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July 24, 1992

Mr. Douglas Tomchuk
Hudson River PCBs Site Project Manager
U.S. Environmental Protection Agency
Region II - Room 747
26 Federal Plaza
New York, New York 10278

Dear Doug:

Enclosed are three copies of GE's comments on EPA's Phase 2 Work Plan and Sampling Plan (Review Copy) for the Hudson River Reassessment. I can provide you with additional copies as needed for EPA's staff, the Agency's contractors, and the administrative record.

I recognize that, as was the case for GE's comments on the Phase 1 Report, our comments on the Phase 2 Work Plan are once again quite lengthy. One critical point should not, however, be missed in the volume of information we have provided. If GE's comments, or for that matter any other party's comments, are not seriously considered before EPA's contractors begin the proposed data collection efforts, then the entire public participation process will have been a sham. In many areas, GE has pointed out flaws in the Work Plan that could make the Phase 2 results useless or, at a minimum, highly unreliable, thereby calling into question the credibility of the entire Reassessment process.

EPA cannot afford to wait eight (8) months to consider and respond to the enclosed comments, as it did to GE's Phase 1 comments. That will simply be too late. EPA may have, by that time, wasted government funds on work that will not lead to a scientifically supportable decision.

Very truly yours,

John H. Claussen

JHC:jgf

cc: P. Simon
D. Blazey
W. McCabe
K. Callahan

COMMENTS OF THE GENERAL ELECTRIC COMPANY

ON THE

JUNE 1992 REVIEW COPY

OF THE

PHASE 2 WORK PLAN AND SAMPLING PLAN

FOR THE

HUDSON RIVER PCB REASSESSMENT RI/FS

July 24, 1992

COMMENTS OF THE GENERAL ELECTRIC COMPANY
ON EPA'S PHASE 2 WORK PLAN AND SAMPLING PLAN

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APPENDIX

Appendix A: The Effects of Cooking Processes on PCB Levels In Edible Fish Tissue. ChemRisk - A Division of McLaren/Hart, July 9, 1992.

1.0 INTRODUCTION

1.1 Background and Summary

In its comments on EPA's Phase 1 Report, GE demonstrated that if EPA were to proceed with the Reassessment RI/FS, despite the absence of new evidence to warrant a change in the conclusions of the 1984 Record of Decision, EPA must correct three fundamental problems:

1. the absence of critical data;
2. the reliance on outdated, faulty assumptions; and
3. the use of an inadequate, qualitative method of analyzing the complex Hudson River system.

Although EPA has apparently taken several steps in the right direction, these fundamental problems persist in the Phase 2 Work Plan, albeit in a different context. Having recognized some of the shortcomings of its original approach, EPA must not now stop short of the goal -- to use the most scientifically valid, state-of-the art analyses available to ensure a decision that is technically reliable and credible. Regrettably, EPA's Work Plan does not measure up to this standard.

In essence, the deficiencies in the Work Plan fall into three major categories:

1. unjustified and unreliable shortcuts in the collection and analysis of data;
2. scientific techniques that are unproven or inherently unreliable as applied to the Upper Hudson River; and
3. insufficient detail regarding the nature of the work proposed and the connection (if any) between the work proposed and the Reassessment objectives.

If a PRP had submitted the Phase 2 Work Plan at any Superfund site, EPA would have rejected the document and demanded a much more detailed and extensive revision. For EPA itself to issue such a document at a site where it insisted on conducting the Reassessment RI/FS itself, to ensure that the work would be beyond reproach, undercuts its own credibility. The flaws in the Phase 2 Work Plan are particularly troublesome because the Hudson River is one of the most technically complex Superfund sites in the United States.

More important, these deficiencies create the substantial likelihood that, at the end of Phase 2, EPA will lack data of sufficient certainty and reliability to answer the fundamental questions posed by the Reassessment. As a result, the Agency will be forced to employ excessively conservative assumptions and revert to the simplistic, qualitative approach that was described in the Phase 1 Report. For reasons stated in GE's Phase 1 Comments, the risk that such an approach will reach erroneous conclusions is unacceptably high, particularly where an extensive dredging remedy will have disastrous environmental effects on a river that is by all accounts recovering naturally.

In this comment document, GE has taken a hard look at EPA's proposals for Phase 2 and has endeavored to provide EPA with workable suggestions for improving the Phase 2 work to the level and scope where it may serve as the basis for a Record of Decision.

1.2 Overview

Sections 2.0 through 8.0 below contain GE's detailed comments on seven major aspects of the Phase 2 Work Plan. The following sets forth the thrust of GE's comments.

1.2.1 Project Objectives

GE agrees with the general Reassessment objectives that EPA has, for the first time, articulated on page 5-1 of the Work Plan. The objectives correctly focus on the future effects of "No Action" versus other remedial alternatives.

A fundamental problem with the Work Plan, however, is that there is a pervasive "disconnect" after this statement of general objectives. Specifically, EPA has not taken the next step of refining the objectives to the point where they can be linked to specific data collection and analysis tasks. The project planning process, for instance, can be visualized as a pyramid with the overall project objectives at the top of the pyramid and the data collection activities at the base. What is missing in EPA's Work Plan is the middle of the pyramid -- *i.e.*, the logical framework for connecting the data collection and analysis tasks to the questions that need to be answered.

For example, the Work Plan states (p. 1-3) that one of two major questions to be addressed is "which source areas, if any, may require remediation" to achieve necessary reductions in fish tissue concentrations. Nowhere in the document, however, does EPA delineate what specific source areas it will examine. Although EPA has divided 200 miles of river into four study areas, EPA never dissects the study area that appears to be the primary focus for possible remediation: Study Area B (Federal Dam to Fenimore Bridge). For instance, EPA fails to distinguish between the area north of the remnant deposits, the remnant deposits themselves, various reaches of the Thompson Island Pool, and the area south of the Thompson Island Pool. Without such a clear delineation -- *i.e.*, without the middle of the pyramid -- EPA's data collection program will be unable to pinpoint "which source areas . . . may require remediation."

Thus, EPA's failure to build a sound structure for connecting its data collection and analysis with specific project objectives raises the possibility that EPA will ultimately rest its decision, not on good data and good science, but on unarticulated assumptions and qualitative speculation.

1.2.2 <u>Data Collection</u>

EPA's failure to articulate the Reassessment objectives in sufficient detail irreparably taints the Phase 2 Work Plan's description of data collection and analysis efforts. Indeed, the Phase 2 Work Plan does not even comply with EPA's own RI/FS guidance documents, which require work plans to contain a Quality Assurance Project Plan and detailed discussions of matters such as sampling locations and frequencies, sampling equipment and techniques, and chain-of-custody documentation. These omissions prevent GE and other parties from fully commenting on the Work Plan and call into question EPA's ability to perform the Reassessment in a manner consistent with the National Contingency Plan.

Where GE has been able to discern the data tasks proposed for Phase 2, it is apparent that EPA has outlined a program better described as a research agenda, rather than a sensible data collection plan based on technically reliable and appropriate analytical methods. As a PRP, GE could not propose such unreliable research tasks for an RI/FS, nor would it be liable under CERCLA to reimburse EPA for such a program.

A prime example of this misuse of scientific techniques is EPA's proposal to embark on a high resolution sediment coring program and to employ a novel radionuclide-dating technique of data analysis. Among the purposes of this data collection and analysis plan is to reconstruct historical PCB concentrations and sources in the Upper Hudson. This effort, however, is seriously misguided.

Although the measurement of radionuclides to mark dates in sediment cores has been applied by researchers in lakes and ocean environments where quiescent hydrodynamic conditions produce relatively constant deposition rates over broad regions of a water system, such conditions do not necessarily exist in river environments, where wide periodic and spatial variations in flow and mixing prevent orderly chronological and undisturbed layering of sediments. In particular, although the radionuclide dating technique might be validly applied in certain areas in the Lower Hudson, there is little question but that this approach cannot validly be applied in the Upper Hudson. Indeed, Dr. Richard Bopp (a leading researcher in this field) remarked at a July 1992 meeting of the Scientific and Technical Advisory

Committee that in attempting to use the radionuclide dating technique in the Upper Hudson for the purposes articulated by EPA, the Agency was taking the technique beyond the point of feasibility.

Misuse of radionuclide dating might not be so significant if the program were a peripheral exercise in which EPA was attempting to use creative methods to check data and conclusions reached by other means or otherwise attempt to reduce uncertainties. In this case, however, the radionuclide dating program is one of the main data collection tasks, and it apparently forms the basis for the most important scientific determinations that EPA must make in this matter. This cannot be.

What is more, EPA proposes (pp. 3-10, 3-17) to reconstruct history by analyzing sediment and water samples that have been literally sitting on a shelf for over a decade. The collection, extraction, and storage conditions of these samples are unknown, yet EPA plans to draw some of its most crucial conclusions about river trends from these samples. If a PRP had proposed this data element for the Work Plan, EPA would not hesitate to reject it out of hand. The Agency's double standard in this respect is both inexplicable and appalling.

1.2.3 Quantitative Modeling

EPA has taken the appropriate step of recognizing that an integrated, quantitative model of PCB fate and transport is an essential component of a credible and technically defensible Reassessment. Unfortunately, the contaminant fate and transport analysis proposed in the Phase 2 Work Plan employs numerous oversimplifications and shortcuts that will increase the uncertainties associated with the results.

For example, EPA's model analyzes broad spatial reaches of the River over long periods of time, even though conditions are known to change dramatically over much smaller spatial and temporal scales. It also relies on questionable techniques such as the use of radionuclide dating to define historical sediment concentrations in the Upper River. Moreover, the Work Plan fails to detail how EPA's model will be calibrated and verified with the existing data.

EPA justifies its proposal to use a cheaper, cruder model by stating that detailed answers are not necessary for the questions it has framed. The fallacy of this approach lies in the assumption that the answers for the Hudson are simple. The Hudson River is one of the most complex river systems ever to be examined by EPA, yet EPA proposes a simpler model for the Hudson than previously used by EPA at many other sites, including the James River, the Saginaw River, and New Bedford Harbor. EPA must reverse its rejection of the use of a state-of-the-art model to analyze contaminant fate and transport at this highly complex and dynamic site.

1.2.4 <u>Human Health Risk Assessment</u>

Although EPA has recognized that significant new scientific information regarding PCB toxicity exists, Region II has unfortunately abdicated its responsibility to consider such new information in the context of the Reassessment. The Region cannot simply wait for EPA Headquarters to act. The "it's not my job" attitude expressed in the Phase 2 Work Plan is contrary to EPA's risk assessment guidance and irresponsible.

Moreover, although GE is encouraged that in the area of risk assessment EPA has recognized the value of Monte Carlo analyses, EPA has mistakenly underestimated the utility of a Monte Carlo simulation by relegating it to the status of an uncertainty check. Monte Carlo analyses are valuable tools for estimating risks because the technique considers the full range of possible exposure scenarios, rather than relying on unrealistic default assumptions about hypothetical maximum exposures. This fact is explicitly recognized in EPA's new risk assessment policy (EPA, 1992b). Because EPA considers the driving force behind the Reassessment to be human health risks due to consumption of PCB-contaminated fish, EPA must use the most up-to-date, tested methodology for estimating such risks. To estimate risks to the average and high-end individuals, EPA must now use Monte Carlo simulations.

In conducting a Monte Carlo analysis, EPA must take into account information regarding site-specific fish consumption rates (rather than default rates based on salt water fisheries), appropriate fish tissue data (species that humans eat), and losses of PCBs during cooking. Most important, EPA must consider the latest NYSDEC data (the 1991 survey) on PCB concentrations in Upper Hudson fish -- these data show continuing dramatic decreases in average PCB concentrations to levels near the FDA limit.

1.2.5 Ecological Risk Assessment

The ecological risk assessment framework presented in the Phase 2 Work Plan is ill-defined, open-ended, and ultimately unproductive. EPA proposes to do little more than it did in Phase 1 -- namely, identify species of concern and compile findings based on a review of the toxicity literature. The only additional task proposed in Phase 2 is some sort of vague "reconnaissance survey."

EPA must move beyond the use of mere buzzwords and headings to create the illusion that appropriate substantive analyses are being undertaken. In reality, EPA is presuming the very issue under consideration -- a cause-and-effect relationship between the presence of PCBs in Hudson River sediments and harm to the ecosystem. EPA must define its ecological assessment goals and then rewrite the Phase 2 Work Plan to describe how those goals will be achieved through an examination of real-world conditions.

Such an analysis will require EPA to shift its focus from a "bottom-up" approach to a "top-down" assessment that will analyze the impacts of various stressors, not just PCBs, on the ecosystem. A top-down assessment must address two objectives: (1) assessing the current overall health of the River by examining its ecological history or by comparing the ecological health to that of a similar river (*e.g.*, one with locks, dams, and active barge traffic) and (2) identifying actual PCB-related effects that significantly impair the ecosystem (looking at specific species present in the ecosystem). The amorphous "reconnaissance survey" proposed by EPA will fulfill neither objective.

If an ecological risk assessment is to play a meaningful role, EPA must re-evaluate the information to be gained from such an assessment and revise its Work Plan accordingly. EPA's recent report entitled Framework for Ecological Risk Assessment (EPA, 1992f) may serve as a guide for this revision.

1.2.6 <u>Other Source Investigations</u>

GE's Phase 1 Comments addressed the need to identify and characterize other sources of PCBs to the River for two purposes: (1) to assess the benefits of potential remedies (*i.e.*, whether the correct areas of contamination are being addressed) and (2) to fulfill EPA's obligation to identify all PRPs. The former objective is particularly important at this site, because unless other sources are adequately characterized, EPA may well order a misguided remedial action that not only grossly overstates the potential remedial benefit, but also actually causes significant environmental harm to a generally healthy river.

Obviously, the identification and characterization process requires EPA to look not only to *present* sources, but also to the many and varied *historical* sources (areas of contamination) that may continue to influence PCB levels in Hudson River sediment, water, and biota. In its Phase 2 Work Plan, however, EPA reveals its intention to look only at SPDES discharges. Such a superficial inquiry is clearly inadequate to fulfill either objective mentioned above.

For example, EPA completely ignores the illustrative information on other sources that GE provided in its Phase 1 comments. EPA's proposed approach also severely hampers its ability to identify remedial actions, if any, necessary to achieve acceptable risk levels, because necessary actions cannot be identified until all non-negligible sources of PCBs have been adequately defined. In particular, EPA must identify sources that have contaminated Lower River sediments where resident and migratory fish eat and spawn. EPA's decision not to use methods that are uniquely available to it to identify and determine the significance of other PCB sources is inexplicable.

1.2.7 Feasibility Study Analysis

EPA's proposed feasibility study analysis in the Phase 2 Work Plan places the cart before the horse. EPA has taken a giant leap in proposing (p. 8-1) to identify "the areas and volume of sediments . . . subject to possible remedial action," before it has even determined the effects of No Action versus other remedial alternatives. GE is at a loss to understand how EPA can identify areas and volumes subject to remediation at the same time that it is determining (through risk assessment and modeling) whether in fact a significant current and future risk exists. EPA's proposed Phase 2 feasibility study apparently presumes the conclusion of these analyses.

Moreover, even to the extent EPA properly identifies feasibility questions for Phase 2, the Work Plan ignores the complexities and difficulties of any removal option. Ultimately, EPA must face the reality that removal also means stockpiling, dewatering, treating, handling, and disposing of potentially massive amounts of sediment. The practicalities and adverse impacts of all those activities must be consciously and realistically weighed against the perceived benefits. As currently written, EPA's Phase 2 Work Plan will not enable EPA to measure and weigh those costs and benefits in a sound, scientific manner. The Work Plan must be revised.

* * *

For all the differences between EPA and GE (discussed in detail in these comments), this much is common ground: To reach a legitimate and credible decision in this Reassessment, EPA must perform scientifically valid analyses that are based on reliable and appropriate data. As these comments indicate, however, the data collection and analysis tasks outlined in the Phase 2 Work Plan do not meet this standard. As a result, EPA will spend a great deal of time and money collecting and analyzing data that ultimately will contain unacceptably large uncertainties. GE is therefore genuinely concerned that EPA will then "fall back" on the sort of simplistic and qualitative analysis that was described in the Phase 1 Report and that GE criticized in its Phase 1 Comments. To avoid such a result, EPA should take an earnest look at the Phase 2 Work Plan and revise it to ensure that good science and good data prevail.

2.0 PROJECT OBJECTIVES AND DATA ANALYSIS

For the first time in the two and one-half years since EPA began this Reassessment RI/FS, EPA has articulated a set of project objectives and has ostensibly formulated a data collection and analysis plan designed to meet those objectives. Unfortunately, while GE generally agrees with EPA's overall project objectives, GE fails to see the connection between the data collection and analysis plan contained in the Phase 2 Work Plan and those overall objectives. Any connection is at best unclear, and at worst nonexistent.

A major failing of the Phase 2 Work Plan -- and hence a focus of these comments -- is that EPA's proposed data collection and analysis plan fails to specify how the results of those tasks will be used to fulfill the project objectives. This failure is a critical flaw in the Work Plan, for at the end of the day EPA will have collected and analyzed significant amounts of data without a logical plan for *using* the data to answer the questions that lie at the heart of the Reassessment. EPA's failure to map a coherent plan for connecting its data collection and analysis with specific project objectives therefore raises a significant possibility that EPA will ultimately rest its decision not on good data and good science, but on unarticulated assumptions and qualitative speculation.

The need to define and refine project objectives is not unique to a Superfund RI/FS. Rather, it is the essence of responsible project management. Such an approach is necessary for not only the most complex research projects, but also for the most mundane daily tasks. This process of project planning can be depicted as a pyramid, where the broad project objectives or goals sit atop the pyramid. (See Figure 2-1.) At the base rest the data collection activities. In order to reach the top of the pyramid, one must first identify the necessary building blocks. Thus, a project manager must examine the broad project objectives and determine the steps that must be taken to reach that goal. This process includes identifying suitable methods of analyses to answer the relevant question and the data needed to conduct such analyses. The connections between the project goals and the analyses -- and between the analyses and the data needs -- consist of refined and detailed objectives that provide the structural support for the pyramid. In the Superfund context, these refined and detailed connections are generally referred to as "data quality objectives" (DQOs). The DQOs provide a logical framework for data analysis and interpretation and serve to establish the requisite quantity and quality of the data to be collected.

When EPA's Phase 2 Work Plan is viewed in the context of the above framework, it is clear that the Work Plan is poorly conceived. As these comments demonstrate, although EPA has articulated overall project goals, it has failed to specify, or perhaps even to consider, how its proposed data collection efforts will achieve the overall project objective. Data quality objectives are not even mentioned, and the data interpretation and analysis framework is presented in the sketchiest of terms. Detailed comments on specific flaws and limitations of the Phase

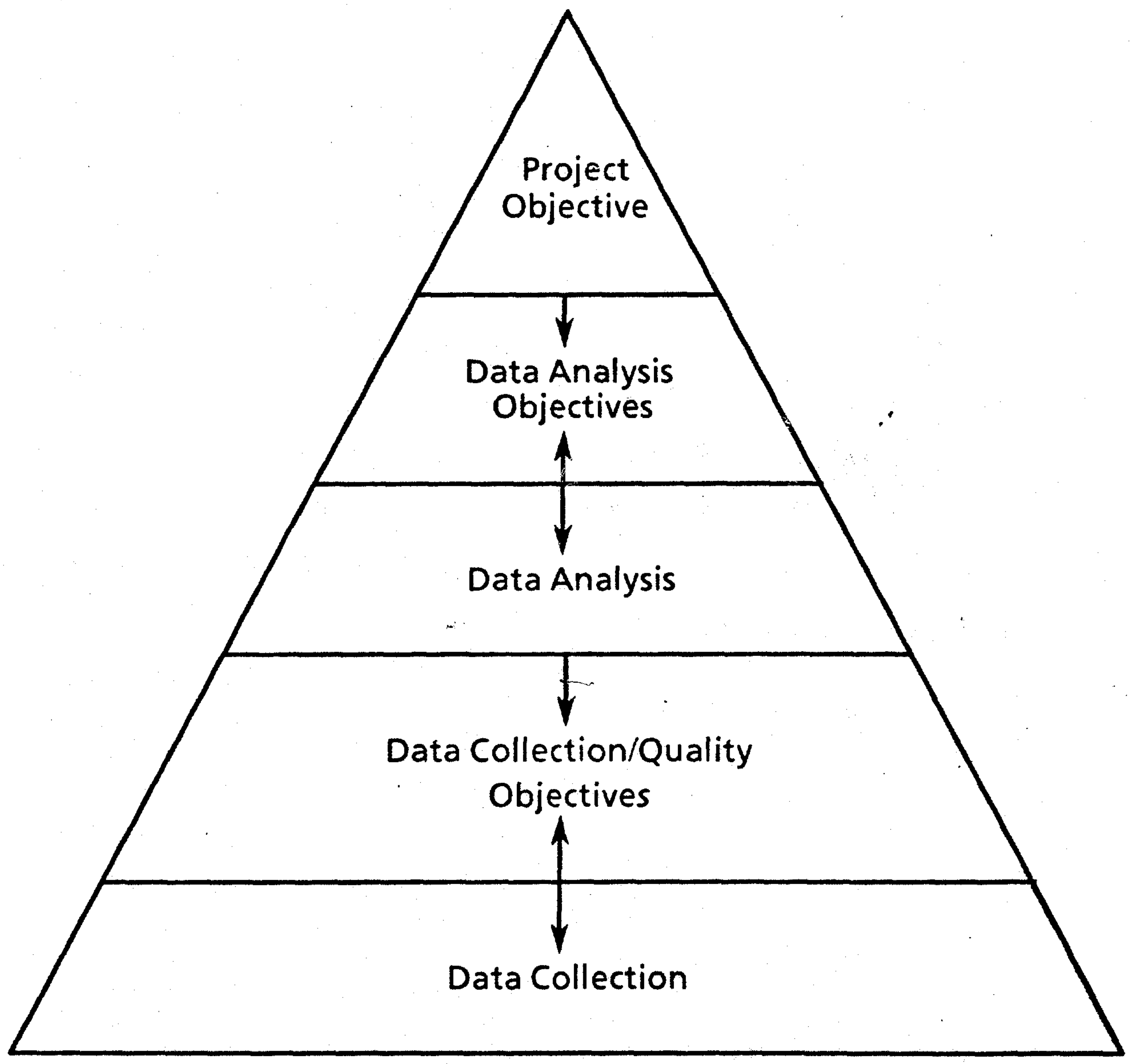

Figure 2-1
Project Planning Pyramid

2 Work Plan scheme are presented in the remainder of this comment document. In this section, GE sets forth its attempt to understand the project objectives and to provide EPA with the requisite refinements necessary to adequately scope and plan data analysis, interpretation, and collection activities. GE trusts that upon consideration of the questions posed in this section of the comment document, EPA will take a hard look at its proposed Phase 2 activities and come to the recognition that they do not measure up to the task at hand.

2.1 EPA's Articulation of Project Objectives

EPA first articulates the general objective of the Reassessment in the introduction to the Phase 2 Work Plan, where EPA correctly states (p. 1-3) that "[t]he Reassessment requires knowledge of the source areas of PCBs and the future impact of PCBs in the Hudson River system under conditions of No Action and various remedial alternatives." In an attempt to focus the Phase 2 work based upon the results of the Phase 1 analyses, EPA specifies (p. 1-3) two "major questions" to be addressed:

> what is the reduction in PCB levels which is necessary to decrease fish tissue concentrations to levels that meet human health criteria and; the ancillary question of which source areas, if any, may require remediation in order to achieve that reduction.

Although this statement presupposes that unacceptable concentrations and human exposures currently exist, GE considers this statement to be generally consistent with the requirements of CERCLA and its implementing regulations. While this objective can be used as a general guide to develop data analysis and collection approaches, it is too broad to be used to specify the details of such approaches.

Perhaps in an attempt to refine the introductory statement into workable project objectives, the Work Plan later lists (p. 5-1) the following, somewhat more specific objectives:

1. When will PCB levels in the fish population recover to levels meeting human health criteria under continued No Action?

2. Can remedies other than No Action significantly shorten the time required to achieve acceptable risk levels, or could it make the current condition worse?

3. Are there sediments now buried and effectively sequestered from the food chain which are likely to become "reactivated" following a major flood, resulting in an increase in contamination of the fish population?

Subject to the comment that EPA must also assess the human health and ecological risks both of current conditions and of any remedial action selected, GE also agrees that these questions are appropriate ones on which the Reassessment should focus. However, GE believes that EPA has not undertaken the requisite analysis of the components of these questions, and, as a consequence, has failed to propose data collection and analysis activities that will enable EPA to reach a scientifically credible and reliable decision in the Reassessment.

2.2 Critical Analysis of EPA's Objectives

When EPA's project objectives are separated into their various components and compared with the proposed Phase 2 data collection and analysis program, two things are clear: (1) numerous questions relating to the objectives remain unanswered and (2) the proposed Phase 2 work cannot sufficiently answer the questions posed by the objectives. Discussed below are some of the questions and issues that EPA must consider when it re-defines the data analysis framework and the details of the data collection effort.

2.2.1 **"PCB Levels in the Fish Population"**

EPA fails to define both the relevant PCB levels and fish populations of concern. With respect to the former, PCB levels may be measured either on a wet-weight basis or on a lipid-normalized basis. PCBs in fish may also be measured by reference to the whole fish or by reference to fillets. And PCB levels have been shown to change as a result of cooking. To ensure that the correct data collection and analysis is performed, EPA must clarify which of these many ways of identifying "PCB levels" it will use in addressing the project objectives.

With respect to the fish populations of concern, EPA must specify the fish species and river locations that are relevant to the project objectives. As discussed in Sections 3.0 and 5.0 of these comments, the primary species of interest should be those that recreational fishermen are likely to consume. Although other species could be evaluated for ecological effects, there are currently no data to indicate adverse impacts to such other species. The focus should therefore be only on fish of recreational interest.

EPA must also define the specific portions of the River that are of concern. EPA oversimplifies the sources of PCBs to the Lower Hudson fish and apparently assumes that Lower River fish act as receptors for PCBs coming over the Troy Dam. As detailed in Sections 5.0 and 7.0 of these comments, EPA's oversimplification neglects the existence of other present dischargers of PCBs to the Lower River as well as areas of historic sediment contamination. To the extent that EPA fails to evaluate these other sources of PCBs to Lower River fish, EPA should restrict its analysis to Upper River fish.

2.2.2 <u>"Continued No Action"</u>

GE concurs with EPA's statement that a primary goal of the Reassessment RI/FS is to understand how PCB levels in fish -- and hence potential human health risks that are associated with fish consumption -- change with time under No Action and alternative remedial scenarios. Because PCB levels in fish are declining over time, and because EPA currently assumes (for carcinogenic risk purposes) that the period of exposure is cumulative and is 30 years, EPA must estimate PCB levels in Upper Hudson fish for a period of 30 years from the time a decision might be made on this project.

In doing so, EPA must specify the conditions under which it assumes "continued No Action." For example, does "continued No Action" include the effect of fishing restrictions or advisories? Will EPA account for natural bioremediation of PCBs in Upper Hudson sediments? How will EPA account for the contribution of PCBs to the system from the remnant deposits? This question is particularly important, because the existing data on PCB levels in sediment, fish, and the water column include an unknown contribution of PCBs from the remnant deposits (which have been the subject of a Superfund remedy). A 30-year projection of PCB levels in fish, based on this unrepresentative data and using an overly simplistic statistical model or correlation, will yield questionable results with high levels of uncertainty. Accordingly, EPA must account for the fact that the remnant deposits have been capped and that future contributions of PCBs from the remnant deposits to the system are greatly reduced.

2.2.3 "Remedies Other Than No Action"

EPA must specify the various remedial alternatives that it will use in evaluating the effect of remedies other than No Action. This definition of remedial alternatives is important, because GE cannot fully comment on EPA's approach without knowing the different types of remedial scenarios EPA that will be considering.

In particular, the existing database indicates that several potential sources of PCBs to the fish may exist in the Hudson River. A fundamental objective of this Reassessment must be to isolate the effects of different PCB sources on fish levels. Because EPA must understand what effect a given remedy might have in comparison to No Action, EPA must clearly define the current and potential sources of PCBs in the Hudson River and how they will behave over a 30-year period. In addition, such an analysis will ensure that the proper data collection will be undertaken, because only by doing so will EPA be able to model the behavior of these sources 30 years into the future under No Action and the remedial alternatives that it has defined.

Possible sources that GE believes EPA should consider include:

1. <u>The Remnant Deposits</u>: This source has been capped, and GE is currently monitoring the effects of this capping. Data on how this PCB source will behave in the future must be incorporated in the data collection effort.

2. <u>Upstream of the Remnant Deposits</u>: The data presented to EPA by GE in early 1992 show the presence of a source of PCBs below the Fenimore bridge and above the Remnant Deposits. This source may be a significant percentage of the PCB load in the Hudson River. A data collection effort is needed to identify the nature of this source so its current and future impact can be evaluated.

3. <u>Upstream of the Study Area</u>: A careful definition of background concentrations of PCBs in water and fish should be made. EPA must account for background levels for the obvious reason that any current and future risks that result from such levels must be distinguished from PCB contributions within the Study Area.

4. <u>PCBs Bound to Sediment in the Upper Hudson</u>: EPA must analyze the extent to which these sediments contribute PCBs to current and future fish levels. Such an analysis requires an understanding of both the transport of sediment during a range of flow events and the fate of PCBs released from these sediments. In particular, EPA must evaluate two distinct pathways of PCBs

from the sediment to the water and the fish: resuspension of PCB-laden particles into the water column and direct uptake of PCBs from the sediment to the biota. Because the existing data are inadequate to fully characterize such mechanisms, EPA must collect additional data to ensure that this source is adequately considered.

Also, the spatial distribution of PCBs in Hudson River sediment has historically been recognized as highly heterogeneous. EPA must therefor specify what spatial scale is of interest. Will EPA look at an area of the river such as a so-called "hot spot"? Will EPA instead view the sources as portions of each pool (*e.g.*, one- or two-mile segments)? Or, will EPA merely view the sediments in each pool as a separate potential source of PCBs? It is necessary to have sufficient data on sources at the spatial scale selected so that the effect of action versus No Action can be simulated for the control of the particular source at issue.

5. PCBs in the Pore Water of Sediment in the Upper Hudson: PCBs present in the pore water of sediment may enter the food chain by at least two mechanisms: (1) direct ingestion or contact by benthic organisms or (2) diffusion or advection of the pore water into the water column and subsequent uptake of the water by the biota. Because the existing data are inadequate to fully characterize such mechanisms, EPA must also collect additional data to ensure that this source is adequately considered.

6. <u>Current and Future Sources to the Lower River</u>: In addition to PCB transport from the Upper River to the Lower River, a number of probable active sources of Lower River PCBs also exist. Details on these sources can be found in Section 6.0 of these comments and in GE's comments on the Phase 1 Report. As with the other sources mentioned above, EPA must design a data collection and analysis plan to separate the effects of PCBs from these different sources.

2.2.4 "Significant" Time Frame

As part of its project objectives, EPA must compare the time required for PCB levels in fish to reach an acceptable level under conditions of No Action and under various remedial alternatives. EPA must therefore have sufficient data and a reliable predictive tool for projecting PCB levels in fish under various remediation scenarios, including No Action.

EPA must also (but does not) define the term "significant." To be justifiable, a remediation project must of course result in some significant benefit to human health and the environment. In the context of the Hudson River Reassessment RI/FS, the reduction in the time for PCB levels in fish to decrease to a level benefiting the risks to human health associated with a particular remedial action must be sufficient to justify any negative environmental consequences of the remedial action. In both the New Bedford and Commencement Bay Superfund sites, EPA concluded that a significant time frame for reduction of PCB levels was ten years. GE believes that ten years is a reasonable point of departure and should be the initial criteria employed by EPA in the Reassessment RI/FS.

2.2.5 PCBs "Reactivated" by a Flood

EPA also proposes to consider the effects of extraordinary river flow (*e.g.*, 100- and 500-year floods) on PCB levels in the Hudson River. Although GE believes that this analysis is less important than understanding the River as it generally behaves, if EPA is intent on performing such an analysis it must properly perform such an analysis.

Proper analysis requires that EPA first define the relevant flood event. The Work Plan suggests (p. 5-18) that EPA will consider both a 100-year and a 500-year flow event. Although the use of a 100-year event (which is used in flood management efforts) seems reasonable, EPA's proposal to use a 500-year flood in its decision-making is unusual and unnecessary. Not only is analysis of a 500-year flood overly conservative, but any calculation of the magnitude and effects of a 500-year flood is bound to be subject to great uncertainty.

More important, EPA must define how any such flood will affect PCB levels in fish over the 30-year period of interest. The fact that sediments containing PCBs are moved does not necessarily demonstrate an unacceptable effect. What is the effect, for instance, of a five percent redistribution of sediment in the Thompson Island Pool? To answer these sorts of questions, EPA must connect its flood model to a food-web model so that the effects of a flood on PCB levels in fish over a 30-year period can be properly evaluated.

2.2.6 "Making the Current Conditions Worse"

EPA must also assess the negative impacts of a given remedial action with the same level of detail and precision as it assesses the positive effects. Such an evaluation must include not only the effects of resuspension of PCB-contaminated sediments during dredging, but also the time it takes for the ecosystem to recover due to the loss of habitat that results from removal of sediment in the shallower areas of the River.

2.3 Summary of Objectives

The brief analysis above shows that EPA must refine its project objectives and design a data collection and analysis program that will fulfill these objectives. Specifically, GE believes that EPA's objectives require the following refinements:

- The analytical tool or quantitative model must be able to project, as reliably as the data will permit, PCB levels in fish 30 years into the future.

- No Action projections must account for the fact that the existing database includes PCB contributions from remnant deposits that have since been remedied, and that contributions to the problem are coming from sources that EPA appears to deem outside of the scope of this Reassessment.

- The scope of the project must be carefully defined, and EPA should focus its resources on investigating the effects on PCB levels in fish in the Upper River, due to confounding factors in the Lower River and to the attenuated effects of Upper River remedies on Lower River fish. Moreover, efforts should be particularly focused on those Upper River fish that are of interest to anglers.

- Due to the size and complexity of this Reassessment, EPA should understand and minimize the uncertainties in the estimated risks. This may be accomplished by using Monte Carlo modeling techniques and by relying on site-specific data instead of overly conservative, inapplicable default exposure assumptions.

- Multiple sources of PCBs exist in the Upper River. Since remediation will be targeted at these sources, EPA will need a tool that will predict, 30 years into the future, how PCB levels in fish change over time if one or some of the PCB sources are eliminated or minimized. This projection must be able to account for the fact that the processes affecting the release of PCB's from these sources may change over time. Additionally, the data collection effort must be targeted to fulfilling the data requirements of the model, not only to understand the processes that affect PCBs in the river, but also to incorporate a spatial resolution sufficient to reflect the potential scale of remediation.

- The results of the flood model must be linked to a food-web model so that 30-year projections of PCB levels in fish can be made.

In sum, EPA must clearly define its project objectives and modify its data collection and analysis approach to ensure that its proposed approach will meet the project goals. In addition, EPA must adopt a more rigorous approach for this project and move away from untested and unfocused research projects. EPA should instead adopt reliable, scientifically defensible techniques that will allow predictions to be made on the behavior of PCBs in the River with the highest level of certainty.

2.4 EPA's Proposed Analyses Are Inadequate

From the foregoing analysis, it is clear that the overriding problem with the Phase 2 Work Plan is that EPA has separated its development and discussion of proposed data collection and analysis activities (Sections 3.0 and 4.0 of the Work Plan) from its development and discussion of project objectives (Sections 1.0 and 5.0 of the Work Plan). Thus, it is not at all clear that EPA has thought through the issue of whether the data to be collected and the analyses to be undertaken will be adequate to answer the questions fully or meet the objectives. (A variation on this theme is present in Sections 7.0 and 8.0 of the Work Plan where neither the data collection or analysis activities nor the project objectives associated therewith are presented with anything approaching clarity.)

A detailed assessment of EPA's data collection and analysis plan -- *in the context of EPA's stated project objectives* -- raises serious concerns about the adequacy of the Phase 2 Work Plan. The most significant of these concerns is that EPA will ultimately have insufficient data to perform the level of modeling required to answer the questions of concern. As a result, there is a significant possibility that EPA will be forced to revert to a simplistic, qualitative evaluation of the questions posed. Because such an approach necessarily generates greater uncertainties, EPA and other public health regulatory agencies will be constrained to invoke overly conservative assumptions and will therefore likely select a remedial alternative that produces negligible benefits, if any.

Such a result may well be acceptable at some sites, particularly where some inherent uncertainty is unavoidable and where the consequences of making an incorrect decision are not significant. At the Hudson River site, however, an extensive dredging program could have devastating short- and long-term impacts on the environment. As GE explained in its comments on EPA's Phase 1 Report, EPA must therefore employ the best and most reliable tools available to meet its objectives. Given the importance of this Reassessment decision, EPA must fully refine its projects objectives and revise the Phase 2 Work Plan to provide for data collection and analysis that will provide the requisite information. By forgoing such a refinement, EPA will find itself with a decision clouded with uncertainty.

3.0 DATA COLLECTION

At first blush, EPA's proposed data collection program appears to be an ambitious plan for collecting data relevant to the project objectives. Upon closer scrutiny, however, it becomes apparent that the Phase 2 Work Plan suffers from flaws ranging from the omission of routinely required documentation (such as a Quality Assurance Project Plan) to the proposed analysis of sediment and water samples that have been archived for over a decade. As discussed in detail below, these and other flaws demonstrate that the Phase 2 Work Plan is glaringly inadequate to the task at hand.

3.1 Insufficient Detail

At the outset, the data collection section of the Phase 2 Work Plan lacks sufficient detail to determine whether the broad objectives specified by EPA will be met or whether the Work Plan even meets the requirements of EPA's own program guidances or policies. The Work Plan does not, for example, contain the details of sampling and analysis methodologies or a Quality Assurance Project Plan (QAPP). Such sampling and analysis methodologies are required under EPA's own RI/FS guidance document for an RI/FS in which field activities are planned (EPA, 1988b, p. 2-12). EPA cannot satisfy this requirement merely by appending a "Sampling Plan" onto the Phase 2 Work Plan, particularly where EPA's "Sampling Plan" fails to describe the sampling activities with sufficient detail and fails to include an implementation schedule. The Phase 2 Work Plan thus does not meet EPA's own requirements for an RI/FS Work Plan.

More important, the data collection elements of the Work Plan are conceptual at best. EPA should hold itself to the same standards that it would use to judge the adequacy of work performed by a PRP. If a PRP were to submit a work plan that failed to include the level of detail sufficient to convey the complexities of the work or that failed to include entire sections (*e.g.*, a QAPP), EPA would certainly order that PRP to revise the document (probably under threat of penalty) prior to implementation. EPA's double standard in this respect is grossly unfair.

Specifically, the Phase 2 Sampling Plan does not adequately address the following required elements of a proper Field Sampling Plan (FSP): sample location and frequency, sampling equipment and procedures, and sample handling and analysis. With regard to sample location and frequency, the number of samples to be collected along with the appropriate number of replicates and quality assurance/quality control (QA/QC) samples must be clearly identified. (EPA, 1988b, p. B-7). Although EPA's Work Plan indicates general sampling locations, it does not indicate the number of replicates or QA/QC samples to be collected.

The following description provided in EPA's RI/FS guidance regarding sampling equipment and procedures illustrates how the Phase 2 Work Plan fails to meet the requirements of EPA's own guidance:

> Sampling procedures must be clearly written. Step-by-step instructions for each type of sampling are necessary to enable the field team to gather data that

> will meet the [data quality objectives]. A list should include the equipment to be used and the material composition (e.g., Teflon, stainless steel) of the equipment along with decontamination procedures. (EPA, 1988b, p. B-7).

The Phase 2 Work Plan blatantly omits the level of detail required for a proper description of sampling procedures and equipment. For example, with respect to the high resolution sediment coring program, the Work Plan states (p. A-7): "All cores will be collected using a hand coring technique whenever possible." EPA, however, fails to describe any details of the hand coring procedure or of the method to be used if hand coring is not possible.

Another example of the lack of detail is EPA's discussion (p. 3-3) of water column transect sampling in the Work Plan: "The individual sampling events will be performed so as to follow in a general fashion the same parcel of water as it travels through the Upper Hudson." The Work Plan fails to provide a specific sampling procedure to accomplish this goal. The Work Plan's discussion of equipment required for Phase 2 activities is also sketchy at best. For example, the Work Plan fails to specify the filter size to be used for water column samples and the details of EPA's plan to x-ray sediments to confirm geophysical survey results.

In its RI/FS guidance of the sample handling and analysis section of an FSP, EPA states "a table should be included that identifies sample preservation methods, types of sampling jars, shipping requirements, and holding times." (EPA, 1988b, p. B-7). Yet, the Phase 2 Work Plan omits these important details. A proper FSP also includes site-specific procedures for proper handling and disposal of wastes generated on-site (EPA, 1988b, p. B-8), but EPA's Phase 2 "Sampling Plan" makes no mention of such procedures.

In addition, as stated in EPA's RI/FS guidance, "the FSP should be written so that a field sampling team unfamiliar with the site would be able to gather the samples and field information required." (EPA, 1988b, p. 2-16). The Phase 2 Work Plan falls short of this standard. Armed with only the Work Plan as written, a sampling team would likely be unable to accomplish sampling objectives effectively or to determine whether the sampling and analysis program will be implemented in a manner consistent with industry standards.

As indicated earlier, EPA's failure to include a QAPP in the Phase 2 Work Plan makes a thorough review of EPA's proposed data collection program impossible. At a minimum, however, review of the following elements is critical to gain an understanding of how an RI/FS program will meet the program objectives: quality assurance objectives, sample custody, analytical procedures, data validation, and internal quality control. (EPA, 1988b, pp. B-4 to B-7).

3.1.1 Quality Assurance Objectives

Discussion of quality assurance objectives in a QAPP includes the presentation of quantitative limits for accuracy of spikes and reference compounds, precision, and method detection limits. (EPA, 1988b, p. B-5). This information -- missing in the Phase 2 Work Plan -- is required to determine whether the data collection tasks will meet program objectives. Moreover, data quality characteristics that should be considered during study planning include completeness, representativeness, and comparability. (EPA, 1988b, p. B-5).

Comparability is especially critical to the congener-specific analyses of archived water and sediment samples, because EPA intends to compare those results with congener-specific analyses of new water and sediment samples. To evaluate the data collection elements of the Work Plan properly, EPA must determine whether it is scientifically reasonable to compare data from samples possibly archived as long as fifteen years with data from new samples (which may have been collected under different conditions or with different sampling methods).

In short, EPA must construct a "bridge" between the current data and the extensive historical database. The Work Plan as written fails to provide sufficient information to permit a neutral observer to compare current data to past data and to understand the reasons for any differences in the data (*e.g.*, whether observed differences are due to changes in analytical or sampling methodology or whether there has actually been a change in conditions over the intervening years since sample collection).

3.1.2 <u>Sample Custody</u>

The Phase 2 Work Plan likewise fails to discuss sample custody documentation, as required by EPA guidance documents. (EPA, 1988b). Sample custody procedures and documentation are important both for EPA's data collection and for its proposed analysis of archived water and sediment sample extracts. Documentation is particularly critical for the latter analyses, because the results of those analyses will be compared to newly-generated data to assess changes in PCB concentrations and type over time. Thus, to evaluate the ability of this task to meet this objective, the Work Plan must include information on the status of sample custody for the lifetime of *each* archived sample extract and on the procedures to be followed for newly collected samples. Inexplicably, this important information is missing from the Work Plan.

3.1.3 Analytical Procedures

Although the Work Plan mentions various analytical parameters, EPA does not always delineate the specific analytical methods to be employed and their associated detection limits. For example, although GE agrees with the application of PCB congener-specific analyses of Hudson River sediment and water, EPA fails to mention any specific analytical methodology. Such a discussion is relevant to assess whether the method can be used to achieve the desired detection limit and the proper resolution of specific and important PCB congeners. This assessment is particularly important for the analysis of Thompson Island Pool sediment, where over 50 percent of the PCBs are one of three congeners: 2-monochlorobiphenyl, 2,2'-dichlorobiphenyl, and 2,6'-dichlorobiphenyl (Brown *et al.*, 1987).

With respect to the detection limit for PCB analyses, EPA proposes a non-standard sample collection method (the collection of 20-liter water samples instead of 1-liter water samples) in an apparent attempt, for unspecified reasons, to reduce the PCB detection limit to an unspecified level. Yet EPA fails to discuss what detection limit is necessary, what limit is achievable by this unusual sampling method, and why the required limit is needed (*i.e.*, what the data quality objectives are). EPA must provide information regarding the specific analytical methodologies, their capabilities, and the basis for their selection if the public is to conduct a comprehensive review of the Phase 2 Work Plan.

3.1.4 Data Validation

Details regarding data validation procedures are likewise not presented in the Phase 2 Work Plan. To assess whether data gathered during Phase 2 will successfully contribute to accomplishment of the project objectives, EPA must provide the public with the criteria that will be used to validate data integrity.

3.1.5 Internal Quality Control

The Phase 2 Work Plan also fails to include internal quality control methods, which are typically identified in a QAPP. Knowledge of these methods -- such as analysis of field and laboratory blanks, matrix spikes, matrix spike duplicates, split samples, and surrogates, and ways in which the generated data will be used to qualify field data -- is essential to evaluate whether the generated data set will support program objectives.

3.1.6 Summary

In sum, the information provided in the Phase 2 Work Plan is insufficient to permit a thorough evaluation of the data collection tasks to determine whether or not they will meet project objectives. Indeed, the Work Plan does not even measure up to EPA's own RI/FS guidance documents. This lack of detail is not a bureaucratic technicality that can somehow later be "cured." Rather, it suggests poor project planning by EPA and its contractors and raises the possibility that EPA will engage in a substantial data collection exercise during Phase 2 that will later turn out to have been misguided. Not only will such a result cause the data collection effort to have been a waste of money and time, but, more troublingly, EPA will consequently have little choice but to resort to the type of simplistic, qualitative approach that was described in the Phase 1 Report and criticized by GE in its Phase 1 Comments. All of this could, of course, be avoided if EPA takes the time now to issue a proper work plan -- *i.e.*, a complete and detailed document that meets all the requirements of EPA's own guidance documents -- and permits full public comment on that document prior to implementation of field activities.

3.2 Lack of Meaningful Comment Opportunity

Given that EPA has issued the Phase 2 Work Plan for public comment, one might assume that the lack of detail in the Phase 2 Work Plan is merely an unfortunate annoyance, because EPA will have the opportunity to respond to public comments and to correct itself before embarking on Phase 2. EPA's past practices in the arena of comments and responses to comments, however, call into question the genuineness of EPA's offer of the Phase 2 Work Plan for public comment. As a result, GE is concerned that EPA may begin to collect additional data without seriously evaluating the comments to the Work Plan.

GE does not make such an assertion lightly and bases its concern on two episodes. First, although the comment period for the Phase 1 Report ended on October 24, 1991, EPA did not release its Responsiveness Summary for the Phase 1 Report until July 13, 1992. Aside from the fact that this response came well after EPA undertook to design the Phase 2 work, EPA did not release the Responsiveness Summary concurrently with or before it released the Phase 2 Work Plan. Had EPA done so, reading the two documents together might have shed some additional light on the rationale behind EPA's Phase 2 activities.

Instead, EPA released its Responsiveness Summary for the Phase 1 Report a mere 11 days before the close of the Phase 2 Work Plan comment period. As a result, although GE has mentioned and cited the Responsiveness Summary in a few instances in these comments, GE has plainly not had an adequate opportunity to review the response document. GE's failure to discuss EPA's responses in these comments should therefore not be construed as any indication that GE concurs with or does not dispute those portions of the response document.

Second, citing the need to collect certain data during the fall 1991 field season, EPA did not permit public comment on its Phase 2A Work Plan when it was issued last fall. Obviously, to the extent EPA believes it can satisfy CERCLA's requirement of public participation in the Reassessment RI/FS process by maintaining the illusion of a comment process, EPA's actions are contrary to regulation and will be considered arbitrary and capricious.

Even apart from the procedural flaws associated with EPA's comment process, GE has been unable to determine precisely which portions of the Phase 2 Work Plan EPA has actually put out for comment. In the fall of 1991, EPA decided that certain priority data had to be collected during last year's field season, and EPA therefore did not allow public comment on that portion of the work. Nevertheless, GE provided EPA with written comments on the so-called Phase 2A Work Plan in a letter to EPA Project Manager Mr. Douglas Tomchuk, dated September 24, 1991. GE's request for a thirty-day comment period was ignored, and GE has yet to receive any response to these comments. As it turned out, EPA missed the field season and delayed implementation of part of the Phase 2A project until the spring of 1992. Even still, EPA did not permit a public comment period. EPA also implemented a major data collection program (the geophysical survey tasks) without having defined data quality objectives (DQOs) or a QAPP.

Apparently, then, EPA is only accepting comment on the following data collection tasks:

- Flow-averaged water column samples;
- Analysis of archived water samples;
- Low resolution coring;

- Sediment shear stress measurements; and
- Analysis of archived high resolution cores.

The data collection tasks not under comment are apparently those from the Phase 2A Work Plan and include:

- Geophysical surveys, including bathymetric, sub-bottom profiling, and side-scan sonar;
- Confirmatory samples for sediment textures;
- High resolution coring; and
- Water column sampling, including equilibrium study and dissolved/particle PCB analysis.

GE again requests that EPA allow formal comment on *all* aspects of data collection not yet completed, *prior* to implementation. The comments submitted today cover *all* data collection items and incorporate GE's earlier comments on the Phase 2A comments by reference. All comments should be considered, and GE requests that a complete copy be placed in the administrative record. GE also reiterates its request for EPA to submit for public comment an FSP and QAPP for all Phase 2 data collection activities. Proper consideration of comments on all Phase 2 work is critical, because (as described below and in the comments submitted in GE's Phase 2A comments) it is clear that EPA is relying in many cases on unproven, experimental techniques.

3.3 <u>High Resolution Sediment Coring</u>

According to the Phase 2 Work Plan, EPA's high resolution sediment coring program and radionuclide dating analysis in the Upper Hudson are intended to provide data regarding:

- historic, water column PCB transport on suspended matter (p. 2-3);
- total water column loading over time (p. 2-3);
- the congener distribution of PCBs on suspended matter (p. 2-3);
- current and historic PCB sources to the river and their relative importance (p. 2-3);
- in situ degradation (p. 2-3);
- the fitting of diagenetic models to describe sediment deposition and contaminant fluxes (p. 5-5);
- the calibration of an annual model of transport in the system (p. 5-5);
- the value of PCB data from datable cores as a predictor of PCB concentrations in fish (p. 5-12); and
- the bioaccumulation pathway from sediment to fish (pp. 5-15, 5-16).

GE agrees that EPA must resolve these technical issues to characterize the site properly, assess risks from the site accurately, and evaluate remedial alternatives meaningfully. GE is concerned, however, that EPA's proposed high resolution sediment coring program in the Upper Hudson is seriously misguided, because it will not provide useful or adequate information that can be used in a scientifically valid way to reach reliable conclusions about these important technical issues.

Radionuclide dating analysis -- *i.e.*, the use of radionuclides to mark dates in sediment cores -- has been developed and used by researchers in lakes and ocean environments where quiescent hydrodynamic conditions produce relatively constant deposition rates over broad regions of the system. (Wetzel, 1983). The analysis, however, assumes (among other things) that (1) a core represents a chronological picture of sedimentation; (2) each core contains different radionuclides with a known time and history of input that can be used to "date" the strata within which they appear; and (3) whatever else is found within a dated stratum was deposited at the date derived from the interpretation of the radionuclides found in the stratum.

Whereas these assumptions may be valid for lakes and ocean environments, they are not necessarily valid in river environments, where wide periodic variations in flow and both biological and anthropogenic mixing prevent orderly chronological and undisturbed layering of sediments. For example, the deposition rate of fine inorganic particles (to which the cesium-137 adsorbs) is a function of local hydrodynamics and varies sharply with both time and location. In free-flowing rivers where there is sediment movement arising from scouring and redeposition, the situation becomes even more complicated.

In particular, even if the radionuclide dating technique might be validly applied in certain areas in the Lower Hudson -- *e.g.*, to the extent sedimentation patterns in the tidal estuary reach the temporal consistency exhibited by tidal coves and inlets -- there is little question but that the radionuclide dating approach cannot validly be applied in the Upper Hudson. Indeed, Dr. Richard Bopp (a leading researcher in this field) has noted that the technique is inappropriate for use in the Upper

Hudson, given its riverine and dynamic nature. At a July 10, 1992 meeting of the Hudson River Scientific and Technical Advisory Committee, for example, Dr. Bopp remarked that in attempting to use the radionuclide dating technique in the Upper Hudson, EPA was taking the technique beyond the point of feasibility.

In short, the fundamental problem with EPA's proposed high resolution coring program in the Upper Hudson is that it relies on a technique derived from and applicable to quiescent lakes, ocean bottoms, and estuaries -- not a high gradient, dynamic riverine environment such as the Upper Hudson. EPA cannot justify its proposed use of the radionuclide dating approach by characterizing sections of the Upper Hudson as "lake-like" environments (Responsiveness Summary, p. A.3-4), because it is precisely the scour, movement, and redeposition of sediment in the Upper Hudson that has caused PCBs in the Hudson to be the subject of regulatory concern.

3.3.1 <u>"Interpretable Cores"</u>

Although radionuclide dating analysis assumes that undisturbed sediments in the river will match an assumed distribution of certain radionuclides, cores from the Upper Hudson do not necessarily reflect undisturbed and uniform sedimentation patterns. Shortly after the Fort Edward Dam was removed in 1973, an estimated 1.5 million cubic yards of sediment that had settled behind the dam moved downstream. The amount of sediment deposited in the Upper Hudson during the mid- to late-1970s is therefore much greater than the amount of sediment currently being deposited in the Upper Hudson (even in depositional areas). Accordingly, there is little reason to believe that the assumption of uniform deposition rates is valid.

Indeed, EPA cannot point to any significant or verifiable empirical evidence from the Upper Hudson to support this assumption. Rather, the vast majority of cores extracted from the river bottom do not fit the assumption and are discarded as "not interpretable." The scientific method, of course, does not generally permit the subjective discarding of data simply because they do not fit a given hypothesis.

In completely circular reasoning, cores that are deemed to fit the assumption (the so-called "interpretable cores") are then used to prove the assumption; all explanations other than those consistent with the assumption are discarded. In the Upper River, for example, a cesium-137 peak in a core is assumed to represent a peak reached via uniform sedimentation from atmospheric input. Yet, as discussed above, such a peak could just as well represent the movement and sudden re-deposition (after the removal of the Fort Edward Dam) of large quantities of upstream sediment in which cesium levels peaked years before. The cesium-137 peak in a mobilized sediment slug that settled downstream would therefore represent a date of deposition a decade or more after the 1963 maximum (derived from the year of maximum fall-out of atmospheric cesium-137 from weapons testing).

In addition, the cesium-137 levels associated with these mobilized sediments are likely to be relatively higher than other sediments (*e.g.*, those in the Thompson Island Pool), because of the high ratio of fine-to-coarse sediment particles in the mobilized sediment. Thus, although the core would look undisturbed because it had a cesium-137 peak, in fact (1) the sediment may have been significantly disturbed and (2) the peak may represent a false chronological marker (not of when the sediment first settled in the river bottom but when it settled at the coring location after having moved from its prior location).

3.3.2 Imprecise Dating

Even if the "interpretable cores" were in fact undisturbed, from which a rough sedimentary history could be estimated, the precise dating of Upper River segments cannot be made except by making other assumptions not supported by empirical evidence and by disregarding inconvenient data. First, the dating protocol assumes uniform annual deposition rates; in the Upper Hudson River, however, it is well known that such uniformity from year to year does not exist. Second, dating at a very high resolution assumes that substances deposited stay in the same stratum over time; in fact, substances move via diffusion vertically within Upper River sediments. Third, dating one substance at exactly the same date as another substance because of vertical congruence, at a very high resolution, assumes that substances contemporaneously deposited always stay together; in fact, different substances with different properties have different fates over time even after they have been deposited in the same place.

Indeed, in its Responsiveness Summary for the Phase 1 Report, EPA concedes (pp. A.3-5, B.4-13) that "the resolution of the sediment cores is limited to an uncertainty of ±2 years because of anticipated variations in sediment deposition and the inherent uncertainty in sediment layer collection." Yet, one of the key proposed uses of the high resolution core data in the Upper Hudson is to compare assumed surficial sediment PCBs with measured PCB levels in water and fish in *specific seasons of specific years*. By EPA's own admission, the dating technique is too imprecise to allow this to be done in the Upper Hudson.

3.3.3 <u>Use of Data to Derive Historical Sources</u>

Even if truly representative cores could be found, identified, and properly dated, they cannot be used (as is proposed in the Phase 2 Work Plan) to develop an accurate history of water column PCB transport in the Upper River or to find the original source of PCBs in Upper River sediments. This proposed methodology assumes that each core segment was surficial sediment at the exact location from which it was cored during the precise year that interpretation of radionuclides determines it settled out of the water column. It also assumes that the PCBs in each such tiny surficial dot are representative of acres and acres of river bottom in the region of the core, or of PCBs in suspended solids flowing past the point where the core was taken, or both (from the Work Plan it is impossible to tell).

These assumptions, however, are contradicted by the following facts about the Upper River:

- PCB mixtures in the Upper River change over time through biodegradation and chemical and physical processes. Thus, a PCB mixture found in sediments today may not be representative of the PCB mixture at the time of sedimentation, or even at the time it first entered the river system.

- PCBs are transported in the water column in both a dissolved phase and as adsorbed to suspended solids. Only a fraction of the solids settle at any given point, and some of the PCBs in sediments represent partitioning from a dissolved phase to solids and visa versa. Thus, the PCB mixture found in Upper River surficial sediments will not be representative of the PCB mixture in the water column at the time of sedimentation or at the time it first entered the river system. A simplistic use of partitioning coefficients cannot account for the complexity of the dynamics in a river with fluctuating flows, differing suspended solids characteristics (both size and organic content), and numerous PCB congeners.

- PCBs differentially adsorb to solids and differentially dissolve. Lower chlorinated PCBs dissolve more easily and adsorb to solids less easily then higher chlorinated ones. For this additional reason, what settles into the sediment is not necessarily representative of what was being transported in the water column. As noted above, simplistic use of partitioning coefficients cannot accommodate all of the relevant variables.

- There is wide spatial heterogeneity over very short distances in the PCB content of Upper River sediments, because the hydrodynamics of the Upper River results in many different deposition patterns. Just as one cannot generalize from a single or few widely spaced sediment samples the sediment characteristics of a large area, one cannot generalize from one surficial sediment sample what PCBs were in the water column across the entire river at the time such sediment settled out.

- Any attempt to take cores from areas previously cored to determine changes over time is completely undermined by (1) the lack of precision in identifying the exact location where cores were once taken; (2) the near impossibility of taking a new core from the same spot; and (3) the spatial heterogeneity over short distances of river bottom.

- There is wide temporal heterogeneity over relatively short periods (measured in days) in water column PCBs and suspended sediments. Generalizing from a surficial dot to the water column falsely assumes PCB and sediment transport in the water column were evenly distributed among all the days in a year.

With regard to application of the radionuclide dating technique in Lower River, EPA has apparently accepted the results of a recent study that purports to show that the technique may be valid in certain portions of Study Area D. Whatever the merits of this study, EPA cannot accept the study's results blindly and must therefore critically evaluate its data and methodologies. If after such a review EPA concludes that the conclusions of the study are valid, EPA must make the supporting data available for public review. In any event, because there is no such similar study for the other Study Areas of concern (Study Areas B and C), and because the geochemical and physical conditions are different in those Study Areas, EPA may not bootstrap its acceptance of the radionuclide dating technique from Study Area D to the other Study Areas.

3.3.4 Use of Data to Derive Fish Concentrations

Of all the technical flaws in EPA's high resolution coring program and radionuclide dating analysis, EPA's plan to use the high resolution coring data to develop a bioaccumulation pathway from Upper River sediment to fish (pp. 5-15, 5-16) and then to predict future PCB concentrations in fish (p. 5-12) is the most problematic. All the problems and uncertainties described above are magnified in any attempt to link past fish concentrations (at a given core location) to past PCB levels in the water column or in the surficial sediment (at that location). Moreover, the Phase 2 Work Plan fails to consider the important effects of spatial and temporal heterogeneity, differential uptake, accumulation, and depuration -- by PCB type, fish species, size, age, and whether from the water column, pore water, or ingestion of solids or other organisms -- on its analysis. EPA must, at a minimum, specify in greater detail how it can justify using the coring data and radionuclide analysis to project future fish levels.

One additional problem arises from EPA's attempt to correlate PCBs in Upper River sediment cores to PCBs measured in fish. EPA proposes to analyze sediment core sections with congener-specific (high resolution capillary) gas chromatographic analysis, but no such analysis has been or will be performed on fish samples. Thus, even if the correlation approach were a valid way to assess any cause-and-effect relationship between PCBs in fish and sediments, which it is not, the inability to match congener profile to congener profile undermines even the theoretical underpinning of EPA's proposed analysis.

3.3.5 Summary and Suggestions

GE urges EPA to abandon its proposed collection of Hudson River sediment cores for the purpose of high resolution coring and radionuclide dating analysis. In particular, GE objects to (1) a data collection exercise (the high resolution coring program) without a sufficiently well-defined protocol to permit replication by any other scientist and (2) a method of core interpretation (radionuclide dating analysis) that, whatever its technical merits, is inapplicable to the Upper Hudson and has questionable validity in the Lower Hudson.

These defects might not be so significant if the high resolution sediment coring program were a peripheral exercise in which EPA was attempting to use innovative methods to check data and conclusions reached by other means or otherwise attempt to reduce uncertainties. But in this case, the high resolution sediment coring program is one of the main data collection tasks and apparently forms the basis for the most important scientific determinations that EPA must make in this matter. This cannot be.

In short, GE believes that EPA's proposed high resolution sediment coring program is ultimately misguided. GE urges EPA to delete the high resolution coring task in the Upper River and replace it with statistically based field studies, laboratory experiments, and well-constructed mathematical models. The proposed sampling technique may be valid in lakes and possibly estuaries, and EPA's goals are laudatory, but the radionuclide dating technique is the wrong analytical tool to answer the questions posed in the Hudson River, particularly the Upper Hudson. Even if the technique could be validly applied in the Upper Hudson, the proposed sampling and analysis plan is incapable of yielding, in a scientifically valid manner, the information sought by EPA (namely, historical PCB fate and transport history in water and fish at the particular coring location). EPA should revise the Work Plan accordingly.

3.4 Other Data Collection Activities

The Phase 2 Work Plan describes three other basic data collection activities: (1) water sampling; (2) geophysical surveys; and (3) low resolution sediment coring. Although the purposes for which some of these data are being collected are not always clear, GE has attempted to infer the objectives and, where the proposed data collection scheme appears insufficient or unreliable, has made comments that indicate the need for a different approach.

Central to the comments that follow is the belief that the purpose of the vast majority of data collection should be to provide sufficient data to develop a quantitative PCB fate-and-transport model that includes a food-web component. To do this, data on PCB levels in the relevant environmental media (*i.e.*, fish, water, and sediment) over time and space (*i.e.*, various river segments at various times) are required. Data over time are necessary since the model will be used to estimate future PCB behavior under No Action and various other remedial alternatives. Data over space are necessary because the potential sources of PCBs are in spatially distinct locations (*i.e.*, upstream, remnant deposits, and various river sediments).

3.4.1 Water Sampling and Analysis

The Phase 2 Work Plan proposes four different forms of water sampling and analysis: (1) transect sampling; (2) PCB equilibrium study; (3) flow-averaged sampling; and (4) analysis of historic samples.

3.4.1.1 Transect Sampling

This task is intended (p. 3-3) to locate sources of PCB to the water column and to evaluate how the PCB load is altered or transferred to the Lower Hudson. GE generally concurs with this objective, but has a number of concerns regarding the method proposed by EPA to fulfill this objective. Specifically, GE is concerned about the selection of the sample locations, the description of the sampling and analytical methods, the selection of parameters specified for measurement, and the frequency of sampling events.

1. Sample Locations: Although GE generally concurs with the sample location proposed by EPA, GE has a number of questions and concerns with the information presented on the locations. For example, EPA fails to define the sampling location for the upper remnant deposit pool. Is this located above the original remnant deposits or within the remnant deposits? The monitoring data submitted by GE as part of the remnant deposit monitoring program, as well as the data submitted by GE to EPA in January 1992, indicate the presence of a PCB source between the Fenimore Bridge (just above Bakers Falls) and the upper remnant deposit area.

In addition, two of the proposed sampling locations have two channels: Rogers Island and Thompson Island Dam. As an initial matter, EPA should collect samples from both channels to determine the extent to which the load passing through each channel varies. The need for this data is illustrated by the work performed by NYSDEC in the remnant deposits area in the early 1980s (Tofflemire, 1984). In that study, dye placed in the river was found to have very little transverse dispersion (*i.e.*, mixing across the river channel). This result suggests that the channels may not contain identical PCB concentrations due to inadequate mixing across the river. Moreover, historical aerial photographs show that a visible sediment plume from the Moses Kill (located in Thompson Island Pool) is prominent during local precipitation run-off events. The visible portion of the plume is confined to the eastern side of the eastern channel of Thompson Island Dam. Because PCBs may interact with this particulate phase, measured PCBs inside the plume could be different from those outside the plume. EPA should therefore perform a channel-comparison study to demonstrate that any samples obtained are representative of the average water column concentration found in the river passing at that point and to understand biases that might be present in the historical database.

The exact sampling location between Bakers Falls and the remnant deposits must also be specified. Based on the data collected by GE in this vicinity, and in light of the lack of transverse mixing, it is not clear that shore samples yield samples with PCB concentrations representative of the water passing through the River at this location. EPA should either evaluate how representative these samples are from this location or rely on the verification study being performed by GE as part of the Remnant Deposits Post-Construction Monitoring Program, which has been submitted to EPA and NYSDEC.

EPA also states (p. A-9) that a sample will be collected from an off-site location to serve as a sampling blank. The reason for this is unclear. Are such samples intended to represent "background" conditions, or will they serve as field, equipment, or trip blanks? If EPA is attempting to determine background PCB levels, then the appropriate sampling location is in the Hudson River just above Bakers Falls and not in some other water body. If the reason is to provide an indicator of interferences due to equipment contamination or handling problems, then EPA should use certified clean water and handle the water just as the samples would be handled. Sampling in an unspecified location serves no apparent purpose and is not a substitute for either proper QA/QC samples or quantifying background PCB loads entering the study area.

2. Insufficient Description of Sampling Techniques: The Phase 2 Work Plan lacks sufficient detail on the sampling and analytical methodology to determine if the proposed methods will meet the project objectives. For example, the Work Plan does not describe in sufficient detail the sampling and analysis methods to be employed for the transect monitoring program. EPA should explicitly identify the number and approximate location of across-stream sampling stations at each site. This information is required to evaluate whether enough sites exist to account for spatial heterogeneity of water-borne PCBs.

The transect monitoring program involves following a "parcel" of water down the River during sampling. This sampling program should be explicitly tied into either the time-of-travel for river water between sampling stations or an equivalent analysis. The U.S. Geological Survey conducted a time-of-travel study on the Hudson River in the late 1960s (USGS, 1969). This information should be used to properly design the transect monitoring program, *i.e.*, to determine the time of travel between each station. EPA should also evaluate the impact of removing the Fort Edward Dam in 1973 on the time-of-travel for water in the northern reaches of the Upper Hudson.

The type of sampling device and its use should also be described. This description is particularly important if the device used is different from that used in the historic water quality program. As an example, if historical data is based on a depth-integrated sample, then EPA should use a method that is comparable to that employed so as to "tie" into the historic data. At the very least, EPA must take duplicate measurements using both techniques to calibrate the new technique.

The Work Plan states that 20-liter samples will be collected and filtered to provide an estimate of both dissolved- and particulate-bound PCBs. Because this is a non-standard technique, EPA must provide a detailed description of this method and an evaluation of its ability to produce high quality, reliable PCB data.

In addition, under conditions generally encountered in the Hudson River, 20-liter water column samples may not generate sufficient particulate material to perform a quantitative, congener-specific PCB analysis with the required QA/QC. Typically, Hudson River total suspended solids (TSS) concentrations are less than 10 mg/l. A 20-liter sample thus produces less than 200 mg (or 0.2 g) of particulate material (20 liters x 10 mg TSS/l). Yet, routine, quantitative, low-level PCB analyses typically require between 5 and 10 grams of particulate matter. (EPA, 1986).

3. Selection of Parameters: As part of the transect sampling program, the Phase 2 Work Plan lists the following parameters to be monitored: (1) dissolved organic carbon; (2) total suspended matter; (3) total organic carbon; (4) chlorophyll-a; (5) total PCB (on only a subset of the samples); (6) dissolved-phase PCB congener concentrations; (7) suspended-matter PCB congener concentrations; and (8) general water quality parameters (Ph, temperature, conductivity, and dissolved oxygen).

With respect to the PCB measurements, it is not clear why EPA is planning to use an unproven sampling technique (20-liter filtered samples), although the purpose may be related to an attempt to show the difference between a dissolved source of PCBs versus a particulate source of PCBs. It is possible that EPA seeks to use such a technique to evaluate whether PCBs in buried sediments are moving into the water column by diffusion (*i.e.*, a dissolved source) or by sediment scour (*i.e.*, a particulate source).

A more reliable approach is to analyze whole water (dissolved plus particulate) samples for total PCB content and total suspended solids (TSS). The PCBs should be analyzed by a capillary column method and reported by homolog groups. By combining this information with the TSS data, one can determine whether scouring of sediments (*i.e.*, increases in TSS) is occurring. By evaluating the homolog data, one can determine whether the PCBs measured in the water are from sediment depths where PCBs are more dechlorinated (*i.e.*, dominated by mono- and dichlorobiphenyl) or whether they originate from the surface where they are more like unaltered Aroclor 1242 or 1016, which are dominated by trichlorobiphenyl. This method relies on standard sampling and analysis techniques and is preferable to the unproven and potentially unreliable methods proposed by EPA.

With respect to the need for total suspended sediment data, GE believes it is necessary to collect this data with all PCB samples. This provides another check for the fate-and-transport calculation (sediment balance) and creates a "tie" to the historical data.

The Work Plan does not specify a reason for the collection of total organic carbon on suspend solids, dissolved organic carbon, or chlorophyll-a. These parameters might be useful in an academic evaluation of partitioning, but they will ultimately be of limited use to EPA, because only a few samples are being collected. EPA must identify the purpose for collecting these data and demonstrate that the method employed can reliably meet the objective (*i.e.*, published literature, use of other Superfund sites, etc.)

The last parameter of concern is the measurement of whole water PCB concentrations. The Phase 2 Work Plan states that a "small subset of sampled will be analyzed using one-liter samples." GE strongly encourages EPA to analyze a large set of whole water samples in exactly the same way as the most recent water column PCB data supplied by the U.S. Geological Survey. This will allow a "tie" to the historical data. Additionally, EPA should abandon its proposed experimental technique of filtering large volumes (20-liter samples) and instead analyze a set of whole water samples by a capillary column technique, with both homolog groups and congeners reported.

GE notes in passing that EPA must clarify a statement in the Work Plan in which EPA provides (p. 3-4) preliminary interpretation of the water column data provided to EPA by GE for the period April 5, 1991 to May 3, 1991. EPA suggests that a significant portion of the PCB load on the days monitored was from Thompson Island Pool sediments and that furthermore the Thompson Island Pool source had a significant portion of mono- and dichlorobiphenyls.

GE concurs with the assessment that during this low flow period, the PCBs contributed by Thompson Island Pool sediments were predominately mono- and dichlorobiphenyls. But EPA must further evaluate whether the total amount of PCB contributed is "significant" relative to the rest of the River. More significant, the measured PCB load at Rogers Island (samples collected from the western channel) is a large percentage of the load found in the River at the Thompson Island Dam (samples collective from the western wingwall of the dam). Care must be taken when evaluating the magnitude of the Thompson Island Pool contribution until such time that the assumption that the east and west channels of Rogers Island and Thompson Island yield similar results.

4. Sampling Frequency: As stated on pages A-8 and A-9 of the Phase 2 Work Plan, the transect monitoring program will be

repeated on at least seven separate occasions. Four of these will occur under low flow conditions, and three will be attempted at high flow conditions. EPA apparently defines (p. A-9) high flow as any flow greater than 8,000 cfs. EPA further states (p. A-9) that the sampling will occur when high flow conditions have been sustained for at least one or two days prior to sampling.

This program has three basic flaws: an inadequate number of samples to develop statistically significant results, the definition of high flow events, and the timing of high flow samples in relation to the flood peak. First, GE believes that seven sampling events is insufficient to understand properly the nature of the sources of PCBs to the river, their relative importance, or their true variability with time. As described more fully in the comments on flow-averaged sampling, the significance of short-term events and seasonal effects may be lost by such a limited sampling program. Indeed, GE submits that EPA could gather more useful data and meet the project objectives by replacing the flow-averaged water column monitoring program with a modified transect monitoring program in which samples are obtained more frequently for the duration of the project.

Second, the Work Plan implies that high flows are those above 8,000 cfs and that low flows are those less than 8,000 cfs. GE presumes that the reason EPA seeks to sample under different flows is to gather data during flow periods in which sediment resuspension and scouring are significant and during periods when resuspension and scouring are insignificant. (GE also assumes that 8,000 cfs or other designated flow applies to flows recorded by measurements by the U.S. Geological Survey at the Fort Edward Gauging Station).

Based on the data on total suspended solid measurements and water flows collected by the U.S. Geological Survey, however, resuspension of sediment appears to occur (see pp. B.4-9 and B.4-10 of the Phase 1 Report) somewhere around 14,000 cfs at Fort Edward. GE therefore recommends that EPA define high flows as those above 14,000 cfs, as measured at Fort Edward. This will result in more useful information on the effects of high flow events than measurements at flows where insignificant resuspension is occurring.

Third, EPA is apparently planning to wait until a high flow event has been occurring for at least one to two days before taking samples. This technique will yield data of very limited utility. GE believes that the need to collect water column PCB data as well as total suspended sediment data during sediment scour events is critical. These data are necessary to calibrate and verify a PCB fate and transport model as well as to indicate (qualitatively) how different sources behave at different flows.

But to monitor a high flow event properly, monitoring must occur on the rising limb of the hydrograph. The reason is that when a critical flow velocity or shear is reached, the sediments are mobilized and then are quickly armored, resulting in a dramatic drop in sediment load. This phenomena can be seen in the historical data collected by the U.S. Geological Survey, in which the peak in total suspended solids (TSS) occurs *before* the peak in flow and drops significantly even though the flows do not. If EPA collects data two days into a high flow event, then the peak in TSS may well have already passed. This process of sediment bed armoring is critical to a quantitative understanding of PCB transport in the Hudson River.

3.4.1.2 PCB Equilibrium Study

EPA also states (p. 3-7) that an objective of Phase 2 is to determine the type and location of PCB sources. EPA proposes to meet this objective by evaluating whether or not the PCBs in the dissolved phase are in equilibrium with those on the particulate phase in the water column. If, based on the interpretation of those measurements, the dissolved and particulate phases are not in equilibrium, then EPA will infer that a source of dissolved or particular PCBs is present.

Although this type of analysis might in theory yield interesting information, alterations may occur after the samples are collected. This technique is at best an experimental technique whose reliability and utility is highly questionable. Furthermore, the same objective can be met by a properly designed sampling and analytical program that relies on reliable, standard methods.

EPA's approach appears to be based on the premise (p. 3-6) that PCB equilibration is not instantaneous in the water column. This approach is based on non-peer-reviewed experimental work described in a report to NYSDEC (Bopp *et al.*, 1985), in which duplicate filtered water samples showed different PCB concentrations and congener distributions in suspended matter retained on the filters. One paired sample was filtered *in situ* using a submersible pump apparatus with 10-inch diameter quartz-fiber filters having an effective pore size of 1.2 micrometer (μm). The other sample consisted of 9 to 20 liters of water filtered in a laboratory several days after collection through a 0.7 μm glass fiber filter. Water samples stored for two to ten days before filtering were reported to have consistently higher concentrations of PCB in suspended matter than samples filtered shortly after collection. Differences in congener distribution and concentration between dissolved and suspended phases due to differences in filter pore size and sampling techniques, as well as sorption of PCB to filters, was considered but deemed insignificant because of the large discrepancies. One *possible* explanation for the differences over time was a condition of "non-equilibrium" in ambient river water and the equilibration of PCB between dissolved and suspended phases occurred during storage (Bopp *et al.*, 1985). The Bopp report (1985) concludes by stating that the situation obviously requires more study, perhaps comparing PCB concentrations on suspended matter collected by settling or continuous flow centrifugation.

Results of these proposed tests will be difficult to interpret due to potential flaws with the methods proposed to collect the data. Environmental samples of hydrophobic compounds, such as PCBs, present problems when attempting to separate dissolved and suspended matter fractions via filtration. (Bopp, 1979). Undoubtedly, the most important problem with using and determining partition coefficients in natural system is the separation of a sample into a suspended matter and aqueous phase.

An additional problem is that congener-specific sorption of dissolved PCB to glassware and the filtering apparatus can affect the distribution of congeners appearing in the filtrate. Also, agglomeration of initially filterable particles during storage may result in formation of particles large enough to be filtered out. The resulting loss of sample will affect the determination of partitioning coefficients and either under- or over-estimate the significance of certain PCB loads to the water column. This approach to defining the type of PCB source is based on comparing ambient PCB congener concentrations to equilibrated sample concentrations. The assumption that ambient samples yielding dissolved phase concentrations greater than those measured in the equilibrated samples indicates a dissolved source to the water column is unfounded. Decreases in dissolved phase PCB congener concentrations can result from biodegradation (Abramowicz, 1990) and volatilization, especially for the lower chlorinated PCB homolog groups during storage. Agglomeration of small particles during storage and sorption of PCB to filtration apparatus may also contribute to alterations of PCB composition in the filtrate.

3.4.1.3 **Flow-Average Sampling**

The Phase 2 Work Plan states (p. 3-8) that one objective of the flow-average sampling program is to identify long-term PCB averages. The Work Plan also states (p. A-11) that another objective for the flow-average sampling program is to determine mean differences in PCB levels between sampling stations, which in turn could allow estimation of contribution (positive or negative flux) of PCBs of the intervening river section by whatever sources may be present (*e.g.*, sediments).

GE agrees that the second objective should be addressed by water column monitoring. The use of flow-averaged samples to achieve the first objective, however, has numerous limitations, including:

- Storage of samples for later compositing will subject them to aerobic biodegradation and other documented PCB loss mechanisms.
- Composite samples will likely be extracted outside of the prescribed extraction holding times of seven days (40 C.F.R. 136, app. A) and will limit their application in the RI/FS process.
- The approach will not produce enough samples to perform a statistically valid analysis of the long-term average PCB concentrations and may over-or under-estimate PCB averages by the inclusion of typical samples.
- The Work Plan does not specifically state the number of days samples will be stored prior to compositing (*i.e.*, what is the sampling period?), the specific compositing procedures, or the conditions under which the samples will be stored. Storage of samples, even under ideal conditions, could subject them to biodegradation, volatilization, and other abiotic loss processes. These processes could preferentially reduce the lower chlorinated PCB within the sample, making accurate determination of the nature of potential PCB sources difficult. For example, diffusive sources contributing predominately lower chlorinated PCB may be underestimated using this approach.

Significantly, the Work Plan blithely states (p. A-12) that "[t]he approach employed for the flow-averaged water column sampling requires that samples be held beyond the USEPA allowed holding time." This casual dismissal of the required extraction holding times for PCB analysis, in light of the inherent limitations of this approach, is arbitrary. This is particularly true since the principal reason for employing such an approach is to save money: "The flow-averaged water column sampling and analysis approach] avoids the large analytical costs involved in establishing a sufficiently large database of daily or weekly samples to permit a statistically valid analysis of the mean PCB loads" (p. A-11).

GE is deeply concerned that the EPA is casually dismissing a standard practice -- adherence to holding times -- that it routinely applies to PRPs. This double standard is clearly unfair. Furthermore, EPA states that the data quality objective will be less than Data Quality Level 5. What does this mean? Will EPA not use the data in a quantitative fashion? Will the data be sufficient quality to use in a PCB fate-and-transport model?

Since this is the only data EPA is collecting to fulfill the indicated objective (*i.e.*, PCB mass contributed by various sources), EPA will be forced to make a decision on potentially unreliable data, and the tendency will be to address the shortcomings or uncertainties of using such data by being overly conservative in estimating the mass contribution from a given source or the mass being transported to the Lower River. EPA must not compromise the investigation by trying to save relatively small amounts of resources.

The flow-averaged water column monitoring program also fails to recognize the importance of short-term variations in PCB concentrations that might be covered by short-term flow events or isolated river disturbances. These events are a fundamental component of PCB fate in the River, and their importance must be understood before assuming they are unimportant. Short-term flow events are known to occur when ice jams form and break in the spring run-off season. Additionally, there is a possibility that data collected when a boat or boats pass through the lock system will include locally higher levels of sediment stirred up by "prop wash" than other locations or times. The compositing scheme will mask these events and could result in large over- or under-estimates of PCB loads.

Considering the importance of the reassessment RI/FS, GE urges EPA to commit the resources necessary to accurately determine the long-term mean PCB levels at different stations on the Hudson River.

3.4.1.4 Analysis of Archived Water Samples

The Phase 2 Work Plan also states (p. 3-10) that archived extracts of water column samples will be analyzed on a congener-specific basis to determine how PCB composition has changed over time. Although this may be an interesting exercise, and might be worthwhile if it were feasible, it is not clear that the method employed to do this will yield reliable results or whether, even if it did, the number and location of samples is sufficient to quantify the anticipated changes over time.

EPA has neglected to discuss in the Work Plan how the proposed analysis of archived sample extracts will meet the objectives of the Reassessment or the protocols of EPA's own guidance. The Work Plan calls for PCB congener-specific analysis of archived sediment and water extracts that were collected from 1977 and 1986. To assess changes in PCB concentrations over time, EPA proposes to compare the results of these analyses with results of PCB congener-specific analyses of newly collected sediment and water samples. However, EPA fails to demonstrate in the Work Plan that the integrity of the archived samples has been maintained during storage over the lifetimes of the samples.

EPA's failure to demonstrate sample integrity conflicts with its own specific requirements that quality assurance and quality control (QA/QC) be demonstrated during a CERCLA RI/FS, as indicated in EPA's RI/FS guidance (EPA, 1988b) and User's Guide to the Contract Laboratory Program (EPA, 1991a). Complete and intact chain-of-custody documentation for the archived samples is critical if, as EPA proposes, the analytical results are to be used for quantitative comparisons. This documentation is not presented in the Work Plan.

For EPA to perform the proper analysis, GE believes EPA needs to do the following:

- Document the sampling and extraction methods by which the extracts were prepared;
- Document the conditions under which the extracts were stored;
- Produce the chain-of-custody documentation for sample collection and storage and demonstrate the

chain-of-custody records show the sample integrity to be intact.

- Demonstrate the PCB concentrations and compositions have not changed during sample extract storage. The Work Plan states (p. A-12) that the integrity of the sample extracts will be confirmed by comparing the original analysis to a comparable analysis. However, neither the comparison method nor the comparison criteria is stated. The documentation referenced on page A-12 needs to be provided.

If EPA is unable to provide such information or documentation, then the archived samples should not be used to make "direct comparison of the status of PCBs at the two different points in time" (p. 5-8).

Although the Work Plan does not identify any specific analytical method for PCB congener-specific analysis, analysis of samples that have been archived for up to 15 years certainly violates the holding times associated with the analytical method. Changes in PCB concentration and composition are likely to have occurred in the archived samples over such an extended period of storage. EPA proposes (p. A-12) to confirm the integrity of the archived water column extracts "by comparing the original analytical results, which were obtained by a packed column gas chromatography technique, with a comparable analysis in Phase 2," but EPA fails to specify the "comparable" analytical technique to be used. The archived samples should be analyzed according to procedures originally employed to quantify PCBs. EPA must also document that past extraction methods would meet current accepted practice for such procedures. Changes in packed column technology, quantification techniques, and QA/QC requirements over time, however, could likely inhibit use of a comparable technique.

There appears to be another objective for which this data will be used. The Work Plan also states (p. 3-11) that sample extracts will be used to "predict total water column PCB concentrations [using literature derived partition coefficients], based on suspended matter or high resolution sediment core PCB concentrations."

But it is not at all clear precisely what EPA is proposing. EPA might attempt to try to "calibrate" a simple model of PCB partitioning in the water column (dissolved versus particulate) by using an unknown "model" for calculating, over time, the water column PCBs from the particulate present in high resolution cores and "calibrating" it with current data on water column dissolved and particulate PCBs and on historical data on water column dissolved and particulate PCBs obtained by the analysis of archived sediment extracts.

If this is the case, this procedure is clearly unproven and is at best an exploratory technique of unknown reliability that requires much further documentation and review prior to its use as part of the decision-making process at the Hudson River. The archived sample (sediment or extract) analyses, the literature-derived partition coefficients, and the interpretation of the high resolution sediment coring data are all subject to significant uncertainties. EPA needs to allow a more thorough debate on the merits and necessity of this unproven, experimental approach.

In addition, the Work Plan should be modified as follows:

- The Work Plan must describe in greater detail what will be done with the collected data and how the data will be integrated with the high resolution coring data.
- The Work Plan should provide equilibrium partitioning equations and sample calculations to show that the approach will yield interpretable results.
- The Work Plan should demonstrate the validity and reliability of the technique and should supply references from peer-reviewed journals to show that it has been successfully applied in situations similar to those of the Hudson River.
- The Work Plan should state the objective for doing each data collection task and should specify the connection between the data collection to the overall project objective (*i.e.*, a quantitative model for predicting the difference between Action and No Action).

3.4.2 Geophysical Surveys and Confirmatory Sampling

EPA has already completed -- in the absence of public comment -- geophysical surveys of selected portions of the Upper Hudson River. The data collected include bathymetric data, side-scan sonar, and sub-bottom profiling. GE commented extensively on this activity in its letter of September 24, 1991, despite EPA's refusal to request or accept formal comments.

GE reiterates those comments here and incorporates them herein by reference. In sum:

- EPA failed to allow any comment on the use of these geophysical techniques on the application to the project, even though comment was requested and application of the techniques to the project was unusual.
- EPA failed to develop any of the plans required as part of any Superfund data collection effort and

did not have a Quality Assurance Project Plan (QAPP) or defined data quality objectives (DQOs).

In addition, EPA did not provide any clear reasons or objectives for collecting the geophysical data. In the Phase 2 Work Plan, EPA retroactively asserts the basic objective of the work was to prepare "maps of river depth and sediment characteristics." EPA apparently intends (pp. 2-3, 2-4) to use these maps to select low resolution coring sites, to estimate sediment PCB inventories, to assess "scourability," and to perform the feasibility study analysis.

With respect to mapping the river bathymetry, GE agrees that this information is needed to assess the hydraulics of river flow and changes in sediment deposition (since the 1977 and 1982 surveys), both of which are necessary for constructing and calibrating a quantitative PCB fate-and-transport model. As GE stated to EPA prior to its data collection (see letter of September 24, 1991), GE has already collected such data, and EPA's effort in this area was thus unnecessary. EPA ignored this existing information.

As stated in Section 4.5 of these comments, GE also agrees that a "scourability" analysis of the sediments in relevant portions of the Upper River is necessary and that a map of the distribution of sediment type and grain size is needed to perform such an assessment. However, as discussed in greater detail in Section 3.4.3.2 below, EPA has not demonstrated that the side-scan sonar technique resolves sediment types or grain sizes to a level required by the sediment scour model.

Specifically, although the side-scan sonar technique may be able to resolve gross changes in grain size, it has not been shown to resolve differences in grain sizes that may be of interest in sediment scour models. This is an example of why data quality objectives must be determined prior to data collection.

To generate a sediment bed map, EPA should implement a program similar to the confirmatory sampling program in which sampling locations are targeted in depositional, transitional, and erosional areas. These locations can be determined by principles of stream bed morphology and the bathymetric survey. Additionally, the sediment bed map generated as a result of the 1984 study (Brown *et al.*, 1988) could be used as a starting point. This approach yields real data on the relevant spatial scale and does not rely on unproven, experimental techniques of unknown reliability.

EPA also intends (p. A-13) to use the data from the geophysical surveys to select locations for low resolution sediment cores. But EPA fails to specify the method by which this will be done or the selection criteria. It is therefore unclear why the geophysical survey data is needed to locate low resolution cores. The next subsection discusses the need for EPA to define the relationship between the side-scan sonar program and the low resolution coring program.

3.4.3 <u>Low Resolution Sediment Coring</u>

The objectives of EPA's low resolution sediment coring program, as specified in the Phase 2 Work Plan, include the following:

- To determine PCB concentrations in sediment (p. 2-3);
- To examine a limited number of previously defined "hot spots" in the Upper Hudson (p. 2-3);
- To classify various sedimentilogical zones defined on the basis of the geophysical surveys (p. 2-3);
- To assist in defining the depth of PCB bearing sediments in Study Area A (p. 2-3);
- To obtain estimates of sediment PCB mass (p. 3-18) and to determine the volume of contaminated sediments in a given area (p. 3-6); and
- To verify PCB degradation rates in the field (p. 5-7) by examining congener patterns in the "hot spot" sediments (p. 5-8).

3.4.3.1 <u>Comments on Low Resolution Sediment Coring</u>

These objectives are muddled, and a clearer definition of objectives and goals is necessary. In addition, EPA may have an additional unarticulated goal, which is to prepare current estimates of PCB mass and current locations of the PCBs residing in the Thompson Island Pool and Reach 7 of the River (Thompson Island Dam to the Fort Miller Dam). EPA has selected two methods for performing this analysis. The first is to sample unspecified locations (so-called "hot spots" perhaps) in the Thompson Island Pool to prepare a current estimate (using the low resolution coring results) of the PCB inventory in the given location. This estimate will then be compared to the results of a kriging analysis performed on the 1984 sediment data from Thompson Island Pool. Apparently, if the PCB mass estimated by kriging of the 1984 data is "comparable" (without defining criteria for comparing), then EPA may (p. 2-10) use the estimate obtained from a small number of low resolution comes in an unspecified portion of the Thompson Island Pool as a surrogate for current data. The Work Plan does not specify which area(s) of the Thompson Island Pool will be investigated or how many samples will be obtained. Therefore, it is not clear whether the proposed technique will yield useful information.

The fundamental problem with this approach pertains to the feasibility of defining the PCB mass in sediments of a small area of the River ("hot spots") based on a "small" number of cores. The problem of estimating the mass of PCBs in any area of the River by use of a small number of samples in the Upper Hudson River is well known (Tofflemire and Quinn, 1979, Brown *et al.*, 1988). The basic problem is that the distribution of PCB concentration is highly heterogeneous. This is illustrated by the data collected by GE at the site referred to as the H-7 site. (the site of the Hudson River Research Station). These data have already been supplied to EPA. GE extensively analyzed the H-7 site in 1990 by employing capillary column PCB analysis of samples collected on an approximately 12-foot by 12-foot sampling grid. The data showed order-of-magnitude changes in PCB concentrations from one location to the next. This indicates the need to obtain a fairly large number of samples to properly characterize the PCB mass in any given area.

GE believes there is a defensible way to estimate the PCB mass in the Thompson Island Pool on a relevant spatial scale. The latter point is extremely important, for GE firmly believes the primary objective of Phase 2 is to determine the amount of PCB reduction (if any) under No Action and various alternative remedial scenarios. This is described more fully in GE's comments in Sections 2.0 and 4.0 of these comments and in GE's Phase 1 Comments. Meeting this project objective requires a quantitative PCB fate-and-transport model that is designed with time and spatial scales relevant to the project. The appropriate spatial scale is determined by the size of the sources to be modeled, the type of remediation scheme being analyzed, and the capabilities and limitations of the model developed.

A final limitation is the fact that to define the concentration in the River on the scale of a "hot spot" (200-300 feet long) would require vast numbers of samples. Therefore, a more refined objective would be to determine the average PCB concentration in one-half to one mile long river segments in the Thompson Island Pool. This will be adequate for the PCB fate and transport model to determine the effects (if any) of the Thompson Island Pool sediments in general and whether the focus of potential remediation (if any) should be on certain segments or on the entire pool.

If the objective can then be defined as given above, the design of a sampling program to meet the objective can move forward. EPA's approach is to confirm the results of the 1984 data and to rely on the 1984 data. The 1984 data may, however, be unreliable for current use for a number of reasons. First, as discussed earlier, it is very difficult to confirm by limited sampling that the 1984 data are still applicable. Second, it is unreasonable to assume that no changes have occurred since 1984. Indeed, loss mechanisms include:

- Diffusion of PCBs into the overlying water column;
- Diffusion of PCBs into the underlying sediments;
- Reduction in mass due to the documented occurrence of significant stepwise dechlorination;
- Burial with "clean" sediment; and
- Scouring of sediment.

There are also two mechanisms that might increase the concentrations of PCBs at a given location: PCB load from the water column entering the segment in question and redeposition of scoured material.

Due to these problems, the most reasonable way to estimate current distribution of PCBs in the sediments of the Upper River is to collect sufficient samples to estimate the mass of PCBs in river segments of one-half to one mile long. Since the main interest is to estimate average PCB concentration in a given area, a sampling program can be devised in which a significant number of samples can be obtained and composited. This will reliably meet the objectives of the program as well as significantly reduce costs.

3.4.3.2 Comments on Side-Scan Sonar Method

Apart from the objectives of estimating the PCB mass as a function of river segment, EPA also appears to want to use the results of the side-scan sonar to report in detail the distribution of PCBs in sediments within the Upper Hudson River. While the mapping of surficial PCB concentrations on a very small spatial scale (feet or inches) is of general interest, it is not clear that is necessary to meet the objective of having sediment

PCB data for a fate-and-transport model. EPA may have a unstated interest in this scale for some purpose related to targeting zones for sediment removal. However, whether EPA's goal is related to the model or a vague feasibility issue is somewhat irrelevant, since the approach advocated is at best a speculative and experimental tool without a firm foundation in scientific theory. Furthermore, the method has not been field-validated at any location, let alone on a CERCLA NPL site.

As best as GE can tell, EPA's approach for mapping PCB concentration by use of side-scan sonar is as follows:

- Side-scan sonar measures the amount of sonic wave energy that is reflected back from sediments;
- Sediment reflectivity depends on a number of variables, including topography (slope), distance from and between the energy source and the sediment bed, presence of gas, sediment grain size, and presumably other factors such as density, stratification, etc.;
- It is possible to correct for surface slope and the distance between the energy source and the sediment bed;
- Two sonic frequencies are used: 100 kilohertz and 500 kilohertz; the respective wavelengths are 15 millimeters and 3 millimeters;
- A rule of thumb for the depth resolution for side-scan sonar is approximately 1 wavelength (3-15 millimeters);
- A relationship between sediment type (as presumably differentiated by grain size) and reflectivity needs to be established;
- A relationship between grain size and PCB content needs to be established;
- From the above, a relationship between reflectivity and PCB content needs to be established.

Many variables must therefore be controlled and understood to derive a map of PCB concentration in the river bed from side-scan sonar data and a limited number of low resolution sediment cores. This analysis also raises two important questions that should be answered before the approach is used: (1) What is the relationship between reflectivity and measures of grain-size or sediment texture? (2) What is the relationship between sediment texture measures and PCB levels?

With respect to the relationship between grain size and reflectivity (or texture), GE assumes that the sonic techniques will only be relevant where the grain size is significantly larger than the frequency of the sonic wave. This would mean that differentiation between grain sizes coarser than approximately coarse-grained sand and those finer might be possible. Finer differentiation may occur at larger grain sizes but certainly not smaller. While this is interesting, it is generally believed that PCBs fractionate onto the fine silt and clay-size portion of sediments. Therefore, if a quantitative relationship exists between grain size and PCB content, it would be a function of the finer grain sizes that theoretically cannot be differentiated by side-scan sonar. GE has requested (see September 24, 1991 comment letter) from EPA any technical information to support that use of this technique. This information has not been supplied to date, and it is not present in the Site Administrative Record.

Furthermore, the basic premise of the approach is that PCB concentration and sediment type are strongly correlated.

This premise is not supported by historical data. Indeed the Phase 1 Report documented to lack of correlation between sediment volatile solids and PCB concentrations. As EPA concluded in the Phase 1 Report (p. B.3-9), "percent volatile solids would make a poor predictive measure of PCB concentrations." GE is unaware of any measure of sediment texture that is strongly correlated to PCB content in the Upper Hudson River. Due to the lack of theoretical basis for differentiating the appropriate grain size fraction in the sediments, and the apparent lack of a correlation of sediment type with PCB concentration, GE again urges EPA to abandon this research program, which is in any event unnecessary for meeting the defined project objectives. EPA should instead focus on a data collection program that can yield reliable results on the PCB concentration and distribution in the Hudson River.

3.5 Collection of Current Biota Data

The final area of concern with the data collection proposed in the Phase 2 Work Plan is the conspicuous absence of data collection related to PCB levels in fish. As EPA concluded in the Phase 1 Report, fish appear to be the most important environmental media at the site, particularly because the human health risk estimates appear to be driven by fish consumption.

Although the data generated by the NYSDEC on PCB levels in fish in various locations of the river are extensive, the data have the following significant limitations:

- Lack of data on specific PCB homologs or congeners;

- Insufficient data on species relevant to the risk assessment; and

- Lack of information on PCB content in fish in the fresh water portion of the estuary.

3.5.1 **Fish Analysis**

The Work Plan should be modified to include the collection of fish and their analysis by GC/ECD capillary column methods. These analyses are required to maintain consistency with sampling and analysis of other media including water column and sediments. Congener-specific PCB analyses for fish will enable an evaluation of the relative importance of different PCB sources to accumulation in fish. For example, if fish contain predominately tri- and tetrachlorinated biphenyls and the Thompson Island Pool contributes predominately mono- and dichlorinated biphenyls to the water column, this would suggest that fish are accumulating PCB from a water column source other than that attributable to the sediments in Thompson Island Pool. Additionally, this may also provide a bioenergetic model of the food web.

The Work Plan should also specify the following:

- Sampling and congener specific PCB analysis of fish from different age classes and trophic levels including bottom feeders, prey species, and predator species;

- Sampling and congener specific PCB analysis of fish from different reaches, particularly from Reaches 5 and 8, to augment the data set gather by the NYSDEC over the past thirteen years; and

- Analyses of a subset of fish for PCBs according to the methods employed by the NYSDEC to ground the newer analyses into the historical database.

Additionally, the specific method employed by NYSDEC should be thoroughly evaluated and made publicly available prior to the inclusion of historical data into the RI/FS process.

3.5.2 Relevant Fish Species

The existing database is also biased toward species not targeted by recreational fishermen. Information gathered from the NYSDEC angler survey (Connelly *et al.*, 1990) indicates that the primary target species in the Hudson River are bass (38 percent of angler effort) and brown trout (6.5 percent of angler effort). While the survey did not specify the bass species that were targeted, it is known that rock bass, smallmouth bass, and largemouth bass are all resident in the Upper Hudson River (EPA, 1991b). However, the fish tissues collected by NYSDEC between Fort Edward and the Federal Dam only included largemouth bass. Thus, there are no data available for the other bass species present in the Upper River. This is an important limitation of the data, because fish bioaccumulate PCBs at different rates. It is therefore inappropriate to assume that tissue concentrations measured in one bass species are representative of tissue concentrations in other types of bass. In addition, NYSDEC has collected no data on brown trout, which probably do not inhabit the portion of the river of interest.

According to the NYSDEC survey (Connelly *et al.*, 1990), yellow perch and walleye are also popular target species in New York State. Because these species are present in the Upper Hudson River, it is reasonable to assume that these species would be popular target species in the absence of a ban. However, none of these species was sampled. Instead, goldfish and yearling pumpkinseed, which are not generally consumed by anglers, were sampled. Due to the low probability that these would be consumed by anglers, these data do not provide a sound and defensible basis upon which to base a risk assessment.

In addition, because there is currently no fishing pressure on the Upper Hudson River, the fish ages and sizes currently found there are not necessarily representative of the fish that would be there in the absence of the ban. As fishing pressure increases, as it would in the absence of a ban, the numbers of fish that would be harvested would reduce the numbers of fish available. In addition, because anglers tend to seek larger, trophy fish, the average age and size of fish present in the river under steady fishing pressure would decrease after a short time because older larger fish would be harvested and smaller numbers of fish would survive to reach such large sizes.

GE therefore recommends that additional fish samples be collected from the Upper Hudson River in an effort to collect species and sizes of fish that would, most likely, be targeted by recreational anglers in the absence of the ban. (EPA, 1989b). Of key importance for additional sampling are rock bass, smallmouth bass, yellow perch, and walleye. It is assumed that trout do not inhabit the portion of the River of concern. Sizes to be sampled should be consistent with size limits set forth in New York State angler guidelines. As such, bass should be of minimum size (10 inches); other species may be of any size but should be large enough to assume that anglers would keep, clean, and consume those fish. Finally, very large fish should not be sampled, because in the absence of a ban, fishing pressure would quickly reduce the population of larger fish. Anglers are therefore unlikely to catch and consume many fish of that size over a long exposure period. If available, creel survey data from other New York river fisheries can be used to predict the ranges of sizes of each species of fish that would be likely to be harvested by anglers over time.

3.5.3 <u>Location and Timing of Fish Sampling</u>

Fish samples should be collected from those areas of the River where access and fishing conditions are likely to be favorable to successful angling. (EPA, 1989c). Experienced fisheries biologists can provide expert recommendations on the most important potential fishing locations on the Upper River. In addition, fish samples should be collected at times when anglers would also be likely to collect fish if fishing were allowed. For example, fishing season for largemouth and smallmouth bass occurs between late June and the end of November. Thus, bass samples should also be collected during this period. Finally, analysis should be conducted on fish fillets rather than whole fish, as consumers are unlikely to eat the whole fish.

The last area of concern is with the database in the freshwater portion of the estuary of fish PCB levels. Because this database is insufficient to make even qualitative risk conclusions, EPA should supplement the existing Lower River database with congener-specific PCB analysis and data from different fish species and locations.

4.0 QUANTITATIVE MODELING

EPA's Phase 2 Work Plan appears to accept GE's position, expressed in its comments on the Phase 1 Report, that an integrated, quantitative model of PCB fate and transport is an essential component of a credible and technically defensible Reassessment RI/FS at this complex and dynamic site. Unfortunately, EPA's proposed analysis contains substantial simplifications and numerous short-cuts that are likely to produce faulty and unreliable information. Indeed, to the extent EPA and the public place unjustified reliance on EPA's "model," the proposed approach could conceivably be worse than having no model at all.

Although at first glance EPA's proposed analysis (or what can be discerned of it) appears to be a step in the right direction -- in that it adopts the *concept* of quantitative modeling -- EPA's proposed *execution* of that concept is technically indefensible. If EPA continues along the path described in the Phase 2 Work Plan, it will have expended considerable sums of money with little or no scientific, technical, or decision-making benefit. Although EPA is beginning to ask the correct questions, the analysis that it proposes has a high probability of leading to meaningless or erroneous answers to those questions.

4.1 Overview: EPA's Technical Analysis Is Flawed

As GE explained in its comments on EPA's Phase 1 Report, the Hudson River Reassessment RI/FS has substantial environmental and remedial cost implications. These implications require that the key technical components and questions be addressed with the best, tested technology available. To predict future impacts of PCBs in the Upper Hudson under conditions of No Action and various remedial alternatives, GE reiterates its view that the use of an integrated, quantitative model of PCB fate and transport -- *i.e.*, one that explicitly accounts for the major physical, chemical, and biological mechanisms that affect PCBs in the river -- provides the only credible mode of analysis.

EPA, however, has given no persuasive reason for failing to perform such an analysis at this technically complex site, particularly where such analyses have been performed and accepted by EPA at sites such as the James River; the Saginaw River; Green Bay, Wisconsin; and New Bedford Harbor, Massachusetts, to name just a few. As EPA's own Science Advisory Board has recognized, "mathematical models of the phenomena provide an essential element of the analysis and understanding" (EPA, 1989e).

At the outset, and as described in greater detail below, the fate-and-transport analysis described by EPA in the Phase 2 Work Plan glosses over several unanswered technical questions. These gaps in the Work Plan defeat the purpose of drafting a work plan and prevent GE from fully commenting on EPA's proposed approach. As with other portions of the Phase 2 Work Plan, if the modeling analysis proposed by EPA were presented for EPA review by a PRP, EPA would certainly reject it for (among other reasons) being insufficiently specific.

Even to the extent GE can discern EPA's proposed approach, each of the three analytical components described in the Phase 2 Work Plan -- mass balance analysis, biotic effects analysis, and erodibility analysis -- is technically inadequate and inappropriate to the task at hand. For example:

- EPA's proposed mass balance analysis fails to include a proper calibration using the extensive range of existing water column and sediment data; relies on questionable and untested techniques for estimating historical sediment and water concentrations; and incorporates inappropriate temporal and spatial scales.

- EPA's proposed biotic effects analysis fails to provide crucial information on cause-and-effect relationships between PCB sources and PCB concentrations in fish; is unsupported by observed sediment concentration data and instead relies on questionable and untested estimates; and is not calibrated with independent data.

- EPA's proposed erodibility analysis also suffers from numerous defects. EPA's use of a one-dimensional model oversimplifies complex physical phenomena and will likely lead to erroneous results. A two-dimensional model would more accurately represent lateral velocity and shear stress variations due to variable bathymetry. In addition, EPA fails to analyze cohesive sediment properties properly and fails to propose any form of calibration or verification of its model.

An important common thread in these comments is that EPA's proposed analysis fails to include an important and essential modeling step: the comparison of modeling results with *actual, observed* historical data (as opposed to data generated by a questionable and uncertain methodology). These comparisons -- over time and space and in different environmental media -- serve as an independent calibration and verification of the model's calculation procedures and assumptions. EPA's failure to employ this fundamental and standard principle of quantitative modeling is a critical technical defect in EPA's proposed approach and will destroy any confidence in the ability of the analysis to evaluate No Action and other remedial alternatives.

For these reasons, any results derived from EPA's proposed modeling exercise will be fraught with uncertainty and will have such limited reliability and usefulness that EPA will ultimately be forced to rely on qualitative speculation rather than the best and most credible science. And, as GE established in its comments on the Phase 1 Report, the quality of the Reassessment decision will suffer accordingly.

4.2 <u>EPA's Rejection of Proper Modeling is Unjustified</u>

EPA claims (p. 5-1) that "an exhaustive investigation of all aspects of the system . . . is not considered necessary." Specifically, EPA rejects (p. 5-2) state-of-the-art modeling on the asserted ground that "the spatial and temporal scales [of such models] are not relevant to the questions [EPA] need[s] to answer for the Reassessment . . . and thus the expense of implementing such a model cannot be justified."

GE emphatically objects to this line of reasoning. The appropriate spatial and temporal scales of analysis are not solely determined by the questions to be answered. Rather, the appropriate scales are those that are required to undertake a valid technical analysis of the controlling physical, chemical, and biological processes. Where the controlling effects are determined by complex, individual interactions that occur over relatively small spatial and temporal scales, the use of average values to describe the physical processes leads to meaningless and potentially misleading results. Thus, before it can answer with any confidence the larger-scale questions that it has posed, EPA must first understand and model individual processes that occur on a relatively small time and spatial scale.

Moreover, to the extent EPA's rejection of a technically appropriate and credible analysis rests on budgetary or scheduling constraints, such a decision is unacceptable. Given the environmental and remedial cost implications of EPA's reassessment decision, EPA cannot risk a technically indefensible decision. A small investment in the appropriate analysis today will yield substantial dividends in the future -- not only by ensuring technical credibility in EPA's remedial decision, but also by earning public confidence in and respect for EPA's decision-making process.

4.3 Comments on PCB Mass Balance Analysis

4.3.1 Failure to Calibrate

EPA's proposed mass balance analysis is deeply flawed. At the outset, the Phase 2 Work Plan suggests (p. 5-3) that an inventory of PCB stores, fluxes, and associated uncertainties provides a useful "reality check" on a more detailed analysis. Such a gross simplification of the complex physical, chemical, and biological processes in the Hudson River, however, is inadequate to the point of being virtually meaningless. Although there may be no harm in doing such an exercise, the broad inventory that EPA envisions is no substitute for a rigorous calibration and verification of an integrated, quantitative model of PCB fate and transport. As a consequence, little reliance or weight can or should be placed on EPA's so-called "reality check."

More fundamentally, the Phase 2 Work Plan indicates (p. 5-5) that "information obtained from dateable cores can be used to calibrate an annual model of transport in the system." As discussed previously (see Section 3.3 above), the radionuclide dating technique uses only a small portion of the available sediment data to generate estimates of historical river sediment and water PCB concentrations. According to EPA, these estimates are to be substituted for data in the model calibration exercise. This approach, however, is inappropriate, not only because the radionuclide dating technique itself contains significant uncertainties, but also because the resulting estimates of historical conditions, as applied to river systems such as the Upper Hudson, will contain even larger undefined errors. The approach that EPA proposes has never been tried in a system of this size and complexity. GE submits that EPA ought not use this site as the guinea pig for evaluating remedial alternatives with such an untested and uncertain technique.

Instead of dabbling in an intellectual exercise, EPA should perform a proper model calibration by comparing *calculated* and *observed* water column PCB and suspended solids concentrations over the range of observed data points, not just a selected few. Moreover, to ensure the credibility and reliability of the model, these comparisons must be made over time at different locations. Such a strict calibration procedure, which is tellingly missing from the Phase 2 Work Plan, performs a necessary "ground truthing" function prior to the use of any model in the Reassessment.

4.3.2 <u>Inappropriate Temporal and Spatial Scales</u>

EPA has also selected inappropriate temporal and spatial time scales for its mass balance analysis. The Phase 2 Work Plan indicates (p. 5-3) that a seasonal or yearly time scale will be coupled with a space scale based on river reaches. EPA must, however, demonstrate the appropriateness of these time and space scales by comparing *observed* annual loading estimates with *calculated* loads at the same location. Moreover, although the Phase 2 Work Plan notes (p. 5-3) that the Thomann model of the Lower Hudson employed comparable scales of analysis, there are important differences between the two systems. For example, the Lower Hudson is a tidal water body with dispersive transport, very large flow cross-sections, and water volumes that are controlled, in part, by the ocean. Time and space scales that may be appropriate to model the Lower Hudson therefore may not be appropriate to model the Upper Hudson.

Indeed, EPA's proposed use of a seasonal time scale in modeling PCBs is inconsistent with the historical data, which show that significant resuspension occurs only during short-term (one to five day) high flow events. Moreover, the data indicate that, as a result of bed armoring, high flow resuspension occurs primarily during the initial period of a high flow event. The use of long-term resuspension in a seasonal time scale model will therefore significantly misrepresent, and may overestimate, the interaction between the water column and the sediment bed.

4.3.3 Other Technical Questions

EPA's proposed mass balance analysis is also deficient in a number of other respects. For example, the Phase 2 Work Plan indicates (pp. 5-6, 5-7) that suspended solids will be separated into settleable and non-settleable fractions, but does not describe how such a fractionation will be accomplished. In addition, it is not clear how EPA intends to interpret the historical data (needed for model calibration) to make such a calculation, and the Work Plan is likewise silent on the way EPA intends to define the sorption characteristics of the two particle types.

EPA's proposed mass balance analysis also assumes (p. 5-6) equilibrium partitioning in the water column. Yet EPA rejects the very same assumption of equilibrium conditions in its discussion of water column particulate and dissolved PCB data. As the Work Plan notes (p. 5-15), "the water column [in the Hudson River] does not remain in one place long enough to allow diffusion limited equilibration between PCBs in the sediment and the water-column." EPA must reconcile these seemingly inconsistent assumptions.

In addition, the Phase 2 Work Plan obliquely refers (p. 5-5) to the use of diagenetic models to determine PCB burial rates. Although such an approach might have merit in a conceptual sense, EPA fails to specify how these (unspecified) diagenetic models would be employed. In particular, it is not clear from the Work Plan how the vertical flux of particles and contaminant will be modeled. The Work Plan is similarly silent on how EPA intends to relate the diagenetic changes in sediment particle characteristics to interactions of the contaminant with the particles.

Relatedly, the Phase 2 Work Plan does not indicate how the diagenetic changes will be considered when EPA uses the high resolution cores to convert sediment PCB concentrations into historic water column PCB loadings. This is a critical omission, for GE cannot fully comment on EPA's proposed approach without knowing, for example, how EPA intends to relate the changes in important sediment characteristics (such as organic matter content and composition) to PCB adsorption and movement within sediment and to the effects of such changes on the relationship between PCB concentrations observed at various depths and at the time of deposition.

4.4 Comments on Biotic Effects/Fish Population Response

The errors in EPA's proposed correlation to estimate PCB concentrations in fish are even more serious than the defects in EPA's mass balance analysis. The Phase 2 Work Plan proposes (p. 5-9) a correlation analysis that considers PCB concentrations in water and sediment to be independent variables and PCB concentrations in fish to be dependent variables. This analysis is flawed for several reasons.

4.4.1 Correlation Does Not Imply Causation

At the outset, EPA correctly recognizes (p. 5-11) that, "[o]f course, statistical correlations do not themselves imply either causality or the ability to extrapolate to future conditions." These limitations on EPA's proposed biotic effects analysis are significant, for determinations of cause-and-effect and projections of future conditions are the *raison d'être* of quantitative modeling. Indeed, EPA appears to brush aside any detailed discussion in the Phase 2 Work Plan of these limitations.

Instead, EPA indirectly asserts (p. 5-10) that knowledge of cause-and-effect relationships in some non-specific sense is somehow adequate to predict in a reliable manner the future effects of No Action and various remedial alternatives. Such a "black-box" approach is not appropriate at this site, however, because the dominant sources of PCBs to fish change over time, and because the composition of the dominant sources changes over time. Thus, even if a particular causal relationship could be determined (for a given set of data at a given time and place in the River), that relationship would be a complex function of many variables and, absent an adequate understanding of the interactions among those variables, cannot reliably be used to generalize about conditions at other times and other places in the River. Moreover, there is no evidence that the independent variables selected by EPA -- water-column and sediment PCB concentrations -- are truly independent over the range of flow conditions. These limitations make the proposed correlation analysis technically unsound. For this reason alone, EPA should be precluded from using its proposed correlation approach in its reassessment of the Hudson River site.

4.4.2 Lack of Sufficient Sediment Data

Even if the leap-of-faith inherent in EPA's correlation analysis were to withstand serious scientific scrutiny, its analysis would be fatally flawed because it cannot be developed from real observed data on sediment PCB concentrations over time.

The Phase 2 Work Plan indicates (p. 5-12) that analysis of high resolution sediment cores will be used to estimate average historical water and sediment concentrations in the Upper Hudson. This analysis apparently uses only a subset of the sediment data, the so-called "interpretable cores," to create a water and sediment database over time. EPA's proposed use of the core data in this manner, however, is inconsistent with the limitations of these data and with the assumptions behind the analytical methods. To illustrate:

- The correlation analysis requires an estimate of the average surface sediment PCB concentration over a reach associated with fish movements on an annual basis. How is the current sediment surface PCB concentration in a high resolution core related to the current average surface sediment concentrations over the area of concern?

- Can this relationship be tested with an independent database? Will the data to be generated in the Phase 2 sampling be used to test this relationship?

- How can these relationships be extrapolated to other areas where there are no "interpretable cores"?

- Sediment PCB concentrations are highly variable in space. Is there any reason to think that the relationship between spatially averaged surface sediment to core PCB concentrations will remain constant over time and space when the observed data indicate that there are relatively large spatial variations (horizontally and vertically)?

These are just a few of the numerous technical issues raised by the proposed application of the "interpretable high resolution cores" as part of EPA's biotic effects analysis in the Upper Hudson. As discussed previously (see Section 3.3 above), GE firmly believes that this technique is inappropriate for use in Upper Hudson and should therefore not be used as a key element in the Reassessment.

4.4.3 Failure to Consider Homolog Variations

EPA's proposed analysis also suffers from a failure to consider different homolog or congener levels. Such an analysis could take the form of (1) direct modeling of PCB homologs or congeners or (2) calculations that document that the modeling results are consistent with PCB homolog and congener patterns (and with variations in such patterns) observed over time and in different environmental media. This omission -- which incidentally is not discussed in EPA's Responsiveness Summary for the Phase 1 Report -- is a distinct and severe limitation in the usefulness of EPA's biotic effects analysis. Without such an analysis, EPA is unable to consider (1) the historical variation observed in the composition of PCBs in fish over time and (2) the different homolog distributions observed in PCBs in fish versus those in sediments.

These observed variations over time are caused by factors such as (1) changes in the dominant sources to the fish over time; (2) changes in the composition of the PCBs released by these dominant sources over time; and (3) differences in physical properties of different homologs. Thus, in determining the effect of various remedial alternatives on PCB levels in fish, EPA must recognize that different remedial alternatives are likely to affect homolog and congener levels in fish differently.

For example, even if a particular remedial alternative removes a given PCB source, that removal will have no effect on actual PCB levels in fish if the relevant congeners or homologs in the fish are not affected. Put simply, removing homolog A from the sediment at location X may well have no effect on the amount of homolog B in fish at location Y. This is particularly true for resident species of fish. Because EPA's proposed biotic effects analysis fails to provide for this essential area of inquiry, EPA risks reaching erroneous conclusions as the actual effects of certain remedial alternatives.

4.4.4 <u>Inappropriate Use of Average Values</u>

Even apart from the conceptual flaws contained in EPA's proposed correlation analysis, the use of such an analysis to predict PCB concentrations in Hudson River fish is subject to considerable uncertainty. Much of this uncertainty results from the significant variability in the relationship between PCB levels in fish, on the one hand, and PCB levels in the water column and the sediment, on the other. This variability, in turn, results from the inability of the exposure history of fish to be accurately represented by the single values of water column and sediment levels that are used in the correlation.

Specifically, PCB levels in fish depend, among other things, on the water column and sediment PCB concentrations to which the fish have been exposed over the previous months or years, depending on the age of the fish and its rates of PCB uptake and depuration. Thus, for example, the relatively good correlation between PCB levels in yearling pumpkinseed (caught in September) and summer-average water-column PCB levels reflects the fact that the summer-average water-column PCB concentration is a good indicator of prior PCB exposure.

Even so, as the Phase 2 Work Plan acknowledges (p. 5-11), this correlation is heavily influenced by the 1979 and 1980 data points. For example, the bioaccumulation factor derived from the 1984 to 1988 data is about 6.8×10^5, as contrasted to the bioaccumulation factor of 1.6×10^6 that is derived from the full data set. In addition, the correlation for large mouth bass (Figure B.4-28 in the Phase 1 Report) is poorer than that of the yearling pumpkinseed and shows no relationship between fish and water column PCB levels after 1980. The reasons for this poor or non-existent correlation are that (1) the large mouth bass were collected in June and were therefore never exposed to the same-year summer-average PCB concentrations against which they are correlated and (2) large mouth bass have much slower uptake and depuration rates than yearling pumpkinseed, which means that their PCB concentrations reflect a much longer historical exposure.

In sum, the correlation analysis proposed by EPA has limited quantitative predictive power, because the underlying relationship between the fish PCB concentrations and exposure concentrations is not known *a priori*. The appropriate averaging period is species- and age-specific and can only be estimated by explicitly considering the PCB uptake and loss rates, as has been done in previous food-chain modeling (*e.g.*, at the New Bedford Harbor Superfund site) conducted by EPA and others.

Indeed, GE is dismayed to learn that EPA has reiterated in its Responsiveness Summary for the Phase 1 Report (p. B.4-14) that it is neither "feasible" nor "appropriate" to develop a detailed food-web model of PCB bioaccumulation in Upper Hudson resident fish. Given that one of the overriding goals of the model is to provide a reliable tool for predicting the effects of No Action and various remedial alternatives on future PCB levels in fish, GE strongly urges EPA to reconsider its rejection of a state-of-the-art food-chain model. In relying on an untested correlation analysis, by contrast, EPA risks reaching an erroneous or unreliable conclusion on one of the most important issues in the Reassessment.

4.5 Comments on Erodibility Analysis

The Phase 2 Work Plan also presents (p. 5-17) an unjustifiably simplified approach to determining the erosional effects of an extreme flow event in the Thompson Island Pool. EPA's simplified approach -- which rests on a series of debatable assumptions -- lacks scientific credibility and is likely to lead to erroneous results. GE urges the use of the best and most credible available technology for this important analysis.

4.5.1 EPA's One-Dimensional Analysis Is Flawed

Two important characteristics of the Thompson Island Pool dictate the appropriate level of hydrodynamic and sediment transport analysis. First, as discussed in GE's comments on the

Phase 1 Report, and as EPA recognizes (p. 5-19), the Thompson Island Pool (and the Upper Hudson River generally) contains a heterogeneous sediment bed consisting of cohesive and non-cohesive sediments. Second, the Thompson Island Pool exhibits significant lateral variations in bathymetry.

These two characteristics compel, at a minimum, the use of a two-dimensional, vertically-integrated hydrodynamic model to predict the effects of a significant flow event in the Thompson Island Pool. The averaging process inherent in a one-dimensional hydrodynamic model produces large errors in predicting local bottom shear stresses and, hence, erosion estimates, especially during an extreme flood event. For this reason, a two-dimensional model will provide much more accurate estimates of bottom shear stresses, which can vary significantly along a lateral transect, compared to the average value produced by a one-dimensional model. This in turn means that, in light of the heterogeneity of the sediment bed, the erodibility analysis that results from a two-dimensional model will yield more scientifically credible results than that produced by EPA's proposed one-dimensional approach.

EPA attempts to justify its use of a one-dimensional model on the basis of a simplistic and ultimately flawed argument. EPA asserts (p. 5-19) that a one-dimensional model, for both hydrodynamic and sediment transport analyses, is appropriate for the Thompson Island Pool because the width-depth ratio is less than 100. This criterion might be valid if this reach of the Upper Hudson River had an approximately prismatic channel (*i.e.*, a channel with a rectangular cross-section), and if the Upper Hudson contained a homogeneous sediment bed. However, as noted above, the Thompson Island Pool has neither of these characteristics. Accordingly, EPA cannot arbitrarily justify its use of a one-dimensional model based solely upon the width-depth ratio of the Thompson Island Pool.

EPA also attempts to justify its proposed use of a one-dimensional model on the ground that the available calibration data do not warrant the use of a two-dimensional model. Even if this point were true, which it is not, the proper response is not to perform a technically inadequate analysis, but to collect the required data. In any event, GE believes that a two-dimensional hydrodynamic model of the Thompson Island Pool could be calibrated as confidently as a one-dimensional model. In fact, EPA presented preliminary calibration results of a quasi-two-dimensional application of DYNHYD5 to the Thompson Island Pool in its Phase 1 Report. This work indicates that EPA considered a two-dimensional analysis to be appropriate at that time. EPA has given no valid reason for suddenly altering its analytical assumptions.

Stage height data, for example, can be used to calibrate either a one- or two-dimensional hydrodynamic model with equal confidence. Moreover, high-resolution water depth data, for historical and current conditions, are and will be available for the Thompson Island Pool. This information can be used to generate an accurate bathymetric map. A two-dimensional hydrodynamic model, in conjunction with such a bathymetric map, could then be calibrated with a high degree of confidence. This hydrodynamic model would then produce a much more realistic and accurate estimate of the bottom shear stress distribution than that derived from a one-dimensional analysis.

4.5.2 <u>EPA Fails To Analyze Cohesive Sediments Properly</u>

Determination of the resuspension potential (and hence erosion probability) of cohesive sediments is of primary importance for estimating the effects of an extreme flood event. The properties of a cohesive sediment bed vary vertically in a manner such that the shear strength of the bed increases with depth. This non-uniformity in shear strength causes the bed to armor itself when a specific shear stress is applied to the bed. In other words, only a finite amount of sediment will be resuspended for a given shear stress. This phenomenon has been well-documented in laboratory flume studies of cohesive sediments (Parchure and Mehta, 1985; Tsai and Lick, 1985; MacIntyre *et al.*, 1990).

In its Phase 2 Work Plan, EPA correctly notes (p. 5-19) that the erosional properties of cohesive and non-cohesive sediment beds are different. The Phase 2 Work Plan fails, however, to recognize the important differences between critical bed shear stress and bed shear strength. The Phase 2 Work Plan emphasizes the need to determine critical shear stress, and EPA's proposed experimental studies are supposedly designed to evaluate variations of this parameter throughout the Thompson Island Pool. But because EPA confuses the importance of critical bed shear stress and bed shear strength, EPA's proposed approach is seriously misguided.

The critical shear stress of a cohesive bed is a measure of the erodibility of a very thin layer of sediment at the sediment-water interface. Critical shear stress therefore indicates only when the initiation of erosion begins. This parameter is not of primary importance in determining what is critical -- the ultimate resuspension potential of the cohesive bed. To determine the resuspension potential of a cohesive bed, EPA therefore needs to measure the bed shear strength and its variation with depth in the bed.

Even apart from this fundamental conceptual flaw in EPA's analysis, the experimental apparatus selected by EPA to determine critical shear stresses will not yield valid results, because the proposed experimental approach is inappropriate for studying cohesive sediment properties. The primary difficulty with a stirring device (Figure A.3.2 in the Work Plan) is that the effective shear stress at the sediment-water interface cannot accurately be determined, because the stirring action generates a turbulent flow that makes it extremely difficult to calculate the shear stress. Even if experimental work is conducted to determine the bed shear stress, such work will not resolve all of the problems with the proposed approach. An additional critical problem with the stirring device is that it generates shear stresses at the sediment-bed interface that vary radially in a complex manner. The sediment bed in the experiment is therefore subjected to a non-uniform shear stress, and any measurements from the device cannot be related to a specific, or even average, shear stress with any confidence. Even if an average shear stress is used, determining an average value that is truly representative will be problematic.

An additional source of error arises from the fact that these experiments will apparently be conducted in a laboratory. Laboratory procedures are likely to alter the properties of the cohesive sediments between the time that the cores are collected in the field and transported to the laboratory. To determine the *in situ* properties of a cohesive sediment bed, these experiments need to performed in the field using undisturbed cores. Parameters derived from laboratory experiments that do not accurately quantify the *in situ* sediment bed will significantly affect the credibility of the erodibility analysis.

4.5.3 <u>EPA Omits Model Calibration</u>

No less critical a flaw in EPA's proposed analysis is EPA's failure to discuss an essential element of any model -- calibration and verification. Without calibration and verification, any results of EPA's erodibility analysis will be tenuous at best, and possibly totally unrealistic. Contrary to EPA's statement that sediment transport model calibration data do not exist for the Upper Hudson River, the historical database contains USGS sediment transport measurements and PCB concentrations during floods (*e.g.*, February 1981, April 1982, and May 1983) that may be used to evaluate the accuracy of the erodibility analysis. There is no question but that EPA must perform model calibration and validation if its erodibility analysis is to have any shred of scientific credibility.

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5.0 HUMAN HEALTH RISK ASSESSMENT

5.1 Toxicology

Although EPA appears to have acknowledged the existence and possible relevance of the toxicological information provided by GE in its Phase 1 Comments, EPA's Phase 2 approach to the evaluation of additional toxicological information falls short of EPA's obligations regarding such information in this Reassessment.

As an initial matter, EPA concedes (p. 6-3) that the new information on PCB carcinogenicity may warrant a revision to the existing potency estimate for PCBs and acknowledges that EPA's Office of Research and Development is performing such a reassessment. Such acknowledgements, however, do not fully alleviate Region II's responsibilities.

GE believes that the EPA staff responsible for the RI/FS has an affirmative obligation to respond to information that casts undeniable scientific doubt on the PCB toxicity information it has been using to date in the RI/FS. EPA guidance (EPA, 1989) requires the "regional staff" to consult with the EPA IRIS coordinator and establish a verification workgroup when confronted with information demonstrating that IRIS toxicity values for PCBs are outdated or inapplicable. The Work Plan should have included a requirement to convene the Carcinogen Risk Assessment Verification Endeavor (CRAVE) Work Group to consider the cancer potency. The "it's not my job" attitude expressed in the Phase 2 Work Plan, as well as in the Phase 1 Report, is improper. The use of inaccurate risk conclusions to drive a decision-making process will only lead to incorrect and inappropriate results.

Specific issues relating to carcinogenic and noncarcinogenic PCB toxicity are set forth below.

5.1.1 Carcinogenic Toxicity

In its assessment of PCB toxicity in the Phase 1 Report, EPA used an estimate of the carcinogenic potency of 7.7 $(mg/kg\text{-}day)^{-1}$ to estimate the potential human cancer risk associated with exposure to PCBs. EPA derived this potency by (1) applying the linearized multistage model to the data generated from the Norback and Weltman (1985) chronic rat bioassay and (2) scaling from rats to humans using a surface area scaling factor ($[body\ weight]^{2/3}$). Using the classification scheme for proliferative rat liver lesions described by Squire and Levitt (1975), Norback and Weltman (1985) reported a combined tumor incidence of 1/49 and 45/47 for the control and dosed female rats, respectively.

In its Phase 1 Comments, GE presented new scientific evidence that requires a change in this potency estimate. Specifically, GE discussed how the classification scheme for proliferative lesions in the rat liver has changed since the Norback and Weltman (1985) bioassay results were published and how the outdated classification scheme of Squire and Levitt (1975) overstates the tumor incidence reported in the pre-1986 rat studies. The current classification scheme for rat liver neoplasms developed by the National Toxicology Program (Maronpot *et al.*, 1986; McConnell *et al.*, 1988) and endorsed by EPA (1986a)

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has been used by the Institute for Evaluating Health Risks (IEHR) to reexamine the rat liver slides from the Norback and Weltman (1985) study as well as from four other rodent studies (Linder *et al.*, 1974; Kimbrough *et al.*, 1975; NCI, 1978; Schaeffer *et al.*, 1984).

As stated in GE's Phase 1 Comments, the reevaluation provides evidence that PCB mixtures of 60 percent chlorine are carcinogenic in rats, but suggests that its carcinogenic potential may be lower than previously estimated. For PCB mixtures containing less than 60 percent chlorine by weight, there is no evidence to suggest that these mixtures are carcinogenic in rats. The chronic bioassays conducted by NCI (1978) of a PCB mixture containing 54 percent chlorine (Aroclor 1254) and Schaeffer *et al.* (1984) of a mixture containing 42 percent chlorine (Clophen A30) did not demonstrate a statistically significant increase in benign, malignant, or combined tumors (IEHR, 1991; Moore, 1991).

Although the Phase 2 Work Plan acknowledges (p. 6-3) the reevaluation of the rat liver slides by IEHR, the Work Plan does not itself deal with this new scientific evidence, pointing instead to the Office of Research and Development (ORD) evaluation of the new information. According to the Work Plan, Region II will use a revised potency factor in the Phase 2 human health risk assessment only if ORD determines that an adjustment to the potency is appropriate. Further, Region II will use a multiple potency approach to determine cancer risks from PCB exposure in Phase 2 only if ORD establishes separate potencies for different Aroclor mixtures. As noted above, Region II's reliance on ORD activities is insufficient to relieve its burden to consider new scientific evidence relating to PCB toxicity in the Hudson River human health risk assessment. EPA should revise the Work Plan to include the convening of a CRAVE work group.

Finally, GE notes that a revision in the estimates of the potency of PCBs is also timely given the Agency's recent proposal to change its policy on inter-species scaling. This proposal has been approved by EPA and other federal agencies and has appeared for comment in the Federal Register. (57 Fed. Reg. 24152, June 5, 1992). The decision to change the scaling factor will reduce the estimate of potency of PCBs by approximately 40 percent.

5.1.2 Non-Cancer Toxicity

The Phase 2 Work Plan notes that the potential noncarcinogenic risks reported in the Phase 1 Report were estimated by using an unsubstantiated reference dose (RfD) of 1 x 10^{-4} mg/kg-day (p. 6-3). This RfD was based on application of a 100-fold safety factor to the no-observable-adverse-effect-level (NOAEL) of 0.0105 mg/kg/day for developmental effects (decreased birth weights) observed in the Barsotti and Van Miller (1984) rhesus monkey study. (EPA, 1988a). GE supports EPA's decision not to use an RfD based on an inadequate study. As explained in GE's comments on the Phase 1 Report (pp. 86-91), numerous methodological problems with the Barsotti and Van Miller (1984) study preclude its use as the basis for the development of an RfD for PCBs.

With respect to EPA's ability to evaluate potential non-cancer toxicities in the absence of a substantiated RfD, the Work Plan states (p. 6-3):

> the Environmental Criteria Assessment Office (ECAO) of USEPA is currently evaluating available non-cancer toxicity data on PCBs to determine whether the data support promulgation of an RfD . . . If available, the new RfD or non-cancer toxicity endpoints will be incorporated into the assessment. Should the ECAO fail to establish an RfD for PCBs, then an evaluation of the potential non-cancer toxicities associated with exposure to PCBs in the Hudson River will not be reported.

GE supports EPA's decision to defer consideration of PCBs noncarcinogenic effects until an RfD has been appropriately established based on good science with the opportunity for public comment.

5.2 Proposed Use of Monte Carlo Analysis in the Phase 2 Assessment

GE is pleased that EPA has recognized the value of Monte Carlo analysis by including (p. 6-2) this simulation technique in the Phase 2 Work Plan for the human health risk assessment. However, GE believes that EPA has inappropriately diminished the value of Monte Carlo simulations by relegating the use of this technique solely to an uncertainty analysis. This minor role given to Monte Carlo analysis is particularly troubling in light of recent changes in EPA's policy on exposure assessments.

As detailed more fully below, this new policy represents a significant departure from the reasonable maximum exposed individual analysis used in the Phase 1 Report. Instead, exposure assessments of individuals (both typical and high-end), populations and important subgroups are required. These exposure analyses will then provide more useful information to allow meaningful decisions regarding risk and the need for action. The Phase 2 Work Plan fails to address the issue of how the Hudson River human health risk assessment will be revised to comport with the new policy so as to provide the most relevant information regarding potential risks to human health from PCBs in the Upper Hudson. Yet, the tool for such analyses is contained in the Work Plan -- Monte Carlo simulation. GE believes that through Monte Carlo modeling of microexposure events, EPA can arrive at risk calculations for individuals and populations that will be meaningful to the determination of what action, if any, is required to reach acceptable risk levels to humans due to PCB exposures.

The subsections below discuss the appropriate use of Monte Carlo analysis for the Hudson River, including a description of the key Monte Carlo modeling parameters. EPA must rewrite the human health risk assessment portion of the Phase 2 Work Plan to reflect EPA's revised approach to exposure assessments through the use of Monte Carlo simulations. At the very least, information must be presented in the revised plan regarding how EPA plans to define target populations and any subpopulations and how EPA plans to calculate population risks, typical individual exposures, and high-end exposures.

5.2.1 Recent Changes in EPA Policy on Exposure Assessment

In the Phase 1 Report, EPA assessed exposure to PCBs from the Hudson River site by means of a reasonable maximum exposed individual (RME) analysis. This analysis was performed using the approach established by EPA in the "Risk Assessment Guidance for Superfund Sites" (RAGS) (EPA, 1989a). Under this approach, EPA developed extreme estimates of the values for each of the parameters in a fish consumption scenario. For many of the parameters, EPA used national or default estimates.

After the Phase 1 Report was issued, EPA revised its policies for performing exposure and risk assessments. This policy revision was announced by EPA Deputy Administrator Henry Habicht in a memorandum dated February 26, 1992 (EPA, 1992b) and in the new Guidelines for Exposure Assessment (EPA, 1992c). The Habicht memorandum states that improvements to federal risk assessments are needed in all EPA offices to provide consistency and comparability in risk assessment and to increase confidence in professional scientific judgment. A key aspect in improving risk assessments is the need for a full and complete presentation of risk. Numerical risk assessments should be accompanied by a full characterization of uncertainties, limitations, and assumptions. Habicht then cites the need to use the multiple exposure descriptors presented in the revised Exposure Assessment Guidelines. These guidelines state that "the use of several descriptors, including descriptors of both individual and population risk, often provides more useful information to the risk manager than a single descriptor or risk value." (EPA, 1992c, p. 44).

Habicht's memorandum goes on to order that "effective immediately," several types of risk assessment information must be provided in new Agency reports, presentations, and decision packages. These include individual risks, population risks, and important subgroups of the population.

The new policy calls for a major departure from the approach set forth in RAGS (EPA, 1989a). Under the new policy, multiple types of exposure assessments are required. Two types of individual exposure must be presented. The first is a typical exposure. This estimate should characterize the exposure received by the typical member of the exposed population. This assessment differs from the RME approach which tends to use extreme non-typical estimates of exposure parameters.

In addition to the typical exposure estimates, the high-end exposure (HEE) estimates are also required. The HEE is intended to estimate the doses received by the small but definable "high end" of the population. This estimate must be a realistic estimate of a possible or actual exposure, not a worst-case or boundary estimate. The HEE differs from the RME estimate established under RAGS in that the HEE must be realistic.

Population risks are the second type of exposure information required. The Guidance lists several forms that descriptors for population risk can take. First, a probabilistic projection of the estimated extent of occurrence of a particular effect in a population or subpopulation can be expressed. This type of result will be typically generated for carcinogenicity assessment. Second, for non-cancer assessments, population risks can be expressed as the number of people receiving doses in excess of the reference dose.

Third, a characterization of the distribution of risk among various segments or subgroups of the population is required. The goal of this third descriptor is to indicate if unacceptable risks may be occurring in small subgroups of the population.

These new policies will require a Phase 2 risk assessment that is significantly different from the Phase 1 risk assessment. The Phase 2 Work Plan therefore must be revised to indicate how the new risk assessment will be performed and what data will be collected. Specifically, EPA must revise the Work Plan to address the following issues:

- How will the target population and any sub-populations be defined?
- How will population risks be calculated?
- How will population size be estimated?
- How will typical individual exposures be estimated?
- How will high-end exposure estimates be prepared?

5.2.2 Use of Monte Carlo Modeling Under the New Experimental Risk Policy

Under previous policy, EPA discouraged the use of Monte Carlo simulations as a means of estimating exposures, but permitted its use in uncertainty analyses. (EPA, 1989, p. 6-50). By contrast, under the revised exposure guidelines, Monte Carlo assessments are endorsed as an appropriate means of determining typical and higher end individual exposures and population risks.

Habicht (EPA, 1992b, p. 24) states that:

> If sufficient information about the variability in lifestyles and other factors are available to simulate the distribution through the use of appropriate modeling, e.g. Monte Carlo simulation, the estimate from the simulated distribution may be used.

The Guidance for Exposure Assessment (EPA, 1992c, pp. 122-23) makes a similar statement:

> If sufficient data on the distribution of doses are available, take the value directly for the percentile(s) of interest within the high end . . . If data on the distribution of doses are not available, but data on the parameters used to calculated the dose are available, a simulation (such as an exposure model or Monte Carlo simulation) can sometimes be made of the distribution.

5.2.3 Monte Carlo Analysis Should be Used to Establish Individual and Population Risk Descriptors

The Phase 2 Work Plan states that a Monte Carlo simulation will be performed as a "quantitative uncertainty analysis." GE supports EPA's decision to perform a Monte Carlo analysis as part of the Phase 2 efforts. GE also agrees with EPA that sufficient data on the key exposure factors exist to justify a Monte Carlo analysis (see Section 5.2.5 below). The Work Plan, however, does not specify what role the Monte Carlo analysis will play in the assessment, except to state (p. 6-2) that:

> This [Monte Carlo] analysis will provide an indication of appropriate upper bound exposure to PCBs from the consumption of Hudson River fish.

In addition, the Work Plan suggests (pp. 6-1, 6-2) that EPA intends to continue to rely on the point estimate approach used in the Phase 1 Report to describe individual risks. If this interpretation is correct, then the Monte Carlo analysis could be relegated to an ancillary role of a quantitative check on a point estimate approach.

GE strongly objects to this ancillary role for the Monte Carlo analysis. As discussed above, EPA's policies for exposure assessment established in the Guidelines for Exposure Assessment (EPA, 1992c) and the Habicht memorandum on Guidance on Risk Characterization for Risk Managers and Risk Assessors (EPA, 1992b) state that where there is sufficient information on the distribution of exposure parameters to allow a Monte Carlo assessment, it can be used to characterize the distribution of doses and to establish the typical and HEE estimates. Specifically, EPA has outlined three alternative methods for determining an HEE of dose:

- The first choice is to directly measure the variation in dose in a large number of individuals, if such data are available (EPA, 1992b, p. 24; EPA, 1992c, p.122).

- If such data are not available, but distribution data on key exposure parameters are known, then a Monte Carlo simulation may be used (EPA, 1992b, p. 24; EPA, 1992c, p.123).

- The third choice should be applied when data on the distribution of the dose are too limited to allow a Monte Carlo assessment. In such cases, the high end is estimated by using maximum or near-maximum values after identifying the most sensitive parameters. All other variables are left at their mean values (EPA, 1992b, p. 25).

Thus, EPA no longer has the option of calculating an RME based on point estimates and then checking the reasonableness of the assessment with a Monte Carlo model. In stating (p. 6-2) that the data are sufficient to perform a Monte Carlo assessment, EPA acknowledges that the results of the assessment should be used as the basis for the HEE.

5.2.4 Monte Carlo Modeling Issues

Monte Carlo modeling of long-term exposures is an established technique in risk assessment and has been the subject of a number of recent publications (Thompson, 1992; McKone and Bogen, 1991). However, useful applications of Monte Carlo modeling to exposure assessment are not achieved by simply replacing point estimates of key exposure parameters with distributions in the lifetime average daily dose (LADD) equation. In this section, GE presents a discussion of several methodological issues on the proper application of Monte Carlo techniques to the determination of long-term exposure to PCBs from fish consumption.

5.2.4.1 Limitations of Traditional Monte Carlo Models of Long-Term Exposure

In many recent publications, Monte Carlo analyses of risk have been performed by replacing point estimates with distributions in long-term exposure equations (Thompson, 1992; Anderson, 1992). This approach raises a number of significant problems. Simple replacement of point estimates with distributions implies that an individual will be exposed to a single environmental concentration for her entire life, and that her rate of intake and body weight will remain constant over her lifetime. Using this approach, the model will typically overestimate the upper-end of the distribution of exposures. In the case of fish consumption in the Upper Hudson River, this approach unrealistically assumes that a person consumes a lifetime of fish containing uniform concentrations. In addition, this approach fails to relate the modeled individuals to the history of the changing levels of PCBs at the site. The solution to this problem is to model individual exposures as a series of microevents (consumption of individual fish) and to estimate the individual's chronic and lifetime exposures based on the collective contribution of each event.

5.2.4.2 Monte Carlo Modeling of Microexposure Events

Monte Carlo modeling of microexposure events is a technique in which an individual's total exposure to a compound is viewed as a sum of many separate exposure events. Each individual event can be modeled using information specific to the key parameters for the event. In addition, the number of events and sequence in which they occur in the individual's life can also be modeled based upon individual long-term behavior.

The difference between traditional Monte Carlo modeling and microexposure modeling can be illustrated by comparing the equations used to determine the total dose accumulated over time. For carcinogen risk assessments in which risks are expressed in terms of lifetime probabilities, doses have been presented as lifetime average daily doses (LADDs) according to the following equation:

$$LADD = \frac{C * IR * ED}{BW * LT} \qquad (1)$$

where LADD is the lifetime average daily dose, C is the average concentration of the chemical in the medium, IR is the average intake rate of the medium, ED is the exposure duration, BW is body weight, and LT is the lifetime (converted to days) over which the dose is averaged. (EPA, 1992c). In contrast, Monte Carlo modeling offers a more realistic approach by defining lifetime exposure as the sum of potential short-term (*e.g.*, annual, daily) exposures represented by the following equation:

$$LADD = \frac{1}{LT} \sum_{i} \frac{C_i * IR_i * ED_i}{BW_i} \tag{2}$$

where C_i is the average concentration of the chemical in the medium for the i^{th} year, IR_i and BW_i are the average intake rate and body weight for the i^{th} year, ED_i is the exposure duration for the i^{th} year, and LT is the lifetime (converted to days) over which each annual dose is averaged.

This technique is not new. In fact, EPA's current Guidelines for Exposure Assessment suggest that a version of Equation 2 should be applied when exposure occurs primarily in the early period of an individual's life, such as inadvertent soil ingestion during childhood, when body weights are changing rapidly. (EPA, 1992c, p. 133).

The application of this approach is very useful in modeling exposures from fish consumption. In a fish consumption scenario, an angler's lifetime dose can be considered the sum of the doses for each year he or she fishes from the site. Each year of fish consumption can, in turn, be modeled as the sum of fish consumed during that year. Equation 3 indicates how a LADD would be calculated using this approach.

(Equation 3) $$LADD = \frac{1}{LT} \sum_{i}^{k} \frac{(\sum_{ji}^{n_i} FC_{ji} * FW_{ji})}{BW_i}$$

where FC_{ji} is the concentration of PCBs in the fillet of the j^{th} fish caught in the i^{th} year of the angler's life, FW_{ji} is the fillet weight of the j^{th} fish caught in the i^{th} year of the angler's life, n is the number of fish that the angler catches in the i^{th} year, BW_i is the body weight of the angler during the i^{th} year, and k is the year the angler stops fishing at the site. The number of fish caught (n) in a single year (i) is a function of the angler's fish consumption rate and the sizes of the fish at the site. As discussed below, an advantage to this approach is that the effects of factors such as age and temporal changes in PCB concentrations in fish can be incorporated into the model.

In addition to calculating LADD, this approach also yields valuable information on annual intakes and is useful for evaluating non-cancer risks at specific points in time. For example, if PCB concentrations were recorded for various species of fish collected in 1991, a Monte Carlo simulation of the distribution of doses received by anglers in 1991 can be performed. This distribution can be used to estimate individual and population risks for that year.

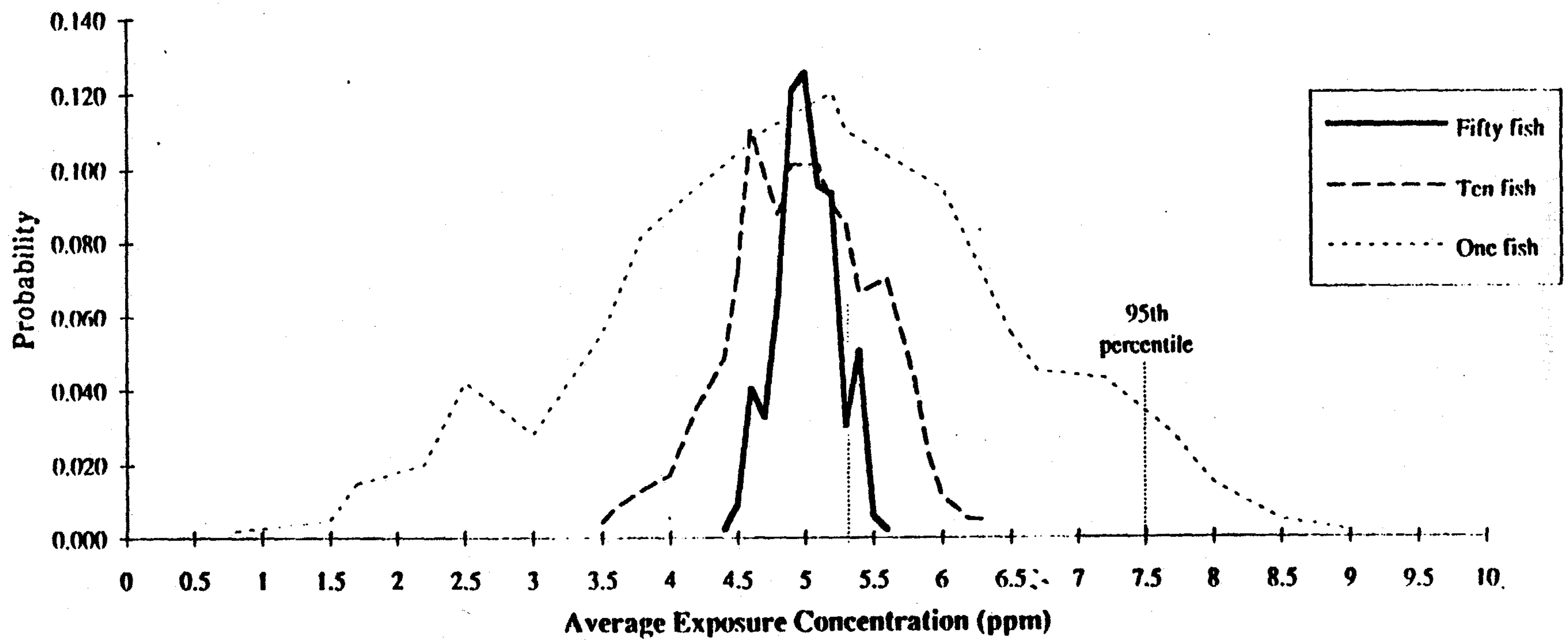
5.2.4.3 Microexposure Events Allows for a Proper Use of Short-term Data

One of the major advantages of microexposure event modeling is that it makes proper use of short-term data. In its Guidelines for Exposure Assessment, EPA (1992c) points out that using short-term data to estimate long-term exposures has a tendency to overestimate the exposure levels at the upper-end of the distribution. The following hypothetical scenario demonstrates how this occurs and what this implies for modeling long-term exposures from fish consumption.

Consider a simplified exposure scenario in which 500 anglers each consume a fixed number of fish a year, and the PCB concentration in the fish population is normally distributed with a mean of 5.0 ppm and standard deviation of 1.5 ppm. In addition, assume there is a uniform probability of any angler catching and consuming any fish. Figure 5-1 presents the distribution of the average PCB concentration in the consumed fish as a function of the number of fish the angler consumes. It should be noted that using EPA's assumption of 30 g/day for fish intake, an angler would consume approximately 50 fish per year in the Upper Hudson region.

Figure 5-1 illustrates several important points. First, the mean PCB concentration in the fish consumed by the anglers is approximately equal to the mean concentration of PCBs in the fish population (5.0 ppm), and is independent of the number of fish consumed. Second, the distribution is collapsed towards the mean (tails become shorter) as more fish are consumed. Based on the simulation using @Risk, the 95th percentile for the distribution of exposure intakes decreases with increased numbers of fish consumed. The distribution of exposure intakes associated with the maximum number of fish

Figure 5-1. Exposure Concentrations Associated with Different Numbers of Fish Consumed



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consumed (50) has a 95th percentile of 5.2 ppm, while the 95th percentile of the PCB concentration in the fish is 7.0 ppm.

This simulation illustrates how using short-term data to estimate long-term doses accurately estimates the mean but can overestimate the high-end risk descriptor. Traditional Monte Carlo models use the same distribution of PCB levels for high consumers as for low and thus overestimates the doses received by the highly successful anglers. Monte Carlo models of microexposure events avoid this problem by allowing multiple iterations of each microexposure scenario to be executed during a single simulation. Thus, the highly successful angler will be allowed to consume fish with varying levels of PCBs and the upper-end of the distribution will be more accurately defined by this technique.

5.2.4.4 Consideration of Age and Gender in Monte Carlo Modeling

In the point estimate determinations of LADD, EPA has not explicitly considered the impact of age and gender. The age of an individual greatly affects his or her mobility (Price *et al.*, 1992) and rate of fish consumption (ChemRisk, 1991a), while both age and gender affect body weights (EPA, 1989b). Therefore, GE strongly encourages EPA to incorporate the age and gender of the individuals when modeling angler intake. One possible technique for incorporating age and gender into the model is discussed below.

A Monte Carlo simulation would assign gender to the hypothetical angler based on the relative frequency of male and female anglers. It is important not to assume an equal probability of an angler being male or female since angler surveys have shown that most anglers are male (Puffer *et al.*, 1981; Connelly *et al.*, 1990; ChemRisk, 1991a). Similarly, EPA should assign an age to each individual of a model based on the age distributions in angler surveys. Once the age and gender are determined, then appropriate distributions of body weight, mobility, and mortality can be selected. For example, body weight is a function of gender and age. In addition, a range of body weights exists for each age and gender. The distribution of body weight ranges can be identified as percentiles for the population at that age based on U.S. census data. The Monte Carlo model would first randomly select a percentile, and then select a specific value for the individual's body weight corresponding to the distribution for each age and gender.

5.2.4.5 Exposure Duration

EPA has traditionally estimated exposure duration to be 30 years based on residential mobility. (EPA, 1989b). A distribution for time spent in a specific home is available (EPA, 1989c) and has been used in Monte Carlo modeling (McKone and Bogen, 1990). An alternative method of estimating duration is to incorporate age-specific data on mobility and angler activity to generate an age-specific probability for an angler ceasing to fish at the site. This type of approach has been used to investigate residential and occupational exposures. (Price *et al.*, 1991; 1992). The approach works as follows: after calculating intakes from one year, the simulation would then determine whether the individual continues to fish for the following year. This determination would be based on age-specific data for ceasing angling and mobility. If the model determines that the angler does fish for a second year then that year's intake is determined and summed with the first year's intake. These steps would be repeated until the angler ceases to fish. At that point, the total of all the years' exposures would become the lifetime exposure.

The exposure duration is thus the difference between the age of the angler when he or she stopped angling and the age when he or she started angling. This would likely be a conservative estimate since it assumes that exposure is continuous throughout this period. Mobility and mortality data are available from census data and will vary according to the age and gender of the individual. Information on the probability of ceasing angling can be obtained from regional information or angler surveys.

5.2.4.6 <u>Consideration of Species and Cooking Loss</u>

The technique of microexposure-event modeling produces a more careful characterization of intake by considering angler preference in the species of fish caught as well as the effect of cooking practices on PCB levels in the consumed fish.

The specific quantity of PCBs consumed in a single meal is a function of the PCB concentration in the fish, the fillet size, and PCB losses from cooking. In order to account for variability in PCB concentrations and fish lengths among fish species, a Monte Carlo model of microexposure events would assign a species to each fish consume based on the consumption frequencies of species identified in angler surveys. After the fish species consumed in a single meal is determined, PCB level will be randomly assigned from the available data on fish species. A size for the fish would also be selected from the range of fish sizes for the species selected.

Likewise, a cooking method for each fish meal would be identified based on the frequency of use (as identified in appropriate surveys). Appendix A describes in detail the effect of cooking methods on PCB levels in fish. During the Monte Carlo model of the meal, the PCB intakes associated with the consumption of the fish would be reduced by the fraction of PCBs removed during the cooking process.

5.2.4.7 **Definition of the Exposure Period**

In the Phase 1 Report EPA did not explicitly discuss the period of exposure modeled. However, scenario 2 of the fish consumption exposure estimate (with the decaying factor) was based on estimated PCB levels in fish in the years 1988 through 2018. (EPA, 1991b, p. B.6-8). GE believes that Monte Carlo modeling should begin at the present year and continue into the future.

5.2.4.8 **Change in PCB Concentrations with Time**

PCB concentrations in fish have declined greatly over time. In the Phase 1 Report, for example, EPA estimated that the 30-year average of PCB levels would be eight times lower than the 1986-88 levels. If this rate of decline is exponential, the annual rate of decline is approximately 26 percent per year.

The microexposure-event modeling technique readily and efficiently incorporates information on future levels of PCBs. The Monte Carlo model would begin with an estimate of current levels of PCBs and then adjust the levels in the fish in each subsequent year. In this way, the model would generate estimates of LADDs that fully reflect predicted levels of PCBs. Since each year is modeled separately, future levels of PCBs need not be expressed in terms of a simple exponential decline.

The technique of modeling microexposure events can also generate estimates of probable risk for a specific year. For example, if one was interested in future risks to anglers who fished four years after PCB concentrations in fish are determined, the approach would account for the changing PCB concentrations by setting the initial year ahead by four years.

5.2.5 Key Parameters Required for Monte Carlo Assessments

The major issue in Monte Carlo modeling is the need for high quality data on the distribution of key exposure parameters. Monte Carlo modeling requires data on (1) angler demographics, such as age, gender, mobility, and mortality; (2) fish consumption rates; and (3) levels of PCBs in the fish consumed. Factors affecting the determination of these key parameters are discussed in detail below.

5.2.5.1 Angler Demographic Data

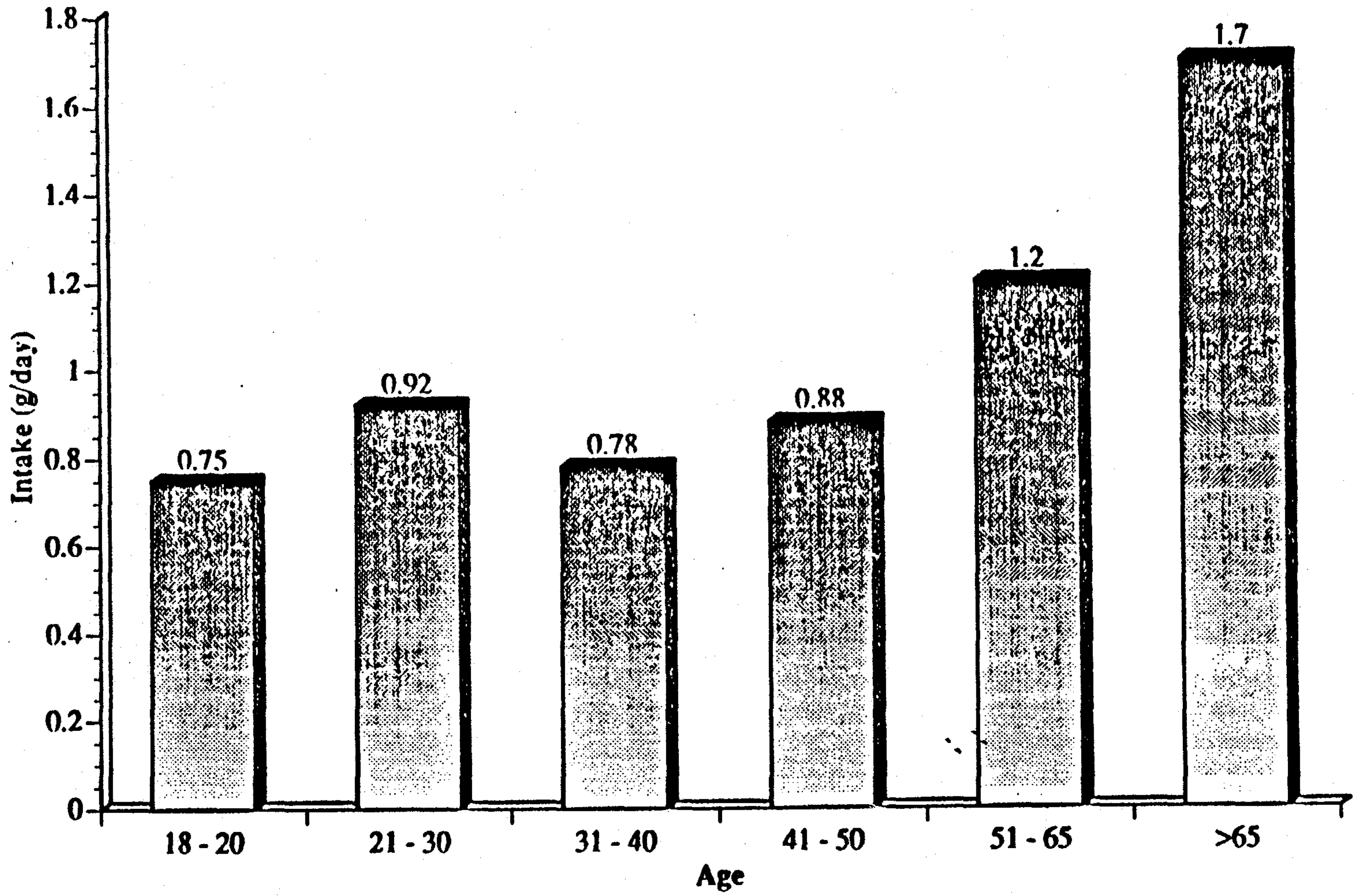
Demographic data for the population of interest can be obtained from the U.S. Census and from appropriate angler surveys. Information on age is also critical for Monte Carlo modeling since the age of the angler impacts many exposure parameters. Data on the distribution of ages in anglers are available from angler surveys. Anglers tend to be older than the general population and are overwhelmingly male. (ChemRisk, 1991a).

Information on mobility and mortality also are available on a national and regional level. However, these data may need to be adjusted to reflect the age/gender distribution of anglers.

5.2.5.2 Fish Consumption Rate

EPA's Phase 1 Report concluded that fish consumption is the most significant source of PCB exposure. To characterize the range of PCB intakes, it is therefore important to determine the range of potential exposures derived from different exposure scenarios. (EPA, 1992b). Where available, it is clearly preferable to use local data on fish consumption rates in a Monte Carlo model because there is regional variability in fish consumption, both in the amount of fish consumed and the species selected. For example, a recent survey of anglers in Maine determined that the median consumption rate increased with an increase in the age of anglers. (ChemRisk, 1991a). Fish consumption data also should be evaluated for factors including the source of fish consumed (*e.g.*, ponds, lakes, small streams, and estuaries) and the age of the angler. As shown in Figure 5-2 (ChemRisk 1991a), fish consumption is age dependant, increasing with age.

Figure 5-2. Median Fish Consumption and Age



(Chemrisk, 1991c)

5.2.5.3 Levels of PCBs in Fish

A significant database is available on the levels of PCBs in fish. GE has commented on how this data could be improved by additional sampling (Section 5.4.2). These data provide a very useful basis for Monte Carlo modeling.

In addition, GE has completed an analysis of cooking losses of PCBs (Appendix A). This report includes estimates of PCB losses for specific cooking methods. The results of this report and the information on cooking preferences in the Maine and New York surveys (Connelly et al., 1990; ChemRisk, 1991a) provide adequate data for Monte Carlo modeling of the levels of PCBs in fish actually consumed by anglers.

5.2.6 Summary of Monte Carlo Modeling

Given the key role of exposure assessments in estimating carcinogenic and non-carcinogenic health risks, it is critical that exposure models accurately reflect the full range of potential exposures and doses to the endpoints of concern. Monte Carlo models offer many advantages over traditional modeling techniques in characterizing a distribution of potential lifetime average daily doses associated with various exposure scenarios. Using Monte Carlo modeling techniques minimizes the assumptions that are often made regarding the endpoints of concern and the exposure conditions, resulting in a more realistic estimate of risks.

Rather than employing extreme point estimates for each of the parameters in the dose calculation, Monte Carlo models enable parameters to be determined based on the available data.

This technique not only minimizes assumptions regarding the distribution of values, but it also allows the model to be designed so that unrealistic exposure scenarios are excluded.

Monte Carlo models also allow risks to be characterized at specific points in time. EPA has stated that one of the key criteria for determining the need for remediation is the number of years until the river will be safe for fishing. The microexposure-event approach outlined in these comments can readily generate this type of information.

5.3 Estimates of Fish Consumption

5.3.1 Use of EPA's Default Fish Consumption Rate Is Unwarranted

EPA has stated (p. 6-1) that it will evaluate whether there are adequate data to justify a different site- or region-specific value for fish consumption that would apply to Hudson in absence of a fishing ban. GE commends EPA for its consideration of this important issue. EPA must evaluate the available data on fish consumption to select an estimate of consumption that is most relevant and appropriate to the Hudson River site.

In its Phase 1 Report, EPA used a default fish consumption estimate of 30 g/day (EPA, 1989b). As stated in GE Phase 1 Comments, GE believes that this estimate represents a substantial overestimate of consumption of freshwater fish from the Upper Hudson River since it is based on consumption of marine and estuarine sport fish (Puffer *et al.*, 1981; Pierce *et al.*, 1981). Rupp *et al.* (1980) have shown that consumption rates for marine fish are considerably higher than rates for freshwater fish. This may be due in part to the fact that marine fish tend to be considerably larger than freshwater species. Consequently, a single marine fish is likely to provide several meals while a single freshwater fish typically only provides one meal or a partial meal. In addition, because marine environments are generally more fertile and productive than riverine environments, more fish per unit area are expected, increasing the relative ease of catching marine species. Thus, fish consumption estimates based on the Puffer *et al.* (1981) and Pierce *et al.* (1981) studies, should not be used by EPA to approximate rates of consumption from the Hudson River.

In the Phase 1 Report, EPA argued that the 30 g/day default estimate is supported by the findings of the NYSDEC angler survey conducted by Connelly *et al.* (1990). However, as described in GE's comments on the Phase 1 Report (pp. 105-106), the NYSDEC data do not support this value. Rather, the annual consumption data (45.1 fish meals) in Connelly *et al.* (1990) yields an average consumption of 28 g/day. Moreover, as also described in GE's Phase 1 Comments, the NYSDEC annual consumption estimate does not reflect only sport-caught freshwater fish. It is clear from the NYSDEC survey that this estimate also includes freshwater, marine, and estuarine fish obtained from markets and restaurants (Connelly *et al.*, 1990). Although licensed anglers are more likely to consume self-caught fish than non-anglers, it is unreasonable to conclude that they catch all or even the majority of the total fish that they consume. West *et al.* (1989) reported that only 39 percent of the freshwater fish consumed by

Michigan anglers were sport-caught, whereas the remaining fish meals were restaurant-purchased, store-bought, or gift fish. Finally, the NYSDEC estimates are based on consumption from all sources and do not consider the relative percentage of the total consumed fish that is obtained from a single water body. For this reason, GE believes that the NYSDEC estimate of 45.1 fish meals per year overestimates the potential consumption of sport-caught fish from the Upper Hudson in the absence of a ban. EPA therefore has no site-specific data that justifies support of the proposed use of the default value.

5.3.2 EPA Must Develop Site-Specific Fish Consumption Data for the Phase 2 Assessment

Since EPA's default number is an overestimate of the intake of fish by Hudson River anglers, GE believes that EPA should develop site-specific estimates of fish consumption that would be appropriate to the Upper Hudson in the absence of a ban.

As discussed in Section 5.2 of these comments, GE agrees with EPA that a Monte Carlo assessment of PCB intake should be an essential portion of the Phase 2 risk assessment. Therefore, EPA should develop not only a point estimate of angler consumption but also information on the full range of angler intakes.

Because of the absence of site-specific consumption data, GE recommends that EPA perform angler surveys to gather the data necessary to characterizing the full distribution of region or site-specific rates of consumption of self-caught freshwater fish as recommended in EPA guidance. (EPA, 1989c). The primary objective of these surveys would be to provide the best possible characterization of the total distribution of annual fish consumption rates that could be used in a Monte Carlo simulation of exposures and risks for the site.

5.3.2.1 Design Considerations for an Angler Survey

The development of an angler survey is not a simple task. The presence of a fishing ban on the Upper Hudson prevents a direct measurement of angling practices at the site. However, with careful design, valid estimates can still be developed. In order to achieve a successful survey which will ensure the most appropriate characterization of consumption estimates to be used in a risk assessment, GE recommends that the survey consider the following factors.

1. The survey should assess consumption of only self-caught freshwater fish. Because there is no history of commercial fishing on the river above the Federal Dam, the consumption of fish from commercial sources should not be considered. Thus, the only population with potential access to Hudson River fish in the absence of a ban are recreational anglers and those who share in their harvest. Accordingly, GE recommends that data be collected concerning consumption of fish by licensed anglers living near the Upper Hudson River.

2. The survey should focus on surrogate populations. Because fishing is prohibited between Fort Edward and Troy, it will be necessary to assess fishing activities on river reaches that are not under a ban and are reasonable models for fishing activities that would occur on the Upper Hudson in the absence of

a ban. To characterize potential consumption of fish from the Upper Hudson River, GE suggests that surveys be conducted of recreational anglers who reside in counties adjacent to a large river on which there is no ban and for which the population demographics are likely to be similar to the region on either side of the affected section of the Upper Hudson. Ideally, the choice of a surrogate county should be preceded by an analysis that confirms the appropriateness of the surrogate area. If time constraints preclude completion of such an analysis, GE recommends sampling in two areas, rather than one area, to provide an additional measure of assurance that an appropriate surrogate will be found.

Warren County and Schenectady County may be reasonable surrogate areas. Because of their proximities to the site, and the availability of good access to a major river fisheries in each (Mohawk River in Schenectady County, and an unbanned section of the Upper Hudson in Warren County), these counties are most likely to be representative of the anglers living close to the banned reaches of the Upper Hudson. In addition, the angler demographics of Schenectady and Warren Counties are likely to be similar to the angler demographics around the lower and upper reaches of the banned portion, respectively.

3. <u>Survey methodology</u>. The design of a survey to characterize the potential consumption of self-caught fish from the Upper Hudson must a achieve a number of goals. These include the verification that the surrogate population of anglers to be surveyed is representative of the Upper Hudson area, the

development of water body specific estimates of annual consumption, and the development of a distribution of intakes rather than a single point estimate.

Many survey techniques have been used to characterize fish consumption rates, including in-home visits, diaries, recall telephone and mail surveys, and creel surveys. (EPA, 1992b). The ideal method for determining consumption rates would be to conduct in-home studies during which the foods consumed by individual anglers and the portion sizes would be recorded at the time of consumption.

Recall surveys provide an alternative lower cost method for obtaining this information without a significant loss as to the utility of the results. Recall surveys have been used by a number of researchers as a cost-effective means for obtaining information on the consumption of fish. (West *et al.*, 1989; Connelly *et al.*, 1990; ChemRisk, 1991a).

Although season-long recall surveys allow researchers to calculate self-reported seasonal fish consumption for individual anglers, the accuracy of the results is likely to be affected to some degree by recall bias. Individuals asked to recall their participation in recreational activities over six-month to one-year recall periods tend to overestimate their actual participation. Because year-round angling is permitted for certain species in New York State, with no clearly defined start and end to the season, anglers may have difficulty in accurately describing their activities for an artificially defined "season." Thus, the distribution of intakes generated by such a survey will tend to overestimate the true distribution, although the degree of overestimation is unknown.

An alternative to a season-long recall survey is to perform periodic short-term surveys throughout the season. A periodic survey of anglers results in far more accurate estimates of fish consumption because of the shorter recall period. For example, anglers can be asked about their fishing activities during the previous two-week period. They can also be asked to indicate the specific locations where they went fishing on each of the trips taken, the species of fish harvested, their sizes, whether or not they were consumed, how they were cooked, and who consumed them.

The results of such a short-term survey can be used to calculate the mean and the median seasonal fish consumption. But the method is limited in its ability to determine the full distribution of annual fish consumption, because seasonal fluctuations in participation, effort, success, and the availability of target species confound the extrapolation of the tails of the distributions.

GE therefore recommends that the preferred survey design include a combination of the two survey methods. Because the extrapolated mean consumption rate from the short-term survey can be expected to be accurate due to the short recall period, this mean could be used to adjust the results of the season-end mail survey to eliminate recall bias. This method will eliminate the need to extrapolate a full distribution of consumption rates based on the short-term survey responses, but would allow the true distribution of consumption from the season-end mail survey to be used once it has been adjusted for bias.

4. Development of Water Body-Specific Estimates of Intake. As discussed above, season-long recall surveys cannot reliably be used to ask questions about consumption from specific bodies of water. The length of time between the administration of the survey and the time of early season fishing -- a time period that may be greater than six months -- is too great to allow accurate measurement of the specific location or species for fish caught during a year. The best detail can be collected in such surveys is "flowing water" (rivers and streams) and "standing water" (ponds, lakes, and reservoirs).

Short-term surveys, however, can provide such information. If adequate data can be collected from the short-term survey, it may also be possible to estimate consumption from specific bodies of water, including the Mohawk River and the Upper Hudson River above Glens Falls. The rate of intake from these two bodies of water would provide a good indication of what the likely intakes from the Upper Hudson would be in the absence of a ban. In addition, the combined surveys would provide detailed information on the species of fish actually consumed and the cooking methods used. Such information is critical to the development of a sound site-specific characterization of the intake of self-caught fish.

At the very least, data analysis can be effectively designed to estimate rates of consumption for lake/pond fisheries and river/stream fisheries. The distribution of consumption rates generated could serve as an upper bound distribution of freshwater fish consumption which would be a surrogate for the hypothetical rate of fish consumption from the Upper Hudson in the absence of a ban. Although this conservative analysis would, most likely, overestimate hypothetical consumption from a single source, it would almost certainly be considerably lower than EPA's default value of 30 g/day. In a recall study of Maine's anglers conducted by ChemRisk (1991a), in cooperation with the University of Maine and the Maine Department of Inland Fisheries & Wildlife, mean fish consumption from rivers and streams was estimated to be 3.7 g/day.

5. <u>Consideration of the Statewide Advisory</u>. Because there is a statewide fish consumption advisory for all water bodies in New York State, it is reasonable to conclude that overall consumption is somewhat suppressed. But this suppression is not related to the specific existence of the ban on the Hudson River, because even if the River contained no PCBs, the statewide advisory would still be in effect.

5.4 Alternative Estimates of Fish Consumption

As stated in the previous section, EPA must develop site-specific estimates of angler intake. If EPA chooses not to collect additional information on potential consumption from the Upper Hudson River, then EPA must base its fish consumption estimates for the Upper Hudson risk assessment on studies that characterize the consumption of self-caught or gift fish harvested from a single freshwater river.

Very few studies have investigated rates of fish consumption, and only a few of these studies provide fish consumption data that can be used to estimate consumption from the Upper Hudson. For a study to evaluate rates for fish consumption, several factors must be considered. First, the fish consumption study must be conducted on a similar type of water body and a similar target population. For example, it is inappropriate to base freshwater fish consumption estimates on consumption estimates from marine fisheries, because of the differences between the species present and the relative productivity of the waters. Thus, if one is attempting to estimate consumption from a large river, the consumption selected should be based on data from another large river. In addition, if no commercial fisheries exist on the water body of interest, then only recreational catches should be considered. Consumption estimates should not be based on fish obtained from restaurants, markets, or other sources.

Many of the available studies fail to distinguish between the consumption of commercially-harvested and recreationally-harvested fish. (Connelly *et al.*, 1990; Javitz, 1980; Rupp *et al.*, 1980; Pao *et al.*, 1982). The most frequently cited estimates of fish consumption are derived from marine or estuarine studies (Puffer *et al.*, 1981; Pierce *et al.*, 1981; Landolt *et al.*, 1985) or include a combination of both saltwater and freshwater species (Connelly *et al.*, 1990; Javitz, 1980). Furthermore, most of the studies that have focused on sport-caught fish have not specifically evaluated consumption from river fisheries (Fiore *et al.*, 1989; West *et al.*, 1989).

5.4.1 Summary of Appropriate Studies

Several studies have specifically estimated consumption of freshwater fish from rivers. Soldat (1970) conducted a creel survey of the Upper Columbia River near the Hanford nuclear plant. This section of the Columbia River is similar to the Upper Hudson in that it is part of a large river which is inaccessible to migratory species. Soldat estimated that the average angler surveyed took 4.7 trips per year and harvested 0.7 meals per trip from the Upper Columbia River annually. Soldat reported that 45,000 meals were caught, representing 20,000 pounds of edible fish or 202 grams per meal. If each meal was 202 g in size, the resulting estimate of consumption from the Soldat study is 1.8 g/day.

Honstead *et al.* (1971; as reported in Rupp *et al.*, 1980) reported that Upper Columbia river anglers consumed an average of 14 meals of sport-caught fish per year and that the average meal size was 200 grams. This translates into 2.8 kg per year or approximately 7.7 g/day on average.

Turcotte evaluated consumption of freshwater species from the Savannah River and estimated that the average angler harvested 22.6 kg of fish per year. If 30 percent of the harvested fish was edible (EPA, 1989c), the edible harvest is 6.78 kg/year. Although Turcotte did not collect information on number of individuals who shared the harvested fish, it is reasonable to project that 2 to 3 individuals shared in the catch.

The Maine survey indicated that the average number of individuals to share in catch was 2.75 (ChemRisk, 1991a). Puffer *et al.* reported that 74 percent of anglers surveyed had two or more adult fish consumers in their households and 82 percent had at least one child fish consumer. Landolt (1985) reported that 87 percent of the anglers surveyed reported two or more fish consumers in their households while 62 percent reported 3 or more fish consumers.

If, based on these data, it is reasonably assumed that 2.5 individuals shared the catch, then the average annual fish consumption rate for the Savannah River, based on information provided by Turcotte (1983), can be estimated to be 7.4 g/day. Although the Savannah River may be similar to the Upper Hudson River in size, climatic conditions and length of fishing season are likely to result in higher estimates of consumption than would be expected from the Hudson River.

ChemRisk conducted an annual recall survey of licensed Maine anglers in 1991 and concluded that the average rate of consumption of fish obtained from rivers and streams in the state of Maine was 3.7 g/day. (ChemRisk, 1991a). This estimate is not a water body specific estimate, but rather is an estimate of total consumption of river/stream fish by Maine's anglers.

ChemRisk (1991b) also conducted a creel survey of the West Branch of the Penobscot River, which supports significant landlocked salmon, smallmouth bass, and white perch fisheries and is a target fishing area for many anglers. For the consuming angling population interviewed, the median fish consumption rate was estimated to be 1.3 g/day. The mean consumption rate for consuming anglers was 5.1 g/day, which corresponded to the 84th percentile of calculated consumption rates. ChemRisk reported that several conservative assumptions were used throughout this analysis. For example, it was assumed that success rate was constant for the individual anglers, *i.e.*, that they caught a similar fish each time they fished. It was also assumed that the reported frequency of fishing trips taken before the time of the interview would continue throughout the remainder of the season.

Because these assumptions are likely to result in overestimates of consumption by the interviewed anglers, ChemRisk conducted a sensitivity analysis, using fisheries management data simultaneously collected from the West Branch, in which the trends in participation and harvest rates over the season were identified. These trends were then used to derive monthly adjustment factors for fishing frequency and harvest rates. These monthly adjustment factors were incorporated into a Monte Carlo analysis to derive a distribution of consumption rates for the West Branch that incorporated seasonal fluctuations. Results of the analysis indicated that the true median rate of consumption was likely to be in the range of 0.5 g/day and the true mean was likely to be approximately 3.0 g/day.

West et al. (1989) evaluated consumption of freshwater fish by Michigan's anglers and found that anglers consumed approximately 18 g/day of freshwater fish from all sources (including restaurants and stores), of which approximately 39 percent were sport-caught fish. Thus, it can be estimated, based on West's data, that average consumption of sport-caught freshwater fish was 7 g/day. This estimate also includes fish from all recreational sources and was not specific to an individual water body. Thus, it is likely that it overestimates consumption from a single freshwater source.

Obviously, none of these studies involved the Upper Hudson and there may be considerable difference in productivity, species availability, size of fish, access and length of season. However, these studies represent the best available and most relevant data for estimating consumption in the absence of additional data collection. All of these studies indicate that a fish consumption rate of approximately 7 g/day or less is likely to be a reasonable estimate of potential consumption from the Upper Hudson in the absence of a ban.

5.4.2 NYSDEC Data Also Support an Estimate of Less Than 7 g/day

As stated previously, GE believes that the NYSDEC (Connelly *et al.*, 1990) estimate of 28 g/day should not be used for the risk assessment. However, information in the NYSDEC survey results are not inconsistent with an estimate of average angler intake of less than 7 g/day.

In GE's Phase 1 Comments, GE used information available in the NYSDEC angler survey to approximate a potential rate of consumption from the Upper Hudson in the absence of a ban. GE assumed that the Mohawk River, due to its similarities in size and physical characteristics, would represent a reasonable surrogate for the Hudson River in terms of likely angler activity and effort. Connelly *et al.* (1990) reported that the average Mohawk River angler completed 9.8 trips per year to the river.

In its Phase 1 Comments, GE conservatively assumed that each trip resulted in two fish meals to derive an annual average of 19.8 meals per year. GE then assumed that each meal was 225 grams in size, resulting in an annual consumption rate for the Mohawk River of 12.2 g/day. However, the number of meals harvested per trip varies from water body to water body. Pierce *et al.* (1981) reported that an average of two meals per trip were harvested from Puget Sound in Washington. Schmitt and Hornsby (1985) also reported two meals per trip in Georgia. However, Soldat (1970) reported an average of 0.7 meals per trip for the Upper Columbia River. A creel survey of the West Branch of the Penobscot River, a well known landlocked salmon fishery in northern Maine, revealed that less than 25 percent of the trips taken resulted in harvested fish intended for consumption. Based on further evaluation of this assumption, GE now believes that an estimated two meals per trip is an extreme estimate and is not likely to be representative of true angler success and harvest rates.

A review of the available river fisheries data indicates that not all trips are likely to be successful and that even those trips which are successful may not result in enough edible fish to make even a single half-pound meal (Soldat, 1970; Turcotte, 1983; ChemRisk, 1991b). For example, Turcotte (1983) reported that the average weight of whole fish caught from the Savannah River was 188 g. When this is adjusted for edible portion of 30 percent, it equates to average edible mass of 57 grams. Thus, to obtain adequate numbers of fish to provide an individual with half a pound, the angler would have to harvest more than four fish per trip and would have to consume all of the fish himself with no sharing. Thus, while creel surveys may report as many as two meals per trip, it is highly unlikely that these meals are all one-half pound in size.

It is unreasonable, based on available data, to assume that each angler takes home two half-pound fish meals from each fishing trip taken. GE's earlier consumption estimate of 12.2 g/day for the Mohawk River should thus be adjusted to be more representative of likely angler harvest. If one assumes that an angler harvests one half-pound fish meal on every fishing trip taken, this results in a total of 9.8 fish meals for the Mohawk River. If each fish meal is one-half pound in size, that equates to a consumption rate of 6.1 g/day annually.

In sum, this consumption estimate is similar to the estimates of consumption derived from the Honstead *et al.* (1971) study of the Upper Columbia, the Turcotte *et al.* (1983) study of the Savannah River, and the 7 g/day estimate that can be derived from the data on sport-caught fish consumption reported by West *et al.* (1989). It is higher than the estimate reported for the Upper Columbia by Soldat (1970), that reported for the Penobscot River in northern Maine (ChemRisk, 1991b), and that reported for statewide river fisheries in Maine (ChemRisk, 1991a). Note that the assumed meal size of 227 g (1/2 pound) is higher than the range of 100 to 200 g recommended by EPA (1989b), thus providing an additional degree of conservatism into the consumption rate.

5.4.3 Definition of Exposed Population

In the Phase 2 Work Plan, EPA states (p. 6-1) that the "Phase 2 human health risk baseline assessment will provide a discussion of the specific population that is targeted by the intake estimate, *e.g.*, whether it is appropriate to target recreational or subsistence anglers, both in the absence of a fishing ban." EPA's Work Plan, however, does not set forth the method by which this determination will be made.

Before EPA addresses consumption by a hypothetical population of low income subsistence anglers who rely on fishing for food, it is important to determine whether such a population actually exists. GE is greatly concerned over the absence of any discussion in the Phase 2 Work Plan as to how this determination will be made. EPA has stated that this pathway is not expected to be relevant for most sites. (EPA, 1991d). GE agrees with this policy and believes that subsistence fishing is not a common occurrence and is likely to be limited to areas of relatively high fish productivity, unlike the Upper Hudson River.

GE believes that most non-tidal river reaches are not sufficiently productive to allow subsistence fishing. Harvesting of freshwater fish from rivers requires a considerable level of skill and effort. Soldat estimated that on the Columbia River, anglers harvested an average of one sport fish per trip (2.7 hours per trip) and that the average edible mass of fish harvested was 0.31 pounds or 144 grams. Similarly, Turcotte reported that freshwater anglers on the Savannah River harvested an average of 1.3 fish per trip of 190 g (edible fish) each and that each trip averaged 4.5 hours. Thus, to obtain 150 g/day for each member of a family of four individuals, an angler would need to spend 11 hours fishing daily throughout the year. To provide meals of 180 g/day for a family of four would require 13.5 hours of effort on the Upper Columbia, and 13 hours of effort on the Savannah River. It is highly unlikely that any individual would expend that level of effort to obtain food. Rather, it is more reasonable to assume that subsistence individuals would raise livestock and practice hunting or trapping to obtain food, rather than relying totally on the consumption of sport-caught fish.

In addition, surveys of licensed anglers do not suggest that low income recreational anglers rely on fishing as a source of food. Rather, available survey data indicate that most anglers are middle class Caucasian males (ChemRisk, 1991a; West *et al.*, 1989; Connelly *et al.*, 1990). An evaluation of consumption by income level in the Maine angler survey indicated that median consumption rates for individuals with family incomes of less than $10,000 were not significantly different from consumption rates for other income groups. Findings of non-elevated consumption by low income anglers were confirmed by the NYSDEC survey which reported that individuals whose annual family income level was less than or equal to $20,000, consumed fewer meals per year than anglers from any of the other income groups evaluated. (Connelly *et al.*, 1990).

Because of this evidence against the likely occurrence of subsistence fishing, GE believes that EPA should have specific evidence that subsistence occurs before considering subsistence anglers as a target population or as a subpopulation of anglers. If EPA does have evidence that subsistence fishing occurs, then the Phase 2 Work Plan must be revised to include a description of the methodology to be used to characterize the size and location of the population and its fish consumption habits.

5.5 Fish Sampling

5.5.1 Collection of Additional Data

EPA asserts (p. 6-2) that it intends to use 1990 and possibly 1991 and 1992 fish tissue data to conduct its baseline human health risk assessment. GE supports EPA's recognition of the need to use current fish data for the Hudson River and its implicit acknowledgement of the changing levels of PCBs in fish. This need is highlighted by EPA's conclusion that consumption of fish is the critical route of exposure for the site.

GE is nevertheless concerned that EPA has not indicated that it intends to collect additional fish samples to be used for the risk assessment. This implies that EPA intends to entirely rely on data collected by the NYSDEC fish monitoring program. Unfortunately, there are several limitations associated with the NYSDEC fish sampling program. These limitations are likely to compromise the quality of the Phase 2 risk assessment and inject unnecessary uncertainty into the evaluation of site risks.

Information gathered from the NYSDEC angler survey (Connelly *et al.*, 1990) indicates that the primary target species in the Hudson River are bass (38 percent of angler effort) and brown trout (6.5 percent of angler effort). While the survey did not specify the species bass that were targeted, it is known that rock bass, smallmouth bass, and largemouth bass are all resident in the Upper Hudson River (EPA, 1991b). However, the fish tissues collected by NYSDEC between Fort Edward and the Federal Dam only included largemouth bass. Thus, there are no data available for the other bass species present in the Upper river. This is an important limitation of the data as fish bioaccumulate PCBs at different rates. Thus, it is not appropriate to assume that tissue concentrations measured in one bass species are representative of tissue concentrations in other types of bass. In addition, NYSDEC have collected no data on brown trout.

According to the NYSDEC survey (Connelly *et al.*, 1990), yellow perch, walleye, and brook trout are also popular target species in New York State. Because these species are present in the Upper Hudson River, it is reasonable to assume that these species would be popular target species in the absence of a ban. However, none of these species were sampled. Instead, goldfish and yearling pumpkinseed, which are not generally consumed by anglers, were sampled. Due to the low probability that these would be consumed by anglers, these data do not provide a sound and defensible basis upon which to base a risk assessment.

In addition, because there is currently no fishing pressure on the Upper Hudson River, the fish ages and sizes currently found there are not necessarily representative of the fish that would be there in the absence of the ban. As fishing pressure increases, as it would in the absence of a ban, the numbers of fish that would be harvested would reduce the numbers of fish available. Moreover, because anglers tend to seek larger, trophy, fish, the average age and size of fish present in the river under steady fishing pressure would decrease after a short time because older larger fish would be harvested and smaller numbers of fish would survive to reach such large sizes.

Because the risk assessment to be conducted for the Hudson River should be based on fish species that correspond to angler activities and preferences, EPA may be required to conduct additional sampling. Of key importance for additional sampling are rock bass, smallmouth bass, brown trout, yellow perch, walleye, and brook trout. Sizes to be sampled should be consistent with size limits set forth in New York State angler guidelines and sizes that would likely be available in the absence of a ban. If available, creel survey data from other New York river fisheries can be used to predict the ranges of sizes of each species of fish that would be likely to be harvested by anglers over time.

Fish samples should be collected from those areas of the river where access and fishing conditions are likely to be favorable to successful angling. (EPA, 1989b). Experienced fisheries biologists can provide expert recommendations on the most important potential fishing locations on the upper river. In addition, fish samples should be collected at times when anglers would also be likely to collect fish if fishing were allowed. For example, fishing season for largemouth and smallmouth bass occurs between late June and the end of November. Thus, bass samples should also be collected during this period. Finally, analysis should be conducted on fish fillets rather than whole fish as it is highly unlikely that consumers would eat the whole fish.

5.5.2 Reliance on Existing NYSDEC Fish Tissue Data

If EPA does not intend to collect more relevant fish tissue data for use in the risk assessment, and chooses instead to rely on data collected by NYSDEC, the available data must be adjusted to be as representative as possible of likely exposures in the absence of a ban. GE strongly encourages EPA to consider interspecies variability in the Hudson data. Because anglers are not likely to consume goldfish, due to preference for other species, it is important that the data on PCB levels in goldfish not be used as a basis for the risk assessment without proper weighting based on their likelihood of consumption. Similarly, EPA should not use the data collected on yearling pumpkinseed. These fish are too small to be harvested for consumption by anglers under any circumstances. Finally, all whole body PCB data should be dropped from the data set so that only PCBs in fillet data are used for the risk assessment. EPA should not use whole body PCB concentrations, because anglers and their families are not likely to consume whole fish.

GE recommends that if the NYSDEC data are to be used, species-specific fish tissue concentrations of PCBs should be used in the risk assessment along with species-specific consumption rates based on angler harvest. This will ensure that estimates of exposure based on fish tissue data receive an appropriate species-specific weighting based on the likelihood that certain species of fish will be consumed.

5.6 Cooking Loss

This section presents the results of an analysis of the recent literature on cooking losses. The full analysis is presented in Appendix A. In addition, the role of cooking losses in Monte Carlo modeling will also be discussed.

GE supports EPA's reconsideration of cooking losses as a factor in determining the intakes of PCBs from the consumption of fish caught in the Upper Hudson River. As stated in GE's Phase 1 Comments, GE believes that cooking losses represent a significant source of reduction in the intake of PCBs and should be considered in any quantitative estimate of PCB exposure.

GE is concerned about the language that is contained in the Phase 2 Work Plan on the subject of cooking losses and the possible underlying assumptions that may have been made by the Agency. The Work Plan states (p. 6-2):

> The Phase 2 assessment will determine whether there are new and adequate data available to confidently determine an appropriate adjustment factor to account for the effects of cooking. (Emphasis added.)

GE is concerned that the use of the term "new" in this statement suggests that EPA is creating a false barrier to the consideration of the information on cooking losses. GE is convinced that existing data on the effect of cooking processes on PCB levels are more than adequate to demonstrate the existence of a significant reduction in PCB levels during cooking processes. In addition, the use of the term "confidently" suggests that EPA is creating a stringent test for the adequacy of the data necessary to demonstrate the existence of cooking losses.

To the extent that the current data are neither exhaustive nor sufficient to answer all questions that may be raised, GE believes that the question of adequacy of the data must be considered in terms of the need for consistency and accuracy in the development of exposure estimates and the need to manage uncertainty in the estimate. The degree of evidence necessary to justify incorporating an effect into the estimation of exposure is a function of the exposure analysis performed and the techniques used in the exposure analysis. Techniques such as Monte Carlo assessment allow for a more reasonable consideration of variable factors such as cooking losses.

5.6.1 Analysis of Literature on Cooking Losses

Appendix A identifies ten studies which examined the effect of cooking processes on levels of PCBs and other lipophilic compounds in fish tissues. In addition to providing a review of the literature, Appendix A examines (1) the degree of variation in the results reported among the studies, and (2) those studies which reported increases in PCB levels as a result of cooking processes.

In the analysis performed, the first step taken was to remove from consideration those studies that had methodological or statistical limitations that prevented the estimation of a cooking loss. This step reduced the number of studies to five.

Next the issue of variation in the extent of decrease was addressed by performing two analyses. The first was to place all of the reductions on a common basis. The basis used was a reduction in the total mass of PCBs in the fish during cooking processes. The second step taken was to organize the results in terms of the cooking methods employed. The mechanism believed to be responsible for the reduction of PCBs during cooking operations is primarily a loss of fat which contains the PCBs and, to a lesser extent, volatilization.

In the five studies found to have followed appropriate methodology and to have provided sufficient information to permit the calculation of the percentage mass loss of PCBs due to cooking, the reduction of PCBs was found to be a direct function of the severity of the cooking method employed. Based upon the results of this analysis, GE believes that approximate estimates of the degree of reduction in PCBs can be established for different cooking operations. As Figure 1 in Appendix A indicates, cooking methods such as microwaving or poaching are least effective at removing PCBs. However, frying seems to be capable of removing more than half of the PCBs present in fish.

When data were expressed on a mass basis, all studies either reported no statistically significant change, or reported a significant decrease in PCB levels, with the one exception of Zabik *et al.* (1982). The authors of Zabik *et al.* (1982) concluded that the apparent increases in PCB levels during cooking operations were the result of an increased availability of PCBs in cooked tissue during laboratory analyses and that actual levels of PCBs were likely to have been reduced during cooking operations.

In summary, GE believes that the available data strongly indicates a consistent decrease in PCBs during cooking operations. Although this data shows variable decreases, the analysis set forth in Appendix A demonstrates that this variation can be significantly reduced by consideration of standardizing the measurement of the degree of reduction and by establishing different reductions based upon the cooking method employed.

5.6.2 Response to Phase 1 Discussion of Cooking Losses

In the Phase 1 Report, EPA stated (p. B.6-8) that:

> Although concentrations of some organochlorine compounds in fish may decrease while cooking (Stachiw, 1988), the data for PCBs are not consistent. One study reported a small decrease in PCB concentrations with cooking (Zabik, 1982), while another study reported a wide range of PCB decrease after cooking (Cordle, 1982). Because, no specific value can be derived based on the available data and no information on PCB concentrations after cooking the species of concern from the Hudson are available, no adjustments were made.

GE disagrees with this conclusion for the following reasons. First, as indicated above, while the data on cooking loss do not present a consistent estimate of the degree of cooking reduction, a proper analysis of the data reveals that consistent findings of the degree of reduction can be assigned to the different types of cooking processes. Second, Cordle *et al.* (1982) is incorrectly cited as stating that there is a wide range of PCB decreases after cooking. Cordle *et al.* (1982) makes only a peripheral mention of the issue of reduction due to cooking and cites only the results from a single study, Humphrey *et al.*

(1978). The results of Humphrey *et al.* (1978), as presented in Cordle *et al.* (1982), indicate that a combination of cooking and trimming resulted in significant (greater than 50 percent) reductions in PCBs. Finally, EPA states that the literature contains no information on the effect of cooking processes on species of fish that occur in the Upper Hudson. This is incorrect. Skea *et al.* (1981) provided information on both smallmouth bass and brown trout, and Zabik *et al.* (1982) provided information on carp.

5.6.3 Use of Cooking Loss Information in Exposure Estimates

In the Phase 1 Report, EPA used a reasonable maximum exposure (RME) point estimate approach to determine the intake of PCBs from the consumption of fish caught in the Upper Hudson River. As discussed in Section 5.2, EPA policy now calls for a revision of this approach in an effort to produce more accurate and realistic risk assessments. As the above discussions indicate, much of the existing literature's variation can be explained on the basis of differences in reporting and on differences between cooking reduction from different cooking processes. GE believes that its recent analysis is adequate to demonstrate that most cooking methods remove more than 25 percent of the PCBs in fish. GE therefore urges EPA to incorporate cooking-method-specific reduction estimates for PCBs into a Monte Carlo model of PCB exposure from fish consumption.

5.7 Lower Hudson

A human health, as well as a baseline ecological risk assessment for the Lower Hudson River, are proposed in the Phase 2 Work Plan. The Work Plan acknowledges (pp. 6-4, 7-1) that both the ecological evaluation and the human health assessment of the Lower Hudson are complicated by additional sources of PCBs other than those from the Upper Hudson areas. (See Section 6.0 for GE's comments on the Phase 2 ecological work.)

In light of the multiple sources of PCBs, EPA has appropriately decided to exclude Area D from the study. According to EPA, the effects of other sources in Area C are less than in Area D. Therefore, EPA intends to evaluate the risks to human health in Area C. However, unless EPA can conclusively differentiate those effects in Area C caused by other PCB sources from those caused by PCBs from the Upper Hudson sediments, EPA should exclude Area C from its human health assessment as well. If EPA believes it can satisfy this differentiation requirement, EPA must describe in its revised Work Plan how it plans to distinguish effects from other sources.

5.7.1 Definition of Study Areas

GE believes that EPA should standardize the definition of Study Area C. In the Phase 2 Work Plan, EPA defines (p. 2-10) the lower boundary of Study Area C as the *average* upstream limit of the salt front, resulting in possible tidal influence in this portion of Area C. Because areas of tidal influence should be excluded from the assessment, GE recommends that the lower border of Study Area C be limited to the *maximum* upper boundary of the salt front.

EPA recognized this transitional zone of Area C (RM 55 to RM 75) in its proposed ecological assessment and correctly chose not to evaluate it. The Work Plan states (p. 7-1), "[w]hile PCBs occur in these zones, the presence of additional sources complicates determining the relationship between environmental PCB levels and the Upper Hudson source areas considered for remediation." Yet, the Work Plan includes the transitional zone in the area under consideration for the human health risk assessment. Based on the same rationale for excluding the transitional zone from the ecological assessment, this area also should not be considered in the human health assessment. Further, as discussed in Section 7.0 below, multiple sources of PCB contamination are present above the transitional zone (RM 75 to RM 153). Therefore, unless EPA can conclusively differentiate effects produced by PCBs from the Upper Hudson from PCBs originating from other sources, risks for this area should also not be evaluated.

5.7.2 Human Health Risk Assessment

The Work Plan is grossly deficient in outlining what EPA intends to do or address in the human health risk assessment for the Lower Hudson. A major deficiency in the Work Plan is the absence of an explicit objective for the area. As stated (p. 1-3) in the Work Plan:

> In the Phase 1 Report it was determined that human health risks from Hudson River PCBs are caused primarily by the consumption of contaminated fish.

> Therefore, two of the major questions that the Reassessment will address are: what is the reduction in PCB levels which is necessary to decrease fish tissue concentrations to levels that meet human health criteria and; the ancillary question of which source areas, if any, may require remediation in order to achieve that reduction.

EPA must develop a similar objective for Study Area C. In the absence of an explicit objective, it is not possible to develop an adequate Work Plan. Once the objective is established, a detailed description of the data to be collected or considered must be provided along with a description of the techniques that will be employed.

Furthermore, any assessment of the risks from consuming fish in Study Area C will be of minimal use in the Phase 2 analysis unless EPA is able to determine how the risks will change as a function of remedial action taken in Study Area B. The Work Plan gives no information as to how this initial determination will be performed. Finally, the Work Plan does not describe how the human health risk assessment for Study Area C will be conducted. In the following sections, GE highlights significant issues in the Lower Hudson human health assessment that should be addressed.

5.7.2.1 Fish Tissue PCB Concentration

In the Phase 2 Work Plan for Study Area B, EPA acknowledges (p. 6-1) that site-specific data should be considered in the risk assessment. EPA does not, however, propose to collect any fish tissue data from the Lower Hudson (Study Area C). The Work Plan indicates that NYSDEC 1990 and 1991 fish data will be used to perform the baseline risk assessment. This data, however, are of limited usefulness for assessing the impact of PCBs to consumers of Lower Hudson River fish.

Problems associated with this dataset and recommendations for additional sampling procedures in Study Area B are presented in Section 5.4. Briefly, fish sampled in the NYSDEC survey were not selected on the basis of species, size, and location of fish that are likely to be consumed by anglers. Since the human health risk assessment will rely on the fish consumption pathway, only fish species that correspond to Lower Hudson angler preference should be included. For EPA to adequately characterize the most realistic risks posed to potential consumers of Lower Hudson River fish, additional sampling that is representative of angler fishing habits (*e.g.*, fishing location, species, age, size, and seasonal preferences) should be conducted.

If EPA intends to rely on the NYSDEC (1990, 1991) datasets rather than collect additional representative data, the data should be adjusted to account for realistic exposures. For example, only fish species consumed by anglers should be included in the analysis. Similarly, fish size should be limited to fish above the legal minimum lengths for consumption. Additionally, whole body fish concentrations should be excluded from the analysis. To calculate the most realistic exposure scenario, species-specific fish tissue concentrations of PCBs should be used.

5.7.2.2 Fish Consumption Rate

According to the Phase 2 Work Plan for Study Area B, site-specific data should be considered in the risk assessment. This same principle should be used for the assessment of risks associated with the consumption of fish from the Lower Hudson (Study Area C). However, data on fish consumption rates and preferred species are presently not available for the Lower Hudson. Based on this lack of data, it can be assumed that EPA intends to conduct their risk assessment of the Lower Hudson using either the 30 g/day consumption rate estimate or a consumption rate estimate derived from the Study Area B risk assessment. Neither of these consumption rates is appropriate for the Lower Hudson. Problems associated with the use of the 30 g/day estimate of fish consumption are detailed in Section 5.3. For similar reasons, this estimate is not applicable to Study Area C.

GE believes that the most appropriate method of deriving a fish consumption rate estimate is to perform a site-specific angler survey on the Lower Hudson (Study Area C). Recommended procedures for the collection of site-specific fish consumption data are outlined in Section 5.4.1. A properly conducted angler survey should provide an indication of the fishing and consumption habits of a specific area. Separate distributions should be derived based on the catch rate, size, and consumption rates for each preferred species.

5.7.2.3 Migratory Species

To be certain that the calculated risks account for only PCB contamination potentially derived from the Upper Hudson River, EPA must recognize the differences in PCB exposures between resident fish species and migratory species. Resident freshwater species of the Lower Hudson spend the majority of their lives in the Study Area. The PCBs in these species may result from exposures to PCBs from the Upper Hudson and other area sources. Migratory species, on the other hand, spend a significant portion of their lives outside of the Study Area and thus have the potential to accumulate PCBs from those outside areas. Because it is inconceivable that these outside exposures are in any way related to exposure from the sediments of the Upper Hudson, the consumption of migratory fish species in Study Area C should not be used in assessing the risks from the Upper Hudson releases.

For example, striped bass are migratory species which, as adults spend 8 to 10 months of the year outside of the Hudson River estuary. Therefore, the majority of PCB accumulation will likely occur outside of the Lower Hudson. This has been supported by the finding that the composition of PCBs found in Hudson River striped bass (higher chlorinated PCBs) do not resemble those found in Hudson River sediments.

Further, different PCB congeners have been identified in striped bass compared to sediments from the Hudson River. A recent study reported that the Lower Hudson striped bass are accumulating the majority of their PCB body burden from marine and estuarine waters. Therefore, Hudson River sediments do not appear to be a main contributor to the PCB body burdens measured in striped bass. Based on these findings, striped bass should not be included in the health risk assessment.

5.7.2.4 Monte Carlo Modeling of PCB Exposure from Fish Consumption

The Phase 2 Work Plan supports the use of a Monte Carlo model in the risk assessment of Study Area B. There is no indication of whether the Monte Carlo model will be used in the human health risk assessment of Study Area C. As discussed in Section 5.2.1, recent changes in EPA's policy for risk assessment requires that Monte Carlo modeling be considered (EPA, 1992d; EPA, 1992e). Proper conduction of a risk assessment for this area should include a Monte Carlo model. A description of the appropriateness of the Monte Carlo model and its proper use are presented in Section 5.2.

5.7.2.5 Water Consumption

Although the Phase 1 Report determined that human health risks from Hudson River PCBs were primarily from fish consumption, the Work Plan proposes to evaluate water consumption from the Poughkeepsie water supply in addition to fish consumption. It is unclear why water consumption is considered an exposure pathway for the Lower Hudson when EPA determined it was not significant for the Upper Hudson. In general, GE believes that pathways excluded from the analysis of Study Area B also should be excluded in the assessment of Study Area C.

5.7.3 <u>Conclusion</u>

The Phase 2 Work Plan for the Lower Hudson risk assessment is inadequate and lacks a comprehensive plan for conducting the assessment. GE believes that EPA faces an extremely difficult task in attempting to characterize the risks to Lower Hudson human health and the environment from current and future releases from the Upper Hudson. The major issue to be addressed is the apportioning of levels of PCBs in fish to reflect:

- past releases of PCBs from the Upper Hudson;
- current releases of PCBs from the Upper Hudson;
- current releases from other sources; and
- migratory exposures.

Until EPA can relate changes in PCB levels in Lower Hudson fish to proposed remedial actions on the Upper Hudson, the proposed Lower Hudson human health assessment will have little use or meaning. If EPA persists in conducting a risk assessment for Study Area C, then EPA must provide a comprehensive plan for what it intends to do.

6

6.0 ECOLOGICAL RISK ASSESSMENT

Section 7 of EPA's Phase 2 Work Plan purports to describe EPA's efforts to conduct a "baseline ecological risk assessment" for the "freshwater aquatic environment" of the Hudson River from RM 195 to approximately RM 75. In a scant and ambiguously drafted seven pages, EPA sets forth (p. 7-1) the work to be undertaken to "build upon the Phase 1 interim assessment." But upon examination of the tasks proposed by EPA to perform this baseline ecological risk assessment, it becomes apparent that other than an ill-defined windshield survey of the study area, EPA proposes to do no more than it did in its Phase 1 review: identify species of concern and peruse the toxicity literature.

The fact that such efforts do not rise to the level of a comprehensive ecological risk assessment was acknowledged in EPA's Phase 1 Report:

> [V]ery little data have been gathered *to relate the measured PCB concentrations in sediment, water and biota to observed ecological effects.* Thus, this preliminary assessment relies on published information concerning PCB toxicity in relation to measured PCB concentrations in Upper Hudson River sediments, water and biota. *A comprehensive ecological risk assessment, including population, community and ecosystem interactions in response to PCB exposure, is not possible with the available monitoring data.* (EPA, 1991b, p. B.7-1 (emphasis added)).

As acknowledged by EPA, the Phase 1 approach provides little more than "an initial evaluation of potential ecological risks for selected species." (EPA, 1991b, p. B.7-2). The utility of a continuation of this type of effort is not readily apparent. Indeed, all that is readily apparent from review of Section 7.0 of EPA's Phase 2 Work Plan is that EPA has yet to determine the objectives to be satisfied by the performance of an ecological risk assessment.

Unlike other areas in the Work Plan, where EPA has at least set forth the goals of the data collection and analysis in terms of the questions EPA deems relevant to its ultimate determination, EPA has yet to identify how the information it is gathering in the context of "ecological risk assessment" will be relevant to its decision- making process. As aptly described in Section 5.0 of the Phase 2 Work Plan (p. 5-1), "[t]he Reassessment requires knowledge of the future impact of PCBs in the Hudson River system under conditions of No Action and various remedial alternatives . . . the effort in Phase 2 must be specifically focused on providing the information for an informed decision among alternative remedial actions." EPA has not "specifically focused" its Phase 2 ecological work to provide such necessary information, and must do so prior to the implementation of Phase 2 Work.

EPA must move beyond the use of the proper buzzwords and headings to create the illusion that appropriate substantive analysis is being undertaken when in reality EPA is presuming the very issues under consideration -- a cause-and-effect relationship between the presence of PCBs in Hudson River sediments and harms to the ecosystem imagined on the basis of toxicity literature. EPA must re-examine its ecological assessment goals, and rewrite the Phase 2 Work Plan to describe how those goals will be achieved through activities designed to examine at real world conditions.

As described in GE's Phase 1 Comments, although laboratory toxicity studies can help define potential ecological effects, they must be validated by examination of the actual ecosystem at issue and comparison with a comparable reference site. Rather than persist in its Phase 1 efforts of evaluating potential risks for certain species, EPA must undertake the analysis necessary to focus its Phase 2 ecological work on establishing site-specific cause and effect relationships -- both for the PCBs present in the Upper Hudson and for remedial alternatives such as dredging on an ecosystem level. Absent such an undertaking and a re-evaluation of the efforts needed to obtain relevant information, EPA will be left with an "ecological risk assessment" which is little more than a compilation of available literature on PCB toxicity for selected species. A site with an ecosystem as complex and diverse as the Hudson River deserves more.

Similar to the questions phrased in Section 5.0 of the Work Plan, EPA must, in the area of ecological risk assessment, ask and seek answers to questions which will enable a choice among remedial alternatives, including no action. These questions must be:

1. What is the impact of the presence of PCBs in the Upper Hudson sediment on the ecosystem?

2. If there are detectable risks to the ecosystem, will remedies other than No Action significantly reduce these risks beyond that which will be accomplished through natural attenuation?

3. If so, do the benefits of such a remedy outweigh the ecological costs?

Set forth below are GE's comments on the particular inadequacies of this section of the Phase 2 Work Plan in light of regulatory guidance, as well as GE's recommendations for focusing the Phase 2 ecological efforts to develop information meaningful to the reassessment and for designing an assessment process which will provide such information.

6.1 The Ecological Risk Assessment Work Plan is Inadequate

Section 7.0 of EPA's Phase 2 Work Plan, which is supposed to describe the sampling, analysis, investigative, and risk assessment efforts that will comprise EPA's characterization of the ecological effects resulting from the presence of PCBs in the Upper Hudson River, is remarkably inadequate. In seven pages, EPA has presented a very vague and ill-defined Work Plan that neither provides specifics on how tasks will be structured and carried out, nor does it sufficiently identify the goals and objectives of the ecological investigation. If a group of PRPs had submitted a Work Plan as incomplete and ambiguous as that appearing in this Phase 2 Work Plan, it certainly would have been rejected by EPA.

6.1.1 Adherence to Regulatory Guidelines

EPA states that it will adhere, in its development of the Phase 2 baseline ecological risk assessment, to EPA's (1989f) Risk Assessment Guidance for Superfund Volume II: Environmental Evaluation Manual ("RAGS II") and to the risk assessment framework outlined in EPA's (1991c) Eco Update. In fact, the Phase 2 Work Plan represents a very meager outline of the frameworks and concepts put forth in EPA guidance or recently released framework documents. EPA has recently released for public comment (57 FR 22236) an EPA Risk Assessment Forum report detailing the elements of a framework for ecological risk assessment. This report, entitled Framework for Ecological Risk Assessment (EPA, 1992f) represents the first step of a long-term Risk Assessment Forum program to develop Agency-wide ecological risk assessment guidelines (EPA, 1992c). Although this document is neither a formal guideline nor a regulatory requirement, it does present a simple, flexible structure for conducting and evaluating EPA ecological risk assessments. This framework, used in conjunction with RAGS II, provides ample guidance, which if followed by EPA, will lend much-needed structure, focus, and efficiency to the ecological risk assessment of the Upper Hudson River. Set forth below is a brief discussion of the elements that comprise a meaningful ecological risk assessment and the deficiencies in those elements in EPA's Phase 2 ecological risk assessment.

6.1.2 Problem Formulation

As detailed in Section 2.0 above, the initial task of any project is to develop project objectives. This is equally true for an ecological risk assessment. RAGS II (EPA, 1989f) emphasizes that the objectives, scope (in terms of spatial and temporal extent, tests to be conducted, time and resources needed and level of detail required), and design of the assessment must be established at the beginning of the assessment to ensure that the results are readily understood and properly interpreted.

This initial phase involves the review and qualitative evaluation of existing data and results in the identification of the environmental values to be protected (assessment endpoints), the data needed to complete the assessment, and the analyses to be used. In addition to establishing the goals, breadth, and focus of the risk assessment, completion of this component ensures that data collection, field studies, laboratory tests, and the overall assessment can answer the questions relevant to making remedial decisions (EPA, 1991c).

These preliminary tasks described in EPA documents and guidance manuals should have been developed as part of the Phase 1 Report and the objectives and scope of the ecological evaluation should be presented as the backbone of the Phase 2 Work Plan. Unfortunately, as described in GE's Comments on the Phase 1 Report, EPA did not conduct an adequate preliminary investigation and did not adequately complete the Problem Formulation component.

Indeed, EPA has yet to clearly define and identify the objectives and scope of the ecological investigation of the Upper Hudson River. This result is not surprising since EPA must first complete the Phase 1 preliminary tasks of Problem Formulation in an adequate fashion before the objects and scope of the Phase 2 Work Plan can be satisfactorily addressed. The public should be given an opportunity to comment on the results of EPA's completed preliminary investigations and should have input to the goals and scope of the subsequent analysis and risk characterization and management phases. Failing these activities, it is not clear that EPA's Phase 2 ecological activities will yield information of relevance to the decision to be made, nor is it clear that all necessary information will be collected.

6.1.3 Site Characterization and Identification of Ecological Receptors

As is discussed above, the lack of a complete preliminary assessment (and consequent lack of adequate problem formulation) has severely limited EPA's ability to construct a detailed and adequate Work Plan for the analysis phase of the ecological assessment. Section 7.1 gives a two paragraph description of the study area description and characterization and includes may of the tasks and investigations that will need to be completed before a risk assessment can be planned and scoped. EPA (1992f), in the description of elements that comprise the problem formulation phase of an ecological risk assessment, lists the ecosystem properties that should be investigated and considered: aspects of the abiotic environment (climate, soil and sediment properties), ecosystem structure (types and abundances of different species and their trophic level relationships), ecosystem function (ecosystem energy source, pathways of energy utilization, and nutrient processing), historical distributions, and the spatial and temporal distribution and variation inherent in these elements. Many of these elements were discussed to some degree in the Phase 1 Report but, as EPA indicates, they have not been sufficiently identified to design a focused ecological risk assessment. This lack of complete site characterization, at least on a spatial and temporal scale, will severely hamper EPA's ability to assess the risks.

6.1.4 Reconnaissance Survey

The stated purpose (pp. 7-3, A-16) of the reconnaissance survey is to provide qualitative field verification of the types of habitats and wildlife on and near the ecological study area. However, the Work Plan also implies that such surveys will be used to verify predicted risks at the site. The Work Plan states (p. 7-3) that the reconnaissance survey is expected to verify types of habitats and species and to provide site-specific observations regarding the condition of the habitats and species. The implications of "field verification of types of habitats" versus "conditions of habitats" require two very different approaches to field data collection and analysis. The purpose of the reconnaissance survey and its associated objectives are not clearly defined; neither is the role of the survey in providing information/data for use in the ecological risk assessment. The data needs for the ecological risk assessment must be clearly defined prior to going to the field (EPA, 1989f). Additionally, the public must be given an opportunity to comment on and provide input on the design and purpose of such data collection exercise.

A reconnaissance survey directed towards identifying types of habitats, presence and type of ecological receptors, among other things, would be a usual component of a site visit and characterization exercise. The vague tasks which comprise the reconnaissance survey will provide qualitative information regarding the areas investigated and organisms observed during a site "walkover." The results of such a survey could be used in the problem formulation to determine the scope of the assessment needed and the potential assessment and measurement endpoints that would need to be evaluated (EPA, 1989f). Specific issues to consider in conducting such surveys are provided in Section 6.2.

EPA does not detail the reconnaissance survey methodology they intend to use to determine ecological effects/conditions, yet the Work Plan does state that the survey effort is expected to provide adequate observation regarding the condition of the habitats and species. Such evaluations cannot be made using the inventory approach outlined in the current Work Plan. Furthermore, the lack of an identification of an appropriate reference or control site/area in the Work Plan also limits the ability to suggest impacts (*i.e.*, conditions) at the site.

The evaluation of sustainable community structure requires that the endpoints of species number, abundance, and frequency be evaluated (EPA, 1992b). Endpoints should characterize the ability of the ecosystem to sustain its structure and function, and characterize the standing stocks and flow of energy and nutrients. Other endpoints to consider include diversity, competition, food-web impacts, sensitivity to keystone species, minimum number of species and their distribution, and productivity. Such data, when compared to that collected from an appropriate reference location, would allow inferences to be made regarding the ecological conditions at the site. All aspects of the ecosystem that would be appropriate properties for evaluation of the health of the ecosystem should be identified in the rewritten and revised Phase 2 Work Plan.

6.1.5 Exposure Assessment

According to Phase 2 Work Plan, tasks associated with the conduct of the exposure assessment phase of the ecological risk assessment include (p. 7-4) the examination of exposure pathways and exposure routes to identify exposure points and quantify exposure point concentrations. EPA has, however, provided no detail in the Work Plan on the methodology to be used for meeting this objective. Furthermore, the plan for the exposure assessment is grossly insufficient in that it omits a number of major components of ecological exposure characterization and neglects to provide any specifics on the planned technical evaluation of the magnitude and spatial and temporal extents of exposure. Again, if a PRP were to submit a four sentence Work Plan for the conduct of an exposure assessment at a major site, it would be flatly rejected by EPA.

Recent EPA guidance (EPA, 1992f) has developed and modified the exposure assessment (profile) framework. This developing exposure assessment framework is organized into four components: (1) stressor characterization, which involves determining the stressor/chemical distribution or pattern of change; (2) ecosystem characterization, which evaluates spatial and temporal distributions of the ecological component and ecosystem attributes that influence the distribution and nature of the stressor; (3) exposure analysis, which focuses on ecological contact with the stressor and, (4) exposure profile, which quantifies the magnitude of exposure for the scenarios identified in problem formulation.

In the four sentences EPA has provided on the scope and design of the exposure analysis phase of the ecological risk assessment, there are no specifics provided as to how the Agency will quantify exposure point concentrations, how it will determine what routes of exposure are important, or whether or not it will estimate doses to individual receptors. It is not clear to what degree exposure point concentrations will be derived from field measurements, if fate and transport modeling will be used in the development of exposure point concentrations, and if so, whether the model(s) will be validated with supporting field measurements. According to EPA, estimates of future PCB levels in fish will be based on estimates of bioaccumulation from water and sediments. Methodologies for the development of these estimates are absent from the Phase 2 Work Plan.

6.1.6 Toxicity Assessment

The ecological effects assessment plan presented in Work Plan (p. 7-5) lacks specific details. In its present state, given the inadequacy of the Phase 1 preliminary investigation, this plan represents a wholly inadequate description of the ecological effects evaluation that will be needed for the Upper Hudson.

The preliminary investigation of ecological effects should have identified relevant field observations, field tests, laboratory tests, and chemical structure-activity relationships, and should have considered factors that influence the utility of these data (such as direct applicability of laboratory-based tests to field situations, natural variability in the field, and the possible presence of stressors other than PCBs) as they apply to the evaluation of the effects of PCBs on the receptors of concern. (EPA, 1992f). In addition, endpoints (assessment and measurement) should have been selected based on the information collected in the preliminary investigation and fully described in the Phase 2 Work Plan, including information on the selection rationale, and the linkages between the measurement endpoints, the assessment end points and the goals and objectives of the reassessment.

In addition, though both field observations and laboratory data can be used to evaluate effects, both types of data include factors that may confound the attribution of observed effects to specific stressors. Because environmental factors are controlled in laboratory studies, responses may differ from those in the natural environment; the presence of multiple stressors and lack of direct correlation between test environment and assessment environment may confound the results of observational field studies (EPA, 1992f).

Moreover, when extrapolating between different laboratory and field settings, differences in physical environment and organism behavior and other factors that will alter exposure, interactions with other stressors, and interactions with other ecological components must be considered.

Evaluation of long-term ecological impacts on the Upper Hudson River will especially require consideration of spatial and temporal distributions of PCBs in the experimental or observational setting and ecological recovery.

6.1.7 Risk Characterization

In the absence of a well-formulated risk assessment objectives, EPA has been able to do little more in the risk characterization section than very briefly mention a few of the numerous important factors that comprise an effective risk characterization. The Risk Assessment Forum (EPA, 1992f) has organized risk characterization into two steps: (1) risk estimation, which consists of comparing the exposure and stressor-response profiles as well as estimating and summarizing the associated uncertainties and (2) risk description, which summarizes the ecological risks thorough a discussion of confidence levels and weight of evidence, and interprets the ecological significance. Though portions of these steps are mentioned (p. 7-5) in the Work Plan for this component of the analysis, specifics on EPA's plans are not provided. Based on the premise that EPA will rewrite and resubmit the Work Plan for the Phase 2 ecological evaluation, GE offers these brief descriptions of the factors that should be considered by EPA for the risk characterization.

6.1.8 Risk Estimation

As discussed by EPA (1992f) in the ecological risk assessment framework document, there are several approaches that could be taken to estimate risk, depending on the original purpose of the assessment and the time and data constraints of the analysis. Though the quotient method introduced by Barnthouse et al. (1986) and referenced by EPA as a method to be used in the Phase 2 analysis has been commonly applied to evaluate the ecological risks associated with the presence of chemicals in the environment, it does not provide a very reliable or accurate estimate of risk. Because the Quotient method compares single effect values with predicted or measured levels of the stressor, there is little to no opportunity for probability to enter into the estimation and, when the Quotient approaches one, a high degree of professional judgement is required to correctly apply the method (EPA, 1992f). As pointed out by EPA (1992f), evaluating the full dose-response curve and incorporating the frequency, timing, and duration of exposure into the risk characterization will result in a more accurate prediction of the magnitude of effects expected at various levels of exposure.

EPA (1992f) also advocates risk estimation methods that compare distributions of effects and exposure, such as the Analysis of Extrapolation Error (AEE) method mentioned by EPA, but warn that valid distributions require the availability of sufficient data amenable to statistical treatment. EPA will need to determine, in the Problem Formulation component, whether or not data are available or can be collected that will meet the needs of statistical analyses, before they plan on using this methodology.

Finally, EPA (1992f) considers the use of simulation modeling to be a promising methodology for obtaining probabilistic estimates of ecological risks. Direct effects of a stressor on single-species or populations can be modeled using measurement endpoints at the individual level; aquatic food web models can be used to evaluate both direct and indirect effects. EPA (1992f) points out that simulation models have not been used extensively to model ecological risks; however, there is no reason that EPA could not apply this methodology if appropriate validated models were identified.

6.1.9 Uncertainty

EPA alludes in several places in Section 7.0 of the Phase 2 Work Plan that it will address uncertainty. In reality, EPA offers little more than a suggestion that uncertainty analyses should be performed during the ecological risk assessment process. Because the primary purpose of a work plan is to provide details in how to conduct a scientifically acceptable risk assessment, it would seem necessary to include information on the types of uncertainty typically encountered in ecological risk assessments and how they will be addressed and potentially overcome.

Four primary types of uncertainty that are typically encountered in an ecological risk assessment (EPA, 1992f). First, there is usually some form of uncertainty created in the conceptual model formulation stage of the risk assessment process. As stated in EPA's framework document (EPA, 1992f), "if incorrect assumptions are made during the conceptual model development regarding potential effects of a stressor, the environments impacted or the species residing within these systems, then the final assessment will be flawed." This type of uncertainty is not only difficult to identify and quantify, but also very difficult to reduce or eradicate.

The second type of uncertainty involves the incompleteness of the data that serves as the basis for the risk assessment. In some cases, additional data can be obtained to reduce this type of uncertainty. In other cases, the data may be unobtainable for a variety of reasons (e.g., an understanding of some type of natural process may be lacking). In these situations, professional judgement must dictate the assumptions that are made and the acceptability of the associated uncertainties.

The third type of uncertainty involves the natural variability that is a basic characteristic of stressors and ecological components as well as the factors that influence their distribution. This type of uncertainty can be described but it cannot be reduced. However, quantitative analyses such as Monte Carlo simulation can be used to describe the variability in this type of uncertainty.

The final type of uncertainty actually focuses on true errors introduced into the risk assessment process. Typically, errors occur in the design phase or in the procedures used for sampling and measurements. Errors can also be introduced during the simulation model development process. There are numerous ways to reduce these types of errors such as following experimental protocol, incorporating carefully designed QA/QC measures, conducting sensitivity analyses and using field validation techniques.

In sum, EPA must recognize the importance, as emphasized in the Habicht memorandum (EPA, 1992d), of integrating uncertainty into the overall risk assessment process.

6.1.10 Risk Description

In the Phase 2 Work Plan, EPA states that it will rely on a weight-of-evidence approach to interpret and characterize ecological risk. While it is appropriate that the results and interpretation of an ecological risk assessment are not driven by a single factor or finding, if not conducted carefully, with clearly defined goals and objectives, such a vaguely defined approach could result in a subjective and loosely interpreted evaluation.

EPA (1992f) has provided in its new framework document brief descriptions of several important considerations that should be included in a weight-of-evidence analysis: (1) sufficiency and quality of the data; (2) corroborative information; (3) evidence of causality; and (4) identification of additional analyses. At the very least, these components should be included in EPA's Work Plan and analysis.

The Phase 2 Work Plan also suggests (p. 7-5) that the interpretation of the ecological significance of the findings of the assessment will be included in the risk characterization. Again, this description is insufficient. EPA (1992f) has provided a reasonable list of the factors that should be included in such determinations, which includes the consideration of the nature and magnitude (and likelihood) of the effects observed or predicted, the spatial and temporal patterns of the effects, and the recovery potential. Because EPA will eventually evaluate the risks associated with remedial alternatives (including dredging), it will be essential that EPA incorporate an evaluation of recovery potential into the description of baseline ecological risks associated with the Upper Hudson.

6.2 An Adequate Ecological Risk Assessment Work Plan Must Focus on Establishing Cause-and-Effect Relationships

In EPA's Phase 2 Work Plan, it is assumed that there is a negative cause and effect relationship between the presence of PCBs and the overall health of the Upper Hudson River ecosystem. The Phase 2 Work Plan continues the approach to ecological assessment established in the Phase 1 assessment. EPA concluded in the Phase 1 assessment that PCBs did potentially pose harm to the Upper Hudson ecology. This conclusion was based on the finding that measured and estimated concentrations of PCB in the biota and sediments of the Upper Hudson Site exceeded certain Federal and New York State criteria and guidelines. These criteria and guidelines were generally based on the findings of laboratory studies or field work performed outside the Upper Hudson region. Based on these extrapolations and comparisons, inferences were made that current and past levels of PCBs are causing significant effects in the Upper Hudson ecosystem.

The approach used in the Phase 1 Report and the Phase 2 Work Plan are considered to be a "bottom up" approach. That is, standards are set for sediments, water, and biota in order to protect the health of the species at the top of the food web that are most at risk. As part of this approach, conservative assumptions are made to relate the levels in the environmental media and biota to the doses received by the species to be protected. In addition, conservative assumptions are made in extrapolating the results of laboratory studies to the site. Because of these conservative assumptions, it is not possible to characterize the degree of impact a chemical will have on a site where one or more of the criteria are exceeded.

This limitation is a major problem for the Upper Hudson site since certain remedies under consideration may themselves pose significant ecological risks. GE believes that the Phase 2 ecological assessment must have an adequate characterization of the current ecological impact of PCBs on the overall health of the Upper Hudson ecosystem in order to consider alternative remedies. Because of these limitations, it is essential that the results of a "bottom up" analysis be verified and further characterized by an adequate and scientifically defensible "top down" assessment of the effects of PCBs in the Upper Hudson ecosystem. The "top down" approach focuses on impacts of the overall ecosystem rather than on impacts to individual organisms within the ecosystem. This alternative approach evaluates chemical, physical, and biological alterations to a particular ecosystem in conjunction with actual effects or stresses on "key species" within the ecosystem.

Clearly, no attempt has been made, either in the Phase 1 report or in the present Phase 2 Work Plan, to determine if the ecological concerns identified in the "bottom up" approach are supported by empirical measurements of impairment of the structural and functional integrity of the site. In the Phase 1 Report, EPA justifies this lack of a validating procedure by suggesting that insufficient ecological data are available to permit a determination of the present integrity of the Upper Hudson River ecosystem or of its components. It is our belief that such a determination of the present integrity of the Upper Hudson River ecosystem via this "top down" approach is both feasible and essential if EPA wants to establish a cause and effect relationship between the presence of PCBs and the overall health of the ecosystem.

EPA must therefore revise the Work Plan to include performance of a "top down" assessment. This assessment should have two objectives, first to assess the current overall health of the river and second to identify and evaluate evidence of actual PCB-related effects.

The first objective, assessing the river's overall health, can be determined by several types of analyses. For example, EPA should evaluate the ecological history of the river, by comparing historical records with more recent data to determine current status and changes in the ecosystem. The objective in this analysis is to understand the effects of PCBs in the context of other factors which effect the ecology of the river. Another technique that can be used to achieve this objective is to compare the health of the Upper Hudson to a comparable river with locks, dams, and active barge traffic (e.g., Connecticut River, Mississippi River).

In the second objective, actual PCB-related effects resulting in significant impairment of the existing ecosystem must be identified and evaluated. To do this, specific species which are most likely to be affected by exposure to PCBs need to be carefully selected. GE believes that if the high risk species are in good health and display no indication of PCB effects, then PCBs are unlikely to be affecting the overall Upper Hudson ecosystem. In conducting this analysis, it is important to recognize that effects potentially stemming from exposure to PCBs must be separated from those occurring from other stressors. This is in accordance with recent EPA guidance (EPA, 1992f).

Because of the critical importance of this "top down" approach, a more detailed description of this alternative approach to evaluating the health of the Upper Hudson ecosystem is presented in the following paragraphs. It is our hope that this brief discussion will provide EPA with an understanding of the importance of a "top down" approach when evaluating the health of the Upper Hudson River ecosystem.

6.2.1 Historical Review of the Upper Hudson River Ecosystem

The impact of PCBs on the current condition and health of the Upper Hudson River is best done in reference to a river that is considered to represent a "normal" set of ecosystem parameters. Thus, it is critical to begin with a brief account of what can be surmised about the "pristine" condition of the river, and how this condition was altered through anthropogenic activities.

Historically, the Upper Hudson contained low quantities of nutrients, which limited its biological productivity (NYS Conservation Department, 1966; Boyle, 1979). The paucity of basic nutrients was likely due to the runoff from rocks and infertile sands in the Upper Hudson watershed. This general impoverishment, in conjunction with acidic humus formed by the combination of cool weather, high rainfall, and the coniferous forests of the upper portion of the watershed, apparently produced a relatively sterile biological component in this original riverine ecosystem (Boyle, 1979). In conjunction with this, there were also fewer wetland habitats and thus, less biological diversity along the river prior to the lock and dam system.

Increased nutrient and energy inputs to the river would have begun with the earliest European settlements, as organic materials released from logging and forest clearing operations were carried to the river. This enhanced nutrient and energy base of the ecosystem was further increased by runoff from rapidly expanding agricultural enterprises and from sewage and other domestic wastes generated in growing villages and towns along the Upper Hudson. This early settlement period was followed by the creation of an industrial corridor, with stretches of industrial concentrations along the river from

Corinth to Troy, and on some of the tributaries entering this reach of the river.

It is clear from the literature that the original, pristine river state was particularly effected by the construction of the current system of locks and dams and an in-river canal system. The dams transformed a free-flowing river into a river of sluggish flow and pools, with consequent changes in biotic community structure and in chemical and physical conditions of this stretch of river. In addition, the overall flow in the Upper Hudson River now is largely regulated by releases from flood control reservoirs at Great Sacandaga and Indian Lakes. The annual flow regimes that earlier included peak flushing discharges as well as periods of low flow are now attenuated and greatly modified by this control. These two modifications have altered earlier patterns of sediment transport, nutrient and contaminant deposition and redistribution, compensation depth and gas exchange, and other factors that influence biological productivity and habitat suitability for aquatic species.

The construction of impoundments on the river also created extensive wetland habitats, and promoted the invasion and spread of exotic macrophytes because of the formation of favorable habitats. Plants such as the aggressive water chestnut gained access to the watershed and spread rapidly at the expense of native flora, reducing the biological richness of the native macrophyte communities. Construction of the expanded Champlain Canal system earlier in this century required displacement of enormous quantities of sediments as the navigation channel was dredged, establishing a "canalized" Hudson River in the 37-mile reach between the confluence of the Mohawk and Hudson Rivers, and Fort Edward.

Channel maintenance dredging, although confined to the channel dimensions within the Upper Hudson, continues the pattern of periodic bottom and water disturbance, which in turn affects the distribution and species composition of bottom and planktonic fauna and flora as well as members of higher trophic levels dependent on these communities for food. And finally, barge traffic adds to the overall effects of the canal on the river's ecosystem, due to occasional spills of chemicals and hydrocarbons at unloading installations, and resuspension and redistribution of sediments affected by barge wakes.

Alterations in the river's chemical and physical environment have been accompanied by parallel shifts in the Upper Hudson's biotic communities, resulting in new assemblages of plant and animal species that are adapted to impounded waters and tolerant of the present environment. While the species may be different from those inhabiting previous free-flowing habitats, they function in equivalent ecological roles as primary producers, detritivores, herbivores, and carnivores. The present Upper Hudson River ecosystem is characterized by good biological diversity and supports a complete trophic structure that includes a complex food web. In contrast to the low productivity that was the primary determinant of the early river's overall diversity, today's river ecosystem undoubtedly has higher productivity, which is reflected in the overall diversity of life it presently supports.

Ecosystems that show significant impairment are often characterized by a species or two that singularly dominate the system, thus breaking the important bonds of interdependency in the overall ecosystem, which may result in uncontrolled blooms or outbreaks. It is clear that such singular species dominance is not present in the trophic structure of this ecosystem; thus, the Upper Hudson does not show the propagation of effects that are typical of stressed aquatic systems. Instead, the Upper Hudson shows stability and self-regulation, attributes of a healthy river.

6.2.2 Potential PCB-Related Effects on Biota Residing in the Upper Hudson River

In view of the diverse influences on the river's ecology, the effects of a single contaminant, such as PCBs, are difficult to establish. However, the available information on the toxicity and fate of PCBs in the aquatic environment provides an indication of where PCB effects are most likely to occur. In general, species should be selected if they are either sensitive to the toxic effects of PCBs, or are likely to have a high level of intake of PCBs. Since the available information on the aquatic toxicity of PCBs is not sufficient to identify any one species in the Upper Hudson ecosystem that is especially sensitive to PCBs, it is important to focus on "key species" identified in the ecosystem. In order to identify a "key species" for evaluation, certain criteria need to be considered.

First, to represent an effective measure of the overall impact of PCBs, biological receptors must be unusually sensitive to PCBs either because of a demonstrated toxicological sensitivity, or because they accumulate PCBs in usually high amounts. Since there is insufficient information on the toxicology of PCBs to identify those species which are unusually sensitive, the latter measure is usually considered. Second, the selected species must exist in sufficient numbers in the ecosystem of interest so that a survey of individual organisms can be undertaken in order to determine if there is a PCB related effect. Finally, there needs to be both toxicological data on the species and information on the status of the species in the Upper Hudson River.

In addition, tissue levels of lipophilic compounds like PCBs are known to increase as species move up the food chain. This effect, which is known as biomagnification, begins with the lowest trophic level, which on the upper Hudson River consists of primary producers such as algae, macrophytes, phytoplankton, and periphyton. Members of this trophic level absorb PCBs and are subsequently ingested by organisms at higher trophic levels. Based upon the available data, the aquatic organisms with the greatest potential for significant PCB intakes are certain predatory and demersal fish as well as bird and mammal species at or near the top of the food chain. Thus, if acute or chronic PCB toxicity is being manifested in the Upper Hudson ecosystem, biomagnification of certain congeners should result in discernable effects in the system's highest trophic levels.

Piscivorous colonial nesting birds (gulls, terns, cormorants, herons) have been identified as excellent indicators of PCB contamination effects. Unfortunately, no species of colonial nesting birds are known to nest between the Federal Dam at Troy and Fort Edwards (Bull, 1985; Anderle and Carroll, 1988). Other piscivorous birds such as kingfishers, osprey and eagles consume fish and may possibly be found in the Upper Hudson River. However, there are a number of drawbacks (resident time on site, small sampling populations) which make them difficult to evaluate. Reproductive parameters of mink also show good potential for PCB cause-effect biomonitoring (Aulerich and Ringer, 1977; Hornshaw, et al., 1983; Wren, 1991). However, the river's wetland communities and adjacent riparian habitats are not likely to support a substantial population of mink for sampling purposes. Since avian and mammalian species cannot be used to provide insights on the health of the Upper Hudson ecosystem, fish occupying higher trophic levels (bass, walleye, trout and carp) should be used as the "key species". While the carp is not a predator fish, its intimate contact with sediments results in relatively high levels of PCB intake and high tissue levels (EPA, 1991b).

There is considerable information on the toxic effects of PCBs in fish, and surveys of fish populations in the Upper Hudson have been performed, thereby providing sufficient data to complete an evaluation. Chronic exposures to PCBs have been associated with liver and kidney effects and with reduced survival of fish larvae. More subtle effects, such as reduced growth rate of larvae or inhibition of ATPase activity, have been reported at lower exposure levels. Based upon these effects, the effect most likely to be seen in the environment is population suppression due to the inability to reproduce. In addition, if effects were to be observed, it is likely that adult fish would have a greater potential for liver and kidney lesions, elevated liver weight, and decreased body weight.

As far as the Upper Hudson is concerned, fish populations could be compared in species, number, and general health to populations in similar areas that have no history of PCB contamination to complete this assessment. As previously stated, if no impacts can be demonstrated for the "key species," then it is unlikely that PCBs are posing subtler impacts on other species within the ecosystem in spite of what a theoretical bottom-up approach might suggest. Thus, this type of top-down validation is an essential component of an ecological evaluation. It should be included in a rewritten Phase 2 Work Plan.

6.3 EPA Cannot Fulfill Its Ecological Risk Assessment Obligations Until It Considers the Ecological Effects of Dredging

As recognized in the Phase 2 Work Plan (p. 5-1), EPA's ability to select from remedial alternatives will require EPA to consider whether "remedies other than No Action [can] significantly shorten the time required to achieve acceptable risk levels, or [whether it could] make the current condition worse." In the context of ecological risk, EPA cannot make that determination unless it has fully considered the ecological risks of remedies other than No Action, including dredging.

As is clear from EPA's Risk Assessment Forum Framework document, ecological stressors include nonchemical stressors such as physical disturbances and their associated indirect effects. (EPA, 1992f, pp. 3, 11, 14, 15, 17, 19-21). It is unclear from the Phase 2 Work Plan whether EPA will collect the information it needs to adequately characterize the ecological risks of dredging. Before EPA can make an informed decision in the Reassessment, it must perform the data collection and analysis needed to characterize the effects of dredging, including gathering that information necessary (1) to characterize the ecosystem which may be impacted and (2) to determine the exposure scenario and the ecological effects of dredging, so that this information is available to be used to arrive at a characterization of the ecological risks from remedial alternatives.

Although it may be premature to complete a characterization of ecological risks from dredging because the potential remedial alternatives have not yet been identified, it is certainly not premature to determine what information will be necessary to make that characterization. For that reason, when EPA re-evaluates the purpose and goals of the ecological risk assessment, it should formulate a conceptual model that describes how dredging might affect the ecological components of the Upper

Hudson River ecosystem so that the necessary data can be collected and the required analysis can be undertaken during Phase 2.

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7.0 OTHER SOURCE INVESTIGATION

The Phase 2 Work Plan contains a woefully inadequate discussion of other sources of PCBs to the Hudson River site. In particular, EPA arbitrarily limits its discussion of other data sources (p. 4-3) to other Upper Hudson sources. Moreover, EPA repeats and compounds the errors contained in its Phase 1 Report, wherein (as GE noted in its comments on the Phase 1 Report) EPA ignored information relating to numerous other PCB sources and failed to use the many investigative tools that are uniquely available to it (*e.g.*, information requests) to find other past and present PCB sources. As established in GE's Phase 1 comments, EPA will not be able to conduct a meaningful assessment of remedial alternatives and fulfill its obligation to identify all PRPs at the site until it fully comprehends the scope and magnitude of other PCB sources in the Upper and Lower Hudson.

But rather than rolling up its sleeves to conduct the work necessary to gather and review this information, EPA has adopted an approach best described as struthious. Section 4.2 of the Phase 2 Work Plan looks only to Upper River sources and, even with respect to that portion of the river, provides for virtually no investigation. Indeed, EPA ignores many additional *known* PCB sources to the Upper Hudson. Accordingly, the Phase 2 Work Plan fails to map a reasonable course toward an adequate understanding of Hudson River PCB sources.

7.1 Point Source Data

In Phase 1 of the Reassessment RI/FS, EPA restricted its investigation of PCB point sources to entities currently holding PCB discharge permits under the State Pollutant Discharge Elimination System (SPDES). But, as GE's comments on the Phase 1 Report indicated (pp. 310-16), such an approach is inadequate and misleading, because most dischargers, particularly those that employed "open-end" or "nominally closed" uses of PCBs, ceased using PCBs before the SPDES system was implemented.

By continuing to look only to SPDES records, EPA repeats this serious error in Phase 2. Despite official guidance to the contrary, EPA is apparently unwilling to issue information requests, review state records, or take other steps to identify historical releases to the site. EPA Directive 9834.3-01a, for example, lists twelve sources of information that should, "at a minimum," be reviewed in a PRP search. (EPA, 1987). Moreover, natural resource trustees are required to "use reasonable efforts to proceed against known [PRPs]." (43 C.F.R. § 11.32(a)(2)). As detailed in GE's comments on the Phase 1 Report, EPA is therefore duty-bound to use all reasonable efforts to investigate all sources of PCBs to the site. Yet EPA has failed to give any -- much less a reasoned -- explanation for its failure to comply with this duty. Indeed, by delaying its investigation, EPA is compounding its error, because subsequent investigations of other sources are made more difficult with the passage of time.

Instead, EPA appears to have gone out of its way to overlook data that demonstrate non-trivial PCB discharges by the State of New York, the County of Albany, Poughkeepsie, New York City, among others. A 1975 NYSDEC survey, for instance, indicates that, as late as September 1975, two facilities operated by the County of Albany discharged PCBs at a rate of 1.37 pounds per day. (NYSDEC, 1976). Although this amount exceeds EPA's estimate (in the Phase 1 Report) of the current load over the Troy Dam, EPA omits any mention of these facilities, this survey, or any other information on other sources presently available to EPA.

Moreover, GE has recently obtained additional Monsanto sales data, which have been available to EPA since at least 1976. These data reveal that over 10 million pounds of PCBs were sold throughout the Lower Hudson River Drainage Basin through the early 1970s, before the SPDES system even went into effect. Over 2 million pounds were sold in Albany alone, over 7 million pounds were sold in New York City, and thousands or tens of thousands of pounds sold in each of at least 15 other cities or towns along the Hudson (*e.g.*, Newburgh, Troy, Poughkeepsie, and Yonkers).

Although GE does not presently possess the names of the particular entities that purchased these PCBs, EPA does possess or could readily obtain this information. In any event, the types of industries that used PCBs were numerous and varied -- ranging from film sensitizing operations to lead acid battery manufacturing, and from material coating operations to assembly operations. (Versar, 1976, p. 311). Because most of these industries employed "open-end" or "nominally closed" applications, their effluent concentrations of PCBs were extremely high, in some cases in the hundreds of parts per million. (Versar, 1976, p. 311). Moreover, according to one prior study (ignored by EPA so far) the Lower Hudson River

Drainage Basin contained approximately 220 industrial direct dischargers and over 200 indirect dischargers during the mid-1970s. (Moskowitz *et al.*, 1977). There is no reason for EPA to fail to use its investigative resources to determine precisely which of the Monsanto customers were past or are present PCB dischargers into the Hudson River.

To the extent EPA considers such an rudimentary investigation unnecessary because the "Hudson River PCBs" site, as listed on the NPL, consists solely of PCBs discharged by GE, such a belief is as erroneous as it is illogical. To characterize the site adequately and to assess remedial alternatives meaningfully, EPA must investigate *all* past and present sources of PCBs to the Hudson, not simply those alleged to have originated from a particular entity. In short, EPA remains obliged to use the resources uniquely at its disposal to search for other Hudson River PCB sources.

7.2 Other Investigations

EPA's efforts have been similarly deficient in reviewing other investigations related to Hudson River PCBs. The Phase 2 Work Plan indicates (p. 4-3), for example, that EPA intends to examine only one or two other facilities during Phase 2, and not to look at any prior investigations. In so doing, however, EPA ignores numerous past and present investigations (contained in the State of New York's and in EPA's own files) of established or potential Hudson River PCB sources. These sources include, by way of illustration only:

- The Watervliet Arsenal, where PCB-contaminated oil was discovered in soils and groundwater adjacent to the Hudson in 1986.

- The Hudson River Psychiatric Center, where Aroclor 1260 was discovered at 1,700 ppm in a landfill through which a stream runs directly to the Hudson. This facility is owned or operated by New York State, and its PCBs possibly originated from the City and Town of Poughkeepsie.

- The Harmon Railroad Yard and Waste Water Treatment Area, where soil samples taken in 1984 show PCBs in 11 areas in the yard, which is located 400 feet east of the Hudson. PCBs were also discovered in wastewater effluent in 1980.

- A pulp recycling plant in the Town of Moreau, where paper sludge has been discharged to the River with PCB levels as high as 224 ppm.

- The Harbor at Hastings, where soil contamination has been found as high as 100 ppm and where fill material extends into the Hudson River.

- An inactive disposal site in Queensbury, with soil contamination as high as 37,737 ppm and with river sediment concentrations of 86.5 ppm.

In addition, the 1976 report prepared for EPA concluded that, even as late as 1976, approximately 12 million pounds of PCBs were estimated to be disposed of in landfills annually. (Versar, 1976, p. 8). Under its interpretation of regulations governing the TSCA program (40 C.F.R. subpt. 761(D)), Region II has done little to remediate, or even to document, PCBs disposed of in landfills prior to February 17, 1978. Thus, many PCB sources along the Hudson remain unremediated -- indeed, not even considered -- by EPA. EPA's failure to study these sites in determining the appropriate response to Hudson River PCBs is both inexplicable and illogical.

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8.0 FEASIBILITY STUDY ANALYSES

The feasibility study analysis contained in the Phase 2 Work Plan is premature and incomplete. EPA must first determine the effects of No Action and various remedial alternatives (through the use of a quantitative model) before proceeding to identify "the areas and volume of sediments . . . subject to possible remedial action" (p. 8-1). Even to the extent EPA properly addresses feasibility questions relevant to Phase 2, the Work Plan is filled with gaps and vague statements. EPA fails to provide a step-by-step discussion of how it intends to conduct its feasibility study analysis. EPA's proposed analysis is therefore inadequate and unacceptable.

8.1 EPA's Proposed Analysis Is Premature

Prior to selecting any remedial alternative with a dredging element, EPA must consider (among other factors) (1) the complexities of the Hudson River; (2) the difficulties of removing sediments from the Hudson River with existing technology, transporting the sediments to a disposal or treatment site, and ultimately disposing or treating the material; (3) the environmental, ecological, and human health effects that will result from dredging, and (4) the feasibility (*i.e.*, the costs versus the benefits) of such a remedial alternative. These matters are discussed in some detail on pages 199-251 of GE's Phase 1 Comments, and GE incorporates by reference those comments here.

The Phase 2 Work Plan makes an effort to address these issues, but the effort is incomplete and ultimately inadequate.

During Phase 2, for example, EPA apparently intends (p. 8-1) to identify "the areas and volume of sediments within Study Area B [that are] subject to possible remedial action." Such an effort, however, places the cart before the horse, because it *assumes* that PCBs in the sediment are causally related (in a non-trivial manner) to PCBs levels in fish, to human health risks, and to ecological risks. EPA's proposed approach also assumes (p. 8-1) that depositional areas are significant sources of PCBs to fish, without first determining whether this is in fact true.

These causal linkages are critical elements of any remedial action that includes sediment remediation. EPA, however, does not -- and cannot -- identify any support for its assumptions, particularly given (1) the current lack of reliable projections of the effects of sediment removal on future environmental conditions and estimated risk levels and (2) the existence of other significant PCB sources. Moreover, EPA gives no clue as to what it means (p. 8-1) by "preliminary remedial action criteria."

In sum, any attempt to determine potential areas to be dredged in advance of scientifically credible modeling and risk assessment is a meaningless, premature, and dangerously misleading exercise. EPA's use of unarticulated and unsupported assumptions -- rather than reliable data, good science, and sound logic -- to drive the feasibility study analysis is unacceptable.

8.2 EPA's Proposed Analysis Is Incomplete

Even to the extent that EPA has a legitimate intent to conduct its feasibility study analysis concurrently with its assessment of remedial alternatives, the Phase 2 Work Plan is deficient. Significantly, EPA's feasibility study analysis fails to define with specificity the remedial action objectives and remediation goals for the site. For example, it is unclear whether EPA intends to consider the effect of other contaminants on various remedial alternatives. Section 8.1 of the Work Plan describes PCB-contaminated sediment volumes as being subject to possible remedial action, and section 8.4.2 discusses PCB treatment technologies and a PCB-related treatability study program. Sections 8.3 and 8.5, however, mention "the ability to meet a range of remediation goals" (p. 8-2), "site-specific contaminants" (p. 8-2), and "various remedial objectives" (p. 8-5). EPA must provide GE and the public with a clear statement of its remedial action objectives and remediation goals.

In addition, the Phase 2 Work Plan discusses the evaluation of individual remedial technologies and processes, but makes no mention of the ultimate step in the Phase 3 feasibility study, in which suitable technologies are arranged into alternative remedial actions. Each alternative remedial action may contain more than one technology and each should be a complete remedial option (addressing, as applicable, all remedial components such as methods for sediment removal, stockpiling, de-watering, treatment, handling of residuals, and ultimate disposal). EPA should not focus on technology processes and treatability studies to the exclusion of questions relating to interim storage and permanent disposal of sediments.

EPA must also identify the relevant data required to evaluate, in a meaningful and reliable manner, various remedial technologies. Such an analysis would ensure that all important analytical and physical sediment and river data applicable to technology evaluation will be collected during Phase 2. The Phase 1 Report, for example, contains (p. C.7-1) a list of data necessary to evaluate thermal treatment technologies. Similar lists should be constructed (and subject to comment) prior to Phase 2 data collection.

With respect to EPA's proposed sediment disturbance impact assessment, EPA asserts (p. 8-4) that "[r]esponse actions involving dredging of sediments have been studied for the Hudson River and widely applied at other Superfund sites." EPA provides no citations to any specific studies, and GE submits that response actions involving dredging of sediments have *not* been "widely applied at other Superfund sites." Indeed, *no* response actions involving dredging of contaminated sediments have been planned or conducted on a river similar in character to the Upper Hudson. Moreover, the fact that the Hudson River has been dredged by NYSDOT for many years (as EPA states on p. C.1-1 of the Responsiveness Summary for the Phase 1 Report) in no way indicates that dredging of contaminated sediments, which raises entirely different issues, is feasible in the Hudson River.

More generally, EPA's sediment disturbance impact assessment fails to consider the range of factors relevant to a complete assessment. For example, EPA should consider, among other factors:

- The ease or difficulty of dredging the bottom material, which is influenced by accessibility for the equipment, presence of obstructions on the river bottom, and continuity of the contamination;
- The amount, extent, and duration of sediment resuspension during the dredging or sediment disturbance, as determined by the type of bottom material, the river conditions, and the type of dredge;
- The effect of dredging or sediment disturbance on dissolved oxygen concentrations in the water;
- Seasonal factors which may be cause to limit the dredging or sediment disturbance; and
- Short and long-term effects of the dredging or sediment disturbance on human health and the aquatic habitat.

The Phase 2 Work Plan addresses only the first and part of the second of these factors. A complete understanding of these factors, however, is vital to a proper assessment of sediment disturbance impacts and, ultimately, for selection of a feasible remedial action. Section 8.5 of the Work Plan should therefore be expanded to describe how these factors will be assessed and what criteria (regulatory or otherwise) will define acceptable versus non-acceptable effects. Possible sources of additional data include:

- The use of U.S. Army Corps of Engineer test data related to maintenance dredging in the Hudson River and compiled over the last 10 to 15 years; and

- An assessment of any new or improved equipment or methods, if any, that have been recently developed for the dredging of contaminated sediments, and determining whether such equipment is available in the United States and appropriate for use in the Upper Hudson.

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9.0 CONCLUSION

If the Phase 2 Work Plan were an architect's blueprint, no builder would be able to construct the building, and no one would be willing to live in it even if it could be built. As a result, if EPA proceeds with the Phase 2 work as proposed in the Work Plan, EPA risks undertaking an ambitious data collection and analysis program only to witness the collapse of the technical framework of the Reassessment when the data it has collected and analyzed turn out to be irrelevant to or too unreliable for its Record of Decision. Indeed, if a PRP submitted a similar work plan to EPA, the Agency would reject it out of hand with instructions to revise it before commencing any further data collection and analysis. Simple fairness requires the same result here.

This comment document reveals numerous significant deficiencies in the Phase 2 Work Plan. By way of illustration only, EPA should therefore reconsider the Work Plan in light of the following general comments:

1. EPA should abandon the use of unjustified and unreliable shortcuts in the collection and analysis of data. GE is exceptionally troubled that EPA has declined, apparently on financial and scheduling grounds, to develop a state-of-the-art, quantitative model of PCB fate-and-transport in the Upper Hudson. The "model" proposed by EPA will not be independently calibrated with the extensive range of existing data; relies on analytical techniques that are of dubious reliability (*e.g.*, techniques to estimate historical sediment and water conditions and to analyze

cohesive sediment behavior); and fails to include the type of sophisticated food-chain analysis that has become standard at other Superfund sites. Without such a tool to predict future PCB levels and to evaluate No Action and other remedial alternatives, EPA will be forced to make simplifying assumptions and qualitative inferences that are likely to result in a decision that is unreliable at best and erroneous at worst.

As another example of the numerous shortcuts proposed by EPA in the Phase 2 Work Plan, EPA persists in relying on mere literature surveys and ill-defined site-specific observations to perform an ecological risk assessment. EPA should instead, at a minimum, (1) gather relevant site-specific data that establish a cause-and-effect relationship, if any, between the presence of PCBs in the Upper Hudson and some ecological harm; (2) perform this ecosystem analysis using a "top-down" approach; and (3) examine the potential harms to the ecosystem that may result from the implementation of remedial alternatives.

EPA's decision not to conduct a comprehensive search for other PCB sources is yet another shortcut that must be eliminated. As GE previously explained in its Phase 1 Comments, a comprehensive search for other PCB sources in the Upper and Lower Hudson is necessary to ensure that remedial alternatives are properly evaluated and to fulfill the Agency's obligation to identify all PRPs at the site. EPA already has the tools and much of the information necessary to complete this task; EPA's rejection of this task is inexplicable.

2. <u>EPA should avoid the use of scientific techniques that are unproven or inherently unreliable as applied in the Upper Hudson River</u>. EPA must, for instance, abandon its plan to conduct quantitative PCB analyses of environmental samples that have literally been sitting on a shelf for over a decade, particularly where the sampling and storage conditions are unknown and likely unknowable. EPA should likewise terminate its proposal to use a speculative radionuclide-dating technique to analyze high resolution sediment cores, at least as currently proposed in the Work Plan. The radionuclide dating technique contains inherent uncertainties and was never designed for use in dynamic, riverine environments. It therefore cannot be used to reconstruct historic PCB conditions in Upper Hudson water and sediment. Even Dr. Richard Bopp, a leading researcher in the field, agrees that the radioactive dating technique cannot validly be applied in the Upper Hudson for the purposes suggested by EPA.

In addition, in its proposed Phase 2 human health risk assessment, EPA persists in using outdated risk assessment data and techniques. To ensure compliance with current EPA guidance, EPA should use the Monte Carlo approach (instead of non-site-specific default assumptions) to estimate risks to the average and high-end individuals. In undertaking such an analysis, EPA must take advantage of the wealth of data available to it, including information regarding site-specific fish consumption rates, appropriate fish tissue data, and losses of PCBs due to cooking. Most important, EPA must consider the latest NYSDEC data on PCB concentrations in Upper River fish, which show continuing dramatic decreases to average levels near or at the FDA limit.

3. EPA must re-evaluate the analytical structure of the Work Plan to ensure that the data collected will meet data quality objectives and will ultimately be sufficiently reliable to be used to achieve the project objectives. Prior to any additional data collection, EPA must re-define its project objectives in sufficient detail to address a number of fundamental questions and issues that are currently left open by the Work Plan. EPA must then re-examine and modify its data collection and analysis effort to address these more specific project objectives. As part of this necessary re-examination, EPA must of course comply with its own guidance documents by submitting a complete Quality Assurance Project Plan and Field Sampling Plan for public comment before it embarks on any additional data collection.

* * *

In sum, if EPA's Phase 2 efforts are to provide meaningful and scientifically valid information, EPA must reexamine the purposes and goals of these efforts and re-write its Phase 2 Work Plan to assure that these goals are met. If EPA fails to undertake such an effort, the Agency will not have the information necessary to form the requisite underpinnings to justify a technically conscientious and credible decision in this Reassessment. Accordingly, EPA will have squandered a precious opportunity to perform a first-rate RI/FS, employ the most credible, up-to-date technical analyses, and thereby produce an exemplary RI/FS for the parties and the public.

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Appendix A

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APPENDIX A

THE EFFECTS OF COOKING PROCESSES ON PCB LEVELS IN EDIBLE FISH TISSUE

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THE EFFECT OF COOKING PROCESSES ON PCB LEVELS IN EDIBLE FISH TISSUE

1.0 INTRODUCTION

A significant issue in estimating human intake of PCBs from fish consumption is the loss of PCBs that occurs during cooking. Because PCBs and other lipophilic compounds are concentrated in body lipids of fish (Reinert et al., 1972; Skea et al., 1981; Armbruster et al., 1987), and lipids tend to be removed from the fish during cooking, this loss of lipids can result in a significant reduction of PCB in the fish tissue. In addition, PCBs may also be lost by direct volatilization during cooking. As a result of these processes, the total amount of PCBs actually consumed in the cooked fish may be significantly lower than the amount occurring in the raw fish.

Several studies investigating the extent of loss of lipophilic compounds during the cooking process have been published in the peer-reviewed literature. Although most of these studies have documented significant reductions in total PCB levels during cooking processes, the degree of reduction reported in each of the studies has varied greatly. In addition, certain studies have reported increases in the concentrations of PCB after cooking. Because of what is perceived as inconsistent and inadequate data regarding the effects of cooking on PCB levels in fish, Federal and State regulators have been hesitant to assume that cooking reduces PCB levels (USEPA, 1991).

In this report we examine the available literature with the goal of developing specific recommendations for incorporating cooking reductions into quantitative exposure assessments. Based upon our analyses, ChemRisk believes that the available data does provide a reasonable basis for quantitatively adjusting estimates of PCB intake for cooking losses. This report reviews the currently available studies which address changes in concentrations of lipophilic compounds as a result of cooking. Estimates of cooking-method-specific alterations in PCB levels are developed based on this review of the literature.

2.0 REVIEW OF LITERATURE

The literature on cooking effects, while not extensive, contains information on a variety of fish species and cooking methods. Species investigated in the various studies include chinook and coho salmon (Smith et al., 1973), lake trout (Zabik et al., 1979; Cichy et al., 1979), brown trout (Skea et al., 1981), smallmouth bass (Skea et al., 1981), carp (Zabik et al., 1982), white croaker

(Puffer and Gossett, 1983), striped bass (Armbruster et al., 1987), and bluefish (Armbruster et al., 1989; Trotter et al., 1989). Cooking methods include boiling, poaching, microwave cooking, broiling, baking, roasting, pan frying, and deep frying.

The analytical methods used in all of the studies are variations of the method developed by Yadrick et al. (1972). This process consists of a Soxhlet hexane-acetone extraction of the freeze dried tissue, acetonitrile partitioning, and Florisil-Celite column cleanup. Characterization and quantification of PCBs were conducted using gas chromatographic analyses.

2.1 Reporting of PCB Declines

A major difficulty in reviewing the literature on PCB losses is that the studies do not report changes in PCB levels on a consistent basis. Reductions in PCBs have been expressed in terms of the amount of PCBs lost per gram of fat, per gram of fish (wet weight), per gram of fish (dry weight), or in total amount of PCB lost. These different reporting methods confound the comparison of the results of the studies and obscure the significance of the literature. It is, therefore, critical to place the results on a more consistent basis. In this review of the literature, the effect of cooking on the amount of PCB in the fish is evaluated on the basis of the change in total mass of PCBs before and after cooking,

$$\text{Percent of total PCB mass remaining after cooking} = \frac{\text{Total mass of PCBs in cooked fillet}}{\text{Total mass of PCBs in uncooked fillet}} \times 100$$

The advantage of presenting data on a total mass basis is that the loss of PCB can be used to directly estimate the impact of cooking losses on the intake of PCBs.

In studies where PCB loss is presented on a wet weight basis or a fat weight basis we have converted the results of the studies to a mass basis using study-specific information. Section 2.3 presents a detailed description of the calculations used to derive the estimates of reduction.

2.2 Discussion of Individual Studies

ChemRisk began this analysis by performing a literature search for articles that dealt with PCBs and cooking losses. This search identified nine studies on PCBs and a tenth study on dioxin. This section presents a brief discussion of the ten studies.

While many of the studies reported evidence of cooking losses, only half of the studies could be used to quantitatively estimate cooking losses. Some of these studies could not be used in this quantitative investigation because of inappropriate experimental methodology. Other studies were not included because of the lack of statistical significance in the study's results. Theses studies typically reported reduction in PCB levels; however, due to small sample sizes and high variability in initial PCB levels in the fish sampled, the results were not statistically significant. In addition, some studies lacked sufficient data in order to determine total (mass) loss of PCB. Table 1 presents a summary of the 10 studies and whether they were included in the final quantification estimates of cooking loss.

Smith et al. (1973) analyzed PCB concentrations in ten raw samples and twenty cooked samples of chinook salmon. PCB levels were expressed as micrograms of PCB per gram of fat in the fish samples. Also two raw samples and four cooked samples of coho salmon were analyzed. The average percent fat content was 2.65 percent in the raw chinook steaks and 3.59 percent in raw coho steaks. Samples were either poached, baked, or baked in a nylon bag. The authors reported both small reductions and increases in average concentrations of Aroclor 1248 and Aroclor 1254 during cooking. Statistical analysis performed by the authors indicated that the reductions were not statistically significant. This lack of a clear trend could have been due to small numbers of samples, large variability in PCB content between individual samples, or low body-fat content of the fish.

ChemRisk also examined the raw data reported in the thesis of Smith (1972), on which Smith et al. (1973) is based. Based on the data in the thesis and Smith et al. (1973), it was possible to estimate on a mass basis an overall percent PCB loss during baking for the Chinook salmon.

Table 1. Summary Evaluation of Studies

Study	General findings	Was method appropriate?	Were results statistically significant?	Was a quantitative estimate of mass loss possible?
Armbruster et al., 1987	Small reduction	Yes	No	No
Armbruster et al., 1989	Large reduction	No	Yes	No
Cichy et al., 1979	Small reduction	No	No	No
Puffer and Gossett, 1983	Large reduction	Yes	Yes	Yes
Skea et al., 1981	Large reduction	Yes	Yes	Yes
Smith et al., 1973; Smith, 1972	Small reduction	Yes	Yes	Yes
Stachiw et al., 1988	Large reduction	No	Yes	No
Trotter et al., 1989	Large reduction	Yes	Yes	Yes
Zabik et al., 1979	Large reduction	Yes	Yes	Yes
Zabik et al., 1982	Slight increase	Yes	No	No

Zabik et al. (1979) assessed the changes in Aroclor 1254 levels in lake trout fillets which resulted from broiling, roasting and microwaving the fish. Duplicate samples from head, middle, and tail portions of the fillets were analyzed for each cooking method. The total masses of PCBs were reduced by an average of 53 percent by broiling, 34 percent by roasting (baking), and 26 percent by microwave cooking. Mean fat content of the raw fillets was approximately 25 percent for samples used in the roasting experiment, 26 percent for fillets used in microwave cooking, and 29 percent for those that were subsequently broiled.

Zabik et al. (1982) reported the effects of several cooking methods on PCB and DDT levels in carp fillets from Saginaw Bay, Michigan. Mean fat content of the raw fillets was approximately 8 percent. These authors reported that PCB concentrations were reduced 25 percent by deep-fat frying, 27 percent by poaching, 25 percent by charbroiling, 33 percent by microwave, and 20 percent by roasting, when data were expressed on a fat basis. However, when they expressed their results on a total mass basis, data for all cooking methods, except microwave, indicated an increase in PCBs. Zabik et al. (1982) attributed these increases to more efficient extraction of phospholipid-associated PCBs during laboratory analyses of cooked tissue as compared with raw tissue. See Section 3.0 below for additional discussion of this finding.

Puffer and Gossett (1983) studied the effects of pan-frying on the concentrations of PCB and DDT in fillets of white croaker from two locations in California. Five composites from each location were tested. Mean fat contents of the raw fillets were 1.2 percent for Santa Monica Bay samples and 0.9 percent for Orange County samples. The results of the analyses were reported both on a wet-weight and on a mass basis. PCB losses were 65 percent for Santa Monica Bay samples and 28 percent for Orange County samples on a mass basis. The authors attributed the greater losses in Santa Monica Bay samples to the fact that PCB concentrations from that location were 11 times higher than concentrations in Orange County samples.

Skea et al. (1981) reported the combined effects of trimming and cooking in reducing the levels of Aroclor 1254 and other oil soluble compounds in brown trout and smallmouth bass. For smallmouth bass, baking of 20 untrimmed, unskinned fillets (mean fat content of 2.8 percent) reduced total PCB levels (mass basis) by 16 percent; deep frying of 20 trimmed fillets (mean fat content of 1.3 percent) in corn oil reduced total PCB levels by 74 percent. For brown trout, smoking of 30 untrimmed fillets (mean fat content of 16.5 percent) reduced total PCB levels by 27 percent, and broiling of 30 skinned, fat-trimmed fillets (mean fat content of 8.8 percent) showed no reduction of PCBs. ChemRisk believes that the apparent lack of PCB reduction by broiling brown trout fillets may have been an analytical error since significant reductions of other lipophilic compounds, mirex and DDE (26 percent and 20 percent respectively), were observed after broiling.

Armbruster et al. (1987) studied the effects of six different cooking methods on PCB concentrations in striped bass. The authors reported that, although declines occurred with most methods, the declines were not statistically significant due to the high variability in PCB levels in the fish tested and the small sample sizes.

Armbruster et al. (1989) reported the combined effects of trimming and cooking on the concentrations of PCBs in bluefish from Long Island Sound. Forty raw bluefish fillets were trimmed and then 10 randomly selected fillets were either baked, broiled, fried, or poached. The study found that a combination of trimming and cooking resulted in PCB reductions of 60 percent by poaching, 68 percent by baking, 68 percent by pan frying, and 71 percent by broiling. Data were reported on a dry-weight basis. No data were presented for fat content of the raw fillets. While the study results suggest that cooking processes did reduce PCB levels in fish, it is not possible to clearly determine the fraction of the decline that was due to cooking versus that resulting from trimming.

Trotter et al. (1989) studied the effects of baking on PCBs and lipophilic pesticides in 20 bluefish fillets. The authors initially reported increases in PCB levels on a wet weight basis. Estimates of PCB reduction on a total mass PCB basis were then calculated based upon information provided in the study relative to PCB concentrations and fillet weights before and after cooking. Expressed on a mass basis, the study found a reduction of 27 percent due to the baking process. Average lipid content of the raw fillets in this study was 11.8 percent.

Cichy et al. (1979) studied the combined effects of irradiation and broiling on the levels of PCBs in lake trout fillets. Significant reductions in PCB concentrations were observed during the broiling of previously irradiated fillets. Because of the study design, which focused on the effects of irradiation and did not investigate the effects of cooking on fish that had not been irradiated, this study was not used to quantitatively estimate PCB losses due to cooking processes.

Stachiw et al. (1988) investigated the effects on levels of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) resulting from the processing and cooking of restructured carp fillets from Saginaw Bay, Michigan. Fish samples were mechanically deboned, chopped, and further processed prior to forming restructured carp fillets. Roasting or charbroiling of these fillets at internal temperatures of 60° to 80°C resulted in significant reductions in the total mass of TCDD. Roasting reduced TCDD levels by 34 to 66 percent (mean of 52 percent) and charbroiling reduced levels by 55 percent to 67 percent (mean of 62 percent). The authors reported that increasing the end point cooking temperature or increasing the surface area of the restructured fillets significantly increased the percentage of dioxin lost in all roasted and charbroiled samples. Because of the considerably altered physical condition of the restructured fillets and the reported increase in PCB removed due to restructuring, this study was not included in the quantitative evaluation of cooking losses.

In summary, of the ten studies identified, five studies contained sufficient data to allow the calculation of the percent of the mass of PCBs lost during cooking. However, with the exception of Zabik et al. (1982), all of the studies present evidence of loss of PCBs or similar lipophilic compounds during cooking.

2.3 Development of Quantitative Estimates of PCB Reduction

This section presents a brief review of how the data in the five studies were used to quantitatively estimate cooking losses.

Smith et al. (1973) did not report the mass of PCBs in cooked and raw fish samples; rather, they reported the average concentrations on a per gram of fat basis, that is,

$$\frac{\mu g \text{ of PCB}}{\text{gm of fat}}$$

As discussed above, Smith et al. (1973) reported cooking loss by comparing PCB levels, expressed on a mean basis, in raw and cooked fillets. That is,

$$\text{Percent of total PCB mass remaining after cooking} = \frac{\text{PCB Concentration in Cooked Fillet}}{\text{PCB Concentration in Raw Fillet}}$$

Because of the high variability of PCBs in individual samples and the relatively small differences between the cooked and raw fillets, cooking loss estimates by this method were not statistically significant.

Based on data provided in the Smith (1972), PCB losses during cooking can be estimated by an alternative method. In Smith (1972) detailed information was provided on the levels of PCBs in the baked fillets and in the drippings collected in the pan below. Thus it is possible to make a conservative estimate of the loss of PCBs by comparing the mass of PCBs in the drippings to the mass of the PCBs in the cooked fillets. The percent of PCBs remaining after cooking is estimated as follows:

$$\text{Percent of total PCB mass remaining after cooking} = \frac{\text{Mass of PCBs in Cooked Fillets}}{\text{Mass PCB in Cooked Fillet + Mass PCB in Drippings}}$$

The mass of the PCBs in the cooked fillets and the dripping from the fillets can be estimated as follow:

$$M_{PCB} = C_{PCB} \times F \times M_f$$

where M_{PCB} is the mass of PCBs in a fillet or dripping, C_{PCB} is the concentration of total PCBs in µg/gm of fat in a fillet or dripping, F is the percent fat in the fillet or dripping, and M_f is the mass of the fillet or dripping. Data on the concentration of PCBs (fat basis) and percent fat for the individual fillets and their drippings are given in Smith (1972). Data on the average mass of the fillets and drippings are given in Smith et al. (1973).

Based on this approach, ChemRisk estimated that the average cooking loss was 10% for baking. The calculated 10 percent loss during baking is a conservative estimate of total PCB loss because data were not available to estimate the portion of PCBs potentially lost by volatilization during cooking. Had this component of cooking loss been included, the estimate of total loss during cooking would have been larger. This analytical approach was also applied to the results of poaching of chinook steaks. However, no meaningful estimates of the percent loss could be made due to the extremely low content of fat in the drip losses resulting from the poaching process.

Zabik et al. (1979) reported changes in PCB content of fish fillets on a whole tissue (wet weight) basis (Table 1, p.139), a fat basis (Table 2, p.140), and a total mass of PCB basis (Table 3, p.141). The values of total mass basis were used in this analysis.

Skea et al. (1981) reported data for changes in PCB content during baking (p.17), broiling (p.16), or frying (p.18) on a whole tissue (wet weight) basis as well as a total mass of PCB basis. The values of total mass basis were used in this analysis.

Trotter et al. (1989) initially reported changes in PCB content of bluefish fillets on a whole tissue (wet weight) basis (Table 1, p.502). Using data on PCB concentrations and weights of individual raw fillets versus cooked fillets, the authors calculated average changes in PCB content on a total mass basis (Tables 1 and 2, p.502). The mass of PCBs in the individual raw fillets was calculated by multiplying the reported concentration of PCB in the fillet by its respective raw weight. Comparable calculations were conducted for these fillets in their cooked state. The percent change in the mass of PCBs for individual fillets in their raw state versus cooked state was determined, and an average of these percentages was calculated to estimate overall PCB loss during baking of the fillets.

Puffer and Gossett (1983) initially reported changes in PCB content of white croaker samples on a wet-weight basis. However, by employing a conversion factor ("weight loss factor") to account for weight loss from cooking, the authors subsequently determined PCB losses on a mass basis (Table 1, p.69).

3.0 DISCUSSION OF REPORTED INCREASES OF PCBs DURING THE COOKING PROCESS

While most studies have reported declines in PCBs after cooking (Table 2), several studies of the effects of cooking on levels of PCBs in the edible portion of fish have indicated that PCB levels can increase during the cooking process (Smith et al., 1973; Skea et al., 1981; Zabik et al., 1982; Trotter et al., 1989). Some of these studies that reported increases in *concentration* of PCBs in cooked fillets generally expressed the data on either a wet weight basis or a fat basis (Skea et al., 1981; Trotter et al., 1989). In these cases, the PCBs appeared to become concentrated due to a greater percent moisture loss than contaminant loss during the cooking process (Skea et al., 1981). Trotter et al. (1989) specifically commented on this issue stating that "the relatively large loss of moisture during cooking compensated for the PCB and oil loss and resulted in similar ppm PCB and percent fat levels in the uncooked and cooked fillets". When these data are expressed on a mass basis, they consistently show a reduction in PCB mass during the cooking process (Table 2).

The one exception to this uniform reporting of decreases on a mass basis is Zabik et al. (1982), who reported that PCB levels were increased by the cooking process. Zabik et al. (1982) suggested that these increases could be due to more efficient extraction of phospholipid-associated PCBs during laboratory analyses of cooked tissue as compared with raw tissue. The analytical method used to extract PCBs from fish tissue (Yadrick et al., 1972) is not necessarily completely effective in extracting intermuscular phospholipids in uncooked fish. Thermal decomposition of the protein-lipid microstructures may facilitate a more complete extraction of these lipids and associated PCBs. Support for this conclusion is presented by Paul (1972, as cited in Zabik et al., 1982) who reported that "cooking often causes an increase in the amount of ether extractable material in the lean portion of meat over that found in raw meat, even when the lipid extract is expressed on a dry basis".

This effect may occur in all cooking processes, however, the effect may be noticeable when total PCB losses are small. As discussed below, several authors have suggested that the degree of PCB removed will be higher in fish with high fat content. In fish with high fat content and high PCB removal rates the small increase in apparent PCB concentration is overwhelmed by the larger reduction in PCB from volatilization and fat loss. In fish with low fat levels (carp used in Zabik et

Table 2. Changes in PCB Levels in Fish Samples Resulting From Various Cooking Methods

Method	Study	Fish Species	Percent Change on a PCB Mass Basis
Bake or Roast	Smith et al., 1973; Smith, 1972	Chinook salmon	-10
	Zabik et al., 1979	Lake trout	-34
	Skea et al., 1981	Smallmouth bass	-16
	Trotter et al., 1989	Bluefish	-27
		Average	-22
Broil	Zabik et al., 1979	Lake trout	-53
	Skea et al., 1981	Brown trout	0
		Average	-27
Fry	Skea et al., 1981	Smallmouth bass	-74
	Puffer and Gossett, 1983	White croaker (Santa Monica Bay)	-65
	Puffer and Gossett, 1983	White croaker (Orange County)	-28
		Average	-56
Microwave or Poach	Zabik et al., 1979	Lake trout	-26
		Average	-26

al. (1982) contained 8 percent fat) the effect is not overwhelmed by a large loss from fat rendering and is thus reported as an increase.

It should be noted that if the Zabik hypothesis is correct then all reported cooking loss measurements will tend to underestimate the true degree of removal. This will occur since the remaining PCB levels in the cooked fish will appear to be larger due to the increased extractability. This phenomenon may explain the apparent contradiction in Smith et al. (1973) where PCB levels in cooked fish appeared to be unchanged while approximately 10 percent of the PCBs were found in the dripping in the bottom of the baking pan.

ChemRisk believes that it is highly unlikely that PCBs are actually formed during the cooking process. PCBs are commercially formed by the direct chlorination of biphenyl in nonpolar solvents (ATSDR, 1991). Such chemical processes are not likely to occur in fish tissue due to the absence of free chlorine, the presence of polar compounds (proteins, carbohydrates, etc.), and the unlikely occurrence of biphenyl or other suitable precursors. Thus, the generation of new PCBs during the cooking process is highly implausible. Because of the absence of a plausible mechanism for the formation of PCBs, and the consistent measurements of reductions in PCB on a total mass basis in the majority of published studies, it can be concluded that PCBs are reduced to varying degrees by different cooking methods.

4.0 REDUCTION IN PCB LEVEL BY VARIOUS COOKING METHODS

The amount of PCB lost during cooking varies with the cooking method in two ways. First, certain cooking methods, such as microwaving or steaming, may be relatively ineffective in removing lipids from the fish due to the low cooking temperatures and/or short cooking times. Second, certain methodologies, such as stewing or using fish in casseroles, result in minimal reduction in PCB levels since volatilization will be minimal and the lipids lost by the fish during cooking are still consumed. Methods such as broiling or baking are more effective in reducing the amount of PCBs consumed because lipids containing these compounds are separated from the fish and not consumed, and because PCBs are volatilized during the cooking process. Finally, processes such as deep fat frying may also reduce the PCB concentration in the fish by an actual lipid extraction. In this process, PCBs would partition in the large volume of fat in the pan or fryer.

While the studies discussed above clearly indicate that cooking reduces the levels of PCBs or other lipophilic compounds in edible fish tissues when expressed on a mass basis, a careful examination of the literature indicates that there is still a wide variation in the degree of reduction associated with the various methods of cooking. The hypothesis that PCB loss is predominantly due to fat loss and volatilization suggests that PCB loss should increase with the temperature of the cooking method. To test this hypothesis, the cooking loss data were sorted by cooking practice and ranked according to the temperature used during the cooking process. The ranking of method from least to most severe was microwaving, baking (or roasting), broiling, and frying. The results of this ranking are presented in Table 2 and in Figure 1. Reduction was greatest in frying; broiling and baking were lower; and data on poaching and microwaving were too limited to reach a conclusion. These results are consistent with the hypothesis that the severity of the cooking method is correlated with the degree of PCB reduction.

It has been suggested by several authors (Zabik et al., 1982; Cordel et al., 1982) that the degree of cooking losses for lipophilic chemicals should increase with the percent total fat content of the fish. Table 3 indicates the percent fat content of raw fillets used in specific studies, and Figure 2 presents the degree of PCB loss as a function of the percent fat for the different cooking methods. It appears that there may indeed be a correlation of reduction for baking. Data are too limited to establish if this correlation in the cooking loss and fat content occurs for other cooking methods.

5.0 SUMMARY AND CONCLUSIONS

An examination of the literature indicates that cooking of fish fillets reduces the amount of PCB in the fillet. The degree of reduction of PCBs can vary depending upon the specific cooking method employed and characteristics of the fillet being cooked. Because authors have presented their research data on a variety of bases, a casual review of the literature suggests considerable variability in results. When the degree of loss is expressed on a consistent basis, however, the variability in the reported data is greatly reduced. Evaluation of the reported reductions resulting from each cooking method appear to demonstrate that PCBs are preferentially removed by cooking processes which involve higher cooking temperature and which allow the separation of rendered fat from the cooked fish.

Figure 1. Percent Reduction of PCBs in Fish Fillets Relative to Cooking Method

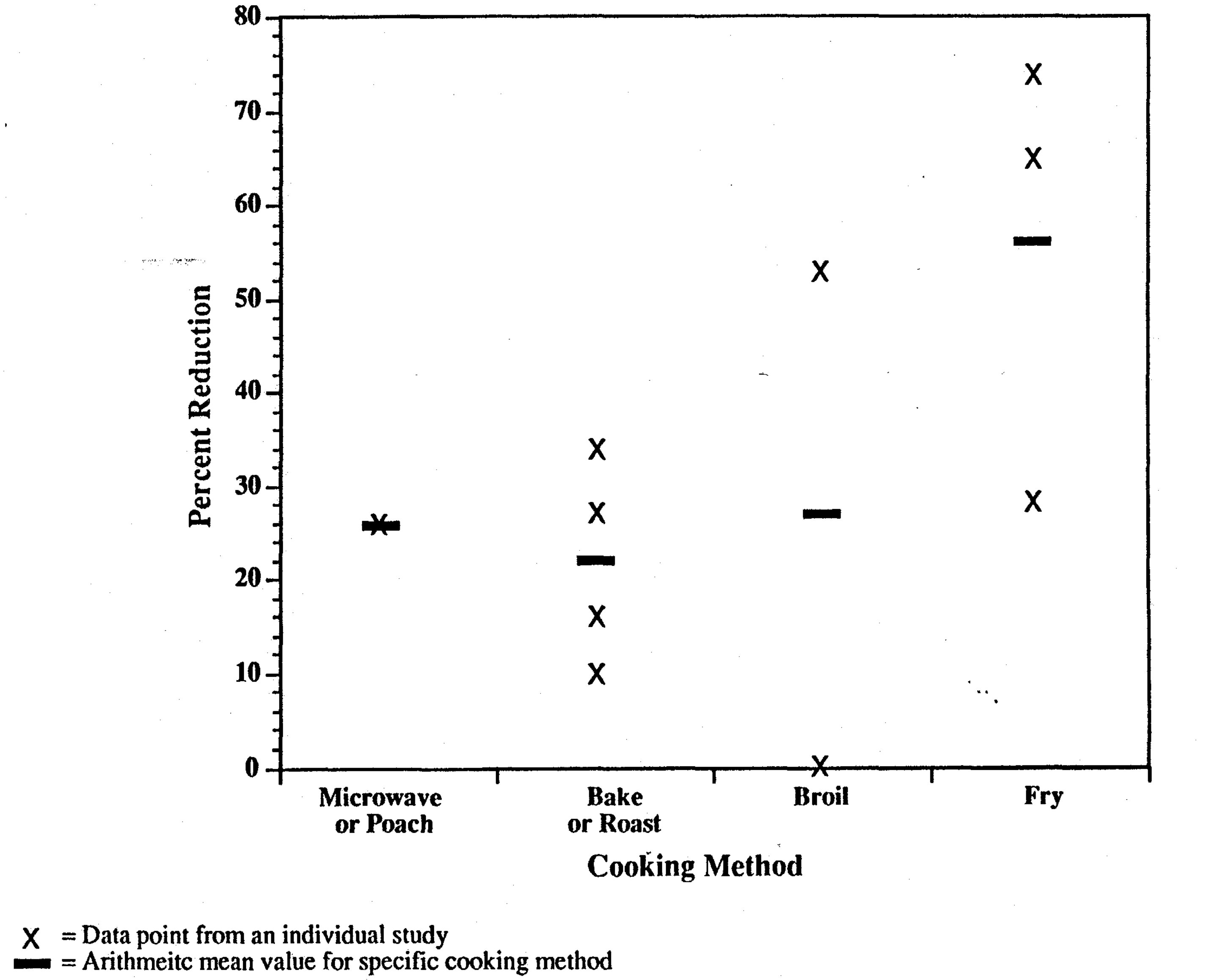
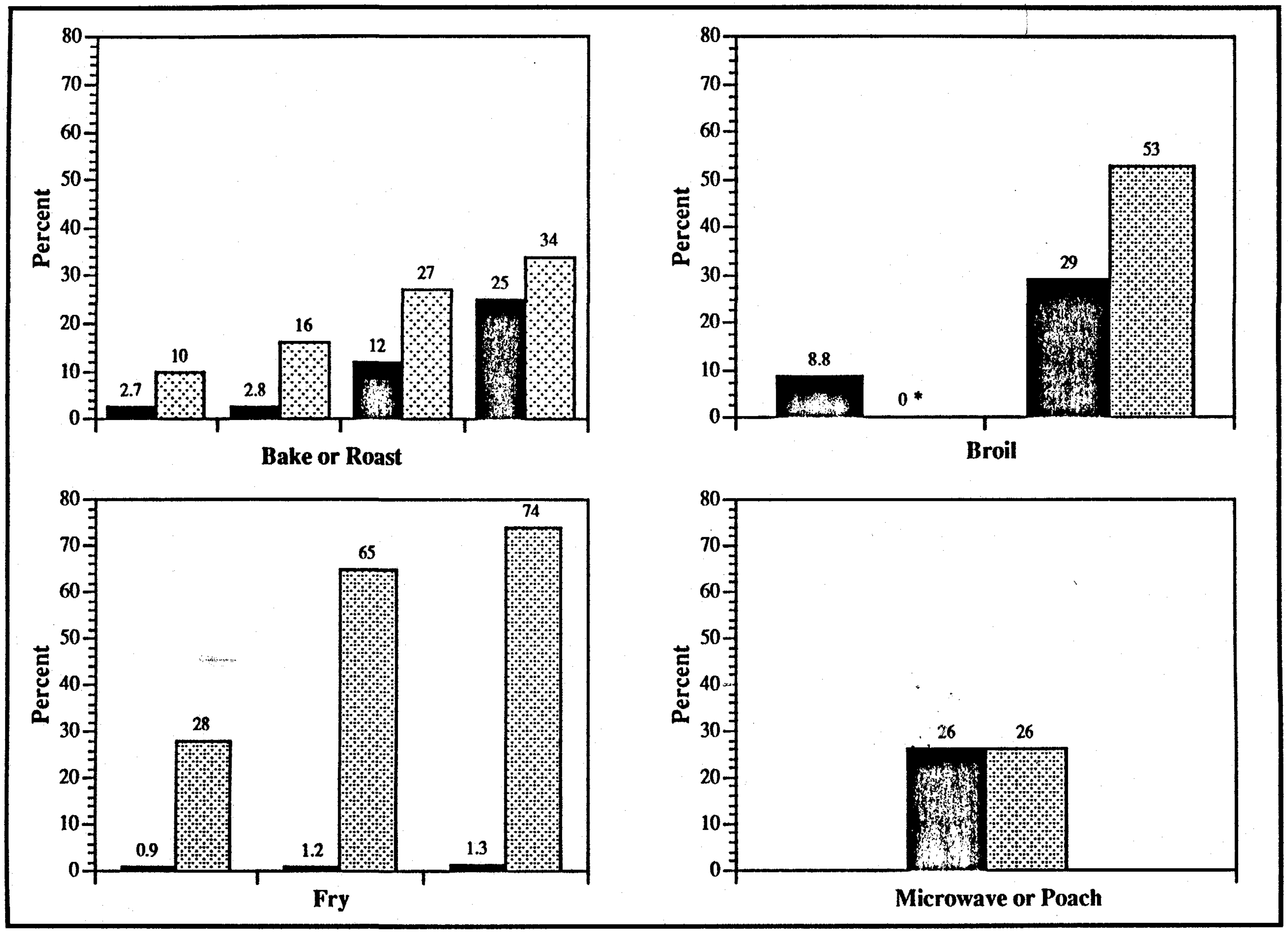


Figure 2. Extent of PCB Reduction in Edible Fish Tissue Relative to Percent Fat Content by Various Cooking Methods



*Value of 0 is believed to be anomalous because significant reductions were reported for specific lipophilic pesticide residues.

10.1493

Table 3. Average Lipid Content of Raw Fish Samples used in Cooking Loss Studies

Method	Study	Fish Species	Percent Lipid Content of Raw Fillets
Bake or roast	Smith et al., 1973	Chinook salmon	2.7
	Zabik et al., 1979	Lake trout	25.0
	Skea et al., 1981	Smallmouth bass	2.8
	Trotter et al., 1989	Bluefish	11.8
Broil	Zabik et al., 1979	Lake trout	29.1
	Skea et al., 1981	Brown trout	8.8
Fry	Skea et al., 1981	Smallmouth bass	1.3
	Puffer and Gossett, 1983	White croaker (Santa Monica Bay)	1.2
	Puffer and Gossett, 1983	White croaker (Orange County)	0.9
Microwave or poach	Zabik et al., 1979	Lake trout	26.4

Based on the available data, typical reduction rates can be estimated for different cooking methods. These estimates are probably inaccurate for estimating PCB lost in individual meals, as actual losses in meals will be affected by fillet size, cooking method, and other factors. However, long-term exposure to PCBs is a function of exposures from many meals. Since the estimate of the average PCB loss by cooking method reflects the results of multiple fish tests in several studies, it provides reasonable guidance for general reductions that are likely to occur over long periods of time. It is, therefore, recommended that the average cooking-method-specific levels derived in this study (Table 4) be used to evaluate actual exposure to PCBs and other lipophilic compounds found in fish.

Table 4. Average Reduction of PCBs in Fish by Various Cooking Methods

Method	Percent Reduction[a]
Microwave or Poach	26
Bake or Roast	22
Broil	27
Fry	56

a. Mean percent reductions as reported in Table 2.

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