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April 30, 1992

Mr. Douglas J. Tomchuk
Remedial Project Manager
U.S. Environmental Protection Agency
Emergency & Remedial Response Div.
26 Federal Plaza - Room 747
New York, NY 10276

RE: HUDSON RIVER PCB SITE

Dear Doug:

The purpose of this letter is to call to your attention the enclosed February 26, 1992 memorandum from Deputy Administration Habicht and the new Guidance for Risk Assessment which accompanies it.

The Preliminary Human Health Risk Assessment which appeared in the August 1991 Phase 1 Report obviously did not comply with the specifications set forth in Mr. Habicht's memorandum and accompanying Guidance. This is understandable since neither the memorandum nor the Guidance was available when the Phase 1 Report was prepared. However, we believe that the memorandum and Guidance is applicable to your Phase 2 effort, and we expect that the Phase 2 work plan will contain tasks and assignments which are consistent with the memorandum and Guidance.

Nevertheless, we would like to take this opportunity to point out some specific elements of the Phase 1 Preliminary Human health Risk Assessment which are at variance with the enclosed materials:

 The "Analysis of Uncertainties" (B.6.4.6) appears to be an after the fact, add on section. It is extremely general, skimpy and incomplete and does not even begin to address the uncertainties attached to each and every component of the Risk Assessment, Because this section is completely disconnected from the rest of the Risk Assessment, it fails to be "a frank and open discussion of the uncertainty in the overall assessment <u>and in each of its components"</u> (emphasis supplied). The Preliminary Human Health Risk Assessment is almost entirely a collection of individual numerical components resulting in single number values for potential risk. As the enclosed Guidance points out:

"A simplified numerical presentation of risk is always incomplete and often misleading".

3) The specific numerical values selected in the Preliminary Human health Risk Assessment are cumulated at maximum or near maximum values. The Guidance points out:

"Maximizing all variables will in virtually all cases result in an estimate that is above the actual values seen in the population."

In our comments on the Phase 1 Report (p.129), we pointed out how the use of a Monte Carlo simulation would be used to deal with the fact that a single number estimate for human consumption of fish failed to accurately reflect the variability of the data being used to generate an estimate. We note that the Guidance identifies this as an appropriate methodology (as does RAGS I on page 10-33). Given the major uncertainties attendant to every single element of the Human Health Risk Assessment for the Hudson PCB Site, we would hope that the Phase 2 Work Plan would call for Monte Carlo simulations for each factor where the data shows variability and where population distribution information is available. We believe that any further Human Health Risk Assessment which follows the patterns of the one set forth in the Phase 1 Report and contained nothing more than a simplified discussion of risk issues expressed in simplified numerical terms without qualitative information on methodology, alternative interpretation, working assumptions and uncertainties would not be consistent with the National Contingency Plan as interpreted by EPA through its various guidances including enclosed memorandum and supporting material.

Please place a copy of this letter and the attached guidance into the Hudson River RRI/FS administrative record.

Truly yours, der 2. d

John G. Haggard Engineering Project Manager

JGH:bp

cc: Albert Di Bernardo, TAMS Yvette Lowney, Gradient Marina Stefanidis, EPA William McCabe, EPA bcc: J. Claussen B. Kafin P. Lanahan

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