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DRAFT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2
290 BROADWAY
NEW YORK, NY 10007-1866

US Environmental Protection Agency
Hudson River PCBs Reassessment Remedial Investigation/Feasibility Study
Community Interaction Program

Joint Liaison Group Meetings
August 4, 1999, Albany, NY
August 5, 1999, Poughkeepsie, NY

On August 4 and 5, 1999, the US Environmental Protection Agency (USEPA) held Joint Liaison Group meetings at the Albany Marriott, Wolf Road, Albany, NY and the Sheraton Civic Center, Poughkeepsie, New York, respectively, to present the findings of the human health risk assessment for the Upper Hudson River and the ecological risk assessment for the entire river. Both risk assessment reports were released to the public this week. The meetings had the same format and speakers; the agendas are contained in Attachment 1. Sign-in sheets for both meetings are found in Attachment 2. The use of brackets - [ ] - indicates clarifications made by the writer in cases where the text would otherwise be unclear to those not at the meeting. Copies of the audio tapes recorded at the meetings are available on request.

Ann Rychlenski, Public Affairs Specialist and Community Relations Coordinator for the project, opened the meeting. Participating in the formal presentations at both meetings were Alison Hess, USEPA Project Manager for the Hudson River PCBs Reassessment Remedial Investigation/Feasibility Study (RRI/FS); Doug Tomchuk, USEPA Project Manager for the RRI/FS; and USEPA environmental scientists Marian Olsen (human health risk assessment) and Gina Ferreira (ecological risk assessment).

Other USEPA and contractor team members present included William McCabe, Deputy Director of the Superfund Program for USEPA Region 2; Douglas Fisher, attorney for USEPA; Katherine von Stackelberg, Menzie-Cura & Associates; David Merrill, Gradient Corporation; and Ed Garvey, TAMS Consultants. Ms. Rychlenski announced that copies of both risk assessment reports will be available in the information repositories. The reports are available for public comment; the comment period closes on September 7, 1999. Comments should be sent to Ms. Hess.

Also present in the audience were Joe Caruso from Senator Moynihan's office; Judy Enck from Attorney General Eliot Spitzer's office, and Kathy Cooke from the Office of the Comptroller.

The executive summaries of the risk assessment reports are found in Attachment 3. Hard copies of Ms. Olsen's and Ms. Ferreira's presentation slides are found in Attachment 4. USEPA's press release and the current expanded-detail schedule for the remainder of the project are in Attachments 5 and 6, respectively. Questions and comments are presented in these minutes in two sections in the order in which the meetings occurred, Albany followed by Poughkeepsie.

In her introductory remarks, Ms. Hess pointed out that the Human Health and Ecological Risk Assessment reports incorporate the results of the Baseline Modeling Report (BMR) released in May 1999. "Baseline" means an assumption of no remediation of the PCB-contaminated sediments or institutional controls, although USEPA recognizes that there are, in fact, institutional controls in place.

Ms. Olsen's presentation opened with the major findings of the human health risk assessment:

- Eating fish is the primary pathway for humans to be exposed to PCBs from the Hudson.
- Under the reasonably maximally exposed scenario (RME; the maximum exposure that is reasonably expected to occur in the Upper Hudson River under baseline conditions) for eating fish, the calculated risk is one additional case of cancer for every 1,000 people exposed. This excess cancer risk is 1,000 times higher than USEPA's goal of protection and ten times higher than the highest risk level allowed under Superfund law.
- For non-cancer health effects, the RME scenario for eating fish from the Upper Hudson results in a level of exposure to PCBs that is more than 100 times higher than USEPA"s reference level (Hazard Index) of one.
- Under the baseline conditions, the point estimate RME cancer risks and non-cancer hazards would be above USEPA's generally acceptable levels for a 40-year exposure period beginning in 1999.
- Risks from being exposed to PCBs in the river through skin contact with contaminated sediments and river water, incidental ingestion of sediments, and inhalation of PCBs in air are generally within or below USEPA's levels of concern.

Ms. Ferreira followed Ms. Olsen with an overview of the results of the ecological risk assessment. Major findings of that risk assessment are enumerated below.

- Fish in the Hudson River are at risk from exposure to PCBs; fish that eat other fish (fish higher on the food chain), such as the largemouth bass and striped bass, are especially at risk.
- Birds and mammals that feed on insects with an aquatic stage spent in the Hudson River, such as the tree swallow and little brown bat, are at risk from PCB exposure.
- Waterfowl feeding on animals and plants in the Hudson River are at risk from PCB exposure.
- Birds and mammals that eat PCB-contaminated fish from the Hudson River, such as the bald eagle, belted kingfisher, great blue heron, and river otter, are at risk.
- Omnivorous animals, such as the raccoon, that derive some of their food from the Hudson River, are at risk from PCB exposure.
- Fragile populations of threatened and endangered species, represented by the bald eagle and shortnose sturgeon, are particularly susceptible to adverse effects from PCB exposure.
- PCB concentrations in water and sediments in the Hudson River generally exceed standards, criteria, and guidelines established to be protective of the environment. Animals that use areas along the river designated as significant habitats may be adversely affected by the PCBs.
- The risks to fish and wildlife are greatest in the upper Hudson River (in particular the Thompson Island Pool [TIP]) and decrease in relation to PCB concentrations down river.

Based on modeled future PCB concentrations, many species are expected to be at considerable risk through 2018 (the entire forecast period).

Further information relative to both Ms. Olsen's and Ms. Ferreira's presentation are found in the executive summaries of the reports provided as Attachment 3, and complete details are available in the reports themselves.

Ms. Hess recapped after the presentations: regarding human health, the cancer risks and non-cancer health effects are above levels USEPA considers of concern; regarding ecological risk, predators at the top of the food chain that eat fish (*e.g.*, bald eagle, largemouth bass, mink, and otter) are especially at risk. She pointed out that the reports indicate that risks are found to be outside USEPA's generally acceptable levels of concern, but the reports do not specify what levels would be acceptable at the site. USEPA will look at [what those levels are] as cleanup alternatives are developed in the FS, which will be released in [December of] the year 2000. Later in 1999, USEPA will finalize two addendum reports: the results of the Mid-Hudson human health risk assessment and the results of future ecological risk in the Lower Hudson River. The risk assessments will be peer reviewed in May 2000; at that time, the peer reviewers will also have USEPA's responsiveness summaries containing USEPA's response to the comments received during the public comment period on the reports, which ends September 7, 1999.

Highlights of the question and comment period from the Albany meeting are in the following section.

A1. George Hodgson of the Saratoga County Environmental Management Council (SCEMC) referred to the county's resolution expressing concern over USEPA's use of baseline modeling report results in the risk assessments prior to the BMR's having been peer reviewed. He asked why USEPA is using modeling information that has not been peer reviewed.

Response: Ms. Hess said EPA considered that question before releasing the reports. EPA determined that the fine tuning currently that is underway on its models would not substantially alter the conclusions EPA is drawing from the risk assessment. Both the BMR and the risk assessments will undergo peer review.

A2. Dr. David Carpenter, Professor of Environmental Health at the State University of New York at Albany and former Dean of the School of Public Health, inquired about non-cancer behavioral effects not mentioned in Ms. Olsen's presentation. He proposed that behavioral effects are the most sensitive indicators of PCB impact. He also "has a sense" that fish advisory levels are set too high to be protective of human health; he said those levels were set at a time when only cancer effects of PCBs were considered. He suggested that with the enormous amount of information now available on toxicity of PCBs on other organ systems, it was time for the appropriate agencies to reconsider those fish advisory levels and adjust them "down to values that are more realistic in terms of what we now know to be the toxicity of these substances."

Response: EPA recognizes that a number of human epidemiological studies have looked at neuro-behavioral effects of PCBs both in the US and internationally. EPA is evaluating these studies as part of the Agency's reassessment of non-cancer toxicity of PCBs, in connection with the on-going process to update/reevaluate the currently accepted reference doses for PCBs that were reviewed in the presentation. For the Upper Hudson risk assessment, EPA used the toxicity values contained in EPA's Integrated Risk Information System (IRIS), which is the Agency's consensus database of toxicity information. Ms. Hess reiterated that the New York State Department of Health has issued a fish consumption advisory for the Upper Hudson to eat no fish, which is consistent with EPA's findings. In the lower Hudson, the advisory recommends that women of child-bearing age and children under the age of 15 should eat no fish.

A3. Merrilyn Pulver, Councilwoman for the Town of Fort Edward, said that, after 20 years of talking about cancer risk, "we don't have any human results to tell us about this."

Response: Ms. Olsen cited a number of epidemiological studies on occupational exposures in the Upper Hudson plant sites. She is not aware of any studies assessing cancer risks or cancer incidence in the Upper Hudson, which would likely be performed either by the Agency for Toxic Substances and Disease Registry (ATSDR, part of the U. S. Department of Health and Human Services) or the New York State Department of Health (NYSDOH). Problems with epidemiological studies in general include difficulties in identifying people who have been exposed at various, known levels of chemicals, classification problems based on disease; looking at a large enough population [for statistical robustness] and following that population over a number of years [to ensure an adequate latency period]. There is a non-cancer toxicity study starting this summer that is being performed by the NYSDOH.

Follow-on Comment: Dr. Carpenter stated, "the evidence that PCBs cause cancer is indisputable." He said every epidemiological study, excepting the study of capacitor workers [by Kimbrough et al., 1999, Journal of Occupational and Environmental Medicine 41(3):161, 171] which he stated was "diluted by adding all the secretaries, definitively proves that PCBs cause cancer." He pointed out that this is documented in rats, and in all major studies of occupational exposure, including a study of 20,000 utility workers. Every one of six of those major studies showed statistically significantly elevations of cancer. Recent studies of cancer in the general population demonstrate that non-Hodgkins lymphoma is "increased in a dose-dependent fashion with serum [blood] PCB exposures at the levels you and I have in our bodies." He cited a recent study of female breast cancer at the University of Buffalo that demonstrated that analyzing only PCBs and breast cancer produces a non-statistically significant correlation, but that the result of analyzing the 15 percent of women who have a genetic difference in the enzyme and the lipid that metabolize PCBs, and assessing whether they have high or low PCBs, is a three-fold increase in cancer. Dr. Carpenter stated that he has testified before the US Congress Environmental Public Health and Public Works Committee after GE released the study by Dr. Renate Kimbrough.

A4. 1) Have you fully assessed teratogenic effects - birth defects - and 2) have you taken into account for future projections that some PCBs are going to dechlorinate and may form more toxic substances?

Response: 1) One teratogenic effect, reduced birth weight, is considered in the basis for developing EPA's reference dose for PCBs [specifically for Aroclor 1016]. An uncertainty factor of 100 lower was applied to be more protective. This is now being reassessed within the Agency to incorporate the latest scientific evidence. 2) EPA evaluated dioxin-like PCBs in the Human Health Risk Assessment for the Upper Hudson River and saw risks similar to those associated with non-dioxin-like PCBs. EPA recognizes that PCBs bioaccumulate more toxic forms of PCBs through the food chain and took that into consideration during the risk assessment.

A5. Are shad included in the "no fish [consumption advisory]?"

Response: Shad is a lower river fish. The "no fish consumption" is for fish from the Upper Hudson River [and for children and women of childbearing age in the entire Hudson River study area].

A6. Cara Lee of Scenic Hudson, Inc.: How will the health risk assessment be used to inform the decision about remediation in the Hudson?

Response: The results of the human health risk assessment will be used to establish acceptable exposure levels at the site in fish, sediment, or water, and those [acceptable exposure levels] will be used to develop potential remedial alternatives for evaluation in the FS. The FS will utilize EPA's nine evaluative criteria, one of which is protection of human health and the environment.

A7. Leigh Foster asked 1) how "random variables" can be applied to angling and 2) if EPA would comment on risk over time to the subsistence angler, particularly if that angler "finds a good spot" and becomes more successful over time; the implication is that the more successful subsistence angler would consume more fish. How does that risk change, and how is it considered? 3) Since subsistence anglers are not necessarily licensed anglers, how did EPA account for them in the RME point estimates?

Response: 1) The purpose of the Monte Carlo analysis that looked at the range of variables was not to see if one person's activities would be random but rather to look at, among a group of anglers, what range there might be in [cancer risks and non-cancer hazards associated with a range in] fish ingestion rates [amount/frequency], how long someone would consume fish [exposure duration], different body weights [for different ages] -- all of which are variable factors among the [Upper Hudson River] angler population. The Monte Carlo analysis was a simulation of 10,000 anglers. 2) The Monte Carlo analysis looked at a range of fish ingestion rates, from people who ate little fish to people who ate a lot of fish. The successful subsistence angler would therefore be accounted for in the Monte Carlo distribution among the people who eat a lot of fish. With respect to successful fishing over a long period of time, the risk assessment expresses cancer risk over a lifetime. [Non-cancer hazards to an RME individual are calculated over an exposure duration of seven years, based on the expectation that an individual would receive the highest dose during this period of time]. 3) The 1991 (Connelly) survey of New York State licensed anglers was used because of the information it provided on different types of river bodies, fish consumed, etc. In contrast, there is little data to quantify exposure to subsistence fishermen. EPA found one relevant study [a study of low income families' consumption of freshwater fish in New York State by Wendt, 1986]. In the Upper Hudson risk assessment, the Agency compared the RME fish consumption rate used in the risk assessment to the [Wendt, 1986] study. EPA found that the low income families [from the Wendt study] reportedly ate less fish than the RME fish consumption rate derived from the Connelly angler study and used in the Upper Hudson River risk assessment. Therefore, EPA determined that the fish ingestion rate used in the risk assessment would not underestimate cancer risks and non-cancer hazards to a subsistence population, even though that population is not specifically identified.

A8. Michael Rivlin of *The Amicus Journal* asked about the presence of bald eagles in the upper river.

Response: There are reports of two nesting pairs along the Upper Hudson River, above the Troy Dam.

A9. Does the ecological risk assessment model have data underlying the "generalizations" presented? Do you have the level of quantification that is going into the human health risk? Is the literature robust enough to sustain that many different conclusions?

Response: Yes, it is. Only a subset of graphs was shown to represent the risks; risks exist in all 18 species that EPA evaluated. All 18 analyses were not depicted in the presentation.

A10. Discussion followed pertaining to quantifying the subsistence fishing population and ability to assess risk to that population without quantification. One speaker contended that it could not "be that difficult" to get a figure on the subsistence population. He also asked how EPA knows there are such fishermen.

Response: EPA does not have exact quantification of that population; there are no known records. Surveys have been done on licensed anglers, but the subsistence population would not necessarily have a license to fish, so there is no way to identify them using that vehicle. EPA believes the community exists because of the study referenced in the response to A6 [Wendt, 1986]. EPA studied ranges of consumption that included [fish ingestion rates] that a subsistence fisherman might have, so the population is in effect included in the risk assessment analysis: of the 1000 responses to [1991 Connelly] New York angler survey that was used, over 100 respondents said they ate 50 or more fish meals per year and some said they ate a fish meal a day or more. Therefore, in the upper end of that distribution, a subset of the population that eats the fish very frequently is being captured.

A11. Did EPA study cancer rates among known fishermen in the impact areas?

Response: No. EPA evaluated current and future cancer risks and non-cancer hazards [to an individual]. Further, the fish advisory in place in the Upper Hudson would make that type of study difficult.

Follow-up Comment: Cara Lee cited a New York State study published this spring [NYSDOH Center for Environmental Health 1996 Survey of Hudson River Anglers] in which a majority of anglers questioned acknowledged both eating fish themselves and giving fish to family and friends. Ms. Lee suggested that rather than questioning the number of people who are at risk, the focus here as set out by the Clean Water Act is to return our waterways to fishable and swimable resources.

A12. Darryl Decker, Government Liaison Group Chair: Re the slide showing use of a control group for a comparison to the RME group, adjusting PCB levels due to cooking by 20 percent for the control group but nothing for the RME group. Why not for that group also?

Response: A number of studies have examined what happens to PCBs in fish when cooked. Some studies showed increases, some showed reductions from nothing [zero] up to 74 percent. In looking at the reasonably maximally exposed individual, EPA was looking at the potential for someone to consume not only the cooked fish but [PCBs in pan drippings that are used as a sauce or gravy on the fish]. The 20 percent reduction was to look at a reduction for the average person. For an RME individual, a zero reduction is appropriate. [As a point of clarification regarding the use of a control group], this is another type of analysis conducted to compare the RME individual to an average or central estimate. It provides more of a range within the point estimate to show what cancer risks and non-cancer hazards would be for those individuals.

A13. Of the various measures taken in the animal studies, which seem to be the most sensitive to reflect the toxic effects?

Response: For ecological risk, EPA stressed reproductive effects - for example, egg production - which are typically the most sensitive. For human health, the effects listed in the presentation are the critical effects.

A14. Michael Rivlin: In cleanup decision-making, do human health effects weigh more than ecological effects?

Response: EPA is charged to protect both human health and the environment, so both are considered in the decision-making process. Clearly, human health is a major concern. Exceedences of risk levels of concern for both ecological and human health are reasons to take action at a site if warranted, but either one can be a trigger to take an action.

A15. Joe Gardner, Appalachian Mountain Club, asked about Anne Secord's [US. Fish and Wildlife Service] study of PCB effects on tree swallows. EPA indicated those effects were interpreted as behavioral, not reproductive effects, which is what EPA was analyzing; however, the Secord study was included in EPA's ecological risk assessment report, and tree swallows were one of the receptors considered in the EPA analysis.

A16. Merrilyn Pulver: "Fort Edward is probably the community hardest hit with PCBs." Does EPA "have evidence of large fish kills or massive loss of life due to cancer that you can prove came from PCBs?"

Response: As to human health, there are no epidemiological studies [in Fort Edward] that EPA is aware of, and it would be difficult to perform one [see comments in response to A3, also]. For ecological risk, EPA used available field observations, which suggested that levels of PCBs are not high enough to prevent survival of particular species. Although the field observations are not able to assess whether the survival, growth, and reproduction are impaired because of PCBs, the ecological risk assessment indicates that PCBs are at levels that may adversely effect growth, survival, and reproduction of the species evaluated.

A17. George Hodgson: Has residency time of mammals on the river been factored into the risk assessment?

Response: EPA considered the home range of the animals - where they live, eat, and roam - as the Hudson River. Mr. Hodgson replied that he did not feel this is a valid assumption, particularly for the mink and otter, which he felt spent a large part of the year away from the river.

A18. Darryl Decker: Confirm that increased risk of 1 in 1000 applies only to the RME group, not to the population at large. Could EPA develop a calculation of risk to the public at large from that calculation?

Response: Ms. Olsen repeated that the increased cancer risk to an individual is based on consuming fish from the Upper Hudson River under the exposure conditions described, considering both exposure to PCBs and their toxicity [Note: As stated in the NCP, Superfund human health risk assessments risks are calculated for an individual, not a population]. To the follow-on regarding the "public at large," Ms. Olsen said "no." Other pathways were analyzed. For example, volatilization of PCBs resulted in an increased risk of 1 in 1,000,000 for someone exposed to volatilized PCBs. Risk is dependent upon the exposures and activities of a given individual.

A19. Michael Rivlin observed that if fish were caught and sold to a fish market, the risk to the general population, or at least the risk to the population buying fish from those markets, could be calculated.

Response: Yes, if EPA knew the concentrations to which those people were being exposed [and the frequency and amount of fish consumed by these individuals from the Hudson River].

Follow-on Comment: A speaker pointed out that EPA is not addressing risk to the general population, rather to the population ingesting these particular fish and it does not decrease the import of EPA's findings by diluting it with a large population that does not eat the fish.

A20. Is the risk of 1 in 1,000 projected additional cancer instances over a year or over a lifetime?

Response: The calculation is over the 40-year period of exposure averaged over a lifetime.

A21. Does the 1991 Connelly study specify species?

Response: EPA looked at the species cited by anglers responding to the survey, and used that information to match the study to the types of fish in the Upper Hudson, particularly the brown bullhead, yellow perch, and largemouth bass.

A22. Is EPA considering others (family, friends) who eat fish, not just anglers? There is a difference between subsistence, something people do to meet their family's needs, and recreation/sport fishing.

Response: EPA did not calculate cancer risks and non-cancer hazards to people receiving fish from family [who were assumed to eat less fish than the anglers themselves]. However, the range of anglers included 15 percent females and age groups starting at age ten. EPA believes that this approach captures the cancer risks and non-cancer hazards to family members receiving fish.

A23. Leigh Foster: I guess the question under my chair is, why no angler study for the Reassessment?

Response: Ms. Hess responded that no angler study was done for the Reassessment because there is a fish consumption advisory in place. Mr. Foster said that was [put in place by New York State] DOH and DEC; he wanted to know from USEPA Region 2 why it was not capable of doing or chose not to do an angler survey? Ms. Hess again attempted to explain that because there is a fish consumption advisory in place, theoretically there should be no anglers consuming fish from the Upper Hudson, so an angler survey [representing the baseline conditions required for the risk assessment] could be performed. Ms. Olsen reiterated that EPA did look at the NYSDOH survey data referenced previously by Cara Lee as a way of verifying that the 1991 angler survey of New York State was in fact representative of a population consuming fish. EPA used all information it identified to evaluate fish consumption within New York, and several water body studies outside the state.

Follow-on comment: Dr. Brian Bush stated one of the strengths of EPA's approach was to consider anglers from Maine, so in fact subsistence anglers from Maine who are not PCB-afflicted were included in the Monte Carlo analysis.

A24. Steven Wilson, Hudson River Environmental Society. Did the Connelly study consider the seasonality of take? The speaker pointed out that if one looks at potential for scour and mobilization of contaminant in the river, that may be in some way related to seasons as well.

Response: The concentration of PCBs in fish were derived from modeling results, which were projected on an annual basis.

P1. Joseph Ruggiero, Councilman, Town of Wappinger. A number of communities along the Hudson use Hudson River water for drinking water. That was not included as an exposure pathway in the presentation. 1) What does the human health risk assessment say about drinking water? 2) Has there been any link to cancer or other form of birth defects, etc., from drinking the water over a 30-year period? 3) Why assess exposure from swimming and not consider ingestion of water?

Response: 1) This particular risk assessment is for the Upper Hudson, above Troy. EPA did compare levels of PCBs found in the river water to Maximum Contaminant Level for PCBs that the Agency uses as its criterion for drinking water [under the Safe Drinking Water Act]. [PCB] levels were below the [MCL]; therefore the water is acceptable for use as drinking water. 2) Ms. Olsen is unaware of any studies conducted to evaluate the specific health effects the speaker identified. She explained that the maximum contamination levels are applicable nationwide. 3) EPA did evaluate exposure from swimming and included the results in the report, which is that the cancer risk and non-cancer hazard level are below the Agency's level of concern.

Ed Garvey of TAMS Consultants pointed out that in addition to the river water from the Upper Hudson's being within EPA criteria, drinking water consumers in the Hudson Valley are drinking water that has been treated through filtration and chlorination. The risk assessment focuses on the incidental consumption of water from the river because it is untreated water. Further, to Dr. Garvey's knowledge, although there are PCBs in the Hudson River water in the vicinity of Waterford, which also gets its drinking water from the river, there are no PCBs in Waterford's treated drinking water. In response to a question about dioxins, Dr. Garvey stated these were not measured.

P2. Scott Emslie, NYS Conservation Council: 1) Why will the human health risk assessment not go further than Poughkeepsie toward the Battery? 2) In the 1991 [Connelly] angler study: were the anglers statewide? Also, did the study divide the upper and lower river? 3) Did the risk assessment take into account the fact that a fishing advisory has been in effect?

Response: 1) The initial study was the Upper Hudson River as far south as Troy; EPA added the human health risk assessment for the Mid-Hudson River. EPA believes the cancer risks and non-cancer health hazards it will see for Mid-Hudson should be lower than what was found in the Upper Hudson, because PCB concentrations in sediment, fish, and water are lower. Although it would be possible to conduct the same sort of study further down river, it becomes complicated by the presence of other sources. Further, there were areas of particular ecological concern below Poughkeepsie that made it important to add them to the original scope of the ecological risk assessment. 2) The Connelly survey was statewide. It was used because when a consumption ban is in place, one cannot conduct a survey and get adequate information on ingestion rates. The risk assessment looked at fish consumption patterns for similar types of fish and waterbodies in New York State, and used information for fish ingestion rates for waterbodies that did not have advisories. EPA also looked at surveys on the Hudson River and in other states to derive a range of different fish consumption rates and ensure that the fish consumption rates used were adequately protective of the public that would ingest the fish.

P3. Were the bodies of water EPA looked at similar in PCB levels [to the Hudson]?

Response: EPA did not evaluate that. The Agency looked at similar types of fish and angler consumption rates in water bodies that did not have fish consumption bans. The purpose was to determine how much fish anglers would ingest if there were no fish consumption advisory. PCB concentrations of the Upper Hudson River fish were used to determine how much PCB contamination people would be exposed to if they ingested fish in the amounts determined.

P4. 1) What levels of PCBs - what range of data from what years - are being used for the human health risk assessment? 2) Did you use the average rate for exposure scenarios or the range? 3) Did you look at exposure scenarios for each species, or did you average the species?

Response: 1) EPA projected into the future using results of the Baseline Modeling Report. Because of projected declines over the 40-year period, concentrations ranged from an average of about two to four parts per million in fish. 2) The concern for ingesting PCB-contaminated fish is long-term ingestion of, on average, a large quantity of fish over time. That average is the measure EPA seeks to characterize. Because there is a declining concentration of PCBs as one moves from upstream to downstream, analysis was done in several ways: averaging over the entire Upper Hudson as the baseline; average consumption at the extreme upper end of the Hudson; and [average consumption at the lower end]. 3) For the point estimate calculations (i.e., a number for fish ingestion, a number for concentration, a number for how often you fish, etc.), EPA averaged across different fish species. EPA used the Connelly survey of anglers in New York State to determine the types of fish preferred, or caught and eaten, developed percentages, and used those percentages to come up with a weighted average by species. In the probabilistic Monte Carlo model, EPA looked at anglers and their individual preferences for particular species.

P5. The man who asked previously about dioxins and dibenzofurans asked why they were not measured, as they are "more toxic" than PCBs. He contended that PCBs form dioxins and dibenzofurans as a reaction with water and air. He accused EPA of taking a cavalier attitude toward dioxins in the study.

Response: The human health risk assessment did look at "dioxin-like" PCBs, based on specific congeners of PCBs. New York State has done some tests to evaluate levels of dioxin in fish and did not see a dioxin problem in the fish; therefore there is no dioxin advisory in place. Mr. Tomchuk stated he did not believe there was evidence to support the contention that dioxins are formed from PCBs.

P6. The next speaker expressed concern over the statement that there is no loss of PCBs from cooking, contending that the cooking process converts PCBs into polychlorinated dibenzofurans, much more toxic than PCBs themselves. He did not agree that there were no studies, but the example he cited did not refer to cooking.

Response: EPA reviewed available literature and found no evidence of the levels that would be produced when cooking fish. It just has not been studied. Also, the exposure during cooking would be for a much lower period of time, happening much less frequently, and the dose level would be lower than has been found through ingestion of fish.

P7. Frank Mancuso: What would be the worst case scenario of impact on a fetus for a woman who lived on the river, ingested 30 fish meals, and was exposed to the other pathways also?

Response: In that example, fish ingestion would be the pathway of greatest exposure. The exact impact to a fetus would be difficult to quantify.

P8. Ann Barchev, candidate for supervisor in the Town of Poughkeepsie: What is the likelihood that her lifetime total consumption (or that of an average person) of PCBs has exceeded a safe or desirable limit? What is the safe or desirable amount of PCBs to ingest? Have you looked at people who drinks the water, eats plants along the river, etc. - taking into effect the cumulative effect? What are the non-cancer hazards, and would a different level of exposure trigger those as opposed to cancer hazards?

Response: The answer is difficult without knowing the amount and frequency of exposure. The risk assessment has looked at the effect over the next 40 years to an individual who ingests 51 fish meals per year for that period of time, with currently defined [PCB] concentrations in the fish; the result is a calculated risk for that person. As shown in the presentation, all pathways were considered; if one added all the pathways, the risk would still be 1 in 1,000 because the risk associated with the other pathways is so much smaller. Non-cancer hazards are derived from animal studies; risk of hazard is based on the activity patterns of people, frequency and levels of exposure. Although specific predictions of the types of human health effects are not possible, animal studies showed such effects on the immune system, reduced birth weight, etc. Some studies of humans include chloracne and reduced IQ. Another area of continuing investigation is the potential for hormonal effects on humans.

P9. 1) Speaker expressed concern about inhalation. Why did EPA not give inhalation consideration as part of the study? 2) Why were tree swallows not mentioned, and how do you know PCBs is the "reason animals are having trouble?"

Response: 1) EPA did evaluate cancer risks from inhaling volatilized PCBs as part of the risk assessment, using data from the river and modeling the concentrations to which a person living on the banks would be exposed. Those risks are below EPA's level of concern. 2) EPA did look at the tree swallow in its reassessment, and used the US Fish and Wildlife's data also. Tree swallows are not eating fish, so EPA did not see a risk to them [from PCB-contaminated] fish.

P10. Eric DuMont, Citizens Campaign for the Environment: Why are no plants or amphibians listed as receptors of concern? Particularly, what was the rationale for excluding frogs?

Response: EPA does not have any field data on plants or a model to uptake PCBs from sediments to plants that could be used for the risk assessment. The assessment looked at species that were consuming [fish] and coming into contact with sediments; receptors selected for the risk assessment, ones that consume fish, are likely to have much higher exposures than amphibian species. Further, although amphibians were not considered as receptors, they are discussed in the report. There is no toxicity information available for amphibians; exposures could be calculated but there are no effect levels to which the exposures could be compared.

P11. Rich Schiafo, Scenic Hudson: 1) Because of the significant findings of the risk assessment, would EPA consider some kind of interim action, or possibly accelerate the decision-making process? 2) Are these reports going to be available on the EPA website? 3) Does EPA have a comment on the report by the National Research Council relative to differentiation between potential risks associated with higher and lower concentrations [of PCBs]. 4) In the Mid-Hudson risk assessment, will EPA consider the angler survey performed by the Department of Health that indicated in the mid- and lower Hudson there are higher levels of fish being consumed.

Response: 1) EPA agrees that the conclusions are significant and that PCBs are posing a serious threat to human health and the environment. EPA is on track with its schedule, including a peer review. Ms. Hess does not expect that the risk assessment conclusions will cause any earlier action, and does not believe there is any way to speed up the current schedule, which is tight as is. 2) Yes, in about two or three weeks. 3) The report was released Monday [immediately prior to the meetings]; Ms. Olsen has not reviewed it yet but EPA experts on endocrine effects would certainly be reviewing it. EPA will share any information that comes out of that review. 4) All available surveys have been evaluated within the human health risk assessment, including the

1996 NYSDOH survey that was just released this year. The problem with a survey conducted while an advisory is in place is that there may be biases in responses.

P12. Was any assessment done for blue claw crabs?

Response: No, that receptor was not used in the risk assessment.

P13. Joel Tyner suggested that in future presentations, EPA address ingestion of water from the river more fully. Another speaker asked how old the MCL standard is on water quality, when was it last evaluated, and how adequate is it based on new information regarding the health effects of lower-[chlorination] level PCBs?

Response: When the MCL was set, the old cancer slope factor (7.7) was used. Exposure times toxicity equals risk, so with the change [i.e., reduction] in the cancer slope factor to 2, the exposure could be higher and pose the same risks. The MCL would be more protective based on the current slope factor.

P14. 1) Is there any measurable effect of PCBs (visible cancers, ulcers, etc.) on the animals? 2) If PCBs were removed from the Hudson River valley, what about other risks animals are exposed to?

Response: 1) Measurable data on PCB concentrations in fish exist dating from 1993 to 1996. EPA is particularly concerned with reproductive effects and the ability of ecological populations to maintain themselves. The tree swallow study found some behavioral effects, though this was not considered a reproductive effect; this is the type of study that can be done. Fish fecundity is another measure of how fish are affected by PCBs. 2) The reassessment did not do a comparative study among potential health threats because the focus was to address PCBs and their impact, but there are certainly other stressors on the ecological population.

P15. What are the reasons for the decrease in the river otter toxicity? The decrease is not from the compound breaking down?

Response: The decrease is tied to the [PCB] concentration in the otter's prey [fish], and is a mirror of the decrease in concentrations of PCBs in fish that were predicted from the bioaccumulation model. The PCBs in the fish are decreasing for a variety of reasons. Dr. Ed Garvey elaborated that there are three ways for PCBs to leave the system as far as impact to fish: burial by cleaner sediment; a resuspension process such as storm or spring flood event; and/or volatilization into the atmosphere after sediment resuspension. The problem is slowly spreading.

Follow-on comment: A speaker proposed that "a more common sense" reason for the decrease in PCB levels in otters is that DEC has been actively trapping fish for years, mostly the larger ones, and is therefore removing the otter's contaminated prey from the river.

P16. Has the EPA considered any cell studies such as the St. John's University study that indicates that 4 parts per billion [of PCBs] alters DNA.

Response: EPA looked at animal and human occupational studies, including tests of DNA and other studies of that type. The test mentioned sounds more recent; it is the agency's policy to look at such studies as they become available. That study was not part of the evaluation on this risk assessment. EPA uses what are called "consensus values," agency-wide values applied to all Superfund sites. Further, EPA uses information on whole animal systems. The information mentioned is supportive and provides information on mechanisms of action, but EPA needs to understand what happens in the body of an animal, where all the systems are working together. A DNA study would not provide this information at that level.

P17. The next speaker objected to the concept that burial is covering PCBs and making them safe, "as GE contends;" he cited the constant river traffic and the potential for turbation.

Response: EPA clarified that there is some burial by cleaner sediment, but by no means does this burial make [PCBs] safe.

P18. Apparently GE does not want to dredge PCBs from the river. Has GE produced a study that would contradict EPA's study?

Response: GE has not provided EPA with any risk assessment it may have done regarding PCBs in the river. EPA does not know what GE's position would be with respect to the Agency's risk assessments results.

P19. What is the next step, why do these studies go back and forth, and who has the power to make GE clean up the river? Follow-on: Will that [December 2000 release] include a model of how many additional PCBs will come down the river [if EPA stirs it up remediating]?

Response: The risk assessments comprise the final step in the study of the river. From here EPA proceeds to evaluation of [remedial action] alternatives. In December 2000, EPA will release the study that evaluates those alternatives and presents EPA's preferred alternative to the public. Follow-on answer: EPA will evaluate the short-term risks posed by implementation of remedial alternatives.

P20. Would you comment on EPA Region 1's ordering of GE to clean the PCBs out of the Housatonic?

Response: There is an agreement to clean certain parts of the Housatonic River but it is not formalized as yet. The site is a two-mile reach of the Housatonic, approximately 30 feet wide during average flow. This portion of the Housatonic identified for cleanup is much different [than the Hudson]. The rest of that system is being studied in the same manner as EPA Region 2 is doing here [on the Hudson].

P21. 1) A speaker observed that EPA and GE have different models, and that GE will never have the same conclusion as EPA. How is EPA going to come to one type of model, and when will it be released to the public? 2) Will that [final] model reflect severe adverse weather conditions?

Response: 1) EPA's model was released to the public in May. EPA will use that model. GE has submitted comments on that model and has submitted its own modeling report. EPA will look at both of those to assist in determining if revisions are necessary to its model. The final model will then be published and peer reviewed to determine if it is credible science upon which to base a decision.. 2) EPA looks at 100-year flood conditions but not at drought conditions. Certain base flows have to be maintained [during dry periods] and although not defined specifically, some of these conditions have been taken into account in the hindcasting to establish hydrodynamic conditions from prior years into the future.

P22. 1) Would you comment on the statement that the cancer risk is 1000 times above EPA's goal of protection and ten times higher than the Superfund level - what is the difference? 2) Given you haven't come up with an acceptable level yet, is it safe to assume that an "acceptable level" is to reduce that cancer risk by 1000 times?

Response: 1) For cancer, there is an acceptable cancer risk range in EPA Superfund regulations. The "goal of protection" is the point below which EPA says the risk is not of concern and above which the risk may be of concern. This is the lower end of that range. At the top end of the range is the highest risk that would be allowed under Superfund law. If you are above that, action is required. The risk for skin exposure is within that range, for example. The risk for fish ingestion is above that upper risk point. 2) In the Feasibility Study, EPA will establish acceptable concentrations of PCBs in fish, water, or sediment and will develop a range of cleanup alternatives to decrease the levels of exposure to something acceptable under Superfund law.

ATTACHMENT 1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2
290 BROADWAY
NEW YORK, NY 10007-1866

HUDSON RIVER PCBs REASSESSMENT
Joint Liaison Group Meeting

HUMAN HEALTH RISK ASSESSMENT REPORT
and
ECOLOGICAL RISK ASSESSMENT REPORT

Thursday, August 5, 1999
7:30 p.m.
Poughkeepsie, New York

A G E N D A

Welcome & Introduction	Ann Rychlenski, Community Relations Coordinator U.S. EPA
General Overview	Alison Hess, Remedial Project Mgr. U.S. EPA
Results of the Human Health Risk Assessment	Marian Olsen, Environmental Scientist, U.S. EPA
Results of the Ecological Risk Assessment	Gina Ferreira, Environmental Scientist, U.S. EPA

Questions & Answers

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JOINT LIAISON GROUP AND PUBLIC MEETING

Albany, NY
August 4, 1999

NAME	ADDRESS	AFFILIATION/TELEPHONE
Echo Cartwright	Leg. Commission Haz. Waste & Toxic Substances Agency #4, 5th Floor E.S.P. Albany NY 12248	NYS Assembly (518) 455-3711
William Potts	NYSDEC 50 Wolf Rd Albany NY, 12233	518-457-5637
B Bush	SUNY DOH	518 463 8280
J. Haggard	GE	518 458-6618
M. Elder.	GE	518 458-6618
MARIAN H. ROSE	Sierra Club & Croton Watershed Clean Water Coalition	914 234-3179
	9 Old Corner Road Bedford, NY 10506	
CALVIN J BURCH	10 RIVERVIEW ST STUYVESANT, N.Y 12173	(518) 758-6474
LISA BARRON	1 NORTH LANE LOUDONVILLE NY 12211	518 436-8638
Cara Lee	Scenic Hudson 9 Vassar St	914-473-4440

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COMMUNITY INTERACTION PROGRAM
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Albany, NY
August 4, 1999

NAME	ADDRESS	AFFILIATION/TELEPHONE
Ron Sloan	NYSDEC 50 Wolf Rd	457-0756
Neil Yandik	P.O. Box 132 Claverack NY 12513	Princeton U - 518-851-7460
Jay Silberwath	POB 8 Schenectady NY 12301	GE 387-5895
Jeff Turner	256 Washington Ave Troy, NY 12180	student
John Braun	GE Corp. R&D POB 8, Schenectady 12301	387-7987
Mark Behan	13 Locust St. Glens Falls NY 12801	GE 518 792 3856
Clarence Gregory Jr.	2112 Baker Avenue East Niskayuna, NY. 12309	518-393-7100
Jim Reagan	32 Dublin Drive Ballston Spa N.Y. 12020	518-457-2562 NYSDEC
Russ Keenan	15 Franklin St. Portland, ME 04101	207-879-4222 Ogden
DAVID SCHEUING	IT CORP 13 BRITISH AMERICAN BLVD LATHAM NY 12110	

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Albany, NY
August 4, 1999

NAME	ADDRESS	AFFILIATION/TELEPHONE
CHRIS BALLANTYNE	85 WASHINGTON ST. SARATOGA SPRINGS, NY. 12866	SIERRA CLUB 518.587.9166
Joe Gardner	68 Carson Rd. Delmar, NY 12054-2503	Mohawk Hudson Chapter Appalachian Mt. Club (518) 439-1074
Craig Carriero	104 Holland Ave Albany, NY 12208	~~(134)~~ (518) 434-2069
Willem Sederel	2201 Pine Ridge Ct NISKAYUNA 12309	(518)-393-7160
Joe Caruso	Office of Sen. Moynihan	607-433-2310
Marilyn Pulver	2842 Cty Rte 46 Fort Edward, NY	518-747-4985
George Hodgson	Saratoga Co. EMC 50 W High St, Ballston Spa NY 12020	Saratoga County 518-884-4778
Robert E. Henshaw	9 Louis Dr, West Sand Lake, NY 12196	Hudson River Environmental Soc, 518-283-0415
William C. Solomon	P.O. Box 377 Tillson, NY 12486	
James Mays	2545 County Rt 3 Olivebridge NY 12461	Sierra Club 914 657 2013 jmays@ulster.net

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Albany, NY
August 4, 1999

NAME	ADDRESS	AFFILIATION/TELEPHONE
PETER SHEEHAN	32 BUCKINGHAM DR ALBANY, NY 12208	SIERRA CLUB (518) 489-5803

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Albany, NY
August 4, 1999

NAME	ADDRESS	AFFILIATION/TELEPHONE
Cathy Cooke	5th floor AESOB Albany NY 12236	NYS Comptroller's office
JACK LAUBER	53 FAIRLAWN DR LATHAM NY 12110	AMC
John Santacrose	PO Box 3705 Alby, NY 12203	Environmental Liaison group.

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Albany, NY
August 4, 1999

NAME	ADDRESS	AFFILIATION/TELEPHONE
Rick Sheldon	P.O. Box 8 Schenectady, NY	GE-CRD
Dr. David Carpenter	School of Public Health U.A.	518 525 2660 1 University Pl Rm B242 Rens 12144
Gerald Burke	10 VANDALE WOODSTOCK 12498	914-679-6240
Mary O'Brien	385 Watervliet – Shaker Rd. Latham 12110	Sisters of St. Joseph 518-783-3519

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Albany, NY
August 4, 1999

NAME	ADDRESS	AFFILIATION/TELEPHONE
Sarah Johnston	597 Rte 9J Stuyvesant, NY 12173	none
Mark Burch	PO Box 153 #10 Riverview St. Stuyvesant, NY 12173	NYS DEC/AmeriCorps (914) 256-3029

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US ENVIRONMENTAL PROTECTION AGENCY
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Albany, NY
August 4, 1999

NAME	ADDRESS	AFFILIATION/TELEPHONE
Bob Gibson	1 Computer Dr. Albany, NY 12205	GE
Mel Schweiger	1 Computer Dr Albany, NY 12205	Behan Comm.
L. Scheuing	125 Wolf Rd Albany NY 12205	HSI GeoTrans
Judith Enck	State Capitol EPB Albany NY 12224	AG
[illegible]	6 N. Park St. Cambridge, NY 12816	Chairman Joint Liaison Group.
Andi Weiss Bartczak	112 Market St. Poughkeepsie NY 12601	andi@mail.clearwater.org Clearwater (914)-454-7673
B. Slotnick	American Univ Wash DC	202 885178C
Stephen Wilson	Exec Dir Hudson River Envir. Society 6626 Stitt Rd Altamont NY 12009	
John Mylod	914 452-2324	

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Poughkeepsie, NY
August 5, 1999

NAME	ADDRESS	AFFILIATION/TELEPHONE
Scott Emslie	17 Corlies Ave Poughkeepsie, NY 12601	NYS Conservation Council 914-485-2051
Leighanne Saltsman	411 Sepasco Ctr St Rhinebeck NY 12572	Rhinebeck Gazette Advertiser (914) 876-0333
Darren O'Sullivan	Pok Journal	Pok Journal 437-4827
Barbara Kendall	PO Box 259 Millbrook	Dutchess Co. EMC 914-677-8223 x126
Jeff Clock	257 Springtown Rd New Paltz	Central Hudson 914-486-5534
Wm. M. Brereton	12 Oak Crescent Poughkeepsie NY 12601	Self
Kathy Tallman	18 Overlook Rd. Poughkeepsie	No. Dutchess Alliance
Dora Schusler	115 S. Cherry St	Poughkeepsie NY 12601

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US ENVIRONMENTAL PROTECTION AGENCY
COMMUNITY INTERACTION PROGRAM
JOINT LIAISON GROUP AND PUBLIC MEETING

Poughkeepsie, NY
August 5, 1999

NAME	ADDRESS	AFFILIATION/TELEPHONE
Eric Fuegel	376 Vassar Rd Poughkeepsie NY 12603	P.K

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JOINT LIAISON GROUP AND PUBLIC MEETING

Poughkeepsie, NY
August 5, 1999

NAME	ADDRESS	AFFILIATION/TELEPHONE
Christine Tyszka	230 Overlook Road Poughkeepsie NY 12603	(914) 454-7236
William Kells	54 S. Mtn. Rd Wallkill NY 12589	UC/EMC 914/895-2041
Brendan James	23 Armadale Court Reading, Berks. RG30 2DF U.K.	
Gerald Chiumento	179 Van Wagner Rd Poughkeepsie 12603	454-2636
SR. LORELLE ELCOCK	284 CARPENTER AVE NEWBURGH, NY 12550	DOMINICAN SISTERS OF HOPE 914-561-6520
Aaron Mintzes	Box 2948 Vassar College 124 Raymond Ave Poughkeepsie NY	
David Straus	1018 Old Ford Rd. New Paltz, NY 12561	SUNY-New Paltz Ulster Cty EMC
Jim Tallman	18 OVERLOOK RD POK 12603	CITIZEN 452-7674
Anthony Clark	148 Hooker Ave Pok. NY 12601	Citizen 473-1624

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COMMUNITY INTERACTION PROGRAM
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Poughkeepsie, NY
August 5, 1999

NAME	ADDRESS	AFFILIATION/TELEPHONE
Paul Case	97 Miller Hill Dr LaGrangeville NY 12540	La Grange CAC 914 223 5293
Ted Tyner	RR1 Box 366 Staatsburg, NY 12580	CHANGES + candidate for Co. legislature
Mark Stevens	218 Henry St. Beacon, N.Y. 12508	(914) 831-4264
Brian Stevens	218 Henry St Beacon NY 12508	(914) 831-4264
Robert Kiendl	11 Baker Rd Hopewell Jct	RT Waterman R&G Club
Nancy Swanson	356 Freedom Rd Pleasant Valley 12569	
Marlene M. Sgala	18 Hillis Terr. Pok. N.Y. 12603	
Gerald A. Davison	22 Anna Lane, Ulster Park, NY	Sierra Club 914-339-4509

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Poughkeepsie, NY
August 5, 1999

NAME	ADDRESS	AFFILIATION/TELEPHONE
LIZA ACUINO	Pendell Road Pough	WEOK/WPDH 473-NEWS
MARK PASTREICH	11 MARKET ST POUGHKEEPSIE	454-1122
FRANK STOPPENBACH	32 ROKEBY RD RED HOOK NY 12571	914 758-6455
Martin Byster	58 Highview Rd Fishkill, NY 12524	914-896-5540

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Poughkeepsie, NY
August 5, 1999

NAME	ADDRESS	AFFILIATION/TELEPHONE
Jim Mays		Sierra Club.
Rich Schiafo	9 Vassar St Poughkeepsie 12601	Scenic Hudson
Will Solomon	~~p 377~~ Here last night	
Jill Truefant	Box 2621 Vassar College 124 Raymond Ave Poughkeepsie, NY 12604	Vassar Greens

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COMMUNITY INTERACTION PROGRAM
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Poughkeepsie, NY
August 5, 1999

NAME	ADDRESS	AFFILIATION/TELEPHONE
Joe Brek	27 Hurleys Ave Kingston	
Pete Page	PO Box 185 Glenfalls NY.	
Mike Schlissel	721 BROADWAY KINGSTON NY 12401	WRNN-TV 1-800-824-3302
Robert E Miller	136 Cannon St Poughkeepsie NY 12601	REMTKE@ YAHOO.COM –
Ann Barcher, Esq.	31 Old Farms Rd Poughkeepsie, NY 12603	Democratic candidate for supervisor, Town of Poughkeepsie
Bill Beehler	11 LA GRANGE AVE POUGHKEEPSIE NY 12603	454-7832
[illegible]	POUGHKEEPSIE	—
Tony Maresco	3A Duryea Pl. Nyack, N.Y. 10960	Citizen of USA + (Environmental Engineer) 914 727-5113

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COMMUNITY INTERACTION PROGRAM
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Poughkeepsie, NY
August 5, 1999

NAME	ADDRESS	AFFILIATION/TELEPHONE
KATHY Kolar Mid-Hudson Interpreting Services	82 Washington St. Suite #214 Pok, NY 12603	452-3913
JOSEPH RUGGIERO COUNCILMAN TOWN OF WAPPINGER	26 Doyle Dr WF NY 12590	297-3982
Will Yendik	P.O. Box 132 Claverack NY 12513	Princeton
John Dougherty	RR3 BOX 31 N.Y. 12514 Clinton Corners	914-266-4679
Tom Lynch	Marist College Environmental Science	575-3000 x2443
Don Sagar	1063 CREEK LOCKS RD ROSENDALE, NY 12472	(914) 331-8429
Jerry Mahoney	12 Ronnie Ln Poughkeepsie NY 12601	(914) 297-9803
Erik DuMont	225A Main Street Farmingdale NY 11735	Citizens Campaign for the Environment (516) 390-7150
William Dey	51 Old State Rd. Wappingers Falls, NY 12590	914-831-4365
JOSEPH QUINN	15 ALLEN ROAD SALT POINT, N.Y. 12578	914-485-3300 x217

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COMMUNITY INTERACTION PROGRAM
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Poughkeepsie, NY
August 5, 1999

NAME	ADDRESS	AFFILIATION/TELEPHONE
Kathy Cooke	NYS Comptrollers Office	
MYRA MORALES	115 So. Cherry St. Poughkeepsie, NY 12601	
FLORA JONES	POB 1085 BEACON, NY 12508	838-0988 CONCERNED CITIZEN
FRANK MANCUSO	75 D Tower hill RD millbrook, N.Y. 12545	[illegible]
LORENZ HERZOG	28 W. DOGWOOD DR. POUGHKEEPSIE, N.Y. 12601-5324	
GEORGE McKIE	62 FORRESTAL HTS BEACON, NY 12508	831-6880
[illegible]	16 [illegible] Dr Poughkeepsie, 12603	452-9894
[illegible]	150 [illegible] Blvd Pok NY	471-5558
CHRIS FISH	21 OLD MAIN ST SUITE 205 FISHKILL NY 12524	OFFICE CONGRESSWOMAN KELLY 914 897 5200
Mary Brockway	RD 3 Fishkill, NY 12524	

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ATTACHMENT 3
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HUMAN HEALTH RISK ASSESSMENT: UPPER HUDSON RIVER
EXECUTIVE SUMMARY
AUGUST 1999

This document presents the baseline Human Health Risk Assessment for the Upper Hudson River (HHRA), which is part of Phase 2 of the Reassessment Remedial Investigation/Feasibility Study (Reassessment RI/FS) for the Hudson River PCBs site in New York.[1] This HHRA quantitatively evaluates both cancer risks and non-cancer health hazards from exposure to polychlorinated biphenyls (PCBs) in the Upper Hudson River, which extends from Hudson Falls, New York to the Federal Dam at Troy, New York. The HHRA evaluates both current and future risks to children, adolescents, and adults in the absence of any remedial action and institutional controls. The HHRA uses current U.S. Environmental Protection Agency (USEPA) policy and guidance as well as additional site data and analyses to update USEPA's 1991 risk assessment.

USEPA uses risk assessment as a tool to evaluate the likelihood and degree of chemical exposure and the possible adverse health effects associated with such exposure. The basic steps of the Superfund human health risk assessment process are the following: 1) Data Collection and Analysis to determine the nature and extent of chemical contamination in environmental media, such as sediment, water, and fish; 2) Exposure Assessment, which is an identification of possible exposed populations and an estimation of human chemical intake through exposure routes such as ingestion, inhalation, or skin contact; 3) Toxicity Assessment, which is an evaluation of chemical toxicity including cancer and non-cancer health effects from exposure to chemicals; and 4) Risk Characterization, which describes the likelihood and degree of chemical exposure at a site and the possible adverse health effects associated with such exposure.

The HHRA shows that cancer risks and non-cancer health hazards to the reasonably maximally exposed (RME) individual associated with ingestion of PCBs in fish from the Upper Hudson River are above levels of concern. Consistent with USEPA regulations, the risk managers in the Superfund program evaluate the risk and hazards to the RME individual in the decision-making process. The HHRA indicates that fish ingestion represents the primary pathway for PCB exposure and for potential adverse health effects, and that risks from other exposure pathways are generally below levels of concern. The results of the HHRA will help establish acceptable exposure levels for use in developing remedial alternatives for PCB-contaminated sediments in the Upper Hudson River, which is Phase 3 (Feasibility Study) of the Reassessment RI/FS.

DATA COLLECTION AND ANALYSIS

USEPA previously released reports on the nature and extent of contamination in the Upper Hudson River as part of the Reassessment RI/FS (*e.g.*, February 1997 Data Evaluation and Interpretation Report, July 1998 Low Resolution Sediment Coring Report, August 1998 Database for the Hudson River PCBs Reassessment RI/FS [Release 4.1], and May 1999 Baseline Modeling Report). The Reassessment RI/FS documents provide current and forecasted concentrations of PCBs in fish, sediments, and river water and form the basis of the site data collection and analyses used in conducting the HHRA.

EXPOSURE ASSESSMENT

[1] A separate human health risk assessment is being conducted for the Mid-Hudson River (Federal Dam at Troy, New York to Poughkeepsie, New York).

Adults, adolescents, and children were identified as populations possibly exposed to PCBs in the Upper Hudson River due to fishing and recreational activities (swimming, wading), as well as from living adjacent to the Upper Hudson River and inhaling volatilized PCBs in the air. Cancer risks and non-cancer hazards were calculated for each of these populations. To protect human health and provide a full characterization of the PCB risks and hazards, both an average (central tendency) exposure estimate and an RME estimate were calculated. The RME is the maximum exposure that is reasonably expected to occur in the Upper Hudson River under baseline conditions.

The exposure pathways identified in the HHRA are ingestion of fish, incidental ingestion of sediments, dermal contact with sediments and river water, and inhalation of volatilized PCBs in air. For these exposure pathways, central tendency and RME estimates were calculated using point estimate analyses, whereby an individual point estimate was selected for each exposure factor used in the calculations of cancer risks and non-cancer health hazards. Incidental ingestion of river water while swimming was not evaluated because the river water meets drinking water standards for PCBs.

In addition to the point estimate analysis, a Monte Carlo analysis was performed to provide a range of estimates of the cancer risks and non-cancer health hazards associated with the fish ingestion pathway. The Monte Carlo analysis helps evaluate variability in exposure parameters (*e.g.*, differences within a population's fish ingestion rates, number of years an angler is exposed, body weight) and uncertainty (*i.e.*, a lack of complete knowledge about specific variables).

Ingestion of Fish

For fish ingestion, both central tendency and RME estimates were developed for each of the parameters needed to calculate the cancer risks and non-cancer health hazards. Based on the 1991 New York Angler survey of fish consumption by licensed anglers (Connelly *et al.*, 1992), the central tendency fish ingestion rate was determined to be approximately six half-pound meals per year and the RME fish ingestion rate was determined to be 51 half-pound meals per year.

For the point estimate analyses, cancer risks and non-cancer health hazards to an adult angler were calculated. Population mobility data from the U.S. Census Bureau for the five counties surrounding the Upper Hudson River and fishing duration data from the 1991 New York Angler survey were used to determine the length of time an angler fishes in the Upper Hudson River (*i.e.*, exposure duration). The exposure duration for fish ingestion was 12 years for the central tendency exposure estimate and 40 years for cancer (7 years for non-cancer) for the RME estimate. Standard USEPA default factors were used for angler body weight. Future concentrations of PCBs in fish were derived from forecasts presented in the Baseline Modeling Report, which were then grouped by fish species and averaged over species for the entire Upper Hudson River. PCB losses during cooking were assumed to be 20% for the central tendency exposure estimate and 0% (no loss) for the RME estimate, based on studies reported in the scientific literature.

In the Monte Carlo analyses, each exposure parameter (*e.g.*, ingestion rate, exposure duration, body weight) was represented by a range of values, each with an assigned probability, rather than as a single point estimate. Cancer risks and non-cancer hazards were calculated for anglers beginning at age 10. Differences in the length of time an angler fishes the Upper Hudson (exposure duration) were obtained from the 1991 New York Angler survey and the U.S. Census Bureau data. Differences in angler body weight through time were obtained from national health surveys summarized in the scientific literature. Future concentrations of PCBs in fish were derived from the Baseline Modeling Report. Fish species consumption variability was evaluated based on consumption patterns determined from the 1991 New York Angler survey and within-species PCB concentrations were averaged over location within the Upper Hudson River. The variability

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in fish ingestion rates was examined by considering surveys of fish ingestion rates in states other than New York. Variability in PCB cooking loss was determined from a review of the scientific literature.

Due to the lack of sufficient information available to define quantitative uncertainty distributions for several important exposure factors, such as exposure duration, an explicit two-dimensional Monte Carlo analysis which examines variability and uncertainty separately could not be performed. Instead, an expanded one-dimensional (1-D) analysis was completed using a sensitivity/uncertainty analysis. Each 1-D Monte Carlo simulation examined variability of PCB intake and was repeated for a range of possible input distributions for important exposure variables. A total of 72 separate combinations of the variable input parameters were examined in the 1-D analysis. Each 1-D simulation consisted of 10,000 simulated anglers, such that the entire 1-D Monte Carlo analysis consisted of 720,000 simulations.

Other Exposure Pathways

For the direct exposure scenarios for river water and sediment, the central tendency exposure estimates for adults and young children (aged 1-6) were assumed to be one day every other week for the 13 weeks of summer (7 days/year) and for the RME were assumed to be one day per week for the 13 weeks of summer (13 days/year). Adolescents (aged 7-18) were assumed to have about three times more frequent exposure, with a central tendency exposure estimate of 20 days/year and an RME estimate of 39 days/year. The risks due to possible inhalation of PCBs in air were evaluated for both recreational users of the river (swimmers and waders) as well as for residents living adjacent to the Upper Hudson River. The concentrations of PCBs in water and sediment were derived from the Baseline Modeling Report. The concentrations of PCBs in air were calculated from a combination of historical monitoring data and modeled emissions from the river using a USEPA-recommended air dispersion model. Standard USEPA default factors were used for certain exposure parameters (*e.g.*, body weight) in the risk calculations for these pathways.

TOXICITY ASSESSMENT

The toxicity assessment is an evaluation of the chronic (7 years or more) adverse health effects from exposure to PCBs (USEPA, 1989b). In Superfund, two types of adverse health effects are evaluated: 1) the incremental risk of developing cancer due to exposure to chemicals and 2) the hazards associated with non-cancer health effects, such as reproductive impairment, developmental disorders, disruption of specific organ functions, and learning problems. The cancer risk is expressed as a probability and is based on the cancer potency of the chemical, known as a cancer slope factor, or CSF. The non-cancer hazard is expressed as the ratio of the chemical intake (dose) to a Reference Dose, or RfD. The chronic RfD represents an estimate (with uncertainty spanning perhaps an order of magnitude or greater) of a daily exposure level for the human population, including sensitive populations (*e.g.*, children), that is likely to be without an appreciable risk of deleterious effects during a lifetime. Chemical exposures exceeding the RfD do not predict specific diseases. USEPA's Integrated Risk Information System, known as IRIS, provides the primary database of chemical-specific toxicity information used in Superfund risk assessments. The most current CSFs and RfDs for PCBs were used in calculating cancer risks and non-cancer hazards in the HHRA.

PCBs are a group of synthetic organic chemicals consisting of 209 individual chlorinated biphenyls called congeners. Some PCB congeners are considered to be structurally similar to dioxin and are called dioxin-like PCBs. USEPA has classified PCBs as a probable human carcinogen, based on a number of studies in laboratory animals showing liver tumors. Human carcinogenicity data for PCB mixtures are limited. USEPA (1996) described three published studies that analyzed deaths from cancer in PCB capacitor manufacturing plants (Bertazzi *et al.*, 1987; Brown, 1987; Sinks *et al.*, 1992). Recently, Kimbrough *et al.*

(1999) published the results of an epidemiological study of mortality in workers from two General Electric Company capacitor manufacturing plants in New York State. Due to the limitations of the Kimbrough *et al.* (1999) study identified by USEPA in its review (*e.g.*, more than 75% of the workers never worked with PCBs, the median exposure for those who worked with PCBs was only a few years, and the level of PCB exposure could not be confirmed), USEPA expects that the study will not lead to any change in its CSFs for PCBs, which were last reassessed in 1996.

RISK CHARACTERIZATION

Point Estimate Calculations

Ingestion of fish contaminated with PCBs resulted in the highest lifetime cancer risks. The RME estimate of the increased risk of an individual developing cancer averaged over a lifetime based on the exposure assumptions is 1×10^{-3}, or one additional case of cancer in 1,000 exposed people. The RME risks associated with the dioxin-like PCBs are comparable. The central tendency (average) estimate of risk is 3×10^{-5}, or 3 additional cases of cancer in 100,000 exposed people. For known or suspected carcinogens, acceptable exposure levels for Superfund are generally concentration levels that represent an incremental upper bound lifetime cancer risk to an RME individual of between 10^{-4} and 10^{-6}. The central tendency cancer risks and non-cancer hazards are provided to more fully describe the health effects associated with average exposure. Estimated cancer risks relating to PCB exposure in sediment and water while swimming or wading, or from inhalation of volatilized PCBs in air by residents living near the river, are much lower than those for fish ingestion, falling generally at the low end, or below, the range of 10^{-4} to 10^{-6}. A summary of the point estimate cancer risk calculations is presented below.

Point Estimate Cancer Risk Summary		
Pathway	**Central Tendency Risk**	**RME Risk**
Ingestion of Fish	3×10^{-5} (3 in 100,000)	1×10^{-3} (1 in 1,000)
Exposure to Sediment*	4×10^{-7} (4 in 10,000,000)	1×10^{-5} (1 in 100,000)
Exposure to Water*	1×10^{-8} (1 in 100,000,000)	2×10^{-7} (2 in 10,000,000)
Inhalation of Air*	2×10^{-8} (2 in 100,000,000)	1×10^{-6} (1 in 1,000,000)

**Total risk for child (aged 1-6), adolescent (aged 7-18), and adult (over 18).*

The evaluation of non-cancer health effects involved comparing the average daily exposure levels (dose) to determine whether the estimated exposures exceed the Reference Dose (RfD). The ratio of the site-specific calculated dose to the RfD for each exposure pathway is summed to calculate the Hazard Index (HI) for the exposed individual. An HI of one (1) is the reference level established by USEPA above which concerns about non-cancer health effects must be evaluated.

Ingestion of fish resulted in the highest Hazard Indices, with an HI of 10 for the central tendency point estimate and an HI of 116 for the RME point estimate. The total HIs for exposure to sediment, water, and air are all below one. Non-cancer hazards due to inhalation of PCBs were not calculated because IRIS does not contain a toxicity value for inhalation of PCBs. A summary of the point estimate non-cancer hazards is presented below.

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Point Estimate Non-Cancer Hazard Summary		
Pathway	**Central Tendency Non-Cancer Hazard Index**	**RME Non-Cancer Hazard Index**
Ingestion of Fish	10	116
Exposure to Sediment*	0.05	0.2
Exposure to Water*	0.007	0.02
Inhalation of Air	Not Calculated	Not Calculated

****Values for child and adolescent, which are higher than adult for these pathways.***

Monte Carlo Estimate

In the Monte Carlo analysis, a distribution of cancer risks and non-cancer health hazards was calculated for the fish ingestion pathway. The tables below summarize the low-end (5th percentile), midpoint (50th percentile), and high-end (≥ 90th percentile) cancer risks and non-cancer hazards. At a given percentile, the risks or hazards are higher than that presented in the table for 100 minus the given percentile. For example, as shown for the base case in the table below, the calculated incremental cancer risk at the 95th percentile is 9×10^{-4}, which means that the cancer risks for only the top 5th percentile are greater than that value.

Monte Carlo Cancer Risk Summary - Fish Ingestion			
Risk Percentile	**Low Estimate**	**Base Case**	**High Estimate**
5th Percentile	7×10^{-7}	5×10^{-6}	5×10^{-5}
50th Percentile	1×10^{-5}	6×10^{-5}	4×10^{-4}
90th Percentile	7×10^{-5}	5×10^{-4}	2×10^{-3}
95th Percentile	1×10^{-4}	9×10^{-4}	3×10^{-3}
99th Percentile	3×10^{-4}	4×10^{-3}	1×10^{-2}

Monte Carlo Non-Cancer Hazard Summary - Fish Ingestion			
Risk Percentile	**Low Estimate**	**Base Case**	**High Estimate**
5th Percentile	0.1	1	7
50th Percentile	2	11	51
90th Percentile	5	31	117
95th Percentile	11	82	233
99th Percentile	19	136	366

Comparison of Point Estimate and Monte Carlo Analyses

The Monte Carlo base case scenario is the one from which point estimate exposure factors for fish ingestion were drawn, thus the point estimate RMEs and the Monte Carlo base case estimates are comparable. Similarly, the point estimate central tendency (average) and the Monte Carlo base case midpoint (50th percentile) are comparable. For cancer risk, the point estimate RME for fish ingestion (1×10^{-3}) falls approximately at the 95th percentile from the Monte Carlo base case analysis. The point estimate central tendency value (3×10^{-5}) and the Monte Carlo base case 50th percentile value (6×10^{-5}) are similar. For non-cancer hazards, the point estimate RME for fish ingestion (116) falls between the 95th and 99th percentiles of the Monte Carlo base case. The point estimate central tendency HI (10) is approximately equal to the 50th percentile of the Monte Carlo base case HI of 11.

MAJOR FINDINGS OF THE HHRA

The HHRA evaluated both cancer risks and non-cancer health hazards to children, adolescents and adults posed by PCBs in the Upper Hudson River. USEPA has classified PCBs as probable human carcinogens and known animal carcinogens. Other long-term adverse health effects of PCBs observed in laboratory animals include a reduced ability to fight infections, low birth weights, and learning problems. The major findings of the report are:

- Eating fish is the primary pathway for humans to be exposed to PCBs from the Hudson.
- Under the RME scenario for eating fish, the calculated risk is one additional case of cancer for every 1,000 people exposed. This excess cancer risk is 1,000 times higher than USEPA's goal of protection and ten times higher than the highest risk level allowed under Superfund law.
- For non-cancer health effects, the RME scenario for eating fish from the Upper Hudson results in a level of exposure to PCBs that is more than 100 times higher than USEPA's reference level (Hazard Index) of one.
- Under the baseline conditions, the point estimate RME cancer risks and non-cancer hazards would be above USEPA's generally acceptable levels for a 40-year exposure period beginning in 1999.
- Risks from being exposed to PCBs in the river through skin contact with contaminated sediments and river water, incidental ingestion of sediments, and inhalation of PCBs in air are generally within or below USEPA's levels of concern.

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Ecological Risk Assessment
Executive Summary
August 1999

This document presents the baseline Ecological Risk Assessment (ERA) for the Hudson River, which is part of Phase 2 of the Reassessment Remedial Investigation/Feasibility Study (Reassessment RI/FS) for the Hudson River PCBs site in New York. The ERA quantitatively evaluates the current and future risks to the environment in the Upper Hudson River (Hudson Falls, New York to Federal Dam at Troy, New York) and the current risks to the environment in the Lower Hudson River (Federal Dam to the Battery in New York City) posed by polychlorinated biphenyls (PCBs) in the absence of remediation.1 This report uses current U.S. Environmental Protection Agency (USEPA) policy and guidance as well as additional site data and analyses to follow up USEPA's 1991 risk assessment.

USEPA uses ecological risk assessments to evaluate the likelihood that adverse ecological effects are occurring or may occur as a result of exposure to one or more chemical or physical stressors. The Superfund ecological risk assessment process includes the following: 1) identification of contaminants of concern; 2) development of a conceptual model, which identifies complete exposure pathways for the ecosystem; 3) identification of assessment endpoints, which are ecological values to be protected; 4) development of measurement endpoints, which are the actual measurements used to assess risk to the assessment endpoints; 5) selection of receptors of concern; 6) the exposure assessment, which describes concentrations or dietary doses of contaminants of concern to which the selected receptors are or may be exposed; 7) the effects assessment, which describes toxicological effects due to chemical exposure and the methods used to characterize those effects to the receptors of concern; and 8) risk characterization, which compares the results of the exposure assessment with the effects assessment to evaluate the likelihood of adverse ecological effects associated with exposure to chemicals at a site.

The ERA indicates that PCBs in the Hudson River generally exceed levels that have been shown to cause adverse ecological effects, and that those levels will continue to be exceeded in the Upper Hudson through 2018 (the entire forecast period). The results of the ERA will help establish acceptable exposure levels for use in developing remedial alternatives for PCB-contaminated sediments in the Upper Hudson River, which is Phase 3 (Feasibility Study) of the Reassessment RI/FS.

Contaminants of Concern

The contaminants of concern identified for the site are PCBs. PCBs are a group of synthetic organic compounds consisting of 209 individual chlorinated biphenyls called congeners. Some PCB congeners are considered to be structurally similar to dioxin and are called dioxin-like PCBs. Toxic equivalency (TEQ) factors, based on the toxicity of dioxin, have been developed for the dioxin-like PCB congeners. PCBs have been shown to cause adverse reproductive and developmental effects in animals. Ecological exposure to PCBs is primarily an issue of bioaccumulation rather than direct toxicity. PCBs bioaccumulate in the environment by both bioconcentrating (being absorbed from water and accumulated in tissue to levels greater

than those found in surrounding water) and biomagnifying (increasing in tissue concentrations as they go up the food chain through two or more trophic levels).

Site Conceptual Model

The Hudson River PCBs site is the 200 miles (322 km) of river from Hudson Falls to the Battery in New York City. As defined in the ERA, the Upper Hudson River is the 40 mile (64 km) stretch from Hudson Falls to the Federal Dam at Troy. The Lower Hudson River extends approximately 160 miles (258 km) from the Federal Dam to the Battery.

The Hudson River is home to a wide variety of ecosystems. These ecosystems differ between the Upper Hudson River and the Lower Hudson River. The Upper Hudson River is non-tidal, consists of a series of pools separated by dams, and is entirely freshwater. In contrast, the Lower Hudson River is tidal, does not have dams, and is freshwater in the vicinity of the Federal Dam, becoming brackish and increasingly more saline towards the Battery. Spring runoffs and major storms can push the salt front well below the Tappan Zee Bridge, and sometimes south to New York City. Both the Upper and Lower Hudson have deep water environments as well as shallow nearshore areas with aquatic vegetation.

PCBs were released from two General Electric Company facilities located in the Upper Hudson River at Hudson Falls and Fort Edward, New York. Many of these PCBs adhered to river sediments. As PCBs in the river sediments are released slowly into the river water, these contaminated sediments serve as a continuing source of PCBs. During high flow events, the sediments may be deposited on the floodplain and PCBs may thereby enter the terrestrial food chain. High flow events may also increase the bioavailability of PCBs to organisms in the river water.

Animals and plants living in or near the river, such as invertebrates, fish, amphibians, and water-dependent reptiles, birds, and mammals, may be directly exposed to the PCBs from contaminated sediments, river water, and air, and/or indirectly exposed through ingestion of food (*e.g.*, prey) containing PCBs.

Assessment Endpoints

Assessment endpoints are explicit expressions of actual environmental values (*i.e.*, ecological resources) that are to be protected. They focus a risk assessment on particular components of the ecosystem that could be adversely affected due to contaminants at the site. These endpoints are expressed in terms of individual organisms, populations, communities, ecosystems, or habitats with some common characteristics (e.g., feeding preferences, reproductive requirements). The assessment endpoints for the ERA were selected to include direct exposure to PCBs in Hudson River sediments and river water through ingestion and indirect exposure to PCBs via the food chain. Because PCBs are known to bioaccumulate, an emphasis was placed on indirect exposure at various levels of the food chain to address PCB-related risks at higher trophic levels. The assessment endpoints that were selected for the Hudson River are:

- Benthic community structure as a food source for local fish and wildlife
- Protection and maintenance (survival, growth, and reproduction) of local fish (forage, omnivorous, and piscivorous)
- Protection and maintenance (survival, growth, and reproduction) of local insectivorous birds
- Protection and maintenance (survival, growth, and reproduction) of local waterfowl
- Protection and maintenance (survival, growth, and reproduction) of local piscivorous birds
- Protection and maintenance (survival, growth, and reproduction) of local wildlife
- Protection of threatened and endangered species
- Protection of significant habitats

Measurement Endpoints

Measurement endpoints provide the actual measurements used to evaluate ecological risk and are selected to represent mechanisms of toxicity and exposure pathways. Measurement endpoints generally include measured or modeled concentrations of chemicals in water, sediment, fish, birds, and/or mammals, laboratory toxicity studies, and field observations. The measurement endpoints identified for the ERA are:

1) benthic community indices, such as richness, abundance, diversity and biomass;
2) concentrations of PCBs in fish and invertebrates to evaluate food-chain exposure;
3) measured and modeled total PCB body burdens in receptors (including avian receptor eggs) to determine exceedance of effect-level thresholds based on toxicity reference values (TRVs);
4) measured and modeled TEQ-based PCB body burdens in receptors (including avian receptor eggs) to determine exceedance of effect-level thresholds based on TRVs;
5) exceedence of criteria for concentrations of PCBs in river water that are protective of fish and wildlife;
6) exceedence of guidelines for concentrations of PCBs in sediments that are protective of aquatic health; and 7) field observations.

Receptors of Concern

The risks to the environment were evaluated for individual receptors of concern that were selected to be representative of various feeding preferences, predatory levels, and habitats (aquatic, wetland, shoreline). The ERA does not characterize injury to, impact on, or threat to every species of plant or animal that lives in or adjacent to the Hudson River; such a characterization is beyond the scope of the Superfund ecological risk assessment. The following receptors of concern were selected for the ERA:

<u>Aquatic Invertebrates</u>

- Benthic macroinvertebrate community (e.g., aquatic worms, insect larvae, and isopods)

<u>Fish Species</u>

- Pumpkinseed (*Lepomis gibbosus*)
- Spottail shiner (*Notropis hudsonius*)
- Brown bullhead (*Ictalurus nebulosus*)
- White perch (*Morone americana*)
- Yellow perch (*Perca flavescens*)
- Largemouth bass (*Micropterus salmoides*)
- Striped bass (*Morone saxatilis*) P/S
- Shortnose sturgeon (*Acipenser brevirostrum*) O

<u>Birds</u>

- Tree swallow (*Tachycineta bicolor*)
- Mallard (*Anas platyrhychos*)
- Belted kingfisher (*Ceryle alcyon*)
- Great blue heron (*Ardea herodias*)
- Bald eagle (*Haliaeetus leucocephalus*)

<u>Mammals</u>

- Little brown bat (*Myotis lucifugus*)
- Raccoon (*Procyon lotor*)
- Mink (*Mustela vison*)
- River otter (*Lutra canadensis*)

Exposure Assessment

The Exposure Assessment describes complete exposure pathways and exposure parameters (*e.g.*, body weight, prey ingestion rate, home range) used to calculate the concentrations or dietary doses to which the receptors of concern may be exposed due to chemical exposure. USEPA previously released reports on the nature and extent of contamination in the Hudson River as part of the Reassessment RI/FS (*e.g.*, February 1997 Data Evaluation and Interpretation Report, July 1998 Low Resolution Sediment Coring Report, August 1998 Database for the Hudson River PCBs Reassessment RI/FS [Release 4.1], and May 1999 Baseline Modeling Report). The Reassessment RI/FS documents provide current and future (*i.e.*,measured and modeled) concentrations of PCBs in fish, sediments and river water, and form the basis of the site data collection and analyses that were used in conducting the ERA. Exposure parameters were obtained from USEPA references, the scientific literature, and directly from researchers.

Effects Assessment

The Effects Assessment describes the methods used to characterize particular toxicological effects of PCBs on aquatic and terrestrial organisms due to chemical exposure. These measures of toxicological effects, called TRVs, provide a basis for estimating whether the chemical exposure at a site is likely to result in adverse ecological effects.

In conducting the ERA, TRVs were selected based on Lowest Observed Adverse Effects Levels (LOAELs) and/or No Observed Adverse Effects Levels (NOAELs) from laboratory and/or field-based studies reported in the scientific literature. These TRVs examine the effects of PCBs and dioxin-like PCB congeners on the survival, growth, and reproduction of fish and wildlife species in the Hudson River. Reproductive effects (*e.g.*, egg maturation, egg hatchability, and survival of juveniles) were generally the most sensitive endpoints for animals exposed to PCBs.

Risk Characterization

Risk Characterization examines the likelihood of adverse ecological effects occurring as a result of exposure to chemicals and discusses the qualitative and quantitative assessment of risks to ecological receptors with regard to toxic effects. Risks are estimated by comparing the results of the Exposure Assessment (measured or modeled concentrations of chemicals in receptors of concern) to the TRVs developed in the Effects Assessment. The ratio of these two numbers is called a Toxicity Quotient, or TQ.

TQs equal to or greater than one ($TQ \geq 1$) are typically considered to indicate potential risk to ecological receptors, for example reduced or impaired reproduction or recruitment of new individuals. The TQs provide insight into the potential for adverse effects upon individual animals in the local population resulting from chemical exposure. If a TQ suggests that effects are not expected to occur for the average individual, then they are probably insignificant at the population level. However, if a TQ indicates risks are present for the average individual, then risks may be present for the local population.

At each step of the risk assessment process there are sources of uncertainty. Measures were taken in the ERA to address and characterize the uncertainty. For example, in some cases uncertainty factors were applied in developing TRVs. The purpose of these uncertainty factors is to ensure that the calculated TRVs are protective of the receptor species of concern. Another source of uncertainty is associated with the future PCB concentrations in fish. Based on a comparison of modeled concentrations to measured values, the PCB concentrations in fish presented in the May 1999 Baseline Modeling Report are expected to be within an order of magnitude, but likely closer to a factor of two, of future measured values.

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To integrate the various components of the ERA, the results of the risk characterization and associated uncertainties were evaluated using a weight-of-evidence approach to assess the risk of adverse effects in the receptors of concern as a result of exposure to PCBs originating in the Hudson River. The weight-of-evidence approach considers both the results of the TQ analysis and field observations for each assessment endpoint. For the mammals and most birds, TQs for the dioxin-like PCBs were greater than the TQs for total PCBs.

Benthic Community Structure

Benthic community structure as a food source for local fish populations was assessed using three lines of evidence. All three suggest an adverse effect of PCBs on benthic invertebrate populations serving as a food source to local fish in the Upper Hudson River. Two lines of evidence suggest an adverse effect of PCBs on benthic invertebrate populations serving as a food source to local fish in the Lower Hudson River. Uncertainty in this analysis is considered low.

Local Fish (Forage, Omnivorous, Piscivorous and Semi-piscivorous)

Risks to local fish populations were evaluated using seven lines of evidence. Collectively, they indicate that current (1993) and future PCB exposures are not expected to be of a sufficient magnitude to prevent reproduction or recruitment of common fish species in the Hudson River. However, current and future exposures to the PCBs may reduce or impair the survival, growth, and reproductive capability of resident fish in the Upper Hudson River, and current exposure to PCBs may have similar adverse effects on upper trophic level fish (such as largemouth bass and white perch) in the Lower Hudson River.

Current fish body burdens exceed most TRVs (*i.e.*, TQ $\geq$ 1) in the Upper Hudson River for all species, and body burdens consistently exceed TRVs for upper trophic level fish in both the Upper and Lower Hudson River. Future body burdens in fish are expected to exceed TRVs through 2018 (the entire forecast period) in the Upper Hudson River for several of the upper trophic level fish species. There is a moderate degree of uncertainty in the modeled body burdens used to evaluate exposure, and at most an order of magnitude uncertainty in the TRVs (for the dioxin-like PCBs, no uncertainty factors were needed). Given the magnitude of the TQs, they would have to decrease by an order of magnitude or more to fall below 1 for most fish species in the Upper Hudson River and for upper trophic level fish in the Lower Hudson River.

Measured and modeled concentrations of PCBs in river water in the Upper Hudson River and sediment show exceedences of their respective criteria and guidelines for protection of fish through 2018 (the entire forecast period). Measured concentrations of PCBs in river water and sediment in the Lower Hudson River typically exceed all but the least stringent criteria and guidelines for protection of fish at most locations.

Insectivorous Birds

Risks to insectivorous birds were evaluated using six lines of evidence. Collectively, they indicate that current and future concentrations of PCBs are not of a sufficient magnitude to prevent reproduction of insectivorous birds. However, anomalous nesting behavior has been observed in tree swallows in the Upper Hudson River and these behaviors may adversely affect reproductive capability at the population level. There is a moderate degree of uncertainty in the calculated doses of PCBs in tree swallow diet and the concentrations of PCBs in eggs. There is a low degree of uncertainty associated with the tree swallow TRVs, which were derived from field studies of Hudson River tree swallows.

Measured and modeled concentrations of PCBs in Upper Hudson River water exceed criteria developed for the protection of wildlife through 2018 (the entire forecast period). Measured concentrations of PCBs in Lower Hudson River water exceed criteria developed for the protection of wildlife at most locations.

Waterfowl

Risks to waterfowl were evaluated using six lines of evidence. Collectively, they indicate that current and future concentrations of PCBs are not of a sufficient magnitude to prevent reproduction of the waterfowl. However, current and future exposures to the PCBs may reduce or impair the survival, growth, and reproductive capability of waterfowl in the Upper Hudson River. To a lesser degree, current exposures may have similar adverse effects on waterfowl in the Lower Hudson River.

Calculated dietary doses of PCBs and concentrations of PCBs in eggs under current and future conditions typically exceed their respective TRVs. TQs for the dioxin-like PCBs consistently show greater exceedences than TQs for total PCBs. Exceedences of TRVs are expected to occur through 2018 (the entire forecast period). There is a moderate degree of uncertainty in the dietary dose and egg concentration estimates. Given the magnitude of the TQs, they would have to decrease by an order of magnitude or more to fall below 1 for the mallard duck in the Upper Hudson River.

Measured and modeled concentrations of PCBs in Upper Hudson River water exceed criteria developed for the protection of wildlife through 2018 (the entire forecast period). Measured concentrations of PCBs in Lower Hudson River water exceed criteria developed for the protection of wildlife at most locations.

Piscivorous Birds

Risks to piscivorous birds were evaluated using six lines of evidence. Collectively, they indicate that current and future concentrations of PCBs are not of a sufficient magnitude to prevent reproduction of these piscivorous species, which have been observed along the Hudson River. However, current and future exposures to the PCBs may reduce or impair the survival, growth, and reproductive capability of piscivorous birds in the Upper Hudson River, and current exposure to PCBs may have similar adverse effects on piscivorous birds in the Lower Hudson River. Calculated dietary doses of PCBs and concentrations of PCBs in eggs exceed all TRVs for the Upper Hudson River through 2018 (the entire forecast period) and current exposures exceed all TRVs in the Lower Hudson River. There is a moderate degree of uncertainty in the calculated dietary doses and concentrations in eggs. Given the magnitude of the majority of the TQs, they would have to decrease by an order of magnitude or more to fall below 1 for piscivorous birds in the Upper Hudson River.

Measured and modeled concentrations of PCBs in Upper Hudson River water exceed criteria developed for the protection of wildlife through 2018 (the entire forecast period). Measured concentrations of PCBs in Lower Hudson River water exceed criteria developed for the protection of wildlife at most locations.

Insectivorous Mammals

Risks to insectivorous mammals were evaluated using four lines of evidence. Collectively, they indicate that current and future concentrations of PCBs are not of a sufficient magnitude to prevent reproduction of insectivorous mammals. However, current and future exposures to the PCBs may reduce or impair the survival, growth, and reproductive capability of mammals in the Upper Hudson River. To a

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lesser degree, current exposures may have similar adverse effects on insectivorous mammals in the Lower Hudson River. Modeled dietary doses for the little brown bat exceed TRVs under current and future conditions in the Upper Hudson River. Given the magnitude of the majority of the TQs, they would have to decrease by an order of magnitude or more to fall below 1. There is a moderate degree of uncertainty in the calculated dietary doses.

Measured and modeled concentrations of PCBs in Upper Hudson River water exceed criteria developed for the protection of wildlife through 2018 (the entire forecast period). Measured concentrations of PCBs in Lower Hudson River water exceed criteria developed for the protection of wildlife at most locations.

Omnivorous Mammals

Risks to omnivorous mammals were evaluated using four lines of evidence. Collectively, they indicate that current and future concentrations of PCBs are not of a sufficient magnitude to prevent reproduction of omnivorous mammals. However, current and future exposures to the PCBs may reduce or impair the survival, growth, and reproductive capability of mammals in the Upper Hudson River. To a lesser degree, current exposures may have similar adverse effects on omnivorous mammals in the Lower Hudson River. Modeled dietary doses for the raccoon exceed TRVs under current and future conditions in the Upper Hudson River. Given the magnitude of the majority of the TQs, they would have to decrease by an order of magnitude or more to fall below 1. There is a moderate degree of uncertainty in the calculated dietary doses.

Measured and modeled concentrations of PCBs in Upper Hudson River water exceed criteria developed for the protection of wildlife through 2018 (the entire forecast period). Measured concentrations of PCBs in Lower Hudson River water exceed criteria developed for the protection of wildlife at most locations.

Piscivorous Mammals

Risks to piscivorous mammals were evaluated using four lines of evidence. Collectively, they indicate that current and future concentrations of PCBs are not of a sufficient magnitude to prevent reproduction of piscivorous mammals. However, current exposures to the PCBs may reduce or impair the survival, growth, and reproductive capability of mammals in the Upper and Lower Hudson River.. Future exposures may have adverse effects on piscivorous mammals in the Upper Hudson River. Modeled dietary doses for the mink and river otter exceed TRVs under current and future conditions in the Upper Hudson River. Given the magnitude of the majority of the TQs, they would have to decrease by an order of magnitude or more to fall below 1. There is a moderate degree of uncertainty in the calculated dietary doses.

Measured and modeled concentrations of PCBs in Upper Hudson River water exceed criteria developed for the protection of wildlife through 2018 (the entire forecast period). Measured concentrations of PCBs in Lower Hudson River water exceed criteria developed for the protection of wildlife at most locations.

Threatened and Endangered Species

Risks to threatened and endangered species were evaluated using four lines of evidence. Collectively, they indicate that current and future concentrations of PCBs are of a sufficient magnitude to adversely affect the reproductive capability of these fragile populations.

TQs for the bald eagle exceed 1 through 2018 (the entire forecast period) in the Upper Hudson River and exceed 1 for all locations in the Lower Hudson River. TQs for the shortnose sturgeon exceed 1 through 2018 (the entire forecast period) for most TRVs developed on the basis of reproductive effects at all locations in the Upper Hudson River. TQs for the shortnose sturgeon exceed 1 for all locations in the Lower Hudson River. There is a moderate degree of uncertainty in the modeled fish body burdens and calculated dietary doses and egg concentrations of PCBs. Given the magnitude of the TQs for the bald eagle, they would have to decrease by two orders of magnitude or more to fall below 1 in the Upper Hudson River.

Measured and modeled concentrations of PCBs in Upper Hudson River water exceed criteria developed for the protection of wildlife through 2018 (the entire forecast period). Measured concentrations of PCBs in Lower Hudson River water exceed criteria developed for the protection of wildlife at most locations. Measured and modeled concentrations of PCBs in sediment in the Upper Hudson River exceed all but the least stringent guidelines at all locations through 2018 (the entire forecast period). Measured concentrations of PCBs in sediment in the Lower Hudson River exceed all but the least stringent guidelines at all locations.

Significant Habitats

Risks to significant habitats were evaluated using two lines of evidence. Together, they indicate that current and future concentrations of PCBs are of a sufficient magnitude to adversely affect the ability of particular habitats in the Hudson River to support sustainable, healthy wildlife populations.

Measured and modeled concentrations of PCBs in Upper Hudson River water exceed criteria developed for the protection of wildlife through 2018 (the entire forecast period). Measured concentrations of PCBs in Lower Hudson River water exceed criteria developed for the protection of wildlife at most locations. Measured and modeled concentrations of PCBs in sediment in the Upper Hudson River exceed all but the least stringent guidelines at all locations through 2018 (the entire forecast period). Measured concentrations of PCBs in sediment in the Lower Hudson River exceed all but the least stringent guidelines at all locations.

Conclusions

The results of the risk assessment indicate that receptors in close contact with the Hudson River are at an increased ecological risk as a result of exposure to PCBs in sediments, water, and/or prey. This conclusion is based on a TQ approach, in which measured or modeled body burdens, dietary doses, and egg concentrations of PCBs were compared to appropriate TRVs, and on field observations. On the basis of these comparisons, all receptors of concern are at risk. In summary, the major findings of the report are:

- Fish in the Hudson River are at risk from exposure to PCBs; fish that eat other fish (*i.e.*, which are higher on the food chain), such as the largemouth bass and striped bass, are especially at risk. PCBs may adversely affect fish survival, growth, and reproduction.
- Birds and mammals that feed on insects with an aquatic stage spent in the Hudson River, such as the tree swallow and little brown bat, are at risk from PCB exposure. PCBs may adversely affect the survival, growth, and reproduction of these species.
- Waterfowl feeding on animals and plants in the Hudson River are at risk from PCB exposure. PCBs may adversely affect avian survival, growth, and reproduction.

- Birds and mammals that eat PCB-contaminated fish from the Hudson River, such as the bald eagle, belted kingfisher, great blue heron, mink, and river otter, are at risk . PCBs may adversely affect the survival, growth, and reproduction of these species.

- Omnivorous animals, such as the raccoon, that derive some of their food from the Hudson River are at risk from PCB exposure. PCBs may adversely affect the survival, growth, and reproduction of these species.

- Fragile populations of threatened and endangered species, represented by the bald eagle and shortnose sturgeon, are particularly susceptible to adverse effects from PCB exposure.

- PCB concentrations in water and sediments in the Hudson River generally exceed standards and criteria and guidelines established to be protective of the environment. Animals that use areas along the river designated as significant habitats may be adversely affected by the PCBs.

- The risks to fish and wildlife are greatest in the Upper Hudson River (in particular the Thompson Island Pool) and decrease in relation to PCB concentrations down river. Based on modeled future PCB concentrations, many species are expected to be at considerable risk through 2018 (the entire forecast period).

ATTACHMENT 4
1 - 5

Upper Hudson River Human Health Risk Assessment

Hudson River PCBs Reassessment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

August 5, 1999

AND AUGUST 4, 1999

What Does this Risk Assessment Address?

- What are the risks from various activities in the river now and in the future?
- What activities have the highest risks?
- Are risks for children or adolescents higher than those for adults?

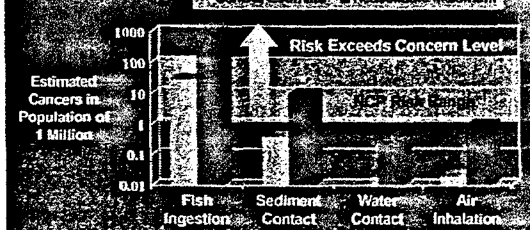
Finding #1 – PCBs in Fish

- Eating fish from the Upper Hudson River is the highest risk pathway
- Individuals who eat 1 half-pound fish meal per week
  - There is a risk of 1 additional cancer per 1,000 people exposed
  - The level of exposure to PCBs is more than 100 times higher than EPA's level of concern for non-cancer hazards

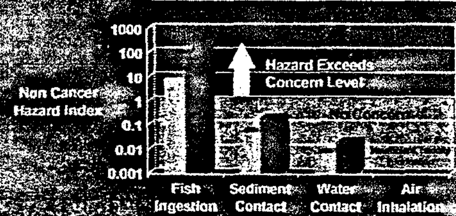
Finding #2 -- PCBs in Water, Sediment and Air

- Risks from skin contact, incidental ingestion, or air inhalation were generally shown to be within or below EPA's levels of concern

Cancer Risks from Fish Ingestion Exceed Levels of Concern



Non-Cancer Hazards for Fish Ingestion Exceed Levels of Concern



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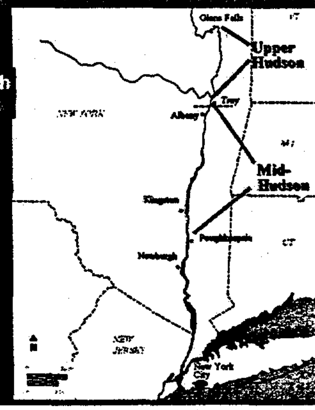
Risk Assessment - Basic Components

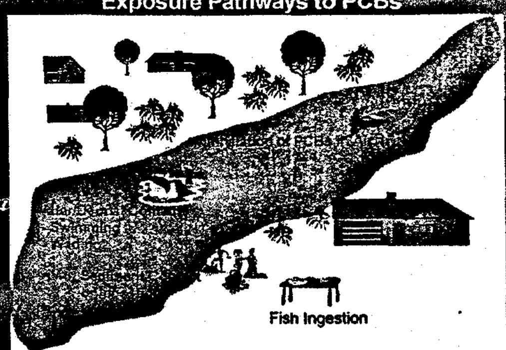
Risk is a function of:

- **Exposure**: Chemicals in food, sediment, water, air and their contact with and entry into the human body
- **Toxicity**: The ability of a chemical to cause adverse health effects

Scope of Human Health Risk Assessments



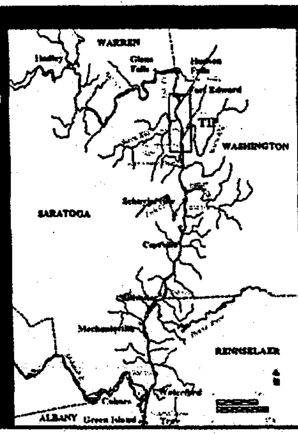
Exposure Pathways to PCBs



Summary of Important Exposure Factors

Exposure Factor	Central Estimate	Reasonable Maximum (RME)
Fish Ingestion		
Consumption (meals/year)	[illegible]	[illegible]
Exposure Duration (years)	12	40
PCBs Lost in Cooking	20%	0%
Exposure to Water/Sediment		
Adult/Child Recreation (Summer)	50% of RME	1 day per week
Adolescent Recreation (Summer)	50% of RME	3 days per week
Residence Duration (years)	[illegible]	41
Air Inhalation		
Residence Duration (years)	[illegible]	41

Scope of Upper Hudson Human Health Risk Assessment



Cancer Toxicity of PCBs from IRIS

- Classified as probable human carcinogen
  - Evidence from occupational studies is inadequate but suggestive
- Sufficient evidence from animal laboratory studies
  - Rats exposed to Aroclors 1260, 1254, 1242 and 1016 exhibited liver tumors (1996 study)
  - Males had increased numbers of thyroid tumors for all Aroclors
  - Commercial Arcolor mixtures cover range of congeners found in environment

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ATTACHMENT 4
2-5

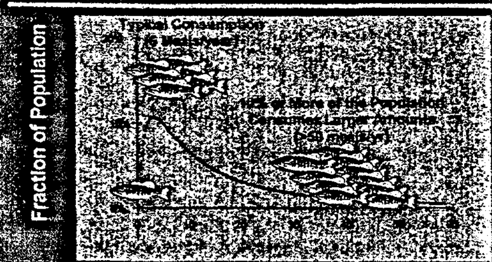
Non-Cancer Toxicity Factors from IRIS

- Reference Dose (RfD): *chemical intake likely to be without an appreciable risk of adverse effects to humans during a lifetime*
- Example adverse effects in animals:
  - Reduced birthweight
  - immune system impairment
  - eye toxicity
- RfD is based on feeding studies with rhesus monkeys
- PCBs have among the lowest reference doses (high toxicity) in EPA's toxicity database (IRIS)

Risk Characterization/Uncertainty Analysis Evaluated Wide Range of Exposure Factors

- Point estimates examined central tendency and reasonable maximum exposure (RME)
- Probability methods (Monte Carlo Analyses) expanded the uncertainty and risk characterization analysis

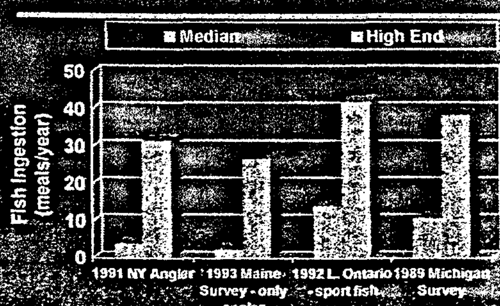
Example of Fish Consumption Variability within a Population



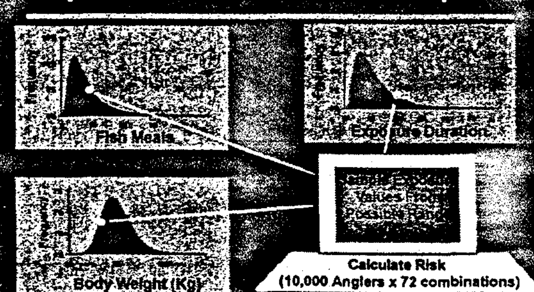
Monte Carlo Analyses 10,000 Anglers x 72 Combinations

Exposure Factor	Base Case	Sensitivity Analysis
Fish Consumption	1991 NY Angler Survey	Maine Survey Michigan Survey L. Ontario Survey
Exposure Duration	Minimum of Fishing and Residence Duration	Residence Duration only
PCBs Lost in Cooking	20% (midpoint)	0% high end 40% low end
Fishing Location (concentration)	Average Thompson Is. Pool, Stillwater, Troy/Albany	Thompson Is. Pool (high) Troy/Albany (low)

Comparison of Fish Ingestion Studies



Schematic of Probability Modeling of Exposure to PCBs via Fish Consumption



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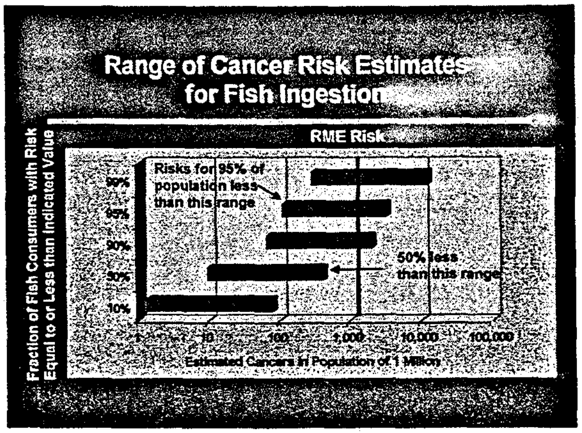
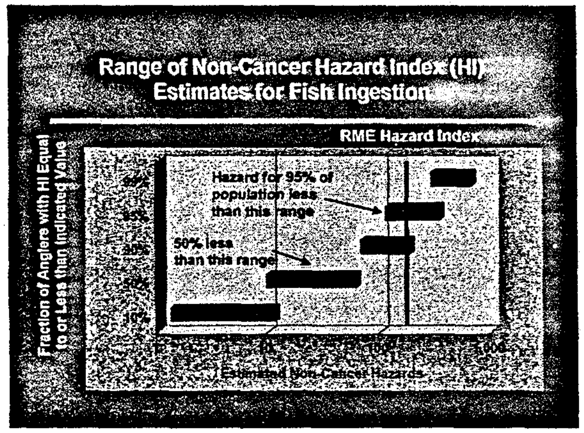
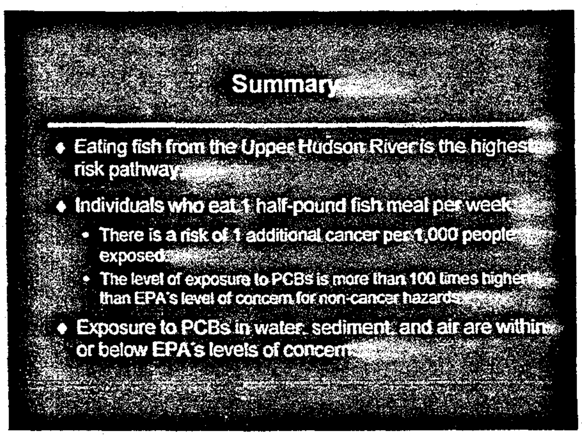

Range of Cancer Risk Estimates
for Fish Ingestion
RME Risk
Fraction of Fish Consumers with Risk
Equal to or Less than Indicated Value
99%
95%
90%
50%
10%
Risks for 95% of
population less
than this range
50% less
than this range
1
10
100
1,000
10,000
100,000
Estimated Cancers in Population of 1 Million


Range of Non-Cancer Hazard Index (HI)
Estimates for Fish Ingestion
RME Hazard Index
Fraction of Anglers with HI Equal
to or Less than Indicated Value
10%
Hazard for 95% of
population less
than this range
50% less
than this range
Estimated Non-Cancer Hazards


Summary
◆ Eating fish from the Upper Hudson River is the highest risk pathway
◆ Individuals who eat 1 half-pound fish meal per week
• There is a risk of 1 additional cancer per 1,000 people exposed
• The level of exposure to PCBs is more than 100 times higher than EPA's level of concern for non-cancer hazards
◆ Exposure to PCBs in water, sediment, and air are within or below EPA's levels of concern

ATTACHMENT 4
3-5

Hudson River Ecological Risk Assessment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

August 5, 1999

AND AUGUST 4, 1999

Definition of Ecological Risk Assessment

The process that evaluates the likelihood that adverse ecological effects are occurring or may occur as a result of exposure to contaminants

Conclusions of the Ecological Risk Assessment

- Birds and mammals that eat fish, such as the bald eagle, belted kingfisher, great blue heron, mink and river otter, are at risk

PCBs may adversely affect the survival, growth and reproduction of these animals

Conclusions of the Ecological Risk Assessment

- Birds and mammals that eat emergent aquatic insects and/or aquatic plants, such as the little brown bat and mallard, are at risk

PCBs may adversely affect the survival, growth and reproduction of these animals

Conclusions of the Ecological Risk Assessment

- Fish at the top of the food chain, such as the largemouth bass and striped bass, are at risk

PCBs may adversely affect fish survival, growth and reproduction

Conclusions of the Ecological Risk Assessment

- Threatened and endangered species, represented by the bald eagle and shortnose sturgeon, are at risk due to exposure to PCBs

Threatened and endangered species face reproductive risks from PCBs

10.9782

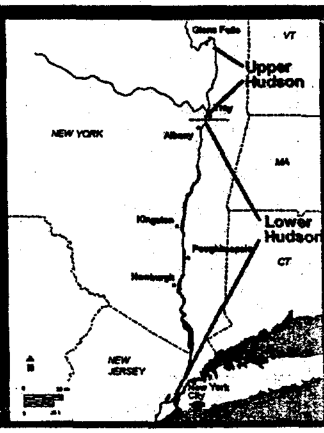
Conclusions of the Ecological Risk Assessment

- PCB concentrations in water and sediments in the Hudson River generally exceed protective guidelines

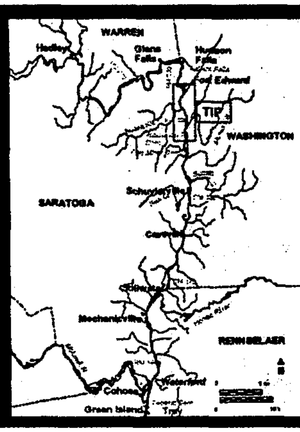
Significant habitats and the animals that use them face risks from PCBs

Conclusions of the Ecological Risk Assessment

- Risks to fish and wildlife
  - Greatest in the Upper Hudson River
  - Generally decrease moving down river
  - Greatest for top level predators
  - Under baseline conditions many species face considerable risk through the entire forecast period (modeled to 2018)



Scope of Ecological Risk Assessment



Upper Hudson River

Ecological Risk Assessment Process

- Prepared according to "*Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments*"

Problem Formulation

- Defines the objectives, scope, and rationale
  - Contaminant of concern (PCBs)
  - Exposure pathways
  - Assessment endpoints
  - Measurement endpoints
  - Receptors of concern
  - Toxicity and effects

ATTACHMENT 4
4-5

Exposure Pathways

- How receptors come into contact with PCBs
  - Ingestion of water
  - Ingestion of food (e.g., fish, insects, etc.)
  - Incidental ingestion of sediment
- Expressed as
  - Dietary dose (mammal, bird)
  - Egg concentration (bird, fish)
  - Body burden (fish)

Assessment Endpoints

- Explicit expression of the environmental value that is to be protected
- Based on
  - Mechanisms of toxicity
  - Receptor groups that are sensitive or highly exposed to PCBs
  - Potentially complete exposure pathways

Assessment Endpoints

- Benthic community as source of prey
- Protection and maintenance (survival, growth, and reproduction) of
  - local fish (forage, omnivorous, and piscivorous)
  - local birds (insectivorous, waterfowl, and piscivorous)
  - local wildlife (insectivorous, omnivorous, piscivorous)
- Protection of threatened and endangered species
- Protection of significant habitats

Measurement Endpoints

- Actual measurements used to evaluate ecological risk
  - Benthic community indices
  - Measured and modeled
    - PCB body burdens in fish
    - PCB dietary doses to wildlife
    - PCB concentrations in bird eggs
    - PCB concentrations in sediment and surface water
  - Field observations

Receptors of Concern

- Representative of wildlife species using Hudson River
- Represent different trophic levels, feeding strategies, habitat preferences
- Receptors include
  - macroinvertebrate communities
  - fish
  - birds
  - mammals

Receptors of Concern

- Fish
  - Spottail Shiner
  - Pumpkinseed
  - Brown Bullhead
  - Shortnose Sturgeon
  - Yellow Perch
  - White Perch
  - Largemouth Bass
  - Striped Bass
- Birds
  - Tree Swallow
  - Mallard
  - Belted Kingfisher
  - Great Blue Heron
  - Bald Eagle
- Mammals
  - Little Brown Bat
  - Raccoon
  - Mink
  - River Otter

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Ecological Effects

- PCBs biomagnify through the food chain
- PCBs shown to exhibit chronic toxicity
- Reproductive, developmental, and neurological effects

Effects Assessment

- Toxicity Reference Values (TRVs)
  - Field and laboratory studies
  - No observed adverse effect levels (NOAELS)
  - Lowest observed adverse effect levels (LOAELS)

Risk Characterization

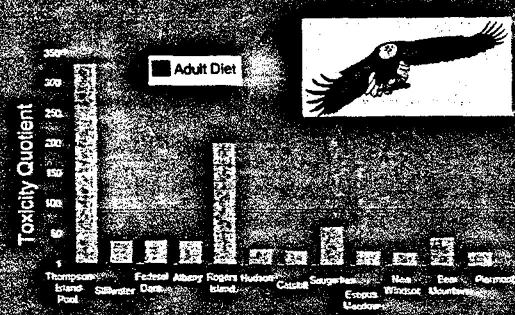
- Integrates the exposure and effects assessments
- Presents risk results

Toxicity Quotient (TQ)

- Comparison of measured and/or modeled doses or concentrations in the receptors of concern to the toxicity reference values
- Toxicity quotients equal to or greater than one (TQ≥1) typically considered to indicate potential risk to ecological receptors

Weight of Evidence

- Weight of evidence approach
  - Multiple measurement endpoints evaluated for each assessment endpoint
  - Each measurement endpoint is a line of evidence



Bald Eagle Risk Based on Tri+ Congeners

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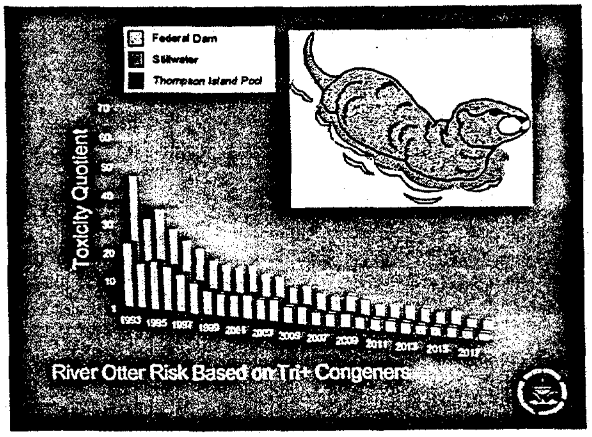
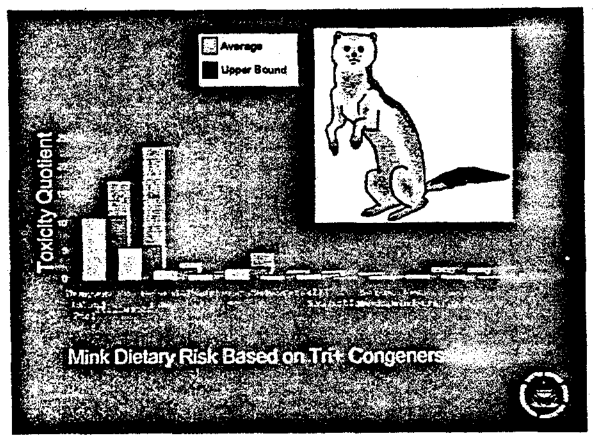
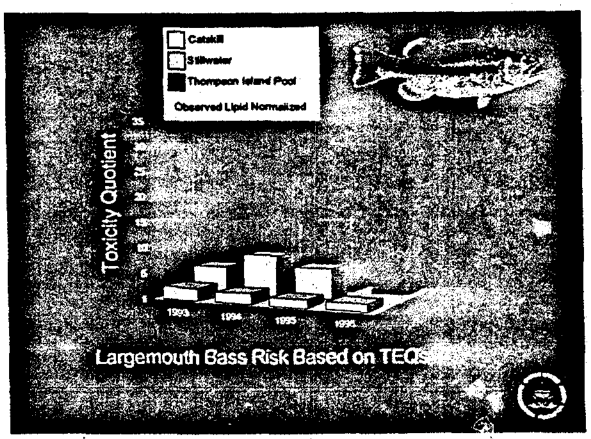
ATTACHMENT 4
5-5







Conclusions of the Ecological Risk Assessment

- Risks to fish and wildlife
  - Greatest in the Upper Hudson River
  - Generally decrease moving down river
  - Greatest for top level predators
  - Under baseline conditions many species face considerable risk through the entire forecast period (modeled to 2018)

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ATTACHMENT 5, 1-2

U.S. Environmental Protection Agency · Region 2
New Jersey, New York, Puerto Rico and the U.S. Virgin Islands
290 Broadway - New York, New York 10007-1866

www.epa.gov/region2

Ann Rychlenski (212) 637-3672

Latest EPA Reports Show Serious Risk to Human Health and Environment from PCB Contamination in Upper Hudson River

EPA Risk Assessments Confirm Exposure to PCBs in River May Increase Cancer Risk, Other Non-Cancer Health Hazards and Threaten Fish & Wildlife

FOR RELEASE: Wednesday, August 4, 1999

(#99125) New York, N.Y. -- The U.S. Environmental Protection Agency (EPA) today released two major reports, which conclude that the PCB contamination in the Upper Hudson River (Hudson Falls to the Federal Dam at Troy) poses considerable risks to human health and the environment. These reports, called baseline risk assessments, characterize current and potential threats posed by the Hudson River PCBs if no cleanup is implemented or no institutional controls, such as fish consumption advisories or fishing bans, are in place. Fish advisories are currently in effect for the Hudson River.

"These reports provide important information about the risks posed by PCBs in the Hudson River," said EPA Regional Administrator Jeanne M. Fox. "Our reassessment of the Hudson River remains on track and on schedule, as we move forward with our evaluation of the best ways to protect the environment and the people who use and enjoy this precious resource."

EPA is conducting separate risk assessments to evaluate current and future risks to human health in the Mid-Hudson River (Troy to Poughkeepsie) and to evaluate future risks to fish and wildlife in the Lower Hudson River (Troy to the Battery in New York City); these other risk assessments will be released later this year. A peer review of EPA's risk assessments will be conducted in May 2000. EPA will use the findings of the risk assessments to establish acceptable exposure levels in fish, sediments and water, and by December 2000, to evaluate cleanup alternatives for sediments in the Upper Hudson River.

In the Human Health Risk Assessment for the Upper Hudson River, EPA evaluated both cancer and non-cancer health effects in children, adolescents and adults. PCBs are probable carcinogens in humans and are known carcinogens in animals. Other long-term adverse health effects of PCBs observed in laboratory animals include a reduced ability to fight infections, low birth weights and learning problems. The report concludes that:

- Eating fish from the Upper Hudson River is the primary way for humans to be exposed to the PCBs.
- Under EPA's approach for ensuring protection of human health, there is an increased risk of one additional case of cancer for every 1,000 people eating an average of one meal a week of fish caught in the Upper Hudson. This increased cancer risk is 1000 times higher than EPA's goal for protection and ten times the highest risk level generally allowed under the federal Superfund law.

- For non-cancer health hazards, the level of exposure to PCBs from eating an average of one meal a week of fish caught from the Upper Hudson River is more than 100 times higher than EPA's level of concern.
- Under the baseline conditions, in which no cleanup is implemented or institutional controls are in place, the cancer risk and non-cancer health hazards would be above EPA's generally acceptable levels for the 40-year exposure period evaluated in the report.
- Risks from exposure to PCBs in the river through other means, such as skin contact with contaminated sediments and river water, incidental ingestion of sediments, and inhalation of PCBs in the air, were generally shown to be within or below EPA's levels of concern.

In the Ecological Risk Assessment, EPA evaluated the risks to more than 15 different fish and wildlife species with various feeding preferences, predatory levels and habitats. These species are intended to represent a range of fish and wildlife potentially exposed to PCBs in the Hudson River. PCBs are persistent in the environment and are known to bioaccumulate, becoming more concentrated and more toxic as they move up the food chain. The major findings of the report are:

- Fish in the Hudson River are at risk due to the PCBs, and larger fish that eat other fish, such as largemouth bass and striped bass, are especially at risk. The PCBs may adversely affect fish survival, growth and reproduction.

- Birds and mammals that eat fish, such as the bald eagle, belted kingfisher, great blue heron, mink and river otter, are also at risk. PCBs may adversely affect the survival and reproduction of these animals.
- PCB concentrations in water and sediments in the Hudson River generally exceed standards and criteria established to be protective of the environment.
- The risks to fish and wildlife are greatest in the Upper Hudson River (Thompson Island Pool at River Mile 189) and decrease as PCB concentrations decrease moving down river. Under baseline conditions for the Upper Hudson River, many species are expected to be at considerable risk for decades to come.

EPA will hold two meetings to discuss these findings with the public. On Wednesday, August 4, 1999, a meeting will be held at 7:30 p.m. at the Albany Marriott Hotel, located at 189 Wolf Road in Albany, New York. On Thursday, August 5, 1999, a second meeting will be held at 7:30 p.m. at the Sheraton Hotel at 40 Civic Center Plaza in Poughkeepsie, New York.

EPA will accept public comment on the Human Health and Ecological Risk Assessments through September 7, 1999. EPA's responses to public comments received will be released in responsiveness summaries in March 2000. ####

ATTACHMENT 6

Hudson River PCBs Site
Reassessment RI/FS
June 10, 1999

Milestone	Completed	To Public
PHASE 1 Report	✔	Aug 1991
PHASE 2 Field Sampling Program - 1992 to 1994	✔	N/A
Database Report (DBR)	✔	Nov 1995
Preliminary Model Calibration Report (PMCR)	✔	Oct 1996
Data Evaluation & Interpretation Report (DEIR)	✔	Feb 1997
Low Resolution Sediment Coring Report (LRC)	✔	Jul 1998
Human Health Risk Assessment Scope of Work	✔	Jul 1998
CD-ROM Database Reissue	✔	Jul 1998
Peer Review 1 - Modeling Approach - Begins	✔	Jul 1998
Peer Review 1 Meeting	✔	Sept 1998
Ecological Risk Assessment Scope of Work	✔	Sept 1998
DBR, PMCR, DEIR Responsiveness Summary	✔	Dec 1998
Peer Review 2 - DEIR & LRC - Begins	✔	Jan 1999
LRC Responsiveness Summary	✔	Feb 1999
Peer Review 2 Meeting	✔	Mar 1999
Human Health Risk Assmt SOW Responsiveness Summary	✔	Apr 1999
Ecological Risk Assmt SOW Responsiveness Summary	✔	Apr 1999
Baseline Modeling Report (BMR)	✔	May 1999
Human Health Risk Assessment (HHRA)		Aug 1999
Ecological Risk Assessment (ERA)		Aug 1999
BMR Responsiveness Summary		Jan 2000
Peer Review 3 - BMR - Begins		Jan 2000
Peer Review 3 Meeting		Mar 2000
HHRA and ERA Responsiveness Summaries		Mar 2000
Peer Review 4 - HHRA & ERA - Begins		Mar 2000
Peer Review 4 Meeting		May 2000
PHASE 3 Feasibility Study Scope of Work (FS SOW)	✔	Sept 1998
FS SOW Responsiveness Summary	✔	Jun 1999
FS Report		Dec 2000
PROPOSED PLAN		Dec 2000
RECORD OF DECISION (including Responsiveness Summary)		Jun 2001