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SEP 7 1999

Post-it® Fax Note 7671	Date 9/10/99	# of pages ▸ 31
To Alison Hess	From Bill Ports	
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Phone # 212-637-3959	Phone # 518-457-5637	
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Ms. Alison Hess
Project Manager
US Environmental Protection Agency
290 Broadway, 19th Floor
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Dear Ms. Hess:

Enclosed are comments on the August 1999 Phase 2 Report - Further Site Characterization and Analysis, Volume 2E - Human Health Risk Assessment, Hudson River PCBs Reassessment RI/FS. The comments were prepared by the New York State Department of Health.

If you have any questions regarding the comments, please contact me at (518) 457-5637.

Sincerely,

William T. Ports

William T. Ports, P.E.
Project Manager
Bureau of Central Remedial Action
Division of Environmental Remediation

cc: John Davis, NYSDOL
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Antonia C. Novello, M.D., M.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

September 7, 1999

Mr. William Ports
Bureau of Environmental Remediation
New York State Department of Environmental Conservation
50 Wolf Road
Albany, NY 12233

Re: Human Health Risk Assessment
Hudson River PCBs
Saratoga County
Site #546031

Dear Mr. Ports:

We have reviewed the United States Environmental Protection Agency's (US EPA) August 1999 "Phase 2 Report – Review Copy, Further Site Characterization and Analysis, Volume 2 F - Human Health Risk Assessment, Hudson River PCBs Reassessment RI/FS." The assessment provides the results of the analysis detailed in the EPA's Scope of Work, which we reviewed in 1998. We agree with the overall conclusion of the assessment that the highest estimated human health risk due to PCBs in the Hudson River is from fish ingestion and that other routes of exposure are of less risk. However, as described below, we have a number of comments on the assessment.

GENERAL COMMENTS

1. The assessment does not include a quantitative evaluation of many possible residential exposure pathways. These pathways include soil and sediment ingestion, dermal contact with sediments and river water, incidental ingestion of river water, homegrown vegetable ingestion and the ingestion of beef and dairy products produced at current or future farms along the floodplain. While the environmental data needed to evaluate these pathways may be limited at this time, to the extent feasible, a quantitative evaluation of all relevant young child and adult residential exposure pathways is needed to characterize the possible risks to residents.

2. NYS DOH staff have completed a preliminary comparison of elements of the assessments prepared by US EPA's consultants for the Hudson River and Rogers Island sites. This comparison identifies numerous differences in the approaches used in the two risk assessments (e.g., different receptors/pathways evaluated, differences in certain exposure parameter values, differences in the toxicological parameters). US EPA should use similar approaches in the

Hudson River and Rogers Island risk assessments unless there are valid technical reasons for not doing so.

3. In a May 20, 1998 letter from Robert Montione to William Ports of the NYS Department of Environmental Conservation, New York State Department of Health (NYS DOH) staff provided comments on the US EPA Scope of Work for this assessment. A copy of that letter is attached for your reference. A number of our comments on the Scope of Work were not addressed in the assessment. Some of the comments not addressed include the following:

- The point estimates of high-end risk should assume lifetime Hudson River fish consumption (comment 3).
- The risk assessment should address the effects of past exposures on current and future exposures and risks (comment 4).
- Statements to the effect that "sub-populations of highly exposed and lesser exposed anglers will be represented in the distributions of risk generated in the Monte Carlo analysis" need to be specifically supported (comment 6).
- The discussion of the Monte Carlo results should include a sensitivity analysis that addresses how using different assumptions about range, frequency or nature of the distribution (e.g., normal, lognormal, uniform) affects the outcome (comment 9).

Addressing these issues would provide valuable information to risk managers.

EXECUTIVE SUMMARY

<u>Executive Summary (page ES-4), and Section 1.4 (page 3) and Section 5.1.2 (page 68)</u>

Statements about the NCP acceptable risk range for carcinogens are misleading to the reader and should either be deleted from the risk assessment document or revised to reflect the NCP and EPA <u>risk management</u> policy. Cancer risks of 1.0 E-6 or less are usually considered insignificant and not a public health concern. Cancer risks greater than 1.0 E-4, on the other hand, typically will trigger actions to lower exposures. When cancer risk estimates are between 1.0 E-6 and 1.0 E-4, a risk management decision must be made on a case-by-case basis whether or not to pursue risk reduction measures. The NCP and EPA state (e.g., US EPA, 1991, Risk Assessment Guidance for Superfund: Volume 1 – Human Health Evaluation Manual (Part B, Development of Risk-based Preliminary Remediation Goals), Office of Emergency and Remedial Response, p. 18) the preference for managing risks at the more protective end of the risk range, other things being equal. Preferably, statements about acceptable risk should be deleted from the risk assessment document. If, on the other hand, US EPA determines that such a discussion should be included, then the contractor must provide an accurate and balanced discussion of the risk management process to avoid the perception that as long as the risks fall in the 1.0 E-6 to 1.0 E-4 range, they are *a priori* deemed acceptable.

CHAPTER 2 - EXPOSURE ASSESSMENT

1. The *PCB Concentration Weighted by Species-Consumption Fractions* section on pages 13 and 14 describes how the assessment classified six species of fish consumed by Hudson River anglers into three groups. There are several deficiencies in this section:

- Group 1 inappropriately uses brown bullhead PCB data to represent PCB levels in American eels and carp. Because brown bullhead generally have lower PCB levels than American eels or carp, exposures from eating Group 1 fish are underestimated. For example, in 1992 collections at Stillwater, average PCB levels were 9.4 ppm in brown bullhead, versus 33.7 ppm in American eel and 38.6 ppm in carp.

- The composition of Group 2 is reasonable, but the third sentence in the second complete paragraph on page 14 states that bass and walleye reach "several feet in length". The term "several" implies that these fish achieve three or more feet in length. Since bass or walleye rarely reach three feet in length this statement is misleading and should be removed.

- No rationale is provided for Group 3 (yellow perch).

- This assessment did not consider white perch consumption because "they're not commonly found in the Upper Hudson River" (last paragraph on page 12). This is inappropriate because white perch was the most frequently caught species (19.7% of all fish caught) in the 1991-1992 Clearwater survey in these waters (between Hudson Falls and Troy).

2. The assessment addresses child fish consumption in the Monte Carlo assessment, but not in the deterministic assessment. PCB exposures and risks from fish consumption should be assessed for at least the high-end child fish consumer. Although most angler surveys do not provide direct measures, fish consumption rates for children can be estimated by applying child/adult fish consumption rate data from other sources to findings from the angler studies of interest. For example, data on meal sizes from Pao et al. (1975, page 264-265) indicate that the average fish meal size for a 1-2 year old child is 68 grams and the average fish meal for a 19-34 year-old male is 191 grams; thus, the child/adult meal ratio is 68/191 = 0.36. If you assume the child eats Hudson River fish whenever the parent does, the child fish consumption rate could be assumed to be equal to the adult consumption rate multiplied by 0.36.

3. In order to expedite the Feasibility Study, the risk characterization section (Section 5) should include a comparison of the modeled fish concentration over time for the different sections of the Upper Hudson to the FDA tolerance level of 2 ppm, which is an Applicable Relevant and Appropriate Requirement (ARAR).

4. The assessment assumes that the high-end fish consumer eats Hudson River fish for 40 years, based on census data regarding local residence duration and survey data on how long an individual fishes. There are two flaws in this approach:

- If the conditional probability of moving out of the area is lower for individuals who have already lived in the area for a long period of time, it is possible that US EPA will have underestimated the fraction of the population whose residence times are very long.

- The assessment assumes that only anglers consume Hudson River fish, so that individuals are only exposed during the part of their lives when they are fishing. This assumption is faulty because angling is often a family tradition where the catch is shared by the extended family, and it is likely that Hudson River fish are included in family meals. Thus, individuals may eat Hudson River fish for their entire lives even if they themselves do not fish or they fish for just a portion of their life.

Based on the likelihood that some avid anglers/fish consumers will reside near and eat Hudson River fish for their lifetimes, we believe the point estimates of high-end risk should assume lifetime consumption of Hudson River fish.

CHAPTER 3 – MONTE CARLO EXPOSURE ANALYSIS of FISH INGESTION PATHWAY

US EPA used the Monte Carlo analysis of the fish ingestion pathway as a means for evaluating its deterministic assessment of the pathway. The comments below are of limited importance given this use of the Monte Carlo analysis. However, if the scope of the Monte Carlo analysis is expanded for any reason, these comments are of greater importance; in addition, we may have additional comments.

1. The Monte Carlo assessment of the fish consumption pathway relies on a number of assumptions that are not supported. For example, the probability that someone moves out of the region is assumed to be a function of age and the assessment assumes that body weights in the population are perfectly correlated over time. Although the Monte Carlo assessment was used to evaluate the CT and RME point estimates of risk, the assumptions used in the Monte Carlo exercise were not evaluated in a sensitivity analysis; therefore, the significance of their potential impact on the outcome of the assessment is unknown. A sensitivity analysis should be done on all the important parameters in this pathway and the significance of the outcome should be discussed in the assessment.

2. The fish concentrations used in the assessment were taken from the 1999 Baseline Modeling Reports. While the modeling exercise only predicted fish concentrations through the year 2018, the risk assessors extrapolated the modeled results to the year 2069 using an exponential trend/regression line. The assessment should discuss why the fish concentrations were extrapolated to 2069 while the point estimates for concentrations in river water and sediment were based on only the modeled concentrations to the year 2018. The assessment should discuss that the fish concentrations are predicted based on current conditions and that there is no guarantee that future events (similar to 1991 plant site releases) will not occur to change the accuracy of these predictions.

CHAPTER 4 - TOXICITY ASSESSMENT

The assessment maintains an artificial dichotomy between the toxicity values for the cancer and non-cancer effects of PCBs. Three examples of this dichotomy are shown below.

- The toxicity values used to evaluate the cancer and non-cancer human health risks of the same exposure (sediment ingestion, dermal contact with sediment, dermal contact with water) are not based on the same Aroclor(s). The dichotomy is not supportable and should be reconciled.

	Aroclor on Which the Toxicity Value is Based	
Exposure Route	**Cancer Slope Factor**	**Reference Dose**
water ingestion	not evaluated	not evaluated
fish ingestion	1254/1260	1254
sediment ingestion	1254/1260	1016
dermal contact with sediment	1254/1260	1016
dermal contact with water	1242	1016
inhalation	1242 (oral study)	not evaluated

- On page 63, it is explained that the RfD for Aroclor 1016 (and not Aroclor 1254) was used to evaluate the non-cancer risks from PCBs in sediments because the congener profile in the sediments more closely resembles Aroclor 1016 than Aroclor 1254. It also is explained that the RfD for Aroclor 1254 (and not Aroclor 1016) was used to evaluate the non-cancer risks from PCBs in fish because the congener profile in fish more closely resembles Aroclor 1254 than Aroclor 1016. We agree with these choices and the scientific reasoning supporting the selections.

  We suggest that the same scientific reasoning for selecting RfDs should be applied to the selection of cancer slope factors (CSFs) to evaluate the cancer risks of exposure to sediments and air. We recommend that the cancer risk assessment for these media follow the advice given in the IRIS datafile for PCBs in Section II.B.4. Discussion of Confidence (Carcinogenicity, oral exposures): "When available, congener information is an important tool to define a potency estimate that was based on exposure pathway." The consideration of dioxin-like PCBs in the assessment of the cancer risks from fish exposures is consistent with this advice. If the CSFs used to assess sediment and air exposures do not change, then the uncertainty associated with using CSFs for Aroclor mixtures that may not adequately match the environmental mixtures found in sediments and air should be discussed in the section on Risk Characterization.

- On page 63, it is stated that the non-cancer risks of inhaling PCBs were not assessed because there are no Reference Concentrations for either Total PCBs or any Aroclor mixture. This situation should not prevent the assessment of non-cancer risks from air exposures. Data from ingestion studies are used to evaluate risks from other routes of exposures in three cases. (1) Oral CSFs for ingestion exposures are used to calculate unit risks values for evaluating inhalation exposures. (2) Oral CSFs for ingestion exposures are used to evaluate the cancer risks of dermal exposures. (3) An oral RfD is used to evaluate the non-cancer risks of dermal exposures. We recommend two additions: (1) the evaluation of air exposures using RfDs and (2) a discussion of the uncertainties inherent when oral studies are used to assess the cancer and non-cancer risks of dermal and inhalation exposures.

CHAPTER 5 - RISK CHARACTERIZATION

1. The discussion (pages 76-77) does not fully characterize the uncertainties in the toxicity assessment. Three major areas could be more fully discussed.

- The discussion does not fully characterize the uncertainty that arises when estimated human PCB exposures are compared to the non-cancer results of animal studies published after the completion of the IRIS RfDs.

  The study by Arnold et al. (1995) on reproductive effects seen in rhesus monkeys should be more fully discussed. Arnold et al. (1995) reported that statistical analysis of the conception rates showed that they were significantly lower in those females ingesting 20, 40, or 80 ug Aroclor 1254/kg/day (P-values of 0.007, 0.043, and 0.003, respectively), and approached significance ($P < 0.059$) in those females ingesting 5 ug Aroclor 1254/kg/day. Moreover, the study also showed that infants of monkeys ingesting 5 ug Aroclor 1254/kg/day showed clinical signs of toxicity during nursing. These effects included inflammation and/or enlargement of tarsal glands, nail bed prominence, elevated nails, nails folding on themselves, and gum recession. These findings, especially the potential effects on reproductive success, should be discussed before concluding that the IRIS RfD for Aroclor 1254 is considered to be "health protective" (page 76). The RfD was derived using, among other factors, a reduced uncertainty factor of 3 because the changes observed in the adult monkeys were not considered to be of marked severity. The new data suggest that the margin of protection afforded by the IRIS RfD may be less.

  The average daily dose for an high-end angler is 2.3 ug/kg/day. The LOEL used to derive the Aroclor RfD is 5 ug/kg/day. Thus, the angler's dose is close to the LOEL. The perception of risk at this dose differs with the nature of the end-points observed at the LOEL. Concern increases with the severity of the observed effects. The draft discussion implies that the only effects seen at the LOEL were mild dermal and immunological effects in the adults. It does not fully address the potential that more severe effects (failure to conceive, developmental toxicity) may also occur at the same LOEL.

  Recent studies on rhesus monkeys show long-term behavioral effects in young animals dosed with 7.5 ug/kg/day of Aroclor 1254 from birth to 20 weeks of age (Rice, 1999a). This dose was chosen because it represented a breast milk dose considered "safe" by Health Canada. Moreover, it lead to blood and fat levels in the monkeys that were within the range of levels seen in the human population. The doses ingested by child anglers, who may consume PCB contaminated fish, should be compared to this LOEL to obtain information on potential risks of neurobehavioral effects. As stated elsewhere, an evaluation of the non-cancer risks of fish consumption by children could be included in the assessment.

- There is a large body of information on the potential reproductive and developmental effects of consuming sport-fish containing PCBs and other contaminants (see attached bibliography). Estimated fish consumption rates and PCB intakes from Hudson River fish could be compared to fish consumption rates and expected PCB intakes (when available) associated with effects in cohort studies in New York State, Michigan, Wisconsin, Sweden, and Quebec. Such an analysis could provide valuable human data to support/contradict the statement (page 76) that the IRIS RfD is considered to be "health protective."

- As stated earlier, the uncertainty associated with using CSFs for Aroclor mixtures that may not adequately match environmental mixtures found in sediments and air should be discussed.

2. The third paragraph of section 5.3.2 (page 76) could be revised to present clearly the summary information (critical studies, critical effects, and uncertainty factors) for the Aroclors 1016 and 1254.

APPENDIX C - TOXICITY PROFILE

The profile is not an up-to-date review of PCB toxicity because it limits itself largely to material contained in the IRIS datafiles for PCBs, Aroclor 1016, and Aroclor 1254. Since the IRIS files were completed, new information has been published, and important studies on the oncogenic, reproductive, and developmental toxicity of PCBs could be incorporated into the text. This is not a request to make the section longer, but to re-focus the section on important studies that are critical to understanding the potential public health risks of environmental exposures. Several suggestions follow:

1. The section on the carcinogenic potential in humans could include a discussion of the potential links between PCBs and specific cancer types (i.e., melanoma, non-Hodgkin's lymphoma, and breast cancer) (see attached bibliography).

2. The discussion on PCBs and breast cancer in the Summary of Non-Cancer Effects in Humans (page C-4) should be placed in the section on the carcinogenic potential in humans.

3. The discussion on potential effects associated with background exposure to PCBs, including PCBs in fish, could be more fully developed. This is a major area of uncertainty. The summary statements on studies Lanting/Patandin (Dutch studies) should be compared with animal studies and other human studies. The discussion could include the findings of cohort studies in New York State, Michigan (infant and adult studies), Sweden, and Quebec on the possible development, reproductive, and neurotoxic effects associated with the consumption of fish containing PCBs and other contaminants (see attached bibliography).

4. The studies by Lanting/Patandin assessed the non-cancer effects of background exposures to PCBs. A recent publication indicates that only a small percentage of a child's daily exposure is from fish (Patandin et al., 1999a). Thus, they are not, as indicted on page C-4, studies of children consuming PCBs in fish.

5. The discussion of non-cancer effects does not include all of the recent studies on reproductive and developmental effects seen in low-dosed animals. Several studies published after the IRIS RfDs for Aroclors 1016 and 1254 were derived could be identified and briefly discussed (see attached bibliography). These include studies (e.g., Arnold et al., 1995; Rice, 1999a) on the reproductive, developmental, and neurobehavioral effects of low-level Aroclor 1254 exposures in rhesus monkeys.

If you have any questions please call me at (518) 402-7870.

Sincerely,

Robert J. Montione, Public Health Specialist III
Bureau of Environmental Exposure Investigation

Attachments

cc: Mr. Tramontano
Dr. Kim
Dr. Carlson/ Dr. Wilson
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STATE OF NEW YORK DEPARTMENT OF HEALTH

Barbara A. DeBuono, M.D., M.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

May 20, 1998

Mr. William Ports
Bureau of Environmental Remediation
New York State Dept. of Environmental Conservation
50 Wolf Road
Albany, NY 12233

Re: Human Health Risk Assessment
Scope of Work
Hudson River PCBs
Saratoga County
Site #546031

Dear Mr. Ports:

We have reviewed the United States Environmental Protection Agency's (US EPA) March 31, 1998 Hudson River PCBs Site, Phase 2, Human Health Risk Assessment Scope of Work. The Scope of Work should explicitly state that the inhalation pathway is one of the "other exposure pathways" (Sections II.2.G and III.2.F) to be evaluated in the risk assessment. There are PCB air data from sites near the Hudson River and other locales that can be used for this analysis (a list of references is attached); we believe that no additional data are required to provide a comparison among exposures from different media. Given our understanding of the air data, intake of PCBs from air is minor compared to the intake from one meal a month of fish at the FDA tolerance level.

General Comments

We agree with the approach that estimates of risk need to be done using the Reasonably Maximally Exposed Individual. For example, the risk from fish consumption should be calculated based on reasonable maximum values for parameters such as fish PCB levels, fish consumption rates and exposure duration. In general, all assumptions should be documented.

Comments on the Risk Characterization from Consumption of Fish

1. The scope of work must include an assessment of risk for those individuals who do not adhere to the fish advisory.

2. The proposed approaches for estimating total and species-specific fish consumption rates (pp. 7 and 16) are generally reasonable.

A factor that needs to be considered in determining the appropriate fish consumption rates is the effect of fish advisories. The scope of work should clarify the issues regarding selection of comparable fisheries to estimate what Hudson River fish consumption would be if fish advisories were not in effect. For scenarios assuming no fish consumption advisories, relevant survey data of anglers would be from waters that have no consumption advisories. The Connelly (1990) survey data for waters such as Oneida Lake and the Mohawk River as well as marine striped bass consumption data (if available) may be useful. Hudson River angler survey data (e.g., Barclay, 1993) are also relevant, but fish consumption advisories are in effect. If Hudson River fish consumption survey data are used for the no-advisory scenarios, the assessment should account for the effects of advisories on fish consumption rates. By this fall, DOH will issue a report on 1996 recreational anglers including information about their consumption of Hudson River fish. As you requested, DOH will provide the raw data from this survey and a copy of the report, when available. In addition, we recommend consideration of data in a recent report on Hudson River striped bass harvest in Peterson (1998; copy enclosed). The angler survey on which this report is based also gathered data about other species which may be useful.

The high end exposure scenarios should include fish consumption rates which are reasonable maximum estimates.

3. The proposed approach estimates exposure duration for the upper and mid-Hudson (pages 10 and 17), assuming an estimated average length of time before an individual moves far enough away from a river stretch to make fishing unlikely. This assumes that anglers fish in these waters only as long as they live within one of the bordering counties.

The assessment plans to determine length of residence in these counties based on local and national county mobility data and national census information derived for the entire population. Based on our knowledge of the census database, it appears that this approach may not properly account for individuals who move from one county to another, but stay within the upper or mid Hudson counties. This error could cause the assessment to underestimate upper and mid-Hudson county residence time and exposure duration. Also, this approach assumes that anglers are similar to the general population in their length of residence in the vicinity of the Hudson River, resulting in additional uncertainty. This uncertainty should be addressed. Based on the likelihood that some avid anglers will reside near and fish in the Hudson River for their lifetimes, it may be appropriate to consider assuming lifetime exposure for point estimates of high-end risks.

4. The proposed approach for accounting for PCB cooking losses in fish meals (pp. 11 and 18) is reasonable. Care should be taken when interpreting studies on PCB losses during cooking and applying these findings to the exposure assessment. These studies typically characterize cooking loss as contaminant mass loss, concentration decrease or both. A study which reports a large contaminant mass loss may report a much smaller concentration decrease, due to moisture loss during cooking. If the assessment assumes that the fish meal portion is based on cooked meal sizes, adjustment of exposure assessment should be based on concentration decrease. If the assessment assumes that the fish meal portion is based on raw fish portions, exposure assessment adjustment should be based on contaminant mass loss.

The scope of work states that PCB losses from fish trimming will not be evaluated since little quantitative data on this issue are available. Actually, there are several studies on this issue (Armbruster et al., 1989; Hora, 1981; Reinert et al., 1972; Skea et al., 1979; and Voiland et al., 1991). Since the effects of fish trimming are highly species-specific and many of these studies are on salmonids, their application may be limited; however, some evaluation may be possible.

5. Page 14 states that "subpopulations of highly exposed and lesser exposed anglers will be represented in the distributions of risk generated in the Monte Carlo analysis". The range and distribution functions developed for the general population may not be the same as the range and distribution functions of subpopulations. This uncertainty is an additional reason why we support including point estimates of risk for the Reasonably Maximally Exposed Individual.

6. The section, "PCB Concentrations for Deterministic and Monte Carlo Analysis" (page 11) states that the upper Hudson risk assessment will estimate fish PCB concentrations at three mile intervals from rivermiles 153 to 195. We suggest that this river stretch could be broken into three or four segments that correspond the pools defined by the dams (barriers to fish movement). The mid Hudson region (rivermiles 70 to 153) could also be broken into two or three segments for the risk assessment. The New York State Department of Environmental Conservation, Division of Fish and Wildlife should be consulted on segment boundaries.

7. The section on fish consumption rates for the mid-Hudson River (page 16) states that the mid-Hudson risk assessment will use the same distribution of total fish ingestion rates as will be developed for the upper Hudson River. This assumption may not be appropriate because of differences in fish species and availability and fish consumer socioeconomic makeup in these river stretches. River stretch-specific fish consumption rates for the upper and mid-Hudson River would be preferable, if feasible.

8. The discussion of exposure duration on page 18 notes that the risk assessment will explicitly describe the choices and assumptions, comment on other alternative methods for addressing exposure duration, and explain why they were not chosen. This approach should be considered for all of the parameters in the assessment, but especially for those for which ranges and distribution functions are assumed rather than developed from Hudson River data. The discussion should include a sensitivity analysis that addresses how using different assumptions about range, frequency or nature of the distribution function (e.g., normal, lognormal, uniform) affects the outcome.

Comments Specific to Toxicity Values - Non-Cancer Effects

1. The Scope of Work states that these reference doses will be used in the assessment for the various routes of exposure. The document should describe how US EPA will evaluate exposures to environmental mixtures of PCBs that do not resemble Aroclors 1016 or 1254. We recommend using the reference dose that most closely resembles the congener profile of the environmental sample. For example, the reference dose for Aroclor 1254 could be used as a surrogate for Aroclor 1260.

2. Although we recognize that US EPA has not established reference concentrations for PCBs in air, one approach to evaluating the noncancer risks of inhalation exposure is to use the oral reference doses; US EPA Region III (4/98) has developed risk-based concentrations for many contaminants in ambient air using oral references doses. In the absence of inhalation reference concentrations, we believe it is scientifically reasonable to include the results of such cross-route extrapolation for PCBs in air along with a discussion of its uncertainties and limitations.

3. The US EPA may also want to cite the guidance values for PCBs derived by the Agency for Toxic Substances and Disease Registry (a minimal risk level of 0.02 ug/kg/day for PCBs, Aroclor 1254, see ATSDR, 1997)) and the Health Protective Value for PCBs (0.05 ug/kg/day) derived by the Great Lakes Sport Fish Advisory Task Force (GLSFATF, 1993). The citation of these values, which are identical to and similar to the US EPA's reference dose, supports the derivation of the US EPA's reference doses for the two Aroclors.

4. The Aroclor reference doses were verified in 1992 (Aroclor 1016, with peer-review in 1994) and 1994 (Aroclor 1254). Since then, several articles on the effects of PCBs on reproductive function and development in rhesus monkeys have been published (e.g., Arnold et al., 1995, 1997; Rice, 1997; Rice and Hayward, 1997). The Agency should review these articles and either re-affirm the RfDs for Arcolor 1016 and 1254 or discuss and characterize the uncertainties that these data introduce into the risk assessment, particularly regarding the risks to nursing infants. The risk characterization also should include a discussion of the large body of information on the human health effects of PCBs, particularly on the neurodevelopment of infants and children of women who eat large amounts of fish (see attached bibliography).

5. The bioaccumulation potential of PCBs in human tissues raises concern for cumulative exposures and makes it likely that current and future exposures will add to past exposures. This should be discussed in the Risk Assessment document.

Comments Specific to Toxicity Values - Cancer

1. The IRIS database of US EPA contains three cancer potency factors for estimating the cancer risks associated with exposure to environmental mixtures of PCBs (high risk and persistence, low risk and persistence, and lowest risk and persistence). These factors were based on cancer potency factors for specific commercial mixtures of PCBs, including cancer potency factors for Aroclor 1016, 1242, 1254, and 1260. The Scope of Work indicates that the health risk assessment will follow the guidelines in IRIS and will assess the risk of environmental mixtures based on the nature of the exposure (i.e., the high risk and persistence value will be used when food chain exposure is evaluated), regardless of the congener or Aroclor composition of the mixture. This approach is scientifically reasonable if adequate congener or Aroclor specific data are not available or insufficient to make a determination. When adequate data are available, a scientifically preferred approach would be to use the cancer potency factor for the Aroclor that most closely resembles the data for the environmental samples. US EPA should include this alternative approach in the risk assessment or explain why the available data are inadequate to deviate from IRIS guidance.

2. In its characterization of risk, the US EPA should include a discussion of the recent information on the risks of malignant melanoma of the skin and brain cancer among occupationally-exposed workers (Loomis et al., 1997), particularly in view of two other studies linking PCBs with malignant melanoma (Sinks et al., 1992; Bahn et a., 1976) and one study linking PCBs with brain cancer (Sinks et al., 1992).

We appreciate the opportunity to comment on this scope of work and would be glad to meet with you to discuss this project. If you have any questions please contact me at (518) 458-6306.

Sincerely,

Robert Montione
Public Health Specialist III
Bureau of Environmental Exposure Investigation

JARATS\HUD.WPD

cc: Mr. R. Tramontano
Dr. N. Kim
Dr. A. Carlson/Dr. L. Wilson/file
Mr. B. Fear - GFDO
Mr. W. Daigle - DEC
Mr. D. Steenberge - DEC Reg. 5
Mr. D. Hutchins - ATSDR

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