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August 26, 1991

Mr. Douglas Tomchuk
Remedial Project Manager
Emergency and Remedial Response Division
U. S. Environmental Protection Agency - Region II
26 Federal Plaza
New York, New York 10278

Re: Reassessment of PCB Toxicity - Reassessment of the Pathological Diagnoses of the Key Rat Feeding Studies

Dear Mr. Tomchuk:

Enclosed for your review and inclusion in the Hudson River Reassessment RI/FS administrative record is a copy of the report entitled: "Reassessment of Liver Findings in the Five PCB Studies in Rats (July 1, 1991)." Included with this report are copies of two letters formally transmitting the report to the Washington D.C. office of the U.S. Environmental Protection Agency (EPA). The reevaluation was coordinated by the Institute for Evaluating Health Risks (IEHR). While the General Electric Company (GE) funded the reevaluation, GE did not participate in the actual reread by the pathology work group nor in preparation of the enclosed report or letters. Additionally, both the U.S. Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA) participated as observers to the reread.

In addition to the reread report, I have also included a copy of comments developed and submitted by GE on the recent Advanced Notice of Proposed Rulemaking (ANPR) of the U.S. EPA concerning disposal of polychlorinated biphenyls. This document contains a concise description of the reread as well as an exhaustive analysis of the existing studies on PCB toxicity. Section 2B and 2C of the document are relevant to the Hudson River project and need to be included in the Reassessment RI/FS Administrative Record.

With respect to the reread the following findings are of importance to the Hudson River project:

1. The study reaffirmed that chronic dietary exposure of rats, in three different studies, to 60% chlorinated PCB formulations resulted in the development of benign and malignant tumors in rats:

2. The study reaffirmed that chronic exposure of rats to a PCB formulation that was 54% chlorinated did not yield a statistically significant increase of either benign or malignant tumors; and

3. The study revealed that rats chronically exposed to a PCB formulation that was 42% chlorinated did not develop any increase in malignant tumors or a statistically significant increase in benign tumors.

Based on this information, the potential impacts of the reread on the specific conditions in the Hudson River are obvious. The PCB's in the Hudson River are lightly chlorinated indicating at most a weak carcinogenic potential. The on-going natural process of biodegradation will continue to reduce the chlorination level even further. In this situation, particularly in light of this new scientific information, for EPA to prepare a risk assessment that assumes all the PCB's in the Upper Hudson are equivalent to Aroclor 1260 is clearly not defensible. As a result, GE believes the following actions are necessary:

1. The final Hudson River risk assessment must be based on Aroclor specific cancer potencies. Specifically, the use of the results from Clophen A30 appear to be most similar to the PCB's currently present in the river and those that will be present in the future.

2. Due to this significant new information (and other reasons already communicated to you) EPA should not publish a Phase I quantitative risk assessment for the upper river at this time. Such an assessment will be terribly misleading if numbers based on Aroclor 1260 are used for the calculation of carcinogenic potency.

3. Your office should follow EPA guidance and initiate a reevaluation of the cancer potency figures currently contained in the IRIS (Integrated Risk Information System) specifically for the Hudson river project. Furthermore, the risk assessment should not be completed until such an evaluation is complete. In Volume 1 of the Risk Assessment Guidance for Superfund (RAGS) it is stated (page 7-14) "If new data are identified suggesting that existing IRIS information may be outdated, or if there is concern or substantial disagreement about the overall findings of particular files, the Agency coordinator should be consulted. The IRIS coordinator can assist in making arrangements should discussions with a verification work group be needed." The guidance also describes the "verification" work group, which is referred to as the Carcinogen Risk Assessment Verification Endeavor (CRAVE) (page 7-13). Based on the data submitted to you today, GE believes that the criteria outlined in the guidance for revaluating the PCB toxicity information in IRIS are present.

GE is concerned that EPA will not act on this relevant and significant new scientific information in a time frame that will allow proper consideration for the Hudson River Reassessment RI/FS. As indicated above, the reread may have profound affects on the outcome of the Reassessment RI/FS. We have been concerned that an EPA internal review may take 2 to 4 years to complete! Additionally, in apparent contradiction to what your guidance directs, you have mentioned to me a number of times that you feel your hands are tied until you are directed by EPA in Washington to use a different toxicity value for PCB's. GE firmly believes that EPA can expedite this review process.

Please let me know if there is any information that we can supply concerning the results of the reread. I would like to again request to meet with EPA's Region II management and consultants to discuss these significant new findings and their importance to the Hudson River project. We are only asking that the results be given due consideration in the Hudson River Reassessment RI/FS. If you require any additional information, please let me know.

Please place a copy of the enclosed documents and a copy of this letter into the Hudson River Reassessment RI/FS administrative record.

Yours truly,

John G. Haggard
Engineering Project Manager

Enclosures

cc: Douglas R. Blazey, USEPA-NY
Kathleen Callahan, USEPA-NY
William McCabe, USEPA-NY
William Ports, NYDEC