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## VIA FACSIMILE AND OVERNIGHT MAIL

February 18, 2000

Ms. Alison Hess USEPA – Region 2 290 Broadway -19<sup>th</sup> 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.

ours truly

🔾 John G. Haggard

JGH/bg Enclosure

### 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?

# **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?

- Field studies of the exposed populations and communities?
- Is the TQ approach, as implemented in the ERAs, appropriate for a sitespecific 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?