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MEMO TO: Hudson River PCBs Environmental Liaison Group

FROM: Cara Lee and Josh Cleland, Scenic Hudson
Andy Mele, Clearwater

RE: **Risk Assessment Issues**

You may have heard in the media in early January that Clearwater, Scenic Hudson, and other groups raised issues related to EPA's health risk assessment for the Hudson River PCBs reassessment. Since the news stories were vague and confusing to those familiar with the reassessment, we are taking this opportunity to clarify these issues for you.

In December, we wrote to EPA with specific concerns about the human health risk assessment methodology. In particular, a complete picture of the health impacts is not likely, because important potential impacts are outside the scope of EPA's current methodology. These issues mostly concern research that has emerged since Phase 1 of the reassessment. The purpose of our letter was to ask EPA to examine these issues to the extent possible. It is important to note that we did not ask EPA to prolong the reassessment. We would like to see EPA do all that is possible to address the issues within the current schedule.

The issues we raised with EPA, plus one more, are described below. Please contact Andy Mele (914-454-7673) or Cara Lee or Josh Cleland (914-473-4440) if you would like to discuss these issues.

Endocrine Disruption and Neurotoxicity

Research in the last few years has identified PCBs as endocrine disruptors. Also, there is a growing understanding of the direct neurotoxicity of PCBs. Subtle endocrine and neurological impacts (e.g., reduced intelligence, immune suppression, impaired memory) are difficult to document, and may not fit easily into EPA's current risk assessment methods. EPA and other federal agencies have instituted a major research program on endocrine disruption, and recent amendments to the Food Quality Protection Act and the Safe Drinking Water Act are causing EPA develop appropriate health protection for some endocrine disruptors. However, updated risk assessment data and methods would take years to develop.

The recent findings help to explain some of the already-known health impacts reflected in EPA's toxicity data. But the rapid pace of research suggests that additional effects are still being overlooked. In fact, a recent review paper lists several alternative PCB reference doses or similar benchmark concentrations that are lower than EPA's.[1] EPA maintains that the risk assessment is based on the most conservative known data, but acknowledges that there may be some effects without sufficient data for quantitative evaluation and intends to discuss them qualitatively. We are concerned that important unquantified PCB impacts will fall by the wayside in a EPA's numbers-driven decision-making.

Definitive quantitative data and methods are not necessary to reasonably conclude that endocrine and neurological impacts seen elsewhere could be occurring along the Hudson. Mothers participating in the Jacobson study ate fish with concentrations comparable to the current concentrations in some Hudson River Sport fish. Although the Jacobsons were unable to test the PCB concentrations in the fish eaten by mothers in their study, average PCB concentrations in Lake Michigan lake trout in the decade before the study began generally ranged from about 6 to 22 ppm. This range encompasses the current average PCB concentrations in some sportfish species in the Hudson.[2] This suggests that children whose mothers routinely eat fish from the Hudson River may be at risk of permanent learning impairment.

It is clear from the existing endocrine disruption research that further study is needed to fully understand the heath risks of PCBs in the Hudson Valley. This is not to suggest, however, that EPA should delay the reassessment. Uncertainty is an inescapable reality of all risk assessments, and further delays will not fill all the gaps. But we are concerned that EPA will minimize or overlook endocrine effects because it lacks established quantitative data and methods. From our experience studying environmental impact statements and assessment, issues relegated to "qualitative discussion" are often treated dismissively and have little real bearing on the outcome.

Population Risk Characterization

Superfund risk assessment policy specifies that cleanup decisions be based on the "reasonable maximum exposure" (RME) expected at a site. However, there are other useful methods of characterizing health risks, and EPA's Guidance for Risk Characterization recommends that risk assessments include multiple risk descriptors. For the Hudson River PCBs site, EPA is supplementing the RME with central tendency and probabilistic (i.e., monte carlo) risk

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[1] Rice, D.C. "Neurotoxicity of Lead, Methylmercury, and PCBs in Relation to the Great Lakes." *Environ. Health Perspect.* Vol 104, supplement 9. December 1995.

[2] In 1994, average PCB concentrations at Griffin Island included largemouth bass, 20 ppm; brown bullhead, 20 ppm; pumpkinseed 16 ppm. At Albany, the average PCB concentrations in Striped Bass was 6 ppm, and at Catskill, largemouth bass averaged 7 ppm.

descriptors. However, the RME and EPA's other chosen risk descriptors do not fully illustrate the magnitude and significance of the PCB contamination, because they do not quantify the *number of people* (i.e., the population) that could be affected. Because of the size of the Hudson River site and nature of the exposures, population-level risk has a significance that does not exist at smaller sites where very few people are exposed.

Population-level risk is difficult to estimate because of the size and complexity of the Hudson River site. EPA's choices are (1) to ignore the population-level risk or (2) estimate it and acknowledge the attendant uncertainty (the same approach EPA uses for the RME). We believe that the actual impact of the site is more accurately characterized by a qualified estimate than no estimate at all.

Angler's Families

The assumed RME scenario for EPA risk assessment involves a hypothetical fisherman who frequently eats fish from the river. EPA's current method should produce a reasonable estimate of the health risk to the fisherman. But because EPA does not plan to estimate the population-level risk, we will not know *how many* fisherman are at significant risk.

More importantly, we will not know how many of the anglers' family members are at risk. EPA overlooks the fact that the (predominantly male) anglers often share their catch with their families. EPA's approach reflects the fact that male anglers eat more fish (i.e., are more highly exposed) than women or children. Their approach is appropriate for the RME analysis. However, in a population risk characterization anyone with potentially harmful PCB exposures is counted, whether or not they receive the maximum hypothetical exposure. Since women of child-bearing age and children are of particular concern, EPA should know how many are at risk when deciding the future management of the Hudson River PCBs.

Data on the numbers and habits of fishermen are limited. At least two additional data sources, the Clearwater Angler Survey and the recent DOH Angler Survey, are both going to be available very soon in electronic database form. We urged EPA to make use of these surveys and to make every possible effort to include angler's families in the risk assessment.

Inhalation Pathway

The inhalation exposure pathway is not included in EPA's risk assessment. But recent research about PCBs in air is bringing to light surprising new information about the behavior of PCBs. The findings, which were not available during the Phase 1 reassessment, have important implications for people living near frequently flooded areas (especially tidal areas) along the river.

In particular, there is evidence of significant seasonal- and temperature-dependant PCB volatilization from water and drying sediments. For example, sediment collected at the

Corning Preserve after the January 1996 flood lost 3 percent of its PCBs as it dried. PCB evaporation from water and sediment may explain significant PCB levels (0.2 - 0.4 ppm) in the bodies of non-fish-eaters living along some portions of the Hudson. These findings are consistent with research in other areas, which document (1) long-range atmospheric transport as an important source of PCB to remote areas of the earth and (2) "urban plumes" of PCBs in air and precipitation.

PCB exposures via the inhalation pathway are much less than exposures from eating contaminated fish. However, the new data challenge EPA's standing assumption that inhalation exposures are negligible. It is reasonable to speculate that EPA's current approach (based only on fish consumption) underestimates the total PCB exposure for the RME angler, especially if he lives near the river. EPA's human health risk assessment should *combine all significant and reasonable exposures.*

Project Scope

Although EPA can not characterize all the impacts of the Hudson River PCBs, it should not truncate the scope of the reassessment where it encounters data gaps. The issues discussed above should be explored to the extent possible using screening-level or bounding analyses. such analyses will add to the overall understanding of the impacts, as long as the limitations are openly acknowledged. We understand that EPA wants as little uncertainty as possible in "the record." This interest will not be well served if difficult but important issues receive nothing more than brief qualitative discussions.

We cannot overemphasize how important it is to investigate all aspects of the human health risks posed by the Hudson River PCBs. As it should, EPA's current approach addresses the most sensitive health effects and the most exposed individuals. However, for a better understanding of the Hudson River site, EPA should address the full range of potential health effects (less sensitive impacts that may in fact be occurring) and the many people (including some not yet born) who are at risk. Just as EPA has thoroughly studied the distribution of PCBs in the river, it must do the same for the populations at risk.