



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 2
290 BROADWAY
NEW YORK, NY 10007-1866

OCT 07 1999

John G. Haggard, Manager
Hudson River PCB Projects
General Electric Company
320 Great Oaks Office Park, Suite 323
Albany, NY 12203

Re: Hudson River PCBs Reassessment

Dear Mr. Haggard:

This is in response to your June 29 and July 13, 1999 letters commenting on the U.S. Environmental Protection Agency's (EPA's) April 1999 Responsiveness Summaries for the Phase 2 Ecological Risk Assessment Scope of Work and the Phase 2 Human Health Risk Assessment Scope of Work.

As you know, the public comment period on the Human Health Risk Assessment Scope of Work ended on August 31, 1998 and the public comment period on the Ecological Risk Assessment Scope of Work ended on November 2, 1998. EPA responded to all significant comments in the Responsiveness Summaries. EPA did not solicit comment on the Responsiveness Summaries. Nevertheless, EPA's responses to comments made in your June 29 and July 13, 1999 letters are provided in Enclosures 1 and 2, respectively.

If you have any questions regarding this matter, please contact me at (212) 637-3959.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Alison A. Hess".

Alison A. Hess, C.P.G.
Project Manager
Hudson River PCBs Site

Enclosures

Enclosure 1

EPA's Response to John Haggard's 6/29/99 Letter Commenting on the
Responsiveness Summary for Phase 2 Ecological Risk Assessment Scope of Work

In your June 29, 1999 letter, you state two major concerns regarding the Ecological Risk Assessment Scope of Work: the use of output presented in the May 1999 Baseline Modeling Report and the bottom-up approach to assessing ecological risks. You also comment on EPA's responses to three comments. Each of these items is addressed below.

Use of the May 1999 Baseline Modeling Report

You state that, while GE concurs with EPA's approach to use the output of its fate, transport, and bioaccumulation models in the Ecological Risk Assessment, you believe that EPA should not rely on the output of models as presented in the May 1999 Baseline Modeling Report because the models "have not been subjected to public comment and peer review."

However, as shown by your comments on the Baseline Modeling Report, GE was aware that EPA held a public comment period on the Baseline Modeling Report through June 23, 1999. By the date of your June 29, 1999 letter, EPA had already announced that the Baseline Modeling Report would be the subject of peer review in March 2000 (see, EPA's June 10, 1999 Reassessment RI/FS Schedule, attached). Waiting until after the peer review for the Baseline Modeling Report to use the model output, as you suggest, would have unnecessarily delayed issuance of the risk assessments by about one year.

Moreover, as explained at the August 4, 1999 Joint Liaison Group meeting for release of the risk assessments, EPA expects that the fine-tuning of the fate, transport, and bioaccumulation models that is currently underway will not change the overall conclusions of the risk assessments. In the unlikely event that the model results change sufficiently to affect the overall conclusions, EPA would recalculate risks to the environment.

Bottom-up Approach

You state that EPA's bottom-up approach to calculating ecological risk is "technically inadequate" and that the Responsiveness Summary for the Ecological Risk Assessment Scope of Work "reveals the Agency's intent to ignore or discount the available site data [from top-down studies on communities and populations]."

EPA previously has addressed GE's comment recommending a top-down approach in lieu of the bottom-up approach outlined in the Ecological Risk Assessment Scope of Work (see, Responsiveness Summary for the Ecological Risk Assessment Scope of Work at p. 13). Specifically, EPA noted that the bottom-up approach (calculating Toxicity Quotients, which are ratios of site-specific exposure to toxicity reference values, or TRVs) is consistent with EPA's guidance on conducting ecological risk assessments (see, EPA's 1997 *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments* at p. 7-3, "...the quotient method of comparing an estimated exposure concentration

to a threshold for a response can be used...). EPA further noted that a weight-of-evidence approach would be used to determine whether concentrations of PCBs in the Hudson River may cause adverse effects in individuals and populations of ecological receptors of concern. In no way did EPA suggest, as you state in your letter, that the Agency would ignore or discount available top-down information. To the contrary, EPA used, among other things, observed concentrations of PCBs in benthic invertebrates and fish in the Hudson River and field studies of birds and mammals in and along the Hudson, in a weight-of-evidence approach to characterize risks to ecological receptors (see, Sections 3.2: Observed Exposure Concentrations and 5.0: Risk Characterization, of the Ecological Risk Assessment).

Your letter misstates the Responsiveness Summary for the Ecological Risk Assessment with respect to the use of concentrations of PCBs forecast by EPA's models to evaluate future risk. Specifically, you state that "the Agency intends to hold exposure concentrations constant in the future." In fact, in the Responsiveness Summary (at p. 23), EPA states, "...the initial concentration may be held constant for the first five or ten years, even if the model suggests a time-varying decrease in concentrations...or may be recalculated annually..." In the first scenario described by EPA, the concentration would have been held constant for only the first five or ten years to be protective of the environment and then would decrease for the remaining forecast period (10 to 15 years) as predicted by the models. Regardless, in the Ecological Risk Assessment, EPA used the second scenario and recalculated the concentrations annually without holding initial concentrations constant (see, Section 3.3: Quantification of PCB Fate and Transport, of the Ecological Risk Assessment at pp. 44-46).

EPA agrees that water quality criteria, although risk-based, are not full risk assessments. In the Ecological Risk Assessment, EPA used the NYSDEC ambient water quality criterion for wildlife as one of several lines of evidence to evaluate risks to ecological receptors. The NYSDEC criterion is derived from studies of mink (a species known to be sensitive to PCBs) and therefore is particularly appropriate as a measurement endpoint for the mink receptor selected by EPA. However, because the water quality criterion is intended to be protective of all wildlife, it is appropriate for receptors of concern other than mink (see, Ecological Risk Assessment, Table 2-7).

In response to your concern regarding uncertainty associated with use of TRVs derived from the scientific literature, EPA responded in the Responsiveness Summary for the Ecological Risk Assessment Scope of Work (at p. 27) that it would address uncertainty associated with the TRVs in the Ecological Risk Assessment (see, Section 6.4: Toxicological Uncertainties of the Ecological Risk Assessment at pp.157-158).

You suggest that EPA consider specific studies, which you cite, that show the mink diet is not solely aquatic but also includes a significant terrestrial component. In the Ecological Risk Assessment, EPA used a winter diet for Hudson River mink of 34% fish and 16.5% aquatic invertebrates, based on diet studies of New York State mink by Hamilton (1959), as cited in EPA's 1993 *Wildlife Exposure Factors Handbook* (see, Ecological Risk Assessment at p. 63). Thus, approximately 50% of the mink diet was assumed to be of terrestrial origin.

Three Additional Comments

You assert that EPA's responses to three of the approximately 80 comments (comments EA-10, EG-11, and EG-19) are "inadequate or misleading." Comment EA-10 concerns EPA's plan, as outlined in the Ecological Risk Assessment Scope of Work, to compare site-specific data to TRVs derived from the scientific literature rather than long-term site-specific toxicological studies. This plan is consistent with EPA's 1997 *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments* and was discussed with technical representatives of NOAA, NYSDEC, USFWS, NYSDOH, and GE prior to issuance of the Ecological Risk Assessment Scope of Work. Long-term toxicological studies were not necessary to conduct the Ecological Risk Assessment and adding them to the September 1998 Scope of Work would have unnecessarily delayed the release of the Ecological Risk Assessment by one year or more (see, Responsiveness Summary for the Ecological Risk Assessment Scope of Work at p. 27).

Comment EG-11 concerns the appropriateness of including aquatic vegetation in the site conceptual model for the Ecological Risk Assessment. As noted by EPA (see, Ecological Risk Assessment Scope of Work at p. 14 and Responsiveness Summary for Ecological Risk Assessment Scope of Work at p. 18), the site conceptual model in an ecological risk assessment identifies the sources, media, pathways and routes of exposure that will be evaluated. Aquatic vegetation in the Hudson River, although it serves as habitat, was not included in the site conceptual model in the Ecological Risk Assessment Scope of Work because, as EPA noted in its response, it generally does not bioaccumulate PCBs and therefore is not a source, media, pathway, or route of exposure evaluated by the risk assessment (see, Responsiveness Summary for Ecological Risk Assessment Scope of Work at p. 18). The concern you raise, that dredging could adversely affect aquatic vegetation serving as habitat, is beyond the scope of the Ecological Risk Assessment and properly addressed as part of risk management in conjunction with the Feasibility Study of remedial alternatives.

Comment EG-19 offers GE's opinion that the lack of site-specific data will make the results of the Ecological Risk Assessment highly uncertain and therefore of little use in the remedial analysis. Your letter states both that EPA failed to respond to the comment and that EPA disagreed with the comment and gave a reason why it disagreed. In fact, EPA provided three reasons why the results of the Ecological Risk Assessment would be adequate to determine whether or not PCBs pose an unacceptable risk to the environment: first, EPA will use site-specific water, sediment, and biota data to evaluate exposure to PCBs at the site; second, EPA will use methods set forth in Agency guidance to derive appropriate reference concentrations of toxicology from the published scientific literature; and third, EPA will discuss and quantify, where possible, the uncertainty in the Ecological Risk Assessment (see, Responsiveness Summary for Ecological Risk Assessment Scope of Work at p. 31).

Enclosure 2

EPA's Response to John Haggard's 7/13/99 Letter Commenting on the Responsiveness Summary for Phase 2 Human Health Risk Assessment Scope of Work

In your July 13, 1999 letter, you state four major concerns regarding the Human Health Risk Assessment Scope of Work: the use of the May 1999 Baseline Modeling Report; toxicity issues (Kimbrough et al. 1999 and ATSDR's December 1998 draft Toxicological Profile); limitations of the New York angler surveys; and rejection of the microexposure event analysis method proposed for the Monte Carlo risk calculations. Each of these items is addressed below.

Use of the May 1999 Baseline Modeling Report

Similar to your comment for the Ecological Risk Assessment, you state that, while GE concurs with EPA's approach to use the output of its fate, transport, and bioaccumulation models in the Human Health Risk Assessment, you believe that EPA should not rely on the output of models as presented in the May 1999 Baseline Modeling Report because the models "have not been subjected to public comment and peer review."

However, as shown by your comments on the Baseline Modeling Report, GE was aware that EPA held a public comment period on the Baseline Modeling Report through June 23, 1999. By the date of your July 13, 1999 letter, EPA had already announced that the Baseline Modeling Report would be the subject of peer review in March 2000 (see, EPA's June 10, 1999 Reassessment RI/FS Schedule, attached). Waiting until after the peer review for the Baseline Modeling Report to use the model output, as you suggest, would have unnecessarily delayed issuance of the risk assessments by about one year.

Moreover, as explained at the August 4, 1999 Joint Liaison Group meeting for release of the risk assessments, EPA expects that the fine-tuning of the fate, transport, and bioaccumulation models that is currently underway will not change the overall conclusions of the risk assessments. In the unlikely event that the model results change sufficiently to affect the overall conclusions, EPA would recalculate risks to human health.

Toxicological Issues

You state that the findings of Kimbrough et al. (1999), which were published after submission of GE's comments on the Human Health Risk Assessment Scope of Work, must be considered in the Human Health Risk Assessment. Naturally, because the Kimbrough et al. (1999) study had not yet been published, EPA did not receive any comments related to it during the public comment period on the Human Health Risk Assessment Scope of Work and, therefore, did not address it in the Responsiveness Summary for the Human Health Risk Assessment Scope of Work. Nevertheless, EPA was aware of this study when it was published and included it in the Human Health Risk Assessment for the Upper Hudson River (see, pp. C-2 to C-3).

You also state that ATSDR's December 1998 draft Toxicological Profile for PCBs, which was released for public comment after submission of GE's comments on the Human Health Risk

Assessment Scope of Work, must be considered in the Human Health Risk Assessment. Similar to the Kimbrough et al. (1999) study, because the draft toxicological profile was not yet released for public review, EPA did not receive any comments related to it during the public comment period on the Human Health Risk Assessment Scope of Work and, therefore, did not address it in the Responsiveness Summary for the Human Health Risk Assessment Scope of Work. Nevertheless, EPA is aware of ATSDR's draft toxicological profile for PCBs and, along with GE and others, has submitted extensive comments to ATSDR. However, in contrast to the Kimbrough et al. (1999) study, EPA did not include a discussion of ATSDR's document in the August 4, 1999 Human Health Risk Assessment for the Upper Hudson River because ATSDR's document is a draft subject to revision rather than a final document.

Limitations of the New York Angler Surveys

You state that the Responsiveness Summary for the Human Health Risk Assessment Scope of Work "ignores the limitations of the Connelly et al. and Barclay data and overstates the difficulty of applying the Ebert data [from a survey of Maine anglers] to the Hudson River." EPA would agree that a survey of Upper Hudson River anglers would be ideal for the Human Health Risk Assessment for the Upper Hudson River but, due to the current ban on consumption of fish as a result of PCB contamination, such a survey cannot be used to establish the fish consumption rates needed for the point estimate and Monte Carlo calculations in the Human Health Risk Assessment.

Instead, for the point estimate calculations for the Upper Hudson River, EPA used the Connelly et al. (1992) data from a 1991 survey of New York State anglers that was conducted by Dr. Connelly of Cornell University and others. The so-called limitations of the Connelly et al. (1992) data described in your letter, namely that the survey was not designed to assess consumption by sports anglers and that no portion size was indicated, were addressed. The survey was designed to assess New York State sports anglers' awareness and knowledge of fishing advisories and contaminants, and the survey data were usable for the Human Health Risk Assessment. With respect to portion size, EPA assumed a 1/2-pound (227 gram) fish meal, which is a typical meal size (see, Human Health Risk Assessment at p. 42). EPA's fish ingestion rate for the reasonably maximally exposed (RME) individual is equivalent to about one 1/2-pound fish meal per week, or 31.9 grams per day, which is similar to the 25 grams per day default high-end value from EPA's 1997 *Exposure Factors Handbook*, the 27 grams per day from Ebert et al. (1993), and the 30 grams per day used by the New York State Department of Health. For the Monte Carlo analysis, EPA used fish ingestion rates from different studies, including Ebert et al. (1993), to establish a range of possible fish consumption rates. In general, the studies indicate similar consumption rates at the high end (i.e., above the 90th percentile) (see, Human Health Risk Assessment for the Upper Hudson River, Table 3-2).

Rejection of the Microexposure Event Analysis Method

In your letter, you urge EPA to apply the microexposure event analysis method developed by ChemRisk (1995) to the Phase 2 Human Health Risk Assessment for the Hudson River PCBs site. As described in the ChemRisk (1995) report, entitled "Hudson River Superfund Project:

Approach for Performing Human Health Risk Assessment," the microexposure event analysis method recalculates fish consumption on a daily basis, which could systematically "average-out" a high-end fish consumer (i.e., a high-end fish consumer for one meal could be a low-end or average fish consumer the next meal). EPA considers it more reasonable that a person consuming fish at the high-end for one fish meal would consume fish at the high end for subsequent fish meals. GE's recommended approach could therefore underestimate the risks and hazards to the high-end individual and may not be protective of the high-end individual. For these reasons, the microexposure event analysis method is not appropriate for use in the Human Health Risk Assessment.

**Hudson River PCBs Site
Reassessment RI/FS
June 10, 1999**

Milestone	Completed	To Public
PHASE 1 Report	✓	Aug 1991
PHASE 2 Field Sampling Program - 1992 to 1994	✓	N/A
Database Report (DBR)	✓	Nov 1995
Preliminary Model Calibration Report (PMCR)	✓	Oct 1996
Data Evaluation & Interpretation Report (DEIR)	✓	Feb 1997
Low Resolution Sediment Coring Report (LRC)	✓	Jul 1998
Human Health Risk Assessment Scope of Work	✓	Jul 1998
CD-ROM Database Reissue	✓	Jul 1998
Peer Review 1 - Modeling Approach - Begins	✓	Jul 1998
Peer Review 1 Meeting	✓	Sept 1998
Ecological Risk Assessment Scope of Work	✓	Sept 1998
DBR, PMCR, DEIR Responsiveness Summary	✓	Dec 1998
Peer Review 2 - DEIR & LRC - Begins	✓	Jan 1999
LRC Responsiveness Summary	✓	Feb 1999
Peer Review 2 Meeting	✓	Mar 1999
Human Health Risk Assmt SOW Responsiveness Summary	✓	Apr 1999
Ecological Risk Assmt SOW Responsiveness Summary	✓	Apr 1999
Baseline Modeling Report (BMR)	✓	May 1999
Human Health Risk Assessment (HHRA)		Aug 1999
Ecological Risk Assessment (ERA)		Aug 1999
BMR Responsiveness Summary		Jan 2000
Peer Review 3 - BMR - Begins		Jan 2000
Peer Review 3 Meeting		Mar 2000
HHRA and ERA Responsiveness Summaries		Mar 2000
Peer Review 4 - HHRA & ERA - Begins		Mar 2000
Peer Review 4 Meeting		May 2000
PHASE 3 Feasibility Study Scope of Work (FS SOW)	✓	Sept 1998
FS SOW Responsiveness Summary	✓	Jun 1999
FS Report		Dec 2000
PROPOSED PLAN		Dec 2000
RECORD OF DECISION (including Responsiveness Summary)		Jun 2001