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

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

Exposure Assessment

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

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

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

Monte Carlo Analysis/Uncertainty Analysis

5. USEPA policy states that probabilistic analysis techniques such as Monte Carlo analysis, given adequate supporting data and credible assumptions, can be viable statistical tools for analyzing variability and uncertainty in risk assessments (USEPA, 1997). 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, 1995). 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).

APPENDIX C

PREMEETING COMMMENTS, ALPHABETIZED BY AUTHOR

Note: This appendix includes a copy of the premeeting comments that were distributed at the peer review meting. Comments submitted by Harlee Strauss and Owen Hoffman just prior to the peer review meeting are included in this appendix.

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

Premeeting Comments

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

Notice

The U.S. Environmental Protection Agency (EPA) strives to provide accurate, complete, and useful information. Neither EPA nor any person contributing to the preparation of this document, however, makes any warranty, expressed or implied, with respect to the usefulness or effectiveness of any information, method, or process disclosed in this material. Nor does EPA assume any liability for the use of, or for damages arising from the use of, any information, methods, or process disclosed in this document.

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Hudson River PCBs Site Reassessment RI/FS
Risk Assessments
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Human Health Risk Assessment Review

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

Recommendations

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

Holly Hattemer-Frey

REVIEW OF THE HUMAN HEALTH RISK ASSESSMENT
HUDSON RIVER PBCs REASSESSMENT RI/FS

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COMMENTS IN RESPONSE TO CHARGE QUESTIONS

1. Chapter 4, Toxicity Assessment: I agree that the toxicity data currently available in IRIS for PCBs should be used in the assessment. This approach is consistent with EPA policy and allows for easy comparison of risks between hazardous waste sites. On the other hand, it is reasonable to discuss the more recently-available data on the potential toxicity of PCBs (e.g., Kimbrough *et al.*, 1999) and the effect using these data would have on risk estimates. For example, if the more recently-available toxicity data were used, would risks increase or decrease and by what factor? Relying exclusively on the more recently-available data is not appropriate, however, since a full peer review of the data has not yet been completed.

2. Fish Ingestion Rates (p. 43, bottom): The reason for selecting the 90th percentile fish ingestion rate of 31.9 g/day versus the 95th percentile value (63.4 g/day) seems arbitrary. The 90th percentile value was selected because it is more consistent with 95th percentile values reported in other studies. While this is true, adopting the 90th percentile value discounts the fact that NY anglers may actually consume more fish that anglers from other states. Since the authors didn't have any *a priori* reason to disbelieve the 91 Angler survey results, the arbitrary selection of the 90th percentile value may underestimate angler fish consumption. This is a minor point, however, since doubling the fish ingestion rate would not substantially increase risk estimates.

3. Section 3.2.4.3, Exposure Duration: Calculation of a site-specific exposure duration using census and mobility data is appropriate. If I understand the approach correctly, a one-year probability that an individual would move out of the region is estimated for a given number of years, and then those 1-year probabilities are summed to determine the probability that an individual would move out in a specified time period. This approach does not seem to account for the fact that individuals who moved out in a given year (e.g., the first year) would not be available to move in subsequent years. If this is true, then residence duration is likely to be over estimated, and the approach used should be modified or the extent to which results may be overestimated should be discussed.

4. Page 23, para 2 notes that the 50th and 95th percentile values for fishing duration are 12 and 40 years, respectively. Since PCB concentrations in fish will decline over time, adopting an exposure duration (ED) of 7 and 12 years for the RME and CT scenarios,

respectively, will yield the highest chronic dose to receptors. Since the HHRA has acknowledged the conservativeness of this approach and calculated a hazard quotient assuming a 40-year exposure duration for comparison, I believe that this approach adequately addresses noncancer hazards.

5. Monte Carlo Analysis: See general and specific comments below.

6. Monte Carlo results associated with using the Maine fish ingestion rates, which were the lowest rates of the studies evaluated, are presented on p. 78-79. For completeness sake, the text should include a discussion of Monte Carlo results using the range of fish ingestion rates reported in West *et al.*, 1989 and Connelly *et al.*, 1996 as well. This is a minor point, as I agree that adopting a different fish ingestion rate in the base case (or point-estimate calculations) will not substantially alter risk results.

7. Overall, the risk characterization adequately estimates cancer and noncancer risks to exposed individuals. Deficiencies in the exposure assessment and other aspects of the risk assessment that affect risk results are detailed below.

GENERAL COMMENTS

1. The method by which PCB concentrations in fish were calculated (p. 11-14, Section 2.3.1 and p. 23-24) is not well presented. While I understand that the details on how fish concentrations were calculated are presented in the Baseline Modeling Report, which has been separately peer reviewed, it is crucial that individuals reading the HHRA have a clear understanding of the process. The description of how fish concentrations were derived is not transparent or adequately summarized. I found it confusing and difficult to follow. A more detailed, step-by-step explanation would enhance the report. Perhaps including a sample calculation and/or a flow diagram of the process would be useful. Furthermore, any significant changes concerning how fish concentrations were calculated raised by the ecological peer reviewers should also be addressed in the HHRA.

2. The Phase 2 assessment did not evaluate potential risks associated with the consumption of home-grown fruits and vegetables and soil for individuals living in floodplain areas where residential soils may have been contaminated during flood events. Information on when and where the Upper Hudson River (UHR) may have flooded during the last 20 to 30 years should be available. If flooding has occurred, information on where floodplain soils may have been contaminated with PCBs should be summarized in the risk assessment. A crude, conservative calculation of potential risks associated with soil and produce ingestion could be completed by assuming that the current soil concentration equals the current sediment concentration. Although exposures via contact with floodplain soils are likely to be a minor relative to fish ingestion, they should still be address in the HHRA.

3. Agree that limiting the focus of the Phase 2 investigation to PCBs is appropriate in this case.
4. Chapter 2 is poorly organized and confusing. The text consistently refers to details presented in Chapter 3. For example, specific information on why the 90th percentile fish ingestion rate (versus the 95th percentile value) was used in point-estimate calculations is described in Section 3.2.1.3 (p. 42)--not in Chapter 2 as it should be. Details affecting point-estimate calculations should be incorporated into Chapter 2 to facilitate better comprehension of how baseline exposures were calculated.

5. Chapter 2 summarizes the exposure parameters used to calculate intakes but does not present the results of the exposure assessment. Tables documenting calculated intakes for each pathway and receptor group should be included in Chapter 2.

6. Chapter 3 does not provide sufficient detail on the range of values used in the Monte Carlo (MC) analysis for each parameter. Tables summarizing the specific range over which each parameter was allowed to vary should be included.

7. The start date for the HHRA is 1999 (p. 72, para 2), which does not consider individuals who may have been fishing in the UHR before 1999. In many risk assessments, exposure-point concentrations are based on measured data only, and extensive modeling to predict future concentrations is not done. In this case, however, extensive modeling has been done, including a short-term hindcast calibration test covering the period 1991 to 1997 (see Baseline Modeling Report Executive Summary p. ES-4, para 1). It may be possible to estimate fish concentrations for periods before 1999 with great difficulty. If it is, then the magnitude of exposures before 1999 should be evaluated (or at least discussed in the uncertainty section).

SPECIFIC COMMENTS

p. ES-3 to ES-4: The actual RfDs and CSFs used to calculate risks and HI values should be reported here instead of stating that the "most current values" were used.

Chapter 2

Table 2-1 and Section 2.1: Both should be revised to include evaluation of exposure to floodplain soils by residential and recreational receptors (e.g., picnickers) via direct ingestion.

page 8, Section 2.1.3, para 1: The text states that ingestion of river water as drinking water was not evaluated since PCB levels in the UHR were less than the Maximum Contaminant Level (MCL). For accuracy and clarity, the text should compare the upper-bound or maximum concentration of PCBs in the river water with the actual MCL.

p. 11, last para: The text states that PCB concentrations were determined for six fish species.

These six species were chosen because they were representative of bottom feeders, top predators, and semi-piscivorous fish. In other words, they were apparently chosen to fulfill the data needs for the ecological risk assessment. A complete list of fish species likely to occur in the UHR as well as those species likely to be consumed by humans should be included to allow the reader to confirm that the fish species selected are representative of species consumed by humans.

p 11, bottom to 12, top: The reason why PCB concentrations in fish were based on a Tri+ concentration (i.e., only data for PCB congeners with three or more chlorine molecules were used) needs to be more clearly explained. The reasons why a Tri+ concentration was used are outlined in paragraph 2, p. ES-4 of the Executive Summary for the Baseline Modeling Report. That information needs to be added here for clarity. Moreover, information on how Tri+ concentrations compare to total PCB concentration and how using Tri+ concentrations (versus total concentrations) has affected risks estimates should be discussed.

p 12, para 2: The text states that fish PCB concentrations were assumed to be lognormally distributed. A test to confirm the distribution of these data (e.g., a Shapiro-Wilk or W goodness of fit test) should have been done and results reported here.

p 23, Averaging Time: The text states that "to avoid confusion" a 70-year life expectancy was used to calculate cancer risk averaging times. The more current estimate of 75 years based on more recent EPA guidance (cited as USEPA, 1997f in the document) should have been used.

Tables 2-6 thru 2-8: These tables are very confusing. Data included in these tables is not defined adequately in the text or footnotes. A more detailed discussion of the difference between columns 3, 8, and 11 and which values were used as the exposure-point concentration needs to be included in the text. Some acronyms/abbreviations cited in the first line of the footnotes don't seem applicable and should be deleted (i.e, Max, UCL-N, 95% UCL-T, and Mean-T). In columns 10 and 13, I recommend including the actual number of years over which data were averaged to clarify (e.g., 40, 7, or 12 years). Column 5 should note that the value listed is the maximum *modeled* concentration. Delete column 6 since it's not relevant. Line 4 should state "species weighted for cancer exposure." Footnotes 1 and 2 should refer to the appropriate column for clarity.

Chapter 3

p. 33, para 1: The text needs to explain more clearly that a Monte Carlo analysis was done on the fish ingestion pathway only because risks associated with the other exposure pathways quantified were minor relative to fish consumption.

p. 35, para 3: The text states that "for reasons describes later" a 2-D Monte Carlo analysis could not be done. Even after reading all of Chapter 3, it is not clear why a 2-D analysis wasn't (or couldn't be) done.

p 51, Adjustment 1: Acknowledging that my area of expertise is not probabilistic analyses, could s and c be rounded to the nearest of 5 (instead of 10) without compromising the robustness

of P(s,c)? Since rounding to 10 is likely to underestimate child exposures, rounding to the nearest five might afford better representation of child exposures.

p 51, Adjustment 2: The assessors opted to include the data for non-respondents even though information on the age at which these individuals started fishing was not reported and had to be estimated. Estimating the age at which non-respondents starting fishing introduces error into the assessment. Discuss the effect on model outcome of adopting these adjustments. Are the assumptions and adjustments adopted likely to over- or underestimate exposures?
p. 52, Discussion of Assumptions: A number of the assumptions associated with the Monte Carlo analysis assume that the angler population is at steady-state, meaning that the age profile remains consistent over time. Do the 1980 and 1990 Census data support this assumption, or do they indicate the population living near the UHR is getting older or younger?

p. 54: Again, more adjustments are made to the raw data before using it in the Monte Carlo Analysis without discussing the error or bias introduced by making these adjustments. Discuss the effect on model outcome of adopting these adjustments. Are the assumptions and adjustments adopted likely to over- or underestimate exposures?

p 66, last sent: Recommend adding text that the magnitude of uncertainty associated with possible endocrine disruption cannot be determined at this time.

Sect. 5.1.2, p 69, top: Point-estimate risks for children consuming fish should be formally calculated and reported here and in the Executive Summary, and child-specific exposure factors be included in Section 2.4.1. Even though 1988 and 1991 New York Angler Surveys (Connelly *et al.*, 1990; 1992) reported that the average individual didn't start fishing in the UHR until age 13 to 14, it is possible that children of anglers were fed fish taken from the UHR. The assumption that children consume portions 1/3 the size of an adult portion would yield RME and CT child ingestion rates of 10.5 g/day and 1.3 g/day, respectively. These values seems reasonable and are fairly consistent with those reported in USEPA, 1990), which reports RME and CT child ingestion rates of 7.5 g/day and 2.8 g/day respectively.

Section 5.3.1: This section should include uncertainty associated with not evaluating potential exposures and risks from direct ingestion of soil and produce.

Monte Carlo Analysis: One possible scenario that was not evaluated (and perhaps should be) is an individual who preferentially consumes fish from the same species and location (e.g., someone who only eats bass from the Thompson Pool area). This scenario will probably not substantially alter risk estimates, since PCB fish concentrations did not vary dramatically within a given species taken from the same location (as exemplified in Table 5-34), but for completeness sake it

should be included.

RECOMMENDATION

Based on my review of the HHRA, I find the report acceptable with the major revisions outlined above.

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Owen Hoffman

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Dr. F. Owen Hoffman, President and Director of *SENES* Oak Ridge, Inc., Center for Risk Analysis, has more than 29 years of experience in the evaluation of doses to humans from the release and transport of radionuclides and chemicals in terrestrial and aquatic systems. In the Oak Ridge Dose Reconstruction project, Dr. Hoffman led the reconstruction of doses to area residents from historic releases of ^{131}I from federal government facilities. Previously Dr. Hoffman was a member of the research staff of the Environmental Sciences Division at the Oak Ridge National Laboratory for 17 years. His studies at ORNL concentrated on environmental transport of radioiodine and other radioactive contaminants and included the development and testing of mathematical models to predict environmental transport, human exposures and doses, and the associated uncertainties.

Dr. Hoffman is widely recognized as an authority on environmental risk. As a member of the Radiation Advisory Committee of the EPA Science Advisory Board, he chaired the subcommittee that reviewed EPA's methods for quantifying the uncertainty in radiogenic cancer risk. He was instrumental in developing and writing guidance documents for the International Atomic Energy Agency and the National Council on Radiation Protection and Measurements on evaluating the reliability of predictions made using environmental transfer models, which includes the application of formal procedures for quantitative uncertainty analysis in risk assessment.

Dr. Hoffman was a leader of international efforts sponsored by the Swedish National Institute for Radiation Protection and by the International Atomic Energy Agency (IAEA) to validate radiological transport models using Chernobyl data. These projects were designed to assess the uncertainty in mathematical models used for exposure assessment and to compare model predictions against independent data sets. Dr. Hoffman served as vice chairman on a task to analyze data from the Chernobyl accident as a means of validating models, which was sponsored by the Department of Energy's Office of Health and Environmental Research (OHER) Task Group on the Health and Environmental Consequences of the Soviet Nuclear Accident. In 1990 he participated in the first International Symposium on the Radiological Consequences of the Chernobyl Accident sponsorship of US-USSR Joint Coordinating Committee on Civilian Nuclear Reactor Safety. Dr. Hoffman has many scientific contacts in the former Soviet Union with whom he is working to obtain Chernobyl databases for the purpose of model validation.

Dr. Hoffman has served as an advisor on issues concerning dose reconstruction for the States of Tennessee and Colorado. Since 1992, he has been a member of the Advisory Committee for Energy-Related Epidemiologic Research (ACERER) for the Department of Human Health Services, Centers for Disease Control and Prevention. Other current appointments include corresponding membership on the International Commission on Radiological Protection, Councilor of the Society for Risk Analysis, President of the local East Tennessee Chapter of the Society for Risk Analysis, and Council Membership in the National Council on Radiation Protection and Measurements.

PEER REVIEW FOR THE HUDSON RIVER PCBs HUMAN HEALTH RISK ASSESSMENT

OVERALL RECOMMENDATIONS

The present EPA risk assessment provides sufficient information to conclude that PCBs released from the General Electric facility into the Upper Hudson River are a regulatory concern. The human health risk assessment does not provide sufficient information to enable evaluation of the potential health risk to humans under baseline conditions. Base-line conditions imply that no restrictions are in place to prevent people from utilizing the Upper Hudson River for sport fishing, harvesting of other aquatic organisms for food, or as a commercial fishery for striped bass.

In general, the toxicity coefficients obtained from the IRIS database are intended by EPA to be conservatively biased, i.e., in the presence of uncertainty their use will err on the safe side to ensure that real people exposed to PCBs are unlikely to suffer harm. The EPA human health risk assessment, however, does not indicate at what concentrations or exposure levels increased levels of harm might be expected to occur. Therefore, although information is adequate to conclude that PCBs are of a regulatory concern, information is inadequate to evaluate the uncertainty associated with anticipated health impacts. To properly assess the effectiveness of risk proposed reduction alternatives during the analysis of the feasibility of remediation, information is needed on the uncertainty in the toxicity coefficients for PCBs, the concentrations of PCBs in fish harvested at future dates, and concentrations of other cancer causing and non-carcinogenic substances in various environmental media of the Upper Hudson River.

The EPA human health risk assessment does not adequately address uncertainty in quantifying health risk. Areas where the uncertainty analysis is deficient are as follows:

(1) *Individuals who would be exposed to contaminated environmental media in the Upper Hudson River are exposed to much more than just PCBs.* They are also exposed to agricultural chemicals and to radionuclides introduced by various facilities and by atmospheric testing of nuclear weapons. All of these add to the overall health burden, and it is this cumulative burden that should be assessed. The current risk assessment focuses only on health the impact of exposure to PCBs.

(2) *The assessment is focused on projected PCB concentrations in fish averaged for the entire 40-mile reach of the Upper Hudson River. Uncertainties on these projected average concentrations are not presented in the report.* In the March 2000 Responsiveness Summary, the projected average concentrations in the various species of fish are too narrow to be plausible. The assessment of uncertainty is limited to a comparison of model predictions with past observed concentrations in various fish species. The uncertainty associated with forecasting PCB concentrations in fish over time is not considered.

The comments in the EPA human health risk assessment about the differences between the uncertainty in the mean concentration of a sample versus the uncertainty in the mean concentration in a model prediction is technically incorrect. Both measured and modeled mean concentrations have associated uncertainty, and this uncertainty should be quantified and reported.

(3) *Averaging concentrations and exposures over the entire reach of the Upper Hudson River is inappropriate.* Clean-up options will be designated for various subreaches of the river, and the HHRA should target those subreaches. In addition, the population exposed to the entire Upper Hudson River would likely be quite large, much larger than the 10,000 anglers referred to in the HHRA documents. It is easy to imagine that the number of people consuming fish out of the Upper Hudson River would include the families of anglers, families of those who harvest fish but who are not licensed, and those who would purchase fish from commercial fisheries, if such fisheries were to go into operation under baseline conditions. Therefore, targeting the upper 95th percentile of a very large population has the potential to substantially underestimate exposure to a significant subpopulation of that group. For example, assume that the total number of people who consume fish from the Upper Hudson River is on the order of 100,000 individuals. The top 5% of the distribution of that population would still entail a population of 5,000 individuals. The top 1% would include a population of 1,000 individuals. Therefore, I believe it is more appropriate to focus on subpopulations that would utilize subreaches of the Upper Hudson River, rather than the entire 40-mile reach. In addition, I would separately assess the exposure and risk for reference individuals characterized as casual, average, and maximal users of the Upper Hudson River, as opposed to treating inter-individual variability as a random process.

(4) *The Monte Carlo analysis is not used to address uncertainty.* Interindividual variability among licensed anglers is simulated as a stochastic process. Instead of subdividing the population into those who would be most likely to consume moderate to average amounts of fish, and those likely to consume maximum amounts of fish, the Monte Carlo analysis simply draws directly on empirical results from slightly more than 200 respondents to a 1991 angler survey conducted for upstate New York. This survey was conducted over a broad region of the state. Sites included many that were subjected to fishing advisories. Thus, the database used to drive the Monte Carlo analysis is not directly relevant to the population of concern who would be consuming fish out of the Upper Hudson River. The degree to which the empirical database is relevant to the Upper Hudson River has been discussed, but the potential for bias is not included in the Monte Carlo analysis.

Many other sources of information that would lead to an expression of interindividual variability have not been included in the Monte Carlo analysis, including

(a) the size of an average meal per person,

(b) the amount of fish that would be caught from other locations besides the Upper Hudson River,

(c) the likelihood that there would be variability in food preparation losses from one meal to another, and

(d) the likelihood that food consumption patterns would change over a period of 7 to 40 years.

The 1991 angler survey itself was a recall study for a single fishing season, and its applicability for an average person over periods of 7 to 40 years is not discussed. I anticipate that the extent of interindividual variability as well as the amount of fish consumed at the upper percentiles of the true frequency distribution has been substantially overestimated.

The sensitivity analysis that is performed to indicate the uncertainty in the Monte Carlo analysis does not fully capture uncertainty. Many of the assumptions made are inappropriate. For example, fish concentrations are assumed to occur entirely at one segment of the river or another. This would be appropriate if one were to assess the interindividual variability in exposure for a subreach. However, the uncertainty analysis

should include an estimate of the limits of credibility on the average concentrations in various fish species caught from each subreach of concern.

Food losses of PCBs as a result of cooking and preparation of fish is treated in the present EPA assessment as an uncertain variable. In actuality, losses due to food preparation should be treated as both a frequency distribution representing individual variability in food preparation, and as a probability distribution representing the state of knowledge in the average amount of loss for the population as a whole. One would expect to have differences in losses of PCBs from meal to meal and from year to year. The assumption of 0% loss for all meals over all years is implausible.

(5) *Uncertainty in cancer and non-cancer health endpoints should be included explicitly.* Although there is EPA policy guidance that discourages risk assessors from explicitly considering the uncertainty in cancer slope factors (CSFs) and Reference Doses (RfDs), the risk calculation cannot be considered to be scientifically defensible until uncertainty is in the toxicity coefficients is properly accounted for in the human health assessment.

It is EPA policy to allow for the expression of uncertainty about toxicity in ecological risk assessment. It is thus inconsistent to exclude the evaluation of uncertainty in the toxicity coefficients from the human health risk assessment of PCBs.

If EPA policy mandates the exclusion of the evaluation of uncertainty in the toxicity coefficients, then the human health risk assessment ceases to become a true risk assessment, and instead is restricted to a regulatory compliance calculation.

A detailed evaluation of potential uncertainty in the PCB toxicity coefficients is important because of the potential exposure of very large numbers of individuals. This is the case for the Upper Hudson River. Under baseline conditions, there would be no restrictions to the access and harvesting of fish. Baseline conditions should include sport fishing, unlicensed fishing, harvesting of other biota, and commercial fishing.

I thus conclude that the present EPA HHRA, although adequate for identifying a situation of regulatory concern, is inadequate as a scientifically defensible risk assessment. The present risk

assessment may either over- or understate the true risk depending upon what information is and what information is not included in the analysis.

The following sections give my answers to specific questions that have been posed by EPA:

EPA Question 1, Hazard Identification and Dose Response

The human health risk assessment uses the most recent values of the cancer slope factors and noncancer risk RfDs listed in the Integrated Risk Information System (IRIS). This is the agency's database of consensus toxicity values. However, IRIS clearly states that risk assessors may use more recent data when such data are available.

The use of IRIS values of PCB toxicity is appropriate for indicating the presence of contamination that warrants regulatory concern. The cancer slope factors and RfDs, however, do not indicate the actual risk of cancer or of noncancer endpoints, because the uncertainties associated with these quantities are not included as a part of the risk assessment. Although RfDs are derived from NOAEL's or LOAEL's by a factor called an "uncertainty factor (UF)," these UF values do not disclose uncertainty. Values of UF are much like safety factors. Their use in the presence of uncertainty leads to a Reference Dose (RfD) to result in an adverse health effect. However, a noncancer Hazard Quotient for PCBs that exceeds 1.0 does not necessarily indicate that there is a significant health threat.

The most current RfDs used for PCBs include an uncertainty factor of 100 to 300. The potential for these values of UF to be overly protective should be assessed. For example, instead of multiple factors of 10 from subchronic to chronic exposure, and from animal studies to human studies, what if a factor of 3 had been used? Recent papers by Swartout et al. 1998, and Price et al. 1997a and 1997b, should be reviewed on this subject. Furthermore, it might be more appropriate to assess the combined amount of exposure to PCBs and other toxic substances, in order to look at the *total Hazard Index* and the *total cancer risk* from utilization of the Upper Hudson River, which would include exposure to water, sediment, and aquatic biota.

In conclusion, IRIS toxicity values of CSFs and RfDs are adequate for indicating levels of regulatory concern. They are in adequate for indicating levels above which human health risk will be

significant or intolerable. The present risk assessment may either over- or understate the true risk depending upon what information is and what information is not included in the analysis.

EPA Question 2: EPA asked the reviewers to comment on whether the specification of central tendency and reasonably maximally exposed individual consumption rates of 4 and 31.9 grams per day, equivalent to approximately 6 and 51 half-pound meals per year, respectively, are reasonable to capture interindividual differences in exposure for point-estimate calculations.

My answer is yes, this is reasonable. Six fish meals per year from the Upper Hudson River can be attributed to any one of a large number of representative individuals that could utilize the Upper Hudson River. Fifty-one half-pound meals per year also appears to be reasonable as a maximum estimate. This maximum estimate could be achieved by someone eating much more than one fish meal per week during the fishing season, and relatively few fish meals during the rest of the year, or by someone consuming multiple fish meals per week, but only harvesting a few of those meals from the Upper Hudson River. I consider both numbers to be adequate for point-estimate calculations.

In fact, for the Monte Carlo calculation, if one is estimating the uncertainty in the exposure and risk to reference individuals, it would be appropriate to fix the dietary intake for the representative (or reference individual). The values of 4 and 31.9 grams per day would then be appropriate for use as fixed reference values. The uncertainty in risk would then be restricted to the uncertainty in the toxicity coefficients, the uncertainty in the concentration of the PCBs in the aquatic media, and the uncertainty associated with losses of PCBs due to food preparation.

EPA Question 3: Along the 40-mile reach of the Upper Hudson River, the EPA has assumed central tendency and reasonably maximal exposure durations of 12 and 40 years, respectively, for a cancer causing substance, and 7 years for exposure to noncancer causing substances.

I believe that these values for point-estimate calculations are appropriate; however, because of the very large population that could be affected along the 40-mile reach, it may be more appropriate to also consider individuals who would spend their entire lifetime accessing fish from this region. The size of the population that potentially could utilize fish from this region may exceed tens of

thousands of individuals. For this reason it would be appropriate to consider individuals who could potentially be in residence for a period much longer than 40 years.

Much more important, however, is the fact that individuals won't necessarily harvest all of their fish from the Upper Hudson River. Some consideration should be given to the situation in which a residential angler living for more than 40 years along the Upper Hudson River actually consumes some amount of fish from other locations.

EPA Question 4: PCB concentrations in fish have declined in past decades, and the decline is expected to continue into the future. To evaluate noncancer effects for the maximally exposed individual, EPA used point concentrations in each medium (water, sediment, and fish), based on the average concentration forecast over the next 7 years from 1999 to 2006. For point concentrations for exposure, the central tendency exposure, EPA used the average of the concentrations forecast over 12 years, which is the 50^{th} percentile of the residence duration developed from population mobility data. In addition, for completeness, EPA averaged the exposure concentration over 40 years to evaluate noncancer hazards for the same time period over which cancer risk was calculated. The review team has been asked to comment on whether this approach adequately addresses noncancer health hazards to the central tendency and reasonably maximally exposed individuals.

I believe it is appropriate to specify a reasonable midpoint for averaging concentrations in fish for a short-term time duration of a 7-year exposure. However, because the Hazard Quotients for PCBs are so large, it is also appropriate to look at subchronic exposures that may affect critical population subgroups. In this case, exposure durations as short as one year should be considered. During a one-year time period, a person could be at much lower body weight than is currently assumed in the risk assessment. The uncertainty in fish concentration at a given location, as mentioned previously, is not adequately expressed in the present EPA human health risk assessment.

My personal preference would be for the assessment to focus on subreaches of the Upper Hudson River and for the uncertainty in the average fish concentrations to be determined for those subreaches. To average the assessment over the entire 40-mile stretch of the river is inappropriate, and there is the possibility that critical subgroups of the population will be missed because of the very large number of people potentially exposed if no restrictions were placed on public utilization of this aquatic resource.

EPA Question 5, The Monte Carlo Analysis: We were asked to discuss whether the Monte Carlo analysis used in the HHRA makes appropriate use of the available data, uses credible assumptions, and adequately addresses variability and uncertainty associated with the fish ingestion pathway; the last item would include defining the angler population, PCB exposure concentrations, ingestion rates, exposure durations, cooking losses, etc.

Having reviewed the Monte Carlo calculations in detail, I find that they capture neither the interindividual variability of potential exposure in risk, nor the uncertainty about a reference average individual or a reference maximally exposed individual.

Monte Carlo calculations serve two distinctly different purposes. The first and perhaps most important purpose is to propagate uncertainty through risk assessment algorithms (when it is difficult or impossible to propagate such uncertainty using algebraic formulae). When Monte Carlo techniques are used to propagate uncertainty, the present state of knowledge is expressed as a subjective probability distribution given all of the evidence available (NCRP, 1996; IAEA, 1989; Cullen and Frey, 1999; National Research Council, 1994). A subjective probability distribution is specified for each variable that can be considered to be a true but unknown quantity.

In the present EPA human health risk assessment, the Monte Carlo calculation is not used to propagate uncertainty, but instead to simulate interindividual variability of exposure. Interindividual variability is assumed to be a stochastic, random process, which, of course, is not the case. There are distinct reasons why some individuals choose to eat more fish than do others.

A more practical approach would be to specify several reference receptors and use Monte Carlo techniques to quantify uncertainty about the health risk to those reference human receptors. At the very least, the Monte Carlo techniques should be used to quantify uncertainty for a reasonable average individual and for a reasonable maximally exposed individual.

In this particular assessment, the Monte Carlo calculation utilizes the average fish concentration of PCBs for a 40-mile reach. This average value is given without uncertainty. The Monte Carlo calculation also assumes that a dietary survey for upstate New York for free-flowing fresh water is directly applicable to the case of the Upper Hudson River. This fish survey is for licensed anglers, of whom 221 responded out of 1000 questionnaires that were distributed.

It is well known that fish surveys that are based on individual recall are biased. The tendency is to overestimate the amount of fish caught and consumed. The extent to which the distribution defined by 221 individuals may be biased has not been assessed. Instead, the 221 values are used verbatim, after unreasonable values at the low and high ends have been censored by the authors of the risk assessment. The censored values include those who reported more than 1,000 fish meals during the year and those who reported no fish meals during the year.

Several items are missing as the result of the empirical use of the 1991 fish survey results: (a) The extent to which the average value for this distribution is biased high, (b) the extent to which the upper end of the distribution is biased high, (c) the extent to which the relative variability reported from the distribution may be biased high, and (d) the extent to which a single-year recall survey is representative of a 7 to 40-year average also needs to be assessed.

The failure of the Monte Carlo calculation to consider uncertainty in fish concentrations, uncertainty in the amount of fish consumed that is actually caught or harvested from the Upper Hudson River, and the uncertainty associated with the use of empirical survey data to represent the dietary pattern of the population that might consume fish from the Upper Hudson River over a period of 7 to 40 years, renders the results of the Monte Carlo analysis uninterpretable.

Simulating individual variability in a large population is a daunting task. Relevant data must either be available or the uncertainty associated with partially relevant data must be explicitly considered. My present evaluation is that the high-end exposure is more than likely over-estimated for the 95^{th} percentile, but the 99^{th} percentile and above are potentially underestimated because the dietary survey is truncated as a result of only 221 respondents. I believe the Monte Carlo calculation for interindividual variability should include the total number of people potentially exposed so that one can judge how many people could have a risk above a regulatory level of concern, and how many people could have risk extending into a region of a likely health threat.

Of course, the present Monte Carlo distribution does not include the variability or uncertainty in cancer slope factors and RfDs. Thus, the risk assessment is interpretable only from the standpoint of regulatory concerns, not from the standpoint of potential health risk. Because exposure to multiple contaminants in the aquatic medium has not been taken into account, it is virtually impossible at present to make an overall assessment of health risk other than to state that if fishing

restrictions were to be removed, it is very likely that the majority of the population who would consume fish from the Upper Hudson River would be exposed to PCBs at a level that would warrant regulatory concern.

EPA Question 6, The adequacy of EPA's evaluation and use of existing angler surveys in the Monte Carlo analysis of the fish ingestion pathway:

I touched upon much of this in my answer to the above question; however, I think that it is important that the potential sources of bias in any fish angler survey be considered explicitly. If the objective of the assessment is to estimate the exposure to the entire population who has consumed fish from the Upper Hudson River, then it is important to evaluate the extent to which angler survey data may be biased and might either under- or overstate the amount of actual fish consumption that occurs.

I believe the upper end of the distribution can be grossly overstated from the true values that would occur over a 10- to 40-year time period. I also believe that the interindividual variability, (or the geometric standard deviation) of the distribution, is overstated because the survey is based on individual recall for a relatively short time period.

For cancer-causing substances, I believe it is more important to look at the uncertainty on the *average* fish consumption than it is to look at the uncertainty on the median. The median in this case will understate the total cancer risk to this population. The total cancer risk (number of cases in the population), is a product of the *arithmetic mean* exposure in the population, the size of the population, and the cancer slope factor.

The sensitivity analysis, which uses (a) a range of variables of fish concentrations in the river, (b) a range of loss fractions due to cooking and preparing fish prior to human consumption, and (c) alternative databases for angler surveys, only partially captures the uncertainty that is present. The cooking loss variable is more appropriately expressed as a source of inter-individual variability of exposure. The uncertainty about the average loss due to cooking over a 10- to 40-year lifetime history of individuals capturing fish from the Upper Hudson River is much less than the range of 0 to 40% assumed in the HHRA.

EPA Question 7, Risk Characterization: Risk characterization in the human health risk assessment summarizes the cancer risk and noncancer hazards to individuals who may be exposed to PCBs in the Upper Hudson River. The reviewers were asked to comment on whether the risk characterization adequately estimates the relative cancer risks and noncancer hazards for each pathway and exposed population. Have major uncertainties been identified and adequately considered, and have the exposure assumptions been described sufficiently?

Again, the HHRA assessment adequately discloses that exposure to PCBs is of regulatory concern. However, to evaluate the health risk from exposure to PCBs and other contaminants existing in the Upper Hudson River, far more information is needed than is available at this time. The uncertainty associated with cancer slope factors and RfDs should be taken into account explicitly in order for the uncertainty in the risk estimates to be properly expressed. Without such uncertainty estimates, the risk of making the wrong decision when determining the feasibility of cleanup cannot be evaluated.

My conclusion is that the risk characterization, although adequate to indicate a situation of regulatory concern, is clearly inadequate for expressing the degree of health risk that may be present under baseline conditions. The true health risk may be grossly overstated in some aspects, and in other aspects, it may be understated. The extent to which it is either overstated or understated cannot be evaluated given the information at hand.

EPA GENERAL QUESTIONS

EPA General Question 1, Clarity and Transparency of the HHRA

This HHRA is consistent with other regulatory documents that I have reviewed; however, this and the other documents all suffer from being written for an audience of regulators, not for an audience of individuals who might be concerned with potential health hazards associated with consuming PCB-contaminated fish from the Upper Hudson River.

My recommendation is that the overall report be carefully edited, the use of regulatory acronyms and jargon eliminated, and the report re-written so that an interested individual can readily comprehend the content of this report.

Many of the figures are presented on a linear arithmetic scale. They should instead be plotted on a logarithmic scale (but retaining the arithmetic units). The use of the logarithmic scale is most appropriate for evaluating *relative differences* (as opposed to absolute differences) in trends over time. The probability plots that are presented in the present HHRA on fish consumption rates from various angler surveys are virtually unreadable to all but statisticians. These plots should be redrawn showing the number of fish meals on the y-axis (preferably using a log scale), and showing the relative probability or cumulative probability on the x-axis. Software is readily available that will allow a more transparent presentation of probability plots.

EPA General Question 2, Provide any other comments or concerns about strengths and weaknesses of the HHRA

I would like to understand how exposure to other contaminants, in combination with the ingestion of PCBs, affect the total cancer risk, as well as the noncancer health risk, to individuals consuming fish from the Upper Hudson River.

I would give a much lower priority to the use of Monte Carlo calculations to simulate interindividual variability, unless it is the objective of the assessment to indicate the fraction of the total population of exposed individuals that would be potentially at risk. If this is the case, then the empirical use of angler surveys are clearly not relevant without some correction for bias. The relevant population of

concern are those individuals who would consume fish from the river under baseline conditions, including the families of licensed anglers, unlicensed individuals who utilize the Hudson River as source of food, and those who eat fish from commercial operations. The latter would involve the consumption of fish shipped to restaurants, supermarkets, and so forth.

I believe the strength of the present human health risk assessment is to demonstrate that even under the most optimistic conditions, PCBs in the Upper Hudson River present a regulatory concern. I believe the most pronounced weakness is the failure to disclose uncertainty in individual exposures and health risk.

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Appendix of Detailed Comments
Volume 2F – Human Health Risk Assessment Hudson River PCBs Reassessment RI/FS

Page ES-2, Exposure Assessment

The RME and CTE capture differences between the high end and the averages, although CTE may be underestimated. Uncertainty about the CTE and RME needs to be quantified. Estimates of RME and CTE need to be made for each location of concern as opposed to the entire 40-mile stretch of river.

Pages ES 2-3, Ingestion of Fish

The extent to which a recall survey of 221 individuals (licensed anglers) is applicable to the population of individuals potentially consuming fish from the Upper Hudson is questionable. Also questionable is the representativeness of the data for exposure durations of 7 to 41 years.

Assumptions about PCB losses during cooking and the fraction of sport fish consumed that come from the Upper Hudson River is questionable. Especially considering a 7- to 40-year exposure duration.

Younger ages may be important if a sub-chronic exposure to PCB is considered important. For non-cancer risk, background PCBs in diet should be accounted for. Uncertainty in UF should be expressed in the risk analysis.

Specific Remarks

1) There is a need to simulate random variability of the high end of the distribution separately, accounting for all potential aspects of partial relevancy of data.

2) The population should be all those consuming fish from the Upper Hudson River, not just licensed anglers.

3) The 1-D Monte Carlo simulations do not consist of 10,000 simulated anglers in that an empirical distribution of New York anglers is used with over 221 data points.

4) The fraction of fish caught beyond the Upper Hudson River should be included as a variable.

5) None of the 72 alternative distributions address uncertainty; they are simply alternative data sources to extreme assumptions about fish concentrations at a fixed location as opposed to the average for the entire reach of 40 miles. Variability in losses due to food preparation are ignored and artificially treated as a source of uncertainty.

6) When the objective is to simulate the frequency of real exposures in a real population of individuals, the best estimate of central tendency is the arithmetic mean, not the 50^{th} percentile.

7) When the objective is to simulate a true frequency distribution of risk, the target population must be rigorously defined and the size of the exposed population estimated. It is presently not known if the Monte Carlo simulation refers to a population size of a few hundred or 10's of thousands of individuals assuming that there would be no restrictions on the harvesting of fish.

To estimate uncertainty, I recommend a 1-D Monte Carlo simulation be performed for the RME and for the CTE at each subreach of the Upper Hudson River.

Page ES-4

Need to state what the results were from Kimbrough et al. (1999).

Since the size of the population representative of the RME is less than 10,000 individuals, this would translate to a low probability of even one excess case of cancer. Again, the CTE for a total population of approximately 100,000 individuals would indicate less than one excess case of cancer. The CTE estimate should be based on the arithmetic mean, not the 50^{th} percentile of the population.

Page ES-4, Risk Characterization

Risk estimates should include a < sign to reflect the fact that the CSF are upper bound estimates.

Uncertainty in RME and CTE risks need to be disclosed.

Cancer risk should be estimated for all chemicals and radionuclides contained in Upper Hudson River Fish, not just PCBs alone, unless it is certain and PCBs are dominant. General bans on fishing may be more health protective than attempts to remediate only for PCBs.

Page ES-5

The Hazard Index should be estimated for all chemicals in food having the potential to induce effects on the same organ or tissue. Background exposures to these chemicals should be added to what is measured in fish tissue from the Upper Hudson River.

Page ES-5, Monte Carlo Estimate

There is a need to show the size of the population that is potentially affected. This Monte Carlo summary is a mere mathematical exercise. There is no rigorous attempt to quantify uncertainty. The table is meaningless. A total revision is recommended.

Uncertainty about variability is not depicted. All data sets used have uncertainty. To say that all fish meals for all persons over 40 years will be taken from one location and subjected to losses of zero percent is unrealistic.

Page ES-6, Table

Need to show uncertainty in UF.

Page ES-6, Comparison of Point Estimate and Monte Carlo Analyses

"For non-cancer hazards, the point estimate RME for fish ingestion (116) falls between the 95th and 99th percentiles of the Monte Carlo base case" this is only because of the assumption of 20% loss for cooking.

Page ES-6, Major Finding of the HHRA

The following statement is not true: "Under the RME scenario for eating fish, the calculated risk is one additional case of cancer for every 1,000 people exposed. This excess cancer risk is 1,000 times higher than USEPA's goal of protection and ten time higher than the highest risk level allowed under Superfund law."

There is a need to assess uncertainty in UF for the following statement: For non-cancer health effects, the RME scenario for eating fish from the Upper Hudson results in a level of exposure to PCBs that is more than 100 times higher than USEPA's reference level (Hazard Index) of one.

Page 2, first paragraph

The baseline risk assessment should include the plausibility of a commercial fishery as existed prior to 1976.

Page 5, 4th paragraph

The following statement is not advised: "...such that the RME can be determined based on estimates from the high-end of the Monte Carlo exposure distributions."

Page 7, Section 2.1.2, Potential Receptors

Without restrictions, how many would consume fish from the Upper Hudson River?

Page 10, Section 2.3 Exposure Point Concentrations

Last two sentences in this section are not true.

Page 13, first paragraph

Variability versus uncertainty.

Page 13, Concentration Averaged Over Locations

Treat each location separately.

Page 35, last paragraph

This is not a risk assessment.

Page 36, second equation

Is not 100%.

Page 37, Section 3.2.1, Fish Ingestion Rate

The first paragraph is not based on the survey.

The last paragraph is not relevant to the assessment question.

Page 39, second paragraph

What is the relevancy?

Page 43, first paragraph

For cancer causing substances, the mean is more relevant than is the median.

Page 46, Single Versus Multiple Waterbodies

This is for the year but not for the 12 to 40 year duration.

Page 48, fourth paragraph

Table should be 3-5.

Page 49, second paragraph

Untrue.

Page 58, second paragraph

Should consider correlation with ingestion.

Table 3-1

There is no uncertainty given for the size of fish meal used.

Table 3-2

Show the mean value.

Table 3-5

Losses due to cooking are both uncertain and variable.

Table 3-16

The information presented is not consistent with the scale of time-averaging of the risk assessment. These distributions do not refer to the 12 to 40 year average. Instead it gives the distribution for the body weight at a given time of measurement. It is not even relevant to the uncertainty in an annual average body weight.

Figure 3-2

Many of the figures are presented on a linear arithmetic scale. They should instead be plotted on a logarithmic scale (but retaining the arithmetic units). The use of the logarithmic scale is most appropriate for evaluating *relative differences* (as opposed to absolute differences) in trends over time. The probability plots that are presented in the present HHRA on fish consumption rates from various angler surveys are virtually unreadable to all but statisticians. These plots should be redrawn showing the number of fish meals on the y-axis (preferably using a log scale), and showing the relative probability or cumulative probability on the x-axis. Software is readily available that will allow a more transparent presentation of probability plots.

Pamela Shubat

Pamela Shubat has an M.S. in Fisheries and Wildlife from Oregon State University and a Ph.D. in Pharmacology and Toxicology from the University of Arizona. During her past eleven years with the Minnesota Department of Health she has been responsible for the state fish advisory program and managed a childhood lead prevention program. Previous to her work with the state she worked as a contractor at the U.S. EPA aquatic research laboratories in Duluth, Minnesota.

Pam is currently a research scientist with the Minnesota Department of Health's Health Risk Assessment Unit. She is working on children's exposures to environmental hazards. Much of this work focuses on assessing risks from exposures to pesticides, metals, and volatile organic compounds. She is involved in state rulemaking on health risk limits for contaminants in drinking water. In addition, she is involved in outreach and communication on environmental health risks at the state and national level.

Shubat,

Peer Review of the Human Health Risk Assessment (Volume 2F) of the Hudson River PCBs Reassessment RI/FS

Pamela Shubat, Ph.D.

May 5, 2000

Hazard Identification/Dose Response

1. Comment on the reasonableness of the approach for evaluating dose-response, specifically, evaluating new toxicity data (available after the most recent update to the IRIS files) in the context of the uncertainty analysis (HHRA pages 76-77 and Appendix C).

A concern in choosing appropriate reference doses is whether the congener profile of the PCBs found in the fish in the Hudson matches a particular Aroclor congener profile closely enough so that the use of the Aroclor-specific toxicity value is justified. Homologue patterns discussed during Edward Garvey's presentation on March 23, 2000, showed that PCBs in fish matched Aroclor 1248 (slides showed river reaches and specific fish species). The Human Health Risk Assessment, Volume 2F (HHRA) makes it clear that risk assessors could only choose between reference doses (RfDs) available from the U.S. Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS). The two available RfDs were for Aroclor 1016 and 1254. The HHRA states (page 62) that although General Electric primarily used Aroclor 1242 in their operations, the congener profile in fish tissue is more similar to Aroclor 1254 than Aroclor 1016 (in this particular paragraph, the resemblance of the congener profile to Aroclor 1248 was not relevant).

The apparent shift from a release of Aroclor 1242 to a profile in fish tissue resembling Aroclor 1248 is consistent with descriptions of environmental partitioning in which the more heavily chlorinated congeners persist in biological tissues. However, it is not until the reach between river miles 0 and 60 (slides from E. Garvey's presentation) that the homologue pattern appears clearly dominated by the more heavily chlorinated homologues. The change in this partitioning (shift to more chlorinated homologues) is not discussed sufficiently to understand whether spatial (down-stream), temporal, fish species, or age of fish considerations will lead to additional changes in the homologue pattern in fish. If additional changes are anticipated over the time

frame of the HHRA, there could be discussion in the HHRA about the appropriate RfD to utilize over time or space.

However, since an IRIS RfD for Aroclor 1248 or 1260 does not appear to be available at this time or the near future, the use of this information would not likely lead to a change in the HHRA for non-cancer health effects. However, I did not review the papers by Arnold or Rice, and am not familiar with the non-cancer dose-response reassessment that is underway by the EPA.

Some issues that could be addressed:

- An RfD based on Aroclor 1248 would be desirable. However, it is not clear whether the long term exposure will continue to be a mix of congeners that resemble Aroclor 1248. Over the duration of the risk assessment it is possible that the mix will eventually more closely resemble Aroclor 1254. This strengthens the rationale for using the 1254 RfD.

- It is not clear that an RfD for Aroclor 1248 would be substantially different from the currently available RfD for Aroclor 1254. The HHRA (page 62) and IRIS files (4/12/00 website) suggests that the toxicologic endpoints for Aroclor 1248 are similar to 1254. This also strengthens the rationale for using the 1254 RfD.

- PCBs appear to be recognized as hormonally and immunologically active and have neurobehavioral effects (Brouwer, et. al., 1999). However, no models are available to extrapolate from these data to a dose-response relationship for risk assessment. While the scientific problems of testing for endocrine disruption were discussed briefly in the risk characterization (HHRA page 77) the public health implications were not discussed. Are there reasons to add additional conservatism and uncertainty in a risk assessment when the endocrine system is affected

Exposure Assessment

2. Comment of the use of the 50th and 90th percentile data from the Connelly study for use as the average and RME individuals (point estimate calculations).

The 1991 Connelly survey (Connelly et. al., 1992) reflects a great deal of experience with fish consumption surveys. There are limitations to the study, largely because the primary purpose of the survey was to collect information on fish advisories rather than fish consumption. Limitations include: (1) anglers were not asked about meal size, (2) anglers were asked to recall fishing activity and fish consumption over an entire year, (3) the mail survey required literacy skills in reading and writing, including entering data into tables, (4) the survey was limited to licensed anglers, and (5) the survey excluded family members (including children) who ate fish caught by an angler.

The strengths of the survey include (1) excellent characterization of non-respondents (unusual to find in fish consumption surveys), (2) a large sample size (1,030 overall, however, for certain purposes it appears that catch data from fewer anglers was used--HHRA Table 3-3), and (3) details on the fishing locale for each fish caught and meal eaten. The HHRA contains an excellent general discussion of the strengths of the mail surveys versus creel surveys, lending support to the use of the Connelly survey.

The following is a detailed discussion of the limitations of the use of the Connelly survey:
(1) Meal Size. The quantity of fish consumed in a single meal is difficult data to collect even with food diaries. A survey participant must receive coaching and use a food scale to accurately report the weight of a serving of fish. Many different approaches have been used to quantify consumption in interviews or mail surveys, with plastic models of serving sizes, scale drawings, or photos of fish arranged on a standard-sized dinner plate being most often used. This survey only collected information on the number of meals consumed per fishing experience. A choice was made by the risk assessors to quantify the meal as 227 g or 0.5 pound based on reports that are unrelated to the Connelly survey.

Other studies support the use of a half-pound fish serving for avid fish eaters. The Chemrisk/Ebert survey of Maine anglers produced an estimated 95th percentile intake for adults

of 26 g/day for all anglers who ate their catch and 12 g/day for river anglers. These meal sizes were based on an arguably more accurate approach of calculating edible portion from what was known about the size of the fish (self-reported). The EPA Exposure Factors Handbook shows "consuming angler" estimates for the mean intake of 6.4 g/day, the 50th percentile of 2 g/day, and the 95th percentile of 26 g/day.

West surveyed Michigan anglers throughout the opening of a fishing season. Each angler estimated their meal size as larger, smaller, or about the same as 8 ounces. The EPA reanalyzed the West data (Exposure Factors Handbook, 1996) using 5, 8, or 12 ounces estimates of meal size. The study was based on very short-term recall (the past seven days) and the angler referred to a picture depicting the meal in order to judge their own meal size. According to the EPA, the mean intake was 14 grams/day, the 50th percentile was 11 g/day, and the 95th percentile was 39 g/day. The West data are important in providing information about children's intake (0.37 grams fish/kg human body weight/day for children 1-5 years old vs 0.14 grams fish/kg human body weight/day for adults 21-40 years old--however, this precision is not warranted).

In summary, a limitation of the HHRA is that a single meal-size was assumed in both the point estimate and, apparently, the Monte Carlo simulation. Meal frequency varied in the point estimate and meal frequency and body weight varied in the Monte Carlo analysis. This would appear to result in an overestimate of exposure (e.g., 227 g/meal for a 60 kg as well as a 70 kg person) assuming that there will be more simulations using less than 70 kg than simulations using a larger body weight. During the oral presentations there was mention of an assumption that the meal size for a child was 1/3 the meal size assumed for an adult. However, this information wasn't apparent in the HHRA. On page 69 of the HHRA, it says "If it is assumed that a child meal portion is approximately 1/3 of an adult portion....". There was insufficient discussion of the relationship between meal size and human body size to understand what was used in the risk assessment.

Information from the 1989 West study (as reported in the exposure factors handbook) suggests that there are large (almost 3-fold) differences in the intake per body weight for children vs adults. If so, 227 g fish per 23 kg (a six-year-old) could be an appropriate assumption of intake. This should be discussed in the HHRA. A minor irritation is the representation of precision in the HHRA estimates given that the assumed consumption is 0.5 pounds fish per meal.

(2) Recall Bias. Recall bias related to the frequency of meals is another extremely difficult issue in fish consumption surveys. The Connelly survey asked the angler to recall a year of fishing including location, catch (numbers of fish per species), and total numbers of meals eaten of each species caught on each body of water. Connelly, in a later recall survey which surveyed anglers who had maintained fishing diaries (Lake Ontario survey), found that anglers who fished frequently were most likely to overestimate the numbers of fish they caught. The implication is that this HHRA will be an overly conservative estimate of intake for the frequent angler. The best fish survey that avoided recall bias was the West study of Michigan anglers, which was based on very short recall (seven days). Multiple "waves" of surveys were sent out to new participants so that the survey covered a large portion of the fishing seasons and, as a result, was administered to a large population.

Encounter surveys (creel surveys) or angler interview surveys are often used for assessing potential exposure, knowledge of advisories, and compliance with regulations and advisories. The more often an angler fishes, the more likely the angler will be included in a creel survey. Therefore, the standard creel survey is most useful for the purpose it was intended--to survey the productivity of the fishery (what is being caught and kept). It was not clear whether creel surveys on the Hudson or its tributaries were available, and any would be difficult to interpret because of the ban on consuming fish. However, the New York State Department of Environmental Conservation River Enforcement Summary of the enforcement on the catch and release fishing program may provide data that could be compared to Connelly survey concerning the type of fish caught and released.

The Connelly survey (Connelly et. al., 1992) did not describe how the species list shown in the survey was drawn up. The list of species and the way they are identified closely resembles the species list in the New York fish consumption advisory for 1991. While this is the appropriate set of data for Connelly to use in a survey of compliance with fish advisories, it is not the set of data to use to determine the species that would be fished if advisories were not in place. It is not clear if the EPA solicited fisheries management data, conservation enforcement data, or recent surveys on fishing preferences.

In summary, it appears that by using the Connelly data for the frequency of fish meals, recall bias could result in a conservative assumption of meal frequency for the frequent angler. It appears that the Connelly data do not provide the best data on the fish that Hudson River anglers would be catching if advisories were not in place. More recent surveys of angler preferences for fish, creel surveys on the lower Hudson, or enforcement data should be used to provide data on the species of fish likely to be sought by anglers.

(3) Literacy. The characterization of the non-respondents should have assisted in determining whether literacy concerns limited the response rate. This was not discussed in the Connelly survey or the HHRA. A simple discussion of the literacy rate in the surrounding counties during the years of the Connelly study, perhaps through census data on language spoken at home, enrollment in literacy programs, or immigration data from the state demographer, would provide assistance in understanding whether literacy was potential concern in 1991 and might have biased the survey.

This leads to the need for an overall discussion of whether the demographics of the population surveyed by Connelly still reflect the population considered as current potential anglers on the Hudson. Demographic data for 1999 were not presented and should be examined for income, racial/ethnic makeup, literacy, barriers to licensure, or other factors that would potentially influence fishing for sustenance.

(4) Licensed Anglers. The discussion of unlicensed anglers is insufficient (HHRA page 45). An understanding of the fishing and fish-eating habits of licensed and unlicensed anglers is important in understanding whether the Connelly survey data (collected through a mail survey to licensed anglers) are appropriate for use in the risk assessment.

Data are not provided on the number of anglers that are thought to be unlicensed or any demographic data for this population. I have presumed that the New York State Department of Environmental Conservation enforcement summary of the catch and release fishing program pertains to the Hudson River (one page summary given to reviewers on March 23, 2000). These data show that 165 of 324 violations were due to "no license." This included warnings, which might have meant that the officer believed the angler was licensed but was not carrying a license.

Of 1437 anglers checked over a three year period, 72 were ticketed for no license. If these were truly unlicensed anglers, the rate is 1 in 20, and if warnings had been given to unlicensed anglers, the figure could be 1 in 10.

Licenses are not currently required on the lower Hudson (Ed Horne, New York Department of Health, personal communication). The HHRA should include information about whether or not Hudson River anglers must be licensed. If anglers were not required to be licensed in the year of the Connelly study, the HHRA should discuss the uncertainty of applying data collected on licensed anglers to the HHRA.

The obvious question is whether these anglers consume more fish than the participants in the Connelly angler survey (see Hudson River Sloop Clearwater survey below). Barriers to purchasing a license could be poverty, poor literacy skills, or resistence to government control, all of which could influence a choice to eat fish from the river despite postings.

(5) Women and Children. A second concern related to surveying only licensed anglers is that the survey will not include children. The Maine survey data by Chemrisk in 1991 included questions about the family and whether the individuals in the family were consuming fish brought home by the angler. A shortcoming of the survey was that participants were not asked about meal size. The Hudson River Angler Study conducted by the Hudson River Sloop Clearwater, Inc. in 1993 included questions about how a catch was shared with others. Surveyors found that 87 percent of anglers who ate their catch shared the fish with others (Exposure Factors Handbook, August 1996). Presumably this included women and children in households.

Other Comments

The Hudson River Angler Study focused on awareness and compliance with fish advisories. Only 336 anglers were surveyed (1991-1992) and all were shore-based anglers. These data have the same limitations as the creel survey in that the more frequently an angler fishes, the more likely the angler is interviewed. The surveyors found that "more low-income than upper income anglers eat their catch" (Exposure Factors Handbook, 1996). They also found approximately ten percent of anglers were fishing for food rather than recreation. Data available in a thesis by

Wendt were cited in the HHRA to show that the arithmetic mean of meal frequency among low-income families was less than that of the Connelly study. The distribution of meal frequency was not discussed.

While anglers do not always eat their catch, it is appropriate to focus this risk assessment on the exposed population. Therefore, eating one's catch at least once a year is an appropriate criterion for inclusion in the risk assessment. This means that the eating habits of those who eat fish less frequently or episodically or not relevant to completing the HHRA.

It is important to ensure that the most exposed populations have been included. It is not clear whether there was an attempt to investigate the population surrounding the river for demographic characteristics that have been associated with high fish consumption. Although children are not likely to eat fish more frequently than the adults in the household who bring home the catch, they may be more exposed due to a larger meal size per body weight. Children's exposures are not adequately addressed in limiting intake to the meal frequency data from the Connelly survey.

Another potential concern mentioned in comments and the HHRA is that the fishing advisories suppress consumption and therefore suppress the potential intake rate. The HHRA states that the effect of general fishing advisories (e.g., 52 meals per year or less) for New York are taken into account because these were in place during the Connelly survey (HHRA, page 46), The effect of repressing consumption would be constant throughout the state and, unless the state is considering removing these general advisories, the suppressive effect would continue into the future.

Reviewers were asked to comment on the use of the 50th and 90th percentiles for fish ingestion used for the central tendency and reasonably maximally exposed (RME) individuals. I have presented all the other questions that may be important to address concerning the fish that would be eaten today and who is eating them. While the Connelly data may not have provided the best data on subpopulations that have been a concern to those creating fish advisories, the survey does to provide the highest quality data on meal frequency to use in the HHRA. The values of 4 and 32 grams per day can be defended for adults.

(3) Comment of the assumption of a 12 and 40 year exposure durations (HHRA pages 23, 49-57) for use, respectively, of average and RME individuals (used in the point estimate for cancer).

The HHRA (Table 2-12) uses a exposure duration of 40 years of exposure to 2.2 mg PCBs/kg fish averaged over a 70 year lifetime to create the RME dose of mg PCB/kg body weight/day for cancer risk estimates. The central tendency estimate uses 12 years of exposure to 4.4 mg PCBs/kg fish averaged over a 70 year lifetime.

These exposure values appear based on reasonable interpretations of fish survey and residence data and reasonable assumptions concerning movement within a relatively small geographic area. Since the risk assessment is concerned with incremental risk from the Hudson River fish and not incremental risk from all sources of PCB-contaminated fish, it appears appropriate to ignore an angler's exposures to PCBs before 1999 or after moving away from the river. These other PCB exposures will hopefully be considered by risk managers interpreting the results in the broader context of PCB exposures from multiple sources. It is clear from the responsiveness summary that some who submitted comments do not trust risk managers to keep in perspective that this is an incremental risk that does not address past exposures to fish contaminated from the same or alternative sources of PCBs.

Cogliano reviewed a study in rats that included less-than-lifetime exposures to Aroclor 1260 (via food) and measured cancer incidence. The results suggested that cancer risk measured at two years could be attributed to the exposures that occurred during the first year of dosing (Cogliano, 1998). Some consideration should be given to whether or not these less-than-lifetime dose response findings are adequately addressed in the HHRA and reflected in the choice of a 70 year averaging time for exposure duration. The other Aroclor mixtures administered in cancer studies did not show this same potency for less than lifetime exposures.

(4) Comment on the average concentration in fish for 7, and 12 years used in the non-cancer point estimates (HHRA pages 67-68).

The HHRA (Table 2-12) uses an exposure duration of 7 years to calculate a high-end fish PCB concentration and averages the exposure over 7 years. Likewise, for the central tendency, the HHRA uses an exposure duration of 12 years and averages the exposure over 12 years.

The span of years for averaging exposures that is described in Risk Assessment Guidelines for Superfund is not specific for the chemical of concern, the toxicologic endpoint of concern, and the environmental conditions. The HHRA thoroughly discusses the decrease in PCB levels in biota over time and the need to represent current levels in the HHRA. The toxicologic endpoints of concern for the RfD used in the point estimate result from exposures during 25 percent of the life span of rhesus monkeys. This is equivalent to a period in a human life between approximately 4 and 23 years of age. Other endpoints of concern (reproductive and fetal development) may result from very short-term exposures.

The length of the exposure duration and averaging time is appropriate for the toxicological endpoints. Each of the selected exposure and averaging times results in an unacceptable hazard quotient. Since there is no attempt to describe health effects associated with a hazard quotient greater than 1, the choice of averaging times in combination with fish tissue levels does not appear to be worth discussing further.

(5) Comment on the Monte Carlo analysis for the fish ingestion pathway (HHRA pages 72-74)

I am inexperienced with Monte Carol analysis but have discussed use of the angler surveys in the analysis (see the next question). There was remarkable effort to work out the out-migration and residence data of anglers. In contrast, it appeared that the fish data were condensed (?) into a few samples (table 5-24?), data were reduced to a few species, and grouped into a few river reaches (Table 3-4). The river must certainly be a more complex system than portrayed in the HHRA.

I cannot tell whether the Monte Carol analysis would have been different or improved by separating meal size and meal frequency parameters rather than using a distribution for ingestion

rate. I would have preferred treating the meal size (0.5 pounds) as a constrained parameter (Equation 3-1) and using the New York Angler Survey to create the variable for frequency of meals. By using meal size as a constrained parameter, it might have been easier to understand the effect of varying meal size based on age and body weight.

The work that went into the Monte Carlo analysis was best described in the risk characterization section on uncertainty, pages 77-80. It was difficult to understand all of the inputs and permutations that were modeled and it is not clear that these were adequately described in the HHRA.

(6) Comment on the use of the angler surveys in the Monte Carlo analysis (HHRA 37-46).

As discussed above, Figure 3-1 of the HHRA shows that body weight and fish ingestion rate are treated as independent distributions. The HHRA (page 46) stated that the same number of meals per year was used for adults as for children, but scaled according to body weight. It is not clear from the text (page 46) what this means and seems contradicted by the description of meal size on page 42. It is not clear how meal size should be scaled to body weight (see description of the West survey data, above, under "meal size").

The Monte Carlo analysis appears to be responsive to a the concern that anglers preferentially fish and eat certain species of fish (Table 3-3 and text page 48). However, the assumed fish species consumed may not apply to the Upper Hudson if angling for food is assumed. While it is not appropriate to use local surveys conducted while local fish advisories are in place in order to determine ingestion rates, it may be appropriate to use these surveys to examine angler preference for fishing certain species. This is because the fishery itself will have a large impact on angler preference for species. The HHRA did not present this type of data or angler perception of the fishery in the Hudson. It is interesting that very little information on fishery and angler management shows up in the HHRA.

Risk Characterization

(7) Comment on whether the risk characterization adequately estimates risks and hazards (chapter 5, pages 67-80).

The risk characterization is a very straight-forward combination of the dose-response and exposure data. It does not over state the non-cancer health effects by attempting to interpret the meaning of hazard quotients greater than 1, 10 or 100.

The risk characterization clearly lays out the concerns that went into choosing exposure durations of 7, 12, and 40 years, and the effect of these different choices.

I believe there could be greater depth and clarity in the explanation of the impact of using central and upper confidence limit PCB cancer potency slopes in the point estimates (HHRA page 64). The relationship between these values and the results of the Monte Carlo analysis is briefly mentioned on page 71, but further interpretation is not offered where I thought readers would look for information (in Section 5.3.3, comparison of point estimate RME and Monte Carlo results). It is not clear whether these choices are explained sufficiently for decision-making by risk managers.

General Questions

(1) Is the HHRA clear, consistent, reasonable, and transparent, as well as adequate (including children). How adequate are the HHRA and Responsiveness Summary when measured against these criteria?

I would have liked to see the relationship between modeled fish tissue concentrations, fish ingestion rates, and hazard quotients/cancer potency slopes also expressed as the length of time before fish would fall into fish advisory categories of 1 meal per month or 1 meal per week. In other words, the fish tissue concentration modeling would have been more meaningful, and consistent with the applied use of risk assessment in fisheries management, if the HHRA had also reported *when* the fish will be "safe" to eat according to current guidelines.

Although I believe the HHRA is adequate, focused in scope, and probably the best possible analysis using Risk Assessment Guidance (RAGs), there was no overall description of what was

important to pursue with detailed analysis and what was not. There were, however, elements of this type of critical thinking in responding to comments. This was a valuable part of the responsiveness survey (although, I'm sure irritating to the authors of the comments). For example, there was discussion that it was not necessary to calculate exposures/risks from some pathways because the contribution to risk was very small. An overall description of what was important to pursue with detailed analysis and what could be dismissed would have been helpful. Overall, I found the responsiveness summary a very important part of the HHRA and it clarified actions taken and assumptions made in preparing the HHRA.

The HHRA does not present an adequate discussion of risks to children, adolescents, or the fetus either in terms of exposure or toxicologic endpoints. There are unique food intake and toxicologic factors for children and adolescents that might have been discussed. No discussion is given to the results for children versus other age groups in the Monte Carlo analysis. While children as consumers of fish are included in the Monte Carol analysis, *in utero* exposure is not discussed. No discussion is presented in the risk characterization about who should be protected when the toxicologic endpoint for Aroclor 1016 is reduced birth weight resulting from exposure to the dam, or that the RfD for Aroclor 1254 is based on a study of monkeys exposed during the human equivalent of approximately 4 to 23 years of age. Adolescence is not specifically discussed and is a time in development that may be uniquely susceptible to immunotoxicants (Golub, 2000). A body of work is available on the effects of PCBs on thyroid hormone metabolism that may be relevant to this concern (Brouwer et. al., 1999).

(2) Please provide any other comments or concerns, strengths or weaknesses.

This was a well-written document. The language was clear and direct, the jargon was minimized, and the only thing missing for ease of reading by a general audience of scientists was a glossary of terms. The text was laid out in a logical fashion that followed standard risk assessment protocol. The tables and figures would have been improved with additional text in the titles or footnotes so that they might be more easily understood by someone browsing through the section. It was apparent in the answers to questions posed by reviewers that the data analysis was more complex and complete than presented in this document. More references to other documents might have been helpful.

There were constraints on the authors because standard Risk Assessment Guidance (RAG) for superfund sites was used to create the risk assessment. Some of these constraints were discussed, but probably not often or clearly enough. The authors could clearly anticipate where risk assessment practices are changing and in potential conflict with the RAG. A strength of the HHRA is that the authors utilize an appropriate conservative approach to interpreting non-cancer health effects. For example, there is no speculation about health implications of a hazard quotient of less than or more than 1.

I am impressed by the vast amount of effort that has gone into this site characterization over the years. Every question that came to my mind while reading the HHRA was also posed in a comment letter.

Recommendations

My views are likely to change after discussion with the other reviewers as I have little experience with some of the important parts of the HHRA that I assume will be discussed at the meeting.

At this time, I believe the risk assessment is acceptable with minor revisions. Those revisions will not result in changes in the inputs or outputs of the risk assessment, but would show up as a discussion of uncertainties.

1) Discussion of how the risk assessment fails or succeeds in addressing exposure and toxicology factors unique to children, adolescents, and fetuses. This should include a discussion of the intake per body weight of food. It should include a discussion of how the cancer and non-cancer health studies selected by EPA for the IRIS files specifically address children. **The uncertainty to address is whether or not risks to children, adolescents, and fetuses are adequately characterized in the risk assessment.**

2) Discussion of the demographic makeup of the statewide potential angler population in 1991 and the specific characteristics of those surveyed by Connelly. This discussion of what was happening in 1991 should include what anglers were and were not required to purchase licenses and therefore made up the pool of potential survey participants. The discussion should also should include a comparison with the current demographic makeup of anglers described in the

current HHRA. With all the detail used on migration in and out of surrounding counties, these data must be readily available. The data should specifically address income, race, ethnicity, and literacy. **The uncertainty to address is whether the pool of licensed anglers surveyed in 1991 matches the pool of current, potential, anglers in the counties surrounding the river.**

3) General discussion of fisheries management for the river and its tributaries. This would include a discussion of the fish species present in the river and tributaries, commercial fishing, and angler perception of fishing this river system (desirable species, perception of abundance of fish). It should also include a discussion of the findings of enforcement programs on the current catch and release fishery. **The uncertainty to address is whether the fish species and sizes used to create the exposure data matches the fish that are likely to be taken from the river today.**

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Lee Shull

Hudson River PCBs Human Health Risk Assessment Peer Review Panel

Comments by: Lee R. Shull, Ph.D., NewFields, Inc.
May 12, 2000

Responses to: Specific Questions

Hazard Identification/Dose Response

Question 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."

Response

My response to this question is based on USEPA's definition of 'reasonableness' as defined in the agency's DRAFT Risk Characterization Handbook (1998). Although this document is DRAFT, I believe definition of 'reasonableness' and the five criteria provided by USEPA to evaluate the reasonableness of risk assessments can be applied to this question. It should be noted that USEPA's 1995 Policy for Risk Characterization does not define 'reasonableness' *per se.* The five criteria in the 1998 Handbook that define 'reasonableness' of risk characterizations are:

i. 'the risk characterization is determined to be sound by the scientific community...because the components of the risk characterization are well integrated into an overall conclusion of risk which is complete, informative, well balanced and useful for decision making,
ii. the characterization is based on the best available scientific information,
iii. the policy judgments required to carry out the risk analyses use common sense given in statutory requirements and Agency guidelines,
iv. the assessment uses generally accepted scientific knowledge, and
v. plausible alternative estimates of risk under various candidate risk management alternatives are identified and explained.'

Applying these criteria (only 1-4 apply) to the toxicity criteria used, I conclude that neither the RfDs nor CSFs used in the HHRA are reasonable.

i. *The toxicity criteria have not been determined to be sound by the scientific community.* In fact, both criteria have been extensively criticized within the scientific community. Good

summaries describing the major toxicological issues and lack of consensus on scientific interpretation of data regarding both the cancer and non-cancer endpoints for PCBs are given in comments made on the HHRA (Responsiveness Summary, Volume 2F - Human Health Risk Assessment). In particular, comments by Exponent on behalf of Chemical Land Holdings and by General Electric describe many of the disparate views on PCB toxicity, and what are scientifically defensible toxicity criteria for use in human health risk assessment.

ii. *The toxicity criteria are not based on the best available science.* Again, I do not believe best available science has been employed by USEPA in establishing these criteria. Valuable epidemiological information has been ignored. Too much emphasis is placed on animal toxicity data instead of using human epidemiological data, which is substantial.

iii. *The toxicity criteria more or less are based on statutory requirements and Agency guidelines.* Although the toxicity criteria used in the HHRA possess serious scientific deficiencies, I believe USEPA has generally followed statutory and Agency guidelines in deriving these criteria (*i.e.,* the process employed is more or less the same as used in deriving criteria for many other chemicals).

iv. *The toxicity criteria are based only partially on generally accepted scientific knowledge.* As already stated, I believe USEPA has not included valuable toxicological and epidemiological information in deriving both the cancer and non-cancer criteria. Reasons are numerous and have been summarized well in the comments of others on the HHRA.

USEPA counters criticism of using obsolete toxicity criteria by addressing the impact of this deficiency as part of the uncertainty assessment. The inclusion of the toxicity criteria in to the uncertainty assessment is important and is essential to risk managers making decisions about the Upper Hudson River. However, I believe the discussion of uncertainty regarding the toxicity criteria is poorly organized and fails to communicate essential information in a concise way to decision makers.

In addition, I believe the toxicity assessment section (4.0) and Appendix C (PCB Toxicological Profile) could be greatly improved and should be updated. I agree with the comments of several commenters in the 'Responsiveness Summary for Volume 2F - Human Health Risk Assessment', that the discussion of Toxicology and Epidemiology information is out of date and incomplete.

In summary, I do not believe it is reasonable for USEPA's to address the new toxicity studies published since the development of the RfDs and CSFs in IRIS in the context of uncertainty associated with the use of the IRIS values. A critical question is whether it is reasonable for USEPA to update cancer and non-cancer toxicity criteria incorporating new information before finalizing this HHRA. On a scientific basis, the answer is YES. On a policy basis, the answer may not be yes. Clearly, confidence in decision making based on the HHRA (and the toxicity criteria used) can be greatly improved by (1) updating Section 4 and Appendix C, and (2) providing a more concise and deliberate presentation of uncertainty regarding the criteria in Section 5.3, notably 5.3.2.

Exposure Assessment

Question 2)

"Since 1976, the New York State Department of Health has issued fish consumption advisories that recommend not eating 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."

Response

Again, my response to this question is based on USEPA's definition of 'reasonableness' as defined in the agency's DRAFT Risk Characterization Handbook (1998) and discussed in the response to Question 1.

Applying these criteria, I conclude that the fish ingestion rates used in the HHRA are not reasonable.

i. *The fish ingestion rates have not been determined to be sound by the scientific community.* EPA does base the fish ingestion rates on a peer reviewed scientific study (Connelly et al. 1992). However, summaries describing the additional interpretation of data regarding fish ingestion are given in comments made on the HHRA (Responsiveness Summary, Volume 2F - Human Health Risk Assessment). Comments by Exponent on behalf of Chemical Land Holdings and by General Electric in particular present evidence for using lower fish ingestion rates.

ii. *The fish ingestion rates are not based on the best available science.* I do not believe EPA used the best available science for establishing fish ingestion rates. EPA discounted important fish ingestion rate information. EPA relied too heavily on the Connelly et al. (1992) data to derive the fish ingestion without utilizing relevant information regarding more applicable fish ingestion rates.

iii. *The fish ingestion rates more or less are based on statutory requirements and Agency guidelines.* Although the fish ingestion rates over-estimate the exposure to PCBs by fish ingestion, I believe USEPA has generally followed statutory and Agency guidelines in deriving these exposure rates (*i.e.,* the process employed is more or less the same as used in deriving exposure rates for many other chemicals).

iv. *The fish ingestion rates are based only partially on generally accepted scientific knowledge.* Again, I believe the USEPA has not included valuable information regarding the development of a reasonable fish ingestion rate.

The use of the Connelly et al. (1992) data does not take into account fish ingestion rates which may change from year to year and the individual who may not consume fish every year. In

addition, the fraction from source (Hudson River) of fish ingestion was assumed to be 100%. Although one might expect that anglers may prefer this area if there were no advisories or restrictions, I disagree with the use of 100%. They state in several of the studies used to support exposure duration (3.2.4) that anglers reported that they traveled an average of 34 miles to fish. There are many waterways, both flowing and standing (lakes) within 34 miles of the Hudson that likely support fishing. The assumption of 100% of all fish taken are from the study area seems high. Although USEPA presents evidence from surveys that illustrate the tendency of a large percentage of individuals to fish the same water body, it is unclear whether this assumption would hold true throughout the exposure duration of an angler.

The use of the Connelly et al. (1992) data results in conservative and unrealistic estimates of fish ingestion. The following items provide an overview of problems with the use of the Connelly et al. (1992) data.

- The entire distribution of the Connelly et al. (1992) data is not used. Only non-zero data were used to generate the fish ingestion rate distributions.
- Although the intent is to assess fish ingestion assuming no "health based" restrictions on catch, assuming that all anglers eat all their catch seems overly conservative as well.
- It doesn't account for anglers who are strictly catch and release.
- The ingestion data (Connelly et al., 1992) is based on a State-wide survey, not just Upper Hudson data, so the data is not strictly biased towards those who fish the Hudson but also fish other fisheries, and some of these anglers clearly don't eat their catch. Throwing out zero values seems to assume that the consumption data is strictly related to the Hudson area and it clearly is not.
- There are State wide conservation-based fishing limitations/advisories that have nothing to do with the health advisories for the upper Hudson fishery that encourage people to catch and release without consuming their catch.
- In light of the use of the fraction from source of fish value of 100%, it's especially conservative.
- The Connelly data is based on mail recall survey, which the authors admit may be high due to recall bias (see section 3.2.1.4).
- Use of non-zero values assumes that the recommendations for conservation based limitations are never effective, which is conservative...there are many hunters and anglers who are conservationists as well.
- Further supported by the fact that in the 1996 and 1991-1992 Hudson River Surveys only 2/3 of the people were aware of the health advisories for fish on the Hudson, yet 92% reported never eating their catch, indicating that a significant number of those not eating their catch were not aware of the health advisories and lack of consumption is not health advisory related.

Based on the conservation related fishing advisories, I suggest (as did GE) that the distribution should be truncated at 32 g/day, or at least adjusted to account for catch and release or consumption of fish from other waterways.

In Section 2.3.1, page 14, "PCB concentration weighted by species", it is made clear that several species identified in the Connelly study used to estimate intake rates are not commonly present or caught in the Upper Hudson study area. These species (trout, salmon, bullhead, and "other") were removed from the analysis to estimate the average exposure concentration of

PCBs in fish tissue. However, it is unclear in this section or in Section 3 pertaining to the fish ingestion rates whether any attempt was made to remove the influences of these same species on the ingestion rate, as they apparently contributed upwards of 62% of the species reported in the Connelly et al. (1992) study as being consumed. If not, then the estimate of fish ingestion rates of these Hudson river-specific species may have been overestimated. Please provide additional clarification on this issue.

In summary, USEPA's approach does not provide reasonable estimates of fish consumption for the central tendency and RME individuals for use in point estimate calculations.

Question 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)."

Response

My response is again based on USEPA's definition of 'reasonableness' as defined in the agency's DRAFT Risk Characterization Handbook (1998).

Applying these criteria, I conclude that the fish ingestion exposure durations used in the HHRA are adequate.

i. *The exposure durations have been determined to be sound by the scientific community.* Several comments on the HHRA (Responsiveness Summary, Volume 2F - Human Health Risk Assessment) addressed concerns over the developed exposure durations. However, given the data constraints in constructing the exposure durations and the methodology applied, overall more reasonable approaches were not available for USEPA.

ii. *The exposure durations are based on the best available science.* USEPA used the best available information in developing the exposure durations. The derivation of site-specific exposure durations seems reasonable given the data constraints.

iii. *The exposure durations more or less are based on statutory requirements and Agency guidelines.* I believe USEPA has generally followed statutory and Agency guidelines in deriving these exposure durations (*i.e.,* the process employed is more or less the same as used in deriving exposure rates for many other chemicals).

iv. *The exposure durations are based on generally accepted scientific knowledge.* Again, I believe the USEPA has included valuable information regarding the development of reasonable exposure durations. I agree with the use of exposure durations different than residential exposure durations.

My response is also based on USEPA's definition of 'transparency' as defined in the agency's DRAFT Risk Characterization Handbook (1998). This refers to the "transparency in the risk assessment process. Making the process open and frank helps make the default policy known and helps achieve full disclosure." The transparency relates to many parts of the assessment including assumptions, extrapolations, models, and choices made during the risk assessment process and the impacts they have on the assessment.

The transparency of the approach to derive exposure durations needs to be improved in the document. The approach used appears reasonable given the data constraints. However, the approach is involved and the results cannot be reproduced with the data presented in the tables (although it may not be possible to give the census data). In addition, it is not clear in the document the impact of the many variables used on the resulting exposure durations. For example, is it likely the age at which a person started fishing may over or underestimate risk? This assumption does not account for when people started fishing in this particular fishery.

Overall, I feel the USEPA derivation of site-specific exposure durations for the fish ingestion pathway is adequate.

Question 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)."

Response

My response is again based on USEPA's definition of 'reasonableness' as defined in the agency's DRAFT Risk Characterization Handbook (1998).

Applying these criteria, I conclude that USEPA's approach to estimate fish exposure point concentrations used in the HHRA is reasonable.

i. *The exposure point concentrations have been determined to be sound by the scientific community.* Comments on the modeling used to estimate fish concentrations do support the conceptual basis of the models used.

ii. *The exposure point concentrations are based on the best available science.* Although full peer review of the modeling may not be complete, this reviewer cannot find fault with science used in developing the models used for media concentrations into the future.

Although the models are not appropriately validated for the use in estimating concentrations for long durations into the future, USEPA did use the best data available to achieve some level of validation, which was based on a data set from 1 year of monitoring.

iii. *The exposure point concentrations more or less are based on statutory requirements and Agency guidelines.* I believe USEPA has generally followed statutory and Agency guidelines in deriving exposure point concentrations (*i.e.,* the process employed is more or less the same as used in deriving exposure rates for many other chemicals). The selection of the seven year average as the RME chronic exposure concentration is the most conservative approach, as seven years is at the low end of what would be considered a chronic exposure as opposed to sub-chronic exposure.

iv. *The exposure point concentrations are based on generally accepted scientific knowledge.* Again, I believe the USEPA has included valuable information regarding the development of reasonable exposure point concentrations. I commend the USEPA for the attempt to account for declining PCB concentrations into future.

The transparency and clarity of the approach presented in the HHRA need to be improved. The seven-year average is the maximum concentration that could be used with chronic toxicity information. The conservativeness of this selection is not presented. In addition, the uncertainties from the modeling results are not clearly presented. The attempts to validate the model were limited to a one-year data set. While the USEPA used the best available data set for the validation, it is still not truly appropriate to validate a long-term model using such short-term conditions. In addition, the uncertainties from model compounding are not adequately addressed. The overall prediction of PCB concentrations in fish is based on the use of several models in series. These combined uncertainties are not adequately addressed. In addition, validation attempts seem to only have been completed for individual models and not on the use of the series of models that is ultimately used to develop fish exposure point concentrations. These sources of uncertainty need to be transparent and discussed clearly in the document.

Overall, I feel the USEPA's approach adequately addresses non-cancer health hazards to the central tendency and RME individuals. However, the HHRA should be improved to address the issues of transparency and clarity.

Monte Carlo Analysis/Uncertainty Analysis

Question 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)."

Response

My response is based primarily on USEPA's definition of 'reasonableness' as defined in the agency's DRAFT Risk Characterization Handbook (1998). The criteria is used to evaluate the several issues raised in question 5.

Applying these criteria, I conclude that the use of available data for fish ingestion rates and cooking losses are not reasonable.

i. *The parameters have not been determined to be sound by the scientific community.* Comments on and review of the use of data for fish ingestion and cooking loss indicate the presence of significant data not used in the HHRA.

ii. *The parameters are not based on the best available science.* Again, there are significant data available that the USEPA has chosen not to utilize.

iii. *The parameters more or less are based on statutory requirements and Agency guidelines.* I believe USEPA has generally followed statutory and Agency guidelines in deriving these parameters for probabilistic assessment (*i.e.,* the process employed is more or less the same as used in other HHRAs).

iv. *The parameters are based only partially on generally accepted scientific knowledge.* Again, I believe the USEPA has excluded valuable information regarding the development of fish ingestion rates and cooking losses.

The issue of fish ingestion rates was addressed in comments to question number 2. Please refer to those comments for more detail regarding my concerns on the over reliance on fish ingestion data from Connelly et al. (1992).

For RME exposures, a value of 0% cooking loss is assumed. For the central tendency exposures a value of 20% loss is used and for lower end exposures, a value of 40% was used. There is clearly plenty of data on the cooking loss of PCBs, which is presented in the back of the report. This data should be used to develop an RME for cooking loss based on the data. The use of 0% cooking loss is not "RME", but rather worst case. The use of 0% is unreasonable especially in light of the other conservative measures used in the report.

The Monte Carlo analysis did make appropriate use of available and relevant data in development of fish ingestion exposure durations. Please refer to my comments for question number 3 in regards to my conclusion that the exposure durations developed are appropriate.

Overall, the Monte Carlo analysis does not make appropriate use of fish ingestion and cooking loss available data. However, the Monte Carlo analysis for fish ingestion exposure duration did make appropriate use of the available data.

Question 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."

Response

My assessment is that the reliance upon the Connelly et al. (1992) survey is unreasonable. Please refer to my comments for questions 2 regarding the assessment and development of fish ingestion rates. The overall assessment that the developed fish ingestion rates are unreasonable is based on the following.

i. *The fish ingestion rates have not been determined to be sound by the scientific community.* USEPA does base the fish ingestion rates on a peer reviewed scientific study (Connelly et al. 1992). However, summaries describing the additional interpretation of data regarding fish ingestion are given in comments made on the HHRA (Responsiveness Summary, Volume 2F - Human Health Risk Assessment). Comments by Exponent on behalf of Chemical Land Holdings and by General Electric in particular describe evidence for using lower fish ingestion rates.

ii. *The fish ingestion rates are not based on the best available science.* I do not believe EPA used the best available science for establishing fish ingestion rates. EPA discounted important fish ingestion rate information. EPA relied too heavily on the Connelly et al. (1992) data to derive the fish ingestion rates without utilizing relevant information regarding more reasonable fish ingestion rates.

iii. *The fish ingestion rates more or less are based on statutory requirements and Agency guidelines.* Although the fish ingestion rates over-estimate the exposure to PCBs by fish ingestion, I believe USEPA has generally followed statutory and Agency guidelines in deriving these exposure rates (*i.e.,* the process employed is more or less the same as used in deriving exposure rates for many other chemicals).

iv. *The fish ingestion rates are based only partially on generally accepted scientific knowledge.* Again, I believe the USEPA has not included valuable information regarding the development of a reasonable fish ingestion rate.

The use of the Connelly et al. (1992) study is overly conservative. There are several trends in fish consumption that are exhibited in other studies but were disregarded in the development of the fish ingestion rate. The use of Connelly et al. (1992) comes with several assumptions, which include the following:

- An angler's ingestion rate is consistent for the exposure duration period.
- Anglers who may consume fish caught less than once year are to be excluded.
- Evidence that anglers fish the same system during a season can be extrapolated to the exposure duration period.

USEPA does not provide sufficient evidence or rationale for making these assumptions nor are these assumptions clearly stated.

Lee R. Shull, Ph.D.

Risk Characterization

Question 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?"

Response

Overall the Risk Characterization is lacking. It is missing key components as well as discussions on important sources of uncertainty. The following issues need to be addressed in order for the Risk Characterization to be a sufficient and transparent source of information for decision makers.

- A standard qualitative uncertainty analysis summary table should be included in Section 5.3. An example table is included with my comments (See Table 1). USEPA risk assessors should identify each potential source of uncertainty and subsequently estimate, using professional judgment and knowledge of scientific information, whether the item would result in a under-estimation or over-estimation of risk. In addition, whether the extent of under- or over-estimation would be expected to be low, medium or high should be included in the table. With this information, the decision maker is better able to incorporate uncertainty into decision-making. Table 2 is shown as an example using the sources of uncertainty in selection of toxicity criteria. If the majority of sources of uncertainty regarding toxicity are found to lead to an over-estimation of risk, which is how I believe it would come out, the decision maker has greater confidence in including uncertainty into decisions.

Table 1. Sample Uncertainty Analysis Summary Table

Source of Uncertainty	Results in Under-estimation of Health Risk			Results in Over-estimation of Health Risk		
	Low	Medium	High	Low	Medium	High
Use of animal data					✓	
Exclusion of scientifically valid epidemiological data					✓	
Etc.						

- The risk characterization focuses more on the deterministic rather than probabilistic results. This is counter to the purpose and intent of performing a probabilistic assessment.
- The HHRA does not contain a conceptual site model (CSM). The purpose of developing a CSM is to provide discussion for the selection of receptors as well as receptor pathways. The HHRA does not provide any reasonable explanation for the exclusion of receptors or pathways. For example a breast milk pathway was not evaluated, but from the HHRA it is unclear as to why. Without a properly developed CSM the risk characterization does not provide decision-makers the ability to judge that all relevant and important pathways were evaluated.
- Section 5.1.3. There is no discussion on estimating the intakes of dioxin-like PCBs in the exposure assessment section. This discussion belongs in section 3 as well. It is confusing that the discussion appears for the first time in the risk characterization section.
- Section 5.2, first paragraph. There is a reference to Section 3.5.1. There is no section 3.5.1.
- Section 5.2. There is no discussion of whether the dioxin-like PCB risks were estimated in the Monte Carlo analysis as it was in the point estimate analysis. There should be some discussion of whether this was done, and if not, rationale for not doing this type of analysis in the Monte Carlo analysis as well.
- The fish ingestion rate selected and the assumption that all fish tissue comes from the Upper Hudson is a very conservative assumption. There is no discussion regarding the possibility of or uncertainties associated with people who consume fish from other water bodies, and that all of their fish consumption from sport angling may not come from the Upper Hudson.
- The use of data to develop the fish ingestion exposure duration assumes that the reported age that a person started fishing is the age for starting fishing at the Hudson. There is no discussion related to the uncertainties associated with this assumption. It is possible that the age a person started fishing is not the age they started fishing at the Hudson. It is not clear how this data was used.
- There is no discussion about using a 100% of fish ingestion fraction from the source value and its impact on the uncertainty in the outcome.
- There is little or no discussion about the uncertainties associated with the exposure values held constant in the Monte Carlo analysis (body weight, for example) or used in the point estimate values (the use of certain values and what percentiles they represent, e.g. inhalation rate).
- Fish ingestion rates. "Although the fish ingestion rates reported in the New York Angler survey are presumably influenced by general, non-specific NYSDEC fishing regulations (that would be in effect regardless of PCB contamination levels in the Hudson)..." There is no discussion on what the effect of throwing out the zero values from the original data may have had. It is possible that some of these data points may have represented anglers who consume fewer fish per year as a result of conservation. Some discussion relating to this is warranted, especially in light of the fact that a source fraction value of 100% is used. There is insufficient discussion of the uncertainties associated with the assumption that the angler will consume at least 1 fish meal per year. There are some that may consume fewer, as in 1 every two years.

Response to: General Questions

Question 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?"

Response

In general, I think the HHRA is well done, even though it lacks seriously in some areas as pointed out in previous comments (e.g., the uncertainty section is poorly done, lacks state-of-the-art toxicity criteria, CSM, etc.). Specifically, the transparency and reasonableness of the HHRA are inadequate and need to be improved. My evaluation of whether the HHRA is transparent, clear, consistent, and reasonable is illustrated in Table 2.

Table 2. Transparent, Clear, Consistent, And Reasonable Assessment

Criteria	Assessment	Comment
Transparency	Deficient	o Explanations of key assumptions o Monte Carlo - Identifying sources of all data o Provide enhanced uncertainty discussion
Clarity	OK	Uncertainty analysis needs improvement
Consistent	Good	Generally consistent with other USEPA HHRAs
Reasonable	Deficient	Reasonable approaches used: o Exposure duration o Fish exposure point concentration Unreasonable approaches used: o Toxicity Criteria o Fish ingestion rates o Cooking loss

Question 2)

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

Response

The following are additional comments ordered by section and page of the HHRA

- Executive summary Page 2 paragraph 2. It is not clear whether the drinking water standards used to evaluate the river water are health based. If the standards are not health based, the point estimates for incidental ingestion while swimming should be included.
- Executive summary Page 3 paragraph 1. Please briefly clarify the use of 10 years old as the beginning age for fishing.
- Executive summary Page 3 paragraph 1. Please be more specific on how surveys of fish ingestion rates in states other than New York were include in examining fish ingestion variability.
- Executive summary Page 3 paragraph 3. It should be stated that the basis for the exposure frequency assumptions will be explained later. Also, please clarify why the assumptions had to be made (i.e. no data).
- Executive summary Page 3 paragraph 4. Is it true that children are a sensitive population for PCBs?
- Executive Summary Page 5 Monte Carlo Cancer Risk Summary- Fish Ingestion Table. Please define what low estimate, base case, and high estimate are based on.
- Executive summary Page 6 paragraph 2. The long-term adverse health effects of PCBs in laboratory animals mentioned here are out of place and should be discussed in the toxicity assessment section.
- Executive summary: Please provide information regarding PCB concentrations in fish, such, congeners found, how exposure point concentrations were developed, and how congener data in fish were reconciled with toxicity criteria.
- Executive summary. Please provide information regarding fish species that are included in the evaluation.
- Executive summary. The Monte Carlo tables need further clarification.
- Section 1.4 Page 4. Please define what the Mid and Lower Hudson River areas are.
- Section 2 Page 5. Please reword the last sentence in paragraph 4 regarding PCB intake estimates.
- Section 2.0 Page 5 Paragraph 4. Provide additional clarification in the description of the RME exposures for the point estimate "combining high end values with average values to...come up with a point value estimate of the RME exposure." The statement is confusing in that "high end" exposure factors are not distinguished from "average" factors.
- Section 2.0 Page 5 Paragraph 4. A question the less-educated reader might have is why use both Monte Carlo methods and point estimate methods to estimate risks. This type of discussion would be helpful in this section. Use of a Monte Carlo method is not simply for the estimation of the RME exposure estimate. The author may not intend this interpretation but the phrasing of the exposure assessment leads one to this interpretation. A discussion of the uncertainty using the point estimate scenario, the clarification achieved in using the Monte Carlo simulation, and then comparison of these results to point estimate for risk management may be helpful to a less technical reader.
- Section 2.1 Page 6. Table 2-1 does not state which pathways are complete.
- Section 2.1. Please include more extensive discussion with references for not including certain pathways. Table 2-1 is too brief.
- Section 2.0 Page 6 Paragraph 2. Consider adding the word "potential" or "hypothetical" in front of words like exposure and risks.

- Section 2.1.1 Page 7 Paragraph 1. Recommend against using the term "site" to characterize the "study area"
- Section 2.1.2 Page 7. Recommend not classifying anglers exclusively as those who eat at least 1 self-caught fish meal per year. There are anglers who simply catch and release regardless of health-based fishing advisories.
- Section 2.1.1 Page 7. Is there literature support for the air pathway being significant?
- Section 2.1.2 Page 7. What is meant by "angling effort?"
- Section 2.1.3 Substitute the word pathway for route. The exposure route denotes either ingestion, inhalation, or dermal. The exposure pathway reflects the means or mechanism of contact.
- Section 2.1.3 Page 8. Please clarify if the MCL used to screen PCB health risks from an exposure pathway is health based.
- Section 2.1.3 Page 8. Please clarify if the detection limit used to detect PCBs is sufficient to detect levels that could cause potential health risks. A screening calculation should be done on the PCB milk detection limit. Cows drink a lot of water. This is not considered in evaluating potential sources of PCBs to a cow's diet.
- Section 2.3. The exposure point concentration development is part of quantification of exposure (Section 2.2). This section should be changed to 2.2.1 and all subsequent sections should be changed accordingly.
- Section 2.3.1 Page 11. Presumably the age of the fish also will have an effect on the PCB concentration.
- Section 2.3.1 Page 11. Please provide a table with fish species used and the rationale for their representativeness.
- Section 2.3.1 Page 12. Concentrations in small fish species are provided for whole body only. This may overestimate the intake of PCBs for these fish, as higher lipid tissues will contain greater PCB concentrations than the fillets.
- Section 2.3.1 Page 12 Paragraph 5. Please clarify which modeled fish species were included in the HHRA.
- Section 2.3.1 Page 13. Please what the results of the location-to-location sensitivity analysis would provide or be used.
- Section 2.3.1 Page 13. Paragraph 4. Change "calculate the concentration of PCBs ingested in fish" to "calculate the dose of PCBs ingested from fish."
- Section 2.3.1 Page 14. Paragraph 2. Add the last sentence of the paragraph, "The six species from the ...", as a footnote to Table 3-4.
- Section 2.3.1 Page 14. Paragraph 3. Please clarify "frequency percentage."
- Section 2.3.1 page 14. "PCB concentration weighted by species". It is made clear in this section that several species identified in the Connelly study used to estimate intake rates are not commonly present or caught in the Upper Hudson study area. These species (trout, salmon, bullhead, and "other") were removed from the analysis insomuch as they contribute to the estimate of average exposure concentration of PCBs in fish tissue. However, it is unclear in this section or in Section 3, pertaining to the fish ingestion rates, whether any attempt was made to remove the influences of these same species on the ingestion rate, since they apparently contributed upwards of 62% of the species reported in the Connelly study as being consumed. If not, then the estimate of fish ingestion rates of these Hudson

River specific species may have been greatly overestimated. Please provide additional clarification on this issue.

- Section 2.3.2 Refer to figure for location reference.
- Section 2.3.2 Page 15. The text here states that two scenarios were assessed in estimating sediment concentrations: 1) assuming a continuing upstream source, and 2) assuming no continuing upstream source. The text then states that the concentrations corresponding to the continuing upstream source were used to calculate exposure point concentrations. No justification for this approach over the other is provided.
- Section 2.3.2 Page 15. Please define cohesive and non-cohesive sediment classes.
- Section 2.3.2 Page 15. It is unclear how segment sediment concentrations relate to fish concentrations.
- Section 2.3.2 Page 16. Modeled Sediment Concentration. There is no discussion why the sediment concentrations were modeled to 20 years in the future rather than 40 years as was done for fish.
- Section 2.3.3 Page 16. Modeled river water concentrations. There is no discussion why the river water concentrations were modeled to 20 years in the future rather than 40 years as was done for fish.
- Section 2.3.3. Are the PCB water concentrations predicted from the PCB sediment concentrations?
- Section 2.3.3. How do the river water segments relate to the river sediment segments?
- Section 2.3.4 Page 17. PCB air concentrations were only detected in May, June, and September during the 1991 sampling efforts. These detections and their associated water samples were used to estimate a water to air transfer coefficient. It is unclear whether there is any known explanation for these detections during only one particular time/season and not during any other times of the year. Is it possibly due to the location of the samples, perhaps water flow rates affect PCB concentrations in the water column? Are there conditions that were present during these times and not present at the others? If these are seasonal, should the modeled concentrations be presented and exposure assessment conducted only during these periods of time as well? Some discussion of these items would be helpful in interpreting the relevance of the coefficient development and the subsequent modeling effort.
- Section 2.3.4 Page 18. Do the empirical air water transfer coefficients relate to the air directly above the water or at air monitoring stations?
- Section 2.3.4 Page 20. Please explain why the Thompson Pool location was selected.
- Section 2.3.4 Page 21 Paragraph 3. The high-end empirical transfer coefficient is given as a concentration. Please add clarification.
- Section 2.4.2 Page 26. Sediment ingestion exposure duration. The sediment ingestion exposure durations and fish ingestion exposure durations are different at both the 50^{th} and 90^{th} percentiles. Although the difference between the values for the same percentiles is only one year and likely has little effect on the overall risk numbers, for consistency, the exposure durations for recreational exposures to sediments and exposure to fish should be the same.
- Section 2.4.2. PCB bioavailability should be addressed for sediment ingestion.
- Section 2.4.3 Page 28. Sediment adherence factor. Given that children will be playing in water and some wash-off will occur, use of the wet soil adherence factor seems as though it will overestimate the adherence of sediment to the skin.

- Section 2.4.3 Page 28. Skin surface area. The skin surface area was calculated using the data for specific age categories (child, age 6-7 data; adolescent, age 12 years data; and the mean for adults). The exposure duration for each age group was 3 years for children, 3 years for adolescents, 23 years for adults. Using whatever definition the assessors have for each age group then the average skin surface area for each age group should represent the average of actual age-specific data within that group and be representative of the entire exposure duration for the receptor group. For example, if children were defined as ages 0 to 7 years old with an exposure duration of 3 years, then the surface area could be calculated as the average of the 3 ages (4-5, 5-6, and 6-7). This approach seems more appropriate than selecting a higher end surface area and applying it for multiple years of exposure.
- Section 2.4.4 Page 29. Swimming time. Additional data in the Exposure Factors Handbook on swimming time is available. A 90^{th} percentile value of 1.9 hours/day may be more appropriate.
- Section 2.4.4 Page 30. Skin exposure to river water. The same comments for exposure duration of sediment ingestion apply to dermal water contact and other recreational events.
- Section 2.4.4. Skin Surface Area Exposed. Please clarify basis for using 100% of full body surface area. Is the assumed exposure activity swimming?
- Section 2.0. A good summary table of chemical data would be useful.
- Section 3.0 Page 33. Paragraph 2. Exchange the word "impossible" for "difficult" in the last sentence.
- Section 3.2. Why couldn't a PDF be developed for exposure frequency?
- Section 3.2.1. Is it proper to group infrequent and frequent anglers?
- Section 3.2.2 Page 48 Paragraph 4. Where are the distributions for the fish consumptions?
- Section 3.2.2 Page 48 Paragraph 5. The reference to Table 3-4 should be changed to Table 3-5.
- Section 3.2.3 Page 49. I do not agree with the assertion that it is not possible to develop probability distributions representing the variability among consumers and cooking methods.
- Section 3.2.4 Page 50. Provide a PDF for exposure duration.
- Section 3.2.4.1 Page 53. Where is the data for the "all angler category?"
- Section 4.1 Page 63. Please provide summary of PCB homologue data in the report.
- Section 5.1.1 Page 68 Paragraph 1. Use "RME" in stead of "high-end" for consistency.
- Section 5.1.1 Page 68 Paragraph 2. Please clarify what is meant by "uniform exposure throughout the Upper Hudson River."
- Section 5.1.1. Stress that the HI's are theoretical.
- Section 5.1.2. Stress that the cancer risks are theoretical and upper bound.
- Section 5.1.2 Page 68 Paragraph 5. Strike "refers to plausible upper bound risks."
- Section 5.1.2 Page 68 Paragraph 6. Clarify the use of "applicable."
- Section 5.1.2 Page 69 Paragraph 6. The discussion of fish ingestion results is confusing?

Recommendations

Based on my review of the information provided, my overall recommendation is:

Acceptable with minor revision (as indicated)

The HHRA needs to be revised by enhancing the Risk Characterization section as well as incorporating available information. The Risk Characterization section is the most inadequate section of the HHRA. This section should be modified to include a comprehensive analysis of uncertainties that arise from the assumptions and procedures implemented in the HHRA. The section should also include an uncertainty analysis summary table to better assist decision makers.

In summary, several assessment parameters were developed without adequately using available scientific data. These issues that need to be re-evaluated are listed below.

- The Toxicity Assessment needs to provide a clear presentation of the new toxicity studies published since the development of the RfDs and CSFs in IRIS in the context of uncertainty associated with the use of the IRIS values.
- The fish ingestion rate should be modified to incorporate additional evidence on fish ingestion behavior. The factors should account for a fraction from source of fish other than 100%, the large number of anglers who do not consume fish due conservation policies, the potential for angler fish consumption to be dynamic from year to year, and anglers eating less than one fish meal per year.
- The RME cooking loss should be based on the available data instead of the worst-case use of 0%.

Harlee Strauss

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Harlee S. Strauss, Ph.D. has a Ph.D. in molecular biology from the University of Wisconsin - Madison and an A.B. in chemistry from Smith College. She was a postdoctoral fellow in biology at MIT and a Congressional Science Fellow sponsored by the Biophysical Society. Dr. Strauss has more than 20 years of experience in the areas of risk assessment and toxicology.

Dr. Strauss is currently the President of H. Strauss Associates, Inc., (HSAI) a consulting firm she founded in 1988. She works on a broad range of projects, from site specific risk assessments, to in-depth evaluations of the toxicity of individual chemicals, to the development of frameworks for risk assessment (e.g., for microorganisms). HSAI clients include private and public sector organizations and citizens groups. Dr. Strauss has served as a member of the U.S. Army Science Board since 1994, and has participated in studies regarding lead-based paint, groundwater and soil remediation at Army facilities, Chem/Bio Weapons Defense, and the Range Rule (pertaining to unexploded ordinance). Dr. Strauss served on the advisory committee for the Society for Risk Analysis Workshop "Key Issues in Carcinogen Risk Assessment Guidelines" and on various peer review committees such as for the EPA Exposure Factors Handbook and the Drake Incinerator risk assessment. She is a community member of the Restoration Advisory Board of the U.S. Army's Soldiers Systems Center (Natick Labs) and an elected Town Meeting member in Natick Massachusetts.

Pre-Meeting Comments
Upper Hudson River Human Health Risk Assessment Peer Review
Harlee Strauss, Ph.D.
May 5, 2000

Introduction

The charge to reviewers asks for a response to several specific questions. Unfortunately, none of these questions are directed to my two major concerns about the risk assessment, which I would like to state up front:

- The lack of consideration of pregnant/lactating women (alternately fetuses, breast feeding infants and young children) as explicit receptors. The omission is particularly problematic in view of: 1) the scientific literature that points to infants/young children as sensitive receptors, 2) the scientific literature that demonstrates that PCBs cross the placenta and that milk is a major route of excretion for PCBs from women's bodies, 3) the scientific data showing that a large fraction of a lifetime PCB dose is obtained in early years, and 4) EPA's initiatives in the area of protecting children.

- Whether the modeled concentrations of PCBs in fish reflect the fattier parts of the fish that may be consumed by some people. For example, it remains unclear to me whether the fillet concentrations that are the output of the FISHRAND model are skin on or skin-less (and whether the model validation took this difference into account). This should be specifically discussed in the HHRA. In addition, there is no accounting for the potential underestimation of exposure for people who may consume the entire fish, either whole or in soups or pastes, even in the uncertainty discussion. Only fillet data are discussed and provided for the three fish species included in the risk assessment.

These concerns could make order of magnitude differences in the risk characterization in the direction of higher risk. Most of the specific points we are being asked to address (outside the dose response question) would make far smaller differences in the risk calculations.

Responses to Specific Questions

Hazard Identification/Dose Response

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.

I think it is appropriate to use the dose response values published in IRIS as the main basis for the toxicity assessment when relevant values are available. For the cancer risk assessment, EPA appropriately used the results from various Aroclors as a substitute for the mixtures actually encountered in various environmental media. While no one could believe this is a perfect substitute for data on the environmental mixture of concern, it is one that has been thought about in the context of multiple situations, and benefits from consistency of approach in decision-making.

The non-cancer dose-response factors are more troubling. Again, the use of RfDs published in IRIS is appropriate for adults. However, the incorporation of the recent data on neurodevelopmental and immunological effects on children is inadequate. The one short paragraph in the toxicity profile in Appendix C does not give the reader the sense of the extent of the database (three cohort studies, not one, with consistent results) and emphasize that the results are in human children exposed to environmental concentrations of PCBs. Furthermore, the uncertainty, and in this case the potential underestimation of the toxicity, should be considered more fully in the main body of the risk assessment.

To evaluate the effect of PCBs on young children in a more quantitative manner, a margin of exposure approach (rather than a toxicity factor) could be used. In this approach, the doses to which the children in the Upper Hudson River would be exposed could be compared with the exposures received by affected children in the various cohort studies. This dose would have to include those received prenatally (i.e, via transplacental exposure) and via breast milk in addition to direct consumption. The dose should be calculated by averaging over a short exposure duration (days to weeks), as the dose during a critical development window, not a long term average, is relevant. Moreover, a high end concentration of PCB in fish should be used in the calculation, not the means that were incorporated into the point estimate calculations.

Part of the problem with the inadequacy of the dose-response assessment with respect to children is the omission of pregnant and lactating women as receptors in the risk assessment. Pregnant and lactating women may be fish consuming anglers, if the receptor population is required to be thought of in those terms. They may also be the recipients of "gift fish", and the exception to the general case where the exposure assessment for the higher consuming angler is protective of the lower consuming family members.

Exposure Assessment

1) *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.*

I have a two concerns with the EPA's selection of a 90th rather than a higher percentile for the RME calculation: 1) high consuming populations are not broken out separately, so they should be very carefully considered in the ingestion distribution, and 2) the distribution is based on a survey of licensed anglers, who may or may not have the same consumption distribution as unlicensed anglers. However, the impact of the selection of 90th or 95th percentile on the calculated risk is less than two fold, and I don't view this as a large problem.

2) *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).*

This is a reasonable approach and the discussion in the report surrounding it pointed out some of the untested assumptions (e.g., whether or not the mobility of the angler and non-angler population was the same). The EPA approach does not account for people RETURNING to the Hudson River counties (as a residence) and resuming fishing activities, or visiting family during a vacation and going fishing with family or old friends. My personal bias would have been to use a longer fishing duration for the RME to account for some of these uncertainties. However, the incorporation of even a 60 year fishing duration would make little difference to the calculated cancer risk and no

difference to the noncancer risk.

3) *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).*

I think that the approach used for the RME is appropriate and should also be used for the CTE. In the model used here, the dose estimate decreases with increasing averaging time. The CTE, like the RME, will be exposed to the fish for 7 years, and then additional years after that. But if a chronic exposure is defined as an exposure for 7 or more years, then both the CTE and RME will undergo chronic exposure to the concentration averaged over 7 years, and should be evaluated as such. In this exposure scenario, factors other than averaging time (exposure duration) will distinguish the RME and CTE.

Monte Carlo Analysis/Uncertainty Analysis

4) *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).*

In general, I found the Monte Carlo analysis acceptable. I thought the comparison of the point estimate and Monte Carlo percentile distributions was illuminating and enhanced the credibility of both analyses. I do have a few comments and concerns, however.

Defining the angler population.
The Monte Carlo analysis, like the rest of the HHRA, defines the at risk population as anglers who consume at least one (self-caught) fish meal per year. Sensitive subpopulations are not considered separately. The HHRA, when justifying this approach, appears to consider only high consumers (including those who use fish as a significant food source) as a subpopulation of concern. This is not the case. As pointed out previously, I consider those who are exposed to PCBs *in utero* and via mother's milk as a population who must be considered separately in terms of both exposure and toxicity.

Another subpopulation of concern is the consumers of single species (especially bottom feeders) who use the entire fish. This subpopulation must be characterized by more than its consumption rate. While the high consuming/single species case is somewhat dealt with as part of the 72 sensitivity analyses (although the use of portions of the fish other than fillets is not considered at all in the HHRA), it is not discussed adequately in terms of how it represents a potential, highly exposed population.

The breadth of the distributions and the sensitivity analysis
For any given percentile, it appears that there is at most a 30 fold difference in cancer risk or hazard index among the various parameters examined in the sensitivity analysis. I am surprised by the narrowness of this range.

Fraction of PCBs lost during cooking, species preferences
I thought the fraction of PCBs lost during cooking of fillets was handled in a reasonable way in the point estimate calculations. In the Monte Carlo analysis, there was no year to year correlation with cooking method, PCB cooking loss, or species preferences. I think that these factors are likely to be correlated from year to year. I am concerned that the lack of correlation will average out risky preparation methods, just as no correlation from year to year in fish ingestion rates would have averaged out continually high consumers. My concern about PCB concentrations in cooked fish if fattier parts of the fish are not removed during cooking was not addressed at all.

5) *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.*

I think the HHRA provided clear justification for its selection of data to include in the analysis. However, the use of the 1991 NY Angler survey does have clear limitations. In particular, this survey of licensed anglers would have underestimated young anglers, who

do not need to have licenses. Yet young children are the most susceptible population to some of the noncancer adverse effects of PCBs.

Another problem with the analysis of the survey data is whether the type of fish consumed is adequately modeled based on the data provided in Connelly et al. 1992 and other surveys. For example, the data summarized in the HHRA indicate that one or a few people ingest large amounts of eel. Are there eel in the Hudson? If so, is the PCB concentration in the fillet of the brown bullhead an appropriate surrogate for the PCB concentrations in the eel?

Comments in the Responsiveness Summary (p.21) suggest that eel (and carp) are caught in the Upper Hudson, but go on to suggest that because the fraction of people who ingest eel and carp is low, so that the risks are averaged out. However, this is not necessarily the case, as people frequently have species preferences (such as the person who eats eels, as reported in Connelly et al 1992). The variability and uncertainty with respect to some species preferences is stated to be captured in the sensitivity analysis for the Monte Carlo runs, but it is not clear to me if this is so. The report also states that the fraction of each species ingested is drawn from a distribution developed from the Connelly et al, 1992 data and are not correlated from year to year, which would average out any species preference. Beyond this, the question of whether a brown bullhead fillet is an appropriate surrogate for eel (and carp) is not addressed in any quantitative way.

Risk Characterization

6) *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?*

In our site visit of the Upper Hudson River, we visited an island area (I think in Ft. Edward) with picnic tables, boat launching facilities, and a beach where children could be swimming all summer. It is clear there is lots of boating on the Upper Hudson, and that people may swim off the boats on hot days. There are also houses along the River which are likely venues for water based recreation including swimming and wading. With these observations in mind, it seems that the assumptions for frequency and duration of swimming (once a week for the RME) and wading activities are too low. That said, however, the exposure scenarios for recreational use of the Upper Hudson are comprehensive, and the correction of the swimming exposure frequency is not likely to significantly change the overall relative risk of the various exposure pathways. The discussion of the uncertainties and exposure assumptions is clear and sufficient.

General Questions

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?

I found the risk assessment to be exceptionally well written. It clearly and concisely described the overall methodology and assumptions, with a few exceptions which are noted in these comments. While I sometimes found the tradeoff of conciseness with detail in the report body to lean too much toward conciseness, the appendices did include much of what was missing. However, the tables in the appendix, especially the Monte Carlo sensitivity analyses, should have been fully described so the reader did not have to guess at the report's shorthand schemes.

The HHRA did not address children, either as infants or as young (under 10) consumers. This omission is especially critical for PCBs, as environmental PCB mixtures have demonstrated effects on the immune and nervous system during development. If there is a fatal flaw in the risk assessment, this is it.

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

The risk assessment should provide more extensive commentary on the strength of the assumption that the boundary conditions in the baseline (HUDTOX) model, i.e., the concentration of PCBs entering the River (modeled from 0 to 30 ng/L with 10 ng/L results used in the HHRA calculations), is correct and fully reflects the range of possible future conditions. While I recognize that EPA does not consider this in the scope of the HHRA, it may be the single most important assumption of the whole risk assessment, as it forms the basis of the predictions of the fish (and sediment) concentrations far into the future.

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).*

My recommendation is to accept the report with revisions (I'm not sure if they are minor or major). The report is acceptable as it now stands with respect to the majority of the population of adult anglers and other adult recreators. It is deficient, and likely

underestimates the risk for children especially those exposed *in utero* and via ingestion of mother's milk. Exposures and hence risk to children swimming and wading in the Upper Hudson River are also underestimated. The uncertainties regarding anglers who consume portions of the fish other than fillets needs to be investigated. However, even if the children were included and showed a high risk, and the eel eaters are at higher risk than shown in the assessment, the conclusion from the risk analysis would be the same as presented in the HHRA and revised HHRA in the Responsiveness Summary: the risks are higher than the benchmark range of acceptable risks.

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Clarification to Pre-Meeting Comments
Upper Hudson River Human Health Risk Assessment Peer Review
Harlee Strauss, Ph.D.
May 22, 2000

I would like to clarify two statements I made regarding non-cancer dose response and the evaluation of the non-cancer effects of PCBs on young children in my pre-meeting comments (page 74 of the premeeting comment book).

1) In briefly mentioning some of the inadequacies of the toxicity profile (Appendix C), I stated that it did not give the reader as sense of the extent of the database with respect to neurodevelopmental and immunological effects on children. Unfortunately, the parenthetical comment that followed that statement could be misleading. I did not mean to imply there are three cohort studies examining immunological effects. In addition, the consistency of the neurodevelopmental findings is true only in a broad sense of the observations of adverse effects at young ages. Some of the studies yield different results with respect to adverse endpoints observed at a young age and the persistence of these deficits into school age years. The three cohorts I was referring to were the Lake Michigan cohort (c.f., Jacobson and Jacobson, 1996), the North Carolina cohort (c.f., Rogan and Gladen 1991), and the Dutch cohort briefly described in the Appendix C toxicity profile. Based on a recent literature survey, it appears that at least one additional cohort study is underway (c.f., Winneke et al. 1998, regarding a study conducted in Dusseldorf, Germany).

2) I suggested a margin of exposure approach be used to evaluate the potential effects of PCBs on children, and that *in utero*, breast milk and direct consumption exposures be included. I further suggested that the dose should be calculated using a short averaging time and high end concentrations of PCBs in fish because of the critical window of development is likely to be short. I would like to clarify that this method of calculating dose only applies to *in utero* exposure (Note: this approach assumes that transient elevations in blood PCBs due to recent PCB-contaminated fish ingestion is important with respect to toxicity, although the maternal body burden is probably the major determinant to *in utero* exposure if averaged throughout gestation). Breast milk exposures should be based on long term averages as PCB concentrations in breast milk reflect the mother's body burden of PCBs. In addition, it may be appropriate to consider the *in utero* exposure separately as well as in combination, as most (but not all) of the neuro-toxicological effects associated with PCBs in the cohort studies cited above appeared to be associated only with *in utero* exposures.

References

Jacobson and Jacobson, 1996. New England J of Med 335:783-9.
Rogan and Gladen, 1991. Ann. Epidemiol 1:407-13.
Winneke et al., 1998. Toxicol Let. 103:423-8.

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Robert Willes

REVIEW COMMENTS ON USEPA BASELINE HHRA ON PCBs IN THE UPPER HUDSON RIVER

Prepared by: Robert Willes, Ph.D.,
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May 5, 2000

1. INTRODUCTION TO COMMENTS:

The following text summarizes the review comments of Robert Willes on the USEPAs Baseline HHRA of PCBs in the Upper Hudson River. The issues and points raised in this review are briefly presented, and more detailed discussions, with appropriate reference materials, will be provided at the up-coming meeting of the review team on May 30/31.

This review has identified and focusses on two separate issues that will be considered when addressing the "Charge" of the HHRA reviewers:

ii) The suitability/accuracy of the HHRA in the estimation of potential health risks/impacts from PCBs found in the Upper Hudson River; and
iii) The usefulness of the HHRA is assisting the USEPA (and potentially other parties) in the selection and application of remedial strategies for PCBs in the Upper Hudson River.

In my view, these are separate questions. For example, in my opinion, the HHRA has serious limitations with respect to accurately delineating the potential health risks/impacts to humans (and other receptors for that matter). However, the HHRA may provide reasonable evidence, when combined with other information (e.g., potential escalation of impacts due to catestrophic-event scouring of sediments, political will, regulatory policies, inferences on potential global impacts) that the current situation related to PCBs found in the Upper Hudson River is not acceptable. Such a conclusion could lead to the decision to proceed with some type of remediation of PCBs in the Upper Hudson River.

Once the decision is made that some type of remediation is required, it is critical that methods are available to evaluate the impact reduction of various remediation options, plus, more importantly, to enable the evaluation of the potential impacts of the remediation options *per se*. For example, it is possible that the end result of a given remediation technique may satisfactorily reduce impacts compared to the "do nothing" option; however, impacts may be unacceptably increased during the remediation process. The HHRA methodology and approach must be suitable to assist in providing information to assist remediation managers in the required decision-making process.

Different attributes and issues need to be considered when judging these two quite different uses

of the HHRA. The first case requires accuracy in the HHRA predictions of human health risks/impacts. The second case requires that the HHRA is sensitive to factors related to the remedial options under consideration that change environmental concentrations and consequent exposures of people and other receptors to PCBs. In addition to assisting in the evaluation and final selection of remedial options for the Upper Hudson River, the HHRA would be useful in identifying which parameters and locations require monitoring (and indications of the frequency of monitoring) to ensure that the selected remediation options do not result in unacceptable impacts/risks to the river system and the various receptors (human and otherwise) of concern.

2. Responses to "Charge" Questions

2.1 Hazard Identification/Dose Response

The consideration by the HHRA methodology of hazard identification and dose response issues related to PCBs is not considered adequate. The approach followed in the HHRA does not present a balanced evaluation of the available scientific information on PCBs and related compounds such as polychlorinated dibenzo-p-dioxins (PCDD) and polychlorinated dibenzofurans (PCDF). Conventional USEPA methodology is followed, with a discussion of one aspect of the uncertainties in such assessments. The discussion of the conservatism in the methodology followed should consider, at least briefly, the various issues discussed in the USEPA (1996) update in guidance of methods and the scientific basis for alternate approaches for estimating potential health consequences from exposure to carcinogens.

Specific points related to the toxicity assessment are given below:

- Pg 28 – Issuance of "tickets" for violation of fishing restrictions has nothing to do with HHRA, the characteristics of the dose/response relationships, or the validity of the risk estimates. For example, law enforcement agencies use a threshold approach for "ticketing" automobile drivers for excess alcohol consumption, whereas the health evaluation information demonstrates that this threshold does not apply to fetal alcohol syndrome (occurs at much lower doses). Using logic on pg 28, the fact that a "ticketing" threshold exists would indicate that there is no concern about fetal alcohol syndrome.

- PgES-4 – Critique of Kimbrough, 1999 that 75% of workers were not exposed — same problem with other studies, but the remaining 25% of Kimbrough cohort that were exposed represents a large number of subjects.

- Pg C3 – There is a lack of detail on discussions of epidemiological studies, except for Kimbrough, 1999 – lacks balance. There are many discussions of these studies by recognized scientific experts in the published literature.

- PgC2 & 3 – The conclusions of HHRA discussions of the conclusions of the epidemiological studies disagrees with the TERA assessment.

- PgC-3 – Overview of the carcinogenic potency in animals – does not mention the Brunner et al (1996) study used with the Norback and Weltman (1985) study to establish the CSFs for PCBs.

- Pg C-2 & 3 – no discussion of genotoxic potential, the uncertainty, lack of consideration of metabolism/repair systems, etc. and the relationship of these issues to the conservatism in the CSF estimates for PCBs. Should at least discuss these issues

qualitatively, and qualitatively consider their impact on the risk characterization. This was done with potential endocrine issues with PCBs, why not when looking at the conservatism in the CSF estimates?

- Pg C-4 – no discussion of whether or not there is evidence that the "low risk and persistence" tier are tumor promoters, genotoxic – similar problem to above.

- PgC-4 – mild liver damage with high doses – doesn't agree with pathology descriptions of the studies. The studies demonstrate severe liver damage, that is believed to result in extensive hyperproliferative responses on liver parenchyma. These hyperproliferative responses are known to result in the expression of genetic lesions related to ageing in rodents, particularly in Spraque Dawley rats. There are a number of peer reviewed publications in the scientific literature by recognized experts in rodent pathology that outline this issue, and the difficulties it causes in the validity of the extrapolation of such effects to humans exposed to doses well below those associated with liver toxicity.

- PgC-4 – large paragraph on work by Patandin (1999) and Lanting (1999) – these are theses, and have not been published in peer reviewed, scientific journals. This is a dangerous practice. Non-peer reviewed data should not be considered other than as supporting information, and does not deserve the apparent weight given here. There is a large body of work that has been published on the issue of the effects of PCBs and Dioxins/Furans on the development of children (e.g., Jackson's group) – this is not quoted or discussed in the PCB toxicity profile, but one reference is given in the reference list. The critiques I am aware of regarding these studies (see Kimbrough and others) seriously discount the causal linkage of the effects observed to PCBs or Dioxins/Furans. This can be discussed in more detail during the May 30/31 reviewer's meetings.

- PgC-4 – endocrine disruption handled qualitatively, why not use this approach for evaluating the degree of conservatism inherent in the toxicity limits for PCBs??

- PgC-5 – no discussion of the problems in interpreting the Barsotti and Allen work – just to mention a few of these problems: lack of measurement of PCB concentrations in diets, coincident studies in the same animal facility on chlorinated dioxins/furans, inadequate documentation of good laboratory practices (GLP) for the studies. This can be discussed in more detail during the May 30/31 reviewer's meetings.

- Pg C-6 – no discussion of relative evidence of relative sensitivity of monkeys versus humans regarding eye, nail and skin lesions – should at least discuss these issues qualitatively. There is abundant evidence that these effects are not observed in workers exposed to very large quantities of the same mixtures of PCBs as used in the monkey studies.

- Pg65 – PCB congeners are "believed to be" responsible for only part of the carcinogenicity of a Total PCB mixture. This is an overstatement of the known science,

and provides a level of confidence to the assessment that is not warranted based on the data available.

- Pg 65 – need a discussion of how international jurisdictions (e.g., WHO, Europe, Canada, Australia, Japan) evaluate PCBs and PCDD/PCDF – not considered genotoxic carcinogens, and use a non-linear dose-response evaluation similar to that outlined in the EPA (1996) Carcinogen Assessment Guidance document. There is an abundance of scientific evidence supporting these contentions (references will be provided at the May 30/31 meeting).

  In addition, the hazard evaluation sections should address recent development in the application of the EPA (1996) Carcinogen Risk Assessment Guidance document. In particular, the application of the guidance to formaldehyde, and the extrapolation of the conclusions of the formaldehyde re-evaluation on PCBs and PCDD/PCDF. In addition, the recent court actions on the assessment of chloroform. Both the formaldehyde and chloroform issues demonstrate the applications of non-linear dose-response methods for the evaluation of non-genotoxic carcinogenic substances, and result in decreases in the estimates of carcinogenic potency (increases in the CSFs) by 10- to 100-fold. These issues need to be discussed in the Risk Characterization section to provide a perspective on the degree of conservatism in the HHRA.

- Pg 65 – Need to discuss the coincidence between the PCDD/PCDF CSF used by the USEPA (150,000 mg/kd.day^{-1}) , the observed background exposures of PCDD/PCDF in people in the US (between 2 and 3 pg/kg BW/day) and elsewhere, so that the use of CSFs for PCBs, Dx/Fr can be put into perspective. For example, using the above CSF and the background exposure estimates for Dx/Fr in the U.S., the liver cancer incidence (basis for the Dx/Fr CSF) would be between 0.3 (30%) and 0.45 (45%):

  CFS for Dx/Fr = 0.15 pg/kg.day^{-1}
  Background Dx/Fr exposure ≈2 to 3 pg/kg/day
  0.15 X 2 = 0.3; 0.15 X 3 = 0.45
  These results mean that current exposures to PCDD/PCDF would be responsible for 100% of the lifetime risk of death of cancers from all causes; and the U.N. estimates that only about 10% of cancers are from environmental sources of chemicals, the remainder are from other causes such as genetics, diet, tobacco smoke, etc.

  Further, the above 30% to 45% incidence rate is the prediction for liver cancer. In the U.S. the total incidence of liver cancer from all causes is between 1 and 5 per 10,000; and the major risk attribution for liver cancer is alcohol consumption and other liver diseases.

  These issues need to be discussed in the risk characterization section and seriously impinge on the accuracy of the HHRA methodology in providing realistic estimates of health impacts to people living in the environs of the Hudson River.

- Pg 65 – wording indicating "sparse data currently available" re: breast cancer and PCBs is inappropriate. State the amount of data that is available (I will provide these References). More appropriate wording, and still very conservative, is that the "available evidence for a causal association is weak to non-existent". This is equivalent to the conclusions of the HHRA report for endometriosis.

- Pg 65 – humans have mechanisms to maintain hormone homeostasis – so do other mammals and animals generally – would be a much stronger statement if included all animal species. In addition, the same homeostatic mechanisms exist for responding to potential carcinogenic insults, for example, those that all people experience from cosmic radiation.

- Pg 65 – the HHRA identifies endocrine disruption agents in foods as a rational for not being concerned about other endogenous endocrine disruptors – This same argument applies to background PCB and PCDD/PCDF exposures.

- The implications of the above issues on the accuracy of the HHRA in predicting health impacts/risk to people living in the environs of the Upper Hudson River will be discussed later.

2.3 Exposure Assessment

The consideration by the HHRA methodology of exposure issues related to PCBs is considered adequate. Specific issues are noted below related to exposure duration and implications on specific types of receptors. The use of Monte Carlo simulations could have been expanded to assist in the identification of critical factors affecting impacts; however, these issues are more important in the use of the HHRA in assessing the feasibility of various remedial options and their application (discussed later).

- The approach used in the HHRA for estimating fish consumption appears reasonable. An additional recommended approach would be to calculate (using the HHRA model) the fish consumption that would result in acceptable impacts/risks, then evaluate the reasonableness of this hypothetical value. The two approaches should be complementary.

- The approach used to develop the 12 (central tendency) and 40 (RME) year values for exposure duration are reasonable.

- The procedures used for estimating the central tendency and RME average tendencies of 7 years for estimating fish concentrations is reasonable for the general population; however, it is not suitable for concerns about exposures of pregnant women, or women nursing infants. The exposure durations of concern for such receptors are much shorter (e.g., a few months related to the gestation and nursing time periods). A suggestion for the assessment of potential impacts to such people would be to conduct a "rolling average" exposure assessment using 3 to 6 month averaging intervals beginning at 1999

and proceeding forward, perhaps to a maximum period of 40 years. This will enable an evaluation of potential impacts to pregnant and lactating women in the Upper Hudson area.

- 90th percentile issue – see pg 29 of responsiveness summary – typographical error on pg 15-16 of HHRASOW.

- Pg5 – components of analysis included variability of concentrations, likelihood of exposure via various pathways, frequency and duration of exposure.

- Pg7 – assume anglers consume fish from Hudson, even though there are fishing bans and Hudson-specific health advisories. This point needs to be stressed in the Risk Characterization section to clearly state that the HHRA considers hypothetical situations that would exist if fishing bans were not in place.

- Pg-8 – refer to New York State data, and Dr. Buckley's data on beef, dairy, and crops, but do not provide the reference.

- Pg12 – were spottail shiner, pumpkinseed and white perch included in the FISHRAND model??

- Pg 13 – Cannot quantify fishing preferences or frequency at specific locations on the Hudson – sensitivity analysis in Chapter 5 to evaluate this issue.

- Pg 13 – Brown Bullhead and White Perch had the highest concentrations, spottail shiner and pumpkinseed were lowest.

- Pg33 – Monte Carlo – was sensitivity analysis conducted on distributions – i.e., what was the impact of assuming different distributions for parameters on the final impact estimates?

- Pg 34 – largest advantage of Monte Carlo simulations are that they avoid the problems of unknowingly combining worst-case or upper bound parameter values, and consequently obviating the understanding of the probability associated with the final impact estimate. This point needs to be emphasized in the risk characterization section.

- Pg 37 – duration of average – may not be appropriate to arbitrarily use 365 days – need to address how the duration is related to clearance t ½ for the substance. For example, duration of exposure should be approximately 5 times t ½ to achieve equilibrium (maybe want to go 7 times t ½ to improve certainty). If t ½ for some PCB congeners is as much as 9 years (some data to support this); then 5 times the t ½ means 45 years of exposure would be required to reach equilibrium state. This is very important because of differences in t ½ between test animals and humans. If it is assumed that the response of all mammalian systems is the same for a given tissue concentration of PCBs (this may or

may not be true), and the primary factors responsible for differences in response are related to the t ½ (metabolism, excretion, storage, etc.); then assuring that equilibrium body burdens are attained would be critical to the impact assessment. Therefore, assuming 365 day exposures for non-cancer end points may not be adequate to achieve equilibrium. For other congeners that have a shorter t ½ (e.g., 1 year), 5 years exposure durations would be sufficient to reach equilibrium body burden concentrations. It is unclear how this issue was considered in the assessment?

- Pg 49 – low toxicity of PCBs by inhalation versus fish consumption – disagree with this statement – likely that differences in apparent toxicity are totally related to exposure rates – in fact, exposure by inhalation, if the doses were great enough, would likely be more hazardous because of lack of "first bypass" through the liver. These statements need to be modified.

- Pg 58 – discuss sensitivity/uncertainty analysis as an alternate means of addressing 2-D issues to assess precision of the analysis – involved repeating the Monte Carlo simulation for separate input distributions for 72 combinations of Fish Ingestion, Exposure duration, Fishing Location and Cooking Loss to assess PCB intake. Performed 10,000 iterations for each of the 72 scenarios evaluated.

2.4 Risk Characterization

The Risk Characterization section does not discuss the issue of the degree of conservatism in the assessment; rather is focusses solely on uncertainties, and leaves the reader with the impression that the conclusions of the assessment have a high degree of uncertainty. A clear discussion needs to be included on how uncertainties are addressed in the USEPA RfD and CSF values, and how these procedures result in a high degree of conservatism in the overall results of the assessment. The inclusion of the discussions outlined in review section 2.2 will provide the balance needed for the reader to draw conclusions about the accuracy of the HHRA in predicting health impacts/risks to people in the environs of the Upper Hudson River.

The exposure assumptions are adequately discussed. The issue of exposure duration for pregnant women and nursing mothers needs to be discussed as appropriate depending what the addition of this analysis shows.

- Pg 69 – CT Cancer risk $\approx 3.2 \times 10^{-5}$; RME $\approx 1.1 \times 10^{-3}$ – these are outside the 10^{-4} to 10^{-6} range considered acceptable. When use PCDD/PCDF TEQ approach, get about the same value. Need a discussion regarding background exposures to PCBs and PCDD/PCDFs in other regions of the U.S. in order to interpret these risk estimates.

- Pg76 – Need to discuss concept of uncertainty and conservatism. CSFs represent upper bound risks – unlikely that risks would be under estimated. Risks could range from zero

to the upper bound value. CSFs do not consider non-genotoxic nature of PCBs, or Dx/F. Need to discuss what risks mean with respect to background cancer incidence; e.g., using Dx/Fr cancer slope factor, and PCB cancer slope factor, compared to background PCB and Dx/Fr exposures and projected cancer risks.

- Pg 76 – TEFs – order of magnitude estimates – correct statement, but need to discuss conservatism together with uncertainty – antagonisms between congeners & ability more potent congeners to stimulate metabolisms of other congeners may result in overestimations of toxicity. Problem with non-dioxin-like congeners; not included in TEFs, but may alter metabolisms, etc.

- Pg76 – Endocrine disruption – the end results of possible endocrine disruption effects are considered in lifetime, multi-generation exposure studies – these studies consider the integrated effects on reproduction and development through two or more generations. If truly adverse endocrine effects occur, their impacts would be observed through studies of intact animal systems.

- Pg 77 – Monte Carlo analysis captures much of the uncertainty, and serves to demonstrate that the CT and RME point estimates are reasonable values. However, the Monte Carlo analysis does not consider the degree of conservatism inherent in the toxicity components of the assessment. If these are combined with the exposure uncertainty, there will be a greater tendency to "shift" the cancer risks and HIs to lower values than to higher values.

- Pg 78 – Fishing location issue – approach reasonable, but likewise need interpretive statements relative to the toxicity uncertainties.

- Pg79 – Characterization needs to discuss exposure duration & t ½ issue in addition to residency time issues – if t ½ is long (e.g., 7 to 9 years), need 35 to 45 years of exposure to achieve equilibrium. Changing concentrations of PCBs in fish over time, means that equilibrium will never be reached. Particularly important with the more persistent PCB congeners with their longer t ½ 's. A sensitivity analysis should be conducted estimating body burdens of "anglers" for groups of congeners with different t ½ values to determine the most critical exposure duration relative to body burdens.

3. Comments on the Suitability and Accuracy of the HHRA in the Estimation of Potential Health Risks/Impacts from PCBs in the Upper Hudson River

Based on the issues outlined in Review Sections 2.2 and 2.4, it is my opinion that the results of the HHRA have a low degree of accuracy in predicting the absolute level of potential health risks/impacts from exposure to PCBs in the environs of the Upper Hudson River. This opinion has nothing to do with the fact that fishing advisories undoubtedly mean that actual risks to the community from PCBs in the Upper Hudson River are negligible. It is also my opinion that the

inability of the HHRA to provide realistic predictions of possible health risks/impacts should be clearly and unequivocally communicated to the reader of the report by appropriate inclusion in the Risk Characterization section, and as part of the conclusions to the HHRA.

The above opinion is not specific to the Upper Hudson HHRA, but is an outcome from the HHRA methods recommended in USEPA guidance documents. This is not the fault of the guidance documents, rather it is a reflection of the use intended for the HHRA.

Clearly, the HHRA guidance procedures followed would provide a high degree of confidence in rates of exposure to PCBs that would not result in measurable adverse impacts/risks to people in the environs of the Upper Hudson River. The conservatism inherent in the USEPA HHRA methodology readily supports the conclusion that, providing the estimated exposures do not exceed the guidance hazard parameters recommended, no unacceptable or measurable adverse health impacts/risk would occur. However, predicting exposures that would not result in unacceptable impacts/risks this is a very different task than predicting the levels of impact/risk that could actually occur from exposures to PCBs that actually exist in the Upper Hudson River. It is here that the HHRA methodology falls short.

In order to assess the accuracy of the HHRA methods, either much greater accuracy is required in the hazard assessment and exposure assessment paradigms, or reference comparisons are necessary that involve comparisons of predicted risks/impacts with real data on human disease, or lack thereof, observed following real-world exposures. This information is available, but the comparisons have not been conducted in the HHRA of the Upper Hudson River. For example, comparisons of impacts/risks that the HHRA would predict based on equivalent exposures should be made with those exposures actually measured or estimated in the epidemiological studies. In addition, comparisons of risks from background exposures, combined with the causal factors causing the diseases predicted assist in interpretation of the impacts/risks predicted by the HHRA methods. Section 2.2 provides such a comparison of the risks predicted using the hazard assessment information for PCDD/PCDF against those actually observed in a population.

Clearly, it can be concluded with a great degree of confidence that the impacts/risks to people in the environs of the Upper Hudson River would not be greater than those predicted by the HHRA. However, the actual impacts/risks may actually be as little as zero, particularly cancer risks.

It is my opinion that the most realistic conclusion from the HHRA conducted on PCBs from the Upper Hudson River is that the situation is not acceptable relative to the environmental occurrence of PCBs in other regions of the U.S. This conclusion, plus other information on estimates of ecological impacts/risks and policy issues, can be used in the decision-making process of the Remediation Investigation/Feasibility Study.

4. Applications the HHRA in the Selection and Application of Remedial Strategies for PCBs in the Upper Hudson River

The HHRA methodology can provide a powerful tool in the decision-making processes involved

in the remedial investigation/feasibility study for the Upper Hudson River. The conservatism and uncertainty associated with predictions of actual levels of impact/risk are not as important in such uses because the HHRA methods are used in a comparative manner (e.g., one remedial option would be compared to another option, including the "do nothing" option). This means that the various sources of conservatism/uncertainty cancel when using the HHRA as a comparative tool.

In order to ensure that the HHRA, ERA and environmental fate methods are optimal for the risk/impact comparisons of various remedial options, it is necessary to ensure that the methods are appropriately sensitive to the specific and unique features of the various remedial options under consideration. Sensitivity analysis techniques, similar to those already conducted as part of the baseline HHRA, are powerful tools in assessing whether or not the various HHRA components are sufficiently sensitive to assess remedial options. It is considered beyond the scope of this review to go into the details required to enable an evaluation of the suitability of the existing HHRA as a tool in comparing remedial options. However, based on my review, the current HHRA approach, especially with the Monte Carlo simulation approaches used, is largely ready for such comparative uses. Care should be taken, however, to ensure that the characteristics of specific remedial options are adequately captured by the HHRA in it's current form.

5. Recommendations

Overall, I recommend that the HHRA is acceptable with major revision.

These revisions should primarily involve the use of various comparisons, as discussed in my specific review comments, to provide an evaluation of the overall accuracy of the HHRA. The discussion of these comparisons in the risk characterization section would provide the reader with a more realistic impression of the degree of conservatism inherent in the HHRA methodology, and the usefulness of the HHRA in evaluating the acceptability, or lack of acceptability of the current situation on the river.

Additional discussions, and possibly sensitivity analyses, should be presented on the use of the HHRA as a comparative tool in the remediation option/feasibility study. For example, sensitivity analyses, using Monte Carlo simulation methods, should be conducted to determine the appropriateness of the HHRA methods in assessing sediment mobilization that could result from specific remediation options. Such sensitivity analyses must also involve the ERA and environmental fate modelling used on the project.

APPENDIX D

LIST OF REGISTERED OBSERVERS OF THE PEER REVIEW MEETING

United States
Environmental Protection Agency
Region 2

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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APPENDIX E

AGENDA FOR THE PEER REVIEW MEETING

United States
Environmental Protection Agency
Region 2

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

Human Health Risk Assessment

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

Agenda

Meeting Facilitator: Jan Connery, Eastern Research Group, Inc.
Meeting Chair: Holly Hattemer-Frey

TUESDAY, MAY30, 2000

12:30PM	**Registration/Check-in**
1:00PM	**Welcome Remarks and Panel Introduction** *Jan Connery, Eastern Research Group, Inc.*
1:15PM	**EPA Overview and Background Remarks** *Alison Hess, U.S. Environmental Protection Agency*
2:00PM	**Observer Comments**
3:00PM	BREAK
3:15PM	**Charge to the Panel/Summary of Premeeting Comments** *Holly Hattemer-Frey, Chair*
3:45PM	**Discussion on Human Health Risk Assessment (HHRA) Question 1**
4:30PM	BREAK
4:45PM	**Discussion of HHRA Questions 2 and 3**
6:15PM	ADJOURN

ERG

WEDNESDAY, MAY 31, 2000

8:00AM	**Discussion of HHRA Question 4**
9:00AM	B R E A K
9:15AM	**Discussion of HHRA Questions 5 and 6**
10:45AM	B R E A K
11:00AM	**Discussion of HHRA Question 7**
11:45AM	**Discussion of General Question 1**
12:30PM	L U N C H (on own)
1:45PM	**Discussion of General Question 2**
2:30PM	**Observer Comments**
3:30PM	B R E A K
3:45PM	**Recommendations and Chair's Summary**
4:30PM	**Closing Remarks**
5:00PM	A D J O U R N

APPENDIX F

SUMMARIES OF OBSERVERS' COMMENTS

List of Observers Who Made Comments

May 30, 2000

David Adams, Saratoga County Environmental Management Council
Rich Schiafo, Scenic Hudson
Jacques Padawer, Ph.D., Member, Conservation Commission, Hastings on Hudson

May 31, 2000

George Hodgson, Saratoga County Environmental Management Council
David Adams, Saratoga County Environmental Management Council
Marion Trieste, Scenic Hudson
Rich Schiafo, Scenic Hudson
Joe Gardner, Conservation Chair, Appalachian Mountain Club, Hudson River Chapter
Ed Valentine, Private Citizen

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—Summary of Observer Comments

Tuesday, May 30, 2000

David Adams
Saratoga County Environmental Management Council

After noting that he has been following activities and providing comments throughout the reassessment of PCBs on the Hudson River, Mr. Adams raised the following three issues:

1. Mr. Adams requested that the peer reviewers consider whether the size of the exposed population is important in characterizing risks to the angler population and how the risk for the reasonable maximally exposed (RME) individual should be used in assessing risks. He expressed concern that EPA indicates in the Responsiveness Summary that the data and assumptions used to estimate dose to anglers were not critical to the risk characterization because the calculation of the RME risk was not dependent on the population exposed. He questioned whether EPA would base its cleanup goals on a single individual if only one person in the Upper Hudson were identified as receiving a dose equivalent to the RME dose.

2. Mr. Adams commented that he believes EPA's analysis to be excessively conservative.

3. Mr. Adams requested clarification on the cancer slope factor used in the Monte Carlo analysis. Upon confirmation that a value of 2 $(mg/kg/day)^{-1}$ was used, he noted that this was too conservative. Mr. Adams stated that a slope factor of 1 $(mg/kg/day)^{-1}$ should have been used.

Rich Schiafo
Scenic Hudson

Mr. Schiafo explained that Scenic Hudson, based in Poughkeepsie, New York, has been involved in Hudson River PCB issue for 15 to 20 years. Mr. Schiafo commented that the risk assessment revealed what has been known for some time—that PCBs in the Hudson river pose a "substantial" and "considerable" risk. He commented that EPA's assumption that no fish advisories exist is appropriate because even with the existing advisories people are consuming fish from the river (as confirmed by anglers surveys conducted by the New York State Department of Health and Hudson River Clear Water group). He commended EPA's work in assessing angler risks.

While not free of technical jargon, the risk assessment is overall clear and will be helpful to his organization. Mr. Schiafo indicated that Scenic Hudson hired Dr. Ian Isbet to review the technical merit of the risk assessment and he generally found it to be a thorough, transparent assessment of present and future risks. The PCB data were used in an appropriate way and the analysis of the target population was reasonable. He urged EPA, however, to update IRIS as soon as possible to reflect the newer toxicologic and epidemiologic studies; he commented that using the data from the newer studies will lead to an increased risk estimate with less uncertainty. He noted that the Monte Carlo analysis was reasonable and scientifically defensible.

Mr. Schiafo commented that the Scenic Hudson does not feel that the Food and Drug Administration's (FDA's) "acceptable" limit of 2 parts per million (ppm) PCBs in fish is adequately protective for fish consumed from the Hudson River.

Lastly, Mr. Schiafo commented that he was disappointed that Dr. Schecter was not included in the peer reviewer group, noting that he did not feel a conflict of interest existed.

Jacques Padawer, Ph.D.
Member,
Conservation Commission
Hastings on Hudson

Dr. Padawer was unable to attend the peer review meeting, but asked that the following statement be read:

> "Too narrow a focus on the effects of PCBs on human health can be misleading because it ignores important indirect interactions with other environment pollutants such as polyaromatic hydrocarbons (PAHs) and other substances. PCBs activate forms of the liver enzyme cytochrome P450 which convert some common PAHs from relatively weaker to strong carcinogens. Other compounds may gain new physiological activities such as endocrine disruption, etc. Statistical population studies that focus solely on PCBs as the dependent variable (all of those I am aware of so far) therefore are likely to be misleading in suggesting no correlation with disease. Whereas these considerations admittedly may be difficult to evaluate in practice, they must be given weight nonetheless in order to adequately protect public health. The hard fact is that negative information is useless.
>
> An EPA paper on PCBs and cancer published by Dr. Brown touched on this point in passing. It is well worth revisiting."[1]

[1]The specific citation was not provided and the reviewers questioned whether this was the correct reference. The citation may be Brouwer, A. et. al. 1999. Characterization of potential endocrine-related health effects at low-dose levels of exposure to PCBs. *Environmental Health Perspectives* 107(4):639-649, or Cogliano, V.J. 1998. Assessing the cancer risk from environmental PCBs. *Environmental Health Perspectives* 106(6):317-323.

Wednesday, May 31, 2000

George Hodgson
Saratoga County Environmental Management Council

Mr. Hodgson first explained that Saratoga County Environmental Management Council is a citizen's advisory group appointed through the county legislature and advise the County Board of Supervisors on various environmental issues. Mr. Hodgson stated that the council has been involved with the PCB reassessment since 1991. He noted that the council's chief researcher, David Adams, commented earlier.

In a letter transmitting the council's comments on the HHRA, Mr. Hodgson commented that the council has concluded that the HHRA is not useful because it overestimates risk. In light of these conclusions, the council feels that significant revisions to the HHRA are needed. He urged EPA not to rush the process in trying to meet the December 2000 goal for the Feasibility Study (FS); EPA should take the time to incorporate reviewer comments and prepare the best possible HHRA to support the FS process.

Mr. Hodgson presented highlights of the comments that the council has submitted to EPA:

- The HHRA reflects an unrealistic degree of scientific overconservatism.

- The information from the 1996 NYSDOH study should be presented. Using the results from the 1996 survey—that indicate that 92 percent of the anglers do not eat the fish—would lead to a 10-fold decrease in the risk estimates. The 1996 survey results also contradict the conclusions drawn by EPA on page 45 (bottom) that the consumption ban would have no effect.

- Page 40 (Section 3.2.1.1): EPA discussions of the 1990 survey focuses on matter irrelevant to the risk assessment. EPA fails to present the following information: what fish the anglers harvested; sex and age of the anglers; differences between shore anglers and boat anglers, fishing tournaments. The HHRA does not identify the percentage of anglers that actually keep the fish or their awareness of the fish advisory.

- Page 54 (Section 3.2.4.2): The surveyed population is too small to obtain reliable values of fish consumption and exposure durations; therefore, conclusions based on this information are not fully supported.

- Page 57 (Section 3.2.4.3): Table 3-6 shows that of the 226 anglers in the survey, less than one angler fished for 70 years. This is meager data on which to base the 70-year fishing duration in the Monte Carlo analysis. Therefore, consideration should be given to using a lower upper bound in the Monte Carlo analysis.

- Page 62: The council recommends that the Monte Carlo analysis include uncertainty as well as variability in the toxicity values.

- The American public expects regulators to err on the side of conservatism, but common sense still needs to be used.

Mr. Hodgson also noted that the council shared their concerns in a letter to EPA Administrator Carol Browner, to which the council's comments on the HHRA were attached. The letter highlighted the concerns regarding unrealistic overestimates of human health risk, specifically criticizing EPA's disregard of the Kimbrough study and failure to use a weight-of-evidence health risk approach. He noted that, because the report so overestimates risk, it is not useful.

David Adams
Saratoga County Environmental Management Council

Mr. Adams commented that he was interested in the panel discussions pertaining to putting the findings of the HHRA into perspective. This reality check would assist those making remedial decisions. He, therefore, requested that the peer reviewers and EPA consider what is known about the health of the Upper Hudson River population. Specifically, he encouraged consideration of the Kimbrough study and the findings that cancer rates are not elevated in this area and that overall health is better than the general population.

Marion Trieste
Scenic Hudson

Ms. Trieste introduced herself as a private consultant hired by Scenic Hudson who lives a few miles south of the Thompson Island Pool. She commented on the importance of making the HHRA more transparent and helping the public better understand what the HHRA means. Ms. Trieste noted that the messages that the public are receiving from General Electric (GE) and EPA are conflicting and therefore confusing. She noted that the HHRA concludes that increased risks exist, yet she presented excerpts from an information piece put together by GE that indicates the following: (1) studies show no threats to human health; and (2) PCBs are considered a probable carcinogen based on studies in which rats were fed large doses of the chemical, but after 20 years of research and 20 studies no evidence exists that PCBs cause cancer or other serious effects in people even among the most heavily exposed populations (i.e., those who worked with PCBs on a daily basis). Ms. Trieste also noted that Dr. Kimbrough will come to public meetings and explain that no risks are associated with eating the fish.

Ms. Trieste closed by stating that, based on her review of the peer reviewer premeeting comments, it appears as though it is important to carefully evaluate potential risks to infants, children, and fetuses. She quoted sections of Dr. Shubat's and Dr. Strauss' comments related to potential hormonal and immunological effects and concerns related to *in utero* and breast milk exposures.

Rich Schiafo
Scenic Hudson

Mr. Schiafo recognized the value of this and the previous peer reviews of the reassessment process. This unprecedented amount of peer review has clearly indicated the importance of good science.

He noted that we are far from a consensus on exactly how to do a risk assessment, but emphasized that the bottom line is that increased risk has been identified. Therefore, it is important to move forward with a decision and Mr. Schiafo encouraged EPA to meet the December 2000 deadline for the FS to ensure the protection of public health, especially children. He commented that potential non-cancer effects definitely need to be emphasized, noting that the Kimbrough study did not really address non-cancer effects.

Joe Gardner
Conservation Chair
Appalachian Mountain Club
Hudson River Chapter

After complimenting and thanking the peer reviewers, Mr. Gardner commented that, while other approaches to conducting the HHRA are possible, it is important to focus on the conclusions of the HHRA. He indicated his great respect for the remediation efforts at Hudson Falls, etc. and complimented EPA for the sound quality scientific effort.

Mr. Gardner commented that he was impressed with Dr. Kimbrough's presentation of her study, but noted that she seemed perplexed when asked whether it was "okay to eat the fish." Mr. Gardner posed two questions: (1) Why are PCBs being removed from Hudson Falls and Fort Edward, but not from Thompson Pool, and (2) Why is so much money being spent to convince the public there is no problem?

Ed Valentine
Private Citizen

Mr. Valentine explained that he worked dredging sediments from the Hudson River in 1974 for about 2 years, with no knowledge that he was being exposed to PCBs at concentrations up to 1,000 parts per million or of potential health risks he and his coworkers faced. He and his coworkers observed that cinders and woodchips were eating paint off of the equipment and turning exposed metal black. He indicated that he now has *myelodysplasia* and may face the need for a bone marrow transplant. He expressed concern that others in that worker cohort also have had health problems, including cancer. Mr. Valentine reported that, of this cohort, 12 or 13 are deceased and 10 reportedly died from cancer. He also noted that a woman who resided on the property where the "pumped" materials were placed died of cancer. Mr. Valentine indicated that he has requested help from numerous state and federal officials to follow up on this matter, but has not received any response other than advice to hire an attorney. Mr. Valentine expressed great concern that nobody seems to want to help him. Mr. Valentine also noted that he was amazed that it has taken 25 years to get to this point in the assessment of the PCBs in the Hudson River.

Mr. Valentine also cited what he thought was a Belgian study that has shown PCBs to be associated with cancer in cows and chickens. He questioned why this has not been pointed out by NYSDOH or GE.

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 II, including the two risk assessment documents. She also listed the reports released as part of Phase I and those scheduled to be released as part of Phase III 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 II 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

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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ERG

United States
Environmental Protection Agency
Region 2

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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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

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