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April 28, 2000

Peter deFur, Ph.D.
President
Environmental Stewardship Concepts
11223 Fox Meadow Drive
Richmond, VA 23233-2218

Re: Hudson River Ecological Risk Assessment

Dear Dr. deFur:

I am writing regarding the upcoming peer review of the Hudson River Baseline Ecological Risk Assessment (BERA) in which you are to participate. General Electric Company (GE) believes there are several fundamental problems with the BERA, and attached to this letter are two short papers summarizing our view. I hope that you consider these papers and find them useful in your deliberations.

The most fundamental problem with the BERA is its lack of transparency and clarity. On March 21, 1995, EPA Administrator Carol Browner issued guidance regarding risk communication.¹ In this guidance, Administrator Browner described the need for objective and balanced communication to the public in all risk assessment documents and policy decisions. She stressed the need for:

- Transparency and clarity in risk communication and management, and
- Consistency and reasonableness in the implementation of risk assessments.

The call for transparency and clarity in the decision-making process refers to the need for full and honest communication of all objectives, assumptions, uncertainties, and criteria that go into the development of an EPA policy decision. On this topic, the Administrator wrote:

This means that we must fully, openly, and clearly characterize risks. In doing so, we will disclose the scientific analyses, uncertainties, assumptions, and science policies which underlie our decisions as they are made throughout the risk assessment and risk management processes.

¹ This memorandum is available for viewing or download on the EPA web page at <http://www.epa.gov/ordntrnt/ORD/spc/rccover.htm>

The BERA falls short of both of the Administrator's clear and unambiguous directives. The risk characterization process and presentation is neither clear nor transparent.

- The BERA contains a detailed discussion of the mechanical steps involved in the evaluation of the various measurement endpoints, but fails to discuss the underlying principles, assumptions, and thought processes implicit in the interpretation of the findings. The BERA purports to use a "weight of evidence" approach in the characterization of risk. EPA did not actually apply this approach, however, instead relying almost exclusively on "toxicity quotients" (TQs). The TQs used by EPA, moreover, are derived from measured or predicted concentrations of PCBs and literature-derived toxicity reference values (TRVs). Virtually no information is presented documenting the actual condition of the ecological resources of the Hudson River Valley or demonstrating any actual harm caused by PCBs. In essence, EPA has redefined the term "at risk" to mean "not proven to be risk-free" using conservative models and assumptions.
- The BERA also mischaracterizes and greatly understates the uncertainties associated with the assessment. The "Uncertainty Analysis" presented as Chapter 6 is largely made up of a discussion of data quality and a generic catalog of the types of uncertainties that may exist in risk assessments in general. There is no attempt to summarize or even roughly quantify the net uncertainty associated with the assessment endpoint evaluations or risk assessment conclusions. With the exception of some food web model input parameters, no uncertainties associated with the various endpoints are quantified. The reader is left with a false impression that uncertainty is relatively low, when in fact, it is orders of magnitude for many assessment endpoints. In general, the assessment contains a large number of assumptions, uncertainties, and implied policy decisions that go unstated and unexplained.
- Policy decisions contained within the BERA are disguised as scientific decisions, in direct conflict with the Administrator's memorandum. The "uncertainty factors" used in the derivation of the TRVs are actually safety factors that increase the conservatism of the assessment without directly addressing scientific uncertainty.

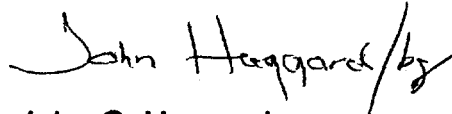
The result is an assessment that is unreasonable and results that are unrealistic. EPA did not rigorously evaluate all available data to reach reasonable and clearly justified conclusions. Data not considered by the Agency include recent studies demonstrating that one of the endangered species determined by EPA to be "at risk," the shortnose sturgeon, has actually greatly increased in abundance throughout the lower Hudson. Another endangered species that was determined to be "at risk," the bald eagle, is now successfully nesting and reproducing in the Hudson River Valley for the first time in decades.

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GE believes that the problems in the BERA make the document of little use for the risk manager. The attached papers provide more detail about these problems. I hope that you review them before reaching a final conclusion about the BERA. Please do not hesitate to contact me if you have any questions.

Yours truly,

A handwritten signature in black ink, appearing to read "John Haggard/bg". The signature is fluid and cursive, with a large initial "J" and a stylized "H".

John G. Haggard

JGH/bg

Attachment

cc: Alison Hess, U.S. EPA
William McCabe, U.S. EPA
Douglas Tomchuk, U.S. EPA
Douglas Fischer, U.S. EPA (ORC)
Steven Sanford, NYDEC
Ron Sloan, NYDEC
Bob Montione, NYDOH
Tom Brosman, NOAA
Jay Field, NOAA
Sharon Shutler, NOAA
Lisa Rosman, NOAA (New York)