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July 1, 1999

Mr. Douglas Tomchuk
USEPA – Region 2
290 Broadway – 20th Floor
New York, NY 10007-1866

Dear Mr. Tomchuk:

I have reviewed the Response summaries for the Human Health and Ecological Risk Assessment SOWs issued in April, 1999. In my opinion there are many relevant, and a number of critical, issues raised by various responders to both assessments which are not adequately addressed in these response volumes. However, I cannot presume to speak for other respondents and my remarks here are specific to my letter of 10/28/98.

In my view these assessment scopes are biased by 1) refusal to consider comparative data (e.g. background, exposures, effects, medical history, and outcomes) from other localities or sites of PCB contamination; with human exposure risk; 2) a reliance on toxicity or carcinogenic reference values extrapolated from indirect, and in some cases arbitrary, sources of data; nearly all of which are derived from other localities, or laboratory work, involving arochlors or congener mixtures different from those now present in the Hudson; 3) a failure to consider the results of occupation mortality studies and contemporary opinion/debate in the medical profession about PCB type and toxicity effects on humans; and 4) a refusal to develop or consider the very relevant medical history data of the Ft. Edward/Hudson Falls workforce and general population, who were subject to PCB exposure by all of the exposure pathways identified.

Points 1, 3, and 4 are central to an assessment of human health risk, because the potentially available medical data is certainly much more relevant, detailed, and timely than the approach described in the SOW, namely (as in point 2, above) an extrapolation from limited studies based on laboratory animals fed PCB assemblages not comparable to those in the Hudson.

The bottom line in this RI/FS is to provide and project an accurate assessment of human health risk, and to this end any and all documented human PCB exposure and related medical data is certainly relevant.

The EPA "ERA "objective" to assess risk on a site-specific basis is, of course, logical to quantifying the parameters and conditions particular to an individual case, but it cannot mean that data and findings from other cases are not to be examined or considered, if relevant. If the latter is indeed EPA's ERA "guidance" (ERA, SOW p. 13), then it is tantamount to saying that

the principle of precedents and discovery in law and evidence progression in scientific investigation (also as applied in peer review) does not apply here; in other words the EPA is to be the sole judge of the basis of estimating risk; and of what risk data is relevant, and therefore can be presented (used in the work plan).

Considering the current debate about the toxicological effects of human exposure to PCBs, including alleged neurological impacts, an examination of the medical history data from documented studies of occupational and general public PCB exposure is certainly relevant, as is the exposure record and current status or recovery of the affected populations, especially where a fish ingestion pathway is present, as in the case of The Great Lakes study data. Moreover, the New York State Department of Health (NYSDOH) has investigated the PCB exposure of the Akwesasne (Mohawk Indian Reservation) on the St. Lawrence River, which includes ingestion of fish and animals. The NYSDOH investigation includes body burden data, and targeted infants and nursing mothers. Since the PCB involved was dominantly the more toxic arochlor 1260, the medical history of the Akwesasne should be very appropriate to consider in evaluating human health risk.

Finally, extensive medical history data is available for the Hudson Falls and Ft. Edward populations through a combination of occupational data from G.E.; local, County, and State medical statistics, and NYSDOH data. Furthermore, these populations have had long term exposure to the same Hudson PCBs now subject to risk assessment, and by every identified pathway including ingestion (local garden crops) and inhalation. The unlined municipal dumps of the Towns of Ft. Edward and Kingsbury contain more PCB than is buried in Hudson River sediments, and area residents have generally been exposed for years to much higher PCB vapor fluxes (discernable odor) than obtained over the River proper. *(Note comment of Dr. Brian Bush at the 6/16/99 STC meeting).

To ignore, or fail to develop, this medical background information under the guise of some EPA technical "objective", would in my view immediately invalidate the Human Health risk assessment and I request my remarks be submitted to the peer review panel. I cannot imagine that in the course of a "scientific" investigation of human risk, with a potential impact of hundreds of millions of dollars that every available and relevant source of risk information and data would not, or is not, to be consulted, weighed, tested for validity, and carefully considered in the outcome.

Very truly yours,

George W. Putman

George W. Putman, Ph.D.
Emeritus Faculty

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