NOAA's Suggested Charge Questions
Submitted February 2000 via email
Peer Review 4

HHRA

The human health risk assessments evaluated risks in the Mid and Upper Hudson River. How important is it for EPA to extend these assessments to the Lower River in light of the findings of risk in the Mid-Hudson?

Is it reasonable to start the risk assessment in 1999 or should some prior exposure be accounted for in future predictions of risk?

Have all the relevant exposure pathways been evaluated?

ERA

Was EPA's overall approach in assessing risks to ecological receptors adequate for making a remedial decision?

Were the modeling efforts for the Lower Hudson River sufficient for predicting future concentrations and anticipated risks?

EPA derived lab- and field-based TRVs for total PCBs and TEQ PCBs from one or two studies. Lab values were sometimes adjusted by interspecies uncertainty factors but field values were not. Ultimately, toxicity quotients were developed from the field-based TRVs, when available, rather than considering both lab-and field-based TRVs. Was the general approach taken reasonable?

The authors assume that PCBs partition equally into the lipid phase of eggs and into the lipid phase of adult fish tissue. Is it appropriate to establish TRVs based on lipid-normalized concentrations?

Water column and sediment data used in the exposure assessment are averaged without regard for habitat preferences for the receptors of concern. Are these generalized exposure areas appropriate for the ecological receptors selected?

The ERA focuses on the effects of total PCBs and dioxin-like PCBs on lethality, growth and reproduction. It does not address other severe adverse effects (e.g., immunosuppression) associated with total PCBs or non-dioxin like congeners. What are the implications for excluding these other effects from the analyses?

How important is the role macrophytes play in cycling of PCBs through uptake and storage from sediment and water and their redistribution through plant senescence or ingestion by receptors?

Is the conversion factor of 1.5 from fillet to whole body fish PCB concentrations appropriate?

TOC and lipid content were set to a single value for the entire Lower Hudson. Is this a reasonable assumption or should more location specific numbers been used? What types of monitoring data would be most useful to verify predicted exposure and toxicity to receptors?

John G. Haggard, Manager
Hudson River Program

General Electric Company
320 Great Oaks Office Park, Ste: 323
Albany, NY 12203
Fax: (518) 862-2731
Telephone: (518) 862-2739
Dial Comm: 8 232-2739*
E-Mail:John.Haggard@corporate.ge.com
Pager: 518-484-3177

VIA FACSIMILE AND OVERNIGHT MAIL

February 18, 2000

Ms. Alison Hess
USEPA – Region 2
290 Broadway -19th floor
New York, NY 10007-1866

RE: Risk Assessment Peer Review Charge

Dear Ms. Hess:

As requested in your Notice to All Interested Parties dated January 31, 2000, GE has prepared the attached questions that we request you include in the human health and ecological risk assessment peer review charge. It is our understanding that the scope of the human health peer review does not include an evaluation of PCB toxicology. As a result we have not offered any suggestions on this topic. If this assumption is in error, please let us know since we would want to make recommendations for the charge related to this issue.

If you have any questions or would like to discuss this further, please do not hesitate to contact me.

Yours truly,

John G. Haggard

JGH/bg
Enclosure

314884

HUMAN HEALTH RISK ASSESSMENT PEER REVIEW CHARGE

Prepared by: General Electric
February 18, 2000

1. Are the conclusions of the human health risk assessment for the Upper and Mid Hudson River of sufficient certainty and robustness to provide useful information for a scientifically defensible solution?
2. Is the HHRA consistent with applicable EPA guidance?
3. How well does EPA's probabilistic model for the Upper Hudson River conform to EPA's guidance for Monte Carlo analysis?
    - Is there appropriate documentation of the model?
    - Is the model transparent?
    - Are the key inputs based on site-specific data and recent data from field and laboratory studies?
4. Is EPA's decision not to conduct a Monte Carlo analysis of fish consumption for the Mid-Hudson River valid and consistent with applicable guidance?
5. Has EPA made use of the most appropriate data in selecting fish consumption rates? Are they sufficiently complete and robust enough to satisfy their application in the risk assessments? Given the limitations associated with the various surveys of recreational anglers, did EPA select the most appropriate survey?
6. How well does EPA's Monte Carlo analysis characterize uncertainty?
    - EPA asserts that data are insufficient to characterize uncertainty and variability jointly. Is this assertion valid?
    - To address uncertainty in the outputs of the model, EPA conducted sensitivity analyses. Is EPA's claim that these sensitivity analyses adequately characterize uncertainty valid? Did EPA select the most important sources of uncertainty to evaluate in its sensitivity analyses?

314885

BASELINE ECOLOGICAL RISK ASSESSMENT PEER REVIEW CHARGE

Prepared by: General Electric
February 18, 2000

1. Do the ERAs conform to best scientific practice in site-specific ecological risk assessment?
   - Was adequate use made of existing site-specific ecological data?
   - Were appropriate supplemental site-specific data collected?
   - Was an appropriate weight-of-evidence approach to risk characterization employed?
2. Is the approach to Problem Formulation adequate to support useful baseline ecological risk assessments?
   - Is the conceptual model adequate?
     - Are other stressors appropriately considered?
     - Are the other sources of PCBs adequately addressed?
     - Are the exposure pathways adequately documented?
   - Is existing information on receptor populations and communities adequately synthesized and considered?
   - Are the assessment endpoints appropriately defined and evaluated?
     - Is "Protection of significant habitats," as used by EPA, a meaningful assessment endpoint?
     - Are population and community-level endpoints adequately addressed?
   - Are the measures of effects adequate?
     - Did the ERAs give appropriate weight to site-specific data concerning wildlife communities and populations?
     - Are generic sediment and water-quality criteria appropriate effects measures for a site-specific baseline ERA?
     - Can effects on Hudson River populations be adequately addressed using literature-derived toxicity reference values (TRVs) for survival and reproduction of individual organisms?
3. Is the Effects Assessment adequate to support useful baseline ecological risk assessment?
   - Can the assessments presented in the ERAs be used to determine potential adverse effects on the assessment endpoints in the absence of site specific studies such as:
     - Whole media or *in situ* toxicity tests?

314886

- Field studies of the exposed populations and communities?

- Is the TQ approach, as implemented in the ERAs, appropriate for a site-specific baseline ecological risk assessment?
  - Were the TRVs selected for the ERAs from the best and most relevant available toxicity studies?
  - Is it more appropriate to use a single TRV or a TRV distribution (or range)?
  - Are TRVs developed from laboratory studies of fresh Aroclors representative of the toxicity of weathered PCBs in the Hudson River?
  - Are the uncertainties and conservative assumptions inherent in the TQ-based approach appropriately characterized?
- Was the TEF/TEQ approach used appropriately?
  - Has the approach been adequately validated for all of the receptor taxa addressed in the ERAs?
  - Are the congener-specific data adequate to support application of the TEF/TEQ approach to Hudson River biota?
- Are the Sediment Effects Concentrations (SECs) used reliable and adequate indicators of effects of PCBs on benthic macroinvertebrates?

4. Is the Risk Characterization adequate to support useful baseline ecological risk assessments?
   - Have the results of the available field studies been interpreted correctly?
     - Are the results of the USFWS tree swallow studies interpreted correctly?
     - Are the results of the macroinvertebrate community effects study correctly interpreted?
   - Has all of the available evidence been weighed appropriately?
     - Do other available data on benthic macroinvertebrate communities of the Hudson River support or contradict the ERAs' conclusions?
     - Do the available field data on fish populations, especially striped bass and shortnose sturgeon, support the ERAs' conclusions?
     - Do the available field data on bird populations, for example belted kingfishers and bald eagles, support the ERA's conclusions?
     - Is appropriate weight given to field data that conflict with predictions derived from the TQs?
     - How should the results of the TEQ approach be weighed with results based on total PCBs?

7. Have the appropriate uncertainty analyses been conducted and clearly represented in the conclusions?

John G. Haggard, Manager
Hudson River Program

General Electric Company
320 Great Oaks Office Park, Ste: 323
Albany, NY 12203
Fax: (518) 862-2731
Telephone: (518) 862-2739
Dial Comm: 8 232-2739*
E-Mail:John.Haggard@corporate.ge.com
Pager: 518-484-3177

VIA FACSIMILE AND U.S. MAIL

February 29, 2000

Ms. Alison Hess
USEPA – Region 2
290 Broadway -19th floor
New York, NY 10007-1866

RE: Risk Assessment Peer Review Charge

Dear Ms. Hess:

I am writing to you as a follow-up to the risk assessment peer review charge questions forwarded to EPA on February 18, 2000. GE submitted suggested charge questions with the understanding that an evaluation of PCB toxicology will not be addressed as part of the peer review. I understand that you discussed this issue with Bob Gibson of my staff on February 22, 2000 and based on this is understood that peer review position is that PCB toxicity and the applicability of specific IRIS values will not be the subject of the peer review. If I have not stated EPA's position accurately, please let me know since this would require that we modifiy our questions to include in the change to the peer review panel.

Once the peer review schedule has been finalized, I request that you forward the iist of selected peer review panelists and the final charge questions. If you have any questions or would like to discuss this further, please do not hesitate to contact me.

Yours truly,

John G. Haggard

JGH/bg

John G. Haggard, Manager
Hudson River Program

General Electric Company
320 Great Oaks Office Park, Ste: 323
Albany, NY 12203
Fax: (518) 862-2731
Telephone: (518) 862-2739
Dial Comm: 8* 232-2739
E-Mail:John.Haggard@corporate.ge.com
Pager: 518-484-3177

VIA FACSIMILE AND U.S. MAIL

March 6, 2000

Ms. Alison Hess
USEPA – Region 2
290 Broadway -19th floor
New York, NY 10007-1866

RE: Risk Assessment Peer Review Charge

Dear Ms. Hess:

This is in response to your letter of March 1, 2000 and our subsequent phone conversation regarding the issue of PCB toxicology in the upcoming risk assessment peer review. In your letter you stated that the scope of the peer review with regard to PCB toxicology would include the toxicity assessments and PCB toxicological profile contained in the HHRA, except for material that previously has been peer reviewed such as toxicity values taken from IRIS. Following our phone conversation to further clarify EPA's position, I understand that although perhaps not the focus of the peer review, questions regarding PCB toxicology (e.g. Toxicological studies completed since the last issuance of IRIS) could be posed to the panel.

General Electric Company (GE) believes that the Hudson River risk assessment peer review panel should not consider issues related to PCB toxicology for the following reasons:

1. The Region used IRIS values in the HHRA and has stated that the evaluation of new studies and their potential applicability to revising IRIS is the responsibility of EPA Headquarters. This approach is consistent with Agency guidance (see RAGS Part A at 7-14).
2. The field of PCB toxicology is highly specialized and it would be extremely difficult to retain peer reviewers fluent in both EPA risk assessment practices and PCB toxicology.
3. We understand that EPA headquarters is currently in the process of re-evaluating the IRIS PCB non-cancer toxicology and the Kimbrough mortality study. A separate EPA review of these issues could lead to conflicting views within the Agency.

Therefore, as you prepare the risk assessment peer review charge, we urge you not to include questions on toxicology issues, but rather focus on more site specific risk assessment issues. If however you decide to vet PCB toxicity issues with this panel, I have attached some suggested questions to assist you.

If you have any questions or would like to discuss this further, please do not hesitate to contact me.

Yours truly,

John Haggard /bg

John G. Haggard

JGH/bg

HUMAN HEALTH RISK ASSESSMENT PEER REVIEW CHARGE
(PCB Toxicology Issues)

Prepared by: General Electric
March 6, 2000

1. Did EPA adequately consider the human epidemiological data when evaluating PCB toxicity?

2. Is the "weight-of-evidence" approach, which is endorsed by EPA, used in the assessment of PCB toxicity?

3. Is the EPA assertion that, as a matter of policy, the variability and/or uncertainty associated with chemical toxicity not considered in the Monte Carlo analysis valid?

4. EPA has used the Integrated Risk Information System (IRIS) to define parameters to describe PCB toxicity. EPA guidance recommends using more current information where it is available. Has EPA adequately considered the information regarding PCB toxicity that is now available since the last IRIS updates?

5. EPA has stated that the Kimbrough et al (1999) epidemiological study of GE capacitor workers "...will not lead to any changes in its CSFs (cancer slope factors) for PCBs." Is this an appropriate response given that EPA is still conducting its "internal" peer review of the study, and the study, the largest and most complete of its kind can likely be used to improve the validity of and certainty associated with EPA's CSFs for PCBs.

6. Following EPA's release of the Human Health Risk Assessment for the Upper Hudson River, GE provided an extensive critique of PCB toxicity in Appendix A of their comments. Has EPA adequately considered these comments and analysis of PCB toxicity? If not, what additional evaluations should EPA perform to adequately evaluate this information?