62473

HUDSON RIVER PCBs REASSESSMENT RI/FS

PHASE 2 HUMAN HEALTH RISK ASSESSMENT

SCOPE OF WORK

JULY 1998

U. S. Environmental Protection Agency
Region II
290 Broadway
New York, N. Y. 10007

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

JUL 23 1998

To All Interested Parties:

The U.S. Environmental Protection Agency (EPA) is pleased to release the Scope of Work for the Human Health Risk Assessment for the Hudson River PCBs Superfund site Reassessment. This document describes the procedures that EPA will use to develop the baseline human health risk assessment for the Hudson River PCBs site. The risk assessment will quantify both carcinogenic and non-carcinogenic health effects from exposure to polychlorinated biphenyls (PCBs) in the Upper and Mid-Hudson River. The assessment will evaluate both current and future risks based on the assumption of no remediation or institutional controls (e.g., fishing restrictions).

The Scope of Work for the Ecological Risk Assessment for the site will be released in September 1998. The Human Health Risk Assessment and the Ecological Risk Assessment will be released in August 1999, after modeling work essential to the reports is completed.

Please note that EPA released a Preliminary Human Health Risk Assessment in the Phase 1 Report in August 1991. The Human Health Risk Assessment to be released in August 1999 will supercede that effort. It should also be noted that the Agency has already completed numerous tasks outlined in the Scope of Work. Nevertheless, a comprehensive scope of work for the risk assessment is being provided at this time for simplicity in understanding the issues.

EPA will accept comments on the Scope of Work for the Human Health Risk Assessment until **Monday, August 31, 1998.** Comments should be marked with the name of the report and should include the report section and page number for each comment. Comments should be sent to:

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

Attn: HHRA SOW Comments

EPA will present the outline for conducting the Human Health Risk Assessment along with the findings of the Low Resolution Coring Report at a joint liaison group meeting in Albany, New York. Notification of this meeting was sent to liaison group members several weeks prior to the meeting. In the interim, between the release of this document and the end of the comment period, EPA will hold two public availability sessions to further answer public questions regarding this document as well as the Low Resolution Coring Report. These sessions will be held on Wednesday, August 19, 1998 at the Holiday Inn Express in Latham, New York from 2:30 to 4:30 p.m. and from 6:30 to 8:30 p.m., and on Thursday, August 20, 1998 from 6:30 to 8:30 p.m. at Marist College in Poughkeepsie, New York.

If you need additional information regarding this scope of work, the availability sessions or with respect to the Reassessment in general, please contact Ann Rychlenski, the Community Relation Coordinator for this site, at (212) 637-3672.

Sincerely yours,

Richard L. Caspe, Director
Emergency and Remedial Response Division

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I. HISTORICAL OVERVIEW OF RISK ASSESSMENT FOR THE HUDSON RIVER AND THE RISK ASSESSMENT PROCESS

1. Introduction

The purpose of this document is to outline the procedures that will be used by U.S. EPA (EPA) in developing the baseline human health risk assessment for the Hudson River as required under the National Oil and Hazardous Pollution Contingency Plan (U.S. EPA, 1990). The assessment will quantify both carcinogenic and non-carcinogenic health effects from exposure to polychlorinated biphenyls (PCBs) in the Hudson River and follow appropriate EPA risk assessment policies and guidance. The assessments will evaluate both current and future risks based on the assumption of no remediation or institutional controls (U.S. EPA, 1990).

The Scope of Work for the ecological risk assessment will be provided separately.

Two human health risk assessments are planned. The Upper Hudson River risk assessment will cover the area between Hudson Falls and the Federal Dam in Troy, New York to Fort Edward, New York, a length of approximately 40 river miles (see Section II). The Mid-Hudson River risk assessment will cover from Albany, New York to Poughkeepsie, New York a length of approximately 83 river miles (see Section III). The risk assessments will be developed using similar methodologies, but may be developed at different times.

The risk assessments will include data collected during the initial Remedial Investigation/ Feasibility study conducted in the late 1970's and early 1980's and data collected during the Reassessment Remedial Investigation and Feasibility Study (RI/FS) started in 1990. The assessment will rely primarily on data from the Phase 2 Investigation contained in the database for the Hudson River PCBs Reassessment RI/FS in the following documents: the Database Report (U.S. EPA, 1995a); the Preliminary Model Calibration Report (U.S. EPA, 1996a); the Data Interpretation and Evaluation Report (U.S. EPA, 1997d) ; and the Baseline Modeling Report currently being developed.

Individual components of the proposed approach may be revised if additional data are identified in the course of preparing the risk assessment.

2. Background

2.1. *The Site.* The Hudson River PCB Superfund Site extends from Hudson Falls, New York to the Battery (at the southern tip of Manhattan) in New York. The site covers approximately 200 river miles.

From 1957 through 1975, between 209,000 and 1,300,000 pounds of PCBs were discharged to the Upper Hudson River from two General Electric facilities; one located in Fort Edward, New York and the other in Hudson Falls, New York (U.S. EPA, 1991). In 1977, the manufacture and sale of all PCBs within the U.S. was stopped under provisions of the Toxic Substances and Control Act (U.S. EPA, 1978).

In 1973, the Fort Edward Dam was removed and subsequently the downstream movement of PCB contaminated sediments was greatly facilitated (U.S. EPA, 1991). Because of potential human health risks due to consumption of PCB-contaminated fish, the New York State Department of Environmental Conservation (NYSDEC) banned fishing in the Upper Hudson River and limited the recommended number of fish meals consumed for specific species in the Lower Hudson River (NYSDOH, 1991). In 1976, the commercial striped bass fishery in the Hudson River was closed based on elevated PCB levels in the bass. The ban on fishing in the Upper Hudson River was subsequently changed to a "catch and release" program in August 1996.

In 1984, EPA issued a Superfund Record of Decision (ROD) for the site. The ROD required: 1) an interim No Action decision concerning river sediments; 2) in-place capping, containment and monitoring of remnant deposit sediments; and 3) a treatability study to evaluate the effectiveness of removing PCBs from the Hudson River water (U.S. EPA, 1984).

2.2. *Phase 2 Reassessment and Risk Assessment.* In December 1990, U.S. EPA Region II began a reassessment of the No Action decision for the Hudson River sediments based on a request by NYSDEC to do so, and by the requirements by the Superfund Amendments and Reauthorization Act of 1986 to conduct reviews for sites where contamination remains on site. The reassessment consisted of three phases: interim characterization and evaluation; further site characterization and analysis; and a Reassessment Remedial Investigation and Feasibility Study. This report presents an outline of the proposed Human Health Risk Assessment that will be developed during the Reassessment for the Upper and Mid-Hudson River. Individual components of the proposed approach may be revised if additional data are identified in the course of preparing the risk assessment.

3. Definition of Risk Assessment

The goal of the Superfund human health evaluation process is to provide a framework for developing the risk information necessary to assist in the determination of possible remedial actions at a site. EPA uses risk assessment as a tool to characterize the contaminants, evaluate the toxicity of the chemicals, assess the potential ways in which an individual may be exposed to the contaminants, and characterize the risks (U. S. EPA, 1989). The risk assessment is designed to evaluate the current and future risks to the Reasonably Maximally Exposed Individual and the Average Exposed Individual for both cancer and non-cancer health effects.

Risk assessment was defined by the National Academy of Sciences (National Research Council, 1983) as involving one or more of the following four steps:

- *Hazard Identification* - an assessment of the types of adverse health effects (i.e., cancer or non-cancer) associated with exposure to chemical(s).

- *Dose-Response* - the relationship between the magnitude of the exposure and the adverse effects.

- *Exposure Assessment* - an estimate of the magnitude of actual and/or potential human exposures, the frequency and duration of these exposures, and the pathways (i.e., inhalation, ingestion, and dermal contact) by which people are potentially exposed.

- *Risk Characterization* - a summary of the results from the first three portions of the assessment (both quantitative and qualitative) and a discussion of the uncertainties.

The quantitative assessment of carcinogenic risks involves the evaluation of lifetime daily average exposure levels and application of toxicity factors reflecting the carcinogenic potency of the chemical. Excess lifetime cancer risk is calculated as:

Risk = Cancer Slope Factor (CSF) X Chronic Daily Intake (CDI).

The cancer slope factor is an estimate of an upper-bound probability of an individual developing cancer as a result of a lifetime of exposure to a particular level or dose of a potential carcinogen. The cancer slope factor is expressed in units that are the reciprocal of those for exposure i.e., $(mg/kg\text{-}day)^{-1}$. The exposure levels are expressed as the chronic daily intake averaged over a lifetime of PCB exposure from the river. The exposure is expressed in units of mg of PCB intake per kilogram (an equivalent of 2.2 lbs) of human body weight per day (mg/kg-day). Multiplication of the exposure level by the CSF yields a unitless estimate of cancer risk. The risk estimate for cancer reflects the incremental increase in the probability of developing cancer following site-specific exposure. The acceptable risk range identified in the NCP (U.S. EPA, 1990) is 10^{-4} to 10^{-6} (or an increased probability of developing cancer of 1 in 10,000 to 1 in 1,000,000).

The evaluation of non-cancer health effects involves a comparison of average daily exposure levels with established Reference Doses (RfDs) to determine whether estimated exposures exceed recommended limits. A Reference Dose is defined as "an estimate, with uncertainty spanning perhaps an order of magnitude or greater) of a daily exposure level for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects during a lifetime" (U.S. EPA, 1989). The comparison is expressed as a Hazard Quotient (HQ), which is the ratio of the estimated exposure to the RfD. When the HQ exceeds a value of 1, unacceptable exposures may be occurring. Both exposure levels and RfDs are typically expressed in units of mg of PCB intake per kilogram of body weight per day (mg/kg-day). Unlike the evaluation of carcinogenic effects, exposures of less than lifetime duration are not averaged over an entire lifetime.

The risk characterization presents the calculated risks and hazards from exposure to PCBs and associated uncertainties. The risk characterization is used by risk managers in their decision-making process.

4. Results of Phase 1 Risk Assessment.

In 1991, EPA issued the Phase 1 Report - Interim Characterization and Evaluation for the Hudson River PCB Reassessment Remedial Investigation/Feasibility Study including a quantitative risk assessment for the Upper Hudson and a qualitative risk assessment for the Lower Hudson River (U.S. EPA, 1991). The Phase 1 Risk Assessment determined that the potential chemical risks from PCBs in fish alone were the major source of health risks associated with exposure to site related contaminants. A brief summary of the results for the Upper and Lower Hudson River assessments are summarized below.

The Upper Hudson River human health risk assessment evaluated current and potential risks from ingestion of fish. The risks from ingestion of fish were found to exceed EPA's cancer risk range of 10^{-4} to 10^{-6} (an increased probability of developing cancer of 1 in 10,000 to 1 in 1,000,000) and 1 for non-cancer (indicating an exceedence of the Reference Dose). The risks from drinking water were within the risk range. Risks from dermal exposure to river sediment, incidental ingestion of river sediment, and dermal contact with river water were within the risk range. Risks from other pathways including ingestion of vegetables, meat, etc. and inhalation exposures could not be quantified at that time based on insufficient data.

The Lower Hudson River human health risk assessment qualitatively evaluated current and potential risks from ingestion of fish based on the findings in the Upper Hudson River. The assessment concluded that the risks from ingestion of fish would be similar to those found in the Upper Hudson River.

5. Changes in EPA Risk Assessment Guidance Since The Phase 1 Risk Assessment.

Since the Phase 1 risk assessment EPA issued several new risk assessment policies and guidance documents (U. S. EPA, 1992a,b; 1995a-c; 1996a-c; 1997a-c; and 1998a-c). A brief summary of the new documents and their impact on the risk assessment are provided below.

- The Oral Reference Dose for Aroclor 1016 used in the original assessment was changed from 1×10^{-4} to 7×10^{-5} on January 1, 1993 (U.S. EPA, 1998a). This RfD is a more stringent RfD than the RfD used in the original assessment.

- A new Oral Reference Dose for Aroclor 1254 was developed and added to the Integrated Risk Information System (IRIS) on October 1, 1994 (U.S. EPA, 1998b). This provides another toxicity value for evaluating non-cancer hazards.

- Risk Assessment Guidelines on Exposure Assessment were issued in 1992 (U.S. EPA, 1992a). These guidelines define the "high end" of population exposure between the 90th and 99.9th percentiles with the 99.9th percentile considered a bounding estimate.

- Risk Characterization guidance was released in 1992 (U.S. EPA. 1992b) and updated in 1995 (U. S. EPA. 1995b). The guidance recommends the Agency adopt the values of transparency, clarity, consistency and reasonableness in the development of risk characterizations including better characterizations of uncertainty.

- Revised Carcinogen Risk Assessment Guidelines were proposed in 1996 (U. S. EPA. 1996b). The proposal includes changes in the method of extrapolating from animals to humans to be more consistent with approaches used by other federal Agencies. For PCBs this resulted in a reduction in the cancer slope factor by a factor of 2 based on the animal studies used in the extrapolation from animals to humans (U.S. EPA. 1996c). The guidance also changed the categories for classifying the carcinogenic potential of chemicals. The assessment will use the new cancer slope factor and the revised carcinogenic classification, as appropriate.

  The Agency reassessed the toxicity data on the potential carcinogenic potency of PCBs in 1996 (U. S. EPA. 1996c). The reduction in the cancer slope factor for fish ingestion from 7.7 mg/kg-day to 2.0 mg/kg-day reflects the re-evaluation of the available animal toxicity data (a factor of approximately 2) and the new policy for extrapolating from animals to humans (a factor of approximately 2) as discussed in the proposed Cancer Guidelines (described above, U.S. EPA. 1996b).

  The reassessment of cancer toxicity resulted in new cancer slope factors for ingestion of fish of 2.0 $(mg/kg\text{-}day)^{-1}$, for inhalation of PCBs of 0.4 $(mg/kg\text{-}day)^{-1}$, and 0.07 $(mg/kg\text{-}day)^{-1}$ if a congener or isomer analysis verifies the absence of congeners with more than four chlorines (concentration less than 0.5% of total PCBs), and for dermal of 0.4 $(mg/kg\text{-}day)^{-1}$ if no absorption factor is applied. The Phase 1 risk assessment used a oral cancer slope factor of 7.7 $(mg/kg\text{-}day)^{-1}$ for ingestion of fish. Inhalation risks were not evaluated based on a lack of toxicity data at the time of the Phase 2 assessment.

- The Agency released "Guiding Principles for Probabilistic Analysis" in 1997 (U. S. EPA. 1997a). These guidelines set forth basic approaches for developing a probabilistic risk assessment and determining when a probabilistic assessment is appropriate. Based on the extent of data from the reassessment a probabilistic analysis will be performed to evaluate variability and uncertainties in the cancer and non-cancer risk assessments.

- The Agency released the "Special Report on Environmental Endocrine Disruption: an Effects Assessment and Analysis (U.S. EPA. 1997b)" and the Science Policy Council's Interim Position on Endocrine Effects (U.S. EPA. 1997c)" in 1997. These documents summarize the existing data on the potential effects of chemicals with endocrine effects and the need for additional research. The assessment will qualitatively address endocrine effects based on this guidance.

II. UPPER HUDSON RIVER RISK ASSESSMENT SCOPE OF WORK

1. Plan, Synopsis & Objectives

This Scope of Work details the issues and tasks that EPA will consider in the development of the Upper Hudson River Phase 2 Human Health Risk Assessment. The Scope of Work is described in the format of the presentation of the final report. Individual components of the proposed approach may be revised if additional data are identified in the course of preparing the risk assessment.

The toxicity values, the Cancer Slope Factors and Reference Doses for cancer and non-cancer health effects will be obtained from the EPA's Integrated Risk Information System (IRIS). IRIS provides the Agency's consensus review of toxicity data (U.S. EPA, 1998a-c). The assessment will also qualitatively address endocrine effects based on the Agency's "Special Report on Environmental Endocrine Disruption: an Effects Assessment and Analysis" (U.S. EPA, 1997b) and recent scientific publications. Although EPA is currently supporting significant research in this area, the available data are insufficient to support a quantitative assessment of endocrine effects. Therefore, a qualitative assessment and discussion in the uncertainty section on endocrine effects will be presented.

The exposure portion of the risk assessment will be divided into two parts. The first part will involve calculating Lifetime and Daily Doses of exposure for individuals using standard exposure equations (U.S. EPA, 1989) where the exposure parameters (ingestion rate, exposure duration, body weight, etc.) are calculated using single point estimates. This method is the same as the approach used in the Phase 1 risk assessment and is described in the Risk Assessment Guidance for Superfund - Part A (U.S. EPA, 1989).

The second analysis involves a probabilistic risk analysis using the most commonly used method termed Monte Carlo analysis (U.S. EPA, 1997a). The probabilistic risk analysis presents risk as a range of values instead of a single point value because individuals may have different responses. The probabilistic risk analysis attempts to capture information on both uncertainties, (i.e., that which is not known) and variability (i.e., observed differences attributable to true differences in a population or exposure parameter).

The Monte Carlo analysis involves a number of steps that are briefly described below. First the scientific literature will be reviewed to identify studies that can provide information on the variability of each of the exposure parameters (ingestion rate, exposure duration, body weight, etc.). Second, using this information a model will be developed that specifies the possible range of exposure values. Third, a simulation is carried out using computer programs whereby the distribution of possible outcomes is generated by letting a computer recalculate the worksheet over and over again, each time using different randomly selected sets of exposure values from the probability distributions for each parameter. Fourth, the results from the analysis will be combined with the appropriate toxicity value and graphed and presented in the final risk assessment.

The final Phase 2 report for the Upper and Mid-Lower Hudson River will include a brief (1-2 pages) synopsis of the 1991 risk assessment. The Phase 2 report will contain an introduction describing the objectives of the Phase 2 risk assessment, namely to confirm the findings from Phase 1, that risks from fish ingestion outweigh other pathways of exposure, and to provide both point and probabilistic estimates of risk associated with human consumption of fish.

2. Exposure Assessment

A. Concentration of PCBs in Fish

The fish concentrations will be developed using data from the Hudson River Database report (U. S. EPA, 1995a); the Preliminary Model Calibration report (U. S. EPA, 1996a); the Data Interpretation and Evaluation report (U. S. EPA, 1997d); and the Baseline Modeling report under development. The risk assessment will summarize the results of these analyses and explain procedures used in developing the fish concentration data.

B. Fish Consumption Rates for the Upper Hudson River

Fish ingestion rates are waterbody specific and depend on a number of factors including weather, available fish species, angler (man, woman or child who fishes), preference for specific species, impact of fishing bans, and distance of the angler from the water body. Numerous scientific studies of various water bodies (lakes, rivers, streams, etc.) were conducted to identify fishing patterns (frequency, fishing practices, fish species preference, etc.) and fish consumption rates (amount of fish consumed on a daily basis). Many studies involve interviews with anglers at the dockside requesting information about the fishing activities (fish preference, consumption rates, cooking methods, age, gender, frequency of fishing the specific water body, etc.). This survey method provides information on both licensed and un-licensed anglers depending upon who is interviewed. Other studies involve sending questionnaires to licensed anglers requesting information on fishing practices, preferred rivers, lakes or streams, fish consumption, and other information. The results from both surveys are evaluated, statistically analyzed, and presented in the published scientific literature, government reports, or reports from organizations.

Using fish consumption information, the risk assessment will include a characterization of a distribution of fish consumption rates for the Upper Hudson River including high-end and central tendency (average exposure) point estimates identified as the 95th and 50th percentiles, respectively from the selected distribution of data on fish consumption. Because fish ingestion rates are waterbody-specific, the review will be limited to a review of studies of anglers in the Northeast inland flowing waterbodies. Based on a preliminary review of the available scientific literature, the focus will be primarily on the Connelly studies of New York State anglers (Connelly *et al.*, 1990, 1992, and 1996) since they provide comprehensive information about angler activities including fish ingestion rates from numerous New York waterbodies which share similarities with the Upper Hudson River. The 1992 Connelly study provides detailed information about 1,030 licensed New York anglers, including their total consumption of sport-caught fish in 1991, the number of fish caught and consumed according to species and fishing location, the number of days fished in 1991, the age anglers began fishing, and background demographic information e.g., socioeconomic, age, gender, etc. (Connelly *et al.*, 1992). A previous study by Connelly in 1990 asked 10,314 licensed New York anglers about their total yearly fish consumption (from all sources), the number of days fished in 1988, the distance traveled to fish, cooking preferences, and whether anglers had a fishing license in the previous three years (Connelly *et al.*, 1992). The 1996 survey objective was to provide accurate estimates of fish consumption among Lake Ontario anglers and to evaluate the effect of Lake Ontario health advisory recommendations (Connelly *et al.*, 1996). The analysis of fish ingestion rates will be based on an evaluation of fish rates from the Connelly databases for all flowing water bodies.

The evaluation will also consider fish ingestion information from the Clearwater survey of Hudson River anglers (Barclay, 1993), the ChemRisk study of licensed Maine anglers (ChemRisk, 1991), and other recent creel surveys (Peterson, 1998 and ongoing 1998 NYSDOH survey), based on availability. Evaluation of more than one fish ingestion study allows consideration of the consistency among studies and comparison of rivers with and without fishing bans. This results in an increased level of confidence in the use of the Connelly data (Connelly *et al.*, 1990, 1992, and 1996).

The following section describes other surveys (mentioned above) and their potential application in the risk assessment:

- The Clearwater survey included 336 shore-based anglers interviewed at 20 different locations along the Hudson, including 3 sites in the Upper Hudson, during 1991 and 1992 (Barclay, 1993). The anglers were asked how often they fished and ate fish from the Hudson in the previous week and month, and the extent to which they shared their catch with other relatives and friends. While the Clearwater survey is less comprehensive than the Connelly dataset, the results are useful because both licensed and non-licensed anglers were surveyed. It is the only available study specific to the Hudson.

- The ChemRisk study involved collecting survey data from 1,612 licensed Maine anglers who completed questionnaires asking the number of fishing trips they had taken in 1990 and the number of each fish species caught and consumed (ChemRisk, 1991). The ChemRisk data will be evaluated for similarities between the Maine and New York water bodies (i.e., water body size, water temperature, dominant harvest species, and the percent of water bodies with fishing bans) to determine relevance to the Hudson River.

- Other surveys including the Peterson study (1998) and the NYSDOH on-going survey of anglers will also be evaluated. The Peterson study (1998) evaluated striped bass harvested from the Hudson River. The NYSDOH on-going survey of recreational anglers activities on the Hudson River will also be evaluated depending when the report is completed.

Review of the scientific literature indicates there are a number of other issues that will need to be considered in evaluating angler surveys. These issues include:

- Recall bias in questionnaire responses, including the assertion based on studies of anglers where fish were measured at the time of catch that people overestimate positive events i.e., anglers might remember catching bigger fish.

- Bias toward frequent anglers in creel surveys (surveys of people fishing) where an interviewer is more likely to interview the angler who spends more time fishing.

- Seasonal limitations/variations on the fishing season, where some anglers might limit fishing to warm weather conditions and not engage in ice fishing.

- Impact of considering data from only licensed anglers in the Connelly and ChemRisk mail surveys as compared to non-licensed anglers.

- Freshwater fish ingestion rates for children since children under the age of 14 are not required to have fishing licenses within New York State and other states.

For the purpose of this risk assessment, a hypothetical study population will be defined as any individual who would consume self-caught fish from the Hudson River at least once per year in the absence of a fishing ban. The population in question will therefore include a range of infrequent to very frequent anglers, who may fish for sport (recreational) or for sustenance (food supplement). To the extent possible both licensed and unlicensed anglers will be included in the assessment; however, it is noted that information about unlicensed anglers is limited to the Clearwater survey (Barclay, 1993) and the Peterson survey (Peterson, 1998). Attempts will not be made to distinguish between the subpopulations of highly exposed or lesser exposed anglers, as these subpopulations will be represented in the distributions of risk generated in the Monte Carlo analysis. The analysis of the various creel surveys and the basis for selection will be documented in the risk assessment, as appropriate.

C. Species-Specific Fish Ingestion

This step will involve the characterization of species-specific fish ingestion rates for anglers fishing the Upper and Mid-Hudson River, using data from a subset of "Hudson-like" rivers and streams from the Connelly databases (Connelly *et al.*, 1990, 1992, and 1996), based on the species of fish present. To generate this information, the data from the Connelly (Connelly *et al.*, 1990, 1992 and 1996) and Clearwater studies (Barclay, 1993) studies will primarily be used. Species-specific data will be derived from a subset of "Upper and Mid-Hudson-like" rivers and streams from the Connelly database for all flowing water bodies. ChemRisk's Maine survey (ChemRisk, 1991) may also be useful, depending on the similarities between the Maine water bodies and the Hudson River. The relative contribution of each species to an individual's total fish intake from the Hudson will be characterized and confirmed based on an analysis of the consistency of the results with all the available data and that the species are present in the Hudson. If any species of fish are present in the Hudson and likely to be eaten, but modeled PCB concentration data is lacking, estimates of PCB levels based on the fat content of the fish and available concentration data from other similar species will be developed.

Although theoretically, there may be ethnic groups or small subpopulations of anglers that preferentially eat different species of fish than the general angling population, there is no data available on this issue. This issue may be addressed as part of the uncertainty analysis, the second tier of the Monte Carlo analysis, using professional judgment to characterize possible species-specific consumption rates.

D. Exposure Duration

An evaluation of the available data on county mobility and angling cessation will be performed to develop a realistic exposure duration for fishing in the Upper Hudson River. While Superfund risk assessments typically use the length of time that an individual remains in a single residence as an exposure duration, such an estimate is not likely to be a good predictor of angling duration, since an individual may move into a nearby residence and continue to fish in the same location, or an individual may chose to stop angling irrespective of the location of their home.

A more reasonable approach to estimate exposure duration is to evaluate the average length of time before an individual moves far enough away from the Hudson so that continued fishing in the Hudson would be unlikely. Connelly *et al.* (1990) reported that anglers traveled a mean distance of 34 miles to fish in the Upper and Lower Hudson River in 1988; however, there was considerable variability in the distances that people were willing to travel. Also, it is unclear how relevant this mean distance of 34 miles is for the Upper Hudson River risk assessment, since the Connelly survey was conducted while there was a fishing ban in effect in the Upper Hudson, and the traveling distance results were combined for the Upper and Lower Hudson. The size of counties will also be evaluated relative to the 34 mile distance. Therefore, as a reasonable approximation, the assessment plans to assume that Upper Hudson River anglers fish in the Upper Hudson as long as they live within one of the counties bordering the Upper Hudson, and that once they move outside of the bordering counties, they would no longer be willing to travel the longer distance to the Upper Hudson to fish. The assessment plans to analyze local and national county mobility data (the In-Migration and Out-Migration Special Project Files from the Census Bureau) as well as national census information such as the length of time people live in a single residence (from the Census Bureau summary tape, population file 1A, U. S. Department of

Commerce, Bureau of Census, 1992) to generate a reasonable estimate of how long people remain living within the counties bordering the Upper Hudson.

To the extent possible, the assessment also will attempt to incorporate the likelihood that an angler may voluntarily choose to stop fishing, based on an analysis of the percent of licensed anglers in the general New York State population at each age. Such an analysis may be possible using census data to determine the number of individuals in each age group (Bureau of the Census, 1992) and the Connelly data (Connelly *et al.*, 1990, 1992 and 1996) to determine the number of licensed anglers in each age group. It is suspected that, generally, anglers are highly dedicated to their sport, and few voluntarily stop fishing.

To the extent possible, the assessment will investigate whether the mobility rates for the general population are applicable to the subset of anglers. Since little if any data are available on this issue, it may be best addressed in the uncertainty analysis, i.e., the second tier of the Monte Carlo analysis.

The start date for the assessment will be 1999, the year in which the Human Health Risk Assessment will be released. The assessment is not planning to model risks for individuals who move into, or are born into the study area following 1999. If PCB levels in fish decline with time, these individuals will have lower risks than the original exposed population.

The assessment anticipates that exposure duration will be one of the most difficult exposure parameters to accurately characterize and the risk assessment will make assumptions protective of public health. The assessment will explicitly describe the choices and assumptions, comment on other alternative methods for addressing exposure duration, and explain why they were not chosen.

E. PCB Cooking Losses

The assessment proposes reviewing the available literature on PCB losses during cooking. Available studies will be evaluated to determine if they have adequately characterized the extent of PCB losses during cooking to support a quantitative estimate of cooking losses (both a point estimate and a distribution). Care will be taken in reviewing the studies to separate those studies that reported raw fish mean portion concentration decreases and cooked fish meals that reported contaminant mass loss. Depending on the findings, it will be determined whether to include a quantitative estimate of PCB cooking losses in the subsequent quantitative risk calculations (point estimate and Monte Carlo analysis), or to address this issue qualitatively. If this issue is quantitatively addressed, the frequency of using each cooking method will be included. PCB losses from trimming will not be evaluated since limited quantitative data on the fish species of interest are available.

While there does seem to be a consensus that some PCBs are lost during cooking, the extent of this decrease has not been well characterized and thus quantitative estimates of cooking losses are highly uncertain. Estimates of PCB losses from cooking are likely to be a function of the cooking method, the temperature during cooking, the lipid content of the fish, the fish species, the distribution of PCB congener species, the magnitude of the PCB contamination in the raw fish, the extent to which lipids separated during cooking are consumed, the reporting method, and the experimental study design. Experimental results have shown considerable variability, both between various cooking methods and within the same method. Furthermore, personal preferences for various cooking methods and other related habits (such as consuming pan drippings) are poorly defined. Based on the scientific literature a determination will be made as to an appropriate approach for assessing this effect.

The preliminary recommendation is to conservatively assume no loss from cooking when calculating point estimates for central tendency and RME exposures. The uncertainty in PCB losses during cooking will be evaluated in the second tier of the Monte Carlo analysis, using a uniform distribution ranging from no loss to a loss of 74 percent, the maximum mean PCB loss observed in all the PCB cooking loss studies.

F. PCB Concentrations for Deterministic and Monte Carlo Analyses

To evaluate PCB exposure via fish ingestion, the risk assessment will estimate fish PCB concentration values (for total PCBs, Aroclor 1016, and Aroclor 1254 since a Reference Dose is not available for Aroclor 1242), for each combination of fish species representative of primary fish consumed by the population (six species), river location (intervals from RM 153 to RM 195) and time (one set of values for each year, modeled for up to seventy years). The modeled values, adjusted to represent standard fillet portions, will be based on the modeled concentrations based on future river water and sediment concentration. Details of the method used in the final determination of PCB concentrations will be provided. Based on the results from the modeling report a determination will be made as to how to best segment the river stretches for the risk assessment (see Section II.2A).

Both high-end and central exposure concentrations for this exposure pathway will be calculated to evaluate risks to the reasonably maximally exposed individual and average individual. To estimate a high end exposure point concentration, the assessment will: 1) use PCB concentration data from the most contaminated species; 2) calculate the 95% Upper Confidence Limit on the mean PCB concentration over a high end estimate of exposure duration; and 3) use data from the most contaminated stretch of the Upper Hudson River. To estimate a central exposure point concentration, the risk assessment will average PCB levels over: 1) fish species (reflecting average angler fish consumption patterns), 2) time (reflecting a central estimate of exposure duration), and 3) all locations in the Upper Hudson River.

The risk assessment will coordinate with other EPA Reassessment activities to obtain the appropriate data. It is assumed that the concentration estimates provided by these parties will be either: 1) point values, or 2) probability distributions that characterize uncertainty in the modeling or variability in the concentrations for each species. If uncertainty or variability distribution information is available for each fish species, year, and location, the risk assessment may use this information to select appropriate point concentration values for inclusion in the risk analysis. For example, if the characterized uncertainty is substantial, the risk assessment will use the arithmetic average fish PCB concentration value from the uncertainty distribution for each fish species, year, and location for calculation of the central point estimate, and the corresponding 95% upper confidence limit on the arithmetic mean (U. S. EPA, 1992c) from the uncertainty distribution for calculation of the high end point estimate. If characterized variability is substantial, the risk assessment will use the median fish PCB concentration from the variability distribution for calculation of the central point estimate, and the 95th percentile of the variability distribution for calculation of the high end point estimate.

For the two-stage Monte Carlo analysis, the risk assessment will calculate exposure concentrations for each year separately, assuming that all anglers consume different fish species in the same proportions. The simulation will employ any appropriate quantitative uncertainty and variability information provided by the baseline modeling report. The risk assessment will investigate two additional possibilities for the risk characterization. First, the risk assessment will investigate the impact of assuming that some individuals consume only one (the most contaminated) fish species. Second, the risk assessment will investigate the impact of assuming that some anglers preferentially fish at hot spot locations.

G. Exposure Calculations From Fish Ingestion

High end and central tendency exposures from fish ingestion (the average daily dose for non-cancer hazards, and the lifetime average daily dose for cancer risks) will be quantified using the exposure point concentrations and point estimates for each exposure parameter, described above, in standard EPA exposure equations (U. S. EPA, 1989).

H. Other Exposure Pathways

Inhalation of volatilized PCBs will also be evaluated using data from sites near the Hudson River. Appropriate exposure assumptions based on inhalation rates and body weights will be made in the assessment.

Exposures from recreational pathways (incidental ingestion of sediment and dermal contact with sediment and water) will also be quantified using data from the Phase 2 database and a methodology that is as close as possible to the methodology used for Phase 1 risk assessment. In addition, other routes of exposure not evaluated in the original Phase 1 risk assessment based on inadequate data will also be evaluated to determine if adequate data is currently available for the quantification of risks and hazards. Assuming the exposures from these pathways are minimal compared to exposures resulting from fish consumption, it is expected to exclude these recreational pathways from further evaluation (i.e., Monte Carlo analysis). Where appropriate. relevant text explaining the exclusion of less significant exposure pathways from the Phase 1 report will be incorporated into this section of the Phase 2 report.

I. Calculation of Total Risks and Hazards

Consistent with EPA risk methodology (U.S. EPA. 1989 and 1986) the total risks and hazards will be calculated for the reasonably maximally exposed individual and the central tendency or average exposure. Risks and hazards will be added together across pathways and presented in the risk characterization.

3. Toxicity Assessment

In the Phase 2 Hudson River risk assessment. the reference doses (RfDs) and cancer slope factor (CSF) for PCBs established by EPA will be used (U. S. EPA. 1996c and 1998a-c). Currently. there are RfDs for two individual Aroclor compounds. Aroclors 1016 and 1254. and the three upper bound and central estimate CSFs for total PCBs. The data are currently available on the Integrated Risk Information System (U.S. EPA. 1998a-c). the Agency's consensus toxicity values. The IRIS values will be used in the assessment for the various routes of exposure for both cancer and non-cancer health effects. The CSFs will be applied for appropriate pathways. The sampling and modeling results will be evaluated to determine the most appropriate Reference Dose.

The toxicity values will not be evaluated in the Monte Carlo analysis consistent with EPA's policies (U. S. EPA.. 1997a).

The potential for endocrine effects will be evaluated using the current EPA assessment of endocrine effects and other scientific studies (U.S. EPA. 1997b.c). At a minimum a qualitative assessment of the currently available information on the potential effects of PCBs on the endocrine system will be provided.

A section summarizing information on the toxicity of PCBs for both cancer and non-cancer health effects will also be provided. The section will summarize appropriate information from the IRIS chemical file and the most recent reported scientific studies. This section will also discuss guidance values for PCBs derived by other federal agencies including the Agency for Toxic Substances and Disease Registry (ATSDR. 1997) and the Great Lakes Sport Fish Advisory Task Force (GLSFATF. 1993) and other appropriate documents.

4. Risk Characterization

The Risk Characterization section of the Phase 2 Upper Hudson Risk Assessment report will closely follow the guidance put forth in the March 21. 1995 Risk Characterization Memo (U.S. EPA. 1995b). reflecting transparency in the decision making process. clarity in communication. consistency with other assessments. and reasonableness. This section will summarize the cancer risks and non-cancer hazards associated with PCB exposure under various exposure scenarios. This section will also provide a statement of confidence, discussing the strengths, limitations, and uncertainties inherent in the key scientific issues and science policy choices involved in the toxicity assessment, exposure assessment, and risk conclusions. Qualitative descriptive information will accompany numerical estimates of central tendency risks and hazards, high end or reasonable maximum risks and hazards, and if available, risks for highly exposed or susceptible subgroups. A detailed qualitative discussion of the uncertainties will be included.

An enhanced Monte Carlo analysis will be performed to evaluate variability and uncertainty in exposure parameters, using two phases to distinguish the impacts of variability and uncertainty, where appropriate. The risk assessment will also provide a qualitative description of additional uncertainties including the quality and quantity of available data, data gaps, measurement uncertainties, model uncertainties, the verification of any models used, the use of defaults, body burdens of PCBs, and plausible alternative approaches. The factors contributing the greatest uncertainty will be explicitly identified in the risk characterization.

A. Calculation of Point Estimates of Central Tendency and High-End Individual Risks

Point estimates of risks and hazards will use standard EPA risk equations and exposure estimates based on central tendency (average) and high-end exposure parameters (> 90th percentile), as described in the preceding sections. The high-end and central tendency values will be derived based on selection of appropriate percentiles from the distributions generated.

B. Risks for Highly Exposed Subgroups

Distinct ethnic subpopulations that may potentially consume unusually high quantities of fish have not been identified living near the Upper Hudson River. Since subpopulations of highly exposed and lesser exposed anglers will be represented in the distributions of risk generated in the Monte Carlo analysis, it is not anticipated that further research will be conducted to distinguish potential subgroups with unusually high exposures.

Theoretically, ethnic groups or small subpopulations of anglers may also preferentially eat different species of fish than the general angling populations, but there are insufficient data available on this issue. Therefore, as part of the uncertainty analysis, the second tier of the Monte Carlo Analysis (described below), will use professional judgment to characterize worst-case species specific consumption rates.

C. Monte Carlo Analysis

The Monte Carlo analysis will evaluate annual exposures on a year by year basis, starting in 1999. The intake distributions will be based on the analyses of various exposure parameters described in the preceding sections (II.2.A-I). The Monte Carlo analysis will assume that each individual consumes fish at the 90th percentile of the distribution for their age with appropriate modification for bodyweight. The consumption percentile from year to year, chosen from the distribution of consumption rates, thereby assumes that fish ingestion rates are perfectly correlated each year. The Monte Carlo analysis will not assume a different ingestion rate each year, which would assume that there is no correlation between yearly ingestion rates and effectively average high-end consumers out of the analysis. Actual year to year ingestion rates are probably correlated to a high degree, but not perfectly (100%); unfortunately no data are available to quantitatively address this issue.

D. Additional Qualitative Discussions

Consistent with guidance from the March 21, 1995 Risk Characterization Memo (U.S. EPA, 1995b), a qualitative discussion about other uncertainties which affect the risk results, such as limitations in the models used to project future PCB concentrations in fish, database uncertainties, available information concerning angler migration within the Hudson River area, and other uncertainties inherent in each chosen parameter and distribution which were not addressed in the uncertainty phase of the Monte Carlo analysis will be included in the document. As appropriate, relevant text from reports such as the Modeling Report and the Data Evaluation and Interpretation Report (U.S. EPA, 1997d) describing these uncertainties will be included in the document.

E. Presentation of Results

The results of the analysis will be presented as described in the Risk Assessment Guidance for Superfund Part D (U.S. EPA, 1997e). In addition, the Monte Carlo Analysis information will be presented following the recommendations outlined in the EPA "Policy for Use of Probabilistic Analysis in Risk Assessment" (U.S. EPA, 1997a).

III. MID-HUDSON RIVER HUMAN HEALTH RISK ASSESSMENT SCOPE OF WORK

1. Plan, Synopsis & Objectives

This Scope of Work details the issues to be considered and the tasks to be completed in preparing the Mid-Hudson River Human Health Risk Assessment. For each task or issue, a description of the approach, an explanation of the analyses or modifications to the Upper Hudson River risk assessment is provided (see Section II). This analysis will depend on the completion of the Upper Hudson River risk and modeling work on the Lower Hudson River being conducted under a grant from the Hudson River Foundation to Drs. Thomann and Farley. Individual components of the proposed approach may be revised if additional data are identified in the course of preparing the risk assessment.

The final human health risk assessment report will include a brief (1-2 pages) synopsis of the 1991 preliminary risk assessment. The body of the report will contain an introduction, that describes the objectives of the risk assessment for the Mid-Hudson.

2. Exposure Assessment

A. Fish Concentration Data.

The fish concentrations will be developed using Mid-Hudson appropriate data from the database for the Hudson River Reassessment RI/FS (U.S. EPA, 1995a); the Preliminary Model Calibration report (U. S. EPA, 1996a); the Data Interpretation and Evaluation report (U. S. EPA, 1997d); and the Baseline Modeling report under development. The risk assessment will summarize the results of these analyses and explain how concentration data was developed.

B. Fish Consumption Rates for the Mid-Hudson River

The risk assessment plans to characterize a distribution of fish consumption rates for the Mid-Hudson River; high-end and central tendency point estimates will be identified as the appropriate percentiles from the chosen distribution. While it is conceivable that fish ingestion rates may differ between the Upper and Mid-Hudson because different fish species are present it is unlikely that adequate data will be available to quantify this difference. Depending on data for the Mid-Hudson risk assessment, the risk assessment may use the same distribution of fish ingestion rates developed for the Upper Hudson reflecting self-caught fish consumption from multiple flowing fresh waterbodies. A complete description of the analysis of fish ingestion rates is included in Section II.2.B. The possibility that fish consumption rates differ in the Upper Hudson versus the Mid-Hudson will be addressed using professional judgement in the uncertainty phase of the Monte Carlo analysis.

C. Species-Specific Fish Ingestion

The risk assessment intends to characterize species-specific intake rates for anglers fishing in the Mid-Hudson River, since PCB levels in fish vary according to species. To generate this information, the risk assessment will rely primarily on the Connelly (Connelly *et al.*, 1990, 1992, and 1996) and Clearwater data (Barclay, 1993), and other studies similar to the approach used for the Upper Hudson (see Section II.2.C). Species-specific data will be derived from a subset of "Mid-Hudson-like" flowing water bodies from the Connelly database (Connelly *et al.*, 1990, 1992 and 1996). ChemRisk's Maine study (ChemRisk, 1991) will be evaluated, depending on the similarities between the Maine waterbodies and the Mid-Hudson River. Once the relative contribution of each species to an individual's total fish intake from the Hudson is characterized, it is planned to confirm that the characterization is consistent with all the available data and that the species are in fact present in the Mid-Hudson. If any species of fish are present in the mid-Hudson and likely to be eaten, but modeled PCB concentration data is lacking, the need to estimate PCB levels based on the fat content of the fish and available concentration data from other similar species will be evaluated.

As in the Upper Hudson, there may be ethnic groups or small subpopulations of anglers that preferentially eat different species of fish than the general angling population but there is insufficient information available on this issue. This issue may be addressed as part of the uncertainty analysis, the second tier of the Monte Carlo analysis, or using professional judgment to characterize possible species-specific consumption rates.

D. Exposure Duration

The risk assessment will evaluate the available data on county mobility and angling cessation to develop a realistic exposure duration for fishing in the Mid-Hudson River. While Superfund risk assessments typically use the length of time that an individual remains in a single residence as an exposure duration, such an estimate is not likely to be a good predictor of angling duration, since an individual may move into a nearby residence and continue to fish in the same location, or an individual may chose to stop angling irrespective of the location of his or her home.

A more reasonable way to estimate exposure duration is to estimate the average length of time before an individual moves far enough away from the mid-Hudson so that continued fishing in the mid-Hudson would be unlikely. Connelly *et al.* (1990, 1992 and 1996) reported that anglers traveled a mean distance of 34 miles to fish in the Upper and Lower Hudson River in 1988; however, there was considerable variability in the distances that people were willing to travel. Also, it is unclear how relevant this mean distance of 34 miles is for the Mid-Hudson River risk assessment, since the Connelly surveys were conducted while there were fishing limitations in effect in the Mid-Hudson, and the traveling distance results are combined for the Upper and Lower Hudson. Therefore, as a reasonable approximation, the risk assessment plans to assume that Mid-Hudson River anglers fish in the Mid-Hudson as long as they live within the one of the counties bordering the Mid-Hudson, and that once they move outside of the bordering counties, they would no longer be willing to travel the longer distance to the Mid-Hudson to fish. The assessment will include a qualitative assessment of the size of the counties to support this assumption. The risk assessment plans to analyze local and national county mobility data (the In-Migration and Out-Migration Special Project Files from the Census Bureau (U. S. Department of Commerce, 1992) as well as national census information such as the length of time people live in a single residence (from the U. S. Census Bureau Summary Tape Population File 1A, U. S. Bureau of Census, 1992) to generate a reasonable estimate of how long people remain living within the counties bordering the Mid-Hudson. This is similar to the approach used for the Upper Hudson, but considers different counties.

The risk assessment will attempt to incorporate the likelihood that an angler may voluntarily choose to stop fishing, based on an analysis of the percent of licensed anglers in the New York State general population at each age. This part of the analysis will be completed as part of the Upper Hudson risk assessment.

To the extent possible, the risk assessment will also investigate whether the mobility rates for the general population are applicable to the subset of anglers. Since little if any data are available on this issue, it may be best addressed in the uncertainty analysis, i.e., the second tier of the Monte Carlo analysis.

As in the Upper Hudson, the risk assessment is not planning to model risks for individuals who move into, or are born into the study area following 1999, the start date of the risk assessment. Since PCB levels in fish are declining with time, these individuals will have lower risks than the original exposed population.

It is anticipated that exposure duration will be one of the most difficult exposure parameters to accurately characterize. Therefore, the risk assessment will explicitly describe the choices and assumptions, comment on other alternative methods for addressing exposure duration, and explain why they were not chosen.

E. PCB Cooking Losses

For the Mid-Hudson, the risk assessment procedures used in the analysis of PCB cooking losses for the Upper Hudson Risk Assessment is proposed. A complete description of our analysis of cooking losses is included in the Upper Hudson Scope of Work (see Section II.2.E).

F. PCB Concentrations for Deterministic and Monte Carlo Analyses

To evaluate PCB exposure via fish ingestion, the risk assessment will estimate fish PCB concentration values (for total PCBs, Aroclor 1016 and Aroclor 1254 since a Reference Dose for Aroclor 1242 is not available), for each combination of fish species (six species), river location (RM 70 to RM 153) and time (one set of values for each year, modeled for up to seventy years).

The modeled values, adjusted to represent standard fillet portions, will be based on the modeled concentrations based on future river water and sediment concentrations. Pathway specific central and high-end exposure concentrations will be calculated. To estimate central tendency exposure point concentrations (i.e., average exposure), the risk assessment will average PCB levels over: 1) fish species (reflecting average angler fish consumption patterns), 2) time (reflecting a central estimate of exposure duration), and 3) all locations in the Mid-Hudson River. To estimate a high end exposure point concentrations, the risk assessment will: 1) use PCB concentration data from the most contaminated species; 2) calculate the 95% Upper Confidence Limit on the Mean PCB concentration (U.S. EPA, 1992c) over a high end estimate of exposure duration; and 3) use data from the most contaminated stretch of the Mid-Hudson River.

The risk assessment will coordinate with other EPA Reassessment activities (U.S. EPA, 1995a, 1996a, and 1997d) on the project to obtain the appropriate data. It is assumed that the concentration estimates provided will be either: 1) point values, or 2) probability distributions that characterize uncertainty in the modeling or variability in the concentrations for each species. If uncertainty or variability distribution information is available for each fish species, year, and location, the risk assessment may use this information to select appropriate point concentration values for inclusion in the risk analysis. For example, if the characterized uncertainty is substantial, the risk assessment will use the arithmetic average fish PCB concentration value from the uncertainty distribution for each fish species, year, and location for calculation of the central point estimate, and the corresponding 95% upper confidence limit on the arithmetic mean from the uncertainty distribution for calculation of the high end point estimate. If characterized variability is substantial, the risk assessment will use the median fish PCB concentration from the variability distribution for calculation of the central point estimate, and the 95th percentile of the variability distribution for calculation of the high end point estimate.

For the two-stage Monte Carlo analysis, the risk assessment will calculate exposure concentrations for each year separately, assuming that all anglers consume different fish species in the same proportions. The simulation will employ any appropriate quantitative uncertainty and variability information provided by the baseline modeling report. The risk assessment will investigate two additional possibilities for the Mid-Hudson risk characterization. First, the risk assessment will investigate the impact of assuming that some individuals consume only one (the most contaminated) fish species. Second, the risk assessment will investigate the impact of assuming that some anglers preferentially fish at hot spot locations.

G. Exposure Calculations From Fish Ingestion

High end and central tendency exposures from fish ingestion (the average daily dose for non-cancer hazards, and the lifetime average daily dose for cancer risks) will be quantified using the exposure point concentrations and point estimates for each exposure parameter, described above, in standard EPA exposure equations (U. S. EPA, 1989).

H. Other Exposure Pathways

Inhalation of volatilized PCBs will also be evaluated using available data from sites near the Hudson River where available. Appropriate exposure assumptions based on inhalation rates and body weights will be made in the assessment.

Exposures from recreational pathways (incidental ingestion of sediment and dermal contact with sediment and water) will also be quantified using data from the Phase 2 database and methodologies that are as close as possible to the methodology used for Phase 1 risk assessment. In addition, other routes of exposure not evaluated in the original Phase 1 risk assessment based on inadequate data will also be evaluated to determine if adequate data is available currently for the quantification of risks and hazards. Assuming the exposures from these pathways are minimal compared to exposures resulting from fish consumption, it is expected to exclude these recreational pathways from further evaluation (i.e., Monte Carlo analysis). Where appropriate, relevant text referring to the exclusion of less significant exposure pathways from the Phase 1 report will be incorporated into this section of the Phase 2 report.

I. Calculation of Total Risks and Hazards.

Consistent with EPA risk methodology (U.S. EPA, 1989 and 1986) the total risks and hazards will be developed for the reasonably maximally exposed individual and the central tendency or average exposure. Risks and hazards will be added together across pathways and total risks and hazards presented in the risk characterization.

3. Toxicity Assessment

As in the Upper Hudson risk assessment (see Section II.3), the Mid-Hudson risk assessment will use the reference doses (RfDs) and cancer slope factor (CSF) for PCBs established by EPA. The values will be developed using the chemical and Aroclor specific chemical files on the Integrated Risk Information System (U.S. EPA, 1998a, b,c), the Agency's consensus database on toxicity. Endocrine effects analysis identified in the Upper Hudson River assessment will also be addressed here.

The toxicity values will not be evaluated in the Monte Carlo analysis in conformance with EPA's guidance (USEPA, 1997a).

The section summarizing information on the toxicity of PCBs for both cancer and non-cancer health effects for the Upper Hudson River risk assessment will also be provided.

4. Risk Characterization

The Risk Characterization section of the Phase 2 Mid-Hudson Risk Assessment report will closely follow the guidance put forth in the March 21, 1995 Risk Characterization Memo (U.S. EPA, 1995b), reflecting transparency in decision making process, clarity in communication, consistency, and reasonableness. This section will summarize the risks and provide a statement of confidence, discussing the strengths, limitations, and uncertainties inherent in the key scientific issues and science policy choices involved in the toxicity assessment, exposure assessment, and risk conclusions. Qualitative descriptive information will accompany numerical estimates of central tendency risks and hazards, high end risks and hazards, population risks, and if available, risks for highly exposed or susceptible subgroups. A detailed discussion of the uncertainties will be included based on the enhanced Monte Carlo analysis to evaluate variability and uncertainty in exposure parameters, using two phases to distinguish the impacts of variability and uncertainty. A qualitative description of additional uncertainties including the quality and quantity of available data, data gaps, measurement uncertainties, model uncertainties, the verification of any models used, the use of defaults, and plausible alternative approaches will also be described. The factors contributing the greatest uncertainty will be explicitly identified.

A. Calculation of Point Estimates of Central Tendency and High-End Individual Risks

Calculated point estimates of risks using standard EPA risk equations (U.S. EPA, 1989) and exposure estimates based on central tendency and high-end exposure parameters, as described in the preceding sections will be developed. The high-end and central tendency values will be derived using selected percentiles from the distributions generated.

B. Risks for Highly Exposed Subgroups

Since subpopulations of highly exposed and lesser exposed anglers will be represented in the distributions of risk generated in the Monte Carlo analysis, the risk assessment will not attempt to further distinguish any hypothetical subgroups with unusually high exposure. However, if any distinct ethnic subpopulations living near the Mid-Hudson River are identified who might consume high levels of fish from the Mid-Hudson in the absence of any fishing restrictions, a worst-case, bounding scenario to estimate the risks for this subgroup may be developed.

Theoretically, ethnic groups or small subpopulations of anglers may also preferentially eat different species of fish than the general angling population, but there are no data available on this issue. Therefore, as part of the uncertainty analysis, the second tier of the Monte Carlo analysis (described below), will use professional judgment to characterize plausible worst-case species-specific consumption rates.

C. Monte Carlo Analysis

As in the Upper Hudson Risk Assessment, the Monte Carlo analysis will evaluate annual exposures on a year by year basis, starting in 1999. The intake distributions will be based on the analyses of various exposure parameters described in the preceding sections. The Monte Carlo analysis will assume that each individual consumes fish at the 90th percentile of the distribution for their age with appropriate modification for bodyweight. The consumption percentile from year to year, chosen from the distribution of consumption rates, thereby assumes that fish ingestion rates are perfectly correlated each year. The Monte Carlo analysis will not assume a different ingestion rate each year, which would assume that there is no correlation between yearly ingestion rates and effectively average high-end consumers out of the analysis. Actual year to year ingestion rates are probably correlated to a high degree, but not perfectly (100%); unfortunately no data are available to quantitatively address this issue.

D. Additional Qualitative Discussions

Consistent with guidance from the March 21, 1995 Risk Characterization Memo (U.S. EPA, 1995b), the risk assessment will also provide qualitative discussions about other uncertainties which affect the risk results, such as limitations in the models used to project future PCB fish concentrations, database uncertainties, and other uncertainties inherent in each chosen parameter and distribution which were not addressed in the uncertainty phase of the Monte Carlo analysis. To the extent possible, relevant text from other reassessment reports, such as the modeling, data evaluation and interpretation report, and database reports, will be incorporated into the risk assessment document (U.S. EPA, 1995a, 1996a and 1997d).

E. Presentation of Results

The results of the analysis will be presented following the Risk Assessment Guidance for Superfund Part D (U.S. EPA, 1997d) guidance. In addition, the Monte Carlo Analysis information will be presented following the recommendations outlined in the EPA "Policy for Use of Probabilistic Analysis in Risk Assessment" (U.S. EPA, 1997a).

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