



John G. Haggard, Manager
Hudson River Projects

General Electric Company
1 Computer Drive South
Albany, NY 12205
Fax: (518) 458-1014
Telephone: (518) 458-6619
Dial Comm: 8* 920-9619
E-Mail: John.Haggard@corporate.ge.com
Pager: 518-484-3177

June 29, 1999

Douglas J. Tomchuk
USEPA Region II
Emergency & Remedial Response Division
290 Broadway, 20th Floor
New York, NY 10007

Re: General Electric Comments on EPA Responsiveness Summary
Phase 2 – Ecological Risk Assessment Scope of Work
Hudson River PCBs Reassessment RI/FS

Dear Mr. Tomchuk:

The General Electric Company (GE) is pleased to submit the enclosed comments on the EPA report entitled "Responsiveness Summary for Phase 2 Ecological Risk Assessment Scope of Work (April 1999)."

Our major concerns with the Ecological Risk Assessment (ERA) Scope of Work (SOW) are twofold. First, the Responsiveness Summary indicates that the ERA will use the output from the EPA transport and bioaccumulation models before subjecting those completed models to public comment and peer review. During the recent public meetings on the Baseline Modeling Report, the EPA referred to their model as a "work in progress". Additionally, as the recently submitted comments on this model by GE documents there are fundamental flaws in this work. However, it is clear EPA plans to utilize projections from this model in the ERA. This will result in a risk assessment of little value to a risk manager in making informed decisions on future conditions of the Hudson.

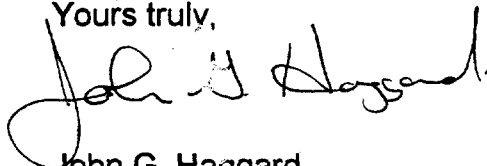
Second, the ERA SOW focuses on a "bottom up" approach by comparing estimated PCB exposures in biota to "toxicity reference values" to assess ecological risks. The results need to be placed in the context of the available status of populations or communities of

Douglas J. Tomchuk
June 25, 1999
Page 2

ecological receptors. This risk assessment is at best a screening level assessment that may identify areas of potential concern that will require a more rigorous and scientifically defensible analysis.

If you have any questions or comments, let me know. Please place a copy of these comments in the administrative record for this site.

Yours truly,



John G. Haggard

JGH/bdg
Encl.

cc: Richard Caspe, US EPA
William McCabe, US EPA
Melvin Hauptman, US EPA
William Daigle, NYDEC
Anders Carlson, NYDOH
Bob Montione, NYDOH
Douglas Fischer, US EPA
Lisa DiPinto, NOAA
Lisa Rosman, NOAA
Jay Field, NOAA

**General Electric Company's Reply to
The United States Environmental Protection Agency's
Responsiveness Summary for Phase 2- Ecological Risk Assessment Scope of Work**

General Electric Company ("GE") submits this reply to the United States Environmental Protection Agency's ("EPA" or "Agency") "Responsiveness Summary for Phase 2 – Ecological Risk Assessment Scope of Work" ("Responsiveness Summary"). This reply highlights GE's significant concerns with the Agency's planned Ecological Risk Assessment ("ERA") for the Hudson River PCBs Superfund Site ("Site").¹

GE's major concerns with the Agency's planned approach for the ERA are twofold. First, the Responsiveness Summary reveals EPA's intent to use the output of its fate, transport and bioaccumulation models before subjecting those models to public comment and peer review. The Company's recently submitted comments on the May 1999 Baseline Modeling Report demonstrate that EPA's model, in their current state, are not capable of accurately and reliably predicting future PCB concentrations in sediment, water and fish. As a result, the models will not provide valid and appropriate inputs for the ERA. Before relying on the models for the ERA, the Agency must consider public and peer reviewer comments and make appropriate and necessary changes to the models.

Second, both the ERA Scope of Work ("SOW") and the Responsiveness Summary reveal the Agency's intent to rely solely on a "bottom up" approach, which compares measured or estimated PCB concentrations against "toxicity reference values," to assess ecological risks. Properly-conducted and scientifically valid "bottom-up" analyses are one of several useful tools for conducting an ERA, but it is scientifically indefensible to use only the output of bottom-up risk estimates and ignore available data on the status of populations or communities. The approach set forth in the SOW and the Responsiveness Summary, moreover, is problematic because it is limited to comparing available PCB concentration data and unconstrained and unvalidated model results against laboratory and field-derived toxicity benchmark (or toxicity reference) values. This approach will fail to provide useful information for remedial decision-making because of the unrealistic assumptions within EPA's models and the lack of model validation. In the end, EPA's approach is no more than a screening analysis to indicate that a potential risk might exist and that further investigation is needed to draw any conclusions with confidence.

We review each of these issues in turn and identify several responses to comments that are inadequate or misleading.

¹ This reply is limited to GE's significant concerns. By not raising an issue, GE is not withdrawing from EPA consideration any of the issues raised in GE's original comments.

I. EPA Should Not Rely on the Output of Fate, Transport and Bioaccumulation Models that Have Not Been Subjected to Public Comment and Peer Review.

A critical component of the ERA is projecting future ecological risks. To perform this task, EPA will need valid and reliable estimates of future PCB concentrations in water, sediment, and fish. The only reliable tools to provide such estimates are properly calibrated and validated fate, transport and bioaccumulation models. Indeed, the Responsiveness Summary states that the Agency intends to use the output of the fate, transport and bioaccumulation models presented in the Baseline Model Report ("BMR") (Responsiveness Summary at 34), and GE generally concurs with this approach.

Although EPA and GE agree on the general approach to estimating PCB concentrations in the future, the Agency's plans for actually doing this work are problematic. EPA issued the BMR on May 18, 1999 and in public meetings described it as a "work in progress." The comment period closed on June 23, 1999. EPA intends to issue its response to comments and initiate its peer review of the models presented in the BMR in January 2000, with the actual peer review to occur in March 2000. Under this schedule, EPA will not be able to make any necessary modifications to the models until the summer of 2000, at the earliest.

Nevertheless, EPA's schedule calls for release of the ERA in August 1999, and it is likely that near-final drafts of the ERA report are now being reviewed within the Agency. This means that, for one of the most important parameters to be considered in the ERA – future PCB concentrations –, EPA will be using the output of models that do not reflect changes that might result from public comments and the peer review. The ERA should incorporate data based on final and complete models, not ones that are very likely to be changed. To use incomplete and non-final models will result in a misleading and incorrect assessment of future ecological risks. An ERA on which one cannot rely has little utility for a risk manager.

II. The Agency's Planned Bottom-Up Approach to the ERA is Technically Flawed, will Ignore Important Data, and will be of Little Benefit to the Risk Manager.

The Responsiveness Summary confirms EPA's intent to rely on what it terms the "bottom-up" method to risk assessment: using available data and modeling to compare measured or estimated PCB concentrations in the environment and in biota against laboratory or field-derived toxicity reference values ("TRVs"). Although bottom-up methods, if conducted correctly (e.g., using site-specific data to derive sediment toxicity benchmarks or using wildlife risk models based on realistic assumptions), can provide useful screening information, EPA's planned approach is technically inadequate because of the scarcity of site-information, the significant reliance on unvalidated models, and the Agency's intent to rely on standards (e.g., ambient water quality criteria) that are not appropriate for use as measurement endpoints. Further, even properly conducted "bottom-up" analyses provide only one uncertain line of evidence and, to provide a fair assessment of ecological risks, must be considered together with "top down" information on the status of communities and populations. The Responsiveness Summary, however,

reveals the Agency's intent to ignore or discount the available site data of this sort. For these reasons, the ERA will fail to provide useful information to the risk manager on PCB impacts to populations or communities of ecological receptors in the Hudson River basin. For example, the risk manager will be forced to make decisions on highly uncertain and theoretical predictions of risk without a comparative analysis with empirical site-specific data. Any risk management decisions based on such information would be tentative and would not be based on an understanding of all available data.

A. The "Bottom-Up" Analyses to be used in the ERA has Limited Utility

There are several significant and serious limitations in the Agency's planned "bottom-up" analyses:

- The Responsiveness Summary (p. 25) states that the Agency intends to "model" exposures of avian and mammalian receptors, yet concedes there are no site data to validate these models. The use of results produced by a model that cannot be validated against real-world data is highly uncertain because it is not known whether the results accurately predict exposure conditions at the site. Available data on PCB body burdens (e.g., for tree swallows) should be used or additional site-specific data on PCB body burdens of avian and mammalian species should be collected to verify models.
- The Responsiveness Summary (p. 23) states that the Agency intends to hold exposure concentrations constant in the future even if the fate, transport and bioaccumulation models show declining concentrations. The stated basis for this is that it is "a conservative approach." Although holding concentrations constant into the future might be construed as "conservative," it is likely to be unrealistic and overly conservative. Indeed, both GE's and EPA's fate, transport and bioaccumulation models predict significant declines in PCB levels in environmental media and biota in the future. Rather than deciding *a priori* to hold future concentrations constant, GE recommends using the results of calibrated and validated models regardless of whether those models show declining or non-declining concentrations. The goal of the ERA is not simply to provide a conservative assessment of ecological risks, but to provide as realistic and accurate an assessment as is necessary. While a screening-level risk assessment may be based on highly conservative assumptions, a baseline risk assessment, such as the one being conducted for the Hudson River site, should be based on realistic exposure scenarios.
- The Responsiveness Summary reaffirms the Agency's intent to use regulatory standards, such as ambient water quality criteria, as measurement endpoints. Responsiveness Summary at 19. Using generic water quality criteria as measures of risk is inappropriate and cannot be used to substitute for a site-specific ecological risk assessment. Although these sort of criteria might qualify as "ARARs," they typically provide little or no information on the level of risk that a particular species might face. Indeed, EPA guidance recognizes that measurement endpoints "should represent the same exposure pathway and toxic mechanism of action as the

assessment endpoint it represents; otherwise irrelevant exposure pathways or toxic mechanisms might be evaluated" (EPA 1997). Similarly, EPA guidance explicitly recognizes the limitations of using water quality criteria in ERAs:

[I]t is instructive to note that although water quality criteria are considered risk-based, they are not full risk assessments. Water quality criteria provide an effects benchmark for decision making and do not incorporate measures of exposure in the environment. Within that benchmark, there are a number of assumptions about significance (e.g., aquatic communities will be protected by achieving a benchmark derived from individual species' toxicological responses to a single chemical) and exposure (e.g., 1-hour and 4-day exposure averages). Such assumptions embedded in decision rules are important to articulate.

(EPA 1998). In other words, EPA must ensure that the measurement endpoint is relevant to the communities and populations being evaluated. Indeed, we note that NYSDEC's PCB water quality standard for protection of wildlife was derived using only mink as a receptor. Putting aside whatever flaws this standard has, it is clear that there is no basis for using this standard as a measure of risk to other biota

- The Responsiveness Summary (at 32) overstates the quality and validity of available TRVs for PCBs: TRVs "are based on the results of scientific studies showing observable, repeatable effects, directly related to PCBs." EPA must recognize the limitations of available TRVs, such as lack of data on specific Aroclors, species and endpoints relevant to the Hudson River site. For example, dose-response studies on bat species are limited (Clark and Lamont 1976, Clark and Krynitsky 1978, Clark 1978, Clark and Stafford 1981) and have only tested effects of Aroclor 1260. The most useful of these studies provide a NOAEL and a lethal brain concentration (Clark 1978, Clark and Stafford 1981). Collectively these studies do not show "observable, repeatable effects." In addition, there are field studies that are the only available dose-response data for certain wild species on the EPA list of potential receptors, such as the tree swallow. The results of these field studies are confounded by concentrations of contaminants other than PCBs in the environment and do not show direct effects of PCBs.
- In establishing exposure concentrations for mink, EPA should consider the work of Burgess and Bider (1980), Birks and Dunstone (1985), Proulx et al. (1987), and other references cited in EPA's *Wildlife Exposure Factors Handbook* (1993), which show that the mink's diet is not solely aquatic, but also includes a significant terrestrial component.

In short, there are significant concerns about the scientific validity of the Agency's planned "bottom-up" approach. These concerns are exacerbated by the Agency's apparent intent to ignore or discount available "top-down" information.

B. The Agency Must Consider all Available Data

The Agency's screening analysis inappropriately discounts the utility and availability of data on the status of relevant populations and communities and the impacts that PCBs may have had on these communities. For example, as GE pointed out in its initial comments, there are voluminous data and studies showing that fish in both the upper and lower Hudson are abundant and healthy and that PCBs have not adversely affected them. Indeed, the Atlantic States Marine Fishery Commission, the National Marine Fisheries Service and the National Oceanic and Atmospheric Administration have all concluded that PCBs in the Hudson did not adversely affect the abundance of striped bass. Studies of Shortnose and Atlantic Sturgeon in the Hudson also testify to the relative health of these populations despite the presence of PCBs.

Rather than address these sorts of data and analyses, the Responsiveness Summary appears to reflect EPA's intent to ignore them and place greater reliance on its "bottom-up" screening analysis. The stated rationale for this approach is that it is more conservative and thus protective of the environment. E.g., Responsiveness Summary at 17 and 19 ("While there is uncertainty associated with extrapolating from an individual-level risk to a community or population, such an approach is protective of the environment"). For example, the Responsiveness Summary (at 28) reveals the Agency's intention to rely on comparison of PCB concentrations to generic regulatory standards or TRVs even if available data on the status of populations provides contrary evidence: "The potential for adverse effects will be based on comparisons of measured and modeled exposure concentrations to both appropriate regulatory standards and TRVs obtained from the scientific literature, even if no adverse effects are observed in the receptors of concern" (emphasis added). Similarly, the Responsiveness Summary (at 29) confirms the Agency's intent to ignore specific measures of population or community status in favor of the "bottom-up" approach set out in the SOW.

Although the Responsiveness Summary asserts that it will use "multiple lines of evidence" in its ERA (Responsiveness Summary at 13, 19), it is clear that EPA intends to dismiss available field data on population and community health and, instead, place sole emphasis on non site-specific laboratory and field studies that show the potential for adverse impacts. Relying on the studies from other sites which purport to find effects when site-specific data show no effects reveals an unjustifiable bias towards "conservatism" and is not a scientifically valid method for weighing different lines of evidence. The critical factor is not merely the "weight" of evidence, but how that evidence is "weighed." The approach set out in the Responsiveness Summary and the SOW shows that EPA does not intend to follow proper scientific practice.

Indeed, the proposed approach to the Hudson River ERA is inconsistent with EPA guidance that supports the use of multiple lines of evidence, including site-specific field surveys. For example, Section 5.2.1 of EPA (1998) provides that:

Using several lines of evidence to interpret and compare risk estimates may increase confidence in the conclusions of a risk assessment. These

lines of evidence may be derived from different sources or by different techniques relevant to adverse effects on the assessment endpoints, such as quotient estimates, modeling results, field experiments, or field observations.

Similarly, Section 5.1.6 of EPA (1998) provides that:

A major advantage of field surveys is that they provide a reality check on other risk estimates, since field surveys are usually more representative of both exposures and effects (including secondary effects) found in natural systems than are estimates generated from laboratory studies or theoretical models.

The Hudson River ERA should follow this guidance and fairly consider available site-specific data.

III. The Responsiveness Summary Does Not Adequately Respond to Some Comments

The Responsiveness Summary contains several inadequate or misleading responses to comments:

- In response to a comment arguing that the Agency had not collected sufficient site-specific data (EA-10), the Responsiveness Summary (at 27) states that EPA did not conduct site-specific toxicological studies because such studies would have taken several years to complete and this would have delayed the process. EPA has been conducting its reassessment for 9 years, and there was ample time to collect the necessary data without slowing down its work.
- The response to GE's comment (EG-11) on the failure to include aquatic vegetation in the site conceptual model (Responsiveness Summary at 18) misconstrues the point of GE's comments. Aquatic vegetation is important to consider because it serves as habitat, not as a direct food source. This is a particularly important issue to consider when an intrusive remedy, such as dredging, might severely impact this habitat, potentially irreversibly.
- The Responsiveness Summary (at 31) fails to respond to GE's comment (EG-19) that the lack of site-specific data will make the results highly uncertain. While the Responsiveness Summary states that EPA "disagrees," the only basis given for this disagreement is that the ERA will follow Agency guidance. Whether or not the ERA follows generally applicable Agency guidance does not explain why the lack of data from this site will ensure that there will be sufficient certainty in the results of this ERA.

REFERENCES

- Birks, J.D., and N. Dunstone. 1985. Sex-related differences in the diet of the mink *Mustela vison*. *Holarctic Ecol.* 8:245-252.
- Burgess, S.A., and J.R. Bider. 1980. Effects of stream habitat improvements on invertebrates, trout populations, and mink activity. *J. Wildl. Manage.* 44:871-880.
- Clark, Jr., D.R., 1978. Uptake of dietary PCB by pregnant big brown bats (*Eptesicus fuscus*) and their fetuses. *Bull. Environ. Contam. Toxicol.* 19:707-714
- Clark, Jr., D.R., Krynetsky, A., 1978. Organochlorine residues and reproduction in the little brown bat, Laurel, Maryland. *Pestic. Monit. J.* 12(3):113-116 BE CLARK 10011 ECORISK
- Clark, D.R., Lamont, T.G., 1976. Organochlorine residues and reproduction in the big brown bat. *J. Wildl. Mgmt.* 40:249-254
- Clark, Jr., D.R., Stafford, C., 1981. Effects of DDE and PCB (Aroclor 1260) on experimentally poisoned female little brown bats (*Myotis lucifugus*): lethal brain concentrations. *J. Toxicol. Environ. Health* 7:925-934
- Proulx, G., J.A. McDonnell, and F.F. Gilbert. 1987. The effect of water level fluctuations on muskrat, *Ondatra zibethicus*, predation by mink, *Mustela vison*. *Can. Field-Nat.* 101:89-92.
- U.S. EPA. 1993. Wildlife Exposure Factors Handbook, Volumes I and II. U.S. EPA 600/R-93/187a & b
- U.S. EPA . 1997. Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments – Interim Final. EPA 540-R-97-006
- U.S. EPA. 1998. Guidelines for Ecological Risk Assessment – Notice. Fed. Register Vol. 63 No. 93, 80 pp.