700065 rec'd 10/7/99

SARATOGA COUNTY
ENVIRONMENTAL MANAGEMENT COUNCIL

PETER BALET
CHAIRMAN

GEORGE HODGSON
DIRECTOR

October 1, 1999

Alison A. Hess, C.P.G.
USEPA Region 2
290 Broadway, 19th Floor
New York, New York 10007-1866

Dear Ms. Hess:

Since our September 2, 1999 Hudson River HHRA and ERA comment submittal, the SCEMC found several errors which we would like to correct.

Please find enclosed corrected versions of these comments which include the following changes:

HHRA Comments:

Pg. 4., 25. *Changed CSF of 20 to CSF of 2.0*
Pg. 5., 31. *Restructure line 2 to bullet format and bulletize paragraph 3*

ERA Comments:

Pg. 1., 1.	*Delete "is" at beginning of line 3*
Pg. 2., 8., line 2,	*Add words "not do" before "data"*
Pg. 3., 21., line 1,	*Replace "Are" with "See"*
Pg. 3., 23., line 6, line 6, 10,	*Delete "2" on km*
Pg. 3., 23., line 11,	*Change "other" to "otter"*
Pg. 3, 23., line 12,	*Change "confined" to "confused"*

Sincerely,

George Hodgson

George Hodgson, Jr.
Director

Encs.
cc: Doug Tomchuk, USEPA, Region 2
SCEMC Members
Darry Decker, Chr., Government Liaison Committee, CIP
The Honorable John Sweeney

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COMMENTS ON THE PHASE 2 HUMAN HEALTH RISK ASSESSMENT
VOLUME 2F, BOOK 1; AUGUST 1999
HUDSON RIVER PCBs REASSESSMENT RI/FS

Prepared by: David D. Adams, Member, Saratoga County EMC and Government Liaison Committee

August 30, 1999

1. **Executive Summary, Ingestion of Fish, P.ES-2 and Section 2-1.2, P.7:** The fish ingestion rates are based on people ignoring the NYS ban on eating fish from the Upper Hudson River. In view of all the other conservatisms in this assessment this is an overly conservative approach, especially for the RME person, as will be discussed in later comments on fish ingestion rates. As a minimum, EPA should include risk factors using a best-estimate of the degree the NYS consumption ban is honored in order to give a better perspective of the risks to human health.

   The health risks should be calculated for fish PCB concentrations for each separate reach of the river rather than averaging the fish PCB concentrations over the entire Upper Hudson River. This would give a better perspective of the risks along the river considering the significant reduction in fish PCB concentrations with decreasing river miles.

2. **Executive Summary, Toxicity Assessment, P. ES-4:** It is unfair that EPA chooses only to comment on possible problems/limitations on the study sponsored by GE. The implication is that the other studies cited have no imperfections. Later comments will more fully address this subject.

3. **Section 2.3, P. 10:** A 95% confidence limit on the mean PCB concentration should be calculated. Certainly there is information on the possible variation of the input parameters to the PCB concentration model so model calculations can be made to generate information from which to determine confidence limits.

4. **Section 2.3.1, P. 11 and Section 5.3.1, P. 72:** Both of these sections discuss the models used to calculate the fish PCB concentrations and reference the Baseline Modeling Report issued in 1999. At meetings in 1999, EPA (or its contractors) acknowledged deficiencies and/or errors in both the PCB Fate and Transport model and the FISHRAND model. Neither of these sections indicate whether the Human Health risk assessment in this report is based on the model as presented in the published 1999 Baseline Modeling Report or on some unpublished correction to that report. If the former is true, publication of this report is premature and the risks presented should be withdrawn until the corrected results are available. If the latter is true, then it is unfair to ask for review of a report that is based on information not available to the reviewer and again, the risks presented should be withdrawn until the correct modeling information is presented. It is also noted that there are unresolved differences between the EPA and GE models and that the EPA model has not been peer reviewed. Both of these factors could change the calculated risks in this report making the presentation of the risks at this time premature.

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5. **Section 2.3.1, P. 12:** It is not understood why the model was not run out to 70 years rather than extrapolating the 20 year curve. Running the model out to 70 years should give better values than extrapolation and should be done (unless EPA has no faith in their model's ability to forecast for 70 years).

6. **Section 2.3.1, P. 13:** The information from the NYSDOH 1996 study should be presented even if it is "limited." The use of "limited" information in other areas has not bothered EPA (for example, see P. 48 where the use of only 226 respondents is used to assess the type of fish consumed and without any knowledge of even how many of the 226 fished the Upper Hudson River).

7. **Section 2.4.1, P. 22:** The formula for PCB exposure assumes 100% of the PCBs ingested are retained for the duration of the exposure. EPA should provide justification for this assumption which seems overly conservative.

8. **Section 2.4.1, P. 24 and Section 3.2.2, P. 48:** The information presented on the 1,000 New York anglers (Connally, et al, 1992) is incomplete. EPA should provide information on how many of the 1,000 anglers fished in the Upper Hudson River and of this number, how many reported eating fish from the Upper Hudson River. Of those eating fish from the Hudson River, what were the percentile values for fish consumed? Also, EPA should provide an assessment of the statistical validity of the small sample size available for the Upper Hudson River versus the estimated 10,000 plus anglers estimated to fish this area (see Section 2.1.2, P-7)

9. **Section 2.4.1, P. 25:** There is no basis for assuming that people who eat more fish (the RME person) eat the pan drippings. Unless EPA can provide data to substantiate this assumption, the 20% cooking loss should apply to the RME estimates.

10. **Section 3.2.1.1, P. 39:** The discussion of the "1992 Lake Ontario Diary Study" indicates that 12 month recall responses of fish consumption were higher than those from diary data but fails to give any information on the amount of the overestimate. EPA should provide this information as it represents another conservatism in the risk estimates.

11. **Section 3.2.1.1, P. 39:** While EPA provides a discussion of the "1992 Lake Ontario Diary Survey" EPA fails to provide any discussion of the "additional Connally Surveys" of 1993. The reason for this omission is not given. It can not be that the 1993 surveys focused on Great Lakes anglers because the 1992 Diary Study also focused on Great Lakes anglers. EPA should either discuss the 1993 surveys or explain why the 1993 surveys were ignored.

12. **Section 3.2.1.1, PP. 39 & 40 and Section 3.2.1.4, P. 5:** Presenting only the combined results of the 1996 and 1991-92 surveys is unacceptable. EPA is requested to provide the separate survey results so that a better assessment of the significance of the survey results can be made. What was the rationale for including the percentages at the bottom of P. 39? It is not clear what relationship any of the categories specified have to the risk assessment. The 1996 survey results (NYSDOH, 1999) at the top of P. 40 are significant in that they indicate the assumption that fish from the Upper Hudson River are eaten despite the NYS ban is incorrect. Using the 1996 survey results 92% of the surveyed anglers don't eat the fish, would cause the calculated risks to decrease by a factor of 10. The 1996 survey results also contradict the conclusions EPA made at the bottom of P. 45 from the analysis of the data not given, that the NYS consumption ban would have no effect. The 1996 survey data reinforce comment No. 1 and are another example of the over-conservatism that EPA has used in this risk assessment. Also, EPA is requested to indicate whether the 1991 survey (Connally, et. al.) showed any difference in the 95th percentile number of meals eaten between areas with and areas without fish advisories. This information is significant to assessing the RME risk.

13. **Section 3.2.1.1, P. 40:** The discussion of the 1990 Mid-Hudson Survey (Jackson, 1990) says the survey included the percentage of anglers that keep and eat fish and are aware of fish advisories. The EPA discussion of the 1990 survey, however, focuses on matters irrelevant to the risk assessment such as what fish the anglers were after, sex and age of the anglers, differences between shore and boat anglers, and fishing tournaments. The EPA discussion ignores the factor significant to the risk assessment, i.e. the percentage of anglers that keep and eat fish and the awareness of fish advisories. EPA is requested to provide this information.

14. **Section 3.2.1.2, P. 41:** The stated objective of evaluating exposures to PCBs in fish in the absence of Hudson River-specific health advisories is overly conservative and should be abandoned in light of the 1996 NYSDOH survey. As a minimum, the recommendation of Comment 1 should be honored by EPA. An additional argument for this course is the Kimbrough, et al (1999) study of GE workers at the Ft. Edward and Hudson Falls plants. Workers at these plants were likely anglers in the Upper Hudson yet the Kimbrough study showed no significant increase in causes over that of the general US population.

15. **Section 3.2.1.3, P.44:** The discussion at the end of this section of the 1996 and 1991-92 surveys is unconvincing in its disregard of these surveys showing significant impact of the fish advisories on the consumption of fish. Despite difficulties (and just what are these difficulties?) in extrapolating the 1996 and 1991-92 values to annual average ingestion rates, the fact remains that the 1996 and 1991-92 surveys provide direct data on the Upper Hudson River and are more recent than EPA's preferred 1991 Connally, et al survey. How many of the anglers in the 1991 survey were from the Upper Hudson River and how much of the year did the respondents say they fished?

16. **Section 3.2.1.4, P. 46:** The contention that children (and perhaps women also) eat as many fish meals as men is suspect, especially given the merchant food preferences of younger children. This could be especially true for the RME estimate. Consideration of children eating less fish should be factored in to the RME estimates.

17. **Section 3.2.4.1, P. 52:** The assumptions stated here that the fishing population is in steady state and the corollary that 1991 survey data represents 1999 and 70 years into the future is speculative and highly questionable. Preferences for spending leisure time do not remain consistent, especially in today's climate of rapidly changing technology. Witness the rise in time spent on the web and computer games which could especially impact the younger age groups. Another example is the leveling off in the number of downhill skiers indicating changing demographics for this sport. Is there any survey results from years before the 1991 Connally, et al survey that could shed light on this subject? The current EPA position represents an unsubstantiated assumption and another facet of the conservatism in EPA's risk assessment.

18. **Section 3.2.4.1, P. 53:** Where do Tables 3-6 and 3-7 fit in? I could find no reference to them in the text. Also, aren't Tables 3-6 and 3-7 constructed using procedures given in this section and not directly from the 1991 survey as implied in the footnote to these tables?

19. **Section 3.2.4.2, P. 54:** The uncertainty discussions on this page highlight a significant problem with this risk assessment. The survey population is too small to get reliable values of fish consumption and duration of exposure. This raises questions about the validity of the risks calculated in this report, especially when all the conservatisms in the calculations are considered.

20. **Section 3.2.4.3, P. 56:** What evidence is there that the populations in the Upper Hudson counties are in steady state? It seems doubtful they are. Couldn't census data be used to evaluate this assumption? It also seems unlikely that the assumption of the same number of individuals moving each year in a 5-year period is true. What are the effects on the risk assessment if these assumptions are incorrect?

21. **Section 3.2.4.3, P. 57:** Table 3-6 shows that of 226 anglers in the 1991 survey, less than 1 angler (or 0-1 angler) fished for 70 years. This seems like very meager data on which to base using 70 year fishing duration in the Monte Carlo analysis. Consideration should be given to using a lower upper bound in the Monte Carlo analysis. Perhaps 60 years should be used as discussed in the last paragraph of this section.

22. **Section 3.3.1, P. 59:** The meaning of "Minimum of Fishing Duration and Residence Duration" for the Base Case calculation is not clear. Please provide additional explanation of this parameter.

23. **Section 4.1, P. 62:** Can the four standard uncertainty factors be multiplied together giving a total factor of safety of 10,000 in some cases? If so, do any of the data used in this assessment have safety factors of 1000 or 10,000? Even the uncertainty factor of 100 for Aroclor 1016 and 300 for Aroclor 1254 are so large as to raise questions about whether any conclusions about risk can be drawn from the base data.

24. **Section 4.1, P. 63:** Given the apparent uncertainty in the RfD as evidenced by the large factors of safety cited on P. 62, it is recommended that the Monte Carlo analysis include uncertainty and variability in the toxicity values.

25. **Section 4.2, P. 64 and Section 5.2.2, P. 71:** In view of all the other conservatisms present in the risk analysis, it is an unreasonable additional conservatism to use the upper bound CSF of 2.0 in the Monte Carlo analysis. The CSF of 1.0 should be used as in the central point estimate.

26. **Section 5.3.1, P. 72:** The fact that the risk assessment does not quantitatively evaluate those born after 1999 or those who move to the area after 1999 raises questions as to the validity of the risk assessment, as these populations would have less exposure to PCBs. This makes it even more important to be very careful and not overly conservative in calculating the PCB exposure, the duration of exposure, and the total population at risk.

27. **Section 5.3.1, P. 74:** EPA's statement that the point estimates of angler exposure duration are likely to be underestimates is not substantiated. EPA should either acknowledge that the point estimate could also be overestimates or provide the basis for the statement on this page.

28. **Section 5.3.3, P. 79:** The statement that the 50% decrease in the risks using the Maine angler study does not change the results significantly is true in itself but is misleading in that it ignores the potential cumulative effects of this change plus others that remove unnecessary conservatism. The cumulative effects of such changes could be very significant.

29. **Section C.2.2, P. C-2 and Section C.3.1, P. C-4:** It is my understanding that the Agency for Toxic Substances and Disease Registry (ATSDR), part of the US Department of Health and Human Services, is charged by Congress with specifying toxicities for various substances including PCBs. EPA references this agency on P. 61 of the risk assessment where EPA refers to a 1997 review of the toxicity profiles by ATSDR. I have seen excerpts from an updated draft of ATSDR s toxicological profile of PCBs dated February 1999. This updated draft concludes that no studies have shown death in humans due to PCBs by any exposure route and that acute lethality data do not suggest PCBs would be acutely toxic in humans. Excerpts go on to cite ATSDR conclusions that the weight of evidence does not show PCB's cause cancer or have other toxic health effects. How is EPA going to factor this latest information from ATSDR into the risk assessment?

30. **Section C.2.2., P. C-2:** Kimbrough, et al (1999) state that the studies cited on this page by EPA in support of the carcinogenic potential of PCBs in humans are deficient in that the standardized mortality ratios (SMRs) reported in these studies were not correlated with factors which would suggest a PCB dose-response relationship, namely the SMRs were not correlated with higher and/or longer exposures to PCBs or longer latency periods. Why does EPA not include a discussion of these deficiencies and their significance in this section? (Note: some discussion of deficiencies in the Sinks Study are presented). These deficiencies are the same reasons EPA has cited for rejecting studies of TRVs.

31. **Section C.2.2., P. C-3:** EPA cites what it believes are several deficiencies of the Kimbrough study on this page.

- EPA statement - More than 75% of workers in the study never worked with PCBs. Comment – the Kimbrough study still included about 1750 people who did work with PCB's, almost the same as the 2100 people in the Bertazzi study used by EPA.

- EPA statement: Less than 25% of workers who were exposed to PCBs at the General Electric facilities were, employed in their jobs for less than 1 year. (Note: I believe this statement quotes incorrectly EPAs position, but the point is that EPA criticizes the "short exposure"). Comments: The median exposure time for those heavily exposed in the Kimbrough study is 1.2 years for hourly male workers (1,268 workers) and 1.6 years for females hourly workers and even longer for the smaller number of heavily exposed salaried workers. Also, the Kimbrough study only included employees who worked at least 90 days at the GE facilities. In contrast, the Bertazzi study used by EPA included people who had only worked at least one week.

- EPA cites other deficiencies of the Kimbrough study such as the actual PCB exposure level is not confirmed, the age of the workers was young at the end of the study period, and vulnerable populations were not evaluated. However, EPA provides no evidence or discussion that these same deficiencies are not present in the studies being used by EPA. It does not seem that EPA has given a fair evaluation of the Kimbrough study in relation to the studies cited by EPA in defense of the potential for PCBs to cause cancer.

32. **Section C.2.3, P. 6-3:** Is the CSF "central estimate" an upper bound as implied by the opening sentence of this section? If no, the upper bound of the central estimate is "an upper bound of an upper bound" making the upper bound very conservative.

33. **Section C. 2.3, P. C-3:** Why aren't the Brunner and Norback and Weltman stidies included in the list of references? Some discussion of these studies should also be included. How do these studies relate to those cited on page C-2?

34. **Section C. 3.1, P. C-4:** Since the Patandin and Lanting studies relate both to exposure of PCBs and dioxins, it would appear that conclusions can not be drawn from these studies regarding the effects of PCBs. EPA should provide a discussion as to why these studies can be used to predict PCB effects. Also, why is the discussion of breast cancer here and not in cancer section (C. 2.2)? The lack of a cause and effect relationship for breast cancer suggests there may also be a lack of such a relationship for other cancers.

35. **Section C. 3.2.1, P. 6-6 and Section C. 3.2.2, P. C-6:** The uncertainty factor of 100 in C. 3.2.1 is greater than the straight multiplication of the factors (81) as is the uncertainty factor of 300 in C. 3.2.2 (270 by direct multiplication). There are further examples of extra conservatism in the risk analysis.

36. **Section C. 4.2, P. C-7:** EPA's acceptance of a risk of 10^{-4} for ingestion of PCBs in drinking water would seem to define this as the acceptable risk for this report. Does EPA agree?

37. **General:** Many instances have been mentioned throughout these comments where EPA has compounded conservatism on top of conservatism in the risk assessments. EPA should consider removing some of the conservatisms to achieve a more realistic estimate of the health risks, including the upper bound risks.