effect relationships are important, and there are uncertainties associated with using those data. But those are equally (if not more) effective than using results from lab-gavaged chickens to assess risks to Belted Kingfishers.

Exposure Assessment

4) *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 question, as stated, requests that we focus principally on fish, avian, and mammalian species — and specifically the modeling parameters used to estimate current and future risks. In that regard I offer the following:

- *Avian and Mammalian Exposure Modeling Approach.* The oral dose models developed and applied within this ERA are consistent with current practice. Model parameterization — including the area use factors — are appropriate for the assessment of avian and mammalian risks along the Hudson River. Presentation of the oral dose models was well written and clear.

- *Projection of Future Risk Using HUDTOX/FISHRAND.* Fate and transport modeling is an important tool in evaluating the effects of remedial alternatives. While I not specifically reviewed the model documentation for HUDTOX, FISHRAND is based on the algorithms developed by Frank Gobas (1993), which have previously been applied to in the Great Lakes Water Quality Initiative, the Lower Fox River RI/FS, and for the Sheboygan River, WI Ecological Risk Assessment with good predictive success.

- *Appropriateness of Biomagnification Factors derived from the scientific literature.* In the absence of site specific information, using bioaccumulation or biomagnification factors derived from refereed scientific journals is appropriate, and consistent with current ERA practice.

Beyond these narrow questions, I offer the following observations and recommendations concerning the Section 3 — Exposure Assessment.

Page 40. Sect. 3.1.2 Estimating Future baseline Conditions

I understand the need for, and generally concur with the methodology presented in this section for estimating future TEQ risks from the FISHRAND output. What is not clear in this section was whether the mean, median, 90th percentile, or 95% UCLM was utilized for estimating the future TEQs. There is no discussion of whether there were sufficient data points to make this calculation sufficiently robust to be confident in the projections. Given that there are likely limited congener data, then I believe that the future risk analysis should be strengthened by estimating the probability distribution around the TEQ estimate, and calculating the future hazard quotients around that distribution.

Table 3.2, cited in this section, is difficult to understand. What is Value 1 fish vs. Value 2 fish, mammals, avians? Do these represent different trophic levels?

Page 40. Section 3.2 Observed Exposure Concentration

The ERA uses mean, median, 90th percentile, and 95% Upper Confidence Limit on the Mean for different endpoints. While this is clarified to some degree in the *Responsiveness Summary* (page 21, response to EF 1.9), there are still some outstanding questions in reviewing the exposure concentrations.

For example, were distributions for PCBs assumed to be lognormal, or were normality tests applied? The current ERA does discuss calculation of a 95% upper confidence limit on the mean (95% UCL), but omits a discussion of what happens when the 95% UCL exceeds the maximum concentration (see for example Table 3-7 where 95% UCLs for Brown Bullhead and Largemouth Bass exceed the maximum measured concentration). Was the maximum, or 95% UCL used for estimation of exposure in these situations? This section should also include rules for determining percentiles (which the current ERA omits). For example, what is the minimum number of samples needed to determine a percentile (n >10), and what value is used when "n" data are not available.

Pages 41 - 44. Sects. 3.2.1 - 3.2.6. Observed Concentrations and associated Tables.

Table summarizing exposure concentrations based on measured observations currently only present the mean and an associated percentile or UCL. It would be useful to include in the tabular presentation of the number of samples (N), the minimum, the maximum value, and whether risk characterization is based upon the 95% UCL or maximum value.

Table 3-7 provides an example of the confusion over which values are used for risk characterization. For example, for Brown Bullhead at River Mile 189 (Federal Dam), the 95% UCL for 1993 exceeds the maximum wet weight value. This is also true for the 1993 lipid-normalized concentration for Largemouth Bass at RM 113, the 1993 and 1994 wet weight concentrations for White Perch, and the 1996 lipid-normalized white perch and the 1993 lipid-normalized yellow perch concentrations. Furthermore, for the purpose of clarity, it would be useful to have the percent lipids used in Table 3-7. It is not clear if the average lipid is divided into the average wet-weight PCBs (which I assume must be the case).

Finally, for fish exposure the ERA uses fillet PCB concentrations for estimating whole body risks. First, clarification would be useful to know if this is skin-on, or skin-off filets. Secondly, use of fillets likely underestimates risks, as correctly pointed out in the ERA and the Uncertainty Section. Fillet-whole-body ratios for several fish species, including bluegill and largemouth bass, were used as part of the Clinch River Operable Unit Ecological Risk Assessment at Oak Ridge Tennessee, and were published in 1996. I would recommend that EPA consider looking at the values in the following reference for any future assessments at the Hudson:

> Bevelhimer, MS, BE Sample, GR Southworth, JJ Beauchamp, and MJ Peterson. 1996. Estimation of whole-fish contaminant concentrations from fish fillet data. EA/ER/TM202. Oka Ridge National Laboratory, Oak Ridge, TN.

Table 3-10 of the ERA, and Table 3-10 of the *Responsiveness Summary*, reflect the transparency issue I have discussed previously. In ERA Table 3-10, there are projected values for whole water average and 95% UCL concentrations for 1993 through 2018. The difference between the predicted average water and the 95% UCL is negligible, but not discussed in the ERA. For the Thompson Island Pool, the concentrations in 1993 are identical, and only differ by 2×10^{-7} in 2018. For the Stillwater Reach, there are no differences. The same is fairly well true in Table 3-11 for sediments.

In Table 3-10 of the *Responsiveness Summary*, the 95% UCL calculations are dropped. There is no reflection of this in the text.

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.

These were well written. I wish to commend the authors for Appendices C through G. I thought the life history sections were well researched and presented, and found myself enjoying reading those. I have no further comments here.

ThermoRetec

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.*

- *Field-based NOAELs.* In general I concur that for most studies and receptor species, developing field-based NOAELs is appropriate. There are some exceptions, however, worth noting. Giesy et al (1994), and Tillit et al (1992) developed effects-based regressions for piscivorus bird fecundity based upon field observations of TCDD-Eq and field effects using double crested cormorants and Caspian Terns from field data collected in the Great Lakes. These equations can be used to estimate a 20% or 30% field-based effect, as opposed to strictly a NOAEL.

  Giesy, J, J Ludwig, and D Tillitt. 1994. Deformities in birds of the Great Lakes Region: Assigning causality. *Environ Sci. Technol.* 28: 128 - 135.

  Tillit, D., *et al* 1992. Polychlorinated biphenyl residues and egg mortality in double-crested cormorants from the Great Lakes. *Environ. Toxicol. Chem.* 11: 1281 - 1288.

- *Application of Uncertainty Factors.* This is a hotly debated topic within the risk community, and one that cannot be borne up by science, *per se*, but only by the respective opinions of the policy makers and risk managers at a site. If the narrow question is asked, "Are UFs common practice in establishing TRVs for ecological risk assessments?", the answer is yes. This includes interspecies UFs (that may range from 10 to 1,000), LOELs to NOELs, and subchronic to chronic. Complete discussions of the history and application of uncertainty factors may be found in Calabrese and Baldwin (1993), and in Chapman et al (1998).

  I would caveat that, however, that in my own experience I have seen this done only for screening level ERAs, not baseline ERAs. My own opinion regarding the use of UFs for a baseline ERA is that they are not appropriate. I share the opinion expressed by Chapman *et al* that a UF applied to derive an NOAEL from an LOAEL is not appropriate for application to decisions that effect remedial alternative decisions. If the UFs are to be applied or TRVs for that matter), then they must be appropriately bracketed and placed in context.

For example, the ERA develops LOAEL and NOAEL TRVs for total PCBs in eggs of the Great Blue Heron by using the chicken fecundity value of Scott (1977). Those values are:

LOAEL	2.21 mg PCBs/kg egg
NOAEL	0.33 mg PCB/kg egg

In this case, interspecies UF or subchronic to chronic UFs were not applied, based on the known documentation of gallinaceous birds. The ERA states that their were no field studies that examined effects of PCBs to eggs of the great blue heron or birds of related taxonomy.. Thus, no context was provided in the ERA.

Custer et al (1997) examined the effects of organochlorines (including PCBs), mercury and selenium on pippin of great blue heron eggs collected from 10 colonies on the upper Mississippi. These eggs were field collected, incubated in the laboratory, and a comprehensive set of chemical, EROD, egg-shell thinning, and hatching data were collected. While having a geometric mean PCB concentration of 2.9 mg/kg egg, the PCB concentrations in the embryos were too low to induced EROD activity, and those authors concluded that PCBs (and the other studied COPCs) did not "seem to be a serious threat to nesting GBHs" on the upper Mississippi. While other contaminants are involved in this study, context is applied in the sense that a more appropriate NOAEL might be closer to 2 mg/kg egg — which is the LOAEL proposed for the Hudson ERA.

Likewise, Halbrook et al (1999) measured PCB concentrations in field collected Great Blue Heron eggs from four colonies as part of the Clinch River ERA at the Oak Ridge, TN. While concentrations of Arochlor 1260 were measured at a mean of 2 mg/kg ww, there were no statistical differences in the number of chicks fledged per next or in the mean weight of eggs of shell thickness between site, and reference site collections. Again, when placed in context with this study, the appropriate NOAEL for GBH along the Hudson River might be closer to 2 mg/kg ww.

I would point out that the Custer et al (1997) work supports the LOAEL/NOAEL for field-based TEQs in the GBH. The geometric mean TEQ for PCB congeners and PCDDs/PCDFs from the GBH eggs collected was 0.551 ug/kg TEQ (using the Kennedy et al chicken TEFs). This compares well with the values selected of 0.5 ug TEQ/kg egg, and 0.3 TEQ/kg egg, respectively.

Calabrese, E., and L. Baldwin. 1993. *Performing Ecological Risk Assessments.* Lewis Publishers. Chelsea, MI.

Chapman, P., A. Fairbrother, and D. Brown. 1998. A critical evaluation of safety (uncertainty) factors for ecological risk assessment. *Env. Toxicol. Chem* 17:99 - 108.

Custer, T.W., et al 1997. Contaminant concentrations and biomarker response in Great Blue Heron eggs from 10 colonies on the Upper Mississippi River, USA. *Env. Tox. Chem.* 16: 260 - 271.

Halbrook, R., L. Rober, and D. Buehler. 1999. Ecological risk assessment in a large river-reservoir: 7. Environmental contaminant accumulation and effects in great blue heron. *Env. Tox. Chem.* 18: 641 - 648.

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.*

The methodology of calculating toxicity quotients is consistent with current practice. There is a substantive body of evidence that support the used of the Toxicity Equivalent Quotient in evaluating risks to birds and mammals. As noted above, it is not the determination of the TEQ exposure concentration that effects the assessment of risk, it is the selection and defense of the appropriate Toxicity Reference Value that most greatly influences the process.

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.*

Benthic community structure

The assessment of baseline PCB risks as assessed in the ERA for benthic community structure are hampered by (1) the inconclusive results of infaunal community analysis, (2) ommission of a discussion of the other COPCs, and (3) the lack of a complete presentation of the spatial extent of PCB levels in the non-1993 sampled sections of the Hudson River. As noted previously, the levels of lead, chromium, and mercury at the infaunal stations sampled are at levels that exceed several different sediment benchmarks, including both the threshold effects, and the probable effects concentrations, of the consensus-based sediment quality guidelines for freshwater ecosystems (MacDonald et al, *in press*). While I concur that the HQs using the sediment quality thresholds for infauna do indeed suggest a level of risk for infauna, the conclusion of risk is hampered by the fact that those HQs are for 19 stations over 200 miles of river.

ThermoRetec

Health and maintenance of local fish populations

This is an excellent data set, and the conclusions of potential risk appear to be supported by the data. The relative magnitude of the calculated HQs for baseline, and future risks, for most species appears to fairly low (< HQ of 10 for most species by the year 2018) — given the conservative assumptions built into this ERA. I would interpret the results to be consistent with the conclusion that the current lines of evidence indicate that the current and future PCB exposures are not of sufficient magnitude to prevent reproduction or recruitment.

I would still recommend, however, that the ERA incorporate what existing fish population data is available. For example, striped bass measured HQs (Table 5-36 of the *Responsiveness Summary*) are relatively low (at or near 1). Data are apparently available on stripped bass populations; these should be used to examine the effects at least of these species.

Health and maintenance of insectivorous bird populations

Here to the data set is strong and supports the general conclusion that the lines of evidence indicate that current and future concentrations of PCBs are not of a sufficient magnitude to prevent reproduction of insectivorous bird species, especially as they are represented by tree swallows. While the debate may rage for years on just what does anomalous behavior in nesting birds mean from the standpoint of population effects, the conclusions of the ERA appear to be supported.

Health and maintenance of local waterfowl

These lines of evidence relies extensively on the use of modeled uptake, bioaccumulation factors derived from the scientific literature, conservative toxicity reference values, and predicts high TEQ-HQs for feeding female mallards and eggs throughout the modeling period. The use of any available field-population data would benefit the determination that mallards remain at risk currently, and throughout the modeling period.

Health and maintenance of local piscivorous bird populations

These lines of evidence relies extensively on the use of modeled uptake, bioaccumulation factors derived from the scientific literature, conservative toxicity reference values, and predicts high TEQ-HQs for both kingfishers and great blue herons throughout the modeling period. For GBH, the ERA should look again at the available scientific literature of toxicity reference values. Never-the-less, even using the NOAEL suggested in this review would still result in unacceptable risks (expressed as high HQs) currently, and throughout the modeling period.

ThermoRetec

Health and maintenance of endangered species

Like piscivorous birds, the lines of evidence for bald eagles relies extensively on the use of modeled uptake, bioaccumulation factors derived from the scientific literature, conservative toxicity reference values, and predicts high TEQ-HQs throughout the modeling period. The ERA should make better use of the excellent plasma data and population date provided in the *Responsiveness Summary*, pages 88 and 89. This is an excellent argument, with good field data, that should be placed directly into the risk assessment revision, or if the ERA is to be recompiled, directly into the exposure assessment.

Health and maintenance of local wildlife

The same arguments made previously could be applied here. Risks to mink and otter are probably supported by the existing data, but should be buttressed by any available habitat and population information.

Protection of Significant Habitats

This characterization is the hardest to define and defend. Significant habitats were never completely defined, and the use of sediment concentrations (from 19 stations over 200 miles of River) to suggest that these habitats are at risk is difficult to support. It is this reviewers recommendation that the significant habitats of the Hudson River be mapped, that a definition of what is significant habitat be developed, and a set of measurement and endpoints be developed beyond the current two to evaluate this.

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.*

In general, the uncertainties for the data and TRVs used in this ERA are characterized in Chapter 6. However, given that there is no clear view in the readers mind as to what the spatial extent of contamination is over 200 miles of river, there is considerable uncertainty unaccounted for in using sediment and benthic infaunal data from only 19 stations.

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?

Please see previous comments on clarity and transparency.

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

Please see previous comments on report organization.

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).

John Toll

Hudson River PCBs Site Reassessment RI/FS
Ecological Risk Assessment Peer Review

Written Comments
John Toll
May 5, 2000

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?*

   Response to Conceptual Model Question

   The conceptual model presented in Figure 2-4 of the Baseline Ecological Risk Assessment (BERA) adequately describes the different pathways by which ecological receptors could be exposed to PCBs in the Hudson River from the GE facilities, but it does not adequately describe the different pathways by which ecological receptors could be exposed to PCBs in the Hudson River from non-point sources. The conceptual model should include sources other than the GE facility, even if they are arguably insignificant. The model could be revised to show (qualitatively or quantitatively) the relative significance of different sources and exposure pathways, but should not exclude minor sources or pathways. This becomes an issue, for example, for the mink, because the BERA exposure assessment assumes the mink gets about half its food from non-river related sources.

   Consistent with this last point, the conceptual model could be improved by adding sediment, water column and lower trophic level compartments that are not connected to the GE Facilities PCB source. This would better represent the possibility of non-river related diet sources. Again, this seems appropriate because one receptor (mink) has a significant non-river related diet source (49.5%) in its nominal exposure assumptions (Table 3-24).

   Response to Receptor Species Question

   I found the information presented in Section 2.6 of the BERA report, and Appendices C – F sufficient to demonstrate that the receptor species selected are sensible representatives of their respective trophic levels in the Hudson River ecosystem. What was less clear to me was the process whereby the assessment endpoints were selected that led to these receptors.

The selection of receptor species is in part a value decision that should flow from the assessment endpoints. Assessment endpoints should represent the values to be protected using information from the risk assessment. The values to be protected should reflect the views of USEPA, technical team members and interested and affected organizations, groups and individuals. USEPA and the technical team prepared the BERA. Therefore, I focused my review as it pertained to this question on how the views of interested and affected organizations, groups and individuals were solicited and incorporated into the receptor species selected for exposure modeling.

The BERA does a good job of identifying the interested and affected organizations, groups and individuals, how their views were solicited and incorporated into the problem formulation. Chapter 1 identifies the interested and affected organizations that were consulted with regard to the problem formulation. The second paragraph of chapter 2 describes the process by which the problem formulation was completed. In particular I noted the statement that most of the issues considered in the problem formulation were discussed with the interested and affected organizations during a number of technical and public meetings. It was not clear to what extent other interested and affected groups and individuals had the opportunity to observe these discussions because there was no statement about the content of the discussions at technical versus public meetings. Therefore, I do not have sufficient information to evaluate whether information provided on the Hudson River ecosystems during the problem formulation was sufficient for selecting appropriate receptor species.

Next I turned my attention to the BERA report itself, and evaluated whether the information provided *a posteriori*, in the report, was sufficient for selecting appropriate receptor species. The pertinent data for evaluating this are the public comments on the BERA and responses to these comments. I found the BERA Responsiveness Summary to be well organized and helpful for this evaluation. I found no comments suggesting that appropriate receptor species were excluded from the risk assessment.

In light of all these factors, it's my conclusion that sufficient information has been 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?*

Please see my response to the receptor species portion of question #1.

3. *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.*

While the weight-of-evidence concept is described at the beginning of Section 2.5, I did not find a description of the approach. Clearly, one element of the weight-of-evidence approach is the use of multiple, independent measurement endpoints (multiple lines of evidence) to evaluate assessment endpoints. The multiple measurement endpoints described in Section 2.5 really fell into two, more or less independent groups. Group 1 involves measured or predicted exposures (doses or concentrations, measured in total PCB or TEQ-based units) that were compared to effect thresholds by a quotient approach. Group 2 is comprised of the field observations on presence and relative abundance of receptor populations. This second group was not well enough defined for me to evaluate their suitability for use in the risk assessment. For example, there was no discussion of observational interpretation methods, of conditioning variables or of methods for accounting for confounding factors (see comments in Table 1). In the absence of further information about the Group 2 measurement endpoints, I have reservations about the ability to use the combination of measurement endpoints in a weight-of-evidence approach.

General comment – the definitions of measurement endpoints (measures of exposure and measures of effect) should be sufficiently specific for a reviewer, when provided with the raw data used by the risk assessor, to reproduce the exposure estimates and effect thresholds. Some of the measurement endpoints defined in Section 2.5 did not.

Specific comments on the measurement endpoints are provided in Table 1 (attached).

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.*

<u>General Comments</u>

I frequently found myself wanting more detail about the exposure analysis. For example, as I write this I'm looking at the introduction to Section 3.2, where it would have been very helpful to see the normality test results for the various subsets of the PCB concentration data used in the exposure assessment. These results may be contained in the baseline modeling report. I was expecting to receive a copy of that report but haven't yet; I apologize for any

oversight on my part that may have occurred. I would still like to see the baseline modeling report before the ecological risk assessment peer review meetings. (Please see also Response to Modeling Question below.)

Response to Sampling Data Question

It always seems to be true that reviewers come up with many specific questions about ecological risk assessment databases, and this one is no exception. Of course hindsight is always 20/20. Having said that, for the most part I found the sampling data to be appropriate and sufficient.

A specific area where I do have questions about the sufficiency of the data is in the mallard exposure assessment. Specifically, site-specific mallard diet information, and measurements of PCB concentrations in vegetation types consumed by mallards on the Hudson River seemingly would have been appropriate. This is in light of the relatively high contribution of vegetation to the mallard ADD (as reflected in Tables 3-30 and 3-31).

Response to Modeling Question

Estimating the PCB concentrations that were used to compute average daily doses is a fundamental element of the exposure assessment that is not covered in baseline modeling report, rather than the BERA report. Reviewing these estimates takes on greater significance because the sensitivity analysis for risk models (Section 6.5.2) identifies uncertainties in the PCB concentrations used to compute average daily doses as the most sensitive inputs to the toxicity quotient equations, for all avian and mammalian receptors.

A discussion of the ADD estimation results would have been helpful. All I found were summary tables of numerical results. The discussion could be placed in Chapter 3 (Exposure Assessment), Chapter 6 (Uncertainty Analysis) or a new exposure assessment appendix. Chapter 6 might be the best place for the discussion. Currently, the sensitivity and uncertainty analyses do not address exposure modeling in sufficient detail. For example, the sensitivity analysis for exposure models is lumped into the brief (three-paragraph) section on sensitivity analysis for risk models (Section 6.5.2).

I found contradictory statements about the assumed dietary composition for mallards. On page 54, end of the first paragraph, the diet is described as 50% aquatic invertebrates and 50% vegetation. On page 162, in the last sentence of the second-to-last paragraph, the diet is described as 70% aquatic invertebrates.

Response to Biomagnification Factor Question

The decision to use the BMF published by Giesy *et al.* (1995) may be defensible, but it has not been defended in the BERA report. BMFs are empirical constants, so it is important that any time a non-site specific literature value is used, that use be defended. Issues that should be considered include:

- similarity of the PCB mixtures in the literature study and at the site,
- similarity of avian species (Giesy *et al.* is a bald eagle study),
- similarity of fish PCB body burdens in the literature study and at the site,
- similar quality of dietary exposure concentration estimates in the literature study and at the site,
- similarity of exposure levels from other significant exposure pathways,
- availability of other literature BMFs (subject to the same sort of evaluation).

Even limited corroborative evidence – in the form of paired site-specific dietary exposure and egg concentration data – would be very useful for evaluating the appropriateness and sufficiency of the biomagnification factors used in the BERA.

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.*

Modeled Water Concentrations

Specific HUDTOX modeling assumptions and parameters are not presented in the BERA report, so I cannot comment on whether they were appropriately selected. I hope to be able to review the baseline modeling report as it pertains to the BERA peer review questions before the peer review meetings.

Modeled Sediment Concentrations

Specific HUDTOX modeling assumptions and parameters are not presented in the BERA report, so I cannot comment on whether they were appropriately selected. I hope to be able to review the baseline modeling report as it pertains to the BERA peer review questions before the peer review meetings.

Modeled Benthic Invertebrate Concentrations

Sections 3.3.1.3 and 3.4.1indicate that invertebrate PCB concentrations were estimated by the product of sediment concentration and a biota-sediment accumulation factor (BSAF). This approach is adequate (i.e., it's a reasonable conceptual approach), but I cannot comment on whether the BSAF was selected appropriately because I did not find a description of the specific modeling assumptions in the BERA.

Detailed documentation should be added describing how BSAF was estimated from sediment and invertebrate PCB concentration data. Presumably BSAF was derived using co-located

data from the ecological sampling stations, and used to predict aquatic invertebrate concentrations in other locations. Plots of BSAF versus sediment concentration and versus sampling station location (river mile or segment) would be useful for evaluating the BSAF selected.

Modeled Fish Concentrations

Specific FISHRAND modeling assumptions and parameters are not presented in the BERA report, so I cannot comment on whether they were appropriately selected. I hope to be able to review the baseline modeling report as it pertains to the BERA peer review questions before the peer review meetings.

Benthic Exposure Pathways

See comments under the heading "Modeled Benthic Invertebrate Concentrations."

Sections 3.3.1.3 and 3.4.1 are redundant and I recommend they be merged.

Fish Exposure to Surface Water Sources of PCBs

See comments under the heading "Modeled Fish Concentrations."

I would merge Section 3.4.2 with Section 3.3.1.4.

The last sentence in the first paragraph of Section 3.4.2.1 seems tautological in that slower depuration that uptake is necessary for bioaccumulation to occur.

Fish Exposure to Sediment Sources of PCBs

See comments under the heading "Fish Exposure to Surface Water Sources of PCBs."

Avian Surface Water Ingestion

Three avian parameters are introduced in Section 3.4.3.1: normalized water ingestion rate (*NWI*), areal forage effort (*FE*) and body weight (*BW*):

- *NWI*, calculated using an equation from the USEPA *Wildlife Exposure Factors Handbook*, is adequately described and appropriately selected.

- *FE* is adequately described. Setting $FE = 1$ is arguably appropriate, although one could also argue that some portion of avian receptor populations' diets and ingested waters come from upstream of Hudson Falls or from surface waters off the main stem of the Hudson River. A discussion of this assumption ($FE = 1$) should be added to Chapter 6 (Uncertainty Analysis).

- *BW* is adequately described in Appendix E and appropriately selected.

The model for average daily dosage from surface water ingestion (equation 3-5) is adequately described and appropriately selected.

Avian Incidental Sediment Ingestion

Two avian parameters are introduced in Section 3.4.3.2: fraction of abiotic media in the diet (*FS*) and total food ingestion rate (*NIR*):

- *FS* is adequately described and appropriately selected.
- *NIR*, calculated using an equation from the USEPA *Wildlife Exposure Factors Handbook*, is adequately described and appropriately selected. The switch in nomenclature from *NIR* to *FI* (top of page 50) is a little bit confusing.

The model for average daily dosage from incidental sediment ingestion (equation 3-7) is adequately described and appropriately selected.

Avian Dietary Exposure

Several avian parameters are introduced in Section 3.4.3.3:

- The first three: normalized field metabolic rate (*NFMR*), metabolizable energy (ME) and gross energy content of dietary component (GE), all based on the USEPA *Wildlife Exposure Factors Handbook*, are adequately described and appropriately selected.
- Assimilation efficiency (*AE*) often is the most sensitive parameter in bioaccumulation models, so greater justification for the selected values is appropriate. A section on assimilation efficiency uncertainty should be added to Chapter 6 (Uncertainty Analysis).
- Dietary fractions (*PD*), derived from the scientific literature and from consultations with NYSDEC and USFWS staff, also are adequately described and appropriately selected.
- Dietary fractions for the tree swallow are based on the work of McCarty and Winkler (in press). Some version of that work should be made available for peer review, since it is the basis for exposure assumptions used in the BERA.

The models for average daily dosage from fish consumption (equation 3-11) and invertebrate consumption (equation 3-12) are adequately described and appropriately selected.

The use of the model for PCB concentration in macrophytes (equation 3-13) was the subject of comments on the exposure assessment, under the heading "Response to Sampling Data Question." At a minimum, it would be useful to obtain a small amount of coincident PCB concentration data in water (dissolved PCB concentration) and plants consumed by waterfowl on the Hudson River, to corroborate the predictions of equation 3-13. Better yet would be to obtain site-specific mallard diet information, and measurements of PCB

concentrations in vegetation types consumed by mallards on the Hudson River.

Avian Behavioral and Temporal Modifying Factors Relating to Exposure

See comments on areal forage effort (*FE*) under the heading "Avian Surface Water Ingestion."

Biomagnification Factors for Predicting Egg Concentrations

See comments on this topic under the heading "Response to Biomagnification Factor Question."

Mammalian Surface Water Ingestion

Same comments as for avian surface water ingestion.

Mammalian Incidental Sediment Ingestion

Same comments as for avian incidental sediment ingestion.

Mammalian Dietary Exposure

Several avian parameters are introduced in Section 3.4.4.3:

- The first three: normalized field metabolic rate (*NFMR*), metabolizable energy (ME) and gross energy content of dietary component (GE), all based on the USEPA *Wildlife Exposure Factors Handbook*, are adequately described and appropriately selected.

- Assimilation efficiency (*AE*) often is the most sensitive parameter in bioaccumulation models, so greater justification for the selected values is appropriate. A section on assimilation efficiency uncertainty should be added to Chapter 6 (Uncertainty Analysis).

- Dietary fractions (*PD*), derived from the scientific literature and from consultations with NYSDEC and USFWS staff, also are adequately described and appropriately selected.

The models for average daily dosage from fish consumption (equation 3-22) and invertebrate consumption (equation 3-23) are adequately described and appropriately selected.

Mammalian Behavioral and Temporal Modifying Factors Relating to Exposure

See comments on areal forage effort (*FE*) under the heading "Avian Surface Water Ingestion."

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.

Question on Use of Field-Based Toxicity Studies

In general, I would not use NOAELs generated from field-based toxicity studies to derive TRVs if factors that may be confounding the measurement of a PCB dose-response relationship cannot be controlled. A better choice is to use laboratory-based toxicity studies to derive TRVs, and use the field data (without censoring the observed effects portion of the database) in a weight-of-evidence approach.

Question on Use of Toxicological Uncertainty Factors

I will in defer to the peer review team's wildlife toxicologists on this question.

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.*

   The methodologies used in calculating the *TQ*s appear to have sufficient uncertainty factors built in (both for exposure and toxicity) to ensure that the probability of a false negative (*TQ* < 1 when risk from PCB exposures is present) is low.

   The BERA only looks at baseline risks, so the question of risks to ecological receptors from remedial actions driven by false positives (*TQ* > 1 when risk from PCB exposures is absent) does not apply in Phase 2, although it will apply in Phase 3, where, as stated in the charge to the risk assessment peer reviewers:

   > "*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.*"

   Therefore, when this risk assessment is used in Phase 3, it will be important to evaluate both false positive and false negative probabilities, as well as the potential consequences of false positive and false negative results on the remedial action decision.

8. *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.*

It is likely that the risk characterization adequately characterizes the relative risks to different trophic level receptors (e.g., piscivores, insectivores) because of the bioaccumulative nature of PCBs.

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.*

   I am not confident that the major uncertainties in the BERA have been identified. I would like to have seen much greater discussion of model error (Section 6.5.3). In particular, the statement at the top of page 165, "(i)n this assessment, model error is probably not a significant source of uncertainty" is a sweeping statement that needs to be substantiated. Also, Section 6.5.3.1 provides a very brief summary of the uncertainty analysis for FISHRAND model predictions. I was surprised not to find an equivalent section for the HUDTOX uncertainty analysis.

   I would have liked to have seen much more extensive sensitivity and uncertainty analyses, although it is really in Phase 3 of the Reassessment RI/FS that they will be needed. For Phase 2, the uncertainties and their effects on conclusions arguably are adequately described, though the uncertainty analysis is minimal. The sensitivity and uncertainty analyses I would like to have seen, and that I think will be needed in Phase 3, would systematically review each data set and model that feeds into the ecological risk estimates, including HUDTOX and FISHRAND. Each review would explicitly answer the following questions:

   How well do the estimators derived from the (data set or model) represent the intended parameter needed for the risk assessment?

   For those estimators with significant uncertainties, what is the cause of the uncertainty and how could it be reduced?

   The uncertainty analysis results then would be rolled up to produce probability distributions on levels of PCBs in fish (for baseline conditions in Phase 2, for each remedial alternative in Phase 3), from which the probability of exceeding appropriate levels of PCBs in fish could be calculated.

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?*

   The BERA is comparable on these criteria to other ecological risk assessments I have reviewed.

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

   No additional comments.

Recommendations

1. *Based on your review of the information provided, please select (from among the following) your overall recommendation for the ERA and explain why (this is your overall recommendation):*

   - *acceptable as is*
   - *acceptable with minor revision (as indicated)*
   - *acceptable with major revision (as outlined)*
   - *not acceptable (under any circumstance).*

   My overall recommendation for the Phase 2 Baseline Ecological Risk Assessment is that it is acceptable with minor revisions (as indicated in my comments), with the caveat that major revisions will likely be needed before the risk assessment can be used for the purposes of Phase 3, as it is explained in the third paragraph of the Charge for Peer Review 4.

Table 1

Assessment Endpoint		Measurement Endpoint	Comments
Benthic community structure as a food source for local fish and wildlife	1a	Field observations of benthic community abundance in relation to measured PCB concentrations and habitat characteristics	The measures of community abundance and habitat characteristics are undefined. **This is a general comment that applies to many of the measurement endpoints.** The measure of PCB concentrations isn't clearly stated in Section 2.5. My assumption is that it's tri+ congener concentration (unless the measurement endpoint specifically says TEQ-based concentration), but I don't think these concepts are introduced until Chapter 3.
	1b	Field observations of benthic community composition in relation to measured PCB concentrations and habitat characteristics	The measures of community composition and habitat characteristics are undefined.
	2	Measured and modeled average and 95% UCL PCB concentrations in water (fresh and saline) compared to NYSAWQC for the protection of benthic aquatic life or wildlife	**This is a general comment that applies to many of the measurement endpoints.** Is this the 95% UCL on the mean or on some other population statistic? Is this by river segment by year? What level of spatial and temporal averaging of the water concentration data? Are the AWQCs both acute and chronic? Are the water concentration averaging periods different for comparing to acute and chronic AWQC? Are the PCB water concentrations water column or pore water? Why is comparison of water concentrations to wildlife AWQC included under this assessment endpoint?
	3	Measured and modeled average and 95th percentile UCL PCB concentrations in sediment compared to sediment benchmarks such as NOAA sediment effect concentrations for PCBs in the Hudson River, NYSDEC Technical Guidance for Screening Contaminated Sediments, Persaud *et al.* (1993), Ingersoll *et al.* (1996), Washington Department of Ecology (1997), and Jones *et al.* (1997) for protection of aquatic life	Should be specific about the sediment benchmarks to which concentrations are compared. Is this the list or are these just possible examples. Also, do you compare to all the benchmarks, or are they ranked in terms of applicability and the most applicable benchmark used? Washington State sediment management standards are for Puget Sound sediments and wouldn't be applicable to the Hudson River.

Table 1

Assessment Endpoint		Measurement Endpoint	Comments
Protection and maintenance (i.e., survival, growth and reproduction) of local fish populations (forage, omnivorous, piscivorous)	1	Measured and modeled median and 95th percentile PCB body burdens in fish for each river segment over 25 years to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	Are the data stratified by age or size class? Whole body or fillet body burdens? Wet weight or dry weight?
	2	Measured and modeled TEQ-based median and 95th percentile PCB body burdens in fish for each river segment over 25 years to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	same as above
	3	Measured and modeled TEQ-based median and 95th percentile PCB concentrations in water (fresh and saline) compared to NYSAWQC for the protection of benthic aquatic life	Why compared to criteria for protection of benthos? Is this by river segment by year? What level of spatial and temporal averaging of the water concentration data? Are the AWQCs both acute and chronic? Are the water concentration averaging periods different for comparing to acute and chronic AWQC? Which river segments are treated as saline? Filtered or unfiltered water?
	4	Measured and modeled average and 95th percentile UCL PCB concentrations in sediment compared to sediment benchmarks such as NOAA sediment effect concentrations for PCBs in the Hudson River, NYSDEC Technical Guidance for Screening Contaminated Sediments, Persaud *et al.* (1993), Ingersoft *et al.* (1996), Washington Department of Ecology (1997), and Jones *et al.* (1997) for protection of aquatic life	repeat, see above
	5	Available field observations on the presence and relative abundance of fish species within the Hudson River for each river segment as an indication of the ability of the species to maintain populations	For each species, what's the threshold for ability or inability to maintain a population? Are there any conditioning variables on the threshold for ability or inability to maintain a population (e.g., time of year, carrying capacity)? Any confounding factors (e.g., stocking, habitat quality, habitat abundance, presence/absence of predators or competing species, etc.)?

Table 1

Assessment Endpoint		Measurement Endpoint	Comments
Protection and maintenance (i.e., survival, growth and reproduction) of local insectivorous birds	1	Modeled total average and 95% UCL PCB dietary doses to the tree swallow to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	The measure of exposure is expressed as a dose. Presumably the TRV is expressed as an egg concentration. Both should be in the same units (i.e., both concentrations or both doses, both wet weight or both dry weight etc.). Where can the reader find the model for predicting egg concentration from dose? Is exposure during the nesting season by year for 25 years, by river segment? Doe total PCB mean tri+? 95% UCL on what (e.g., mean, median, 95th %ile, etc.)? What's the benchmark for adverse affects (e.g., EC10, EC50, LOEC, NOEC)?
	2	Modeled TEQ-based average and 95% UCL PCB dietary doses to the tree swallow for each river segment over 25 years to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	The measure of exposure is expressed as a dose. Presumably the TRV is expressed as an egg concentration. Both should be in the same units (i.e., both concentrations or both doses, both wet weight or both dry weight etc.). Where can the reader find the model for predicting egg concentration from dose? 95% UCL on what (e.g., mean, median, 95th %ile, etc.)? What's the benchmark for adverse effects (e.g., EC10, EC50, LOEC, NOEC)?
	3	Modeled total average and 95% UCL PCB concentrations in tree swallow eggs to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	How does this differ from the first measurement endpoint for protection and maintenance of local insectivorous birds? The numerator (measure of exposure) and denominator (effect-level threshold) must be in the same units (dose or concentration); and converting between dose and concentration won't change the ratio.
	4	Modeled TEQ-based average and 95% UCL PCB dietary doses concentrations in tree swallow eggs for each river segment over 25 years to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	How does this differ from the second measurement endpoint for protection and maintenance of local insectivorous birds?
	5	Modeled and measured average and 95% UCL PCB concentrations in water (freshwater and saline) compared to NYSAWQC for the protection of wildlife	Which river segments are treated as saline? +D24
	6	Available field observations on the presence and relative abundance of insectivorous bird species within the Hudson River for each river segment as an indication of the ability of the species to maintain populations	Just the receptor (tree swallow) or other species as well? For each species, what's the threshold for ability or inability to maintain a population? Are there any conditioning variables on the threshold for ability or inability to maintain a population (e.g., time of year, carrying capacity)? Any confounding factors (e.g., quality or abundance of habitat, presence/absence of predators or competing species, etc.)?

Table I

Assessment Endpoint	Measurement Endpoint	Comments
Protection and maintenance (i.e., survival, growth and reproduction) of local waterfowl	1 Modeled total average and 95% UCL PCB dietary doses to the mallard duck to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	The measure of exposure is expressed as a dose. Presumably the TRV is expressed as an egg concentration. Both should be in the same units (i.e., both concentrations or both doses, both wet weight or both dry weight etc.). Where can the reader find the model for predicting egg concentration from dose? Is exposure by year for 25 years, by river segment? Is it cumulative or nesting season? Does total PCB mean Inf+? 95% UCL on what (e.g., mean, median, 95th %ile, etc.)? What's the benchmark for adverse effects (e.g., EC10, EC50, LOEC, NOEC)?
	2 Modeled TEQ-based average and 95% UCL PCB dietary doses to the mallard duck for each river segment over 25 years to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	The measure of exposure is expressed as a dose. Presumably the TRV is expressed as an egg concentration. Both should be in the same units (i.e., both concentrations or both doses, both wet weight or both dry weight etc.). Where can the reader find the model for predicting egg concentration from dose? 95% UCL on what (e.g., mean, median, 95th %ile, etc.)? What's the benchmark for adverse effects (e.g., EC10, EC50, LOEC, NOEC)?
	3 Modeled total average and 95% UCL PCB concentrations in mallard duck eggs to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	How does this differ from the first measurement endpoint for protection and maintenance of local waterfowl? The numerator (measure of exposure) and denominator (effect-level threshold) must be in the same units (dose or concentration); and converting between dose and concentration won't change the ratio.
	4 Modeled TEQ-based average and 95% UCL PCB dietary doses concentrations in mallard duck eggs for each river segment over 25 years to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	How does this differ from the second measurement endpoint for protection and maintenance of local waterfowl?
	5 Modeled and measured average and 95% UCL PCB concentrations in whole water (freshwater and saline) compared to NYSAWQC for the protection of wildlife	Which river segments are treated as saline? Does whole water mean unfiltered?
	6 Available field observations on the presence and relative abundance of duck species within the Hudson River for each river segment as an indication of the ability of the species to maintain populations	Just the receptor (mallard) or other species as well? For each species, what's the threshold for ability or inability to maintain a population? Does presence indicate the ability to maintain a population? How are non-resident waterfowl accounted for? Are there any conditioning variables on the threshold for ability or inability to maintain a population (e.g., time of year, carrying capacity)? Any confounding factors (e.g., quality or abundance of habitat, presence/absence of predators or competing species, etc.)?

Table 1

Assessment Endpoint	Measurement Endpoint	Comments
Protection and maintenance (i.e., survival, growth and reproduction) of local piscivorous birds	1 Modeled total average and 95% UCL PCB dietary doses to the belted kingfisher, great blue heron and bald eagle to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	The measure of exposure is expressed as a dose. Presumably the TRV is expressed as an egg concentration. Both should be in the same units (i.e., both concentrations or both doses, both wet weight or both dry weight etc.). Where can the reader find the model for predicting egg concentration from dose? Is exposure by year for 25 years, by river segment? Is it cumulative or nesting season? Does total PCB mean tri+? 95% UCL on what (e.g., mean, median, 95th %ile, etc.)? What's the benchmark for adverse effects (e.g., EC10, EC50, LOEC, NOEC)?
	2 Modeled TEQ-based average and 95% UCL PCB dietary doses to the belted kingfisher, great blue heron and bald eagle for each river segment over 25 years to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	The measure of exposure is expressed as a dose. Presumably the TRV is expressed as an egg concentration. Both should be in the same units (i.e., both concentrations or both doses, both wet weight or both dry weight etc.). Where can the reader find the model for predicting egg concentration from dose? 95% UCL on what (e.g., mean, median, 95th %ile, etc.)? What's the benchmark for adverse effects (e.g., EC10, EC50, LOEC, NOEC)?
	3 Modeled total average and 95% UCL PCB concentrations in belted kingfisher, great blue heron and bald eagle eggs to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	How does this differ from the first measurement endpoint for protection and maintenance of local insectivorous birds? The numerator (measure of exposure) and denominator (effect-level threshold) must be in the same units (dose or concentration); and converting between dose and concentration won't change the ratio.
	4 Modeled TEQ-based average and 95% UCL PCB dietary doses concentrations in belted kingfisher, great blue heron and bald eagle eggs for each river segment over 25 years to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	How does this differ from the second measurement endpoint for protection and maintenance of local piscivorous birds?
	5 Modeled and measured average and 95% UCL PCB concentrations in water (freshwater and saline) compared to NYSAWQC for the protection of wildlife	Which river segments are treated as saline? +D24
	6 Available field observations on the presence and relative abundance of piscivorous bird species within the Hudson River for each river segment as an indication of the ability of the species to maintain populations	Just the receptors (belted kingfisher, great blue heron and bald eagle) or other species as well? For each species, what's the threshold for ability or inability to maintain a population? For example, does absence of a bald eagle (or nesting pair) in a river segment indicate an inability to maintain a population? Are there any conditioning variables on the threshold for ability or inability to maintain a population (e.g., time of year, carrying capacity)? Any confounding factors (e.g., quality or abundance of habitat, presence/absence of predators or competing species, etc.)?

Table 1

Assessment Endpoint	Measurement Endpoint	Comments
Protection and maintenance (i.e., survival, growth and reproduction) of local wildlife	1 Modeled total average and 95% UCL PCB dietary doses to the little brown bat, racoon, mink and otter to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	The measure of exposure is expressed as a dose. Presumably the TRV is expressed as an body burden. Both should be in the same units (i.e., both concentrations or both doses, both wet weight or both dry weight etc.). Should indicate where can the reader find the model for predicting body burden from dose. Is exposure by year for 25 years, by river segment? For reproductive endpoints, is exposure cumulative or during the breeding season? Does total PCB mean tri+? 95% UCL on what (e.g., mean, median, 95th %ile, etc.)? What's the benchmark for adverse effects (e.g., EC10, EC50, LOEC, NOEC)?
	2 Modeled TEQ-based average and 95% UCL PCB dietary doses to the little brown bat, racoon, mink and otter for each river segment over 25 years to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	The measure of exposure is expressed as a dose. Presumably the TRV is expressed as an body burden. Both should be in the same units (i.e., both concentrations or both doses, both wet weight or both dry weight etc.). Should indicate where can the reader find the model for predicting body burden from dose. 95% UCL on what (e.g., mean, median, 95th %ile, etc.)? What's the benchmark for adverse effects (e.g., EC10, EC50, LOEC, NOEC)?
	3 Measured total PCB concentrations in the liver of mink and otter	Why no effect-level threshold? Wet or dry weight?
	4 Modeled and measured average and 95% UCL PCB concentrations in water (freshwater and saline) compared to NYSAWQC for the protection of wildlife	Which river segments are treated as saline? Filtered or unfiltered water?
	5 Available field observations on the presence and relative abundance of wildlife species within the Hudson River for each river segment as an indication of the ability of the species to maintain populations	Just the receptors (little brown bat, racoon, mink and otter) or other species as well? For each species, what's the threshold for ability or inability to maintain a population? Does absence from a river segment indicate inability to maintain a population? Are there any conditioning variables on the threshold for ability or inability to maintain a population (e.g., time of year, carrying capacity)? Any confounding factors (e.g., quality or abundance of habitat, presence/absence of predators or competing species, etc.)?

Table 1

Assessment Endpoint		Measurement Endpoint	Comments
Protection of threatened and endangered species	1	Modeled total median and 95th %ile PCB body burdens in shortnose sturgeon using surrogate upper trophic level fish species to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	Is exposure by year for 25 years, by river segment? Does total PCB mean tri+? 95% UCL on what (e.g., mean, median, 95th %ile, etc.)? What's the benchmark for adverse effects (e.g., EC10, EC50, LOEC, NOEC)?
	2	Modeled TEQ-based median and 95th %ile PCB body burdens in shortnose sturgeon using surrogate upper trophic level fish species to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	Is exposure by year for 25 years, by river segment? 95% UCL on what (e.g., mean, median, 95th %ile, etc.)? What's the benchmark for adverse effects (e.g., EC10, EC50, LOEC, NOEC)?
	3	Modeled total PCB dietary doses to the bald eagle to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	Subset of the first measurement endpoint for piscivorous birds; see comments above
	4	Modeled TEQ-based PCB dietary doses to the bald eagle to determine exceedance of effect-level thresholds based on TRVs derived in Chapter 4	Subset of the second measurement endpoint for piscivorous birds; see comments above
	5	Modeled and measured average and 95% UCL PCB concentrations in water (freshwater and saline) compared to NYSAWQC for the protection of wildlife	Same as fourth measurement endpoint for piscivorous birds; see comments above
	6	Measured and modeled average and 95th percentile UCL PCB concentrations in sediment compared to sediment benchmarks such as NOAA sediment effect concentrations for PCBs in the Hudson River, NYSDEC Technical Guidance for Screening Contaminated Sediments, Persaud *et al.* (1993), Ingersoll *et al.* (1996), Washington Department of Ecology (1997), and Jones *et al.* (1997) for protection of aquatic life	repeat; see above

Table 1

Assessment Endpoint		Measurement Endpoint	Comments
Protection of significant habitats	1	Measured and modeled PCB concentrations in water (freshwater and saline) compared to NYSAWQC for the protection of benthic aquatic life or wildlife	What statistics on water concentrations? Which river segments are treated as saline? Filtered or unfiltered water?
	2	Measured and modeled PCB concentrations in sediment compared to applicable sediment benchmarks such as NOAA sediment effect concentrations for PCBs in the Hudson River, NYSDEC Technical Guidance for Screening Contaminated Sediments, Persaud *et al.* (1993), Ingersoll *et al.* (1996), Washington Department of Ecology (1997), and Jones *et al.* (1997) for protection of aquatic life	What statistics on sediment concentrations? Should be specific about the sediment benchmarks to which concentrations are compared. Is this the list or are these just possible examples. Also, do you compare to all the benchmarks, or are they ranked in terms of applicability and the most applicable benchmark used? Washington State sediment management standards are for Puget Sound sediments and wouldn't be applicable to the Hudson River.

APPENDIX D

LIST OF REGISTERED OBSERVERS OF THE PEER REVIEW MEETING

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 E

AGENDA FOR THE PEER REVIEW MEETING

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

Agenda

Meeting Facilitator: Jan Connery, Eastern Research Group, Inc.
Meeting Chair: Peter deFur, Environmental Stewardship Concepts

T H U R S D A Y , J U N E 1 , 2 0 0 0

8:00AM	**Registration/Check-in**
8:30AM	**Welcome Remarks and Panel Introduction** *Jan Connery, Eastern Research Group, Inc.*
8:45AM	**EPA Overview and Background Remarks** *Alison Hess, U.S. Environmental Protection Agency*
9:30AM	**Observer Comments**
10:15AM	B R E A K
10:30AM	**Charge to the Panel/Summary of Premeeting Comments** *Peter deFur, Environmental Stewardship Concepts*
11:00AM	**Discussion on Ecological Risk Assessment (ERA) Questions 1 and 2**
12:30PM	L U N C H (on own)
1:45PM	**Discussion of ERA Question 3**
2:30PM	**Discussion of ERA Question 4**
3:15PM	B R E A K
3:30PM	**Discussion of ERA Question 5**

THURSDAY, JUNE 1, 2000 (Continued)

4:15PM **Discussion of ERA Question 6**

5:00PM BREAK

5:15PM **Discussion of ERA Questions 7 and 8**

6:45PM ADJOURN

FRIDAY, JUNE 2, 2000

8:00AM **Discussion of ERA Question 9**

8:45AM **Discussion of General Question 1**

9:30AM BREAK

9:15AM **Discussion of General Question 2**

10:00AM **Observer Comments**

10:45AM BREAK

11:00AM **Recommendations and Chair's Summary**

12:30PM **Closing Remarks**

1:00PM ADJOURN

APPENDIX F

SUMMARIES OF OBSERVERS' COMMENTS

List of Observers Who Made Comments

Day 1 (June 1, 2000):

David Glaser, Quantitative Environmental Analysis
Mike Moore, Exponent
Larry Barnthouse, LWB Environmental Services, Inc.
Tom Ginn, Exponent
George Hodgson, Saratoga County Environmental Management Council

Day 2 (June 2, 2000):

Joe Gardner, Appalachian Mountain Club
George Hodgson, Saratoga County Environmental Management Council
Ron Sloan, New York State Department of Environmental Conservation

The remainder of this appendix summarizes the comments made by the observers listed above. Comments are summarized in the order in which they were presented. As the meeting agenda in Appendix E shows, observer comments were scheduled on both days of the peer review meeting.

Appendix F—Summaries of Observers' Comments

Day #1, Comments from David Glaser, Quantitative Environmental Analysis

Mr. Glaser's comments addressed the risk posed by PCBs to bald eagles in the Lower Hudson River and a discrepancy between findings of bald eagle population field studies and the hazard quotients documented in EPA's ecological risk assessment. To explain where this discrepancy lies, he first summarized data collected by Peter Nye of the New York State Department of Environmental Conservation (NYSDEC) on bald eagle productivity in three bald eagle nests located in counties along the Lower Hudson River. Mr. Glaser explained that the bald eagle population in the Lower Hudson River resulted from a NYSDEC reintroduction program during the 1980s and that productivity data are available for three nests for the years 1992 to 1999.

Reviewing the NYSDEC data set, Mr. Glaser indicated the number of fledglings produced by bald eagle pairs in the three nests, one each in Columbia County, Green County, and Duchess County. Summarizing the data, he reported the average "number of young fledged per occupied nest" for the three nests observed. Mr. Glaser noted that this average number was 0 from 1992 to 1996, but then increased in three successive years, from 0.5 in 1997 to 1.7 in 1999. He stressed that, as of 1999, the eagles in all three nests were producing young, with an average productivity rate of 1.7 fledglings per nest per year. To interpret the data, Mr. Glaser compared the average productivity rate among Lower Hudson River nests for the years 1997 to 1999 (i.e., 1.25 young produced per occupied nest per year) to the goals for productivity recommended by the U.S. Fish and Wildlife Service for bald eagle recovery plans (i.e., 0.9 to 1.1 young per occupied nest) and to the minimum productivity rate reported in the scientific literature as being sufficient to maintain an eagle population (i.e., 0.7 young per occupied nest). Mr. Glaser stressed that the productivity rate observed clearly exceeded these two distinct productivity goals.

To contrast the results observed in the field, Mr. Glaser then presented the findings reported in EPA's ecological risk assessment. Specifically, he showed four hazard quotients for bald eagles for 1999 exposure levels; the different hazard quotients were based on various combinations of exposed individuals (i.e., egg and adult) and dose metric (i.e., Tri+ PCBs and TEQ). These hazard quotients, which Mr. Glaser acknowledged are estimates based on information presented in EPA's Responsiveness Summary, ranged from 6 to 117. Mr. Glaser explained that the hazard indexes for adults are based on NOAELs for other species (chicken and pheasant), with associated uncertainty factors, and that the hazard indexes for eggs are based on field studies that either could not attribute effects exclusively to PCBs or did not observe effects on productivity. For these reasons, Mr. Glaser stressed that the NOAELs used in EPA's analyses to calculate hazard quotients are excessively conservative.

Summarizing his comments, Mr. Glaser reiterated that the site-specific field studies indicate that the nesting bald eagle population is "increasing and reproducing," with "no evidence of current impact." Conversely, he said EPA's hazard quotients, which he thought were based on

conservative and uncertain assumptions, "suggest important ongoing impacts." Mr. Glaser concluded, therefore, that the site-specific bald eagle population data and EPA's hazard quotients are contradictory. Given that the population "appears healthy," even with the elevated hazard quotients, Mr. Glaser interpreted that EPA's analyses are "overly conservative," which limits the utility of the ecological risk assessment for making sediment remediation decisions.

Day #1, Comments from Mike Moore, Exponent

Mr. Moore commented on the reproductive success of tree swallows along the Hudson River by reviewing results of a study conducted by the U.S. Fish and Wildlife Service (USFWS) and critiquing EPA's interpretation of this study. He stressed the importance of fully considering the implications of the USFWS study, because it reportedly presents "the only empirical data on reproductive success of birds along the Hudson River."

Mr. Moore opened his comments by describing the scope of the USFWS study, which examined various reproductive effects (e.g., clutch size, hatch rate, fledgling rate), plumage formation, and nest quality. He focused the remainder of his comments on the implications of the reproductive endpoint, noting that reproductive effects likely have greater implications at the population level than do either of the other endpoints studied. To illustrate the main findings of the USFWS study, Mr. Moore displayed graphs showing how hatch rate (percent) among tree swallows varied with PCB concentration in chicks for various areas along the Hudson River. He explained that one would expect to see hatch rates decreasing with increasing PCB concentrations if PCBs truly were having a negative impact on reproductive success. However, Mr. Moore indicated, no such trend was observed. To the contrary, he noted that the nesting areas with some of the lowest hatch rates actually had some of the lowest PCB concentrations in chicks.

When interpreting the USFWS data, Mr. Moore explained that researchers often evaluate the significance of their observations using comparisons to observations made in a "reference" study area. He acknowledged that USFWS attempted to make such comparisons, but the designated "reference area" was also found to have elevated PCB levels and thus could not serve this purpose. To put the Hudson River data into perspective, Mr. Moore compared the USFWS observations to those documented in the scientific literature. Specifically, he showed a plot comparing a distribution of average clutch sizes from published studies to clutch sizes observed in 1994, 1995, and 1998 at selected Hudson River locations. Mr. Moore noted that the observed clutch sizes in the Hudson River clearly "fit within the distribution" of clutch sizes derived from studies in the literature. Further, Mr. Moore added that the other "reproductive parameters for Hudson River tree swallows are comparable with" mean values in reference areas.

Summarizing his interpretation of the USFWS study, Mr. Moore indicated that the study found no dose-response relationship between PCB exposure in tree swallows and "any measure of

reproductive performance," and he concluded that the variability in measures of reproductive performance among Hudson River tree swallows is comparable to those reported for tree swallows elsewhere in North America. Further, Mr. Moore acknowledged that USFWS reported differences in plumage development and nesting quality among Hudson River locations, but he suspected that the variability in these observations is comparable to that which would be observed in comparison populations. He added that even if effects on plumage development and nesting quality among Hudson River tree swallows are significant, these outcomes do not have any impact on reproductive success, which he considered to be "the ultimate endpoint of concern."

Finally, Mr. Moore commented on how EPA interpreted the USFWS study, noting that the ecological risk assessment concludes that "hidden effects" occur among Hudson River tree swallows and that these effects might "be reflected at the population level." Mr. Moore thought that the USFWS data do not support this conclusion, and he recommended that EPA reevaluate the USFWS data and revise the conclusion accordingly.

Day #1, Comments from Larry Barnthouse, LWB Environmental Services, Inc.

Mr. Barnthouse's comments stressed the importance of considering field data on the Hudson River fish population as part of the site's ecological risk assessment. He opened his comments by noting that EPA's *Guidelines for Ecological Risk Assessment* indicates that "field data on the condition of populations and communities" are a relevant component of ecological risk assessments. The remainder of his comments addressed a large volume of data characterizing fish populations in the Lower Hudson River and those data's relevance to the Hudson River PCBs ecological risk assessment.

Describing the types of data available, Mr. Barnthouse indicated that Hudson River utility companies, NYSDEC, and the National Marine Fisheries Service have compiled various types of data relevant to fish populations over the last 25 years to support the licensing of power plants along the Lower Hudson River. He noted that the available data are extensive, assessing conditions throughout the Lower Hudson River (i.e., from New York City to Troy) and characterizing all life stages of striped bass and many other species, thus "providing abundance trends for all major estuarine fish species." Mr. Barnthouse added that the data on Lower Hudson River fish populations is "the most complete fish community data set that has ever been made available for a Superfund ecological risk assessment."

Mr. Barnthouse then identified three general trends apparent from the field data for selected receptors of concern in EPA's ecological risk assessment. First, the field data indicate that the abundance of striped bass and shortnose sturgeon has greatly increased over the last 25 years. Second, the abundance of yellow perch has fluctuated over this period, for various reasons

(e.g., the changing habitat quality and the variable striped bass predation). Third, the data suggest "few changes in the fish community as a whole" in the Lower Hudson River since 1974.

For a more detailed account of the field data, Mr. Barnthouse interpreted trends among the striped bass population—a species he intentionally selected for summary for three reasons: (1) because striped bass are predators, they most likely received higher PCB exposures than other fish species for which data are available; (2) fish tissue sampling studies have measured PCB concentrations in adult striped bass over the past 20+ years; and (3) data characterizing the abundance of all life stages of striped bass (i.e., egg, larva, juvenile, and adult) are available for the same time frame. Mr. Barnthouse noted that the available data are useful for testing various hypotheses on how PCB exposures might affect striped bass at the population level.

As a specific example of interpreting the field data, Mr. Barnthouse explained that one would expect to see reproductive success among striped bass increase (e.g., more surviving larvae produced per spawner, higher abundance of juveniles produced) as PCB exposures decrease if PCBs truly have an impact at the population level. To test this hypothesis, he presented plots showing how "post yolk-sac larval index" and the "NYSDEC index of juvenile abundance" varied with levels of PCBs measured in adult female fish during the spawning season over the last 20–25 years. Mr. Barnthouse explained how the trends in these plots contradict the hypothesis that PCB exposure causes decreased reproductive success among striped bass. Specifically, he noted that the post yolk-sac larval index among striped bass peaked in the early 1980s, when PCB exposures were considerably higher than they have been since, and that the index of juvenile abundance was essentially uncorrelated with PCB levels among adult female fish over the years of record.

Based on this evaluation and other evaluations he did not have time to summarize, Mr. Barnthouse indicated that the available field data present "a very strong line of evidence that fish populations of the Lower [Hudson] River are not at risk due to PCB exposure, either past or present." Mr. Barnthouse then concluded his comments by presenting three summary statements on the status of fish populations in the Lower Hudson River: (1) he noted that the abundance of the "major" fish species have either increased or remained stable over the last 25 years; (2) he indicated that "there have been few changes in the fish community as a whole"; and (3) he noted that the reproductive success of striped bass—the species for which field data are most voluminous—appear to be uncorrelated with trends in PCB body burdens.

Day #1, Comments from Tom Ginn, Exponent

During his comments, Mr. Ginn answered two "big picture" issues raised in charge questions 3 and 8. Specifically, he addressed the charges to "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" (question 3)

and "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" (question 8). Mr. Ginn's insights on these questions follow.

Addressing charge question 3, Mr. Ginn first stressed that a weight of evidence approach should draw from "multiple, independent lines of evidence" that are evaluated and weighted into an integrated ecological risk assessment. Mr. Ginn explained that individual lines of evidence might include population studies, comparisons with toxicity reference values (TRVs) documented in the scientific literature, or toxicity studies; he further explained that a weight of evidence analysis brings together these independent results, evaluating them in terms of their quality, uncertainty, and ecological relevance. Characterizing EPA's approach, Mr. Ginn noted that the ecological risk assessment draws almost exclusively on a single line of evidence (comparisons with toxicity quotients [TQs]), thus not relying on a true weight of evidence approach. He concluded that EPA's analyses do not provide a weight of evidence approach, but rather rely on "a single, highly uncertain, overly conservative line of evidence." He added that, in some instances, the ecological risk assessment presents results of multiple lines of evidence, but does not weigh the different results. Mr. Ginn stressed that EPA's conclusions "are based entirely on the TQ approach."

Addressing charge question 8, Mr. Ginn first provided examples of how risks to ecological receptors have been adequately characterized at sites other than the Hudson River. For instance, he noted that many different methods have been used at numerous sites since the 1980s and earlier; he added that "site-specific, empirical assessments of exposed populations provide much more reliable assessments" than the theoretical TRV approach used by EPA; and he stressed that a variety of PCB-related adverse effects on individuals can be measured, as supported by numerous studies published in the scientific literature. Using the example of assessing risks to piscivorous wading birds, Mr. Ginn then critiqued EPA's methods of characterizing ecological risks. Specifically, he listed several different methods that EPA could have used to characterize risks (e.g., measuring population abundance, PCB levels in eggs, reproductive performance), saying EPA chose instead to assess PCB levels in the birds' diets. Mr. Ginn criticized this approach as being too theoretical and relying on "the one line of evidence where you do not measure the birds themselves."

Overall, Mr. Ginn found EPA's approach to be appropriate as a "screening-level assessment" or an initial assessment, but he did think the approach was appropriate for capturing the complex conditions in the Hudson River or for justifying the magnitude of remedial options EPA is considering. He added that the available field data (as summarized in the preceding observer comments) "do not indicate that adverse effects are occurring" among tree swallows, benthic macroinvertebrates, fish, and bald eagles. Reviewing his criticisms, Mr. Ginn stressed that EPA's risk assessment does not adequately characterize risks to ecological receptors because it ignores the available empirical data suggesting that PCB-related effects are not occurring and

relies too heavily on an "overly conservative" TQ approach. Mr. Ginn closed his comments by again characterizing EPA's work as a screening-level ecological risk assessment that is not appropriate in the Superfund decision making process. He recommended that EPA consider the types of information presented in the observer comments to develop a "truly definitive risk assessment."

Day #1, Comments from George Hodgson, Saratoga County Environmental Management Council

Mr. Hodgson opened his comments by explaining his role on the Saratoga County Environmental Management Council and noting that he has been following, and commenting on, EPA's Hudson River PCBs Site Reassessment since 1991. Citing comments the Environmental Management Council submitted to EPA, Mr. Hodgson indicated that the findings of the ecological risk assessment are very conservative, with the combined effect of many individual conservative assumptions leading to "a great degree of over-conservatism" in the overall study.

Reviewing specific comments he submitted on EPA's report, Mr. Hodgson noted that the risk assessment lacks meaningful analyses of what high TQs truly mean to species of concern in the Upper Hudson River. He argued that evaluations at the population level, both prior to and after the presence of PCB contamination, would provide better insight into actual ecological risks. Citing a quote on page 29 of the ecological risk assessment, Mr. Hodgson noted that even EPA acknowledges that data documenting ecological risks are more convincing than "projections" of ecological risk that draw from many assumptions. He then criticized EPA for not having collected data on the species of potential concern in the Upper Hudson River since the onset of the site reassessment in 1991. Had EPA done so, according to Mr. Hodgson, the current ecological risk assessment could be based on 9 years of ecological data, rather than being based on "conjecture about what might happen to environmental populations." Mr. Hodgson called EPA's failure to collect ecological data "another example of poor planning" in the reassessment methodology.

Mr. Hodgson then commented on the merit of a conservative TQ analysis, which he thought yielded findings that contradicted the fact that no PCB-related ecological effects have been observed among Upper Hudson River ecological populations. In short, he said, the discrepancy between the high TQs reported in EPA's risk assessment and the lack of observed effects means that EPA's ecological risk assessment has "questionable value" and is "based on conjecture and speculation raising alarms about things which have not been observed."

Citing examples of the Saratoga Environmental Management Council's specific comments, Mr. Hodgson noted that the risk assessment failed to consider the "home range" and hibernation of species of concern, which should have been evaluated for species (e.g., river otter, mink,

migratory birds) that migrate or "are not dependent upon the Hudson River for year-round food sources or for habitat." Further, he questioned the validity of the conclusions EPA draws in Section 5 of the risk assessment, given that uncertainty factors between 10 and 100 and possibly higher (according to Mr. Hodgson) were applied to lowest-observed-adverse-effect levels (LOAELs) and no-observed-adverse-effect levels (NOAELs). Mr. Hodgson listed several other criticisms of EPA's approach: consistently selecting the lowest LOAEL or NOAEL for purposes of evaluation; estimating dietary intakes of PCBs, in some cases, by assuming that winter diets represent year-round intakes; overlooking the effects of home range, migration, and hibernation; and possibly, in its baseline modeling analyses, overpredicting PCB levels in the food chain.

Given the many conservative assumptions inherent in EPA's analysis, Mr. Hodgson was not surprised that the ecological risk assessment found all species of concern to be at risk, but he questioned the meaning of such a finding. In contrast to EPA's conclusions, Mr. Hodgson argued that "all indications" suggest that wildlife in the Upper Hudson River is "thriving." Specifically, he noted that observers along the Hudson River have only provided positive reports on the populations of waterfowl, avian species, river otter, racoons, mink, and fish. Mr. Hodgson added that the local press have not recently documented evidence of "dying or malformed wildlife in the Upper Hudson River." Despite these signs of a thriving ecosystem, Mr. Hodgson was puzzled at the elevated TQs derived in EPA's ecological risk assessment. Referring to data in Tables 5-12 to 5-14, he noted that EPA concludes that many species are at risk (TQ > 1) from the present through the year 2018. He cited specific TQs to emphasize this point: mallard ducks (TQ > 1,000 in some cases), mallard eggs (TQ > 5,000 in some cases), bald eagles (TQ > 1,000 in some cases), otter (TQ > 10,000 in some cases), and mink (TQ > 1,000 in some cases). Though he acknowledged that TQs only estimate "potential risks," Mr. Hodgson argued that either (1) the elevated TQs would suggest that PCB-related effects would be evident in Upper Hudson River species or (2) the analysis is so excessively conservative as to provide a useless risk characterization. Citing the "lack of observed problems" in the Upper Hudson River, Mr. Hodgson stated that the Saratoga County Environmental Management Council could only draw one conclusion: EPA's ecological risk assessment "so overestimates risk as to not be useful."

Concluding his comments, Mr. Hodgson cited a quote from Carol Browner (Administrator of the U.S. Environmental Protection Agency) that was documented in a letter on EPA's "Guidance for Risk Characterization":

> While I believe the American public expects us to err on the side of protection in the face of scientific uncertainty, I do not want our assessments to be unrealistically conservative. We cannot lead the fight for environmental protection into the next century unless we use common sense in all we do.

Reflecting on this quote, Mr. Hodgson concluded that EPA's ecological risk assessment is excessively conservative, "not in the best interest of the public," and therefore inconsistent with Administrator Browner's sentiments, expressed above.

Day #2, Comments from Joe Gardner, Appalachian Mountain Club

Mr. Gardner introduced himself as a Conservation Chair of the Appalachian Mountain Club. He then commended the peer reviewers for their efforts in critiquing the ERA and commended the staff of EPA for conducting the ecological risk assessment. Mr. Gardner indicated that his organization is "deeply concerned" about the vast amount of resources that have been allocated to downplay the concern about the Hudson River PCBs Superfund site. He hoped that the talented staff working on "both sides of this issue" could come together to help "restore the Hudson River."

Day #2, Comments from George Hodgson, Saratoga County Environmental Management Council

Mr. Hodgson offered several brief observations and comments. First, he thanked the peer reviewers for conducting a thorough evaluation of the ERA. Second, Mr. Hodgson noted that ospreys are present in the Thompson Island Pool area of the Upper Hudson River, and he suspected they are present in other reaches of the Hudson River. Having seen ospreys in the area and feeding in the Thompson Island Pool, Mr. Hodgson thought the authors of the ERA should have been aware of the presence of osprey had they done sufficient research on the Hudson River ecosystem. Third, Mr. Hodgson found it "obviously clear" that the peer reviewers found the ERA "totally inadequate to predict valid and appropriate environmental impacts of PCBs in the Hudson River." As a result, he indicated that EPA thus needs to revise the ERA to portray risks more accurately and adequately before proceeding with the feasibility study and making a remedial decision. Finally, Mr. Hodgson stressed that the inadequacies of the ERA are too serious to leave unresolved, and he noted that failure to address the shortcomings in the document would amount to a "flagrant abuse" of the public trust.

Day #2, Comments from Ron Sloan, New York State Department of Environmental Conservation

Mr. Sloan, an employee of the New York State Department of Environmental Conservation's (NYSDEC's) Department of Fish and Wildlife, indicated that he has helped NYSDEC collect and analyze fish tissue samples from the Hudson River for nearly 25 years. His

comments focused primarily on trends among the PCB sampling data and various ecological studies.

On the topic of PCB levels in Hudson River fish, Mr. Sloan said "some declines" in PCB concentrations have been observed in the Hudson River, particularly in the Lower Hudson River, but he noted that declining PCB levels in fish tissue are not as apparent for samples collected in the Thompson Island Pool. Though he acknowledged that PCB levels in fish tissue in the Thompson Island Pool remain elevated and that "apparent risks" might occur, Mr. Sloan indicated that researchers have not examined changes in the genetic structure of fish populations, thus potential effects of PCBs on genetic diversity remain unknown.

Next, Mr. Sloan stressed that most of the ecological studies discussed at the peer review meeting were conducted along the Lower Hudson River, while studies along the more contaminated stretches of the Upper Hudson River have not been widely conducted. Because of this, Mr. Sloan said a need clearly exists for future research to examine the potential for populations to exist (e.g., bald eagle, osprey) in the Upper Hudson River. Regardless of the absence of extensive studies, he noted that PCB bioaccumulation has clearly occurred as a result of sources in the region (e.g., contaminated sediments). Mr. Sloan concluded his comments by emphasizing his hope that these sources of PCBs can eventually be removed.

APPENDIX G

MINUTES FROM THE MARCH 2000 BRIEFING MEETING

Minutes from the Briefing and Site Visit for the Peer Review of the Hudson River PCBs Risk Assessment Reports

On March 22–23, 2000, Eastern Research Group, Inc. (ERG), conducted a meeting at the Sheraton Hotel in Saratoga Springs, New York, to provide independent peer reviewers with background information on the U.S. Environmental Protection Agency's (EPA's) ecological and human health risk assessments for the Hudson River PCBs Superfund site. Thirteen peer reviewers attended the meeting; another peer reviewer (Dr. Dwayne Moore) could not attend, but was given a video tape of the meeting for his reference. The presentations at the meeting focused on the history of the Hudson River PCBs site and the technical content of EPA's risk assessments. Seven of the reviewers were hired to critique the ecological risk assessment, and seven others to critique the human health risk assessment.

ERG facilitated the meeting, which was open to the public. The meeting was attended by the peer reviewers, representatives of EPA and its contractors, and approximately 30 observers. The minutes below summarize the presentations made during the meeting. Attachments to these minutes include (1) the meeting agenda, (2) a list of the peer reviewers, (3) a list of EPA and contractor participants, and (4) a list of observers at the meeting.

Ms. Jan Connery (ERG), meeting facilitator, welcome remarks and introduction. Ms. Jan Connery opened the meeting by welcoming the peer reviewers and observers and describing the meeting's purpose: to provide the reviewers background information on the Hudson River PCBs site and on the risk assessments, such that the reviewers understand the site history and the scope of EPA's site reassessment efforts. Ms. Connery stressed that the purpose of the meeting was not to peer review the risk assessments, but rather to provide the reviewers context for conducting their reviews. She indicated that the actual peer review meetings would take place in Saratoga Springs, New York, on May 30–31, 2000 (for the human health risk assessment) and on June 1–2, 2000 (for the ecological risk assessment). Ms. Connery then reviewed the agenda for the two-day meeting, after which the reviewers, representatives from EPA, and representatives from EPA's contractors introduced themselves.

Ms. Alison Hess (EPA), site background. Ms. Hess' presentation reviewed the history of the Hudson River PCBs site and the timeline of EPA's involvement with the site. First, Ms. Hess showed a series of maps and photographs of various sites along the Hudson River, and she explained the distinction between the Upper Hudson River and the Lower Hudson River. Ms. Hess then identified the locations of the General Electric facilities that had discharged PCBs to the Upper Hudson River, after which she indicated locations of the Thompson Island Pool, the Thompson Island Dam, remnant deposits, and the former Fort Edward Dam. Ms. Hess gave a brief overview of historical releases of PCBs to the Upper Hudson River as well as the controls that have been implemented to reduce them. Ms. Hess also reviewed the current fishing advisories for the Hudson River.

Ms. Hess then gave an overview of EPA's role in the Hudson River PCBs site. She reviewed details of EPA's 1984 Record of Decision, including the "interim No Action" decision for the contaminated sediments. Ms. Hess explained that EPA decided to reassess this decision

in 1989, at the request of the state of New York. To provide a general overview of the reassessment, Ms. Hess presented the three principal reassessment questions and how EPA proposes to address the questions in the three phases of the reassessment. For additional site history, Ms. Hess briefly listed the available sources of environmental sampling data, explaining how the scope of, and methods used in, these various sampling studies differed. Focusing specifically on EPA's sampling programs, Ms. Hess highlighted the results of the Agency's water column, sediment, geophysical, and ecological sampling. She also compared and contrasted the scope of EPA's sampling with sampling conducted by other parties, including General Electric, the New York State Department of Environmental Conservation, the New York State Department of Health, and others.

According to Ms. Hess, the data collected by the various parties provided the basis for EPA's site reassessment, which she indicated was being conducted in three phases. Ms. Hess then listed the different reports EPA had prepared as part of Phase 2, including the two risk assessment documents. She also listed the reports released as part of Phase 1 and those scheduled to be released as part of Phase 3 of the reassessment. Ms. Hess closed her presentation by describing relevant aspects of the Superfund process, such as EPA's criteria for selecting remedies and EPA's general decision making process at Superfund.

Ms. Alison Hess (EPA), findings from previous reports. After her site background presentation, Ms. Hess gave another presentation reviewing key findings from EPA's Phase 2 reports on the Hudson River PCBs site. This presentation focused on the findings documented in EPA's Data Evaluation and Interpretation Report (DEIR), Low Resolution Sediment Coring Report (LRC), and Baseline Modeling Report (BMR). Ms. Hess listed major conclusions from these reports and indicated that the DEIR and LRC have already undergone external peer review, during which the reviewers found the reports to be acceptable with minor revisions, and that the BMR will undergo peer review on March 27–28, 2000. Finally, Ms. Hess briefly highlighted findings of the site's human health and ecological risk assessments. Ms. Hess did not review the approach and conclusions of the risk assessments, because other presentations would address this topic.

Mr. Doug Tomchuk (EPA), site tour of the Upper Hudson River. Before starting the site tour, Mr. Tomchuk outlined the itinerary for the day trip along the Upper Hudson River. Mr. Tomchuk identified six locations that the reviewers would see. Observers were invited to join the site visit, and several did so. The reviewers, observers, and representatives from EPA and its contractors then boarded a bus and visited the following six locations along the Upper Hudson River:

- An observation point adjacent to Bakers Falls and directly across the Hudson River from GE's Hudson Falls plant

- An overlook of the Hudson River, near a former outfall from GE's Fort Edward plant

- An overlook of the Hudson River, directly across from capped remnant deposit #4 and upstream from the former Fort Edward Dam and Rogers Island

- The northern tip of Rogers Island
- The western wall of the Thompson Island Dam
- Lock #5 on the Hudson River

At every location listed above, Mr. Tomchuk briefly described the surroundings, after which he answered reviewers' questions. The first day of the two-day briefing ended upon the bus' return to Saratoga Springs.

Presentations on the ecological risk assessment. EPA provided an overview of the ecological risk assessment and guidelines for the peer review in four presentations. First, Mr. Ed Garvey (TAMS Consultants) provided background information on how PCB fish body burdens in the Hudson River related to the media (sediment, water, diet) to which they are exposed. To address this topic, Mr. Garvey reviewed relevant sampling data, presented results of statistical analyses of these data, and discussed how the PCB congener profile in fish varied with species and with location in the Hudson River.

Second, Ms. Helen Chernoff (TAMS Consultants) gave an overview of the process followed to conduct the ecological risk assessment. Ms. Chernoff highlighted general features of the problem formulation, conceptual model, exposure and effects assessment, and risk characterization. She also illustrated the key exposure pathways considered in the analysis and listed the assessment endpoints selected for the risk assessment.

Third, Ms. Katherine von Stackelberg (Menzie-Cura & Associates, Inc.) provided more detail on the inputs, assumptions, and models used to quantify exposures and effects. Specifically, she summarized key findings from EPA's fish bioaccumulation modeling efforts and described how the models were designed, calibrated, and validated. Ms. von Stackelberg also described how models were used to estimate exposures to species not considered in the fish bioaccumulation model (e.g., piscivorus birds). She then presented a detailed account of exposure factors, effects assessment, and risk characterization documented in the final ecological risk assessment. After Ms. von Stackelberg's concluding remarks, Ms. Chernoff reviewed results of relevant field studies and stepped through the final risk characterization and key conclusions in the reports. Ms. von Stackelberg and Ms. Chernoff then answered the reviewers' questions of clarification.

Fourth, Mr. Damien Hughes explained the purpose of the peer review and the charge to the reviewers. During his presentation, Mr. Hughes reviewed every question in the charge and answered several of the reviewers' questions regarding the charge. Mr. Hughes asked that the reviewers direct any questions they have over the course of the peer review regarding the charge or the modeling documents to ERG.

Presentations on the human health risk assessment. EPA provided an overview of the human health risk assessment in three presentations. First, Ms. Marion Olsen (EPA) described the scope of the risk assessment, explaining that the risk assessment was designed specifically to meet EPA guidance for Superfund. For background, Ms. Olsen depicted the relevant exposure

pathways considered in the risk assessment, but stressed that EPA's evaluations found that exposure from fish ingestion posed the greatest risks. Ms. Olsen then explained the process by which EPA selected toxicity factors (i.e., cancer slope factors and reference doses) for the risk assessment. After briefly describing some assumptions made in the exposure assessment, Ms. Olsen presented some key findings from the risk assessment.

Second, Mr. David Merrill (Gradient Corporation) then gave a brief presentation outlining more detailed information on exposure factors and specific risk calculation approaches. For instance, Mr. Merrill explained how the exposure durations were determined for the cancer and noncancer risk assessment. Further, he described how exposure point concentrations (i.e., fish tissue concentrations) were determined for the Hudson River. To do so, Mr. Merrill reviewed some key findings from EPA's fish bioaccumulation modeling efforts, indicating how the modeling results were handled to develop exposure concentrations for the central tendency and reasonably maximally exposed individual evaluations. Mr. Merrill also reviewed several other key assumptions, including how EPA selected fish ingestion rates from the various studies that had been published on this issue. Mr. Merrill then stepped through the Monte Carlo analyses conducted on the fish ingestion pathway—from input distributions to results. Finally, he discussed how certain findings in the August 1999 version of the human health risk assessment have been revised, due to the release of EPA's Revised Baseline Modeling Report. Mr. Merrill and Ms. Olsen then answered the reviewers' questions of clarification regarding the human health risk assessment.

Third, Mr. Damien Hughes again explained the purpose of the peer review and the charge to the reviewers. During his presentation, Mr. Hughes reviewed every question in the charge and answered several of the reviewers' questions regarding the charge. Mr. Hughes asked that the reviewers direct any questions they have over the course of the peer review regarding the charge or the modeling documents to ERG.

Attachments:

- Meeting agenda
- Peer reviewers
- EPA and contractor participants
- Observers

United States
Environmental Protection Agency
Region 2

Informational Meeting for the Peer Review of Hudson River PCBs Ecological & Human Health Risk Assessment

Sheraton Saratoga Springs
Saratoga Springs, New York
March 22-23, 2000

Agenda

Meeting Facilitator: Jan Connery, Eastern Research Group, Inc.

WEDNESDAY, MARCH 22, 2000

8:00AM	**Registration/Check-in**
8:30AM	**Welcome Remarks** *Jan Connery, Eastern Research Group, Inc.*
8:45AM	**Presentation on Site Background** *Alison Hess, U.S. Environmental Protection Agency*
10:00AM	BREAK
10:15AM	**Presentation on Findings from Previous Reports** *Alison Hess, U.S. Environmental Protection Agency*
11:00 AM	**Adjourn for Site Tour**
11:30AM	**Board Bus for Site Tour**
12:00AM	LUNCH (on own, bus will stop at local restaurant)
5:00PM	**End of Site Tour/Return to Hotel**

THURSDAY, MARCH 23, 2000

8:30AM	**Presentations on Ecological Risk Assessment** *Helen Chernoff and Ed Garvey, TAMS Consultants, Inc.* *Katherine von Stackelberg, Menzie-Cura & Associates, Inc.*
10:30AM	BREAK
10:45AM	**Review the Charge to Reviewers on the Ecological Risk Assessment** *Damien Hughes, U.S. Environmental Protection Agency*
11:45AM	LUNCH (on own)

(over)

THURSDAY, MARCH 23, 2000 (CONTINUED)

1:00PM **Presentations on Human Health Risk Assessment**
Marian Olsen, U.S. Environmental Protection Agency
David Merrill, Gradient Corp.

3:00PM BREAK

3:15PM **Review the Charge to Reviewers on the Human Health Risk Assessment**
Damien Hughes, U.S. Environmental Protection Agency

4:15PM Adjourn

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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Peer Review of Hudson River PCBs Reassessment RI/FS Phase 2 Reports

Human Health Risk Assessment

Holiday Inn
Saratoga Springs, New York
May 30–31, 2000

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Informational Meeting for the Peer Review of Hudson River PCBs Ecological & Human Health Risk Assessment

Sheraton Saratoga Springs
Saratoga Springs, New York
March 22-23, 2000

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Informational Meeting for the Peer Review of Hudson River PCBs Ecological & Human Health Risk Assessment

Sheraton Saratoga Springs
Saratoga Springs, New York
March 22-23, 2000

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